

## Appendix A

### Incidence of Congenital Anomalies

Table 1

Incidence of Selected  
Congenital Anomalies Among Live Births in 1983 1/

Congenital Anomaly	Total		White		Other	
	Rate/ 10,000	Number	Rate/ 10,000	Number	Rate/ 10,000	Number
<u>Central Nervous System</u>						
Anencephalus	1.9	691	2.0	581	1.8	132
Spina Bifida w/out Anencephalus	4.8	1747	5.1	1481	3.9	287
Hydrocephalus w/out Spina Bifida	5.8	2111	5.5	1597	6.7	492
Encephalocele	1.1	400	1.1	319	1.1	81
Microcephalus	2.5	910	2.2	639	3.8	279
<u>Cardiovascular</u>						
Common Truncus	0.3	109	0.3	87	0.2	15
Transposition of Great Atresia	1.1	400	1.2	349	0.9	66
Tetralogy of Fallot	1.1	400	1.2	349	1.0	73
Ventricular Septal Defect	17.1	6223	17.5	5083	15.4	1131
Atresia Septal Defect	2.1	764	2.1	610	2.0	147
Endocardial Cushion Defect	0.8	291	0.7	203	0.8	59
Pulmonary Valve Stenosis & Atresia	1.9	691	1.5	436	3.4	250
Tricuspid Valve Stenosis & Atresia	0.3	109	0.3	87	0.3	22
Aortic Valve Stenosis & Atresia	0.6	218	0.6	174	0.5	37
Hypoplastic Left Heart Syndrome	0.8	291	0.8	232	1.0	73
Patent Ductus Ateriosus	29.6	10772	26.9	7813	39.6	2910
Corctation of Aorta	0.7	255	0.8	232	0.5	37
Pulmonary Artery Anomaly	2.0	728	1.4	407	3.9	287
Lung Agenesis & Hypoplasia	3.2	1165	3.2	929	3.0	220

Table 1 (Cont'd)

Incidence of Selected  
Congenital Anomalies among Live Births in 1983

Congenital Anomaly	Total		White		Other	
	Rate/ 10,000	Number	Rate/ 10,000	Number	Rate/ 10,000	Number
<u>Gastrointestinal</u>						
Tracheo-esophageal Anomalies	2.1	764	2.3	668	1.4	103
Rectal & Intestinal Atresia	3.5	1274	3.6	1046	3.1	228
Renal Agenesis	1.8	655	1.9	552	1.3	96
Bladder Exstrophy	0.3	109	0.3	87	0.2	15
<u>Musculoskeletal</u>						
Clubfoot w/out CNS Defects	26.1	9498	27.4	7958	21.1	1550
Reduction Deformity Upper Limbs	1.6	582	1.7	494	1.3	96
Reduction Deformity Lower Limbs	0.9	328	0.9	261	0.8	59
Congenital Arthro-gryposis	2.2	801	2.4	697	1.5	110
<u>Chromosomal</u>						
Down Syndrome	8.5	3093	8.7	2527	8.0	588
Trisomy 13	0.8	291	0.8	232	0.6	44
Trisomy 18	1.0	364	1.0	290	1.1	81

Source: Centers for Disease Control: Congenital Malformation Surveillance Report, January 1982 - December 1985

## Notes:

1/ Incidence rates are averages for the period 1982-85 as reported in Table 2 of the above mentioned source. These rates are based on live and still births and, therefore, overstate the rates for live births alone. Only in the case of anencephalus is the difference significant: in this case the live born rate reported in Table 5 was recorded for "total" births and rates for "whites" and "others" were calculated to reflect the comparative rates for anencephalus in Table 2.

The number of cases of each anomaly is a population estimate derived by multiplying the rate by total births in 1983.

Table 2

## Deaths Caused by Congenital Anomalies in 1983 1/

Congenital Anomaly	Number of Deaths for which Anomaly is the Underlying Cause			[1]/[3] X 100 [4]	Underlying and Contributing Cause Total [5]
	Under 1 Year [1]	Age 1-4 Years [2]	Total [3]		
<u>Central Nervous System</u>	<b>1368</b>	<b>173</b>	<b>1892</b>	<b>72%</b>	<b>n/a</b>
Anencephalus	693	7	702	99	729
Spina Bifida	122	25	197	62	339
Hydrocephalus	227	61	382	59	564
Encephalocele	70	4	81	86	124
Microcephalus	50	33	138	36	282
<u>Cardiovascular</u>	<b>4400</b>	<b>535</b>	<b>7111</b>	<b>62%</b>	<b>n/a</b>
Common Truncus	112	7	136	82	167
Transposition of Great Arteries	157	39	253	62	326
Tetralogy of Fallot Ventricular Septal Defect	98	65	253	39	317
Atrial Septal Defect	194	56	502	39	962
Endocardial Cushion Defect	53	13	256	21	508
Pulmonary Valve Atresia & Stenosis	114	71	223	51	326
Tricuspid Atresia & Stenosis	19	2	31	61	63
Aortic Valve Insuffi- ciency or Stenosis	27	14	71	38	97
Hypoplastic Left Heart	54	4	176	31	258
Patent Ductus Arteriosus	574	6	583	98	642
Coarctation of Aorta	108	0	149	72	478
Pulmonary Artery Anomaly	152	4	187	81	292
Agenesis of Lung	99	14	148	67	292
	773	2	782	99	1516
<u>Cleft Palate &amp; Cleft Lip</u>	<b>15</b>	<b>0</b>	<b>15</b>	<b>100%</b>	<b>n/a</b>
Cleft Palate	7	0	7	100	56
Cleft Lip (Total)	8	0	8	100	65

Table 2 (Cont'd.)

Deaths Caused by Congenital Anomalies in 1983 <sup>1/</sup>

Congenital Anomaly	Number of Deaths for which Anomaly is the Underlying Cause			[1]/[3] X 100 [4]	Underlying and Contributing Cause Total [5]
	Under 1 Year [1]	1-4 Years [2]	Total [3]		
<b><u>Gastrointestinal</u></b>	<b>148</b>	<b>47</b>	<b>315</b>	<b>47%</b>	<b>n/a</b>
Tracheo-esophageal Fistula	20	2	29	69	106
Rectal, Large Intestine Atresia or Stenosis	5	0	5	100	71
<b><u>Genitourinary</u></b>	<b>498</b>	<b>4</b>	<b>890</b>	<b>56%</b>	<b>n/a</b>
Renal Agenesis	401	0	423	95	617
Bladder Exstrophy	1	0	1	100	12
<b><u>Musculoskeletal</u></b>	<b>738</b>	<b>20</b>	<b>845</b>	<b>87%</b>	<b>n/a</b>
Clubfoot*	0	0	0	-	30
Reduction Deformities of Upper Limbs	1	0	1	100	9
Reduction Deformities of Lower Limbs					
<b><u>Chromosomal</u></b>	<b>727</b>	<b>56</b>	<b>952</b>	<b>76%</b>	<b>n/a</b>
Down Syndrome	84	31	272	31	942
Trisomy 13	198	6	204	97	244
Trisomy 18	328	12	343	96	415
<b>All Congenital Anomalies</b>	<b>8732</b>	<b>913</b>	<b>13173</b>	<b>66%</b>	<b>n/a</b>

Source: Unpublished tabulations provided by the National Center for Health Statistics.

## Notes:

<sup>1/</sup> n/a-not available

Column 1 - Number of children under 1 year whose underlying cause of death was the indicated congenital anomaly.

Column 2 - Same as Column 1 for children 1-4 years.

Column 3 - Same as Column 1 for all ages.

Column 4 - Column 1 as a percentage of Column 3.

Column 5 - Total number of deaths for which indicated congenital anomaly was either the underlying or a contributing cause.

Underlying cause of death is defined as: "(a) the disease or injury which initiated the train of events leading directly to death, or (b) the circumstances of the accident or violence which produced the fatal injury." Article 23 of the Constitution of the World Health Organization.

Table 3

Infant Deaths in 1983 Caused by Congenital Anomalies  
Adjusted for Racial Differences in Births and Occurrence Rates 1/

Underlying Cause of Death	Infant Deaths		Nonwhite Infant Deaths Adjusted for Racial Differences in:	
	White [1]	Other [2]	Births [3]	Births plus Anomaly Occurrence Rates [4]
<u>Central Nervous System</u>	1144	224	885	n/a
Anencephalus	602	91	359	398
Spina Bifida	81	14	55	72
Hydrocephalus	172	55	217	178
Encephalocele	55	15	59	59
Microcephalus	44	6	24	14
<u>Cardiovascular</u>	3453	947	3741	n/a
Common Truncus	89	23	91	137
Transposition of Great Arteries	136	21	83	110
Tetralogy of Fallot	79	19	75	83
Ventricular Septal Defect	145	49	193	220
Atrial Septal Defect	42	11	43	45
Endocardial Cushion Defect	98	16	63	55
Pulmonary Valve Atresia & Stenosis	14	5	20	9
Tricuspid Atresia & Stenosis	21	6	24	24
Aortic Valve Insuffi- ciency or Stenosis	47	7	28	34
Hypoplastic Left Heart	457	117	462	370
Patent Ductus Arteriosus	79	29	115	78
Coarctation of Aorta	127	25	99	158
Pulmonary Arteries Stenosis	82	17	67	24
Agenesis of Lung	625	148	585	626

Table 3 (Cont'd.)

Infant Deaths Caused by Congenital Anomalies in 1983  
Adjusted for Racial Differences in Birth and Occurrence Rates 1/

Underlying Cause of Death	Infant Deaths		Nonwhite Infant Deaths Adjusted for Racial Differences in:	
	White [1]	Other [2]	Births [3]	Births plus Anomaly Occurrence Rates [4]
<u>Gastrointestinal</u>	110	38	150	n/a
Tracheo-esophageal Fistula	16	4	16	26
<u>Genitourinary</u>	430	68	269	n/a
Renal Agenesis	353	48	190	277
<u>Musculoskeletal</u>	631	107	423	n/a
Anomalies of Diaphragm	429	60	237	n/a
<u>Chromosomal</u>	589	138	545	n/a
Down Syndrome	64	20	79	86
Trisomy 13	165	33	130	173
Trisomy 18	267	61	241	219

Source: Unpublished tabulations provided by the National Center for Health Statistics. Centers for Disease Control: Congenital Malformations. Surveillance Report, January 1982 - December 1985.

1/ Infant refers to a child under 1 year of age.

Column [3] = Column [2] X 3.95, where 3.95 = white births/nonwhite births.

Column [4] = Column [3] X R where R, is the occurrence rate of a specific congenital anomaly among white children divided by the occurrence rate among children of all other races (Source: Table 1).

## Appendix B

### Statement of H. Rutherford Turnbull III\* on Incidence of Discriminatory Denial of Medical Treatment

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My purpose today is to bring to the attention of the Commission evidence of a contemporary attitude in the medical profession that supports discrimination in medical care against children, particularly newborns with moderate to severe/profound disabilities. This predisposition toward discrimination, if carried out, will result in unwarranted deaths and indeed has been linked to unwarranted deaths. Such an attitude and behavior is sufficient to justify federal action to *prevent* discrimination from being carried out.

In addition, there is a very real need, as I will indicate, for the federal government to monitor hospital Human Rights Committees and Infant Care Review Committees to determine precisely what role they play, if any, in combatting or authorizing nontreatment that constitutes abuse under the Child Abuse Act Amendments of 1984, under state statutes or other state law, under equal protection doctrines, and under Section 504 to the extent that it now still applies to children and medical decisions. Given the physician attitudes and incidence data to which I will refer below, there is reason to believe, as Dybwad points out (Dybwad, *Ethical and Legal Problems in Rehabilitation and Medicine*, in Warms, D. (ed.) (1986), *The Changing Rehabilitation World: Into the 21st Century*. New York: United Cerebral Palsy of New York City, Inc.), that such committees "may serve well in institutions with good practices, but will serve poorly where they are most needed." And, further, there is *no* reason to believe that such committees will be independent of the physicians and hospitals whom they purport to review. Until such time as data are available and persuasive that the HRCs and ICRCs in fact play a salutary role in

preventing discrimination, they may not be assumed to do so.

Finally, there also is a very real need—both human and legal—for the federal government to expand its support of adoption, foster-care placement, and even interim institutionalization for newborns or others whose biological parents refuse to allow them to be treated. While the prospect of legitimizing such institutionalization is thoroughly distasteful, it is less noxious than tolerance of nontreatment of treatable children, namely, those identified by the Child Abuse Act Amendments of 1984 and by the widely adopted Principles of Treatment of Disabled Infants, which I helped draft. Naturally, a far more desirable federal role is helping states to expand the adoption and foster-care placements of such children. Any of these alternatives—and all of them in the aggregate—make it possible for treatable children to be treated and for unjustifiable and prejudicial parental and physician objections to be functionally voided.

A 1975 survey of representative pediatric surgeons and pediatricians conducted by the Surgical Section of the American Academy of Pediatrics disclosed that 76.8 percent of the surgeons and 49.5 percent of the pediatricians would "acquiesce in parents' decision to refuse consent for surgery in a newborn with intestinal atresia if the infant also had Down's syndrome." Shaw, Randolph and Manard, *Ethical Issues in Pediatric Surgery: A National Survey of Pediatrician and Pediatric Surgeons*, 60 *Pediatrics* 588, 590 (1977). And 63.3 percent of the surgeons and 42.6 percent of the pediatricians said that in such cases where they "accept parental withholding of lifesaving surgery" they would also "stop all sup-

Commission, June 26, 1986.

\* Professor of Special Education and Law, University of Kansas, Lawrence, Kansas, statement made to the U.S. Civil Rights

portive treatment including intravenous fluids and nasal gastric suction." *Id.* at 592-93. Another 1975 survey, this one of California pediatricians, showed that 61 percent would not object to a parental decision not to correct a life-threatening intestinal obstruction of an infant with Down's syndrome. *Treating the Defective Newborn: A Survey of Pediatricians Attitudes*, Hastings Ctr. Report, April 1976, at 2. A 1977 survey of Massachusetts pediatricians disclosed that 51 percent believed that such a child should not receive surgery. Todres, Krans, Howell and Shannon, *Pediatricians' Attitudes Affecting Decision-Making in Defective Newborns*, 60 *Pediatrics* 197, 198 (1977). Even among the 46 percent who would advocate surgery, only 40.2 percent (18.3 percent of the full group of pediatricians) would pursue a court order to secure treatment. Sixty-seven percent (67 percent) of the pediatricians would recommend no surgery for a child with severe myelomeningocele (spina bifida). Of those who advocate surgery, 60 percent said they would allow the parents to withhold surgery. *Id.* at 198-99.

A study covering the period from 1977 to 1982 and a more recent survey reinforce this data. CAVC (complete atrioventricular canal defect) is a heart malformation which usually leads to pulmonary vascular disease and premature death. Open heart surgery can correct the malformation and avert the death, and a technique known as pulmonary artery banding can delay the need for this surgery until a child is mature enough to tolerate it. Prompt referral of infants with CAVC to cardiac care facilities for this treatment is vital, since delay can result in the development of irreversible pulmonary vascular disease, when lifesaving surgery is impossible. During the years 1977 through 1982, pediatric cardiologists at the State University of New York-Upstate Medical Center in Syracuse were referred 8 children with CAVC but without Down's syndrome and CAVC at an appropriately early age. However, 10 children with CAVC and Down's syndrome were not referred until between 19 months to 15 years of age. By the time they were referred, 5 of these 10 children with Down's syndrome had deteriorated to a point at which surgery could not be performed. The physicians who reported the study wrote, "Some of our patients with late referral were initially evaluated elsewhere, and informed that surgical procedure was not recommended or not available (by parental report). We question if the parents of these children were being allowed the

opportunity to make an appropriate decision." Sondheim, Byrum and Blackman, *Unequal Cardiac Care for Children with Down's Syndrome*, 139 *Am. J. Dis. Child.* 68, 70 (1985). They concluded, "Children with treatable medical conditions should not be denied routine care because of other handicapping conditions. . .our review of CAVC in children with and without Down's Syndrome suggests that just such a denial of care may have occurred in some instances between 1977 and 1982." *Id.* at 70.

Still more recently, a 1984 survey of nurses at two hospitals in Houston indicates that denial of treatment to children with disabilities remains an accepted practice. Berseth, Kenny and Durand, *Newborn ethical dilemmas: Intensive care and intermediate care: Nursing attitudes*, 12 *Crit. Care* 508 (1984). The nurses surveyed either worked in neonatal intensive care units (ICUs) or in intermediate care nurseries (INTs). Of those surveyed (75 respondents, 39 from ICUs and 36 from INTs), 70.6 percent (53, 32/21) said they felt an infant with severe mental defects should never be resuscitated. (Examples of severe mental defects were given as anencephaly or severe brain damage.) Forty-eight percent (36, 21/15) would only occasionally resuscitate an infant with a severe defect (examples were congenital hydrocephalus and myelomeningocele, popularly known as spina bifida). The percentage of those responding that infants with severe defects should never be resuscitated was 13.3 percent (10, 3/7). An interesting side note is that one respondent from an intermediate care nursery felt that even infants with only minor birth defects (examples given were skin tags or extra digits) should never be resuscitated. *Id.* at 509. Also, 37 percent of the nurses felt that sometimes a doctor should act in such a way as to cause an infant's death. Thirty-one percent believed that the decision on whether to treat a sick newborn should be influenced by the presence of healthy children at home. *Id.* at 509.

I myself have recently completed a review of the literature concerning the incidence of infanticide in America and the public and professional attitudes toward the treatment/nontreatment of children born with birth defects. I wish to summarize what I found and reported (H. Turnbull, *Incidence of Infanticide in America: Public and Professional Issues*, 1 *Issues in L. & Med.* 363 (1986)).

1. Public attitudes toward persons with mental or physical disabilities are largely negative (p. 364).



2. Stigma and discrimination go hand in hand in contemporary America (p. 365).

5. Professional attitudes concerning children with disabilities are variable. Some disability professional organizations (such as AAMD and TASH) have adopted resolutions objecting to the withholding of medical care and treatment on the sole basis of disability; others (AAMD, TASH, AAUAP) have advocated in the United States Supreme Court for the application of Sec. 504 to newborns; and some (AAMD, AAP) have signed the 1984 Principles of Treatment of Disabled Infants (p. 371). Most parent-advocacy organizations (ARC, TASH, NDSC) take similar positions (p. 371). Disability-related professional and parent-advocacy organizations were nearly unanimous in supporting a policy that would put a halt to nontreatment (p. 372).

6. Medical associations did not aggressively pursue a federal role (p. 372).

7. Reported attitudes of physicians are overwhelmingly negative concerning the mandate to treat treatable newborns (p. 374, esp. notes 69-72, 80-85, 87). I wrote, "Absent more comprehensive research about physician attitudes, it is difficult to make a broad generalization about current physician attitudes and their relationship to nontreatment. The history of reported attitudes, however, is negative. They reflect unjustified pessimism about the quality of life of the child and family and advocate criteria for nontreatment that are more pessimistic than those of the 'Principles of Treatment' (p. 379)."

My basis for that conclusion was not merely the research that I have just cited. It also included Adams' 1982 report that physicians' advice concerning services is influenced by parents' socioeconomic status, the physicians' years in practice, the population of the town where the physicians practice, and the physicians' participation in training in mental retardation (Adams, *Referral Advice Given by Physicians*, 20 *Mental Retardation* 16 (1982)). Further, it included Wolraich and Sipperstein's 1983 conclusion, based on inquiries of physicians, that physicians are significantly more pessimistic than psychologists, educators, allied health professionals, and social workers toward the prognosis for individuals with mental retardation (Wolraich and Sipperstein, *Assessing Professionals' Prognostic Impressions of Mental Retardation*, 21 *Mental Retardation* 8 (1983)).

Voices have been heard to claim that the data I have just reviewed are outdated and no longer relevant. The former President of the American Academy of Pediatrics, Dr. James Strain, has objected that his organization's 1975 survey is no longer relevant. "Since then," he has written, "I believe there has been a major shift in the attitude of the medical profession and of society as a whole concerning the care of mentally retarded infants in the nursery and in later life." Deinstitutionalization, the passage of the Education for All Handicapped Children Act, and the "change" in "society's concern for the care of children" which has led to a recognition that children sometimes must be protected from abusing parents have resulted in a consensus that "in cases in which well-established surgical techniques have proven successful in correcting the defect, retardation, or other handicapping condition should not preclude treatment." Strain, *The Decision to Forego Life-Sustaining Treatment for Seriously Ill Newborns*, 72 *Pediatrics* 572 (1983). This change in societal attitudes, according to Strain, has had an effect on pediatricians' attitudes "in making decisions to recommend surgical correction of associated defects and to continue life support treatment in handicapped infants." *Id.* at 572.

In his testimony before this Commission on June 12, 1985, Dr. Strain stated he felt infants with Down's syndrome and spina bifida were now almost universally accorded treatment by the medical profession. He specifically stated that "all of the pediatric literature favors supporting corrective surgery for [infants with] Down's syndrome" and "most babies with spina bifida are treated" with surgery. *Protection of Handicapped Newborns: Hearing Before the United States Commission on Civil Rights* (June 12-14, 1985) (Statement of James Strain, M.D., past president, American Academy of Pediatrics) at 47.

Were Dr. Strain's view correct, one would expect to see it substantiated in the recent medical literature. On the contrary, however, the recent commentary on the issue is overwhelmingly in favor of denying treatment to those deemed to lack a sufficient "quality of life." Beyond the evidence of the quite recent 1984 survey I have described, books and articles authored or coauthored by physicians that insist quality of life must be taken into account in treatment decisions and that argue a low quality of life ethically justifies or even mandates letting some children with disabilities die are legion.

Dr. Robert M. Blizzard, chairman of the Department of Pediatrics at the University of Virginia School of Medicine, has written, "The ethic of many [pediatricians] is (and we believe it justified) that the quality of life in some instances should take precedence over the equality of life." Blizzard, *The Pediatrician: Advocate or Enemy of the Child*, HELIX Autumn 1984, quoted in Cooper, *The Pediatrician Is the Child's Advocate*, 60 J. Med. Educ. 496, 497 (1985). According to a 1983 piece by Marcia Angell, M.D., Deputy Editor of the New England Journal of Medicine, "[t]he premise that the quality of life has no bearing on medical decisions. . . is a dubious premise. It is in direct conflict with most current thinking about medical ethics." Angell, *Handicapped Children: Baby Doe and Uncle Sam*, 309 N. Eng. J. Med. 659 (1983). It is the current and official position of the Judicial Council of the American Medical Association that, "In the making of decisions for the treatment of seriously deformed newborns. . . [q]uality of life is a factor to be considered. . . ." *Current Opinions of the Judicial Council of the American Medical Association* 2.14, at 10 (1984). This opinion was also contained in the AMA's statement to the House Select Education Committee, opposing a bill that in modified form would become the Child Abuse Amendments of 1984. *Statement of the American Medical Association to the Select Education Sub-Committee, Committee on Education and Labor, House of Representatives*, 47 Conn. Med. 29, 29 (1983).

A piece by Dr. George Crile, former head of the Department of General Surgery of the Cleveland Clinic, was widely reprinted in December of 1984 in a number of medical newspapers and then in *USA Today*. Dr. Crile wrote:

The law now states that in obstetrical units, babies must be fed and given full support regardless of how extensive and hopeless their congenital malformations. Despite the law, the debate. . . continues. . . [The question] must be viewed not only in the light of the individual's right to life, but in that of society's right for its members to have pleasant and productive lives, not to be lived mainly to support the growing numbers of hopelessly disabled, often unconscious people whose costly existence is consuming so much of the gross national product. . . .

No child with Down's syndrome ever grew up to be self-sustaining. . . . If the parents still want to rear their child, that should be their decision, but there should be no support from the community or the state.

Crile, *The Right to Life*, Medical Tribune, Dec. 19, 1984, at 27.

In a March 6, 1986, editorial in the New England Journal of Medicine, Angell stated, "Quality of life is an important consideration as the weight of our ethical, medical and legal traditions suggests." Angell, *The Baby Doe Rules*, 314 N. Eng. J. Med. 642 (1986).

A 1983 editorial in *Surgical Rounds* stated:

Take the simplest case of the Down's Syndrome child with esophageal or duodenal atresia (like Bloomington's Infant Doe). With luck his life can be saved, and he can be trained to the point of being a happy family pet. But the break-up rate in families whenever a grossly abnormal child is brought home is very high.

Ravitch, *Big Brother Comes to the Nursery*, 6 Surgical Rounds 10, 10 (1983).

Dr. Steven Ragatz and Dr. Patricia Ellison, from the Departments of Pediatrics and Neurology at the Medical College of Wisconsin, stated their position that "consideration should be given to withdrawal of support from infants who are. . . likely to be severely retarded and dependent later in their lives." Ragatz and Ellison, *Decisions to Withdraw Life Support in the Neonatal Intensive Care Unit*, 22 Clinical Pediatrics 729, 729 (1983).

If one thought that these children had a quality of life representing that which one treasures as a human, perhaps the care and frustration of the parents would be justified. However, these children have very limited capacities for human relationships and participation in human experiences, criteria that others have considered for withdrawal of support.

*Id.* at 729.

Dr. John Britton, from the Department of Pediatrics, Section of Perinatal and Nutrition Science, University of Arizona Health Services, has written that decisions regarding treatment of handicapped infants should be made on a case-by-case basis, not mandated by legislation. J.R. Britton, *'Baby Doe' Rulings—Review and Comment*, 140 West. J. Med. 303 (1984). Further, "Quality of life considerations, desires and concerns of the parents and economic implications for the family and society must be weighed in the decision-making process." *Id.* at 306.

Anthony Shaw, M.D., professor of surgery and pediatrics, University of Virginia School of Medicine, has defined quality of life as the product of an infant's natural endowment and the contributions made to the child by the home and family unit and

by the society as a whole. Shaw, *Defining The Quality of Life*, 7 Hastings Ctr. Rep. 11, 11 (1977).

In his testimony before this Commission, Dr. Shaw tried to justify his formula by saying that his intention was to "maximize those factors that would improve quality of life." *Protection of Handicapped Newborns: Hearing Before the United States Commission on Civil Rights* (June 12-14, 1985) (Statement of Dr. Anthony Shaw) at 82. He claims to have been particularly motivated by the fact that Down's syndrome children often were placed in institutions.

Back in the seventies, particularly early seventies, late sixties, many of us were discomfited by the idea that we as pediatric surgeons could operate on these babies and open up their intestinal tract so that they could eat, and the parents would then through their own decision or suggestion to them by family, friends, pediatricians or whatever, turn the baby over to an institution. And those of us who took the trouble to look at these institutions were by and large horrified at the conditions that existed and the way babies were subsequently managed. *Id.* at 89.

However, Shaw's writings in that time period show a different point of view. In a 1972 article published in the *New York Times Magazine*, Shaw wrote of having seen "families emotionally and financially drained by mongoloid children" and "marriages destroyed by the inability of the partner to deal with . . . a mongoloid child." A. Shaw, *Doctor, do we have a choice?* *New York Times Magazine*, Jan. 30, 1972, 44. Later in the same article, he wrote:

[T]he emotional and financial resources of many families are poured out for helpless retardates while children with real potential are stunted in institutions or a series of foster homes.

Parents of mongoloids have the legal (and, I believe, the moral) responsibility of determining if their child with a potentially deadly but surgically correctible defect should live or die.

*Id.* at 52-53.

Shaw now claims that the sole purpose of his formula was to keep alive those infants who might otherwise not receive treatment and would die. However, in his article defining his quality of life formula, Shaw pointed to "a child born normally formed but . . . in an urban ghetto to an unwed teenage drug addict." If society did not provide for such a child, even with a "respectable quantity" of natural endowments, the child's quality of life would be worthless because, according to Shaw, nothing

would be provided by the home. Shaw, *Defining the Quality of Life, supra*, at 11.

Shaw's formula [ $QL = NE \times (H + S)$ ] was used as the basis for initial decisions not to treat 33 infants with spina bifida over a 5-year period at Oklahoma Children's Memorial Hospital. Gross, Cox, Tatyrek, Pollay, and Barnes, *Early Management and Decision Making for the Treatment of Myelomeningocele*, 72 *Pediatrics* 450 (1983).

Writing in support of such a definition of quality of life and against "the federal government'[s]" effort to "declare severe mental impairment irrelevant to medical decisions" in mandating nondiscriminatory treatment for children with disabilities, Dr. Joel Frader, a pediatrician at Pittsburgh Children's Hospital, expostulated, "Why shouldn't non-medical considerations, like family and community resources, a family's religious beliefs, or similar factors become important to the decisions? Good reasons for permitting death may exist." Frader, *Treating Baby Doe Con: The Benefits Must be Weighted*, Pittsburgh Press, May 18, 1984, at 83.

The attitude of the Bioethics Committee of the American Academy of Pediatrics is that while treatment should not be withheld if the sole reason for doing so is to benefit the psychological or social well-being of others, if the infant's life is deemed to be one that will be filled with suffering, familial concerns are also to be used in the treatment decision.

While the needs and interests of parents, as well as of the larger society, are proper concerns of the pediatrician. . . [w]ithholding or withdrawing life-sustaining treatment is justified only if such a course serves the interests of the patient. When the infant's prospects are for a life dominated by suffering, the concerns of the family may play a larger role. Treatment should not be withheld for the primary purpose of improving the psychological or social well-being of others, no matter how poignant those needs may be.

American Academy of Pediatrics, Committee on Bioethics, *Treatment of Critically Ill Newborns*, 72 *Pediatrics* 565, 566 (1983).

Irwin Krasha, M.D., Department of Pediatrics Surgery and Pediatrics, Rutgers University, asks us to "[t]hink about the family's right to happiness without this tragic creature [the seriously ill newborn] ruining their lives." Krasha, *The Infant: Right to Privacy and Patient's Right to Know*, 51 *Mt. Sinai J. Med.* 25, 25 (1984).

Dr. Blizzard argues that "it is wrong to prolong the life of an infant. . . who will never think, walk, or talk, when the parents decide that they and the infant's siblings cannot cope with such prolongation, and that prolongation is to the detriment of the family stability." Blizzard, *The Pediatrician: Advocate or Enemy of the Child*, HELIX, Autumn 1984, quoted in Cooper, *supra*, at 497 (1985).

Physicians often claim that life with a severe enough disability is a life of suffering. "Where treatment has a high probability of causing significant pain and suffering and a low probability of preserving a life valuable to the patient should we not permit a decision to withhold it?" Moskop and Saldanna, *The Baby Doe Rule: Still a Threat*, 16 Hastings Ctr. Rep. 8, 9 (1986). Moskop, associate professor of medical humanities, and Dr. Saldanna, assistant professor of pediatrics/neonatology, East Carolina University School of Medicine, feel there is a threat of "unjustified prolongation of life" to some handicapped children. *Id.* at 9.

Carol Lynn Berseth, M.D., from the Pediatrics Department at the Mayo Clinic, has written, "To offer extraordinary support to these infants [with severe handicaps] is to prolong their suffering by traumatizing them further with invasive techniques." Berseth, *A Neonatologist Looks at the Baby Doe Rule: Ethical Decisions by Edict*, 72 Pediatrics 428, 429 (1983). Angell wrote that decisions regarding treatment for newborns "properly include considerations of future suffering." Angell, *The Baby Doe Rules*, *supra*, at 643.

In Angell's 1983 editorial, she stated the issue involved in treatment decisions was "one of future suffering. Do we have the right to inflict a life of suffering on a helpless newborn just because we have the technology to do so. . .?" Angell, *Handicapped Children: Baby Doe and Uncle Sam*, *supra*, at 660. Kathlyn E. McGoldrick, M.D., editor of the *Journal of the American Medical Women's Association*, has written that the view of most physicians is "that aggressive management, which only prolongs the pain and suffering of a hopelessly impaired infant, is neither humane nor rational." McGoldrick, *Baby Jane Doe: questions and quagmires*, 39 J. Am. Med. Wom. Assoc. 67, 67 (1984).

Another reason given for the denial of treatment to children with disabilities is based on limited financial resources. An anonymous neonatologist, writing in a popular magazine, protested that the "mandatory treatment of all infants with serious

defects would soon exhaust the capacity. . . of all [Neonatal Intensive Care Units] in the country." Dr. "N," *Should This Baby Be Kept Alive. . . Who Can Best Decide?* Woman's Day, Apr. 24, 1984 at 69. See also Moskop and Saldanna, *supra*, at 12.

Dr. Ravitch has written that "at some point along the line the mere dollar cost of these efforts [to treat seriously ill newborns] will be questioned." Ravitch, *supra*, at 12. Ragatz and Ellison also stated that financial considerations should play a part in the determination of what treatment should be given: "[T]hat factor [finances] must be included in the analysis, especially at a time when programs for the handicapped are losing funding, community support services are disappearing, maintenance funds and services for institutionalized children are decreasing, and funds for health care are limited." Ragatz and Ellison, *supra*, at 729.

Dr. Britton also spoke of the increasing financial burdens that are likely to result from federal regulations on treatment of handicapped newborns.

If current rulings are upheld, the cost to society could be enormous. Although the potential economic impact of Baby Doe rulings has not been assessed, the personal financial burden to parents of long-term home care for chronic problems and frequent physician visits and hospital admissions for acute problems to which many such infants are prone may be great. . . because intensive care is required for many defective newborns, increasing the number of such infants will likely necessitate expansion of both physical facilities and nursing and physician staff in neonatal intensive care nurseries. Such expansion of health care supply to meet an increase in demand is likely to occur slowly, if at all, and in the interim other infants requiring intensive care may either be denied admission to an intensive care unit or receive compromised care by overextended staff. The institution of Baby Doe regulations could precipitate a health care shortage of crisis proportions, compromising both the quality and quantity of that care.

Britton, *supra*, at 306.

The realities of neonatal intensive care units also contradict any assertion of a change in attitudes in the medical profession. Norman Fost, M.D., Assistant Professor of Pediatrics at the University of Wisconsin School of Medicine, has written, "It is common in the United States to withhold routine surgery and medical care from infants with Down's Syndrome." Fost, *Passive Euthanasia of Patients with Down's Syndrome*, 142 Arch. Intern. Med. 2295 (1982). Dr. Walter Owens, the physician who first counselled nontreatment for "Baby Doe" in Bloom-

ington, testified at an April 13, 1982, hearing before Judge John Baker, that even if life-saving treatment had been administered, the infant would not have possessed what he considered a "minimally acceptable quality of life." Further he stated:

[T]his would still not be [a] normal child. . . Some of these [Down's Syndrome] children. . . are mere blobs. . . [M]ost of them eventually learn to walk and most eventually learn to talk. . . [T]his talk consists of a single word or something of this sort at best. . . These children are quite incapable of telling us what they feel and what they sense, and so on.

Petition for Certiorari at 8, *Infant Doe v. Bloomington Hospital*, filed Sept. 13, 1983, *cert. denied* 104 S.Ct. 394 (1983).

Likewise, Dr. John Pless, the Bloomington baby's physician, has written: "The potential for mental function and social integration of this child, as of all infants with Down's Syndrome, is unknown." (Pless, *The Story of Baby Doe*, 309 *New Eng. J. Med.* 664 (1983)).

Further, the experience of the 5-year study performed at Oklahoma Children's Memorial Hospital is a resounding indication that physicians still feel that there are certain infants who should not be treated.

Of 69 infants with myelomeningocele who were admitted to the hospital, 33 (48 percent) were recommended for nontreatment. Of these 33, 5 were treated at the request of the parents, two were later treated aggressively, 1 was treated by crisis management, and there was no followup on 1. The remaining 24 children who were recommended for nontreatment died within 189 days after birth. Factors used to determine which infants would be treated included, among others, the existence of other handicaps which would prevent self-care as an adult and the economic and intellectual resources of the family. Gross, Cox, Tatyrek, Pollay, and Barnes, *Early Management and Decision Making for the Treatment of Myelomeningocele*, 72 *Pediatrics* 450, 451 (1983). During the 18 months following the 5-year study reported by the Oklahoma team, an additional 15 children were sent to the same shelter

where the original 24 had died. All but one of these infants died before the shelter was closed by state officials for various health and safety violations. C. Sherwood, *Oklahoma "charnel house" held 38 infants sent to die*, in *Baby Doe: The Politics of Death* 9 (1984).

With respect to the actual incidence of selective nontreatment, abuse, and neglect, I noted in my article (Turnbull, *Incidence of Infanticide in America: Public and Professional Attitudes*, 1 *Issues in L. & Med.* 363 (1986)) that the data are scarce. They nonetheless exist. Set out below are excerpts from my article.

#### Incidence of Selective Nontreatment, Abuse, and Neglect

Here, again, the data are scant. Duff and Campbell reported that of 299 consecutive deaths in a special-care nursery, 43 (14%) were related to the withholding of treatment.<sup>1</sup> Hardman<sup>2</sup> has noted that, if those data are extrapolated to a national figure multiplied by the number of newborn intensive care nurseries in existence in 1973, the result would be that "several thousand infants a year" would not be treated and would have died during that year.

The John Hopkins Hospital case also was reported that year, and the report intimated that the death of that one child is replicated at the hospital and elsewhere.

The 1975 survey of pediatricians and pediatric surgeons,<sup>3</sup> the 1976 survey of the San Francisco physicians,<sup>4</sup> and the 1977 survey of Massachusetts physicians<sup>5</sup> concerned the Senate Committee on Labor and Human Resources. The Committee noted that, if, since 1975, physicians have been acting on their convictions, federal policy on the civil rights of handicapped people is being contravened<sup>6</sup> and presumably some children were dying because of selective nontreatment. The Senate Committee noted, quite properly that "incidence of actual denial on the basis of disability is difficult to document."<sup>7</sup> But it also cited the testimony of Dr. David M. McClone, Chairman, Department of Pediatric Neurosurgery, Children's Memorial Hospital, Chicago, that in 1983, 10 of 200 children born with spina bifida referred to his hospital for treatment "had been denied prompt surgical therapy" before transfer. Dr. McClone concluded, if that sample is nationally representative, approximately 5% of newborns with spina bifida (400 infants) are subjected to some form of nontreatment annually.<sup>8</sup> The Committee also reported Dr. Koop's testimony that, "in recent months" he had received "over

<sup>1</sup> Duff, *Human Ambiguity*, *supra* note 81. [Editor's note: Footnote text is reprinted as it appeared in the article; the note numbers have been changed.]

<sup>2</sup> Hardman, *The Role of Congress in Decisions Relating to the Withholding of Medical Treatment from Seriously Ill Newborns*, 9 *J. ASSOC. PERSONS SEVERE HANDICAPS* 3-7 (Spring 1984).

<sup>3</sup> Shaw, *Ethical Issues*, *supra* note 71.

<sup>4</sup> *Treating the Defective Newborn*, *supra* note 73.

<sup>5</sup> Todres, *supra* note 72.

<sup>6</sup> SENATE COMM. ON LABOR AND HUMAN RESOURCES, CHILD ABUSE PREVENTION AND TREATMENT AND ADOPTION REFORM ACT AMENDMENTS OF 1983, S. Rep. No. 246, 98th Cong., 1st Sess. 9 (1983).

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

20 contacts" from nurses who objected to carrying out physicians' orders to deny food to handicapped newborns.<sup>9</sup>

Shurtleff and his colleagues<sup>10</sup> recommended aggressive treatment for all spina bifida children (if good intellectual prognosis is present), regardless of the level of the spinal lesion. Of 88 patients treated with supportive care, only 52 were born before 1965 (the "early" group). In 1965, the physicians began an evaluative process of newborns. They selected 36 of the 88 (40.9%) for only supportive treatment after 1965 (the so-called "younger" group). Of the 36, there were 34 whose parents accepted the initial recommendation of nonintervention; the children were discharged to nursing homes. Of the early group, 30% survived to be at least twenty years old and 10% of the younger group survived to be at least two years old. In other words, some babies survived in spite of the pessimistic initial evaluation.

A study by Feetham and his colleagues<sup>11</sup> noted that 31 of 75 newborns (41.3%) with spina bifida initially were not treated, but 70% of them were still alive at the age of eighteen months.

Wolraich<sup>12</sup> reported an evaluation of 27 babies with spina bifida who were followed over a three year period. Among them, 12 met Lorber's criteria as not qualifying for aggressive treatment; nonetheless, four families opted for vigorous treatment, and two of the four babies died within seven months. With respect to the other 8 in that nontreatment cohort of 12, 3 (25%) were treated subsequently, 5 (41.6%) were not, and 5 died.

Gross and his colleagues<sup>13</sup> reported in 1983 that, during a five year period beginning in 1977, 33 babies out of 69 (47.8%) who had spina bifida were subject to decisions about nontreatment. Five were initially treated at the parents' request, two underwent delayed vigorous treatment, one was subsequently treated by crisis management, one moved and dropped out of the study, and 24 (34.7%) received only supportive care and died between 1 and 189 days of life (mean, 37 days).

Fost<sup>14</sup> reported that it is "common in the United States to withhold routine surgery and medical care from infants with Down syndrome for the explicit purpose of hastening death."

<sup>9</sup> *Id.*

<sup>10</sup> Shurtleff, Hayden, Lowser & Kronmal, *Myelodysplasia: Decision for Death or Disability*, 291 NEW ENG. J. MED. 1005 (1974).

<sup>11</sup> Feetham, Tweed & Perrin, *Practical Problem in Selection of Spina Bifida Infants for Treatment in the USA*, 28 *Kinderchair* 301 (1979).

<sup>12</sup> Wolraich, *Medical, Ethical and Legal Issues in Selective Use of Rehabilitative Care in the Management of Children with Spina Bifida*, 2 *SPINA BIFIDA THERAPY* 213 (1980).

<sup>13</sup> Gross, Cox, Tatyrek, Pollay & Barnes, *Early Management and Decision-Making for the Treatment of Myelomeningocele*, 72 *PEDIATRICS* 450 (1983).

<sup>14</sup> Fost, *Passive Euthanasia of Patients With Down's Syndrome*, 142 *ARCH. INTER. MED.* 2295 (1982).

Ragatz and Ellison<sup>15</sup> reviewed twenty "cases" in a neonatal unit at a university hospital in which the decision to withdraw treatment was made; they noted that these twenty children represented 2.7% of all neonatal intensive care unit (NICU) admissions during the sixteen months of their review.

Of course, some very strong inferences can be made from the reports of nontreatment. Horan and Robertson<sup>16</sup> have concluded that the practice of selective nontreatment apparently is "common" and "may be gaining status as 'good medical practice'" in America. Indeed, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research has endorsed selective nontreatment and reported that it occurs, without being able to say how often.<sup>17</sup>

Finally, the Department of Health and Human Services has reported that it has not been able to reach any finding of discrimination after investigating forty-nine cases of alleged discriminatory withholding of medical care during the few months that it was enforcing the Baby Doe regulations under Section 504.<sup>18</sup>

Here, then, is the situation. Some physicians elect not to treat some children. Some parents agree not to have their children treated. Some nontreated children (the majority) die sooner or later (usually sooner) after the nontreatment decision is made. It is not known for certain how many physicians elect not to treat, how many parents agree to nontreatment, how many physicians chose to treat and how aggressively they treat, how many parents agree to treatment and to aggressive treatment, how many children who are treated nonaggressively or aggressively survive, how long they survive, how they live once they survive, and whether selective nontreatment ever will be accurately reported, since some of it may be done covertly or outside of those facilities.

Furthermore, it is increasingly unlikely that there will be reliable research data about the incidence and consequence of nontreatment. The climate about nontreatment has changed (selective nontreatment seems less defensible in these days of a disability rights ethos) and because the laws concerning nontreatment have either been changed (as in the case of the federal child abuse laws) or seem to be more likely to be applied.

<sup>15</sup> Ragatz & Ellison, *Decisions to Withdraw Life Support in the Neonatal Intensive Care Unit*, 22 *CLIN. PEDIATRICS* 729 (1983).

<sup>16</sup> Horan & Robertson, cited in *ETHICAL, MORAL AND LEGAL CONSIDERATIONS ON THE PRACTICE OF WITHHOLDING MEDICAL TREATMENT FROM INFANTS WITH CONGENITAL DEFECTS* (P. Guess, B. Dussault, F. Brown, M. Mulligan & F. Orelve eds. (1984)).

<sup>17</sup> PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, *DECIDING TO FOREGO LIFE-SUSTAINING TREATMENT* 217-223 (1983).

<sup>18</sup> 49 Fed. Reg. 1646-1649 (1984).

There most likely is—and probably always will be—the occurrence of nontreatment of infants who, under the President's Commission's guidelines, the "Principles of Treatment" and the federal and state child abuse laws, nonetheless should be treated. Parental and physician attitudes about some disabled newborns will encourage and tolerate some underground practices of nontreatment.

There will always be difficult line-drawing problems. There may be reasoned differences among medical experts whether a particular child should have been treated as a medical matter, assuming the experts are in consensus about the meaning of the applicable law. There also may be reasoned differences about the meaning of the law, without regard to its application. The fact that there may always be indefensible cases of nontreatment does not mean, in any way, that those cases should be tolerated. It simply means that, whatever little we know for certain today about the incidence of nontreatment, we are likely to know nothing more, and perhaps even less, about it in the future.

Ironically, this survey of contemporary medical literature is reinforced by the testimony offered before this very Commission in June 1985. Numerous witnesses gave their feelings on how treatment decisions should be affected by quality of life considerations. Mildred Stahlman is head of the Division of Neonatology at Vanderbilt University School of Medicine. In her testimony before this Commission, Dr. Stahlman stated that "an easily remedial surgical condition ought to be performed *if* it offers a relatively pain-free existence beyond that." *Protection of Handicapped Newborns: Hearing Before the United States Commission on Civil Rights* (June 12–14, 1985) (Statement of Mildred Stahlman, M.D.) at 16 (emphasis added). She later testified that in making a treatment decision, consideration should be given to "whether or not the individual. . . has any humanness in the quality of their life." *Id.* at 16. Joseph Boyle, president of the American Medical Association, told the Commission that federal intervention through section 504 of the 1973 Rehabilitation Act would "create a state in which an infant will be forced to live in pain, spasticity, under heavy sedation and narcotics." *Id.* (Statement of Joseph Boyle, M.D.) at 48. Dr. Siva Subramanian, director of the nursery at Georgetown University Medical Center, indicated that, when the assessment of the doctors was that the treatment would "bring more pain and suffering without any benefit for that patient," withdrawal of life support systems would be discussed with the parents. *Id.* (Statement of Siva Subramanian, M.D.) at 91. According to Mary Anne Warren of the Department of Philosophy, San

Francisco State University, it is impossible to avoid quality of life considerations. To her, the relevant question is whether the child will ever "have a level of human experience. . . beyond the simple capacity to suffer." *Id.* (Statement of Mary Anne Warren, Ph.D) at 150. Jeffrey Ponerance, director of neonatology at Cedars-Sinai Medical Center in Los Angeles, continued the support for quality of life considerations. He labelled the DHHS regulations allowing for the withdrawal of care if such care were futile, but not the withdrawal of care if the infant were handicapped, as "inappropriate reasoning." *Id.* (Statement of Jeffrey Ponerance, M.D.) at 180.

Critical to the quality of life, in the opinion of many of the witnesses at the 1985 hearings, were the societal and familial interests involved. Dr. Cynthia Barrett, director of the Newborn Intensive Care Unit and head of neonatology at UCLA Medical Center, spoke directly to the costs to the family by saying, "[T]heir emotional costs [after the birth of a child with disabilities] are very high. They see a child over whom they have not control, whom they cannot carry, handle, nurture . . . .[F]urther, the financial costs are inordinate." *Id.* (Statement of Cynthia Barrett, M.D.) at 93. Dr. Subramanian testified that the question of treatment for infants was one of "familial autonomy in terms of the family as a unit, and the parents in the best interests of the patient will be able to express their opinion in terms of autonomy." *Id.* (Statement of Siva Subramanian, M.D.) at 90. Later during the hearings, Joy Penticuff, Associate Professor at the University of Texas School of Nursing, told the Commission that "if the family say they can't deal with this situation [a handicapped newborn], if they believe that their baby's life is going to be a life full of pain and suffering," the family should be able to withhold treatment from their child. *Id.* (Statement of Joy Penticuff, Ph.D) at 205. Dr. Warren also expressed the opinion that the decision to treat is one which the family must make. *Id.* (Statement of Mary Anne Warren, Ph.D) at 160.

The bias of the physicians also extends in the area of decision-making by affecting what the doctors tell the infant's parents. A Michigan doctor says that "The worst possible prognosis is often the only one presented." Turkel, *After Baby Doe*, 78 South. Med. J. 364 (1985). Thomas Elkins, Assistant Professor, Chief, Division of Gynecology, University of Michigan Medical School, and Doug Brown, Assistant

Professor, Harding Graduate School of Religion, in their recent article in *Issues in Law and Medicine*, stated, "In an new era of noninstitutionalization, increased educational opportunities and increased socialization, the medical literature describing physical, mental, and social prognosis data for Down syndrome and many other disabilities is often obsolete." Elkins and Brown, *An Approach to Down Syndrome in Light of Infant Doe*, 1 *Issues in L. & Med.* 419, 432 (1986). Further, they detail the frustration parents of Down's syndrome children often feel because doctors frequently fail to acknowledge and talk to the parents of the benefits which such a child can bring to the family, dwelling instead on the child's limitations. *Id.* at 433.

A 1985-86 article published in the *Journal of Law and Health* described the parents' role as largely passive. The information they receive supports the recommendation of the physician, and the consent given is based upon such biased information. Malone, *Medical Authority and Infanticide*, 1 *J. of L. and Health* 77, 98 (1985-86). Malone goes on to say: "While parents can influence what a doctor recommends depending on whether physicians perceive the parents as positive or negative toward the infant, they are seldom active decision-makers in a meaningful way." *Id.* at 98-99. This information makes it much more likely that a bias by physicians will have a profound effect on the treatment decision that is made for a newborn with a disability.

It is obvious that many health care professionals still feel that there are circumstances in which it is proper to deny medical care to children with disabilities. Overwhelmingly, these decisions appear to be based on the doctor's own opinion regarding the child's "quality of life" after treatment. Governmental action to protect these children from death is, therefore, amply justified and urgently needed.

Attitudes elicit behavior. If societal attitudes concerning people with mental disabilities were not negative, one would not expect the same type of societal and legal discrimination against them as has existed, including by way of discrimination in medical treatment.

Because attitudes elicit behavior, it is important to consider them. The professional literature that I have reviewed consists of surveys about physician attitudes. Not surprisingly, physician attitudes are not significantly different (as reported) from general societal attitudes, both now and historically.

There is, however, another aspect of attitudes—one that the Commission, like the professional community, has overlooked. It is the attitude of people with disabilities and their families.

If attitudes truly do elicit behavior, then the attitudes of people with disabilities and their families must be considered as the proper federal governmental behavior is shaped by the Commission, Congress, and the courts.

Orlansky and Heward's *Voices: Interviews with Handicapped People* (1981) are strong first-person testimony concerning the positive quality of life that people with severe to mild physical or mental disabilities can and do have. Turnbull and Turnbull's *Parents Speak Out* (1986) contains powerful first-person accounts of the strength that parents of children with mental, emotional, and physical disabilities draw from their unusual parenthood, always in the face of devaluing and discriminatory attitudes held by some physicians and other professionals. *No More Stares* (1982), a publication of the Disability Rights Education and Defense Fund, Inc., gives further testimony to the fact that a positive quality of life can derive solely from being disabled.

My wife, Ann P. Turnbull, a professor at the University of Kansas, and I have been troubled by the almost single-minded focus on the pathology in disability—on the pervasive attitude, held by physicians and other professionals, that disability automatically equates with nothing except burden. Yet, as parents of a child with low moderate mental retardation who have been obliged (by lack of services) to institutionalize him, who brought him home, who began school programs for him, who are seeing him through his P.L. 94-142 education, and who believe that he has contributed mightily to our development and to that of our other children and his friends, we know that there is a potent positive part of life with such a child.

Some researchers have been surprised by findings that parents and others report that the child's life has consisted of positive dimensions (Wikler, Wasow, and Hatfield, *Chronic Sorrow Revisited: Attitude of parents and professionals about adjustment to mental retardation*, 51 *Am. J. of Orthopsychiatry* 63 (1981)). These researchers even dismissed those feelings, sometimes in error (Wikler, Wasow, and Hatfield, *Seeking strengths in families of developmentally disabled children*, *Social Work* 313-15 (1983)) and sometimes as rationalization (Wasserman, *Identifying counseling needs of the siblings of mentally retarded*



children, 61 Personnel & Guidance School J. 622 (1983)). Knowing of these developments, we have begun a line of research at the University of Kansas on the positive aspects of the life of the person with a disability.

Concerning the Commission's attention to medical discrimination and attitudes of physicians and my argument in favor of considering attitudes of people who have disabilities and their families, we obtained copies of letters sent by parents or relatives and individuals who themselves have disabilities to the Department of Health and Human Services, commenting on the 1983 proposed regulations under section 504. We were interested in the opinions of these three groups concerning whether they supported the regulations and the reasons cited for their support.

We coded 174 letters according to the criteria of type of respondent, reasons for supporting the regulations, and the inclusion of recommendations pertaining to providing parent support or adoption options. We found that 173 respondents unanimously supported the regulations, and the 1 remaining respondent did not express support or objection. The qualitative analysis of reasons for supporting the legislation resulted in the identification of eight categories. The category of insuring equal treatment for newborns with disabilities received the highest number of citations—70 percent of respondents.

Of particular interest to our discussion is the category of positive contributions. Thirty-five percent of the respondents identified at least one positive contribution that the person with a disability had made to others. We identified six types of positive contributions.

The most frequently mentioned type was the person with a disability being a source of joy to the family. This category was mentioned by 39 percent of those respondents who indicated a positive contribution. An example of this kind of positive contribution is as follows:

I am a thirty-five year old parent of a sixteen month old child diagnosed as having Down Syndrome and a severe congenital heart defect. And yet, as imperfect as he may appear to many "professionals" and "intellectuals" of our day, I wouldn't trade him for any other child in this world. I cannot begin to sufficiently articulate the profound joy this child has brought into our lives. He may never grow up to be president of anything, but that surely doesn't mean that he does not contribute in a positive way. His life is so very precious us.

An equal number of respondents (28 percent) addressed the next three types of positive contributions. The first of these is a source of learning life's lessons. Many different types of lessons were mentioned, including "patience," "less self-centered," "greatness of character," and "worth and dignity of all individuals." A more complete description was provided by a mother on what her family had learned from her child with severe mental retardation:

My life and the lives of my family were changed forever on January 18, 1980. At about 6:00 p.m. our daughter Sarah was born. She weighed three pounds. Her diagnosis from the doctors was hopeless, 24 hours to live, deaf, blind, severely retarded.

As I looked at her, fighting to live, held her in the palm of my hands, amazed that this little one was my daughter, hope became eternal for me.

For the next 26 months she taught us more about love, courage, faith and life than most of us could teach or learn in 100 years.

The next type, source of love, as also identified by 28 percent of the respondents. We coded comments in which the respondent described family members or friends being the primary beneficiary of the love. An example of such a comment is as follows:

Anyone who feels that someone else is a burden has not learned to love. Love feels someone else's needs above their own. My son, Matthew, was not useless. . . . If he served no other purpose than to give me love, then he served that one and if he served to other purpose than to teach me love, he served that one.

The category, source of blessing or fulfillment, was the third type of positive contribution identified by 28 percent of the respondents. Key words mentioned in these passages were "blessing," "fulfillment," "cherish," "enriched," and "completeness." An example of this kind of positive contribution is:

We are the parents of a brain-damaged son. Todd is now 20 years old and although we encountered some very stressful times during his early years, we believe very definitely that God allowed him to be born in our family. Although he is somewhat handicapped mentally he is. . . a blessing and encouragement to many (including us). I shudder to think that someone might have decided that he had no right to live.

The final two categories were identified by substantially fewer respondents—source of pride by 8 percent and source of strengthening family by 5

percent. A quote from one mother provides an illustration of both of these categories:

My son and only child is thirty-four years of age and considered profoundly retarded. His presence has strengthened our family ties and he is a source of pride. Surely the lives of my husband and I would be barren indeed without him.

I respectfully request the Commission to accept into the record as evidence the complete set of letters that we obtained under the Freedom of Information Act.

These letters also revealed that, although the greatest percentage (70 percent) of the correspondents favored the section 504 regulations because of equal treatment concerns, the second (42 percent) greatest portion favored them because of the positive characteristics of the person with a disability, and the third (35 percent) greatest portion favored them because of the positive effects of the person on others. A loss of confidence in the medical profession was expressed by 30 percent of the writers, and inaccurate medical prediction was noted by 9 percent of them.

Along with others (A. Lipsky, *Parental Perspective on Stress and Coping*, 55 *Am. J. Orthopsychiatry* 614 (1985); A. Turnbull, Blue-Banning, Behr, Kerns, *Family Research and Intervention: A Value and Ethical Examination*, in Docecki and Zaner (eds.) (1986), *Ethics and Decision-Making for Persons with Severe Handicaps: Toward an Ethically Relevant Research Agenda*, Baltimore: Paul H. Brookes Publishing), I believe that professionals and government agencies alike make serious errors in assuming that disability alone is horrific and burdensome for the person, families, and society. Surely disability can be a factor in a "poor quality of life." But quality of life is inversely related to public and professional attitudes and behavior. If the Commission is serious about the federal role in improving the quality of life of people with disabilities, their families, and the public, it had better recognize that the federal government has the power to change the discriminatory attitudes and behaviors, and that there is another side of attitudes, one that proclaims, that although a person is less able, that person is not less worthy of our protection, concern, and support.

Finally, I would like to reiterate and expand my comments on the parent-physician relationship and its role in the process of deciding whether to treat a newborn with a disability. The Supreme Court's

*Bowen* decision posits a parent decision concerning treatment and from that predicate holds section 504 rules inapplicable to treatment/nontreatment decisions. The factual basis for the plurality opinion is seriously to be doubted.

Oftentimes, families' decisions concerning treatment will depend on how physicians approach the family, the child, and the "problem" of the child's disability. It is for this reason, among others, that parent-professional interactions and counseling have been thoroughly covered in the literature (see, e.g., K.L. Moses (1983), *The impact of initial diagnosis: Mobilizing family resources*, in J.A. Mulick and S.M. Pueschel (eds.), *Parent-professional partnerships in developmental disability services*, Cambridge: The Ware Press; S.M. Pueschel (1983), *Parental reactions and professional counselling at the birth of a handicapped child*, in J.A. Mulick and S.M. Peuschel (eds.), *Parent-professional partnerships in developmental disabilities services*, Cambridge: The Ware Press; E. Sassaman (1983), *The parent-physician decision-making team*, in J.A. Mulick and S.M. Peuschel (eds.), *Parent-professional partnerships in developmental disabilities services*, Cambridge: The Ware Press; B.Z. Friedlander, G.M. Sterritt, and S.G. Kirk (eds.) (1975), *Exceptional infant—assessment and intervention*, New York: Brunner/Mazel; L. Buscaglia (1975), *The disabled and their parents: A counselling challenge*, Thorofare, N.J.: Charles B. Slack; T.B. Brazelton, B. Koslowski, and M. Main (1974), *The origins of reciprocity: The early mother-infant interaction*, in M. Lewis and L. Rosenblum (eds.), *The effect of the infant on its caregiver*, New York: John Wiley & Sons). Indeed, physicians who themselves are parents of disabled children are especially sensitive and expert about this delicate relationship (G.H. Durham (1979), *What if you are the doctor?* in T. Dougan, L. Isbell, and P. Vyas (eds.), *We have been there*, Salt Lake City: Dougan, Isbell, and Vyas Associates; Pueschel (1983)), and one of them, Dr. S. Peuschel, is a pediatrician whose child is mentally retarded and is a member of the national advisory board for this research proposal. In addition, "how-to" literature abounds concerning effective techniques for physician-parent interaction, but much of it is written from the perspective of the physician (J. Howard (1982), *The role of the pediatrician with young exceptional children and their families*, 48 *Exceptional Children* 316-22; M.L. Wolraich (1982), *Communication between physicians and parents of handicapping children*, 48 *Exceptional Chil-*

dren 324-29; A.L. Rubin and R.L. Rubin (1980), *The effects of physician counselling technique on parent reactions to mental retardation diagnosis*, 10 *Child Psychiatry & Human Devel.* 213-21; S.M. Peuschel and A. Murphy (1976), *Assessment of counselling practices at the birth of a child with Down's syndrome*, 81 *Am. J. Mental Deficiency* 325-30).

In fact, the scant research on the factors that physicians take into account when they meet with parents suggests that physicians mediate their advice according to factors that relate to the family, not the child (A.C. McDonald, K.L. Carson, D.J. Palmer, and T. Slay (1982), *Physicians' diagnostic information to parents of handicapped neonates*, 20 *Mental Retardation* 12-14; R.I. Clyman, S.H. Sniderman, R.A. Ballard, and R.S. Roth (1979), *What pediatricians say to mothers of sick newborns: An indirect evaluation of the counselling process*, 63 *Pediatrics* 719-23). In addition, it is almost certain that physicians do not disclose all of the information that parents need for the treatment/decision. I myself have experience with physicians withholding important treatment information (Turnbull, *Jay's Story*, in H. Turnbull and A. Turnbull (1986), *Parents Speak Out*, Columbus, Ohio: Charles E. Merrill Publishing Co.).

One of the witnesses before this Commission, Rosalyn Benjamin Darling, has written extensively concerning physician-parent relationships and raised questions about the thoroughness of disclosure, and therefore, about the information element of informed consent, in the newborn treatment decision (Darling, *Parent-Professional Interaction: The Roots of Misunderstanding*, in M. Seligman (ed.) (1983), *The Family with a Handicapped Child: Understanding and Treatment*, New York: Grune & Stratton, Inc.; Darling, *The Birth Defective Child and the Crisis of Parenthood: Redefining the Situation*, in Callahan and McCluskey (eds.) (1983), *Life-Span Developmental Psychology*, New York: Academic Press; Darling, *Parents, Physicians, and Spina Bifida*, Hastings Ctr. Rep., August 1977).

Harrison (*The Parents' Role in Ethical Decision Making*, 2 Support Lines 11-23 (1984)) reviewed the parents' role in decision-making and noted the following:

1. the decision to designate a particular case as one requiring parental participation in decision-making is itself a medical staff decision;
2. parents usually are presented by medical staff with only one option, under the theory that

exposure to diverse views would lead to parental confusion and frustration;

3. parents are such "hostage(s) to circumstances" that, in one physician's view, parental choice is a misnomer, the staff managing the decision-making "absolutely";

4. physicians and other medical staff have such extensive power of persuasion that parental informed consent is a "farce";

5. physician opinion is shaped by physician attitudes and values, not just philosophical values but also scientific values of acquiring new knowledge by providing treatment that will be of little, if any, benefit;

6. physician opinion also is shaped by the prevailing legal climate, particularly one that causes physicians to practice defensive medicine;

7. physician opinion also is shaped by financial considerations, namely, the parents' third-parties' ability to pay for medical attention.

It is undisputed that the manner in which parents are informed by medical staff concerning the child and the treatment options has a distinct bearing on parents' decisions to consent or not consent to treatment (Shaw, Randolph, and Manard, *Ethical Issues in Pediatrics Surgery: A National Survey of Pediatricians and Pediatric Surgeons*, 60 *Pediatrics* 588 (1977); Clyman, Sniderman, Ballard, and Roth, *What Pediatricians Say to Mothers of Sick Newborns: An Indirect Evaluation of the Counselling Process*, 63 *Pediatrics* 719 (1979)).

Research studies have clearly demonstrated parents' need to receive honest and complete information about the child's condition and to have that information given on a continual basis (Drotar, Baskiewicz, Irvin, Kennel, and Klaus, *The Adaptation of Parents to the Birth of an Infant with a Congenital Malformation: A Hypothetical Model*, 56 *Pediatrics* 710 (1975); Solnit and Stark, *Nurturing and the Birth of a Defective Child*, 16 *Psychoanalytic Study of the Child* 523 (1961). It is ironic in the extreme, therefore, that some physicians assert that offering treatment alternatives to parents is dishonest because parents are highly influenced by physicians' opinions (Nolan-Haley, *Defective Children, Their Parents, and the Death Decision*, 4 *J. Legal Med.* 9 (1976)). Others even assert that the physician should be the sole decision-maker in order to relieve parents of guilt should the child die as a result of not treating it (Strong, *The Neonatologists' Duty to Patient and the Parents*, 14 *Hastings Ctr. Rep.* 10 (1984)).

There also is reason to believe that physicians' information and counselling is not value-neutral (Hauerwas, *The Demands and Limits of Care: Ethical Reflections on the Moral Dilemma of Neonatal Intensive Care*, 269 *Am. J. Med. Sciences* 222 (1975)) and that medical criteria should be, in any event, the major issue, not physician value judgments that can

cloud the decision-making process (Duff and Campbell, *On Deciding the Care of Severely Handicapped or Dying Persons: With Particular Reference to Infants*, 57 *Pediatrics* 487 (1976); Fost, *Counselling Families Who Have a Child with a Severe Congenital Anomaly*, 67 *Pediatrics* 321 (1981)).

## Appendix C

### State by State Evaluation of Child Protective Services Agencies

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#### Preface

This appendix contains an analysis of State CPS agency compliance with the Child Abuse Amendments (CAA) and their implementing regulation. The Commission examined each State's policy and procedures for investigation of reports of withholding of medically indicated treatment from infants with disabilities who have life-threatening conditions as of the third quarter in 1988. In carrying out this examination, Commission staff conducted telephone interviews with State CPS agency workers, reviewed additional material received from the States, and made use of information from a survey of the State agencies conducted in 1987 by the journal, *Issues in Law and Medicine*.

As a result, the following evaluations suffer from one very important caveat. With rare exceptions, they can examine only what might be called "paper compliance"—the degree to which written procedures appear to reflect the requirements of the relevant Federal regulation. A State could be in complete "paper compliance," yet in practice choose medical consultants hostile to the law they are in theory enforcing, defer unduly to the views of the physicians they are investigating, or give only cursory examination to reports. The Commission could detect such important failures of compliance only when other information shed unexpected light. (For an example of a State in paper compliance but which other information disclosed was substantially out of compliance, see the section on New Hampshire.)

For this reason, a conclusion contained in this appendix that a State appears on the face of its procedures to be in compliance with the CAA should not be cited as a definitive finding by the

Commission that the State is in fact fully fulfilling its responsibilities to enforce the law.

In general, the compliance review contained in the following State by State analysis concentrates on certain key features. The number and disposition of relevant reports of medical neglect is recounted, and a comparative description of the extent to which the agency sought input in designing its procedures from representatives of the class the law was designed to protect (disability rights groups) and representatives of the class the law was intended to regulate (medical groups) is given. Central to the CAA, of course, is the standard of care required to be enforced. This is embodied in the definition of "withholding of medically indicated treatment," so the compliance review reports on the State's inclusion of a definition of this term that corresponds to that in the Federal regulation.

Of similar importance is delineation of the class protected by the standard of care, so the review reports on the adequacy of the State's definition of "infant." Vital to effective enforcement is the ability and readiness of the State agency to obtain access to medical records and to obtain court orders for independent medical examinations, so the State's compliance with Federal regulatory provisions relating to these is assessed. Perhaps most crucially of all, the compliance review assesses the degree to which the agency appears to equip itself with adequate independent medical advice in order to assess effectively whether legally required treatment is being provided, or, on the other hand, the extent to which it abdicates its duties by deferring to views expressed by committees at the institution whose staff is being investigated or even by the subject of the investigation herself or himself.

The following prefatory notes discuss the more common forms of failure to comply with Federal law.

**NOTE A: CPS delegates to an ICRC the question of medical neglect.** The Federal regulation is clear that it is the State's CPS system which must make the determination whether treatment is legally required because it meets the definition of medically indicated under the CAA. The existence of an infant care review committee (ICRC) has no bearing on a State CPS agency's duty to investigate all known or suspected cases of medical neglect and determine whether treatment of the child is required or whether one of the three treatment exceptions is applicable. Nor does the existence of an ICRC amend the duty of the hospital or medical professionals to notify the CPS of suspected or known instances of medical neglect. Moreover, the existence of an ICRC does not permit an abdication of the agency's duty to determine what circumstances exist to invoke the power of the State. Unwarranted agency reliance on ICRC views compromises the intent of the statute and places an agency out of compliance with the Child Abuse Amendments.

As shown in chapter 10, the statute and HHS' implementing regulation elucidate the separate and distinct roles of the ICRC and the CPS agency. HHS envisioned that the ICRC would, in effect "offer counsel to the attending physician(s), the hospital and the family to assure that the parents have the benefit of prudent, knowledgeable and professional evaluations, recommendations and services, consistent with appropriate medical standards, to assist them in making sound decisions regarding the welfare of their child. The CPS agency, on the other hand, represents the interests of the infant and must determine those circumstances in which the power of the State must be invoked to protect the infant, and then to take appropriate action to do so."<sup>1</sup>

**NOTE B: CPS treats ICRCs as the independent medical examiner.** Federal regulations require that State CPS agencies must have the ability to obtain "[a] court order for an independent medical examination of the infant, . . . when such access is necessary to assure an appropriate investigation for a report of medical neglect (including instances of

withholding of medically indicated treatment from disabled infants with life-threatening conditions)."<sup>2</sup> The term "independent" by definition denotes an individual free from the influence, guidance, or control of another. A hospital's ICRC does not qualify; it is not independent of the hospital, whose alleged neglect is presumably being investigated. To conduct truly independent examinations, a CPS agency must develop its own bank of independent consultants. Yet in some States, the CPS agency evidently regards the judgments of the ICRC as akin to an "independent medical examination." This practice subverts the intent of the CAA and their implementing regulation to construct an independent enforcement mechanism for the purpose of protecting the right to treatment of infants with disabilities.

**NOTE C: CPS fails to provide for access to medical records.** Federal regulations require that a CPS agency's investigative policies and procedures "must be in writing" and "must specify" the manner in which it will obtain "[a]ccess to medical records and/or other pertinent information when such access is necessary to assure an appropriate investigation of a report of medical neglect (including instances of withholding of medically indicated treatment from disabled infants with life-threatening conditions). . . ."<sup>3</sup>

**NOTE D: CPS fails to provide for obtaining court orders for independent medical examination of an infant.** Federal regulations require that a CPS agency's investigative policies and procedures "must be in writing" and "must specify" the manner in which it will obtain "[a] court order for an independent medical examination of an infant or otherwise effect such an examination in accordance with processes established under State law when necessary to assure an appropriate resolution of a report of medical neglect (including instances of withholding of medically indicated treatment from disabled infants with life threatening conditions)."<sup>4</sup>

Concerning these sections of the regulation, HHS stated in its section-by-section analysis:

We have added language to paragraph (c)(4) to require that as a part of the development of programs and/or procedures required in paragraph (c), the State child protective system must specify the procedures to be

<sup>1</sup> *Services and Treatment for Disabled Infants, Model Guidelines for Health Care Providers to Establish Infant Care Review Committees*, 50 Fed. Reg. 14,901 (1985).

<sup>2</sup> *Id.*

<sup>3</sup> 45 C.F.R. § 1340.15(c)(4)(i) (1987).

<sup>4</sup> 45 C.F.R. § 1340(c)(4)(ii) (1987).

followed, consistent with State law, to carry out these actions

. . . These additions to paragraph (c)(4) of the final rule clarify that, in connection with this conformity requirement, the State's programs and/or procedures must make provision, consistent with State laws, for access to medical records and medical examinations when necessary. Although these actions will not be needed in every investigation of reported medical neglect, the specific identification of these procedures for use by agency staff increases the protections for disabled infants.<sup>5</sup>

**NOTE E: CPS fails to provide adequate definition of the term "infant."** Many CPS agencies have policies which either do not define the term "infant" or—in direct contravention of the governing regulation—define the term to encompass only infants of less than one year in age. The Child Abuse Amendments standard of medical treatment States that:

The term "infant" means an infant less than one year of age. The reference to less than one year of age shall not be construed to imply that treatment should be changed or discontinued when an infant reaches one year of age, or to affect or limit any existing protections available under State laws regarding medical neglect of children over one year of age. *In addition to their applicability to infants less than one year of age, the standards set forth . . . should be consulted thoroughly in the evaluation of any issue of medical neglect involving an infant older than one year of age who has been continuously hospitalized since birth, who was born extremely prematurely, or who has a long-term disability.*<sup>6</sup>

Supplemental Information HHS published with the Final Rule explained the above definition by noting that, as a condition of receiving child abuse and neglect grants, States must have procedures that ensure the detailed standards in the CAA are thoroughly consulted with regard to certain categories of infants over 1 year of age.

[A]s a general rule, issues of medical treatment for infants over one year of age are to be considered under the less precisely defined, but clearly applicable, standards of "medical neglect." Issues of medical treatment for disabled infants under one year of age with life-threatening conditions must be considered under the more precisely defined standards of the definition of "withholding of medically indicated treatment."

. . . [But f]or certain infants over one year of age, the Conference Committee believed the more precisely defined standards of the definition of "withholding of medically indicated treatment" might be more appropriate to use in considering the question of medical treatment

<sup>5</sup> 45 Fed. Reg. 14,883 (1985).

<sup>6</sup> 45 C.F.R. § 1340.15(b)(3)(i) (1987) (emphasis added).

than the more general standards of "medical neglect." . . . The apparent Congressional intent is to recognize that these three categories of infants, although over one year of age, share important characteristics with those infants under one year of age who are the principal focus of the statutory provision.<sup>7</sup>

It is noteworthy that the third category, those over 1 year of age who have "a long-term disability," is extremely broad. Thus, it is arguable that under the law the more precise standards should be consulted concerning medical treatment decisions for practically all children with disabilities, of whatever age.

**NOTE F: CPS fails to provide an adequate definition of the term "withholding of medically indicated treatment."** Many CPS agencies do not define medical neglect, or define it in such a way as to invite ambiguity. Properly defined, "withholding of medically indicated treatment" is:

the failure to respond to the infant's life-threatening conditions by providing treatment (including appropriate nutrition, hydration, and medication) which, in the treating physician's (or physicians') reasonable medical judgment, will be most likely to be effective in ameliorating or correcting all such conditions, except that the term does not include the failure to provide treatment (other than appropriate nutrition, hydration, or medication) to an infant when, in the treating physician's (or physician's) reasonable medical judgment any of the following circumstances apply:

(i) The infant is chronically or and irreversibly comatose;

(ii) The provision of such treatment would merely prolong dying, not be effective in ameliorating or correcting all of the infant's life-threatening conditions, or otherwise be futile in terms of the survival of the infant; or

(iii) The provision of such treatment would be virtually futile in terms of the survival of the infant and the treatment under the circumstances would be inhumane.<sup>8</sup>

This legal provision was scrupulously crafted by Congress to create narrow circumstances in which maximal treatment is not required.

Resort to "quality of life" considerations by any party are completely inconsistent with the law. HHS stated in its Final Rules that "[a] number of commenters argued that the interpretation should permit, as part of the evaluation of whether treatment would be inhumane, consideration of the infant's future

<sup>7</sup> *Child Abuse and Neglect Prevention and Treatment Program*, 50 Fed. Reg. 14,878, 14,882 (1985).

<sup>8</sup> 45 C.F.R. § 1340(b)(2) (1987).

'quality of life.' *The Department strongly believes such an interpretation would be inconsistent with the statute.*<sup>9</sup> HHS has made clear that the focus is on the treatment itself and not on the nature or quality of child's life.

## ALABAMA

In Alabama, the Division of Child Protective Services in the Bureau of Family and Children's Services of the Department of Pensions and Security is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

In designing its approach to implementation, the division consulted with hospitals in the State; it could not name any disability groups that were invited to participate. In selecting physicians to serve as independent medical consultants, it used doctors designated by the Alabama chapter of the American Academy of Pediatrics.<sup>10</sup>

As of 1987, the agency stated that it had responded to two reports of medical neglect of infants with disabilities since 1985, when the regulations took effect. In 1988 the agency stated that it had received no reports in the last year.<sup>11</sup>

The State agency's procedures were reviewed for compliance with the Federal regulations that implement the CAA. The Alabama *Family and Children's Services Manual* sets forth the procedures required to be followed in investigating reports of child abuse and neglect. The manual defines "withholding of medically indicated treatment" and "reasonable medical judgment" in accordance with the Federal regulation. However, absent from the manual is any definition of "infant." Moreover, the introduction of the section concerning medical neglect of handicapped infants is entitled, "Reports of Medical Neglect of Handicapped Infants Under One Year of Age."<sup>12</sup> The absence of a definition of "persons protected by the CAA" and the incorrect limitation reflected in the title give the impression that the agency will only respond to reports of medical neglect to infants younger than 1 year old. Under this language, the agency would fail to protect a

large group of infants within the group covered by the CAA.

In a letter dated October 7, 1988, the Assistant Attorney General and Legal Counsel for the Alabama Department of Human Resources responded on behalf of the agency to a draft of relevant portions of the Commission report. The State argued that because Alabama law provides that a child is anyone under the age of 18, the department would always investigate a report of medical neglect of any child regardless of age: "Those procedures go on to state that special procedures on handicapped infants under one year of age... are found in another section. Thus, the Department does investigate cases of medical neglect of handicapped infants and other children as well."<sup>13</sup>

The State's response did not recognize that the "special procedures" required under the CAA apply as well to handicapped infants past their first birthday. Although Alabama may assert that it investigates reports of medical neglect of infants older than 1 year, there is no indication in its procedures that it will apply to them the detailed standard of care the CAA creates for "disabled infants with life-threatening conditions." (For an elaboration of the requirements governing this area, see Preface, NOTE E.)

The procedures also fail to specify in writing the manner in which the CPS agency will obtain access to the medical records of a handicapped infant in the event that medically indicated treatment has allegedly been withheld. Surprisingly, in its response to the Commission's preliminary draft, the Assistant Attorney General for the State of Alabama stated: "There is no provision in the federal regulations requiring that the State plan or procedures outline in writing a procedure for obtaining medical records." The plain language of 45 C.F.R. §1340.15(c)(4)(i) refutes this assertion. (See Preface, NOTE C.)

Most egregiously, the Alabama procedures manual explicitly abdicates to a hospital infant care review committee (ICRC) the authority to decide whether illegal denial of treatment is taking place, contrary to the requirements of the Federal regulation that the CPS must make the determination

<sup>9</sup> 45 C.F.R. pt. 1340 app. no. 9 (1987).

<sup>10</sup> Telephone interview with Mary Carswell, Bureau of Family and Children's Services, by *Issues in Law and Medicine* (June 10, 1987).

<sup>11</sup> *Id.* and telephone interview with Mary Carswell, Bureau of Family and Children's Services (July 28, 1988).

<sup>12</sup> Alabama Dept. of Pensions and Security, *I Family and Children's Services Manual*, at VII-53 (Rev. May 1988)

<sup>13</sup> Letter from James E. Long, Assistant Attorney General and Legal Counsel, Alabama Department of Human Resources, to William J. Howard, General Counsel, U.S. Commission on Civil Rights (Oct. 7, 1988).



whether treatment is legally required under the CAA. The procedures provide: "In cases where there is agreement between the treating physician and the [ICRC], . . . the County Department will simply apprise the court having jurisdiction over juveniles of the case by submitting a written summary."<sup>14</sup> Independent medical opinion will be sought, according to the procedures, only in those cases in which there is no internal committee. The procedures state: "In counties where there are no Infant Care Review Committees nor multidisciplinary teams operational, the County Department must consult a local independent physician for a medical opinion on the case."<sup>15</sup> The flaw disclosed by this formulation is its failure to anticipate a circumstance in which the parents and the medical providers agree to withhold treatment—the typical situation that the CAA attempts to address. The foregoing language clearly allows the hospital that has had a complaint lodged against it to sit as a judge in its own case.

In his response to the Commission, the Assistant Attorney General and Legal Counsel for the State of Alabama Department of Human Resources wrote:

Alabama's procedures recognize that duly authorized ICRCs are made up of a broad range of medical professionals. If a duly authorized ICRC decides that treatment may be withheld, there is no difference of medical opinion which would support a court petition. As an attorney who has litigated these cases, I find your objection to Alabama's procedures puzzling. On what ground and with what evidence would the Commission propose to present to a court? If a duly constituted ICRC agrees with a course of action, there is nothing to present to a court. Of course, Alabama will review the report to determine if the ICRC adequately analyzes the case. However, the Alabama experience has been that a team determination by a group of medical professionals, absent proof of actual bias, will nearly always be given more weight than a nonmedical opinion or even an opinion by a lone independent physician.

Alabama's response reinforces the conclusion that the CPS has unlawfully abdicated authority to

<sup>14</sup> *Id.*, para. 6.

<sup>15</sup> *Id.*, para. 1.

<sup>16</sup> Information provided to the Commission by *Issues in Law and Medicine* based upon a telephone interview with Dee Ann

hospital ICRCs. Alabama's response does not appear to recognize that Federal law has vested the CPS agency with the duty of ensuring that the medical treatment standards under the CAA are being properly applied. It is well established that the existence of an infant care review committee in a hospital does not relieve a State child protective services agency of the responsibility to provide the objective third-party inquiry into suspected cases of withholding of medically indicated treatment. (See chapter 10.) Alabama would do well to obtain an independent medical consultant, not affiliated with the hospital, to assist the CPS in the investigation of a report of withholding of medically indicated treatment of an infant with a disability. (For an elaboration of the requirements governing these areas, see Preface, NOTES A and B).

Alabama presents a case of a State CPS agency that has wrongfully delegated to the hospital ICRCs the legal question whether there is a withholding of medically indicated treatment. In addition, the agency does not have in its procedures a definition of "infant" or a provision for access to medical records. It is fundamentally out of compliance with the CAA and its implementing regulation.

## ALASKA

In Alaska, the Division of Family and Youth Services of the Department of Health and Social Services is the State agency responsible for compliance with and enforcement of the Child Abuse Amendments of 1984 (CAA).

In designing its approach to implementation, the division did not consult with either medical or disability groups.<sup>16</sup> After the policy had been in effect for a year, however, the agency wrote State health care facility directors expressing the hope that they found the agency's approach "to be of assistance with these unusual cases" and inviting their comment on any "areas of our policy which you feel are impediments to effective coordination in

Grummett, Division of Family and Youth Services, on June 11, 1987.

these cases.”<sup>17</sup> There is no record of any similar inquiries made of disability groups.

Agency procedures identified by the agency as its written division policy and procedure<sup>18</sup> reprint verbatim the relevant sections of the CAA and its implementing regulations. A copy of this interim policy and procedure was provided to the Commission in August 1988 by the division when the Commission requested copies of current policies and procedures. In view of the interim policy’s inclusion of relevant sections of the CAA and implementing regulations, it is surprising to find that the interim policy includes a definition of infant that is inconsistent with the Federal definition. The interim policy provides: “These policy [sic] and procedures relate only to handicapped infants under the age of one year in hospitals or other health care facility [sic].”<sup>19</sup> This limitation illegally excludes those infants over 1 year of age who meet the criteria set forth in the Federal regulations, as well as any child with a disability who might be in a health care facility. (See Preface, NOTE E.)

Asked to comment on this criticism, the agency provided the Commission with copies of agency policies that define infant in conformity with the CAA. The policies, both issued in April 1988, indicate that they were superseded by policies issued in June 1988 and October 1988. Neither of the superseding policies was provided to the Commission.

The Alaska procedures explicitly abdicate the State’s responsibility to investigate reports in hospitals where there exists an infant care review committee (ICRC). The division summarizes its policies as follows:

[F]ederal and state law require that medical providers report immediately to the Division of Family and Youth Services if they have reason to believe that medical treatment is being improperly withheld from a disabled infant. Division policy requires that once such a report is received, the complaint be immediately referred to the medical facility’s review board, if one exists, for a determination as to whether or not the complaint is valid.

<sup>17</sup> Letter from Michael L. Price, Director, Division of Family and Youth Services, to Health Care Facility Directors (Oct. 6, 1986).

<sup>18</sup> Report of Harm Regarding Medical Neglect of Handicapped Infants in Hospitals and Health Care Facilities, §300.05.045, cited in Division of Family and Youth Services documents provided to the U.S. Department of Health and Human Services by cover letter dated Oct. 15, 1985, from Michael L. Price, Director.

<sup>19</sup> *Id.* at §5.045(b).

If a committee does not exist within the facility, Division policy provides that this agency will assist the medical facility in arranging for an independent medical examination of the alleged victim. If the evaluation by the review board or independent evaluator indicates that medical treatment is being improperly withheld, the Division would proceed as in any case requiring protective action for a child in danger of harm by filing a petition with the court.<sup>20</sup>

The State regulations provide, “*Consensus of the [Internal Review] Board that Treatment is Appropriate.* Upon notification to the [agency] worker that treatment is appropriate in relation to criteria outlined in the Federal regulations cited under (a)(2) of this section, the worker shall close the case.”<sup>21</sup> When the infant care review committee fails to achieve consensus, “the worker shall assist the board in arranging for an independent medical examination of the infant.”<sup>22</sup> If a facility has no internal review board, “the worker receiving the complaint will immediately contact the designated personnel at the facility and request assistance and cooperation in arranging for an independent medical evaluation of the infant.”<sup>23</sup>

In other words, the agency worker is to ask those charged with discriminatory denial of treatment to name the “independent” individual who is to rule on whether or not what they are doing is proper. Thus, whether or not a health care facility has a review committee, the Alaska agency seems to believe that it exists to rubber stamp the practices of hospitals that are the subject of a denial to treatment report rather than investigate them. (See Preface, NOTES A and B.)

In response to an inquiry, an agency representative stated that there had been no cases reported to the agency since the regulations went into effect.<sup>24</sup> In a update inquiry this year, the division manager reported that she had not heard of any reports of withholding of medically indicated treatment.<sup>25</sup>

Alaska presents a case of a State CPS agency that has wrongfully delegated to the hospital ICRC’s the legal question whether there is a discriminatory

<sup>20</sup> Letter to Health Care Facility Directors from Michael L. Price, Director, Division of Family and Youth Services (Oct. 6, 1986).

<sup>21</sup> Alaska Admin. Code tit. 300, § 5.045(c)(B)(iii) (January 1987)

<sup>22</sup> *Id.*, § 5.045(c)(1)(B)(i). Emphasis added.

<sup>23</sup> *Id.*, § 5.045(c)(2)(A).

<sup>24</sup> Telephone interview with Dee Ann Grummett, Division of Family and Youth Services, by Andrew Sondag (June 11, 1987).

<sup>25</sup> Telephone interview with Martha Holmberg, Manager, Division of Family and Youth Services, by Vincent Mulloy (Aug. 1, 1988).

withholding of medical treatment to a disabled infant. In so doing, the agency has distorted the CAA's intent to create a strong enforcement mechanism for the treatment of disabled children and should be regarded as in violation of Federal law.

## ARIZONA

In Arizona, the Administration for Children, Youth and Families of the Arizona Department of Economic Security is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

In 1987 the Arizona CPS reported that it had received only one report alleging denial of medical treatment to an infant with a disability since enactment of the CAA. In describing that situation, the agency stated:

We have had one CPS report that was classified as "Baby Doe." A petition was filed with the Juvenile Court to monitor the child's treatment. When it was determined that further treatment would do no more than temporarily prolong the act of dying the court dismissed the petition and the child died a natural death while hospitalized.<sup>26</sup>

In an update, a representative of the agency stated that it had received no reports in the past year.<sup>27</sup> The agency has reported that medical associations were consulted in the preparation of its policies and procedures for medical neglect situations but that no disability rights groups were consulted.<sup>28</sup>

Although the procedures of the Arizona CPS incorporate by reference the Federal regulation implementing the CAA, they contain language that is ambiguous or inconsistent with the regulation. The CPS definition of "medically indicated treatment," which establishes the standard of care, differs from that in the Federal regulation. Thus, it states not only that treatment would not be mandated where it would be "futile or would do more than temporarily prolong the act of dying when death is imminent," but also that treatment would not be mandated "in circumstances where it is not necessary to save the life of the infant, [or] the potential risk to the infant's life or health outweighs the

potential benefit to the infant of the treatment or care. . . ."<sup>29</sup>

The term "potential risk to the infant's life. . . outweighs the potential benefit" is ambiguous enough to allow a judgment that because of disability the child's quality of life would be so poor that lifesaving treatment would not be of "benefit" to the child. "Quality of life" considerations are inconsistent with the statute. (See Preface, NOTE F.)<sup>30</sup>

The policy directive also states that infant "means a newborn child less than one year of age."<sup>31</sup> The scope of this definition fails to include a large group of infants protected by Federal law. (See Preface, NOTE E.)

In at least some cases, the Arizona CPS has explicitly abdicated to hospital ICRCs the authority to decide whether illegal denial of treatment is taking place, contrary to the requirements of the Federal regulation. (See Preface, NOTE A.) When the hospital concerning which a report has been received has an ICRC, the policy states the Arizona CPS will file a dependency petition "if unresolvable disagreement exists between the parent(s) or guardian(s) plan to not provide nourishment or necessary medical treatment or surgical care for the child(ren) and recommendation of the hospital ICRC. . . ."

In the absence of a hospital ICRC, it further states, the CPS will file a dependency petition when disagreement exists between the parents or guardians, or physician, or "specialized medical consultation." These two types of situations do not include circumstances in which the parents and the medical providers wrongfully agree to withhold treatment—the very situation that the CAA were primarily intended to remedy. The clear implication is that the CPS will usually act only when there is disagreement among the parties named in section E. The procedures do provide for the filing of a petition "under circumstances other [than those listed above], including when medical records are not available on request, after decisionmaking process including the child protective services supervisor, and advice and counsel from an Assistant Attorney

<sup>26</sup> Letter from Carol Ann Erikson, CPS Specialist, Administration for Children, Youth and Families, to *Issues in Law and Medicine* (May 20, 1987).

<sup>27</sup> Telephone interview with Beth Rosenberg, Manager, Policy Unit, Administration for Children, Youth and Families (July 28, 1988).

<sup>28</sup> Telephone interview with Carol Ann Erikson, CPS Specialist, Administration for Children, Youth and Families (June 24, 1987).

<sup>29</sup> Arizona Department of Economic Security Instruction 5-55-08.A (1988).

<sup>30</sup> A State statutory provision prohibits depriving "a newborn child of food, nutrients, water or oxygen. . . for any reason including. . . a handicap which, in the opinion of the parent or parents of the child, the physician or another person, diminishes the quality of the child's life." Ariz. Rev. Stat. §36-2281(A).

<sup>31</sup> *Id.*

General.”<sup>32</sup> However, the CPS evidently regards intervention in these circumstances as the exception rather than the rule, a conclusion reinforced by its letter commenting on a draft of relevant portions of the Commission report: “Policy. . . provides clear direction concerning use of the agency’s legal authority, which is to petition the Juvenile Court in cases of specified disagreement as to treatment of the child.”<sup>33</sup>

The State denied that its policy constitutes an “abdication to the ICRC” because “specialized medical consultation. . . is obtained as appropriate to the reports and investigations.”<sup>34</sup>

Although the agency’s policies do provide for the availability of such consultation, nothing in the letter of comment or the Arizona procedures negates the disturbing indication that the CPS agency regards the typical cases for its efforts to obtain a court order to be those in which there is disagreement between the hospital ICRC or a physician, on the one hand, and the parents, on the other, as opposed to cases in which legally mandated standards of treatment are being violated with the involvement of medical providers, the sort of situation that prompted enactment of the CAA.

Taking into account its inappropriate definition of the standard of care and the class protected, and its improper deference to committees of the very hospitals where staff would be the subject of reports of medical neglect, Arizona is out of compliance with the CAA and its implementing regulation. In so doing, the agency has distorted the CAA’s intent to create a strong enforcement mechanism for the treatment of disabled children.

## ARKANSAS

The Arkansas Division of Children and Family Services in the Department of Human Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

<sup>32</sup> *Id.*, § 5-55-08.E(3).

<sup>33</sup> Letter from Darwin J. Cox, Program Administrator, Arizona Administration for Children, Youth and Families, to William J. Howard, General Counsel, U.S. Commission on Civil Rights (Oct. 11, 1988).

<sup>34</sup> *Id.*

<sup>35</sup> Telephone interview with Sandra Haden, Staff Manager, Child Protective Services, by *Issues in Law and Medicine* (June 12, 1987); telephone interview with Jeanette Lewis, Manager, Child Protective Services, by Commission staff (Aug. 1, 1988).

<sup>36</sup> The agency does have the authority to obtain a court order for an examination under Rule 35, ARCP. It also possesses subpoena

The agency stated on two occasions that there have been no reports of denial of medical treatment to infants with disabilities.<sup>35</sup>

The State agency’s policies and procedures were reviewed for compliance with the Federal regulation that implements the CAA. The procedures do not specify the manner in which the agency will obtain access to medical records or a court order for an independent medical examination, contrary to the requirements of the Federal regulation.<sup>36</sup> The policy merely instructs the county CPS officer to contact the State office for guidance on the investigation. The procedures do not state the manner in which the investigation will proceed.

Arkansas properly describes the standard of care and the class protected by it as required by the Federal regulations.

In a telephone interview, the CPS staff manager stated that the agency’s regulations were developed with the assistance of Arkansas Children’s Hospital and that no disability groups were consulted. The manager also stated that the independent medical examiner for an investigation of medical neglect has been designated by Arkansas Children’s Hospital.<sup>37</sup>

According to a letter from a State CPS administrator to HHS, Arkansas Children’s Hospital “handles 90 to 95 percent of all ‘Baby Doe’ cases in the entire State.”<sup>38</sup> In other words, the hospital that is most frequently under investigation for medical neglect was permitted to write the rules of investigation and to name the “independent” medical authority who will provide crucial medical assessments that will serve as the basis for the CPS determination whether a course of treatment or nontreatment is proper.

The CPS manager confirmed that a video had been made and was used in the training of State CPS personnel on the issue of medical neglect.<sup>39</sup> “Ethical Issues in the Medical Care of Infants and Children”<sup>40</sup> contains much discussion of medical ethics, but

power for the production of medical records under Rule 45, ARCP. However, 45 C.F.R. § 1340.15(c)(4) (1987) requires that the agency specify in writing the procedures it will follow to exercise this authority.

<sup>37</sup> Telephone interview with Sandra Haden, Staff Manager, Child Protective Services, by *Issues in Law and Medicine* (June 12, 1987).

<sup>38</sup> Letter from Bobbie Ferguson, Acting Administrator, Child Protective Services, to Tommy Sullivan, Regional Director, Health and Human Services (Apr. 10, 1986).

<sup>39</sup> *Id.*

<sup>40</sup> On file with the U.S. Commission on Civil Rights.

nowhere does it include any mention of Federal law regarding the denial of medical treatment.

The Arkansas CPS agency appears to have abdicated large portions of its duties under the CAA to the hospital whose treatment practices it has responsibility for investigating. It must be regarded as substantially out of compliance with the CAA and its implementing regulation.

## COLORADO

The Colorado Division of Family and Children Services in the Department of Social Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency stated that there have been no reports of withholding of medically indicated treatment since the regulation went into effect.<sup>41</sup>

The agency's procedures were reviewed for consistency with the requirements of the CAA. Definitions for "withholding of medically indicated treatment," establishing the standard of care, and "infant," describing the class protected, accurately restate the Federal standards. As required by the Federal rule, the procedures provide for obtaining medical records.<sup>42</sup>

The agency has made explicit in its procedures the method to be used to obtain a court order for an independent medical examination to evaluate a specific charge of neglect (see Preface, NOTE D).

Absent from the procedures is any provision for an independent medical consultant to be available to review all reports of medical neglect. Such a consultant would be necessary to help the CPS investigator to do the examination, review the medical records, or otherwise assist the CPS worker. If the medically untrained CPS worker is unassisted in determining whether the health care facility is providing appropriate treatment, the CPS must rely solely upon the medical information received from the hospital against which the complaint was lodged.

The agency notes that "hospital review committees" exist in some hospitals "to deal with medical and ethical dilemmas."<sup>43</sup> A pamphlet produced for the agency by the University of Colorado Health

Sciences Center with HHS funding discusses these committees. Although the pamphlet states that an infant care review committee is "not a decision making body," it then says, "It is hoped that the difficult decisions regarding medical treatment will be made here. If dispute about treatment persists, the state may need to step in."<sup>44</sup>

The two statements appear contradictory and could indicate a subordination of CPS authority to the infant bioethics committee (IBC). Moreover, the pamphlet implies that the CPS will take a passive approach to the enforcement of the CAA if it intends to step in only when there is a dispute with the IBC. It bears repeating that the CAA are intended to respond to a circumstance in which both the parents and the medical provider agreed to withhold medically indicated treatment, food or water from an infant with disabilities. The pamphlet indicates that the agency may not be particularly zealous in its responsibilities to the child.

In most respects the procedures in effect in Colorado are in substantial compliance with the CAA. However, the effectiveness of any investigation would be substantially improved were the agency to provide for the use of an independent third-party medical consultant, selected with input from disability groups, to assist the CPS worker in all nonfrivolous cases. In addition, explicit provisions for a court order for an independent medical examination should be added to the agency's procedures manual to clarify the investigatory process.

## CONNECTICUT

The Connecticut Department of Children and Youth Services (CYS) is the State agency responsible for compliance with and enforcement of the Child Abuse Amendments of 1984 (CAA).

There have been no reports of medical neglect of infants with disabilities in Connecticut since the implementation of the CAA.<sup>45</sup> In response to an update conducted by the Commission, the agency stated that there had been no cases reported since its policy went into effect.<sup>46</sup>

Pediatricians, neonatologists, and disability groups were part of a task force that determined State

<sup>41</sup> Telephone interview with Janet Motz, Child Protection Administrator, Department of Social Services (Aug. 25, 1988).

<sup>42</sup> Colorado Department of Social Services, Staff Manual Volume 7, Social Services, Program Area V, Section 7.501.86.

<sup>43</sup> *Id.*, sec. 7.501.81(E).

<sup>44</sup> Medical Neglect and Disabled Infants, Responsibilities of the Medical Profession.

<sup>45</sup> Telephone interview with Linnea Loin, State Liaison Officer, CYS by *Issues in Law and Medicine* (May 4, 1987).

<sup>46</sup> Telephone interview with Linnea Loin, Program Supervisor, Department of Children and Youth Services (Aug. 3, 1988).

policy on medical neglect.<sup>47</sup> This State policy is reflected in a joint agreement between CYS and the Connecticut Department of Health Services (DHS).<sup>48</sup>

The agreement was based on: “[T]he need to clarify and define the functions of the [DHS] and [CYS] with regard to coordination and consultation with health care facilities providing inpatient newborn care and response to reports of medical neglect. . . .”<sup>49</sup> The agreement states that DHS will review policies on critically ill newborns, identify contact persons in health care facilities, maintain an ongoing dialogue with CYS on the handling of complaints of medical neglect, and “promote the establishment of Infant Care Review Committees in health care facilities with newborn units.”<sup>50</sup>

CYS is responsible for investigating complaints of medical neglect upon order of the CYS chairman. Reports are to be received from a toll-free 24-hour “careline” established under the agreement. Health care facilities with newborn units were informed by CYS that they were required by law to report all cases of medical neglect. The investigative team consists of agency staff and a CYS-designated neonatologist from a hospital other than the one being investigated. The team is to make findings according to 45 C.F.R. § 1340.15, inform parents and physicians, and forward its report to the CYS regional office. If there is a determination of medical neglect, CYS is to petition the court for custody so that treatment can be provided.

On its face, this joint policy appears to provide an objective investigation of reports that Federal standards of care for disabled infants are being violated. Its deficiencies lie in the absence of terms specifying the manner in which CYS will obtain “access to medical records and/or other pertinent information” or “a court order for an independent medical examination of the infant.” (See Preface, NOTES C and D.)

In a letter dated October 11, 1988, the agency responded to a preliminary draft of relevant portions of the Commission’s report. Documents submitted with their response did not demonstrate that its

procedures explicitly provide for obtaining medical records or a court order for an independent medical examination as required by 45 C.F.R. § 1340.15(4)(i) and (ii) (1987).

The agency did not directly respond to the Commission’s assertion that the agency lacks a written policy specifying, pursuant to 45 C.F.R. § 1340.15(4)(i)(1987), the manner in which it would obtain medical records to investigate a report of medical neglect. Rather, it argued that a CYS investigator’s discretion to obtain court orders to remove the children whose welfare is threatened fulfills the requirement of the regulation at issue:

The DCYS Policy Manual Volume 2, Chapter II Section 246.5 provides emergency guidelines whereby an investigator may remove a child without parental consent from dangerous surroundings. The criteria for emergency removal include reference to “caretaker(s) who refuse to permit the child to receive immediate medical care or to comply with on-going treatment recommended by a physician who examines such child.”

Section 244 of the same Policy Manual, provides for placement options for children in danger. No. 2, *Order of Temporary Custody—Superior Court—Juvenile Matters* provides for “a court order to safeguard the immediate welfare of a child which may be issued without a hearing and vests the care and custody of the child concerned in the . . . agency. . . pending the adjudication on the merits of Petition of Alleged Neglect.”<sup>51</sup>

This information appears inadequate to fulfill the plain language of the Federal regulation, which requires that agency programs or procedures “must be in writing” and “must specify the procedures the state agency will follow to obtain. . . medical records.”<sup>52</sup>

With regard to the requirement of a written policy providing procedures to obtain a court order to secure an independent medical examination, the agency cited § 46b-121 of Connecticut General Statutes, which empowers the juvenile court to make and enforce orders protecting juveniles, and a 1985 State attorney general opinion attesting to the sufficiency of the agency’s policies:

Section 46b-121 of Connecticut’s General Statutes, in defining the authority of the juvenile court, states in

Services Regarding Medical Neglect of Infants in Connecticut Health Care Facilities, Oct. 9, 1985.

<sup>50</sup> *Id.*

<sup>51</sup> Letter from Patricia Wilson-Coker, Acting Director, Children’s Protective Services, to William J. Howard, General Counsel, U.S. Commission on Civil Rights (Oct. 11, 1988).

<sup>52</sup> 45 C.F.R. § 1340.15(c)(4) (1987).

<sup>47</sup> Telephone interview with Robert Gossart by *Issues in Law and Medicine* (June 2, 1987).

<sup>48</sup> Telephone interview with Linnea Loin, State Liaison Officer, CYS by *Issues in Law and Medicine* (May 4, 1987).

<sup>49</sup> Agreement Between The Connecticut Department of Health Services and the Connecticut Department of Children and Youth

pertinent part: "In such juvenile matters, the superior court shall have authority to make and enforce such orders directed to parents. . .custodians or other adult persons owing some legal duty to a child or youth therein, as it deems necessary or appropriate to secure the welfare, protection, proper care and suitable support of a child or youth subject to its jurisdiction. . . ."<sup>53</sup>

This fails to meet the requirements of the Federal regulation. It is too broad in scope even to suggest to a CPS worker that an independent medical examination would be in order.

In some respects, the procedures in effect in Connecticut are in compliance with the CAA. However, the agency has failed to specify the manner in which it will obtain medical records or a court order for an independent medical examination of an infant in the manner required by Federal regulations.

#### DELAWARE

In Delaware, the Division of Child Protective Services in the Department of Services for Children, Youth and Their Families is the agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency reported that it had not received any reports of possible withholding of medical treatment from disabled infants with life-threatening conditions.<sup>54</sup>

According to the agency, "medical personnel were necessarily involved in developing procedures in order to insure any reports would be made to our department."<sup>55</sup> However, there is no record that disability rights groups were consulted in the formulation of State policy for medical neglect cases.

Agency procedures were reviewed to determine consistency with Federal law. The definition of withholding of medically indicated treatment complies with the Federal regulation. However, there is no definition of "infant." (See Preface, NOTE E.)

The procedures abdicate the first portion of a medical neglect investigation to the hospital's "contact person." The procedures state that upon a receipt of a report, the CPS worker should immediately talk to the hospital's contact person to begin an

inquiry. The contact person is to ascertain names of the parties, the status of the child's medical condition, and "whether the child's condition and treatment fall under the stated definition" of withholding of medically indicated treatment.<sup>56</sup>

"If the information received [from the contact person] indicates that the report does not come within the definition of medical neglect of handicapped infants, [further] procedures are not applicable in this case."<sup>57</sup> In effect, CPS will rely on the judgment of a contact person at the very hospital whose staff is allegedly denying legally required treatment to make an initial determination whether the allegation should be further investigated. This practice is contrary to the intent of Federal law that vests the CPS agency with the responsibility of determining whether treatment of an infant is legally required under the CAA. (See Preface, NOTE A.)

If the information provided by the contact person indicates that the case falls within the definition of medical neglect, CPS will contact the parents and consult with the hospital's PC/ICR. The latter individual is preselected "by the hospital with the agreement of the Division of Child Protective Services."<sup>58</sup> The CPS worker will rely on the judgment of this PC/ICR that the parents, the treating physician, and the hospital ethics committee (if one exists) are pursuing the proper course of treatment. Further, "if the parents and/or physicians have already obtained the PC/ICR's consultation and treatment is considered consistent with recommendations, the referral is deemed to be an 'unfounded' report of medical neglect."<sup>59</sup>

This approach gives rise to an obvious conflict of interest: the entity being investigated has a key role in designating the physician who will sit in judgment on the case.

The CPS authority to make a determination of medical neglect is further diminished by an agreement between the Delaware Division of Public Health (DPH) and the CPS to investigate "jointly" complaints of "improper medical or nutritional care being delivered to handicapped newborn infants."<sup>60</sup>

<sup>53</sup> Letter from Patricia Wilson-Coker, Acting Director, Children's Protective Services, to William J. Howard, General Counsel, U.S. Commission on Civil Rights (Oct. 11, 1988).

<sup>54</sup> Telephone interview with Robert Lindekamp, Coordinator, Division of Child Protective Services (Aug. 19, 1988).

<sup>55</sup> Letter from Kate Lorenz, Planner I, Department of Services for Children, Youth and Their Families, to *Issues in Law and Medicine* (June 18, 1987).

<sup>56</sup> *Medical Neglect of Handicapped Infants, Procedures*, at 2.

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*, Attachment "B."

<sup>59</sup> *Id.*

<sup>60</sup> Memorandum of Understanding for Responding to Complaints of Improper Medical or Nutritional Care Being Delivered to Handicapped Newborn Infants Between the Division of Public Health, Department of Health and Human Services, and the

This agreement was signed and dated by the parties in October 1985. No reference to this agreement is made in the CPS procedures. According to the terms of the agreement, the DPH will "[a]pply the guidelines of the Bioethics Committee of the American Academy of Pediatrics in evaluating the medical aspects of the case in question" and the CPS will "[r]eview the case for violation of State Law, rules or regulations or Federal regulations."<sup>61</sup> Both "will jointly file a report with the respective Division Directors for further action."

In addition to failure to define the class protected by the CAA treatment standards, Delaware's CPS agency has diminished its authority by agreeing to conduct investigations jointly with other State agencies that are not obliged to enforce Federal standards and that are in fact applying antithetical standards. Most important, it has abdicated the crucial aspects of a medical neglect investigation to the agent of the hospital that is the subject of the investigation or to a physician chosen by that hospital. Delaware is significantly out of compliance with the CAA and its implementing regulation.

## DISTRICT OF COLUMBIA

In the District of Columbia, the Child and Family Services Division in the Family Services Administration within the Department of Human Services is the agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency reported that it had not received any reports of medical neglect of an infant with a disability. An administrator wrote: "There have been no referrals in the District of Columbia of cases in which a handicapped infant with life-threatening conditions has been denied medical treatment. However, we are aware of cases which have been resolved by the hospital and the parents without intervention from Child and Family Services."<sup>62</sup> In response to a followup inquiry, the agency confirmed that there had been no reports. An adminis-

Division of Child Protective Services, Department of Services for Children, Youth and Their Families (October 1985).

<sup>61</sup> *Id.* See chap. 2 for a description of the significant differences between the American Academy of Pediatric guidelines and those in the Federal regulation.

<sup>62</sup> Letter from Dorothy Kennison, Administrator, Family Services Administration, to *Issues in Law and Medicine* (Apr. 10, 1987).

<sup>63</sup> Telephone interview with Carolyn Smith, Chief of Intake for Protective Services (Aug. 9, 1988).

<sup>64</sup> Telephone interview with Carolyn Smith, Chief of Intake for Protective Services, by *Issues in Law and Medicine* (June 15, 1987).

trator stated that the hospitals' infant care review committees generally meet with the parents and the case is resolved at that level.<sup>63</sup> Thus, these cases are not reported beyond the institution and the CPS does not appear interested in becoming involved in them.

The agency reported that when it developed policies to implement the CAA, it consulted with a team of 47 health care professionals over a period of 5 months, contracting with the Children's National Hospital to coordinate the group. In addition, it stated that the procedures were reviewed by every major hospital organization and the American Bar Association.<sup>64</sup> An additional source wrote: "The draft procedure was reviewed by representatives from the Child Advocacy Center, Superior Court, the Metropolitan Police Department, St. Elizabeth's Hospital, the American Bar Association and all of the hospitals in the District of Columbia."<sup>65</sup> Noteworthy is the absence of any disability rights group.

The procedures were reviewed for consistency with the Federal regulation implementing the CAA. The standard of care established by the procedures contains an exception to the general requirement of maximal treatment that is not provided for in the Federal regulation: "if the treatment is part of an experimental research protocol."<sup>66</sup> However, supplementary information published with the Federal regulation does state:

Nothing in the statute or rule forces use of experimental procedures. To the contrary, medical ethics, federal regulations, and many State laws require that patients (or their parents) provide "informed consent" based on free choice and without coercion when physicians propose human experimentation. These rules do not require such experimentation.<sup>67</sup>

Because the class protected by the standard of care includes all children,<sup>68</sup> and "child" is defined as "a person under 18 years of age,"<sup>69</sup> the standard covers a class that includes and is larger than that

<sup>65</sup> Letter from Dorothy Kennison, Administrator, Family Services Administration, to *Issues in Law and Medicine* (Apr. 10, 1987).

<sup>66</sup> Department of Human Services Policy and Procedure, pt. IX, ch. 1, sec. C, topic 5 (I)(e)(ii) at 11 (date indeterminate).

<sup>67</sup> *Child Abuse and Neglect Prevention and Treatment Program*, 50 Fed. Reg. 14,878, 14,886 (1985).

<sup>68</sup> *Id.*

<sup>69</sup> *Id.*, (E)(6) at 3.



required to be protected under the Federal regulation.

In accord with the Federal regulation, the procedures specify the manner in which the department will obtain access to hospital records and obtain court orders for independent medical examinations and treatment. In addition, agency procedures present a detailed method for investigation by an independent medical consultant. The procedures indicate that the decision whether there exists an illegal withholding of medical treatment is vested in the department's medical officer with the assistance of the consultant:

(2) When the allegation concerns a child in immediate danger from medical neglect in a medical facility,

. . . .

(e) Consult with the DHS Commission on Social Services medical officer. . . to ascertain, based on the information obtained:

(i) Whether there has been a withholding of appropriate nutrition, hydration, and medication from the child;

(ii) Whether there has been a withholding of treatment which in his or her reasonable medical judgment will be most likely to be effective in ameliorating or correcting all of the child's life-threatening conditions. Treatment is not medically indicated if the child is chronically and irreversibly comatose; if the treatment would merely prolong the child's dying or not be effective in ameliorating or correcting all of the child's life-threatening conditions, or would otherwise be futile in terms of the child's survival; would be virtually futile and the treatment itself under such circumstances would be inhumane; or if the treatment is part of an experimental research protocol;. . . .<sup>70</sup>

The District of Columbia presents a case of a CPS agency that has established investigative and enforcement procedures that meet the requirements of the CAA. However, it appears that the staff regards the hospital's ICRC as the appropriate forum to resolve the cases and does not seem interested in having these cases reported to them.

<sup>70</sup> Department of Human Services, Policy and Procedure, pt. IX, ch. 1, sec. C, topic 5, at 10.

<sup>71</sup> Telephone interview with C. Christmas, Senior Human Services Specialist, Children, Youth and Family Services, by *Issues in Law and Medicine* (June 6, 1987).

<sup>72</sup> *Id.*

## FLORIDA

The Children, Youth and Family Services Unit in the Florida Department of Health and Rehabilitative Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

In designing its approach to implementation of the regulations underlying the CAA, the agency reported that it had consulted medical groups but not disability groups.<sup>71</sup>

In 1987 an agency staff person stated that there had been a rumor of a case of medical neglect, but no report to the agency.<sup>72</sup> In an update in 1988, a staff person stated that he knew of only one case in the last year. An attorney in Tampa called to report a case, but it was "handled appropriately by the hospital." He added that he "suspect[s] that cases of disabled infants are occurring in the State of Florida, but that the hospitals are handling the situations appropriately—which is the best of all worlds, really."<sup>73</sup>

Commission staff examined the agency's policies and procedures for consistency with the CAA and their implementing regulation. These procedures explicitly abdicate to the hospital the agency's responsibilities under Federal law to investigate and enforce the CAA. The procedures state that upon receipt of a report of medical neglect of a disabled infant, the CPS worker must contact the hospital "liaison" and that if this person reports that the treatment is proper "there is no need for further investigation."<sup>74</sup> If an infant care review committee (ICRC) exists at the hospital, the procedures state that the liaison person will arrange for it to meet and inform the CPS of the results of the meeting. The hospital's own ICRC reviews the case, and the liaison person will instruct the CPS, "based on [ICRC] response, whether there is reason for you to proceed further with provision of treatment for the infant."<sup>75</sup> When there is no ICRC at the hospital, the procedures direct that:

The hospital liaison will inform you whether an independent medical examination is required to reach a conclusion or to protect the interest of the child. If such an examination is required, that liaison, if qualified, will

<sup>73</sup> Telephone interview with Chris Christmas, Senior Human Services Specialist, Children, Youth and Family Services (July 25, 1988).

<sup>74</sup> Florida Health and Rehabilitative Services Pamphlet 175-1, Special Procedures Relating to Medical Neglect of a Disabled Infant, § 3.4.17.5.

<sup>75</sup> *Id.*, § 3.17.7(1)(b).

conduct the examination or will assist you by finding the appropriate physician to conduct the examination.<sup>76</sup>

In the event that there is a question whether the hospital is in compliance with the law, the policy states that “[s]ince there are so many medical decisions involved, [the hospital liaison] will carry the primary responsibility for conducting the investigation.”<sup>77</sup>

In a letter dated September 30, 1988, the agency responded to a preliminary draft of relevant portions of this report. The director of Children, Youth and Family Services in the Florida Department of Human Resources submitted the agency policy, quoted from above, for the position that “Health and Rehabilitative Services Pamphlet 175-1 dated July 1, 1988, specifically requires that CPS staff respond to reports of known or suspected abuse or neglect immediately or within 24 hours.” This did not address the criticism in the portion of the report sent to the agency, which stated that on its face the policy explicitly abdicates to internal hospital infant care review committees or hospital staffs the authority to decide whether illegal denial of treatment is taking place when a report of suspected denial of treatment is received by the State agency.

The Florida CPS procedures do not provide for an independent medical review of a report of withholding of medical treatment from a disabled infant. The procedures establishing this review system present real conflicts of interest and present fundamental questions regarding the degree of protection given vulnerable children. (See Preface, NOTES A and B.) The procedures contain no provision for obtaining a court order for an independent medical examination. (See Preface, NOTE D).

In addition, in apparent response to the Commission’s draft report, the director asserted that the “Child Protective Investigator’s Decision Handbook further delineates the responsibility of the protective investigator to obtain a court order for treatment, if necessary.” No documentation was provided for this assertion, and the fact remains that the current procedure lacks a specific provision, as required by the Federal regulation, that states the method the CPS agency will use to obtain a court order for an

independent medical examination in a Baby Doe situation.

Florida presents the paradigm case of a State CPS agency that has wrongfully delegated its investigative responsibility to the very hospitals whose staff are the subject of alleged illegal denial of treatment.

## GEORGIA

In Georgia, the Division of Family and Children Services in the Department of Human Resources is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The State CPS office stated that it was not aware of any cases of medical neglect in Georgia. The representative added that this “was left to the local authorities.”<sup>78</sup>

The agency reported that it had consulted members of the State’s infant care review committees in formulating its procedures for investigating of a report of withholding medical treatment from a disabled infant. No other associations, such as disability rights groups, were consulted.<sup>79</sup>

The State agency’s procedures were reviewed for compliance with the Federal regulation that implements the CAA. The Georgia procedure does not specify in writing the manner in which it will obtain medical records (see Preface, NOTE C) or the manner in which it will obtain a court order for an independent medical examination of the infant (see Preface, NOTE D).

Most seriously, the agency procedure codifies an abdication of its responsibility to conduct an independent agency investigation of a report of medical neglect to infant care review committees. (See Preface, NOTES A and B.) The agency’s *Guidelines for Medical Neglect of Disabled Infants* state that all medical neglect cases will be handled by a three-part system of infant care review committees (ICRC). The guidelines describe a system in which treatment decisions are made by the hospital’s ICRC or, if such a committee does not exist at the hospital, a regional ICRC. A statewide committee is also to be available for guidance, advice, and precedent case decisions on “multiple congenital malformation syndromes incompatible with life.” If a complaint is filed with the CPS agency, the guidelines state: “Cases reported directly to CPS will be handled in the same

<sup>76</sup> *Id.*, §3.4.17.6(2).

<sup>77</sup> *Id.*, §3.4.17.5(4).

<sup>78</sup> Telephone interview with Gerald Gouge, Chief, Child Protective Services Unit, Division of Family and Children Services (July 20, 1988).

<sup>79</sup> *Id.*

manner with initial (local in-hospital), secondary (regional ICRC), and if necessary, tertiary (state-wide) reviews.”<sup>80</sup>

The CPS guidelines rationalize this abdication of responsibility and perhaps attempt to dispel fear of liability for this system by stating:

As the ICRCs work in close association with CPS and committee members they would be afforded the same legal immunities or safeguards as CPS workers since in effect they would be acting as consultants, advisors to CPS and the State of Georgia. These safeguards are supported by the Attorney General’s Office.<sup>81</sup>

The Georgia procedure lacks methods to secure review of medical records or an independent medical examination. Instead, the State CPS agency defers entirely to the judgments of infant care review committees. Georgia is fundamentally out of compliance with the CAA and their implementing regulations.

## HAWAII

In Hawaii, the Child Protective Services Unit within the Department of Human Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

Program assistants developed the investigative procedures for implementation of the Federal regulations. The agency reported that neither medical nor disability rights groups were consulted.<sup>82</sup>

The agency stated that no reports of medical discrimination have come to its attention since the regulation went into effect.<sup>83</sup>

Hawaii’s procedures for an investigation of a medical neglect report were reviewed for compliance with the Federal regulation that implement the CAA. In contravention of Federal regulatory requirements, the procedures themselves fail to specify in writing the manner in which agency staff will obtain a court order for an independent medical examination of the infant, although the agency possesses authority to seek one.<sup>84</sup>

The most serious failure of compliance is that the CPS agency has abdicated its duty to investigate reports of medical neglect to decide whether illegal

denial of treatment is taking place. The procedures direct the CPS worker to log a medical neglect report “as a *non-CPS case* if the treating physician does not recommend treatment and a second medical opinion (including another physician, the hospital’s review committee, the Hawaii Medical Association’s review committee, CPS Team physician) concurs with this recommendation.”<sup>85</sup> Although a CPS team physician is mentioned, in short, a physician who wishes to deny treatment in violation of the standard of care established by the CAA need merely find one other physician or a review committee to agree in order to prevent any intervention by the CPS agency on behalf of the child’s right to receive treatment. This clearly runs counter to the requirement of the CAA that the CPS agency serve as an independent investigating authority to ensure that the Federal standard of care is provided to the disabled infant.

Commenting on a draft of relevant portions of the Commission’s report, the administrator of Services Program Development of the Hawaii Department of Human Services stated:

Section 1100.9.2 states in effect that further investigation may not be required if inquiry by child protective services staff, upon receiving a report of alleged medical neglect, finds that a second opinion concurs with the opinion of the treating physician. By requiring initial investigative action by child protective services following receipt of a report, this procedural guideline does not completely abdicate the investigative responsibility to an infant care review committee but serves to assist the investigator in the process of disposition.

Far from refuting, this confirms that the Hawaii CPS abdicates its responsibility to physicians selected by the physician or hospital against whom a complaint has been lodged the determination of whether legally mandated treatment requirements are being met. (See Preface, NOTE A.) Hawaii should ensure that medical consultants not affiliated with the hospital or physician charged with neglect are made available to assist the CPS worker in the investigation of a report of withholding of medically indicated treatment of a handicapped infant.

<sup>80</sup> Georgia Department of Human Resources, Child Protective Services Manual, sec. 2103.14, app. H, *Guidelines for Medical Neglect of Disabled Infants*, at 4.

<sup>81</sup> *Id.* at 2.

<sup>82</sup> Telephone interview with Stanley Inkyo, Program Administrator, Child Protective Services, by *Issues in Law and Medicine* (July 6, 1987).

<sup>83</sup> Telephone interview with Stanley Inkyo, Program Administrator, Child Protective Services, by Commission staff (July 28, 1988).

<sup>84</sup> Hawaii Rev. Stat. §587-21.

<sup>85</sup> Child Protective Services Policy Manual sec. 1100.9.2 (June 1987). Emphasis added.

Hawaii is fundamentally out of compliance with the CAA and its implementing regulation.

## IDAHO

The Idaho Department of Health and Welfare is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

Agency personnel reported that they have had no reports of medical neglect of infants with disabilities since the regulation went into effect.<sup>86</sup>

The agency reported in a January 3, 1988, letter to the Commission that: "In our formulation stage of preparing draft policy and procedures on this topic a committee was convened to draft proposed materials. This committee included the Chief of the Bureau of Developmental Disabilities of the Department of Health and Welfare. He received input from appropriate groups to include the Downs Syndrome Parents Groups, Coalition of Advocates for the Disabled, and other parents support groups for children with various disabilities."

The agency procedures were reviewed for compliance with the Federal regulation that implements the CAA.

All definitions of terms mirror the Federal standards. As required by Federal regulations, CPS social workers are instructed to "obtain a copy of the infant's medical treatment record from the health care facility or hospital as a function of the investigation process. . . ."<sup>87</sup> In addition, the procedures meet the Federal requirement to provide for obtaining a court order for an independent medical examination of the infant when cooperation from the medical provider is not forthcoming.<sup>88</sup>

The procedures indicate that the agency alone is responsible for determining whether appropriate treatment is provided. The determination of whether illegal withholding of medical treatment is taking place is vested in the medical chief, Bureau of Child Health:

The initial determination that withholding of medically indicated treatment as defined in Manual Section 3-2304.03 is occurring or is being prescribed by the infant's physician, will be made by the Medical Chief,

<sup>86</sup> Telephone interview with Ed Van Dusen, Social Services Coordinator, Department of Health and Welfare (July 20, 1988).

<sup>87</sup> Social Services Manual, sec. 3-2305.06(c).

<sup>88</sup> *Id.*, sec. 3-2305.13.

<sup>89</sup> *Id.*, sec. 3-2305.08.

Bureau of Child Health or his designee, with or without independent medical examination.<sup>89</sup>

On their face, Idaho procedures appear to comply with the requirements of the CAA and its implementing regulation.

## ILLINOIS

The Illinois Department of Children and Family Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

Regarding reports of incidents of medical neglect of infants with disabilities, Illinois stated:

Fortunately, the number of reports alleging the withholding of medically indicated treatment from disabled infants has remained small. This low level may be the result of cooperative efforts between the Department of Children and Family Services, the Illinois State Medical Society and other service providers which have focused their efforts on expanding the availability of support resources to troubled families.

During FY 86 (July 1, 1985 through June 30, 1986) a total of ten *medical neglect of disabled infants* allegations were made. After investigations, three were indicated.

So far, during FY 87 (July 1, 1986 to date) one allegation was made. After a thorough investigation, this case was indicated.<sup>90</sup>

In response to followup inquiry by Commission staff, the department stated that during FY 88 (July 1, 1987, through June 30, 1988) it had received three reports. After investigation, two were found to be indicated (i.e., a violation was found).<sup>91</sup>

The agency reported that it consulted the Illinois State Medical Society when it developed procedures for the investigation of a report of withholding medical treatment from a disabled infant. There was no indication that disability rights groups were consulted.<sup>92</sup>

The procedures were reviewed for compliance with the Federal regulation that implements the CAA. The definitions of terms correctly reflect the Federal standards. In accord with the Federal regulations, the procedures specify the manner in which the Department will obtain "administrative

<sup>90</sup> Letter from Bobby J. Hall, Program Specialist, Department of Children and Family Services, to *Issues and Law and Medicine* (Mar. 30, 1987) (emphasis in the original).

<sup>91</sup> Telephone interview with Foster Centola, Program Specialist, Department of Children and Family Services (July 20, 1988).

<sup>92</sup> Telephone interview with Bobby J. Hall, Program Specialist, Department of Children and Family Services (June 1987).

subpoenas or court orders to obtain access to hospital staff or records. . . .” and the manner in which it will obtain court orders for independent medical examinations.<sup>93</sup>

The department has engaged a “perinatal coordinator” to advise the social worker investigating a report of whether treatment is necessary, to arrange independent medical evaluations, and if necessary, to advise whether the child should be taken into protective custody. This person is a medical specialist who practices at a special care nursery for infants. The procedures direct: “All reports of medical neglect of disabled newborns and infants under one year of age must be reviewed by the Department’s Perinatal Coordinator.”<sup>94</sup> The department procedures delineate the particular roles of the perinatal coordinator and the CPS worker:

The Perinatal Coordinator shall provide a professional judgment whether there is evidence of medical neglect for each report of medical neglect involving a disabled infant under one year of age. However, the investigative worker is responsible for making the recommendation of indicated or unfounded based upon the Perinatal Coordinator’s judgment and other facts of the report.<sup>95</sup>

The procedures acknowledge the existence of hospital infant care review committees but correctly recognize that their judgments on treatment may not be correct and are not binding upon the CPS: “Whenever a hospital has an Infant Care Review Committee, Department investigative staff or the Perinatal Coordinator will consult with the Committee and will document, in writing, any disagreements with the Committee’s recommendations and the reasons for them.”<sup>96</sup>

On their face, the Illinois procedures appear to comply with the CAA and their implementing regulation.

## IOWA

In Iowa, the Child Protective Services Program within the Bureau of Adult, Children and Family Services of the Department of Human Services is

<sup>93</sup> Department of Children and Family Services, Rules and Procedures, sec. 302.130 (i), 160 (g).

<sup>94</sup> *Id.*, sec. 302.130 (i)(2)(B).

<sup>95</sup> *Id.*

<sup>96</sup> *Id.*, sec. 302.190 app. A.

<sup>97</sup> Telephone interview with Tim Barber-Lindstrum, Program Manager, Child Protective Services, by *Issues in Law and Medicine* (June 12, 1987).

the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

In developing procedures for the investigation of a report of medical neglect of an infant with a disability, the agency reported that it had consulted the Iowa Medical Association, the Iowa Hospital Association, and the Iowa Academy of Pediatrics. There is no indication that disability rights groups were consulted.<sup>97</sup>

The agency stated that no reports of medical neglect of disabled infants had been received since the regulation went into effect.<sup>98</sup>

The Iowa procedures are set forth in a cover memorandum from the CPS to the chief executive officers of Iowa health care facilities.<sup>99</sup> These procedures were reviewed for compliance with the Federal regulations that implement the CAA.

The State code includes a definition of “withholding of medically indicated treatment,” establishing a standard of care that conforms to Federal law although this definition is absent from the agency’s procedures manual. The procedures manual properly states the definition of the protected class of infants.

The Federal requirement that an agency have a specified method to gain access to an infant’s medical records is met where the procedures provide that: “Court action may be necessary to secure access to medical records or other pertinent information when access is necessary to assure an appropriate investigation.”<sup>100</sup> The procedures do not expressly state the manner in which the agency will obtain a court order for an independent medical examination, as required by 45 C.F.R. § 1340.15(4)(ii) (see Preface, NOTE D).

It appears that the agency has agreements with four independent medical examiners, chosen by the Iowa chapter of the Academy of Pediatrics, to assist CPS investigators with reports of medical neglect.<sup>101</sup>

The agency procedures delineate the particular roles of the “medical consultant” and the CPS worker: “The medical consultant will assist the worker in evaluating all medical information. The

<sup>98</sup> Telephone interview with John Holcamp, Program Manager, Child Protective Services (Aug. 4, 1988).

<sup>99</sup> Memorandum from Timothy Barber-Lindstrum, Program Manager, Child Protective Services, to Chief Executive Officers, Iowa Health Care Facilities, Subject: Baby Doe Procedures (June 23, 1987).

<sup>100</sup> *Id.* at 4.

<sup>101</sup> Information obtained from Tim Barber-Lindstrum, Program Manager, Child Protective Services, by *Issues in Law and Medicine* (June 12, 1987).

amount of assistance rendered by the medical consultant shall be jointly determined by the worker and the medical consultant, based upon the needs of the case."<sup>102</sup>

On the face of its procedures, the agency appears ready to evaluate both parental refusals to consent to treatment and attending physician decisions to deny treatment to an infant. The memo does not reflect an abdication of responsibility to a hospital's infant care review committee on the question whether treatment (or nontreatment) is legally correct.

With the exception of the failure to describe the manner in which court orders will be obtained for independent medical examinations, the Iowa procedures on their face appear to comply with the requirements of the CAA and their implementing regulation.

### KANSAS

In Kansas, Youth Services within the Department of Social and Rehabilitation Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

In developing its approach to implementation of investigation procedures, the agency stated, "The Department did not consult disability rights groups. We did consult medical experts, hospitals, and the Kansas Regional Perinatal Medical Committee."<sup>103</sup>

The agency said that there had been no reports of withholding of medically indicated treatment from infants with disabilities since the CAA went into effect.<sup>104</sup>

The Kansas agency's procedures were reviewed for compliance with Federal regulations. Definitions for "withholding of medically indicated treatment," establishing the standard of care, and "infant," establishing the class protected, are included and accurately restate the Federal standard. The enforcement mechanisms that are required by the Federal regulation to be specified in the agency's procedures, such as the manner in which the CPS will obtain medical records and a court order for independent medical evaluation, are also set forth. The procedures provide that an independent medical consultant is available from either one of the

<sup>102</sup> Memorandum from Timothy Barber-Lindstrum, Program Manager, Child Protective Services to Chief Executive Officers, Iowa Health Care Facilities, Subject: Baby Doe Procedures, at 4. (June 23, 1987).

<sup>103</sup> Telephone interview with Roberta Sue McKenna, Attorney, Youth Services, by *Issues in Law and Medicine* (Apr. 10, 1987).

State's perinatal center hospitals. It specifies that a medical consultant from the other hospital shall be used in the event a case is reported in one of these centers.

On their face, the Kansas procedures appear to comply with the CAA and their implementing regulation.

### KENTUCKY

In Kentucky, the Child Protective Services unit within the Department for Social Services of the Cabinet for Human Resources is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency stated that it consulted the Easter Seals Hospital for assistance in developing a procedure for investigation.<sup>105</sup> It gave no indication that disability rights groups had been consulted.

The agency said that there had been only one case reported since the CAA went into effect, and that was not considered to involve denial of treatment based on disability, since the parents wished to withhold treatment because of religious principles. A court order for treatment was readily obtained. A CPS specialist stated that there had been "only one reported Baby Doe case in the three years I've been here. Of course, we hear through the grapevine from medical personnel that cases go unreported."<sup>106</sup>

Despite this, the agency appears to have actively responded to the requirements of the CAA, and the agency procedures indicate that the agency has established a toll-free hotline so that "medical personnel or other interested persons can notify the Department of suspected or known instances of the withholding of medically indicated treatment of disabled infants with life-threatening conditions in hospitals or health care facilities."<sup>107</sup>

The agency's procedures were reviewed for compliance with Federal regulation. Definitions of "withholding of medically indicated treatment," establishing the standard of care, and "infant," establishing the class protected, are included and accurately restate those in the Federal regulation. The enforcement mechanisms required by the Fed-

<sup>104</sup> Telephone interview with Roberta Sue McKenna, Attorney, Youth Services (Aug. 3, 1988).

<sup>105</sup> Telephone interview with Betsy Farley, Child Protective Services, by *Issues in Law and Medicine* (June 22, 1987).

<sup>106</sup> Telephone interview with Michele Gore, Child Protective Services Specialist, Child Protective Services (July 21, 1988).

<sup>107</sup> Family and Children's Services Manual, ch. IV, A. 11

eral regulation to be specified in the agency's procedures, such as the manner in which CPS will obtain medical records and court orders for independent medical evaluations, are included. The procedures provide for an independent medical consultant to be available for an investigation of a medical neglect report. The procedures state: "Upon receipt of a report of suspected medical neglect of a handicapped infant in a hospital (from the hotline or local staff), the designated Central Office staff indicated above will immediately notify one of the Department's medical consultants. The medical consultant will immediately investigate the report."<sup>108</sup> The agency reported that two specialists from two perinatal centers in the State, one in the eastern part of the State, the other in the west, are under contract with the State to respond to the reports. To avoid professional conflicts, if a report is from the west, the specialist from the east responds and vice versa for a report from the east.<sup>109</sup>

On their face, the Kentucky procedures appear to comply with the CAA and their implementing regulation.

#### LOUISIANA

In Louisiana, the Division of Children, Youth and Family Services of the Office of Human Development in the Department of Health and Human Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

In response to a Commission inquiry, the agency stated that "the hospitals had not reported any cases."<sup>110</sup>

The State agency's policies and procedures were reviewed for compliance with the Federal regulation that implements the CAA. Louisiana's procedures are contained in *A Statewide Program for the Implementation of Procedures for the Reporting and Investigation of Suspected Instances of Medical Neglect of Disabled Infants*. This is a comprehensive manual for the investigation of a Baby Doe report and appears to implement much of HHS's supplementary information in the final regulation. The manual

<sup>108</sup> *Id.*

<sup>109</sup> Telephone interview with Betsy Farly, Child Protective Services, by *Issues in Law and Medicine* (June 22, 1987).

<sup>110</sup> Telephone interview with Terry Gibson, Bureau Director, Division of Family, Youth and Family Services (July 21, 1988).

<sup>111</sup> Telephone interview with Sue Steib, CPS Specialist, Division of Children, Youth and Family Services, by *Issues in Law and Medicine* (June 1, 1987).

offers step-by-step investigation directions and has appendices with pertinent questions for the hospital liaison, the parents, and the hospital's infant care review committee.

Definitions presented in the manual fully conform to those contained in the Federal regulation. The enforcement mechanisms required by the Federal regulation to be specified in the agency's procedures are included in the manual, including the manner in which the CPS agency will obtain medical records or court orders for independent medical evaluations. The manual provides for an independent medical consultant to provide assistance to the CPS investigator. The agency reported that the State has contracted with 14 physicians across the State to assist in these cases.<sup>111</sup>

On their face, Louisiana's procedures appear to comply with the CAA and their implementing regulation.

#### MAINE

In Maine, Child Protective Services within the Department of Human Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency stated that it has received no reports of medical neglect of infants with disabilities since the CAA went into effect.<sup>112</sup>

In developing procedures for implementation of the CAA, the agency reported that it had consulted with individuals from hospitals and medical associations; disability rights groups were not consulted.<sup>113</sup>

The State agency's procedures were reviewed for compliance with the Federal regulation implementing the CAA. Enforcement mechanisms required by the Federal regulation to be specified in CPS agency procedures, such as the manner in which a CPS agency will obtain medical records and court orders for independent medical evaluations, are included. The intake procedures include a definition of "withholding of medically indicated treatment," establishing the standard of care, that mirrors the Federal definition. However, there is no definition for the term "infant," meaning that the protected class is not

<sup>112</sup> Telephone interview with Phyllis Miriam, Child Protection Program Consultant, Department of Human Services (July 27, 1988).

<sup>113</sup> Telephone interview with Barbara Churchill, Department of Human Services, by *Issues in Law and Medicine* (June 15, 1987).

described. This is a significant omission.<sup>114</sup> (See Preface, NOTE E.) The procedures also direct that, if an allegation of withholding of medically indicated treatment meets the Federal standard, the CPS worker should alert the central office program manager. The procedures then require:

(2) The Program Manager to seek medical consultation and contact the designated hospital liaison personnel.

(3) If the allegations are confirmed, and with consultation by the Central Office Program Manager and the Assistant Attorney General, the regional office staff will seek a Medical Treatment Order.<sup>115</sup>

This procedure appears to meet the regulatory requirement for independent CPS investigation of a report of medical neglect of an infant with a disability. The agency reported that an employee of the Maine Bureau of Health is the designated medical reviewer.<sup>116</sup> However, a "Fact Sheet" interpreting the CAA that was distributed by the central agency office to all CPS regional program managers in April 1985 misstates the legal responsibilities of the CPS. The fact sheet, developed by an organization known as Action for Child Protection, gives general background information on legal requirements of the CAA. In a question and answer format designed to instruct a CPS audience, the following misstatements of law are given:

4. QUESTION: What is required of CPS in receiving suspected reports of medical neglect of handicapped infants?

ANSWER: The CPS response would be similar as in all other reports of medical neglect. Upon receiving a report, CPS must first verify, through consultation with the treating physician, review team, or other hospital designee

<sup>114</sup> Commenting on a draft of relevant portions of the Commission report, the agency stated:

"infant" is not defined in statute or policy in Maine but the definition in the policy [enclosed] was the federal definition for what cases require investigation by the Department and if substantiated specify that court protection be sought for that infant.

Letter from Sandra S. Hodge, Program Manager, Child Protective Services, to William J. Howard, General Counsel, U.S. Commission on Civil Rights (Oct. 12, 1988). Although the referenced policy includes a definition of withholding of medically indicated treatment that uses the term "infant," it nowhere defines "infant."

<sup>115</sup> Department of Human Services Policy Manual, C. Intake Screening, 8.(a).

<sup>116</sup> Telephone interview with Sandra Hodge, Child Protection Services Program Manager, Department of Human Services, by *Issues in Law and Medicine* (June 15, 1987).

that adequate nutrition, hydration, and medication is being given to the infant, whether special medical attention is needed to correct a life-threatening condition, and whether legal intervention is required.<sup>117</sup>

This response misstates the law by giving the hospital that is being investigated because its staff is accused of medical neglect the task of informing the investigator "whether legal intervention is required." The pamphlet goes on to say:

7. QUESTION: Does CPS have to get involved if the treating physician and the child's parents are in agreement to withhold treatment from a handicapped infant?

ANSWER: New procedures should provide for CPS to utilize medical consultants such as a hospital Infant Care Review Committee to determine if treatment is "medically indicated." Again, determination if treatment is "medically indicated" is made by a reasonably prudent physician as defined above. If the treating physician, and the Infant Care Review Committee or hospital designee agree that treatment is not "medically indicated" CPS does not need to further investigate.<sup>118</sup>

This, of course, is contrary to the defined roles of the CPS and the infant care review committee set forth in the Federal regulation. The determination whether treatment is medically indicated is a CPS decision, not to be abdicated to a review committee at the hospital being investigated. (See Preface, NOTE A.)<sup>119</sup>

Apart from their failure to define the protected class, on their face the Maine procedures appear to comply with the CAA and their implementing regulation. However, the distribution of the Action for Child Protection Fact Sheet raises significant questions about whether Maine CPS workers have erroneously been led to believe that they should

<sup>117</sup> Action for Child Protection *Fact Sheet*, NEW REQUIREMENTS FOR CPS AGENCIES, Regarding Cases Involving the Withholding of Treatment From Disabled Infants with Life-Threatening Conditions, question 4.

<sup>118</sup> *Id.*, question 7.

<sup>119</sup> In a letter dated Oct. 12, 1988, the agency responded to a preliminary draft of relevant portions of the Commission report. The Child Protective Services program manager, without making reference to the Fact Sheet, submitted the intake policy, also quoted above, to demonstrate that the agency makes the decision on the question of medical neglect. She wrote that:

The material related to medical treatment clearly gives the decision making about whether a case meets the "Baby Doe" criteria to the Department not a hospital. The medical consultant is an employee of the Department. This section also directs that specific court action be taken by Department staff to protect the infant.

Letter from Sandra S. Hodge, Program Manager, Child Protective Services, to William J. Howard, General Counsel, U.S. Commission on Civil Rights (Oct. 12, 1988).



uncritically defer to the conclusions of hospital infant care review committees.

## MARYLAND

In Maryland, the Child Protective Services Unit of the Social Services Administration within the Department of Human Resources is the State agency responsible for compliance with and enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency stated that it had received only one report of withholding medically indicated treatment since the regulation went into effect. This report, occurring in 1986, concerned an infant with anencephaly who was given proper care according to the investigation. The child died a week after his birth.<sup>120</sup>

The agency's investigation procedures for a medical neglect report were reviewed for compliance with the Federal regulations that implement the CAA. The "procedures were developed in consultation with the Maryland Hospital Association, the Fetus and Newborn Committee of the Maryland Academy of Pediatrics, and the Medical-Chirurgical Faculty of Maryland."<sup>121</sup> No disability rights groups were listed as being consulted.

Enforcement mechanisms required by the Federal regulation to be specified in CPS agency procedures, such as the manner in which a CPS agency will obtain medical records and a court order for independent medical evaluation, are set forth. In both the "preliminary" and "further investigation" procedure provisions, social workers are instructed that "[i]t may be necessary to petition the court in order to gain access to the child's medical records or to conduct or to obtain an on-site investigation or to obtain an independent medical examination."<sup>122</sup> CPS workers are further instructed to "[c]ontact the agency attorney so that compliance with the applicable laws may be determined."<sup>123</sup> These provisions appear to satisfy the Federal requirement that the State agency specify in its procedures the manner in which it will obtain access to medical records and/or other information and "a court order for an independent medical examination of the infant."<sup>124</sup>

<sup>120</sup> Telephone interview with Gisele Meek, Policy Specialist, Social Services Administration (Aug. 12, 1988).

<sup>121</sup> Memorandum from Frank Farrow, Executive Director, Maryland Department of Human Resources, to Chief Executive Officers, all Maryland Acute-Care Hospitals 2 (Oct. 4, 1985) (available in files of U.S. Commission on Civil Rights).

<sup>122</sup> Social Services Administration Procedures Manual, Special Procedures, Policy .03, Procedure .01, para. 5, at 175.

The procedures establish a method for an independent medical examination of a child:

Upon conclusion of the preliminary inquiry, the worker will consult with a medical expert specializing in the type of medical problem or disabling condition identified in the health care provider's preliminary report. The expert will assist the local department in understanding the medical reports and technical issues involved in determining whether medically indicated treatment is being withheld.<sup>125</sup>

The procedures provide that when further inquiry is needed:

If it is not possible to determine from the preliminary inquiry and technical review whether medical neglect is "confirmed" or "ruled out" in the reported instance, the worker shall initiate further investigation, with the assistance of medical experts, into the circumstances of the case, in order to come to a determination of what further action, if any, is needed.<sup>126</sup>

The procedures include an accurate definition for "withholding of medically indicated treatment." However, there is no definition of the term "infant." In a letter dated September 28, 1988, commenting on a preliminary draft of relevant portions of this report, the program manager acknowledged the omission. However, he stated that under Maryland law protective services are provided "to any individual under the age of 18 years." With the important exception of their failure to define "infant," the Maryland procedures appear on their face to comply with the requirements of the amendments and their implementing regulation.<sup>127</sup>

However, as Preface NOTE E explains in detail, the standard of care the Child Abuse Amendments require for "disabled infants with life threatening conditions" is far more precise and detailed than the general language applicable to all minors. The failure to define "infant," so as to describe accurately the class of children protected, is a significant failing.

The agency's procedures appear on their face to be an approach to enforcement that is objective and adequate. They would be improved if the term

<sup>123</sup> *Id.*

<sup>124</sup> 45 C.F.R. § 1340.15(c)(4)(ii) (1987).

<sup>125</sup> *Id.*, Procedure .02 at 176.

<sup>126</sup> *Id.*, Procedure .05 at 176.

<sup>127</sup> Letter from Laura Skaff, D.P.A. to William J. Howard, General Counsel, U.S. Commission on Civil Rights (Sept. 28, 1988).

"infant" were added to the procedure to lend clarity to enforcement.

## MASSACHUSETTS

The Massachusetts Department of Social Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency stated that it had received no reports of medical neglect of handicapped infants with life-threatening conditions since the regulation went into effect.<sup>128</sup>

In developing procedures for implementation of the CAA, the agency reported that it consulted with the New England Medical Center, the Federation for Children with Special Needs, the Developmental Disabilities Council, and a panel of 20 to 30 persons that included an ethicist from Boston City Hospital, attorneys, public health officials, neonatologists, and pediatricians.<sup>129</sup>

Agency procedures were reviewed for compliance with the Federal regulation implementing the CAA. All definitions of terms mirror the Federal standards. The procedures state that "[i]f necessary, a DSS attorney initiates appropriate court action to gain access to the hospital, medical information or medical examination of the reported infant."<sup>130</sup> These provisions would appear to satisfy, if in a somewhat cursory fashion, the Federal regulatory requirement of the CAA regulation that the State agency specify in its procedures the manner in which it will obtain access to medical records and court orders for independent medical examinations.

If there is a weakness in this policy, it is the fact that notwithstanding the instruction to the DSS attorney to "gain access . . . to an independent medical examination," there is little in the procedure that indicates that there is an independent third party medical examiner to assist the CPS. The procedures appear to instruct the CPS worker to rely on the medical information received from the hospital against which the complaint was lodged:

After obtaining the signed consent of the infant's parents, the investigator determines from a review of the infant's medical record and an interview with the hospital representative the nature of the child's medical record and an interview with the hospital representative the nature of the

child's medical condition(s); the proposed treatment; how the infant's course of treatment was selected; if alternative treatment options were considered; if physicians other than the primary physician participated in the formulation of the treatment plan and/or second opinions from other specialists were obtained; if there was consensus among the treatment providers (nurses, physicians, etc.) with regard to the appropriateness of the treatment; and if the treatment decisions were reviewed by a hospital Infant Care Review Committee or comparable review body.<sup>131</sup>

"Medical consultation" is not obtained until the investigation has been completed,<sup>132</sup> and no reference is made to an outside medical reviewer. The CPS worker appears to be alone in determining whether the medical establishment is providing appropriate treatment. The effectiveness of any investigation to discover if treatment is medically correct would be substantially improved were the agency to specify in its procedures the use of an independent third-party medical consultant, selected with the benefit of advice from disability groups, at an early enough stage to assist the CPS worker in investigating all nonfrivolous cases.

The procedures developed by this agency are in compliance with the Federal regulatory standards, although use of independent third-party medical personnel to assist the CPS in the determination of medically indicated treatment would substantially improve the ability of the CPS to make a truly independent determination on whether treatment being provided to the subject of a report is in fact in compliance with the standards of the CAA.

## MICHIGAN

In Michigan, the Office of Children and Youth Services within the Department of Social Services is the State agency responsible for compliance with the Child Abuse Amendments of 1984 (CAA).

The agency stated in 1987 that:

To date, Michigan has had only one report when medically indicated treatment was withheld from a disabled infant with a life-threatening condition. In this report, the parents, at first, did not consent to the recommended medical treatment. Prior to initiating court action, however, they consented for their child to be treated.<sup>133</sup>

Somewhat surprisingly, the agency responded to a followup inquiry that "the information system that

<sup>128</sup> Telephone interview with Jane Waldfogel, Case Practice Specialist, Office of Professional Services, Department of Social Services, by Commission staff (July 22, 1988).

<sup>129</sup> Telephone interview with Judith Riley, Department of Social Services, by *Issues in Law and Medicine* (July 13, 1987).

<sup>130</sup> DSS Policy No. 86-010 at 4, para. 7.

<sup>131</sup> *Id.* at 3, para. 4.

<sup>132</sup> *Id.*, para. 5.

<sup>133</sup> Letter from Laura Daniel, Program Consultant, Department of Social Services, to *Issues in Law and Medicine* (Apr. 22, 1987).

we have does not factor out these types of cases. These cases are only classified as medical neglect."<sup>134</sup>

In developing procedures for the implementation of the CAA, the agency reported that "[m]edical organizations and disability rights groups were involved in developing this policy."<sup>135</sup>

Agency procedures were reviewed for compliance with the Federal regulation that implement the CAA. Definitions of terms stated in the procedures mirror the Federal standards, and the procedures contain instructions for the CPS worker to petition a court for orders for review of medical records and independent medical evaluations, in accord with Federal requirements.

However, investigations are to be pursued only when a report alleges a parental refusal to consent to treatment for their child. When a parent or anonymous source reports to the agency that a hospital is withholding medically indicated treatment from an infant with a disability, the procedures expressly prohibit CPS involvement. The procedures state:

CPS is responsible for responding to reports that *parents* are neglecting their child's health and welfare by withholding medically indicated treatment. . . . *Reports from parents or others that the hospital or health care provider is neglecting. . . provide proper or suitable care for the infant is outside the scope and responsibility of CPS, and are not appropriate referrals for CPS investigation.* Existing procedures including medical review committees within the health care facility are to be used for addressing such concerns.<sup>136</sup>

The Federal regulations clearly require that upon receiving a report the State's CPS system must make the determination whether treatment is medically indicated under the CAA. This self-imposed limitation on CPS investigations is inconsistent with the respective roles and responsibilities of the CPS and the infant care review committee, as set forth in the Federal regulations. (See Preface, NOTE A.) These procedures explicitly abdicate to the hospital the agency's responsibilities under Federal law to investigate and enforce the CAA.

The foregoing language allows the hospital that has had a complaint lodged against it to review the case, or to serve as the equivalent of an independent

medical examiner. Because of the obvious conflicts of interest between the ICRC member's duty to the hospital, the child, and the parents, this runs counter to the requirements of the CAA that the CPS agency serve as the independent investigating authority to ensure that the Federal standard of care is provided to the infant with a disability.

Commenting on a draft of relevant portions of the Commission's report, the agency argued that the parents are legal guardians of the child and are thus the decisionmakers responsible for the child's health and welfare; if the parents act responsibly, there is no basis for involvement of the CPS agency.

The agency stated:

Based on the preceding discussion that parents are the decision makers concerning the care and treatment for their disabled infant, CPS involvement is appropriate when *parents* are alleged to be neglecting their infant's care. An entity which is not the decision maker or responsible for the child's care is not appropriate for CPS involvement.<sup>137</sup>

Whatever may be the case with regard to other forms of child abuse and neglect, however, Federal law requires that State agencies receiving Federal funds do what is necessary to prevent illegal denial of treatment to children with disabilities. The statute provides that to qualify for Federal funding, a CPS agency must possess:

authority, under State law, for the State child protective service system to pursue any legal remedies, including the authority to initiate legal proceedings in a court of competent jurisdiction, as may be necessary to prevent the withholding of medically indicated treatment from disabled infants with life-threatening conditions.<sup>138</sup>

This language encompasses circumstances in which medical providers, as well as parents, are withholding legally mandated treatment.

The agency's response goes on to state that "where it is alleged there is collusion between the parents and the medical care provider to neglect a child's health or welfare, CPS involvement is appropriate." Although the agency may assert that it investigates reports of this nature, there is no indication of this category, although it is the typical

<sup>134</sup> Telephone interview with Henry Hofstra, Program Consultant, Department of Social Services (July 25, 1988).

<sup>135</sup> Letter from Laura Daniel, Program Consultant, Department of Social Services, to *Issues in Law and Medicine* (Apr. 22, 1987).

<sup>136</sup> Michigan Department of Social Services, Children and Youth Services Manual (1986) (emphasis added).

<sup>137</sup> Letter from C. Patrick Babcock, Director, Michigan Department of Social Services, to William J. Howard, General Counsel, U.S. Commission on Civil Rights (Oct. 10, 1988) (emphasis in original).

<sup>138</sup> 42 U.S.C.A. § 5103(2)(k)(iii) (West Supp. 1988).

denial of treatment situation the CAA was enacted to address.

Michigan should obtain an independent medical consultant, not affiliated with the hospital, to assist the CPS in the investigation of a report of withholding of medically indicated treatment to a handicapped infant (see Preface, NOTES A and B).

Michigan presents a case of a State CPS agency that has wrongfully delegated to the hospital ICRCs the legal question of whether there is a withholding of medically indicated treatment. In so doing, the agency has distorted the CAA's intent to create a strong enforcement mechanism for the treatment of disabled children.

Michigan operates on the premise, stated in its procedures, that "[m]ost reports of medical neglect involving the withholding of medically indicated treatment from infants with life-threatening conditions by parents will originate from a health care provider or hospital. It is logically in the best position, with its medical expertise to know what is medically indicated and necessary treatment."<sup>139</sup>

Accordingly, its investigative procedures provide for heavy reliance on the hospital's position on whether treatment should be provided.<sup>140</sup> Only when "there remains some doubt or uncertainty regarding the hospital's recommendation, the parent's refusal to authorize medically indicated treatment, or there is a need for additional documentation to arrive at a conclusion" do the procedures provide for possible consultation with a "medical consultant."<sup>141</sup>

Throughout the crucial decisionmaking in most investigations, therefore, the medically untrained CPS worker appears to be alone in determining whether the health care facility is providing appropriate treatment, relying solely on medical information and analysis by personnel at that facility.

This approach fundamentally misconceives the nature of the problem the CAA were enacted to

confront. As chapter 2 of this report suggests, in many cases in which parents nominally agree to deny treatment, they have been heavily influenced by the information and advice of the health care providers. Michigan's reliance on those same providers as the primary source for assessment of whether legally mandated medically indicated treatment is being withheld is not likely to result in fulfilling the statutory mandate to ensure that such treatment is provided.

The effectiveness of Michigan's investigations would be significantly improved were the agency to specify procedures for the use of an independent third-party medical consultant, selected with the benefit of advice from disability rights groups, to assist the CPS worker in all nonfrivolous cases.

Although Michigan's definitions of the standard of care and class protected, as well as its provisions for access to medical records and for a court order to secure an independent medical examination, appear on their face to be in technical compliance with the CAA and their implementing regulation, Michigan's failure to provide for independent investigations and its unwarranted apparent deference to health care providers raise serious questions concerning its substantial compliance.

## MINNESOTA

In Minnesota, the Child Protection Program in the Department of Human Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency reported that it had not "had any reports of withholding of medically indicated treatment from disabled infants since the amendments to the national child abuse act came into effect."<sup>142</sup> In response to a followup inquiry by the Commission, the agency confirmed that it had not received any reports.<sup>143</sup>

<sup>139</sup> Michigan Department of Social Services, Children and Youth Services Manual 47 (1986). If a report comes "from someone other than a health care provider or hospital," it is to be investigated only if there is "reasonable cause to believe" the report:

Reasonable cause to believe is defined as: what reasonable people, in similar circumstances, would conclude from such things as the nature of the condition of the child, health care professional statements, and information that the parents have refused to consent to recommended treatment.

*Id.* at 53.

<sup>140</sup> *Id.* at 47-49; see also *id.* at 53 (even when report is received from someone other than a health care provider, if an investiga-

tion is warranted, it is to be conducted "under the steps indicated. . . for responding to a report received from a health care provider or hospital").

<sup>141</sup> *Id.* at 50. Even then, the consultant is part on a par with internal hospital sources; under the described circumstances, "there should be further consultation with ICRC, other review committee or medical consultant, if available."

<sup>142</sup> Letter from John Langworthy, Child Protection Specialist, Department of Human Services, to *Issues in Law and Medicine* (Apr. 3, 1987).

<sup>143</sup> Telephone interview with Sara McNeely, Child Protection Program Advisor, Department of Human Services (Aug. 3, 1988).

The agency reported that it developed its procedures by contracting with the Minnesota Hospital Association to formulate them. There is no indication that disability groups were consulted.<sup>144</sup> The result was a publication entitled *Guidelines for Responding to a Report of Suspected Medical Neglect of a Hospitalized Disabled Infant with a Life-Threatening Condition*. The publication states that the guidelines were developed for the Minnesota Department of Human Services under a grant from HHS and were prepared by the Technical Advisory Committee to the Minnesota Baby Doe Implementation Project, Minnesota Hospital Education, Research Trust Fund, and the Minnesota Hospital Association.

The guidelines were reviewed for compliance with the Federal regulation implementing the CAA. The manual offers step-by-step investigation directions and has appendices that instruct the CPS on developing information on the case and how to come to a conclusion whether treatment is "medically indicated."

The enforcement mechanisms required by the Federal regulation to be specified in the agency's procedures are present in the manual. These include the manner in which CPS will obtain medical records and court orders for independent medical examinations. The manual provides for an independent medical consultant to be available to provide assistance to the CPS worker at each phase of the investigation. The standard of care defined in the manual conforms to the Federal regulation.

However, its definition of "infant" is limited to those under 1 year of age, an underinclusive definition of the protected class.<sup>145</sup> In a letter dated September 30, 1988, the acting supervisor of Child Protective Services addressed this shortcoming in responding to a draft of relevant portions of the Commission report. The acting supervisor argued that other provisions protect older children against medical neglect. This position fails to recognize that the general standards concerning medical neglect for all children are dramatically less detailed and precise than those the CAA makes applicable to

"disabled infants with life-threatening conditions (see Preface, NOTE E).

Apart from their underinclusive definition of the protected class, which is a significant failing, the Minnesota procedures appear to comply with the CAA and their implementing regulation.

## MISSISSIPPI

In Mississippi, the Protection Department within the Department of Public Welfare is the agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency stated that it had not received any reports of possible withholding of medically indicated treatment from infants with disabilities who had life-threatening conditions.<sup>146</sup>

In developing procedures for the implementation of the CAA, the agency reported it had consulted the University of Mississippi Hospital, Mississippi Medical Association, and the Mississippi Hospital Association. There is no indication that disability rights groups were consulted.<sup>147</sup>

Agency procedures were reviewed for compliance with the Federal regulation that implements the CAA. The procedures are limited to one page and lack provisions that are required by Federal law for agency compliance. The substance of the current policy can be described as nothing more than instructions on what persons to interview and where to send the report regarding disposition of the case. Although the 1985 manual adequately met the requirements of the CAA, the 1988 Child Protective Services manual does not.

The current procedures fail to define the required standard of care (see Preface, NOTE F) or to describe the class to be protected by it (see Preface, NOTE E). Contrary to Federal regulatory requirements, they do not specify in writing either the manner in which the agency will obtain access to medical records or the manner in which it will obtain court orders for independent medical examinations.

Furthermore, the procedures appear to instruct the CPS worker to rely on the medical information received from the hospital against which the com-

<sup>144</sup> *Id.*

<sup>145</sup> Minnesota Rules, part 9560.0218, subpart 1 (1988); Minnesota Department of Human Services, Social Services Manual XVI-4120.5 (1987); *Guidelines for Responding to a Report of Suspected Medical Neglect of a Hospitalized Disabled Infant with Life-Threatening Condition* (1986).

<sup>146</sup> Letter from Melzana Fuller, Programs Manager, Child Protection Services Unit (Aug. 19, 1988).

<sup>147</sup> Letter from Melzana Fuller, Programs Manager, Child Protection Services Unit, to *Issues in Law and Medicine* (Apr. 6, 1987).

plaint was lodged; they make no provision for an independent assessment by a medical consultant:

b. Reports received in county are reported immediately, to the Area Social Work Supervisor who will investigate.

c. Area Social Work Supervisor is to:

- 1) Notify immediately the designated contact health care facility and Child Protective Services Unit.
- 2) Interview at health care facility:
  - a) Designated contact person
  - b) Family
  - c) Others involved with the infant<sup>148</sup>

Upon inquiry, the agency reported that it would not have a "child specialist." Instead, the agency indicated that it uses a social worker from the child protective staff and, if necessary, consults with physicians.<sup>149</sup>

Mississippi's procedures appear to be ad hoc and incomplete. In every significant respect, they fail to comply with the requirements of the CAA and its implementing regulation.

## MISSOURI

Missouri Children's Services in the Department of Social Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

In 1987 the agency stated, "We have not received any reports of possible withholding of medically indicated treatment from disabled infants with life threatening conditions."<sup>150</sup> In response to a follow-up inquiry by the Commission, the agency stated that it was not aware of any such cases reported to it in the past year.<sup>151</sup>

In developing procedures to implement the CAA, the agency reported that it used material from the American Bar Association and discussed the procedures "with the Missouri Hospital Association and physicians associated with the Division of Medical Services—the State Medicaid agency."<sup>152</sup> The

<sup>148</sup> Child Protective Services Procedure For Service Activity, vol. IV, sec. B at 2014 (1988).

<sup>149</sup> Telephone interview with Melzana Fuller, Programs Manager, Child Protection Services Unit, by *Issues in Law and Medicine* (June 1, 1987).

<sup>150</sup> Letter from Melody Emmert, Deputy Director, Children's Services, to *Issues in Law and Medicine* (Apr. 8, 1987).

<sup>151</sup> Telephone interview with Fred Proebsting, Program Development Specialist, Children's Services (July 25, 1988).

agency gave no indication that disability groups were consulted.

Agency procedures were reviewed for compliance with the Federal regulations that implement the CAA. The agency's procedures contained a definition for "withholding of medically indicated treatment" that fully conforms with the Federal standard.

A deficiency in the policy is that there is no definition for the term "infant," leaving the class protected by the standard of care unclear. In response to this criticism, the agency argued that because the State statute defines "child" in its medical neglect statute as one under 18 years of age, and it will investigate any report of medical neglect against a child, it, therefore, need not be more specific in its procedures.<sup>153</sup> This argument fails to recognize the necessity of applying the more detailed standards of the CAA to the class of "disabled infants." (See Preface, NOTE E.)

The procedures specify the manner in which the CPS agency will obtain medical records and court orders for independent medical evaluations as required by Federal regulation. The manual provides for an independent medical consultant to be available from "the Division of Medical Services or other independent doctors to determine if appropriate medical and nutritional services are being provided."<sup>154</sup>

Despite its statement that there will be an independent agency medical evaluation available, there is evidence that the agency assigns a substantial amount of its investigative and decisionmaking authority to a hospital's infant care review committee (ICRC). The policy states:

In the event of the following circumstances the CSW (Child Services Worker) or other appropriate DFS personnel should inform the parent that a recommendation will be made to the Juvenile Court to secure a court order for an independent medical examination.

When the parent(s) of the infant does not consent to review of the infant's treatment;

<sup>152</sup> Letter from Melody Emmert, Deputy Director, Children's Services, to *Issues in Law and Medicine* (Apr. 8, 1987).

<sup>153</sup> Letter from Melody A. Emmert, Deputy Director, Missouri Children's Services, to William J. Howard, General Counsel, U.S. Commission on Civil Rights (Oct. 7, 1988).

<sup>154</sup> Children's Section Special Child Abuse/Neglect Investigation Procedure: Baby Doe, No. A-7, para. 7.

*When the attending physician and/or parents does not agree with the recommendation of the Review Committee;*

When there is no Review Committee and the parent(s) does not consent to a consultation and/or individual medical examination.<sup>155</sup>

At least in some circumstances, the foregoing language allows the hospital that has had a complaint lodged against it to review the case, or to serve as the equivalent of an independent medical examiner.

In a letter commenting on a draft of relevant portions of the Commission report, the deputy director of Children's Services wrote, "Our policy clearly allows for our staff to request a court order in any situation where they believe an independent examination is required. Item I above refers to consent for any review, not only the Infant Care Review Committee."<sup>156</sup> Although, given this clarification, it appears that the agency retains independent authority to initiate a medical examination, it remains the case that, at least in some circumstances, Missouri appears to regard a committee of the hospital against whose staff the complaint has been lodged as a legitimate review board. (See Preface, NOTE B.)

Because of its failure to define adequately the class protected by the standard of care, and what appears, in at least some circumstances, to be its improper deference to hospital infant care review committees, Missouri is out of compliance with the CAA and their implementing regulation in significant respects.

## MONTANA

In Montana, the Department of Family Services in the Department of Social Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency stated that it had not received any reports of medical neglect of infants with disabilities since the regulation went into effect.<sup>157</sup>

In response to an inquiry about the participation of outside groups in the development of procedures to implement the CAA, the agency reported they were created by agency staff in a wholly internal process.<sup>158</sup>

Agency procedures are very brief and based on earlier regulation issued under section 504 of the Rehabilitation Act of 1973, rather than those implementing the CAA.

Although the terms are defined in the State's child abuse statutes, the federally required standard of care and definition of those protected by it are absent from the Montana procedures.

Agency policy shows that CPS staff have the ability to initiate independent medical examination of infants in cases of suspected medical neglect and provides for obtaining access to medical records consistent with Federal regulatory requirements.

In response to a Commission inquiry regarding medical technical assistance to the CPS worker, the agency reported that the State had a contract with the Montana chapter of the American Academy of Pediatrics, and that this organization would immediately contact a specialist in the area. The agency stated that the Academy-designated physician and the attending physician would conduct a "joint examination." When asked whether the CPS worker would have to rely heavily on the pediatrician in determining whether treatment was in fact medical neglect of a child with a disability, the agency responded that the decision was a medical decision and not a decision for the social worker.<sup>159</sup> The Federal regulations are clear, however, that it is the State's CPS system that must make the determination whether treatment is medically indicated under the CAA and whether circumstances exist to invoke the power of the State (see Preface, NOTE A). Involving the very physician who presumably is the subject of a report alleging illegal denial of treatment in a "joint examination" to determine whether the report is well founded creates an obvious conflict of interest, and gives little assurance that there will be a searching and arms-length investigation of the charges.

Montana's CPS has developed procedures that meet the requirements of current Federal regulations. However, the practice of deferring the legal question of medical neglect to a physician indicates a fundamental misunderstanding of the role of the CPS in enforcing the CAA.

<sup>155</sup> *Id.*, para. 8 (emphasis added).

<sup>156</sup> Letter from Melody A. Emmert, Deputy Director, Missouri Children's Services, to William J. Howard, General Counsel, U.S. Commission on Civil Rights (Oct. 7, 1988).

<sup>157</sup> Telephone interview with Gary Walsh, Administrator of Policy and Planning and Evaluation, Department of Family Services (Aug. 3, 1988).

<sup>158</sup> Telephone interview with John Madsen, Department of Social and Rehabilitation Services, by *Issues in Law and Medicine* (June 1, 1987).

<sup>159</sup> Telephone interview with John Madsen, Department of Social and Rehabilitation Services, by *Issues in Law and Medicine* (June 1, 1987).

## NEBRASKA

In Nebraska, the Human Services Division within the Department of Social Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency stated that it had not received a report of medical neglect of an infant with a disability since the regulation went into effect.<sup>160</sup>

The procedures for implementation of the CAA appear to exist as ad hoc administrative memoranda from the director of the Department of Social Services. Two memoranda appear as evidence of the agency's policy on medical neglect of handicapped infants. They were reviewed for compliance with the Federal regulation implementing the CAA.

The first directive, dated October 8, 1985, instructs CPS workers to refer all reports of suspected medical neglect of disabled infants to the department's central office or to the child abuse/neglect hotline during nonoffice hours. The directive contains definitions for "withholding of medically indicated treatment" and "infant" that accurately restate the Federal standards.<sup>161</sup>

The second directive, dated September 29, 1986, fulfills the Federal mandate that the department establish a list of hospital contact persons. In accord with the Federal regulation, the directive provides that the department will exercise subpoena authority for access to medical records if they are not made available. Also in accord with the Federal rule, the directive provides that an independent medical examination will be obtained by a court order "allowing/requiring such an exam as part of our investigation and efforts to protect a suspected victim of child abuse/neglect."<sup>162</sup>

On their face, the Nebraska procedures appear to comply with the CAA and their implementing regulation.

## NEVADA

In Nevada, the Welfare Division in the Department of Human Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency stated that there had not been any reports of medical neglect since the CAA took effect.<sup>163</sup>

The agency reported that in developing procedures to implement the CAA, it had consulted with the Nevada medicaid staff; neither medical groups nor disability rights groups were consulted.<sup>164</sup>

The procedures were reviewed for compliance with the Federal regulation implementing the CAA. Definitions in the procedures mirror those of the Federal regulation. The enforcement mechanisms required to be specified in the agency's procedures, involving the manner in which the agency will obtain medical records and court orders for independent medical evaluations, are present.

However, the CPS agency appears to treat the infant care review committee (ICRC) in the hospital against which complaint has been lodged as though it were an independent medical consultant. The procedures state:

### C. INVESTIGATION OF REPORTS OF MEDICAL NEGLECT

4. Treating physician recommends against providing treatment (applicable in Baby Doe cases)

The worker needs to determine by *interviewing the treating physician or by reviewing the recommendations of the hospital review committee* or by using the agency's medical consultant if:

- a. The child is irreversibly comatose; or
- b. Treatment would merely prolong dying, not be effective in ameliorating or correcting all of the child's life threatening conditions or otherwise be futile in terms of survival of the child; or
- c. Treatment would be futile in terms of survival of the child and treatment itself under such circumstances would be inhumane.

If these can be clearly determined to be the case, the investigation can be discontinued. If the above cannot be clearly determined from interviewing the treating physician, the worker should either contact the *hospital review committee*, if one exists, or contact the agency's medical consultant (for Welfare Division cases, contact the Medi-

<sup>160</sup> Telephone interview with Mona Way, Program Specialist, Division of Human Services (Aug. 8, 1988).

<sup>161</sup> Nebraska Department of Social Services Administrative Directive—Human Services No. 3-86.

<sup>162</sup> Nebraska Department of Social Services Administrative Memorandum—Human Services No. 10-86.

<sup>163</sup> Information obtained from Connie Martin, CPS Specialist, by Commission staff (Aug. 2, 1988).

<sup>164</sup> Letter from Carol Johnston, Acting Assistant Chief, Social Services, to *Issues in Law and Medicine* (Apr. 9, 1987).



caid Unit in Central Office for the name of the consultant) to help in making the determination.<sup>165</sup>

The clear implication of this statement is that the Nevada CPS agency places an ICRC on a par with the agency medical consultant as the source for a determination whether care is being provided in accordance with the Federal treatment standards. Placing a hospital committee in this role gives rise to a self-evident conflict of interest (see Preface, NOTE B).

Nevada presents a case of a State CPS agency that has for the most part effective investigation and enforcement measures to react to a report of medical neglect of a disabled infant. Notwithstanding, the agency erroneously regards the hospital against which a complaint is lodged as an "independent" medical examiner in such a case.

Although the Nevada standard of care, definition of the class protected, and provisions for obtaining medical records and independent medical examinations comply with the Federal regulation, the State's apparent willingness to defer to infant care review committees at hospitals whose staff is charged with illegal denials of treatment for crucial medical analyses of whether such charges are founded creates a significant failure of compliance.

## NEW HAMPSHIRE

In New Hampshire, the Bureau of Children in the Division of Children and Youth Services of the Department of Health and Human Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency reported that there have been no reports of withholding of medically indicated treatment from infants with disabilities in New Hampshire since 1985.<sup>166</sup>

The agency said that when developing its procedures to implement the CAA, it consulted the ethics committee chairman of Mary Hitchcock Hospital, the only tertiary infant care hospital in the State. The New Hampshire Hospital Association assisted in dissemination of the policy. Disability rights groups were not consulted.<sup>167</sup>

Agency procedures were reviewed for compliance with the Federal regulation implementing the

CAA. Definitions presented in the procedures mirror those in the Federal regulation. The enforcement mechanisms required by the Federal regulation to be specified in the agency's procedure, that is, the manner in which CPS will obtain medical records and court orders for independent medical evaluations, are also present.

Although the procedures appear to show that the CPS agency will conduct independent investigations of reports of medical neglect, interviews with the agency staff responsible for protecting the infants raised questions in this regard. The agency's infant medical neglect social worker stated that if a report of medical neglect is received, the opinion of an second physician would be obtained to ensure that the treatment is appropriate. There was no indication that there would be a determination by agency staff about whether the treating or consulting physician was complying with the CAA standard of care. When asked from whom the second opinion would come, the infant medical neglect social worker indicated that the ethics committee at Mary Hitchcock Hospital would review the medical treatment and that, if it gave approval, there would be no further investigation. The staff person also indicated that hospitals in outlying areas call on the Mary Hitchcock ethics committee for advice.<sup>168</sup>

Under the Federal regulation, the existence of an ICRC has no bearing on the duty a State CPS system has to investigate all known or suspected cases of medical neglect. If the agency has delegated to a hospital review committee the authority to determine whether treatment is medically indicated or whether the treatment exceptions are applicable, it has compromised the intent of the statute and is not in compliance with the Federal standards. (See Preface, NOTES A and B.) The Federal regulations are clear that it is the State's CPS system that must make the determination whether treatment is medically indicated under the CAA.

New Hampshire's procedures appear on their face to comply with the CAA and its implementing regulations. However, the practice of deferring the legal question of medical neglect to a hospital ICRC indicates a fundamental misunderstanding of the role of the CPS in enforcing the CAA.

<sup>165</sup> Welfare Division Service Manual, sec. 417.11(C)(4) (emphasis added).

<sup>166</sup> Telephone interview with Roger Desrosiers, Administrator of Management and Operations, Children's Bureau, Division of Children and Youth Services (July 28, 1988).

<sup>167</sup> Telephone interview with Paul Tamburro, Infant Medical Neglect Social Worker, Division for Children and Youth Services, by *Issues in Law and Medicine* (June 10, 1987).

<sup>168</sup> *Id.*

## NEW JERSEY

In New Jersey, the Division of Youth and Family Services in the Department of Human Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency stated that since the CAA went into effect there had been three reports of medical neglect, one in 1985 and two in 1986. In all three cases, the investigators found that the complaint was "not substantiated."<sup>169</sup>

When developing procedures to implement the CAA, the agency reported that it consulted with the State attorney general's office, the chief pediatrician at a local hospital, and a disability rights group at Rutgers University.<sup>170</sup>

The agency procedures were reviewed for compliance with the Federal regulation that implements the CAA. The enforcement mechanisms required by the Federal regulation to be specified in the agency's procedure, namely, the manner in which CPS will obtain medical records and court orders for independent medical evaluation, are included.

However, the procedures contain no definition of the term "infant," thus failing to describe the class they protect. In response to a draft of relevant portions of the Commission report, the director of the Division of Youth and Family Services addressed this criticism. He conceded that the agency's procedures did not define the term "infant," but contended that such a definition was unnecessary because "[e]xisting protections available under present New Jersey statutes. . . define any person from birth to eighteen years of age and would include all children under and over one year of age." This argument fails to recognize that the general standards concerning medical neglect for all children are dramatically less detailed and precise than those the CAA make applicable to "disabled infants with life-threatening conditions." (See Preface, NOTE E.)

The procedures also contain no definition of the term "withholding of medically indicated treatment," thus failing to establish the standard of care required. The agency states that "[t]he New Jersey statute which specifically addresses the issue of failure to supply a child with adequate medical care

was seen as adequately defining standards of medical neglect which would include the withholding of medically indicated treatment." Examination of this statute revealed that there is no explanation of withholding of medically indicated treatment offered other than "failure of. . . a parent or guardian, . . . in supplying medical or surgical care. . . ."<sup>171</sup> This falls significantly short of the detail contained in the meticulously negotiated CAA standard of care. (See Preface, NOTE F.)

The agency appears to have contracted with two independent pediatricians to assist the CPS worker in determining whether treatment is legally required:

Upon receipt of a referral, the appropriate regionally based supervisor or Senior Investigator will be contacted along with the pediatric consultant. The pediatric consultant will contact the person named by the facility as their Baby Doe contact as specified by the federal regulations governing this act. The consultant will review the child's condition and make an appointment to initiate an on-site investigation if it is indicated.<sup>172</sup>

Although, on their face, the New Jersey procedures otherwise appear to comply with the CAA and their implementing regulation, the failure of the procedures to define either the standard of care or the class the standard protects constitute a significant lack of compliance.

## NEW MEXICO

In New Mexico, the Social Services Division in the Human Services Department is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency stated that it has not received any reports of medical neglect of an infant with a disability since the CAA went into effect. The agency also reported that procedures for the investigation of a report of medical neglect were created with the help of the University of New Mexico Hospital; no disability rights groups were consulted.<sup>173</sup>

The State agency's policies and procedures were reviewed for compliance with the Federal regulation that implements the CAA. Enforcement mechanisms that are required by the Federal regulation to

<sup>169</sup> Telephone interview with Constance Ryan, Coordinator, DYFS Medical Unit, Division of Youth and Family Services (Aug. 17, 1988).

<sup>170</sup> Telephone interview with Sue McGrory, Supervisor, Institutional Abuse Unit, Division of Youth and Family Services, by *Issues in Law and Medicine* (June 24, 1987).

<sup>171</sup> N.J. Stat. Ann. §9:6-8.9. (West Supp. 1988)

<sup>172</sup> Division of Youth and Family Services, Procedures for the Investigation of Baby Doe Cases in New Jersey.

<sup>173</sup> Telephone interview with Judy Mayhon, Planner, Social Services Division, Program Services Bureau, New Mexico Human Services Department, by *Issues in Law and Medicine* (June 4, 1987).

be specified in CPS agency procedures are included in a memorandum issued by the main office to agency staff. These include a description of the manner in which the agency will obtain an infant's medical records and a court order for independent medical evaluation. Also included in this memorandum are definitions for "withholding of medically indicated treatment" and for "infant in accordance with the federal regulation." When the agency's most recent procedures manual was reviewed, these provisions had been incorporated.

However, the New Mexico CPS agency abdicates its responsibility to determine whether the law is being followed to those alleged to be violating the law, contrary to the requirements of the Federal regulation that the CPS must make the determination whether treatment is medically indicated under the CAA (see Preface, NOTE A). The procedure states that a report is "unsubstantiated when. . .the parents and the treating physician are in agreement that medical treatment should be withheld from the infant."<sup>174</sup> Nowhere in the procedure is there mention of an independent medical consultant to be available to review all reports of medical neglect and to determine if the decision falls below the Federal standard of care. Instead, the hospital that is the subject of a complaint is given the responsibility to review the case or to serve as the equivalent of an independent medical examiner.

To refuse to investigate a report of medical neglect because there is no disagreement on treatment between the parents and the attending physicians blatantly flouts the intent of the CAA to create an enforcement mechanism for the protection of a disabled infant's right to treatment. The New Mexico procedures clearly run counter to the CAA's requirement that the CPS agency serve as the independent investigating authority to ensure that the Federal standard of care is provided to the infant with a disability.

Although its policies are in place, New Mexico is out of compliance with the CAA and their implementing regulation in considering any report unsubstantiated when the physician and parents agree to withhold treatment.

<sup>174</sup> New Mexico Human Services Department, Social Services Procedure §4.8.3.1, §4.8.3.2.(1).

<sup>175</sup> Telephone interview with Sally Perry, Division of Family and Children Services, by *Issues in Law and Medicine* (June 24, 1987).

## NEW YORK

The New York Division of Family and Children Services of the Department of Social Services is the State agency responsible for the enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency stated that there had been two cases of denial of medically indicated treatment to disabled infants reported since the regulation went into effect.<sup>176</sup> In response to a followup inquiry by the Commission, the agency reported that it was impossible to distinguish reports of medical neglect of infants with disabilities from reports of "lack of food" or "lack of medicine" categories and was therefore unaware of whether there had been any cases within the State.<sup>176</sup>

The agency reported that it did not find it necessary to establish any new regulations and procedures for implementation of the CAA because it thought that present mechanisms were sufficient. Therefore, no consultation with outside groups took place.<sup>177</sup>

New York's failure to promulgate rules specifically implementing the CAA regulations has resulted in clear violations of Federal requirements. Federal regulations require that a State CPS develop written procedures with regard to medical neglect reports, specifying the manner in which it will obtain the child's medical records. These appear to be absent. (See Preface, NOTE C.) The regulation requires written procedures under which the CPS agency may obtain a court order for an independent medical examination of an infant. The New York procedures should make explicit provision for court-ordered, independent examinations. (See Preface, NOTE D.) The definition of such terms as "infant" and "withholding of medically indicated treatment," essential to establish the standard of care and the class of those protected by it, do not appear in any of the agency's materials. (See Preface, NOTES E and F.)

Because no specific procedures were established to respond to a medical neglect situation, there is no method for obtaining an independent medical consultant to conduct the examination, review the medical records, or otherwise assist the CPS worker in evaluating a report of medical neglect. In fact, an

<sup>176</sup> Telephone interview with Sally Perry, Division of Family and Children Services, and Patty O'Donnell, Assistant Director, New York State Child Abuse Hotline (Aug. 9, 1988).

<sup>177</sup> Information obtained from Sally Perry, Division of Family and Children Services, by *Issues in Law and Medicine* (June 24, 1987).

agency staff person indicated that there were no specific guidelines indicating who should be consulted should a medical neglect situation arise. She stated that possibly the independent consultant would be another doctor within the hospital if it was a large facility.<sup>178</sup> It is possible, therefore, that a New York CPS worker would be relying for critical evaluations solely on personnel at the hospital against which the complaint is lodged. A letter from the deputy commissioner of the Division of Family and Children's Services to district CPS officials states:

While CPS will need to rely heavily upon the judgment of the physicians involved in the case (including in some instances newly established hospital based Infant Care Review Committees, recommended by the federal regulations) the CPS caseworker and supervisor will need to be capable of sorting out some particularly complex issues, involving medical, legal and ethical areas where no societal consensus has been reached.<sup>179</sup>

In short, the State of New York has not complied with the Federal legal requirements that it establish specific and identifiable enforcement mechanisms for the response to a report of the denial of medical treatment to a handicapped infant. It is substantially out of compliance with the Child Abuse Amendments.

## NORTH CAROLINA

In North Carolina, the Division of Children's Services in the Department of Human Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency stated that there had been no reported cases of medical neglect of infants with disabilities since the 1985 Federal law was passed.<sup>180</sup>

In developing procedures for implementation of the CAA, the agency reported that "[r]epresentatives from the four teaching hospitals in the state and the State Council on Developmental Disabilities as well as other related state and local

agencies were a part of our planning process throughout the process. . . ."<sup>181</sup>

The procedures were reviewed for compliance with the Federal regulation that implements the CAA. The definitions of terms correctly reflect the Federal standards. In accord with the Federal regulations, the procedures specify the manner in which the agency will obtain access to medical records and other pertinent information and will obtain court orders for independent medical examinations.

However, the North Carolina procedures fail to specify a method for obtaining an independent third-party medical expert to assist the CPS worker in evaluating a report of medical neglect. Instead, the procedures state:

Because of the complex nature of the medical conditions that an infant might have, medical consultation will be needed in conducting the investigation. *The hospital or health care facility staff in which the infant is receiving care will, in most cases, be the primary resource for that consultation.*<sup>182</sup>

In other words, the facility being investigated is made the "primary resource" for "consultation" about whether it is engaged in illegal denial of treatment. This approach, with its obvious conflict of interest, significantly undermines the responsibility of the CPS agency to conduct an effective arm-length investigation to ensure that the rights of infants with disabilities to receive legally mandated treatment are respected. The independence and effectiveness of North Carolina investigations would be substantially improved were the agency to establish procedures for the use of an independent third-party medical consultant, selected with input from disability rights groups, to assist the CPS worker in all nonfrivolous cases.

## NORTH DAKOTA

In North Dakota, the Children and Family Services Division in the Department of Human Services

<sup>178</sup> *Id.*

<sup>179</sup> Letter from Joseph Semidei, Deputy Commissioner, Division of Family and Children Services, to CPS District Officers (Oct. 4, 1985). This letter evinces a dismaying failure to recognize that the standard of care established by the Child Abuse Amendments, enacted by an overwhelming vote, should be treated as constituting the "social consensus" by the agency charged with its enforcement.

<sup>180</sup> Telephone interview with Alice Coleman, CPS Program Consultant, Division of Social Services (July 21, 1988).

<sup>181</sup> Letter from Mary Lee Anderson, Program Manager, Child Protective Services, Division of Social Services, to *Issues in Law and Medicine* (May 29, 1987).

<sup>182</sup> North Carolina Division of Family Services, *Family Services Manual*, vol. I, ch. VIII Medical Neglect of Disabled Infants with Life Threatening Conditions (emphasis added).

is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency stated that it had one report of medical neglect of a infant with a disability since the regulation went into effect.<sup>183</sup>

The agency reported that during the development of agency procedures concerning report of medical neglect, it consulted with the Health Department's Maternal and Child Health Division, the North Dakota chapter of the American Academy of Pediatrics, and the University of North Dakota Children and Family Services Training Center.<sup>184</sup>

The North Dakota procedures were reviewed for compliance with the Federal regulation that implements the CAA. The enforcement mechanisms that are required by the Federal regulation to be specified in the agency's procedures, namely, the manner in which CPS will obtain medical records and court order for independent medical examinations, are present. In addition, the procedures provide for an independent medical consultant to be available to provide assistance to the CPS worker at each phase of the investigation. The definition of the standard of care is given in the manual and conforms to the Federal regulation. However, there is no definition of "infant," the class protected. (See Preface, NOTE E.)

Apart from the significant omission of a comprehensive definition of the class protected, the North Dakota procedures appear, on their face, to comply with the CAA and their implementing regulation.

## OHIO

The Ohio Bureau of Children's Protective Services in the Department of Human Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency reported that its office had "received two calls since the amendment became effective in October 1985. Both calls were determined to not fit the criteria necessary to be considered reports of withholding medically indicated treatment from disabled infants."<sup>185</sup> The agency confirmed in

<sup>183</sup> Telephone interview with Gladys Cairns, Children and Family Services Division (July 20, 1988).

<sup>184</sup> Telephone interview with Gladys Cairns, Children and Family Services Division, by *Issues in Law and Medicine* (June 12, 1987).

<sup>185</sup> Letter from Jean Schafer, Chief, Bureau of Children's Protective Services, to *Issues in Law and Medicine* (Apr. 2, 1987).

response to a followup inquiry that these had been the only reports to the agency.<sup>186</sup>

The agency reported that the procedures that it established to respond to reports of medical neglect of disabled infants "were written in cooperation with a committee of medical professionals." There is no indication that disability rights groups were consulted.<sup>187</sup>

The procedures were reviewed for compliance with the Federal regulation that implements the CAA. The agency recognizes that it alone has responsibility to determine the question of medical neglect of a disabled infant:

The PSCA (Public Children's Services Agency) shall investigate all reports which allege that a disabled infant with life-threatening conditions is a neglected child due to the withholding of appropriate nutrition, hydration, medication, or medically indicated treatment. This investigatory responsibility may not be delegated to any other public or private agency or organization.<sup>188</sup>

In accord with the Federal regulations, the procedures contain enforcement mechanisms that specify the manner in which the agency will obtain access to medical records and secure court orders for independent medical examinations. Also present in the procedures is a detailed method for obtaining an independent medical consultant to conduct the examination, review the medical records, or otherwise assist the CPS worker. The agency reported that it had "developed an on-call system, in operation 24 hours a day, 7 days a week, which has workers with the Bureau of Children's Protective Services and medical consultants available to assist the local agencies."<sup>189</sup>

However, the procedures contain an underinclusive definition of the term "infant." The procedures define "disabled infant" to mean "a child less than 1 year of age who has a physical or mental handicap which substantially limits or may limit in the future one or more major life activities such as self-care, receptive and expressive language, learning and mobility."<sup>190</sup> Limiting enforcement of the CAA solely to the class of children under 1 year of age is underinclusive with respect to those that were

<sup>186</sup> Telephone interview with Georgia McGill, Social Program Developer, Bureau of Program Policy (July 22, 1988).

<sup>187</sup> Letter from Jean Schafer, Chief, Bureau of Children's Protective Services, to *Issues in Law and Medicine* (Apr. 2, 1987).

<sup>188</sup> Ohio Administrative Code § 5101:2-35-77(F) (1987).

<sup>189</sup> Letter from Jean Schafer, Chief, Bureau of Children's Protective Services, to *Issues in Law and Medicine* (Apr. 2, 1987).

<sup>190</sup> Ohio Administrative Code § 5101:2-35-76(F) (1987).

intended to be protected by Congress under the CAA.

In a letter of October 11, 1988, the agency, commenting on a draft of relevant portions of the Commission report, addressed this criticism. The agency did not deny that the quoted agency rule limits the application of the term "disabled infant" to those under one year. Instead, it pointed out that other provisions in the agency code provide protections against medical neglect of "handicapped person[s]" under 21 years.<sup>191</sup> While this is accurate, it fails to recognize that the general provisions defining medical neglect are significantly less detailed and specific than those in the CAA standard of care, which the Federal regulation specifically makes applicable to certain categories of infants older than 1 year (see Preface, NOTE E).

Although it received grants under the Child Abuse Prevention and Treatment Act in prior years, Ohio did not receive such a grant in fiscal year 1988,<sup>192</sup> and thus was not legally subject to the requirements of the CAA. However, with the significant exception of an underinclusive definition of the class of those protected, the Ohio procedures on their face appear to comply with the CAA and their implementing regulation.

## OKLAHOMA

The Oklahoma Department of Human Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

In the development of procedures to implement the CAA, the agency reported that neither Children's Hospital of Oklahoma nor disability rights groups were consulted.<sup>193</sup>

The agency reported that there had been three cases of medical neglect reported since 1985. The first, in January 1985, was "ruled out" and the child died a month later. In the second, in November 1985, a child was placed in the agency's custody, received treatment, but died later. In July 1986, the agency placed another child in its custody and required that the child be treated. The staff person stated that this child is alive today.<sup>194</sup> In response to

<sup>191</sup> Letter from Georgia McGill, Social Program Developer, and Dora Sterling, Supervisor, Policy Development Unit, Ohio Department of Human Services, to T. Burke Balch, Office of General Counsel, U.S. Commission on Civil Rights (Oct. 11, 1988).

<sup>192</sup> Telephone interview with Mary McKough, Program Analyst, National Center for Child Abuse and Neglect, Office of

a more recent inquiry, the agency reported that these were the only cases concerning medical neglect of disabled infants in which the agency has been involved.<sup>195</sup>

Agency procedures were reviewed for compliance with the Federal regulation that implements the CAA. They were found to be short, consisting of less than a page, and missing provisions that are required by Federal law for agency compliance. The procedures cite for their authority previous Federal regulations under section 504 that are without present effect and make no mention of the agency's responsibilities under the CAA and the Federal regulation that implements it.

The procedures fail to fulfill the Federal regulatory requirements that the agency specify in writing the manner in which it will obtain medical records of the child (see Preface, NOTE C) and that the CPS agency specify in writing the manner in which it will obtain a court order for an independent medical examination of the infant (see Preface, NOTE D). Also missing from procedures is any definition of the term "infant" or the term "withholding of medically indicated treatment" (see Preface, NOTES E and F).

The procedures are silent with respect to the use of an independent third-party medical examiner. Instead, the agency informed the Commission that it would make use of hospital-based infant care review committees.<sup>196</sup> This practice is an abdication of authority to the very hospital whose staff is alleged to be denying legally required treatment. The Federal regulations are clear that it is the State's CPS system that must make the determination whether treatment is legally required under the CAA and whether circumstances exist to invoke the power of the State. (See Preface, NOTES A and B.)

The Oklahoma CPS agency has not developed procedures that remotely attempt to comply with present regulations under the CAA. Further, the agency has abdicated its responsibility to investigate, effectively delegating it to the hospital infant care review committees which are to be investigated.

Human Development Services, Department of Health and Human Services (Dec. 2, 1988).

<sup>193</sup> Telephone interview with Diana Stell, Program Field Representative, Department of Human Services (July 6, 1987).

<sup>194</sup> *Id.*

<sup>195</sup> Telephone interview with Diana Stell, Program Field Representative, Department of Human Services (July 27, 1988)

<sup>196</sup> *Id.*

## OREGON

In Oregon, the Children's Services Division in the Department of Human Resources is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency stated that as of 1987 there had been only one reported case of withholding of medically indicated treatment from an infant with disabilities.<sup>197</sup> In response to a followup inquiry, the agency reported that there had been an additional case, but it was not truly a report of medical neglect. The hospital had requested State neonatologists to confer with them about an infant born with only 2 inches of intestine. All parties agreed that there was nothing that could be done and the child died.<sup>198</sup>

The agency reported that "[e]xtensive contact with the medical community was utilized in developing Oregon's implementation of the Child Abuse Amendments of 1984 (CAA)."<sup>199</sup> The agency gave no indication that disability rights groups were consulted.

Agency procedures were reviewed for compliance with the Federal regulation that implements the CAA. Although the definition of "withholding of medically indicated treatment" conforms to the Federal regulation, the definition of "infant" does not; it applies only to those "less than one year of age."<sup>200</sup> As required by the Federal regulation, the agency's manual specifies the manner in which it will obtain medical records and a court order for an independent medical examination. The manual also includes a detailed methodology for an independent medical consultant to conduct the medical examination, to review the medical records, or otherwise to assist the CPS worker. The agency reported that it had the assistance of five neonatologists from teaching hospitals in the State to serve in this role.<sup>201</sup>

The Oregon procedures appear to recognize that a report may be against either a parent for refusal to consent or against a medical provider for a recommendation against treatment. The agency is to take custody of the child in either instance if the medical

examiner finds that treatment is indicated. The case worker is instructed to assist the parent with referrals to support groups, community educational resources, agencies that provide services for disabled infants and their families, and agencies with financial resources for medical and rehabilitative services.

The agency procedures contain a number of apparent weaknesses. Although the definition of "medically indicated treatment" properly makes clear that "appropriate nutrition, hydration, and medication" must be provided even when one of the three exceptions to the general requirement of treatment is applicable,<sup>202</sup> the procedures themselves direct that "the investigation shall be terminated and the case closed" when a hospital review committee (HRC) decides whether treatment is medically indicated:

Grounds for overriding the refusal of the parents of the infant to consent to medical care and treatment exist only if any reasonable medical judgement would be that treatment is medically indicated. *The parents' refusal to consent shall be respected if the Review Committee, if any, and a consulting physician finds that treatment is not medically indicated.*<sup>203</sup>

And further in the rule the agency instructs:

If the infant's parents do not desire medical treatment beyond that being provided by the treating physician and *if the reasonable medical judgement of HRC and other consulting medical professionals* is that medically indicated treatment is being provided, the Medical Neglect Investigator will document this agreement in the case record. The CPS worker will close the case and take no further action.<sup>204</sup>

It is unclear from the face of the policy whether the "consulting physician" is to be another doctor at the same hospital or whether this reference is meant to point to the CPS consultant neonatologist. In either case, it is clear from the face of the procedures that a HRC has been given a stake in decisionmaking. Federal regulations are clear that it is the CPS agency alone that makes the decision whether

<sup>197</sup> Letter from Robert Pinkerton, Manager of National Center for Child Abuse and Neglect Grants, Children's Services Division, to *Issues in Law and Medicine* (Mar. 30, 1987).

<sup>198</sup> Telephone interview with Robert Pinkerton, Manager of National Center for Child Abuse and Neglect Grants, Children's Services Division (July, 22, 1988).

<sup>199</sup> Letter from Robert Pinkerton, Manager of NCCAN Grants, Children's Services Division, to *Issues in Law and Medicine* (Mar. 30, 1987).

<sup>200</sup> Children's Services Division, Client Services Manual I, Rule I-B.2.2.2 (Definitions 412-61-004 (3)) (1986). Cf. Preface, NOTE E.

<sup>201</sup> Letter from Betty Uchytel, Assistant Administrator, Office of Family Services, to William J. Howard, General Counsel, U.S. Commission on Civil Rights (Sept. 29, 1988).

<sup>202</sup> Children's Services Division, Client Services Manual I, Rule I-B.2.2.2 (Definitions 412-61-004(9)).

<sup>203</sup> Children's Services Division, Client Services Manual I, Rule I-B.2.2.2(C)(3)(a)(1) (emphasis added).

<sup>204</sup> *Id.*, Rule I-B.2.2.2(3)(C) (emphasis added).

treatment (or nontreatment) is appropriate. This practice subverts the intent of the CAA to create a strong enforcement mechanism for the defense of infants with disabilities. (See Preface, NOTES A and B.)

In a letter dated September 29, 1988, the agency commented on a draft of relevant portions of this report and addressed the above concern. The assistant administrator of the Office of Family Services assured the Commission that:

The Medical Neglect Investigator determines the course of action to be taken including whether or not there should be court involvement. Information is obtained from the attending physician, the hospital review committee, the consulting neonatologist and other appropriate medical professionals, but the Medical Neglect Investigator is the one responsible for deciding if legally required treatment is being withheld.

Despite the construction this response puts on this provision in the procedures, the Commission believes that the procedures can be interpreted to allow an inappropriate amount of authority to the hospital review committee on the question whether treatment is medically indicated that can allow the real responsibilities of the CPS to remain unclear at critical junctures.

## RHODE ISLAND

In Rhode Island, the Division of Child Protective Services in the Department of Children and Their Families is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency stated that only one report of medical neglect of an infant with a disability had been received since the effective date of the CAA.<sup>205</sup>

The agency was unable to say whether medical or disability rights groups were consulted when its procedures were developed.<sup>206</sup>

The procedures were reviewed for compliance with the Federal regulation that implements the CAA. The definitions of terms correctly reflect the Federal standards. In accord with the Federal regulations, the procedures specify the manner in which the agency will obtain access to medical records and other pertinent information and the

<sup>205</sup> Telephone interview with Jo Ann Loher, Policy and Planning Manager, Division of Child Protective Services (July 21, 1988).

<sup>206</sup> Telephone interview with Kenneth Fandetti, Division of Child Protective Services, by *Issues in Law and Medicine* (June 30, 1987).

manner in which it will obtain court orders for independent medical examinations.

The Rhode Island procedures do not specify the method for obtaining an independent third-party medical expert to assist the CPS worker in evaluating a report of medical neglect. The procedures merely state:

## II. PROCEDURE

.....

D. The CPI [Child Protection Investigator] and the "Baby Doe" Coordinator will discuss the situation prior to the initiation of the investigative process.

E. The Department must investigate the allegation(s) in accordance with standard procedures for the investigation of child abuse/neglect.

F. The "Baby Doe" coordinator will contact the individual designated by the appropriate hospital to gather preliminary case information. The Coordinator and CPI will discuss the situation prior to initiating legal proceedings.

G. The CPI will contact the Department's Legal Counsel to initiate the necessary legal proceedings to obtain an independent medical examination, to gain access to medical records, or to seek a court order for medical/surgical treatment.<sup>207</sup>

Notwithstanding a reference in the procedures for a court order for an independent medical examination, there is no mention of any method for obtaining an independent medical consultant to do the examination, review the medical records, or otherwise assist the CPS worker. The medically untrained CPS worker appears to be alone in determining whether the health care facility is providing appropriate treatment. In effect, the procedures appear to authorize the CPS worker to rely in some cases solely on the medical information received from the hospital against which the complaint was lodged.

The most serious weakness in the procedures, however, is that they appear to address only situations in which parents do not wish to provide treatment despite the advice of the child's physician. The procedures call for intervention in only one set of circumstances:

<sup>207</sup> Department for Children and Their Families, Procedure for Medical Neglect of Infants with Life-Threatening Disabilities, No. 428 at 3.



The Department shall immediately intervene upon receipt of a report that parents refuse, despite the advice of their physician, to consent to further evaluation by a specialist or to the transfer of their infant to a more specialized facility. In responding to reports of medical neglect, the Department is responsible for coordination and consultation with individuals designated by each hospital. This communication can help to diminish disruption to the hospital and the family during the course of the child protective investigation.<sup>208</sup>

There appears to be no specific provision for investigation of a report of a case in which a physician, with or without the concurrence of the parents, is denying legally required treatment.

Despite their apparent technical compliance with the CAA in a number of respects, the Rhode Island procedures do not appear to be designed to address the most typical circumstance in which treatment is denied: at the instance of the child's physician. They also provide for the CPS worker to place undue reliance on the judgment of the health facility where neglect is alleged to be occurring. The effectiveness of any investigation to discover if legally mandated treatment is being denied would be significantly improved were the agency to specify procedures for the use of an independent third-party medical consultant, selected with the benefit of advice from disability rights groups, to assist the CPS worker in all nonfrivolous cases.

## SOUTH CAROLINA

In South Carolina, the Child Protective and Preventive Services in the Department of Social Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

Upon inquiry, the agency stated that it had not received any reports of medical neglect of infants with disabilities since the regulations went into effect.<sup>209</sup>

The agency reported that when developing policies for the implementation of investigative procedures, it had "established a Task Force comprised of representatives from the medical profession, legal

consultants and hospital association to develop the policy and procedures."<sup>210</sup> There was no indication that disability rights groups were consulted.

These procedures were reviewed for compliance with the Federal regulations that implements the CAA. The definitions of terms correctly reflect the Federal standards. In accord with the Federal regulations, the procedures specify how the department will obtain access to hospital records and how it will obtain court orders for an independent medical examination and treatment. In addition, agency procedures also present a detailed method for investigation by an independent medical consultant to conduct an examination, review the medical records, or otherwise assist the CPS worker. The procedures indicate that the medical consultants will be neonatologists from tertiary unit hospitals, and it is specified that these consultants will not investigate in the region where they practice. The procedures assume the agency will make the determination of medical neglect: "The Department of Social Services will make the case determination based on the findings of the medical consultant, interviews with the parents, and if necessary, collateral contacts with other appropriate individuals"<sup>211</sup>

On their face, the South Carolina procedures appear to comply with the requirements of the CAA and their implementing regulation.

## SOUTH DAKOTA

In South Dakota, the Child Protection Services Unit in the Department of Social Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency stated that it had not received any reports of medical neglect of disabled infants.<sup>212</sup>

The agency reported that it had consulted with "medical specialists" in the development of procedures to implement the CAA. The agency described no contact with disability rights groups.<sup>213</sup>

The procedures were reviewed for compliance with the Federal regulations that implement the CAA. The definition of the term "withholding of

<sup>208</sup> Department for Children and Their Families, Policy for Medical Neglect of Infants with Life-Threatening Disabilities, No. 428 at 2.

<sup>209</sup> Letter from Marguerite Campbell, CPPS Consultant, Child Protective and Preventive Services to Vincent A. Mulloy, Office of the General Counsel, U.S. Commission on Civil Rights (July 21, 1988).

<sup>210</sup> Letter from Pamela Bond, Project Administrator, Child Protective and Preventive Services and Shirley Fitz-Ritson,

Director, Child Protective and Preventive Services, to *Issues in Law and Medicine* (Apr. 2, 1987).

<sup>211</sup> Medical Neglect of Disabled Infants, Procedures, South Carolina Department of Social Services, sec. XVIII.

<sup>212</sup> Telephone interview with Merlin Weyer, Program Specialist, Child Protection Services (July 28, 1988).

<sup>213</sup> Letter from Merlin Weyer, Program Specialist, Child Protection Services, to *Issues in Law and Medicine* (Apr. 28, 1987).

medically indicated treatment" in the procedures is consistent with the Federal regulation. Enforcement mechanisms that are required to be specified in CPS agency procedures, such as the manner in which a CPS will obtain medical records and a court order for independent medical examination, are also set forth. In addition, South Dakota ensures that an independent medical consultant, not affiliated with the hospital or a resident of the area, will conduct the examination, review the medical records, or otherwise assist the CPS worker. However, the procedures include no definition of the term "infant." An accurate definition that corresponds with the Federal regulation should be incorporated into the State's procedures to provide notice to agency personnel, parents, and medical providers of the class of those protected by the detailed Federal treatment standards. (See Preface, NOTE E.)

The South Dakota procedures contain a curious and cumbersome method of case review when a hospital has an infant care review committee. The agency appears to have made an attempt to involve the committee in the determination of whether a report of medical neglect is "substantiated." The directive states:

*IF THE INFANT IS IN A HOSPITAL WITH AN ICRC*, the medical consultant will contact the ICRC representative to discuss the referral. All allegations should be presented to the ICRC representative. If the ICRC is aware of the infant and if both the ICRC representative and the medical consultant agree with the treatment/care being provided, the referral will be considered unsubstantiated and the case will be closed. If the ICRC is not aware of the infant, the ICRC will be requested to review the case. The findings of the ICRC as to the appropriateness of care provided will be reviewed by the medical consultant and if he is in agreement it will be accepted by the Department. If it is decided by the medical consultant that the care is not appropriate, but the ICRC is able to institute proper care, no further action will be required. However if the ICRC is not able to ensure adequate care as determined by the medical consultant, the medical consultant shall immediately contact one of the listed State Office representatives who will contact the States Attorneys Office so that appropriate legal action may be taken. The ICRC is to be notified of such action. Appropriate legal action may consist of a court order ordering an independent medical examination of the infant or an order requiring medical treatment.<sup>214</sup>

<sup>214</sup> Child Protective Services Procedures Manual, at 79.

<sup>215</sup> Telephone interview with Pat Overton, Director, Child Protective Services, by Commission staff (July 20, 1988).

These provisions are not as egregious an abdication of agency authority as those in other States that completely defer to the views of an ICRC, because an agency medical consultant has the final word. However, the procedures appear to go beyond the consultation with an ICRC, which HHS has recognized as proper, to an unwarranted integration of a committee of the very hospital that is being investigated into the agency decisionmaking process. The agency's deference is inappropriate because Federal regulations clearly require the State's CPS system to make the determination whether treatment is medically indicated. (See Preface, NOTES A and B.)

In a number of respects, the procedures in effect in South Dakota are in compliance with the CAA. However, the effectiveness of any medical neglect investigation would be substantially improved by correction and clarification of the CPS relationship with the ICRC. In addition, the definition of "infant" found in the Federal regulations should be added to the South Dakota procedures.

## TENNESSEE

In Tennessee, the Child Protective Services Unit within the Division of Social Services in the Department of Human Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency stated that there had been no reports of medical neglect of infants with disabilities made to the agency since the regulation went into effect.<sup>215</sup>

The agency reported that it had created the policy without the assistance of any outside organization and that it had an agreement with Vanderbilt Hospital to provide instruction to CPS staff across the State.<sup>216</sup>

The agency's policies and procedures were reviewed for consistency with the Federal regulations that implement the CAA. They state:

### II. Policy

The Department of Human Services will accept and investigate all reports which allege that a disabled infant is being deprived of nourishment and/or medically beneficial treatment solely on the basis of his/her present or anticipated mental or physical impairment.

<sup>216</sup> Information obtained from Gloria Manhein, Director, Child Protective Services, by *Issues in Law and Medicine* (July 13, 1987).

The Department will take appropriate action to prevent further unlawful medical neglect of such children.<sup>217</sup>

Enforcement mechanisms, such as the method by which CPS staff will obtain the infant's medical records or the method by which the agency will obtain a court order for an independent medical examination for the infant, are not specifically spelled out in the neglect of handicapped infants section of the policy. However, the agency can demonstrate its ability to perform these requirements within the general Child Protective Service policy.

However, no definition of the term "infant" is given in the policy. This is a significant deficiency. (See Preface, NOTE E.) A definition of the term "withholding of medically indicated treatment" is also absent from the procedures. Instead, it appears that the the following is the medical treatment standard the agency uses to determine whether treatment is appropriate:

#### F. Decision Making

After talking with the parents, medical personnel, ICRC, and the Child Abuse Review Team, the staff must decide which action to take. It is possible to seek a court order to require medical treatment of an infant. However, the following test must be met before taking such action:

"Is a health care provider, solely on the basis of present or anticipated physical or mental impairments of an infant, withholding medical treatment or nourishment from the infant, who in spite of such impairments would medically benefit from the treatment or nourishment?"

If after investigation and consultation, the counselor reasonably believes or suspects the above test has been met, he/she should prepare a legal referral to seek court ordered medical treatment. If the test has not been met then the case should be closed.<sup>218</sup>

This definition seems more appropriate to enforcement of section 504 than of the CAA. To comply with the CAA, an agency must employ the legal standard of care it contains, a legal provision scrupulously crafted by Congress to establish only narrow circumstances in which maximal treatment may legally be withheld. (See Preface, NOTE F.)

To the Tennessee agency's credit, a systematic and objective approach to investigating a report of medical neglect is stated by the procedures. The

procedures call for interviews with the parents, medical personnel, the hospital's ICRC, and an entity that apparently reviews all reports of medical neglect:

#### D. Child Abuse Review Team Staffing

These cases must be brought to the Child Abuse Review Team for their recommendations. This is appropriate since the Team is an independent review committee with medical professionals.<sup>219</sup>

The agency reported that this was a panel composed of medical professionals.<sup>220</sup>

In some respects, the procedures in effect in Tennessee are in compliance with the CAA. However, the agency regulations do not properly define the terms "infant" and the terms "withholding of medically indicated treatment." Both of these terms are absolutely necessary to ensure that the CPS agency make appropriate determinations concerning whether the medical treatment of children who are the subject of a report is in accord with Federal standards.

#### TEXAS

In Texas, the Protective Services for Families and Children in the Department of Human Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency reported that in developing procedures for enforcement of the CAA, "the Department consulted with various public and private groups including the Texas Hospital Association, Texas Medical Association, Texas Perinatal Association, and the University of Texas School of Nursing." The agency gave no indication that it had consulted any disability rights groups.<sup>221</sup>

The agency reported that:

Since October, 1985, one report has been received by TDHS [Texas Department of Human Services] indicating withholding of medical treatment of a 5-year old severely handicapped child. Due to the child's extreme disabilities, the parents voluntarily relinquished parental rights to the Department. The child has required repeated hospitalization due to pneumonia, and, the medical facility where the child had previously been taken requested permission from the Department to stop treatment. The Department requested the hospital convene an ICRC to review the

<sup>217</sup> Department of Human Services, Child Protective Services Manual, vol. IV, app. I, Cases Involving Failure To Provide Nourishment and Medically Beneficial Treatment of Disabled Infants with Life Threatening Conditions at 2.

<sup>218</sup> *Id.* at 4

<sup>219</sup> *Id.* at 3.

<sup>220</sup> Telephone interview with Pat Overton, Director, Child Protective Services (July 20, 1988).

<sup>221</sup> Letter from David Brock, Texas Department of Human Services, to *Issues in Law and Medicine* (Apr. 3, 1987).

child's situation, but the facility did not comply; consequently, the child was simply moved to another hospital where appropriate treatment was obtained. The child continues to receive treatment from this facility without difficulty.<sup>222</sup>

The Texas procedures were reviewed for compliance with the Federal regulation implementing the CAA. Enforcement mechanisms required by the Federal regulation to be specified in CPS agency procedures, such as the manner in which a CPS agency will obtain medical records and court orders for independent medical evaluations, are appropriately included. A definition of "withholding of medically indicated treatment" is included that correctly states the Federal standard. However, there is no definition of the term "infant." This is a serious deficiency.<sup>223</sup>

The Texas procedures technically comply in most respects with the CAA, but other clauses disclose flaws. For example, immediately following the definition of "withholding of medically indicated treatment," the procedures state:

If the Department receives a report alleging medical neglect consistent with the above definition and involving allegations against the medical facility or medical personnel, the focus of the investigation is to make sure that the parents or other caretakers authorized to consent to medical treatment have been provided with all reasonably available information regarding possible medical treatment or resources for the child.<sup>224</sup>

This instruction undermines the concept that there are medical treatment standards in effect that are to be enforced by the State CPS, implying that a decision to deny treatment in violation of the legally mandated standard of care will not be disturbed if it is "informed." Moreover, despite the policy's statement that CPS must ensure that "all reasonably available information" is to be made available, the procedures do not specify the method for obtaining an independent third-party medical expert to assist the CPS worker in evaluating a report of medical neglect. The procedures merely state:

6. If an independent medical examination appears necessary to assure an appropriate resolution of a report of

<sup>222</sup> *Id.*

<sup>223</sup> In a letter dated Oct. 5, 1988, the assistant commissioner for Protective Services for Families and Children Branch, responding to relevant portions of the Commission's draft report, acknowledged that "[i]t is correct that Texas does not define the term 'infant' in either the Texas Family Code or the Texas Department of Human Services Child Protective Services Handbook."

medical neglect, staff must determine whether an independent medical opinion is available. Resources for payment of such an examination include the parents (directly or through insurance), medical schools or other community medical resources, county funds or Title IV-B funds.<sup>225</sup>

Perhaps the most disturbing indication of this agency's attitude toward reports of medical neglect of handicapped infants is in a statement made by a Texas CPS administrator to Commission staff. When asked if there had been any reports of withholding medically indicated treatment in the State of Texas in the last year, he replied that there had not and described this form of medical neglect as a "misunderstood issue caused by an extraordinary event in Bloomington, Indiana. This is primarily an issue related to parents' and physicians' decisions concerning treatment of the child—it is a medical issue, not a political issue."<sup>226</sup>

Apart from the significant omission of a definition, Texas procedures are in most respects in technical compliance with the CAA. However, the agency appears ambivalent toward its responsibility to carry out the terms of the CAA. Furthermore, the effectiveness of any investigation to discover if treatment is legally appropriate would be substantially improved were the agency to specify the use of an independent third-party medical consultant (selected with the benefit of advice from disability groups) to participate in the investigation.

## UTAH

The Utah Division of Family Services in the Department of Social Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency states that it has never received a report alleging the withholding of medically indicated treatment from an infant with disabilities. The staff person interviewed by Commission staff volunteered that he was not surprised that there had not been reports of denial of treatment to disabled infants because "a 'Baby Doe' situation would most likely result in a collusion between the parents and the physician. We would have to depend on someone else in the intensive care unit to report denial of

<sup>224</sup> Texas Department of Human Services, Memorandum from James Marquart, Assistant Commissioner, Protective Services for Families and Children Branch, to Regional Directors for Families and Children at 2.

<sup>225</sup> *Id.* at 3.

<sup>226</sup> Telephone interview with David Brock, Texas Department of Human Services (July 29, 1988).

treatment to handicapped infants.”<sup>227</sup> To cultivate such sources, the staff person reported that his office attempts to meet with staff in Utah’s tertiary unit hospitals at least once a year to inform them of their obligation to report these cases.<sup>228</sup>

Procedures to implement the CAA were developed by “an Advisory Committee composed of professionals in Child Protective Services and a local pediatrician specializing in neonatology.”<sup>229</sup> Disability rights groups do not appear to have been consulted in the development of these procedures.

The procedures were reviewed for consistency with the Federal regulation that implements the CAA. The enforcement mechanism to obtain medical records from the hospital is set forth in the procedures. However, the Utah procedures inaccurately restate two critical definitions of terms in the Federal rule.

First, the definition for the term “withholding of medically indicated treatment” from a disabled infant is only partially restated and what is presented adds an incorrect treatment exception for disabled infants. The agency definition completely omits the Federal requirement that “appropriate nutrition, hydration, and medication” must always be given an infant with a disability. Furthermore, in defining exceptions to the normal requirement of maximal treatment, the procedures incorrectly state that treatment is not necessary when “(3) the treatment itself under such circumstances would be inhumane.”<sup>230</sup>

This is a extremely significant misstatement of the third treatment exception of the Federal regulation. Under this exception, treatment is not mandated when “the provision of such treatment would be virtually futile in terms of the survival of the infant and the treatment under the circumstances would be inhumane.”<sup>231</sup> In the Federal guidelines, inhumane treatments are those pursued although recognized as virtually futile with regard to the infant’s survival. The Utah procedures separate the linkage between virtual futility and inhumaneness, and establish “inhumane treatment” as a separate and freestanding

<sup>227</sup> Telephone interview with Gary Jensen, Program Specialist, Division of Family Services (Aug. 2, 1988).

<sup>228</sup> *Id.*

<sup>229</sup> Letter from Gary Jensen, Program Specialist, Division of Family Services, to *Issues in Law and Medicine* (May 14, 1987).

<sup>230</sup> Utah Department of Social Services, Division of Family Services, Implementing Policy for Investigation of Allegations of Withholding of Medically Indicated Treatment To Disabled Infants with Life Threatening Conditions II. B.

<sup>231</sup> 45 C.F.R. § 1340.15(b)(2)(iii).

category. The inherent danger in such a construction is the necessary subjectivity involved in determination of what is “inhumane,” an invitation to the use of quality of life considerations, which the CAA intends to foreclose in its formulation. (See Preface, NOTE F.)

In a September 24, 1988, letter, the agency responded to a preliminary draft of this report and attempted to address this criticism. However, it made no effort to explain or justify its misstatement of the legal standard of care. Instead, the agency’s response concentrated on its exclusive authority to conduct the investigation:

The quote received appears to indicate that the treating physician is the one who determines the “inhumane” treatment. As I view the entire section of procedures I interpret it to be referring to the treating physician not having that exclusive authority. That is, an investigation would be merited to gain consensus on the inability to ameliorate the life threatening conditions which results in the treatment being inhumane.<sup>232</sup>

Efforts to gain “consensus” on such a point violate the Federal rule, which requires that the humaneness of treatment can only be considered in conjunction after it has been determined that, even with treatment, there is only a remote possibility of the child’s long term ability to survive.

The Utah procedures also inaccurately define the term “infant” to mean only an infant less than 1 year of age.<sup>233</sup> This 1-year limitation is clearly underinclusive enforcement of the CAA, and under it the agency fails to protect a large group of those required to be protected by Federal law. Commenting on relevant portions of a draft of the Commission report, the agency stated:

The state has defined infant for purposes of these special procedures at under one year, however, our child neglect laws have mandated investigation of medical neglect for children from birth to age 18 since the initial legislation. I do not see the expressed conflict in Utah’s definition and the regulation cited except that the cumbersome procedures are not in play after the child reaches one year.<sup>234</sup>

<sup>232</sup> Letter from Gary Jensen, Protective Service Specialist, Division of Family Services to T. Burke Balch, Office of the General Counsel, U.S. Commission on Civil Rights (Sept. 24, 1988).

<sup>233</sup> Utah Department of Social Services, Division of Family Services, Implementing Policy for Investigation of Allegations of Withholding of Medically Indicated Treatment To Disabled Infants with Life Threatening Conditions II. C.

<sup>234</sup> Letter from Gary Jensen, Protective Service Specialist, Division of Family Services to T. Burke Balch, Office of the

This reply evades the point that the medical treatment standards for disabled infants, the "cumbersome procedures" as the agency describes them, must be applied under Federal law to medical judgments concerning infants with disabilities beyond the first year. (See Preface, NOTE E.)

A further weakness in the Utah procedures is that there is no specification of the method for obtaining an independent third-party medical expert to conduct the examination, review the medical records, or otherwise assist the CPS worker in evaluating a report of medical neglect. Notwithstanding a reference that "DFS will provide outside medical evaluations as requested," there is no provision "for a court order for an independent medical examination" specified in State agency's procedures as required by the Federal regulations. (See Preface, NOTE D.) The medically untrained CPS worker appears to be alone in determining whether the health care facility is providing appropriate treatment. In fact, according to the policies, before making a determination as to the appropriateness of the treatment, the CPS worker is instructed to request the infant bioethics review committees to convene and review the case in instances where such a committee exists. In effect, the procedures appear to authorize the CPS worker to rely in some cases solely on the medical information received from the very hospital against which the complaint was lodged.

In short, the Utah procedures are completely contrary to Federal standards. The effectiveness of any investigation to discover if treatment is medically correct would be substantially improved were the agency to specify the use of an independent third-party medical consultant, selected with the benefit of advice from disability groups, to assist the CPS worker in all nonfrivolous cases. The procedures are out of compliance with Federal law when they present an underinclusive definition of those to be protected by the CAA, when they erroneously state that treatment need not be provided to a disabled infant if the treating physician considers it as "inhumane," and when they completely omit the legal requirement that infants with disabilities must always be given appropriate nutrition, hydration, and medication. The Utah procedures appear to

allow the starvation of infants with disabilities if there is a "consensus" between the treating physician and the CPS agency that to do so would be "humane." Finally, Utah's characterization of the protective requirements of the CAA as "cumbersome procedures" bespeaks an agency more interested in evading than enforcing them.

## VERMONT

The Vermont Division of Social Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency reported that there had been no reports of medical neglect of infants with disabilities since the regulation went into effect.<sup>235</sup>

There is no record that disability rights groups were consulted in the formulation of State policy for a medical neglect cases. The agency reported that it consulted the Vermont chapter of the American Academy of Pediatrics and a representative from Vermont's only tertiary care hospital.<sup>236</sup>

Agency procedures were reviewed to determine consistency with Federal law. Enforcement mechanisms that are required by the Federal regulation to be specified in CPS procedures, such as the manner in which a CPS will obtain medical records and a court order for independent medical examination, are set forth. The definition of "withholding of medically indicated treatment," which establishes the standard of care, parallels that in the Federal regulation. However, no definition is given for the term "infant," which would establish the class of those protected by that standard of care. (See Preface, NOTE E.)

The agency procedures indicate that it alone makes the determination whether treatment of a child who is the subject of a complaint of medical neglect is in accord with the standards set forth in the CAA. To assist in this task, the procedures instruct the caseworker to "consult with the Pediatric Consultant for Infant Care Review (PC/ICR) to obtain the information and treatment recommendations necessary to the investigation and/or to develop a case plan." The procedures state that "[t]he investigation of the report remains open pending assurance that the PC/ICR consultation occurs

General Counsel, U.S. Commission on Civil Rights (Sept. 24, 1988).

<sup>235</sup> Telephone interview with Maureen Thompson, Case Reviewer, Division of Family Services (Aug. 10, 1988).

<sup>236</sup> Telephone interview with Ellen Furnari, Department of Social and Rehabilitation Services, by *Issues in Law and Medicine* (June 16, 1987).

immediately and that the recommendations of the PC/ICR are implemented."<sup>237</sup>

Apart from the significant omission of a definition of class of children protected, on their face the Vermont procedures appear to comply with the CAA and their implementing regulation.

## VIRGINIA

Virginia Child Protective Services (VCPS) in the Department of Social Services (DSS) is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

In developing its policies and procedures, DSS appears to have placed more emphasis on securing views of health care providers—those being regulated—than of groups representing people with disabilities—those being protected. Only a State agency was consulted for disability rights views; no private disability rights advocacy organizations were contacted, while the views of all the hospitals in the State were solicited.

Our procedures were developed with the guidance of staff from the three major teaching hospitals in our state. Staff involved included physicians, nurses, administrators, clergy, ethics committee members and social workers. Additionally, the procedures, once drafted, were shared for comment with all of the hospitals in the state as well as all of the departments of social services who would be providing protective services. Our attorney provided legal review and the State Department for the Rights of the Disabled was consulted.<sup>238</sup>

Asked to comment on this criticism, DDS responded to the Commission that it solicited input from the Virginia Department for the Rights of the Disabled "as an advocacy office for all of the private disability rights advocacy organizations and individuals in the State." On the other hand, DDS maintained, "[v]iews of all hospitals were solicited since there was no central organization which represented their collective interests."<sup>239</sup>

The State's procedures were reviewed for compliance with the Federal regulation implementing the

CAA. A definition of the term "withholding of medically indicated treatment" is present in the procedures and is consistent with the Federal regulation. Enforcement mechanisms required by the Federal regulation to be specified in CPS agency procedures, such as the manner in which a CPS agency will obtain medical records and court orders for independent medical evaluations, are also included. The procedures include no definition of the term "infant." However, a pamphlet published by the Commonwealth of Virginia for health care providers inaccurately defines an infant as "A child less than one year of age."<sup>240</sup> (See Preface, NOTE E.)

A further weakness is that the procedures do not specify the method for obtaining an independent third-party medical expert to assist the CPS worker in evaluating a report of medical neglect.

## SPECIAL CONSIDERATIONS/PROCEDURES FOR INVESTIGATING COMPLAINTS OF WITHHOLDING MEDICAL TREATMENT OF HANDICAPPED INFANTS

...  
f) if it appears that it is a situation of medical neglect, determine if immediate actions are necessary to maintain the child

*—the worker must assess the immediate situation utilizing any available information from the attending physician, other appropriate resources from the hospital and the complainant. Access to the medical records and an independent medical exam of the infant are to be obtained with a court order when needed to assess the situation.*<sup>241</sup>

Notwithstanding the reference to a court order for an independent medical examination, there is no mention of any method for obtaining an independent medical consultant to conduct the examination, review the medical records, or otherwise assist the CPS worker. Asked to comment upon this, the Virginia Department of Social Services responded that "the procedures do not include specific instructions on how to obtain medical consultation because

<sup>237</sup> Department of Social and Rehabilitation Services Policy Manual, pt. IV-E-16a.

<sup>238</sup> Letter from Janine Tondrowski, Program Specialist, Child Protective Services, to *Issues in Law and Medicine* (June 16, 1987).

<sup>239</sup> Letter from D. Ray Sirry, Director, Division of Service Programs, Department of Social Services, Commonwealth of Virginia, to William J. Howard, General Counsel, U.S. Commission on Civil Rights (Oct. 6, 1988).

<sup>240</sup> Virginia Department of Social Services Policies and Procedures, app. II, vol. VII, sec. III, ch. A, at 63. In commenting upon this, VCPS advised the Commission that it plans to revise the definition of infant contained in its pamphlet to include the definition specified in the Federal regulations. Letter from Janine Tondrowski, Program Specialist, Child Protective Services, to *Issues in Law and Medicine* (June 16, 1987).

<sup>241</sup> Virginia Department of Social Services Policies and Procedures, app. II, vol. VII, sec. III, ch. A, at 63, (emphasis added).

this is a function of the state office.”<sup>242</sup> It further stated:

Contacts were made and developed across the state to enable this consultation to take place when necessary. In the event of a complaint, the local department receiving the complaint is to contact the CPS Hotline. This contact initiates involvement of the state level policy specialist who would coordinate any needed consultation. Because of the geography of the Commonwealth, it was determined impractical to choose one medical consultant. Additionally, because of the adverse reaction to the initial regulations set out by the Federal government, no one physician was willing to accept such a responsibility. However, a number of specialists in neonatal medicine did agree to serve in a consulting capacity on a case-by-case basis should the need arise.

The agency reported in its letter to the Commission of October 6, 1988, that to date it had not received any complaints requiring investigation under its regulations. In addition, the agency had previously reported, in June 1987, that there had been no reports of disabled infants having been denied medical treatment.<sup>243</sup>

In some respects the procedures in effect in Virginia are in substantial compliance with the CAA. However, the effectiveness of any investigation to discover if treatment is medically correct would be substantially improved were the agency to specify in its procedures the use of an independent third-party medical consultant, selected with the benefit of advice from disability groups, to assist the CPS worker in all nonfrivolous cases. In addition, the definition of “infant” in the Federal regulations should be added to the Virginia procedures.

## WASHINGTON

In Washington, the Division of Children and Family Services in the Department of Social and Health Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency stated that it was aware of three reports of medical neglect of infants with disabilities since 1985, but it could not report a definite figure

<sup>242</sup> Letter from D. Ray Sirry, Director, Division of Service Program, to William J. Howard, General Counsel, U.S. Commission on Civil Rights (Oct. 6, 1988).

<sup>243</sup> Letter from Janine Tondrowski, Program Specialist, Child Protective Services, to *Issues in Law and Medicine* (June 16, 1987).

<sup>244</sup> Letter from Richard Winters, Program Manager, Division of Children and Family Services, to *Issues in Law and Medicine* (Mar. 31, 1987).

because a separate reporting category does not exist for these cases. “In each instance, the hospital reported to CPS seeking court intervention to permit continued treatment. The courts intervened and all three children are surviving.”<sup>244</sup>

In a followup inquiry by Commission staff, the agency stated that an additional case had been reported. The staff person stated that all but one of the reports in the past 3 years had occurred when a doctor wished to provide treatment, but the parents refused to consent.<sup>245</sup>

To develop procedures for implementation of the CAA, the agency reported that it convened a Baby Doe Advisory Committee composed of practicing pediatricians, health care providers, representatives of the Washington State Hospital Association, the Washington Chapter of the American Academy of Pediatrics, the Washington State Medical Association, the Developmental Disabilities Planning Council, and numerous State agencies.<sup>246</sup>

These procedures were reviewed for consistency with the Federal standards. They set forth an enforcement mechanism to obtain medical records from the hospital. However, the State policy fails to specify how a “a court order for an independent medical examination of the infant” will be obtained by the agency, as required by the Federal regulation. (See Preface, NOTE D.)

A further weakness of the Washington procedures is the complete absence of definition of terms used in the Federal rule. Although the agency uses the phrase “withholding of medically indicated treatment” when it instructs CPS staff to pursue a dependency action to prevent such a withholding, it merely states “[s]uch treatment is not limited to the providing of appropriate nutrition, hydration and medication regardless of the infant’s condition or prognosis.”<sup>247</sup>

This clause is hardly instructive to the person given the duty to enforce the law. (See Preface, NOTE F.) In addition, the term “infant” is not defined in the procedures. (See Preface, NOTE C.)

<sup>245</sup> Telephone interview with Richard Winters, Program Manager, Division of Children and Family Services, by Commission staff (Aug. 1, 1988).

<sup>246</sup> Letter from Richard Winters, Program Manager, Division of Children and Family Services, to *Issues in Law and Medicine* (Mar. 31, 1987).

<sup>247</sup> Division of Family and Children’s Services Manual, ch. 26.33(F)(7).



The most egregious failure of the Washington procedures, however, is that they indicate the CPS agency has ignored the legal requirement for independent CPS investigations of a report of medical neglect of a disabled infant and assigned this task, at least partially and perhaps wholly, to a hospital infant care review committee. The procedures direct the CPS worker to consider a referral as unfounded when: "[t]he medical records indicate that the attending Physician's plan to withhold medical treatment has been reviewed and concurred in by two (2) consulting physicians or *an infant care review committee (or similar institutional/medical review) which includes the concurrence [of] two (2) consulting physicians.*"<sup>248</sup> In effect, the procedures abdicate determination of whether a hospital's staff is illegally denying treatment to a committee of the hospital, or even to any two consulting physicians presumably selected by the very doctor who is alleged to be engaged in medical neglect. (See Preface, NOTES A and B.)

Thus, the Washington CPS agency has wrongfully delegated its investigative authority to the hospital ICRC (or similar institutional or medical review board) to determine the legal question of whether there is discriminatory denial of medical treatment. In so doing, the agency has distorted the CAA's intent to create a strong enforcement mechanism to ensure legally mandated treatment for children with disabilities.

In virtually all significant respects, Washington is out of compliance with the Child Abuse Amendments and their implementing regulation.

## WEST VIRGINIA

In West Virginia, Services to Families and Children in the Division of Social Services of the Department of Human Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency stated that there has never been a report of medical neglect regarding a disabled infant made to it.<sup>249</sup>

The agency reported that in the development of procedures to implement the CAA it consulted

<sup>248</sup> *Id.* at (F)(5) (emphasis added).

<sup>249</sup> Telephone interview with Rozella Archer, Director, Services to Families and Children (July 25, 1988).

<sup>250</sup> Telephone interview with Michael O'Farrell, Division of Social Services, by *Issues in Law and Medicine* (June 9, 1987).

hospitals that provide neonatal services but did not consult with disability rights groups.<sup>250</sup>

These procedures were reviewed for consistency with Federal law. The agency's procedures are in compliance with Federal regulations with respect to specifying enforcement mechanisms for the manner in which a CPS agency will obtain medical records and a court order for independent medical evaluation. However, completely absent from the procedures is any definition of what constitutes a "withholding of medically indicated treatment," which would establish the standard of care, or who belongs to the protected class "infant." Both of these terms are necessary parts of the procedures and give CPS workers the ability to determine if the treatment of a particular child is in accord with Federal standards.

In an October 6, 1988, letter in response to a preliminary draft of relevant portions of the Commission report, the commissioner of the West Virginia Department of Human Services stated that because it anticipated few reports of this nature, it had not developed a separate system to respond to these reports. She stated, "it was not our intention to misdefine any of the terms associated with this issue. It is our expectation, based upon experiencing, that any questions as to whether or not a child is neglected will be referred to our State Office for review and final decision."<sup>251</sup> The Federal regulation is precise, however, in requiring that procedures be in writing,<sup>252</sup> not left to ad hoc determination on a case by case basis. Concerning the lack of a definition for the class of those protected under the CAA, the agency responded: "Our staff do not make distinctions between infants less than or more than twelve months of age in responding to a report of medical neglect."<sup>253</sup> However, the CAA requires that the precise and detailed standard of care it contains, rather than a generalized definition of medical neglect, be applied with regard to the class of "disabled infants with life-threatening conditions." (See Preface, NOTE E.)

Even more seriously, the procedures explicitly abdicate the agency's responsibility under Federal law, to investigate reports of medical neglect of infants, to the hospital that is to be investigated. (See

<sup>251</sup> Letter from Regina S. Lipscomb, Commissioner, West Virginia Department of Human Services, to William J. Howard, General Counsel, U.S. Commission on Civil Rights (Oct. 6, 1988).

<sup>252</sup> 45 C.F.R. § 1340.15(c)(4) (1987).

<sup>253</sup> Letter from Regina S. Lipscomb, Commissioner, West Virginia Department of Human Services, to William J. Howard, General Counsel, U.S. Commission on Civil Rights (Oct. 6, 1988).

Preface, NOTES A and B.) In instances where there exists an infant care review committee at a hospital, the procedures eliminate the federally required CPS duty to determine if there is a withholding of medical treatment:

#### PROCEDURES

The format for investigating a referral in these hospitals is as follows:

1. Contact will be initiated with the designated representative or the hospital. After contact has been made the worker will: present the allegations contained in the referral; and request a review of the treatment being provided. (The review should be conducted by a hospital group such as an ICRC, bioethics committee, etc. or an ad hoc committee convened to review cases of this nature.)

The worker should make him/herself available to participate in the review process. *By participation it is not meant that the worker is expected to or should attempt to pass judgment on the medical care provided.* Participation by the worker in the review provides an opportunity for discussion of the Department's concerns and can provide the worker with necessary information should further action be required.

2. If the review process indicates that the infant is being provided appropriate medical care, then the referral will be considered unsubstantiated and no further action taken.

Appropriate medical care means that the review process has considered the infant's condition in regard to the need for nutrition, hydration, medication or other procedures which may be appropriate to ameliorate or correct the life-threatening condition.<sup>254</sup>

In those situations in which there is no ICRC, the procedures abdicate the question of determining medical neglect to the hospital contact person. Upon receipt of a report of medical neglect of a disabled infant, the procedures provide that the CPS worker must contact the "hospital liaison" and that "[i]f the hospital liaison determines that the infant in question is a patient and is being provided with the recommended treatment, then no further action will be taken and the report considered unsubstantiated."<sup>255</sup> This procedure disposes of the report of medical

neglect even more summarily than the procedure incorporating an ICRC.

Underlying this CPS system's abdication of its responsibility is a great confidence in the medical providers who are the typical subjects of reports of medical neglect of children with disabilities. The West Virginia procedures state:

#### *Commentary*

The Department believes that medical personnel treating disabled infants are committed to providing appropriate care. The Department also realizes that the treatment of such infants is a delicate, difficult and demanding task for medical personnel. Our responsibility is to work with these medical personnel as necessary to insure that proper care is and continues to be provided.<sup>256</sup>

The West Virginia procedures are responsive only to the situation where parents do not wish to provide treatment. They do not at all contemplate the review of a medical provider's decision to withhold treatment when there may be an opportunity for life—a fundamental provision of the CAA. The flaw in this policy, notwithstanding the instruction to the CPS worker to "request an independent medical examination when necessary," is the fact that there is nothing in this procedure that indicates that there is an independent third-party medical examiner to assist the CPS.

In response to the criticism made in the report, the agency attempted to minimize the language of the policy by simply stating: "The Department directed its field staff to seek the advice of hospital personnel in deciding whether proper care was being provided. Whatever decision is reached by field staff is subject to State Office review before a final determination is made."<sup>257</sup> Notwithstanding this assurance, the policy remains in effect.

The agency's letter of comment evinced a less than enthusiastic commitment to the special need of children with disabilities for protection from discriminatory denial of life-saving medical treatment. The agency's Commissioner wrote:

I trust that your report will place the issue of the protection of handicapped children with life threatening conditions from medical neglect in its proper perspective. This is an extremely sensitive issue as well as a controver-

<sup>254</sup> West Virginia Department of Human Services, Memorandum from Rozella Archer, Director, Services to Families and Children, to Area Administrators, Social Service Coordinators [and] Child Protective Services Supervisors, Child Protective Services Policy pt. 3 (Aug. 28, 1986) (emphasis added).

<sup>255</sup> *Id.*, pt. 2.

<sup>256</sup> *Id.*, pt. 1.

<sup>257</sup> Letter from Regina S. Lipscomb, Commissioner, West Virginia Department of Human Services, to William J. Howard, General Counsel, U.S. Commission on Civil Rights (Oct. 6, 1988).

sial one. The number of cases comprise a tiny segment of the CPS population and should not be singled out for special treatment to the detriment of other children.<sup>258</sup>

In light of its deference to the hospitals that would be the subject of denial of treatment reports and its failure to promulgate adequate written procedures, West Virginia is fundamentally out of compliance with the CAA and its implementing regulation.

#### WISCONSIN

In Wisconsin, the Bureau for Children, Youth and Families of the Division of Community Services in the Department for Health and Social Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency stated that there had been no reports of medical neglect reported to the agency.<sup>259</sup> In a followup inquiry conducted by the Commission, the agency confirmed that there had been no reports in the State.<sup>260</sup>

The agency produced *Guidelines in Handling a Report of Possible Medical Neglect of a Disabled Infant* to implement a response system to reports of withholding of medically indicated treatment. In a policy memorandum dated August 4, 1988, the agency stated: "These guidelines were developed over the last nine months with the participation of a 30-person multidisciplinary informal advisory group (The Baby Doe Forum), Child Protective Services (CPS) Work Group and by an extensive internal review that included Department of Health and Social Services staff, developmental disabilities advocates, and legal counsel."<sup>261</sup>

The Wisconsin guidelines were reviewed for compliance with the Federal regulation implementing the CAA. They appear to be a comprehensive manual for a professional investigation of a report of medical neglect of an infant with disabilities. The manual offers step-by-step investigation directions and has appendices that instruct the CPS on information-gathering needs and the process of coming to a conclusion whether treatment is "medically indicated."

Definitions presented in the guidelines manual conform to the Federal regulation. The enforcement

<sup>258</sup> *Id.*

<sup>259</sup> Telephone interview with Michael Becker, Division of Community Services, by *Issues in Law and Medicine* (June 24, 1987).

<sup>260</sup> Telephone interview with Mary Dibble, Child Abuse and Neglect Specialist (Aug. 2, 1988).

mechanisms that are required by the Federal regulation to be specified in the agency's procedures, such as the manner in which CPS will obtain medical records and court orders for independent medical evaluations, are set forth. The guidelines also provide for an independent medical consultant to be available to provide assistance to the CPS worker.

The Wisconsin procedures appear to comply with the Federal regulation implementing the CAA.

#### WYOMING

In Wyoming, the Children and Family Services Unit in the Division of Public Assistance and Social Services of the Department of Health and Social Services is the State agency responsible for enforcement of the Child Abuse Amendments of 1984 (CAA).

The agency reported that it had conducted one case investigation since the regulations went into effect.<sup>262</sup>

Regarding formation of its procedures, the agency reported that:

In developing our materials [for investigations under the CAA] we cooperated with the Colorado State Department of Social Services and held joint training sessions. We also relied greatly on material prepared by the American Bar Association in their model procedures, and referenced the journals published by the National Legal Center for the Medically Dependent and Disabled.<sup>263</sup>

There was no indication, however, whether disability rights groups were consulted.

The procedures were reviewed for compliance with the Federal regulation that implements the CAA. The definitions of terms correctly reflect the Federal standards. In accord with the Federal regulation, the procedures specify how the department will obtain access to medical records and how it will obtain court orders for independent medical examinations and treatment. In addition, agency procedures present a detailed method for investigation by an independent medical consultant to conduct an examination, review the medical records, or otherwise assist the CPS worker. The agency reported that the medical consultants will be American Academy of Pediatrics board-certified neonatol-

<sup>261</sup> State of Wisconsin, Department of Health and Social Services, Division of Community Services, Memo Series DCS-88-66, Aug. 4, 1988.

<sup>262</sup> Telephone interview with Paul Blatt, Program Manager, Children and Family Services Unit (July 20, 1988).

<sup>263</sup> Letter from John Steinberg, Children and Family Services Unit, to *Issues in Law and Medicine* (Mar. 30, 1987).

ogists who had expressed concern about treatment of infants with disabilities issues. It stated that no consultant will investigate in the region where he or she practices.<sup>264</sup> The procedures state that “[a] decision to seek informal resolution, court ordered treatment or additional information, refer to case [sic] involving an infant death, or to close an

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unfounded case, shall be made by the CPS specialist in consultation with the CPS medical consultant and SD-PASS consultant.”<sup>265</sup>

On their face, the Wyoming procedures appear to comply with the CAA and their implementing regulation.

<sup>265</sup> Children and Family Services Manual, vol. VI, pt. VI(A).

AFFECTED CPS AGENCY COMMENT PROCESS

STATE	RELEVANT EXCERPTS SENT TO CPS	CPS RESPONSE AND REPORT REVISIONS	REVISED EXCERPTS SENT TO CPS	ADDITIONAL CPS RESPONSE
ALABAMA	9/14/88	Alabama claimed that it is proper for an ICRC to decide if treatment is correct: "If a duly authorized ICRC decides that treatment should be withheld, there is no difference in medical opinion which would support court petition." With regard to the definition of infant, the State argued that because Alabama law provides that a child is anyone under the age of 18, the department would always investigate a report of medical neglect of any child regardless of age. And with regard to the report citing the agency for failure to include in its policy a provision for access to medical records, the agency wrote: "There is no provision in the federal regulations requiring that the State Plan or procedures outline in writing a procedure for obtaining medical records."	12/28/88	By letter of 1/5/89, the agency stated that: "Alabama will revise its regulations to state that a court order shall be obtained to obtain access to medical records . . . . Alabama will further clarify its written procedures to provide that a court order shall be obtained where examination of the infant is denied by the hospital . . . . Alabama will revise its written procedures to clarify that the medical neglect procedures apply to children past one year of age." With regard to the agency's reliance on a ICRC, the agency stated that: "Alabama's procedures have been approved by the federal Department of Health and Human Services. . . . In any case, duly constituted ICRCs are rare in Alabama."
ALASKA	9/14/88	By letter of 10/12/88 the agency wrote: "The report names Alaska among the states that 'explicitly abdicate to internal hospital infant care review committees or hospital staffs the authority to decide whether illegal denial of treatment is received by the state agencies.' The Division of Family and Youth Services has promulgated no such policies and procedures and I am advised by the Office of the Attorney General that no other Alaska State agency has done so."	12/28/88	None.
ARIZONA	9/14/88	The agency disagreed with the report citing the agency for abdicating to ICRCs the question whether an illegal denial of medical treatment is taking place: "Infant Care Review Committees are always part of the investigation. This not an abdication to the ICRC, but rather inclusion of a major source of information." The agency denied that its reformulation of the treatment standard was inconsistent with the Federal rule: "This definition is in compliance with the Arizona statute and federal regulations . . . ."	12/28/88	By letter of January 23, 1989, the State asserted that it is neither the policy nor practice of the agency to consider the quality of life of an infant who is under an existing disability. Nevertheless, the State informed this office that it will suggest the following revision: "In any investigation under this Section the infant's current 'quality of life' due to an existing handicap or disability shall not be considered in determining whether Child Protective Services has sufficient grounds for action." In addition, the State asserted that CAA protection is limited to children less than 1 year of age because this is the scope of protection enumerated in the

STATE	RELEVANT EXCERPTS SENT TO CPS	CPS RESPONSE AND REPORT REVISIONS	REVISED EXCERPTS SENT TO CPS	ADDITIONAL CPS RESPONSE
ARIZONA (cont.)				statute and that the regulation merely suggests protection "to other classes." Nonetheless, the State informed this office that it will suggest the following revision: "In addition to applying to infants less than one year of age, the standards and procedures set forth in this article should be consulted thoroughly in the evaluation of any issue of medical neglect involving an infant older than one year of age who has been continuously hospitalized since birth, who was born extremely prematurely, or who has a long term disability." The agency also assured the Commission that investigations by CPS would not cease merely because the parents and medical providers agree to withhold treatment. Nonetheless, the State informed this office that it will suggest the following revision: "In situations where the medical personnel and the child's parents or guardians are in agreement to withhold medical treatment for the infant, a dependency petition shall be filed, after decisionmaking process including the Child Protective Services supervisor and advice and counsel from an Assistant Attorney General, if Child Protective Services' independent evaluation shows that such medical care is being wrongfully withheld under applicable state and/or federal rules and regulations."
ARKANSAS	9/14/88	By letter of 10/10/88, the agency stated: "In our opinion Arkansas does meet the eligibility requirements of Public Law 93-247." The agency enclosed a packet of documents to demonstrate compliance. However, review of the documents found no specified manner in which the agency will obtain access to medical records or an independent medical examination, contrary to the requirements of the Federal regulation.	12/28/88	The agency sent a duplicate of its October submission and wrote: "We believe the enclosed information covers the issues you raised and is self-explanatory."
COLORADO	9/14/88	Colorado did not respond directly to the criticism that its policy did not show the method to be used to obtain an independent medical examination. Instead, the agency wrote: " <u>Colorado county departments of social services do have the ability to obtain court-ordered independent medical examinations.</u> Please find enclosed a copy of an Opinion of Colorado's Attorney General dated September 23, 1986 which addresses this issue. This Opinion was distributed to all county departments of social services and all hospitals as well as all other interested parties."	12/28/88	With regard to the fact that the agency has not made explicit in its procedures the method to be used to obtain an independent medical examination, the agency submitted revised procedures which showed that such a procedure exists. The report was revised accordingly. With regard to the absence of a specified medical consultant to assist the CPS, the agency wrote: "In this state supervised county administered system, the counties would make their own arrangements for independent medical examinations."

STATE	RELEVANT EXCERPTS SENT TO CPS	CPS RESPONSE AND REPORT REVISIONS	REVISED EXCERPTS SENT TO CPS	ADDITIONAL CPS RESPONSE
CONN.	9/14/88	Connecticut did not address the fact that its policy lacks written procedures for access to medical records and court orders for independent medical examinations. Instead, the agency cited State statutes which gave it legal authority to investigate.	12/28/88	Connecticut wrote: "We have taken steps to assure that our procedures are specific in regard to the manner in which the Department can obtain medical records or a court order for an independent medical examination."
DELAWARE	9/14/88	None.	12/28/88	With regard to the definition of infant, Delaware wrote: "[A]s noted, the Division procedures do not currently define the term 'infant'. A supplemental memorandum to the procedures has been issued to correct this." With regard to the report citing the agency for allowing hospital staff to initially determine if there is medical neglect, the agency claimed that it merely obtains initial information from the hospital staff. The agency did not directly respond to the report's observation that a conflict of interest exists when a hospital approves the independent medical reviewer. The agency claimed that "in a state the size of Delaware, it would be difficult, if not impossible, to locate a physician who did not in some way have an affiliation with the hospital or treating physician so as to avoid the impression of a conflict."
D. C.	No.	---	12/28/88	None.
FLORIDA	9/14/88	With regard to the report citing Florida for abdicating authority to an ICRC, the agency claimed "Health and Rehabilitative Services Pamphlet 175-1 dated July 1, 1988, specifically requires that CPS staff respond to reports of known or suspected abuse or neglect immediately or within 24 hours. State law mandates that health care personnel report these situations to the protective agency."	12/28/88	Florida wrote: "While we felt that we have been in compliance with federal guidelines it is clear that we need to readdress the issue based on your evaluation. Steps will be taken immediately to do this."
GEORGIA	9/14/88	None.	12/28/88	None.
HAWAII	9/14/88	With regard to the absence of a provision in agency policy to obtain a court order for an independent medical examination, the agency cited a State statute which "provides the basis upon which child protective services social workers may seek court intervention." Hawaii also defended a provision in its policy which abdicates authority to a hospital ICRC. Hawaii claimed: "Section 1100.9.2 states in	12/28/88	None.

STATE	RELEVANT EXCERPTS SENT TO CPS	CPS RESPONSE AND REPORT REVISIONS	REVISED EXCERPTS SENT TO CPS	ADDITIONAL CPS RESPONSE
HAWAII (cont.)		effect that further investigation may not be required if inquiry by child protective services staff, upon receiving a report of alleged medical neglect, finds that a second opinion concurs with the opinion of the treating physician." The agency also showed in its response that it had a method to obtain medical records and that the cite in the report was incorrect. The report was revised accordingly.		
IDAHO	No.	---	12/28/88	Idaho stressed that it is in full compliance with all Federal requirements. The agency also supplied the commission with the names of the organizations which contributed to the development of the agency procedures for the investigation of a report of medical neglect: "In our formulation stage of preparing draft policy and procedures on this topic, a committee was convened to draft proposed materials. This committee included the Chief of the Bureau of Developmental Disabilities of the Department of Health and Welfare. He received input from appropriate groups to include the Downs Syndrome Parents Support Groups, Coalition of Advocates for the Disabled, and other parents support groups for children with various disabilities." This information was included in the report.
ILLINOIS	No.	---	12/28/88	Illinois wrote: "The Department of Children and Family Services is the responsible agent for making the determination whether treatment is legally required under the 'medically indicated' definition set forth in the Child Abuse Amendments. In such role DCFS represents the interests of disabled infants and determines circumstances in which the power of the state must be invoked to protect infants and then take appropriate follow-up actions."
IOWA	9/14/88	With regard to the definition of infant, Iowa wrote: "I have attached proposed changes to the Iowa Administrative Code which we believe will bring us into compliance with CFR 1340.15. We have replaced the term 'infant' with 'child' as it is our belief that the regulation should apply to all children not just infants."	12/28/88	Iowa did not directly respond to the reports finding its agency lacked a policy seeking a court order for an independent medical examination as required by Federal regulation. Instead, the agency cited State statutes which gave the agency legal authority to investigate.



STATE	RELEVANT EXCERPTS SENT TO CPS	CPS RESPONSE AND REPORT REVISIONS	REVISED EXCERPTS SENT TO CPS	ADDITIONAL CPS RESPONSE
KANSAS	9/14/88	Kansas wrote: "If your Commission were to publish the report as presented to us it would not accurately reflect the policies and procedures in Kansas." Enclosed were the policies that the report had cited as absent and the report was revised accordingly. The agency stated: "We regret that we were not aware of the focus of your report nor that our statutes and administrative regulations would have been useful to you in addition to the policies requested."	12/28/88	The agency wrote: "Kansas has no comment."
KENTUCKY	9/14/88	Kentucky wrote "we appreciate the opportunity to respond to these areas in your report which reflect on medical discrimination against handicapped infants. As stated, we do take exception to your report in that regard and have cited Kentucky Revised Statutes and Departmental Policy in reaching our conclusions . . . ." Enclosed were policies that the report had cited as absent. The report was revised accordingly.	12/28/88	None.
LOUISIANA	No.	---	12/28/88	None.
MAINE	9/14/88	In response to the report excerpts citing the agency for allowing ICRC's to determine if treatment met CAA standards, the agency wrote: "The material related to medical treatment clearly gives the decision making about whether a case meets the 'Baby Doe' criteria to the Department not a hospital." With regard to the definition of "infant", the agency conceded that "infant" is not defined but claimed that investigations would take place if the definition under medical treatment standard is met. With regard to the report citing the agency for noncompliance with Federal regulations pertaining to independent medical exams and access to medical records, the agency submitted policies which showed that both were present. The report was revised accordingly.	12/28/88	The agency wrote: "I believe your conclusion is that Maine is in compliance other than not having an acceptable definition of infant. If this is indeed your conclusion, then I would concur."
MARYLAND	9/14/88	With regard to the lack of a CAA definition of infant, Maryland claimed: "Protective Services are provided to 'any individual under the age of 18 years,' when there is a report of medical neglect of a child with a life-threatening condition."	12/28/88	None.
MASS.	No.	---	12/28/88	None.

STATE	RELEVANT EXCERPTS SENT TO CPS	CPS RESPONSE AND REPORT REVISIONS	REVISED EXCERPTS SENT TO CPS	ADDITIONAL CPS RESPONSE
MICHIGAN	9/14/88	Michigan focused on parental autonomy in the treatment decision as the reason it did not investigate reports that a hospital is withholding treatment illegally: "Based on the preceding discussion that parents are the decision makers concerning the care and treatment for their disabled infant, CPS involvement is appropriate when <u>parents</u> are alleged to be neglecting their infant's care. An entity which is not the decision maker or responsible for the child's care is not appropriate for CPS involvement."	12/28/88	None.
MINNESOTA	9/14/88	Minnesota claimed that its policy's definition of infant was consistent with the Federal regulation: "Consistent with 45 C.F.R. section 1340.15(b)(3)(i)(1987) Minnesota Rule on Child Protective Services and policy guidelines define infant less than one year of age."	12/28/88	The agency wrote: "We respectfully disagree with the conclusion that Minnesota's definition of the protected class is underinclusive. While the term infant is defined as less than one year of age, it is clear that the definition of infant medical neglect includes but is not limited to those children less than twelve months of age, which in essence more readily addresses the population of children protected by this section."
MISS	9/14/88	None.	12/28/88	Mississippi wrote: "[W]e are reviewing your report along with our policies and procedures. We are also reviewing your report with our Regional Office of Health and Human Services who has found our policy to be in compliance."
MISSOURI	9/14/88	Missouri submitted a policy that showed it had in fact an explicit procedure to be used to obtain an independent medical examination. The report was revised accordingly. With regard to the definition of infant, Missouri claimed that "[t]he regulation defines 'infant' as an infant less than one year of age. It then clarifies that treatment should not be changed or discontinued when the infant reaches one year or older. 'All children, including sub-population known as 'Baby Doe,' are protected through our child abuse and neglect statute . . . . Therefore, once an infant reaches one year of age our statute still requires appropriate treatment to be provided."	12/28/88	Missouri submitted a policy with a current medical treatment standard. The report was revised accordingly. Concerning the agency's deference to ICRCs, Missouri wrote: "The Division is very aware of its responsibility under federal and state statute to assure that a comprehensive investigation is conducted and to make the final determination relating to a child abuse/neglect report. Again, in order to make that commitment clear to the Commission I have attached a revision to Procedure A-7 of the Investigation Handbook." With regard to the definition of infant, the agency wrote: "I have attached a revision to our definition of infant which will immediately be inserted in the Investigation Handbook."

STATE	RELEVANT EXCERPTS SENT TO CPS	CPS RESPONSE AND REPORT REVISIONS	REVISED EXCERPTS SENT TO CPS	ADDITIONAL CPS RESPONSE
MONTANA	9/14/88	Montana did not directly respond to the fact that it is not explicit in the methods it will obtain independent medical examination and access to medical records as required by Federal regulation. Instead, the agency emphasized that it had statutory authority to do so if need be. The agency explained that "the department does not restate provisions of state law in its policy manual since to do so would be duplicative and would result in an unnecessarily voluminous policy manual." Concerning the absence of a defined standard of care and the lack of a definition of the class protected, the agency cited State statutes which defined both. The agency claimed that "[i]t is necessary to read the statutes and the policy together to gain an accurate understanding of Montana's program for reports of medical neglect."	12/28/88	Montana submitted a current policy which showed that procedures are in effect to obtain medical records and an independent medical examination. The report was revised accordingly.
NEBRASKA	9/14/88	Nebraska submitted policies that showed that it had in fact explicit procedures to obtain access to medical records and a court order for an independent medical examination.	12/28/88	None.
NEVADA	9/14/88	None.	12/28/88	None.
NEW HAMPSHIRE	No.	---	12/28/88	The agency disavowed statements made by its Medical Neglect Investigator concerning the futility of treating a disabled child. The Director stated that the individual did not speak with authority and was no longer with the agency. The agency wrote that "[t]he Division does not decide to conduct an investigation based on the quality of a child's life and it certainly will not decide to obtain medical treatment based on the quality of a child's life." The report was revised accordingly.
NEW JERSEY	9/14/88	New Jersey claimed that it was unnecessary to print the CAA treatment standard and the class the standard protects in its policies because pre-CAA State statutes served the same purpose: "It is our contention that the present New Jersey statutes meet the definitions of the standards of treatment set forth in the Child Abuse Amendments of 1984, and that N.J.S.A. 9:6-8.9 and N.J.S.A. 9:6-8.21 adequately define the terms 'child' to include infants and children over one year and 'withholding of medically indicated treatment'. The policy on the other hand, sets forth the philosophical orientation as well as a process by which to conduct these investigations in the least intrusive manner to the family, the physician, and the health facility."	12/28/88	None.

STATE	RELEVANT EXCERPTS SENT TO CPS	CPS RESPONSE AND REPORT REVISIONS	REVISED EXCERPTS SENT TO CPS	ADDITIONAL CPS RESPONSE
NEW MEXICO	9/14/88	None.	12/28/88	New Mexico wrote that it would remove from its policy that provision which instructs CPS staff to list reports of medical neglect as "unsubstantiated" when both parents and physician agree to withhold treatment. The agency also submitted policies that showed it had the ability to obtain medical records, independent medical examinations, defined the standard of care, and defined the class protected. The report was revised accordingly.
NEW YORK	9/14/88	New York wrote: "I would say that we do not expressly define infant and withholding of medically indicated treatment. I would add though existing New York law is sufficiently clear as to who is afforded protection and under what circumstances protection is needed."	12/28/88	With regard to the fact that there are no express policies to obtain access to records and independent medical examination as required by Federal regulation, New York pointed to informal procedure and statutes that could be availed: "Obtaining a child's medical records is a well established procedure. Family Court law in New York State contains written procedures for obtaining an independent medical examination when medical neglect is suspected."
NORTH CAROLINA	No.	---	12/28/88	None.
NORTH DAKOTA	9/14/88	None.	12/28/88	North Dakota wrote that it would revise its policy to include an expanded definition of infant.
OHIO	9/14/88	Ohio cited an administrative rules definition of "child" as the reasonable facsimile for the CAA's definition of "infant."	12/28/88	None.

STATE	RELEVANT EXCERPTS SENT TO CPS	CPS RESPONSE AND REPORT REVISIONS	REVISED EXCERPTS SENT TO CPS	ADDITIONAL CPS RESPONSE
OKLAHOMA	No.	---	12/28/88	By letter of January 23, 1988, the agency explained why it did not develop specific procedures under the CAA: "[L]ongstanding policy and state law authorized a full panoply of legal remedies, access to children's medical records, and medical examination of children whenever abuse or neglect of any kind was at issue. . . . Additionally, recently proposed revisions (developed from DHS's standard ongoing review of policy) incorporates all of the criteria and purposes of the federal regulation. . . . These provisions simply consolidate existing memos in one section, and adoption by the Director is anticipated very soon."
OREGON	9/14/88	With regard to agency policy language that allows overruling a parental decision of nontreatment only when an ICRC finds treatment is medically indicated, Oregon claimed: "The Medical Neglect Investigator determines the course of action to be taken including whether or not there should be court involvement. Information is obtained from the attending physician, the hospital review committee, the consulting neonatologist and other appropriate medical professionals, but the Medical Neglect Investigator is the one responsible for deciding if legally required treatment is being withheld."	12/28/88	Concerning policy language which allows an inappropriate amount of authority to the ICRC, Oregon claimed: "Nowhere in these sections does it state that the Hospital Review Committee or a physician have the authority or responsibility to determine whether or not there has been an illegal denial of medical treatment."
RHODE ISLAND	No.	---	12/28/88	With regard to policy language that limits CPS intervention to parents who refuse consent to treatment, Rhode Island claimed: "I wish to advise you very clearly that we would initiate an investigation if an allegation is received that a physician with or without the consent of the parent is denying legally required treatment."
SOUTH CAROLINA	No.	---	12/28/88	None.
SOUTH DAKOTA	No.	---	12/28/88	With regard to ICRC involvement, South Dakota wrote that "the procedure by which Child Protection Services relies on the results of the medical consultant's discussion with the ICRC representative will be reviewed by the South Dakota Department of Social Services." Concerning the definition of infant, the State wrote that its "procedures will be updated to define infant as defined by HHS regulations."

STATE	RELEVANT EXCERPTS SENT TO CPS	CPS RESPONSE AND REPORT REVISIONS	REVISED EXCERPTS SENT TO CPS	ADDITIONAL CPS RESPONSE
TENNESSEE	9/14/88	Tennessee showed that it had policies which enabled it to obtain independent medical examinations and an infant's medical records. The report was revised accordingly. With regard to the absence of the CAA standard of care in its policy, Tennessee wrote: "Within CPS policy severe abuse is defined to include a life-threatening condition. This CPS policy allows us to intervene on behalf of handicapped infants." Concerning a definition of infant, the State wrote: "Within policy and practice we investigate and provide services to all children under the age of 18 who are at risk of abuse or neglect. Handicapped infants are included within this mandate."	12/28/88	None.
TEXAS	9/14/88	Concerning the definition of infant, Texas wrote: "It is correct that Texas does not define the term 'infant' in either the Texas Family Code or the Texas Department of Human Services Child Protective Services Handbook."	12/28/88	The State claimed: "We disagree that not defining infant is a deficiency. We apply the regulations to all children (under age 18) who meet the criteria in the regulations, including infants."
UTAH	9/14/88	Utah made no effort to justify or explain policy language which misstates the legal standard of care. Instead, the agency explained its exclusive authority to determine medical neglect, an issue never brought out by the report: "The quote received appears to indicate that the treating physician is the one who determines the 'inhumane' treatment. As I view the entire section of procedures I interpret it to be referring to the treating physician <u>not</u> having that exclusive authority." Concerning the definition of infant, the State wrote: "The state has defined infant for purposes of these special procedures at under one year, however, our child neglect laws have mandated investigation of medical neglect for children from birth to age 18 since the initial legislation. I do not see the expressed conflict in Utah's definition and the regulation cited except that the cumbersome procedures are not in play after the child reaches one year."	12/28/88	None.
VERMONT	9/14/88	None.	12/28/88	With regard to a definition of infant, Vermont wrote that "we will be adding immediately the definition of 'infant' to our regulations using the HHS definition in the Federal Register."
VIRGINIA	9/14/88	Virginia advised that it would revise its definition of infant to reflect the HHS regulation.	12/28/88	Virginia wrote: "The revised draft accurately reflects our comments as submitted to you in an October 6, 1988, letter."

STATE	RELEVANT EXCERPTS SENT TO CPS	CPS RESPONSE AND REPORT REVISIONS	REVISED EXCERPTS SENT TO CPS	ADDITIONAL CPS RESPONSE
WASHINGTON	9/14/88	Washington did not directly address the substance of the report. Instead, the agency wrote: "I am concerned by the lack of coordination with Department of Health and Human Services, especially region offices and with this state. Information which is readily available through either of these sources would appropriately address some of the concerns highlighted in the report."	12/28/88	Washington claimed: "If you have concerns with the HHS interpretation of its own rule, then your challenge should be directed to that agency and not be directed at the states. Perhaps their further clarification would address your concerns."
WEST VIRGINIA	9/14/88	With regard to the lack of a definition of infant and the standard of care, West Virginia wrote: "It is our expectation, based upon experience, that any questions as to whether or not a child is neglected will be referred to our State Office for review and final decision." Concerning its deference to the hospital under investigation, the agency wrote: "The Department directed its field staff to seek the advice of hospital personnel in deciding whether proper care was being provided. Whatever decision is reached by field staff is subject to State Office review before a final determination is made."	12/28/88	None.
WISCONSIN	9/14/88	Wisconsin submitted current policy that contained those procedures that the report had previously cited as absent. The report was revised accordingly.	12/28/88	None.
WYOMING	No.	---	12/28/88	Wyoming wrote: "I have reviewed the excerpts from the draft report on Medical Discrimination Against Children with Disabilities. I am not aware of any errors in these materials."

## ANALYSES OF CPS COMPLIANCE WITH THE CAA

STATE	CAA REQUIREMENT FOR INDEPENDENT MEDICAL EXAM?	CAA REQUIREMENT FOR ACCESS TO MEDICAL RECORDS?	CAA DEFINITION OF INFANT USED?	CAA TREATMENT STANDARD USED?	RETAINS FULL CAA RESPONSIBILITY FOR THE INVESTIGATION?
ALABAMA	Yes - but an opinion will be sought only when no ICRC exists at a hospital.	No - procedures contain no such provision.	No - protection limited to children less than 1 year of age.	Yes - standard is reprinted verbatim.	No - CPS allows ICRC to determine if treatment is consistent with the CAA and will not investigate if there is no dispute between the attending physician and the hospital ICRC. See app. C, Alabama, for details.
ALASKA	Yes - but an opinion will be sought only when no ICRC exists at a hospital.	Yes - but only when there is no ICRC.	No - protection limited to children less than 1 year of age.	Yes - standard is reprinted verbatim.	No - CPS directs all complaints to hospital review board for a determination whether a complaint is "valid."
ARIZONA	Yes.	Yes.	No - protection limited to children less than 1 year of age.	No - ambiguity permits "quality of life" factors to be considered. See app. C, Arizona, for details.	No - it appears that the agency will intervene only where disagreement exists between the hospital and the parents. See app. C, Arizona, for details.
ARKANSAS	No - procedures contain no such provision.	No - procedures contain no such provision.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	No - the hospital that is most frequently under investigation for medical neglect was permitted to write the rules of investigation and to name the "independent" medical reviewer.
COLORADO	Yes.	Yes.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	Yes - but agency evidently lacks independent medical consultants which could produce undue reliance on the ICRC. See app. C, Colorado.
CONNECTICUT	No - procedures contain no such provision.	No - procedures contain no such provision.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	Yes.
DELAWARE	Yes.	Yes.	No - the protected class is not described.	Yes - standard is reprinted verbatim.	No - CPS allows the hospital "contact person" to determine if treatment is consistent with the CAA and the hospital pre-selects the independent medical reviewer.
DISTRICT OF COLUMBIA	Yes.	Yes.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	Yes - but the agency indicated that it regards the hospital's ICRC as the forum to resolve the cases. See app. C, District of Columbia.



STATE	CAA REQUIREMENT FOR INDEPENDENT MEDICAL EXAM?	CAA REQUIREMENT FOR ACCESS TO MEDICAL RECORDS?	CAA DEFINITION OF INFANT USED?	CAA TREATMENT STANDARD USED?	RETAINS FULL CAA RESPONSIBILITY FOR THE INVESTIGATION?
FLORIDA	No - procedures contain no such provision.	Yes - but only when there is no ICRC.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	No - CPS allows the "hospital liaison" and/or the ICRC to determine if treatment is consistent with the CAA.
GEORGIA	No - procedures contain no such provision.	No - procedures contain no such provision.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	No - CPS allows the hospital ICRC to determine if treatment is consistent with the CAA.
HAWAII	No - procedures contain no such provision.	Yes.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	No - CPS will not investigate a report if any other medical opinion exists to support an attending physician's judgement about withholding treatment.
IDAHO	Yes.	Yes.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	Yes.
ILLINOIS	Yes.	Yes.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	Yes.
IOWA	Yes - but manner of obtaining court order is not mentioned.	Yes.	Yes - definition is reprinted verbatim.	No - standard of care is not described in the procedures.	Yes.
KANSAS	Yes.	Yes.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	Yes.
KENTUCKY	Yes.	Yes.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	Yes.
LOUISIANA	Yes.	Yes.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	Yes.
MAINE	Yes.	Yes.	No - the protected class is not described.	Yes - standard is reprinted verbatim.	No - a circular distributed to CPS staff recommends that CPS allow the ICRC to determine if treatment is consistent with the CAA. See app. C, Maine, for details.
MARYLAND	Yes.	Yes.	No - the protected class is not described.	Yes - standard is reprinted verbatim.	Yes.

STATE	CAA REQUIREMENT FOR INDEPENDENT MEDICAL EXAM?	CAA REQUIREMENT FOR ACCESS TO MEDICAL RECORDS?	CAA DEFINITION OF INFANT USED?	CAA TREATMENT STANDARD USED?	RETAINS FULL CAA RESPONSIBILITY FOR THE INVESTIGATION?
MASSACHUSETTS	Yes.	Yes.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	Yes - but agency evidently lacks independent medical consultants which could produce undue reliance on the ICRC. See app. C, Massachusetts, for details.
MICHIGAN	Yes - but an opinion will be sought only when no ICRC exists at a hospital.	Yes.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	No - CPS will not respond to reports from parents that the hospital is not providing treatment for their child and will direct all complaints to hospital ICRC. See app. C, Michigan, for details.
MINNESOTA	Yes.	Yes.	No - protection limited to children less than 1 year of age.	Yes - standard is reprinted verbatim.	Yes.
MISSISSIPPI	No - procedures contain no such provision.	No - procedures contain no such provision.	No - the protected class is not described.	No - standard of care is not defined.	Yes - but the investigation procedures are ad hoc, incomplete and lack the input of independent medical consultants.
MISSOURI	Yes - but only if no parental consent or if ICRC disagrees with attending physician's treatment.	Yes.	Yes	Yes - standard is reprinted verbatim.	Yes - but the agency places undue reliance on the judgements of the hospital review committee. See app. C, Missouri, for details.
MONTANA	Yes.	Yes.	No - the protected class is not described.	No - standard of care is not described in the procedures.	Yes - but see app. C, Montana, for practice of "joint examination" of an infant between the AAP medical consultant and the attending physician.
NEBRASKA	Yes.	Yes.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	Yes.
NEVADA	Yes.	Yes.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	No - CPS allows the hospital ICRC to determine if treatment is consistent with the CAA.
NEW HAMPSHIRE	Yes.	Yes.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	Yes - but the agency indicated that there would be no further investigation if an ICRC approved the treatment decision. See app. C, New Hampshire, for details.

STATE	CAA REQUIREMENT FOR INDEPENDENT MEDICAL EXAM?	CAA REQUIREMENT FOR ACCESS TO MEDICAL RECORDS?	CAA DEFINITION OF INFANT USED?	CAA TREATMENT STANDARD USED?	RETAINS FULL CAA RESPONSIBILITY FOR THE INVESTIGATION?
NEW JERSEY	Yes.	Yes.	No - protected class is not described.	No - standard of care is not described in the procedures.	Yes.
NEW MEXICO	Yes.	Yes.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	No - CPS will not investigate if parents and a physician agree that treatments should be withheld.
NEW YORK	No specific procedures were established to respond to a medical neglect situation. Therefore, there are no provisions for independent medical examination or access to medical records. Neither the definition of infant nor the CAA standard of care are described. In addition, the agency indicated that there were no specific guidelines indicating who should be consulted if a medical neglect situation arises. See app. C, New York, for details.				
NORTH CAROLINA	Yes.	Yes.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	Yes - but CPS evidently has no independent medical expert and allows the hospital to be the primary resource for "consultation." See app. C, North Carolina, for details.
NORTH DAKOTA	Yes.	Yes.	No - protected class is not described.	Yes - standard is reprinted verbatim.	Yes.
OHIO	Yes.	Yes.	No - protection limited to children less than 1 year of age.	Yes - standard is reprinted verbatim.	Yes.
OKLAHOMA	No - procedures contain no such provision.	No - procedures contain no such provision.	No - protected class is not described.	No - standard of care is not described in the procedures.	No - CPS allows the hospital ICRC to determine if treatment is consistent with the CAA.
OREGON	Yes.	Yes.	No - protection limited to children less than 1 year of age.	Yes - standard is reprinted verbatim.	No - CPS terminates its investigation when a hospital ICRC determines that treatment is consistent with the CAA.
RHODE ISLAND	Yes.	Yes.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	Yes.
SOUTH CAROLINA	Yes.	Yes.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	Yes.

STATE	CAA REQUIREMENT FOR INDEPENDENT MEDICAL EXAM?	CAA REQUIREMENT FOR ACCESS TO MEDICAL RECORDS?	CAA DEFINITION OF INFANT USED?	CAA TREATMENT STANDARD USED?	RETAINS FULL CAA RESPONSIBILITY FOR THE INVESTIGATION?
SOUTH DAKOTA	Yes.	Yes.	No - protected class is not described.	Yes - standard is reprinted verbatim.	Yes.
TENNESSEE	Yes.	Yes.	No - protected class is not described.	No - standard of care is not described in the procedures.	Yes.
TEXAS	Yes.	Yes.	No - protected class is not described.	Yes - standard is reprinted verbatim.	Yes - but the agency evidently lacks independent medical reviewers.
UTAH	No - procedures contain no provision for the court order.	Yes.	No - protection limited to children less than 1 year of age.	No - "inhuman treatment" provision misstates the standard. See app.B, Utah, for details.	Yes - but the agency lacks independent medical reviewers which could cause undue reliance on hospital ICRCs. See app. C, Utah, for details.
VERMONT	Yes.	Yes.	No - protected class is not described.	Yes - standard is reprinted verbatim.	Yes.
VIRGINIA	Yes.	Yes.	No - protected class is not described.	Yes - standard is reprinted verbatim.	Yes - but the agency lacks independent medical reviewers which could cause undue reliance on hospital ICRCs. See app. C, Vir., for details.
WASHINGTON	No - procedures contain no such provision.	Yes.	No - protected class is not described.	No - procedures do not define the standard of care.	No - CPS allows the hospital ICRC to determine whether treatment is consistent with the CAA.
WEST VIRGINIA	Yes.	Yes.	No - protected class is not described.	No - standard of care is not described in the procedures.	No - CPS allows the hospital ICRC to determine whether treatment is consistent with the CAA.
WISCONSIN	Yes.	Yes.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	Yes.
WYOMING	Yes.	Yes.	Yes - definition is reprinted verbatim.	Yes - standard is reprinted verbatim.	Yes.

## **Appendix D**

### **Verified Answers**



COMMISSION  
FOR HUMAN SERVICES  
Burns Hargis, Chairman

State of Oklahoma  
**Department of Human Services**

Sequoyah Memorial Office Building  
P. O. Box 25352  
Oklahoma City, Okla. 73125

January 19, 1989



DIRECTOR  
OF HUMAN SERVICES  
Phil Watson

William J. Howard  
General Counsel  
U.S. Commission on Civil Rights

January 19, 1989  
Page 2

William J. Howard  
General Counsel  
U.S. Commission on Civil Rights  
1121 Vermont Ave., N.W.  
Washington, D.C. 20425

RE: Commission Report on  
Handicapped Newborn

Dear Mr. Howard:

The State of Oklahoma has been and continues to be in substantial compliance with the Child Abuse Prevention and Treatment Act, 42 U.S.C. § 5101 et seq., Section 4(b)(2)(k) of the Child Abuse Amendments of 1984, and its implementing regulation contained in 45 C.F.R. § 1340.15. The Department of Human Services, acting as the "properly constituted authority" within the state, has exerted a good faith and successful program to aggressively pursue and enforce federally mandated goals and objectives of the above referenced laws and regulatory guidelines.

The agency's former Director, Mr. Robert Fulton, initiated the state's efforts on January 2, 1985, in response to draft regulations implementing Pub. L. 98-457. (See copy of memorandum included as Attachment 1.) Subsequent to the publishing of new regulations in the Federal Register in April, 1985, this agency developed appropriate written notices for all hospital facilities in Oklahoma. The Commission's attention is directed to Attachment 2 which is a copy of the formal written notices to hospital administrators transmitted August 23, 1985.

The requirements of Section 1340.15 were fully complied with in the notice in discussing the obligations of facilities under the new rules. Mr. Michael Fogarty, Assistant Director of the agency's Medical Services Division, informed each facility of the strict requirements of the law. For example, he included the criteria of § 1340.15(2)(ii) demanding that each hospital designate a person responsible for reporting suspected medical neglect including the withholding of medically indicated treatment from disabled infants with life threatening conditions. Although the administrator was presumed to be the designee, the facility was required to report the name of the individual.

Within the agency, the Child Abuse Unit was authorized to "coordinate and consult" with designated hospital representatives in compliance with § 1340.15(2)(1). The name, address and telephone number of the supervisor (Ms. Ann Beam) was incorporated in the notice. Concomitantly, the facility was apprised of its obligation under federal law to "promptly" notify the Unit of any cases of suspected medical neglect (as required under subsection (2)(ii)). Indeed, the agency notice exceeds federal requirements by directing designees to utilize the 24 hr./7 day per week Child Abuse Hotline whenever the main office is closed.

The additional facility responsibility to update designee information annually was also noted as mandated under subsection (3) of the regulation. Furthermore, a form was provided for the facility to utilize initially and with subsequent updates. (A copy is included with Attachment 2 for your review.)

Notwithstanding any misunderstandings resulting from informal phone contacts between C.C.R. staff and Ms. Diana Stell, Oklahoma Department of Human Services written policy contains numerous sections which authorize and encourage action to protect infants and children from either abuse or neglect including medical neglect. Additionally, recently proposed revisions (developed from DHS's standard ongoing review of policy) incorporates all of the criteria and purposes of the federal regulation. (See copies of proposed revised policy dated December 12, 1988 marked Attachment 3.) These provisions simply consolidate existing memos in one section, and adoption by the Director is anticipated very soon.

It should be recognized, however, that longstanding policy and state law authorized a full panoply of legal remedies, access to children's medical records, and medical examination of children whenever abuse or neglect of any kind was at issue. For example, sections 620-624 discuss, in minute detail, procedures available to commence investigation of suspected abuse or neglect, initiation of legal proceedings through the appropriate district attorney or the agency's legal division, acquisition and protection of the medical records of children, coordination with various law enforcement officials, and insuring medical exams and treatment. Moreover, state law contained in 21 Okl. Stat. § 845 specifically authorizes legal action for protection of abused or neglected children. The requirement of "prompt notification" was codified previously in Section 846. These statutes, as well as the above written policy, pertain to any child from birth through eighteen (18) years of age.

As evidenced by the attached notices, the National Center on Child Abuse, D.H.H.S., has approved grants encompassing four consecutive fiscal years for Oklahoma's Child Abuse and Neglect (Disabled Infants)/ Infant Care Review Committee Project. (See copies designated Attachment

January 19, 1989  
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4). Considerable time, expense and effort was devoted to the application process as well as operation of the program. Suffice it to say that the State of Oklahoma and this agency considers the program and its purpose to be of major importance.

There have been four (4) cases which were reported as suspected medical neglect and withholding medical treatment. All four cases were investigated by the appropriate authority. Written reports with recommendations were provided to the district attorney for review. Each case was additionally reviewed by the Infant Care Review Committee at Children's Hospital of Oklahoma. However, DHS made the decision as to referral to the district attorney.

In three (3) of the reported cases, the district attorney filed petitions seeking an emergency order for consent to necessary medical treatment and/or placement of custody with Child Protective Services for the purpose of consenting to necessary medical treatment. In all three (3) cases, hearings were held before a Judge. The Court granted the motions with treatment ultimately provided.

Of those three (3) cases, two (2) have since been dismissed and closed and the other remains open with the child a ward of the court. None of the children have died in these three (3) cases.

Records of the fourth case were not received in the state office (from the county DHS office) at the time of the informal phone contact with Ms. Stell in late July, 1988. The allegations contained in the Commission report are incorrect. Indeed, this agency is unable to determine the source of these unfounded allegations. If the Commission desires further verification, please inform this agency of the sources of the information, dates, names and other necessary data such as hospital, physicians/nurses involved, and case numbers.

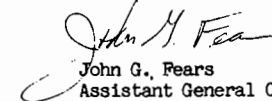
In summary, this agency respectfully disagrees with the Commission's initial report findings. Despite the fact that the report was promulgated based upon incomplete and inaccurate information, this agency feels confident that the Commission will revise its findings accordingly, and consider the Oklahoma Department of Human Services in full compliance with all relevant federal laws, rules, regulations and guidelines.

It is the genuine hope of this agency that the Commission can devote its time and resources to other equally compelling and urgent civil rights matters affecting human dignity such as discrimination based upon race, ethnicity, and sex. These problems have proliferated dangerously in the past several years. This agency is equally committed to aggressively eliminating all vestiges of civil rights discrimination, and will endeavor to vigorously protect the personal rights and freedoms of our clients. Your interest and concern is appreciated, and we trust that this matter is resolved to your satisfaction.

January 19, 1989  
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With regard to future communications on this subject or other significant areas of concern, please direct written inquiries to the Office of General Counsel at the letterhead address. This will avoid future misunderstandings, delay and expense to all concerned.

Respectfully submitted,  
Charles Lee Waters  
General Counsel

  
John G. Fears  
Assistant General Counsel

JGF:la

Enclosures

[Editor's Note: The attachments to this letter are available from the Office of General Counsel, U.S. Commission on Civil Rights, Washington, D.C. 20425. The attachments are:

1. Memorandum, Jan. 2, 1985, from Robert Fulton, on New Draft Federal Regulations on "Baby Doe" Legislation
2. Letter to Hospital Administrators, Aug. 23, 1985, on requirement to name individual to report medical neglect of disabled infants.
3. Rules on Reports of Abuse in Out-of-Home Care, 12/12/88
4. Grant award forms from National Center on Child Abuse for 1985-86, 1986-87, 1987-88, and 1988-89
5. Regulations on Child Abuse/Neglect/Intake/Legal Process issued 10-1-84, secs. 620-624.42
6. Regulations on Oklahoma Children's Memorial Hospital issued 7-15-79, secs. 670-675
7. Regulations on Division of Child Welfare issued 8-3-79, secs. 680-685.5
8. Regulations on Documentation of Service Delivery issued 6-15-79, secs. 690-697.2]



COMMISSION  
FOR HUMAN SERVICES  
Burns Hargis, Chairman

State of Oklahoma  
**Department of Human Services**

Sequoyah Memorial Office Building  
P.O. Box 25352  
Oklahoma City, Okla. 73125

August 10, 1989



DIRECTOR  
OF HUMAN SERVICES  
Phil Watson

Reply to  
the attention of:

Mr. Vincent Mulloy  
Office of General Counsel  
U.S. Commission on Civil Rights  
1121 Vermont Ave., N.W.  
Washington, D.C. 20425

RE: Request for Clarification of January 19, 1989  
Correspondence from Department of Human Services  
Office of General Counsel

Dear Mr. Mulloy,

I have personally reviewed detailed documentation relating to the four cases in which Oklahoma Youth Services personnel investigated alleged medical neglect. Additionally, I interviewed Ms. Diane Stell concerning any conversations she may have had with representatives of your office in 1988.

All four cases reported in my correspondence of January 19, 1989, were correctly recorded and verified, in each case, by treating physicians, the ICRC of the respective hospital, an independent physician not involved in the patient's care, Youth Services investigative personnel and their supervisors, district attorneys, judges in the counties in question, and of course, the State Office of DHS.

Ms. Stell presented the log with information of the referrals for my review. Although she was under the assumption that her phone conversations in 1988 were with federal HHS employees, she stated that it is possible that an employee of the Commission contacted her. However, she is adamant that the information she provided by phone was read directly from the log. Finally, the information I provided in January, 1989 corresponds to the original entries on the log. Indeed, Ms. Stell's statements to me yesterday are identical to statements she made to me in January.

The Commission's rough draft was, in fact, inaccurate. The only conceivable explanation is that the Commission's representative incorrectly recorded Ms. Stell's statements. Of course, one of the cases was not recorded on the log until after the telephone conversations with Ms. Stell. I reported that case, however, in my January

Mr. Vincent Mulloy  
Office of General Counsel  
U.S. Commission on Civil Rights

Page 2  
August 10, 1989

correspondence. In any event, it is highly questionable that the representative failed to request in writing similar verification from Ms. Stell in 1988 immediately following the phone conversations.

Because of applicable statutes, regulations and policy, no identifying information can be provided without written consent of the parties. Investigations indicated that the parents in those cases were refusing to consent to treatment protocols. All four cases were referred to the appropriate district attorney pursuant to state law and agency and hospital policies. In three of the cases, the district attorney sought and obtained court orders granting DHS custody for purposes of consenting to treatment. In those three cases DHS obtained the appropriate treatment, and all three children are alive although severely handicapped.

In the fourth case, the district attorney required further investigation and advice of medical experts. It was determined by an independent physician (who was ultimately in agreement with the treating physician and ICRC) that the infant's condition was inoperable. The infant had already undergone two extensive exploratory operations. The treating physician determined that there was no known cure or surgical procedure available. Separate inquiries by the independent physician and ICRC both determined that there were no known survivors in medical literature with the degree of dysfunction observed and documented in the infant. Further, death was imminent regardless of any treatment protocol that might be chosen. It was also evident that further surgical intervention would have resulted in a slower, painful, more agonizing death.

The district attorney, based upon the above investigative findings, declined to pursue legal action, civil or criminal, against the parents or physician. Although the anonymous complaint was initially made against the treating physician, the investigators, independent physicians, ICRC, and parents were unanimous in stating that the treating physician did not neglect or withhold treatment. To the contrary, the treating physician and parents each stated that the physician fully explained all treatment protocols, the diagnosis and prognosis, and advised them to seek a second opinion. The medical records and laboratory tests supported the opinion of the physician.

The parents refused to consent to additional surgical intervention. Their final stated decision and written consent was to make their infant as painfree and comfortable as possible. Pain medication was prescribed and administered. The physician also prescribed, and



the hospital administered, nutrition and hydration intravenously. This case arose prior to current federal law but would clearly have met all of the three exceptions to mandatory treatment outlined in 45 C.F.R. § 1340.15.

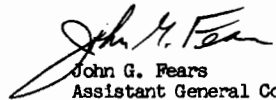
REQUEST TO THE COMMISSION

The verified records of these four cases demonstrate conclusively that the Commission's rough draft was in error. Since publication of inaccurate data would be quite embarrassing to individual Commission members, the State of Oklahoma requests that the final report be corrected prior to printing. In addition, correspondence (with all attachments) including the responses to Mr. Howard dated January 19, 1989, and April 24, 1989, this response to Mr. Mulloy, and the Order granting defendants' Summary Judgment in Johnson, et al v. Sullivan, et al (a copy is attached hereto), should be attached in full to the final report. Finally, please forward a printed copy of the report to the undersigned with appropriate billing.

Because the State of Oklahoma and Department of Human Services are complying fully with the exemplary provisions of the Child Abuse and Treatment Act, 42 U.S.C. § 5101 et seq., Section 4(b)(2)(k) of the Child Abuse Amendment of 1984, and 45 C.F.R. § 1340.15, the General Counsel requests that any other alleged medical neglect, or allegations of failure to investigate properly medical neglect, known to the Commission, be forwarded to the undersigned. The Commission can be assured that immediate and appropriate investigation and action will be initiated by this office.

Please confirm in writing the receipt of this mailing (including attachments) mailed express this date.

Sincerely,

  
John G. Fears  
Assistant General Counsel

JGF:la

cc: Governor Henry Bellmon

IN THE UNITED STATES DISTRICT COURT FOR THE  
WESTERN DISTRICT OF OKLAHOMA

FILED

JUN 27 1989

ROBERT D. DENING  
CLERK, U. S. DISTRICT COURT  
BY \_\_\_\_\_  
DEPUTY

CARLTON JOHNSON by SHARON JOHNSON, )  
as his next friend, et al., )  
Plaintiffs, )  
v. )  
RICHARD H. GROSS, M.D., in his )  
individual capacity, et al., )  
Defendants. )

No. CIV-85-2434-A

O R D E R

Before the Court in this case is defendants' joint motion for partial summary judgment. Defendants seek partial summary judgment under Fed. R. Civ. P. 56(d) on plaintiffs' claims for injunctive and declaratory relief on the ground that the discriminatory practices of which plaintiffs complain do not represent an ongoing harm, and are incapable of repetition. The defendants against whom only injunctive and declaratory relief is sought also seek dismissal from this action.

Plaintiffs bring this action both on their own behalf and on behalf of all children with myelomeningocele who have been, are, or may in the future be evaluated or treated by the myelomeningocele team or its members at Oklahoma Children's Memorial Hospital (OCMH), and on behalf of their parents and legal guardians. Amended Complaint, p. 6, para. 32. Plaintiffs' allege that defendants, medical service providers and administrators at OCMH, and others, discriminate against infants born with

myelomeningocele by basing treatment decisions on non-medical social and economic criteria, such as the family's economic and intellectual resources, geographic location of their home, and the child's projected intellectual capacity. Plaintiffs allege that the use of such criteria constitutes discrimination in violation of their substantive and procedural due process rights, and rights to equal protection under the Fourteenth Amendment. Causes of action 1-8 of plaintiffs' First Amended Complaint seek declaratory and injunctive relief, as well as monetary damages. These causes of action pray that the Court both declare that defendants have engaged in unlawful conduct and also enjoin defendants from further engaging in such conduct.

(1) Injunctive Relief

A claim for injunctive relief is appropriate only where a plaintiff demonstrates that he faces a risk of continuing harm. Evidence of past injury alone is insufficient to warrant an injunction. Palmer v. City of Chicago, 755 F.2d 560, 572 (7th Cir. 1985); O'Shea v. Littleton, 94 S.Ct. 669, 676 (1974). In addition, to maintain a claim for injunctive relief a plaintiff must show more than a mere speculative or theoretical possibility of future harm. There must be some realistic likelihood that the alleged past harm will be repeated. City of Los Angeles v. Lyons, 103 S.Ct. 1660, 1668-1670 (1983).

The Court finds that plaintiffs have failed to show any more than a speculative possibility of future discriminatory treatment by defendants, either with respect to the named plaintiffs, or with

respect to present and future infants with myelomeningocele who will be evaluated by defendants. Although this case has been pending over three years, and extensive discovery has been conducted, plaintiffs have produced no evidence that defendants have engaged in any selective discriminatory treatment of newborns since 1984. On the contrary, the undisputed evidence submitted by defendants reveals that all newborns under defendants' care since 1984, with the exception of one for whom surgical treatment would have been futile, have received aggressive treatment. See Summary of Defendants' Answers to Interrogatory No. 19, Exhibit 3, Defendants' Motion. This evidence strongly suggests that any unlawful discrimination practiced by defendants has long since ceased. Reasonable jurors could not find that defendants pose a risk of continuing harm to children with myelomeningocele presenting at OCMH. Fed. R. Civ. P. 56(c) mandates the entry of summary judgment, after adequate time for discovery, against a party who has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof. Celotex Corp. v. Catrett, 91 L.Ed.2d 265, (1986); Anderson v. Liberty Lobby, Inc., 106 S.Ct. 2505 (1986).

Plaintiffs' argument in support of their proposition that a factual issue exists as to whether discriminatory medical treatment is ongoing is unpersuasive. Plaintiffs rely on deposition testimony by Cara Madison, Cheparney Camp, and Frieda Smith, relatives of the infant plaintiffs in this case, that, prior to the filing of this action, defendants denied them any real choice as

to treatment of their children. This evidence, however, relates only to defendants' past conduct at the time defendants were evaluating the named plaintiff infants. It does not constitute evidence of any existing or future threat of unlawful conduct for which an injunction might lie.

With respect to the risk of future harm to the named plaintiffs in this case, both Melissa Camp and Stonewall J. Smith are deceased. Injunctive relief as to them is therefore clearly inappropriate. Carlton Johnson, however, is surviving and remains an outpatient at OCMH. Although Carlton Johnson has been under defendants' care since his birth in September 1982, plaintiffs have produced no evidence of discriminatory medical treatment of him since October, 1982. Plaintiffs' evidence of a continuing threat of harm to Carlton Johnson consists entirely of unsubstantiated and inadmissible statements of opinion, not based on personal knowledge, by Sharon Johnson, Carlton Johnson's mother. Plaintiffs' Response Brief, p. 10-11. Such statements are not competent evidence for resisting summary judgment on defendants' claims for injunctive relief. Based on the evidence before the Court, reasonable jurors could not find that Carlton Johnson presently faces a realistic likelihood of future discriminatory treatment by defendants.

(2) Declaratory Relief

Having resolved the injunctive relief issue, we now turn to plaintiffs' claims for declaratory relief. The Declaratory Judgment Act is enabling act, which confers a discretion on the

court, rather than an absolute right on the litigant. Green v. Mansour, 88 L.Ed.2d 371, 379 (1985); Public Service Comm. v. Wycoff Co., 73 S.Ct. 236, 239 (1952).

The Court in its discretion declines jurisdiction over plaintiffs' declaratory relief claims for several reasons. First, declaratory relief is appropriate only where the facts show "a substantial controversy . . . of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Maryland Casualty Co. v. Pacific Coal & Oil Co., 85 L.Ed. 826, 829 (1941). As seen above in our discussion of injunctive relief, plaintiffs have failed to show that their controversy retains a quality of immediacy due to an imminent threat of harm.

Second, the declaratory judgment remedy is ordinarily limited to cases where the rights to be protected have not yet been invaded, or where the wrongs to be prevented not yet committed to the extent of actionable damage. Where the wrongful acts complained of have already been committed and the cause of action already exists, declaratory relief will not lie. 26 C.J.S. Declaratory Judgments §17 (1956); Cincinnati Shoe Mfg. Co. v. Vigorith, 212 F.2d 583 (6th Cir. 1954). Plaintiffs in this case are complaining that their rights have already been violated by wrongful acts already committed by defendants.

Third, a declaratory judgment proceeding is primarily intended to construe the meaning of a law, not to determine the existence of controverted facts. A court should ordinarily refuse a declaratory judgment which can be made only after a judicial

investigation of disputed facts. United Mine Workers of America v. Roncco, 314 F.2d 186 (10th Cir. 1963), on remand, 232 F.Supp. 865 (D. Wyo. 1964); Allstate Ins. Co. v. Philip Leasing Co., 214 F.Supp. 273, 276 (W.D. So. Dakota 1963). The present case will turn largely on questions of fact to be resolved at trial. A crucial fact question is whether defendants in fact applied discriminatory criteria in selecting infants for beneficial treatment. Such fact questions make declaratory relief inappropriate in this case.

Finally, the declaratory judgment remedy is ordinarily not appropriate where another equally or more important remedy is already available for the issues or rights sought to be determined or declared. Employers' Liability Assurance Corp. v. Mitchell, 211 F.2d 441, 443 (5th Cir. 1954). This is particularly so where the case is already ripe for relief by such remedy. Dresser Industries, Inc. v. Insurance Co. of No. America, 358 F.Supp. 327, 330 (N.D. Tex 1973), aff'd, 475 F.2d 1402 (5th Cir. 1973). Plaintiffs have a fully adequate remedy for their alleged wrongs in their claim for monetary damages. The existence of this remedy makes declaratory relief unnecessary in this case.

#### Conclusion

For the above stated reasons, defendants are hereby granted summary judgment on plaintiffs' claims for injunctive and declaratory relief. Fed. R. Civ. P. 56(d). Consequently, those defendants against whom only injunctive or declaratory is sought, defendants Reginald Barnes, William Barnes, Chandler, Coussons,

Doenitz, Eaton, Farhas, Furr, Greer, Hargis, Harris, Hartley, Kidd, Orr, Padilla, Stafford, Sullivan, Tatyrek, Toule, Tull, Walters, Watson, Yngve, and Children's Shelter, Inc. are hereby DISMISSED WITH PREJUDICE from this action.

Remaining for trial in this case are plaintiffs' claims for monetary damages against defendants Craig, Gross, Herbeck, Houdesheldt, Livingston, Morris, Olson, Pratt, Razook, Stuenky, and Thompson.

It is so ordered this 27<sup>th</sup> day of June, 1989.

  
WAYNE E. ALLEY  
United States District Judge

*Entered in judgment docket 6-29-89*

Montefiore

Montefiore Medical Center  
111 East 210th Street  
Bronx, New York 10467  
212 920-6736

In association with  
Albert Einstein College of Medicine

Office of Legal Affairs

VIA FEDERAL EXPRESS

November 11, 1988

William J. Howard  
General Counsel  
United States Commission  
on Civil Rights  
1121 Vermont Avenue, N.W.  
Washington, D.C. 20425

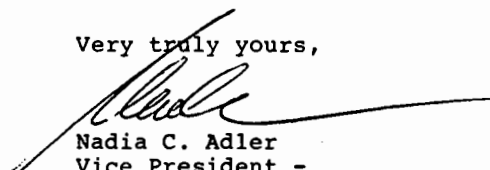
re: Proposed Report on Medical  
Treatment of Handicapped Infants

Dear Mr. Howard:

Enclosed is the response of Montefiore Medical Center to an excerpt from a report being prepared by the United States Commission on Civil Rights on the medical treatment of handicapped infants, which was enclosed with your October 19, 1988 letter to Spencer Foreman, M.D., President of Montefiore Medical Center.

We understand that the enclosed response will be published as an appendix to the report, pursuant to P.L. 87-183 (98th Cong. 1st Sess) (H.R.2230).

Very truly yours,

  
Nadia C. Adler  
Vice President -  
Legal Affairs  
and General Counsel

NCA:bw  
Enc.

cc: Spencer Foreman, M.D.  
Constance Margolin,  
Associate General Counsel

[A:INFANTS/B18]

Henry and Lucy Moses Division  
The Jack D. Weiler Hospital of the  
Albert Einstein College of Medicine  
Beth Abraham Hospital  
Family Health Center  
Loeb Center Skilled Nursing Facility  
Montefiore Home Health Agency

Montefiore Medical Group  
Montefiore Comprehensive Health Care Center  
Montefiore-Rikers Island Health Services  
Valentine Lane Family Practice  
Affiliated with:  
North Central Bronx Hospital  
Nathan Miller Center for Nursing Care, Inc.

RECEIVED  
11-14-88

Response of Montefiore Medical Center  
to Four Typewritten Pages  
Identified as a Portion of  
"Chapter 11, Role and Performance of ICRCs,"  
from a Proposed Report  
by the United States Commission on Civil Rights  
on the Medical Treatment of Handicapped Infants

This statement is submitted by Montefiore Medical Center ("Montefiore") in response to the four-page excerpt from the above-referenced Report, which the United States Commission on Civil Rights (the "Commission") forwarded to Montefiore for review and comment pursuant to the rules and regulations of the Commission (45 C.F.R. Chapter VII).

Although the Commission furnished only a fragment of its Report to Montefiore, it appears that the purpose of the Report is to evaluate compliance by infant care review committees with the Child Abuse Amendments of 1984 (the "Child Abuse Amendments"), which prohibit the withholding or withdrawal of medical treatment from handicapped infants except under certain circumstances.<sup>1</sup>

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<sup>1</sup> 42 U.S.C. §5012. The Child Abuse Amendments define "child abuse and neglect" to include "medical neglect." 42 U.S.C. §5102. The Child Abuse Amendments and the regulations of the Office of Human Development Services of the Department of Health and Human Services ("HHS") thereunder define "medical neglect" as the "withholding of medically indicated treatment," which, in turn, is defined in the statute and the regulations as "the failure to respond to the infant's life-threatening conditions by providing treatment (including appropriate nutrition, hydration and medication) which, in the treating physician's or physicians' reasonable medical judgment, will be most likely to be effective in ameliorating or correcting all such conditions," with certain express exceptions discussed in detail at pp. 6-8, *infra*. (42 U.S.C. §5102; and 45 C.F.R. Part 1340 and Appendix thereto.)

The excerpt provided to Montefiore focuses on the infant bio-ethical review committee of Montefiore and the Albert Einstein College of Medicine (the "Einstein-Montefiore Committee"), and proposes to conclude (p. 4) that Committee has "not been attempting to apply" the standards established under the Child Abuse Amendments.

Montefiore takes strong exception to the conclusions asserted in the Report. These conclusions are inaccurate, unfair and have no basis in fact or law. Montefiore is proud of the members of its infant bioethical review committee -- respected and dedicated professionals who have devoted many anguished hours of thoughtful and difficult work to ensure that no disabled infant is denied medically indicated treatment.

The Einstein-Montefiore Committee was established in 1984 as a set of interlocking committees, one for each of Montefiore's hospital divisions and one for each of the two other hospitals affiliated with the Albert Einstein College of Medicine and Montefiore. A core group of experts, consisting of a neonatologist, three other pediatricians with expertise in neonatology, disabilities and rehabilitative medicine; and bioethicists, with an attorney acting as a consultant to the group, serve on each hospital's committee. The individual hospitals appoint nursing, social work, administrative and community representatives to their respective committees.



The Chairman of the Einstein-Montefiore Committee is Alan Fleischman, M.D., Director, Division of Neonatology and Professor of Pediatrics at Albert Einstein College of Medicine and Montefiore Medical Center. Dr. Fleischman is an eminent bioethicist and neonatologist who is actively involved in many organizations dedicated to the care and rights of disabled infants, including the National Bioethics Committee of the American Academy of Pediatrics; the New York State Task Force on Life and the Law; New York Neonatal Technical Advisory Group (to the New York State Department of Health); the National Advisory Committee, Project Bridge (U.S. Department of Education grant for educating pediatricians about decision-making for disabled infants); and as Chairman for Chapter Grants, March of Dimes. He is the author or co-author of approximately 130 book chapters, articles and abstracts pertaining to neonatology and the care and treatment of disabled infants.

The Einstein-Montefiore Committee chaired by Dr. Fleischman has established a uniform set of principles to guide its members in their deliberations. The principles are intended to assist the Committee members in applying the Child Abuse Amendments to the cases under review. Thus, the principles include explicit statements affirming the intrinsic dignity and worth of every newborn, and provide that all infants, irrespective of disability or handicap, be offered "humane care and appropriate treatment." (See Fleischman, Bioethical Review Committees in Perinatology, 14 Clinics in Perinatology 379 (1987) ("Fleischman"), 384.

In addition, even though mandatory prospective review is not required by federal law, the Einstein-Montefiore Committee has a stated policy of prior review of all cases in which it is proposed that medical treatment be withheld or withdrawn from an infant who is not imminently dying. The Committee's voluntary policy of prospective review clearly adds to the burden of the Committee members, at times requiring Committee members to meet on an emergency basis to consider the needs of a particular infant, but the Committee members view such prospective review as an integral part of their duty to protect disabled infants from denials of medically indicated treatment. It is clear both from the Committee's principles and from its operational procedures that it is dedicated to protecting disabled infants from denial of medically indicated treatment.

It is also clear from the records of Montefiore's Division of Neonatology that not just the Committee, but the neonatology service as a whole, is dedicated to providing medically indicated treatment to disabled infants, and routinely provides that care. In each case, the determinant for treatment is whether, in the reasonable medical judgment of the treating physician, a treatment is available that can ameliorate or correct a life-threatening condition within the meaning of the Child Abuse Amendments. (See pp. 9-10, infra.)

Accordingly, the Office of the Inspector General ("OIG"), the HHS office responsible for auditing compliance with HHS statutes and regulations, has been favorably impressed by the practice and

procedures of the neonatologists and the Einstein-Montefiore Committee. In its 1987 study of infant care review committees under the Child Abuse Amendments, OIG singled out the Einstein-Montefiore Committee from among the ten committees reviewed by it nationally, describing the Einstein-Montefiore Committee in some detail, and concluding that it is "generally structured and functioning in conformance with the HHS model guidelines, and may serve as a useful reference for hospitals considering the establishment of similar committees."<sup>2</sup> OIG reached this conclusion based on a full-day on-site visit to Montefiore, in which OIG staff conducted case reviews and interviewed Committee members to get an in-depth understanding of the Committee's work.

By contrast, it appears that the sole source of information relied upon by the Commission to criticize the Einstein-Montefiore Committee is the article written by Dr. Fleischman on infant bioethical review committees, referred to above. Dr. Fleischman's article, however, does not comprise an exhaustive review and report on the work of the Einstein-Montefiore Committee, and a reading of the article cannot substitute for a thorough examination of the Committee's work. In fact, the sole portion of the article discussing in any way the particulars of cases reviewed by the Committee provides only the most cursory summary of eight of the thirty cases reviewed by the Committee in its early years,

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<sup>2</sup>Office of Inspector General, U.S. Dept. of Health and Human Services, Infant Care Review Committees Under the Baby Doe Program (1987), 11.

in a discussion less than one page in length (Fleischman, 388-389).<sup>3</sup>

Distilled to essentials, the excerpt from the Commission's Report suggests that the Einstein-Montefiore Committee fails to adhere to the Child Abuse Amendments because, as stated in Dr. Fleischman's article, it has permitted treatment to be withheld in some cases. However, the Child Abuse Amendments do not make it unlawful to withhold or withdraw treatment, but only to withhold or withdraw medically indicated treatment. The sheer fact of a denial of treatment in any given case is without legal significance. No inference, much less conclusion, of illegality can be drawn from a denial alone. A finding of illegality must turn on the detailed facts of each individual case, to determine whether the treatment was medically indicated, including whether the denial failed to fit within explicit regulatory provisions permitting treatment to be withheld or withdrawn.

The Child Abuse Amendments and the federal regulations promulgated thereunder explicitly authorize the withholding or withdrawal of treatment under the following circumstances:

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<sup>3</sup>It should be noted that Dr. Fleischman's article, which was not intended to be a comprehensive exposition of the Committee's work, provided minimal information about the cases discussed in order to preserve the confidentiality of patient information.

"when, in treating physician's or physicians' reasonable medical judgment, (A) the infant is chronically and irreversibly comatose; (B) the provision of such treatment would (i) merely prolong dying, (ii) not be effective in ameliorating or correcting all of the infant's life-threatening conditions, or (iii) otherwise be futile in terms of the survival of the infant' or (C) the provision of such treatment would be virtually futile in terms of the survival of the infant and the treatment itself under such circumstances would be inhumane." (42 U.S.C. §5102(2)(B)(3), 45 C.F.R. §1340.15(b)(2).)

To provide guidance to health care providers as to when the Child Abuse Amendments permit the withholding of treatment, HHS issued guidelines which state, inter alia, that the phrase "the treatment itself under such circumstances would be inhumane" in subsection (C) means that "the treatment itself involves significant medical contraindications and/or significant pain and suffering for the infant that clearly outweighs the very slight potential benefit of the treatment for an infant highly unlikely to survive." (45 C.F.R. §1340.15, Appendix, p. 222.)

The Child Abuse Amendments and the regulations thereunder expressly defer to the "treating physician's (or physicians') reasonable medical judgment" to determine what treatment "will be most likely to be effective in ameliorating or correcting all [of the infant's] life-threatening conditions" or whether other

circumstances exist to permit a withholding of treatment under one of the statutory exceptions. (42 U.S.C. §5102; 45 C.F.R. Part 1340, Appendix, p. 217.) In other words, Congress and HHS have made clear that the determination as to what, if any, treatment is medically indicated, is to be left to the professional judgment of the treating physician(s). Given that medical judgments are key to decision-making under the Child Abuse Amendments, it cannot responsibly be suggested that the Committee has violated the Child Abuse Amendments, simply on the superficial observation that medical treatment has been withheld.

Dr. Fleischman's comments on the Committee's decision-making process, cited by the Commission on the second page of the Report excerpt, are entirely consistent with the Child Abuse Amendments, which make medical judgments the key to the propriety of treatment decisions. (45 C.F.R. Part 1340, Appendix.) In discussing the categories of decisions that arise, Dr. Fleischman, as an expert neonatologist, merely observes that in some instances -- in the "grey area" cases -- reasonable medical judgments may differ concerning which of the judgments as to treatment and the infant's condition best protect the infant (e.g., whether the infant should be treated when there are conflicting medical judgments as to the effectiveness of the treatment to ameliorate or correct the life-threatening condition, or when there are reasonable differences among the treating physicians as to whether the very slight benefit to the infant will be outweighed by the pain and suffering that the treatment will bring to the infant). In such

cases, the Committee has not abdicated its role. Rather, in the exercise of its duties the Committee has determined that, based on reasonable medical judgment, selection of any of the treatment options (including the option not to treat) would be a reasonable exercise of medical judgment, and not "medical neglect." That threshold determination having been made, the Committee then permits the parents (or Child Protective Services Agency, as appropriate) to decide among the available options in the infant's best interests.

The Report excerpt itself implicitly recognizes that the mere withholding of treatment does not demonstrate or even raise a question of illegality, when it seeks to justify its proposed conclusions by reference to "context." The context to which the Report excerpt refers is the thirty cases that the Committee reviewed in its early years, noted in Dr. Fleischman's article (pp. 388-389) in only the most superficial and summary fashion. We submit that this is not the appropriate context. The proper context, which the Report excerpt ignores, must be the full details of the treatment provided to (or withheld from) all disabled infants at the hospitals served by the Committee, and not just the treatment provided in the cases coming before the Committee.

Montefiore is a tertiary care institution which provides highly technical treatment and supportive care for about 1,200 infants annually in its affiliated neonatal intensive care units. It is

a place to which extremely ill and disabled infants are brought expressly because of the technologically advanced, quality care that is offered to them. For example, on a weekly, if not daily, basis the Einstein-Montefiore staff assumes that medical and/or surgical treatment is appropriate, and thus regularly provides that treatment in the following categories of cases: (i) to infants suffering from genetic abnormalities (Down's Syndrome and other similar disorders), who are given respiratory support or receive surgery for congenital bowel and/or heart abnormalities (4-6 such infants per year); (ii) to premature infants with severe intraventricular hemorrhage (almost certain to develop cerebral palsy and mental retardation), who are treated medically and surgically for respirator dependence or necrotizing enterocolitis; and (iii) to infants who are born with multiple congenital abnormalities, such as encephaloceoles, myelomeningoceoles, gastroschisis, spinal deformities, or gastrointestinal, renal or cardiac disorders, whose life-threatening abnormalities are aggressively treated and managed by the neonatal service. In most of the cases of infants with potential disabilities, of which there are hundreds each year, there is never an issue for the Committee to consider, because the neonatologists routinely provide medically indicated treatment. Indeed, in a tertiary care center such as Montefiore, where professional expertise and technological capabilities create treatment options not available in other settings, highly specialized life-saving treatment is the routine, and is provided as a matter of course to save the lives of infants with potential disabilities.



It is in this larger context of dedicated care to hundreds of infants with potential disabilities that it is most inappropriate to rely, as the Report excerpt does, on Dr. Fleischman's terse references to three particular cases for criticism of the Einstein-Montefiore Committee. Moreover, even the Commission's discussion of these three cases fails to support the conclusions reached in the Report excerpt.

In the first case discussed in the Report, the Commission notes that the Einstein-Montefiore Committee referred the infant's case to the state child protective services agency because "the attending physician believed treatment should be provided and the parents disagreed." (Report excerpt, p. 2.) The Report implies that the Einstein-Montefiore Committee took a neutral stance and was attempting to evade responsibility. In fact, however, the Committee supported the attending physician, and "the help of the Child Protection Services Agency was invoked to override parental refusal of surgery" -- details clearly stated in Dr. Fleischman's article (p. 389, emphasis added) and omitted from the Report excerpt. Moreover, the Child Abuse Amendments expressly require that such a referral be made, as a procedure for ensuring that medically indicated treatment will be provided to the infant regardless of the parents' wishes. (42 U.S.C. §5103.) The Committee was manifestly acting in complete compliance with the Child Abuse Amendments in making that referral, and the Child Protective Services Agency successfully relied on the Committee's

recommendation for treatment to ask a court to order treatment in the interest of the infant.

With respect to the second case, the Report excerpt accurately states that the Einstein-Montefiore Committee persuaded the treating physician and parents that treatment should be provided even though the treating physician and parents had originally objected to such treatment. Reference to this case hardly supports the Report excerpt's assertion (p. 4) that the Committee operates to "bless denials" of treatment.

Even in the third case, where the treating physicians and the Committee concluded that treatment should not be given despite the parents' wish to have it provided, it cannot be said that the infant was denied medically indicated treatment in violation of the Child Abuse Amendments. On the contrary, surgery simply would not have saved or prolonged the infant's life. As Dr. Fleischman's article plainly states, a retrospective review of the case (the infant was imminently dying and indeed died before the Committee could be convened for prospective review) indicated that the parents' wish to provide treatment would have imposed "undue pain and suffering on an infant for no potential benefit." (Fleischman, p. 389.) The Report, once again, omits this detail. In point of fact, the Child Abuse Amendments, as shown above, permit treatment to be denied when it would "not be effective in ameliorating or correcting all of the infant's life-threatening conditions, or [would] otherwise ... be futile in terms of the

survival of the infant" -- i.e., the circumstances of this particular case. Indeed, even if treatment would be of slight benefit, the Child Abuse Amendments allow treatment to be foregone if "the treatment ... involves ... significant pain and suffering for the infant that clearly outweighs the very slight potential benefit of the treatment for an infant highly unlikely to survive." (45 C.F.R. §1340.15(b)(2).)

After concluding its discussion of the three cases briefly noted in Dr. Fleischman's article, the Report excerpt states (p. 3) that "[I]n all the other cases the Committee agreed with the desire of physicians and parents to withhold treatment," citing Dr. Fleischman's article for this proposition. First, the citation is inaccurate. In fact, the article indicates that in at least two of eight cases involving neonates in the first days of life, the decision to withhold treatment was overridden by the intervention of the Committee, once without the need to secure the aid of the Child Protective Services Agency, and once with such aid where the parents continued to resist treatment notwithstanding the Committee's intervention. (Fleischman 388-389.) As to "all the other cases," the actual comment made by Dr. Fleischman about them is as follows, quoted in full and without ellisions: "In all of the other thirty cases including one in which the help of the Child Protective Services Agency was invoked to override parental refusal of surgery, it is highly likely that the same outcomes would have occurred prior to the existence of our infant bioethical review committee."

(Fleischman, 389.) Moreover, quite apart from the inaccuracy of the citation, the Child Abuse Amendments expressly permit the withholding or withdrawal of medical treatments under certain circumstances, as shown above. The mere fact of withholding or withdrawing treatment does not support the Report's assertion (excerpt, p. 3) that "the Committees are not serving their function."

In addition to its reliance on references to cases only briefly noted by Dr. Fleischman, which reliance is misplaced, the Report seems to find objectionable Dr. Fleischman's discussion of the fact that the Committee's involvement eases the psychological distress of nurses and family members in making agonizing decisions about the rendition of treatment to severely disabled infants. Here, too, the objection is not well taken. This by-product of the Committee's functioning is entirely consistent with lawful and ethical execution of the Committee's duties.

Indeed, the Report excerpt in its last sentence ultimately recognizes that the minimal information before the Commission is insufficient to support any conclusion of illegality, noting that the Commission cannot really determine that any treatment denials violated the Child Abuse Amendments because the Commission does not have the actual facts. (Report excerpt, pp. 3-4.)

Notwithstanding the acknowledged absence of evidence, the Report excerpt (p. 4) startlingly goes on to pronounce that "the

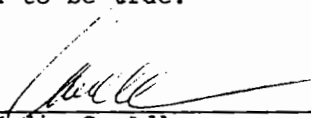
Committees have not been attempting to apply those standards [established by the Child Abuse Amendments]." The basis for this extraordinary conclusion -- which the Report self-servingly declares to be "clear" and "fair" -- is that Dr. Fleischman's article referred to principles that the Committee has found to be helpful in its deliberations and discussions, and that one of these principles is that "[w]ithholding or withdrawing treatment may be considered when the medical treatment imposes a burden that lacks compensating benefits for the infant.'" (Report excerpt, p. 4.) As shown above (pp. 7, 12-13), the Child Abuse Amendments and the regulations and HHS guidelines thereunder clearly permit the weighing of the benefits and burden to the infant to ensure that the Committee protects the disabled infant from "inhumane treatment." The mere fact that the principle permits the Committee to utilize a balancing standard in certain circumstances does not, by itself, constitute a violation of the Child Abuse Amendments. The Commission is not aided in this regard by its speculative assertion -- without any basis in fact -- that the Committee's recommendations are based on other than the criteria set forth in the Child Abuse Amendments and the regulations and HHS guidelines thereunder.

Nor is the Commission able to carry its burden of demonstrating that there have been violations of the Child Abuse Amendments merely by out-of-context quotes from Dr. Fleischman's article, particularly in view of the fact that the Einstein-Montefiore Committee's activities have been carefully examined by the OIG

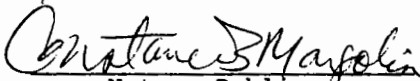
and held up as a model for other infant care review committees. In contrast to the superficial basis for the Report excerpt, OIG personnel spent a full day on-site, interviewing Dr. Fleischman and other members of the core Committee and reviewing cases. OIG staff were also provided with an advance print of the very article by Dr. Fleischman upon which the Commission bases its criticism of the Einstein-Montefiore Committee, but, following its thorough review of the Einstein-Montefiore Committee, OIG reached a far different conclusion from the Commission.

In sum, the Einstein-Montefiore Committee is a first-rank infant care review committee, comprising dedicated, compassionate medical and other professionals devoted to providing infants, including those who are potentially disabled, with high quality, appropriate, humane medical care consistent with applicable law. The proposed conclusions of the Report excerpt are erroneous and unsupportable, and we respectfully urge that they be re-evaluated and withdrawn.

The foregoing statement is made on information and belief, and I believe the matters stated herein to be true.

  
 \_\_\_\_\_  
 Nadia C. Adler  
 Vice President & General Counsel  
 Montefiore Medical Center

Sworn to before me this  
~~11th~~ day of November, 1988

  
 \_\_\_\_\_  
 CONSTANCE B. MANGOLIN  
 Notary Public, State of New York  
 No. 02-4888207  
 Qualified in Westchester County  
 Commission Expires March 9, 1989

BLOOMINGTON OBSTETRICS AND GYNECOLOGY, INC.

WALTER L. OWENS, M.D.  
WILLIAM R. ANDERSON, M.D.  
LELAND R. MATTHEWS, M.D.  
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DWIGHT L. STAUFFER, M.D.  
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September 16, 1988

William J. Howard  
General Council  
United States Commission on Civil Rights  
1121 Vermont Avenue Northwest  
Washington D.C. 20425

Dear Mr. Howard,

Thank you for enclosing portions of the report of the Commission on Civil Rights. The conclusions appear to be out of touch with reality, but much of what goes on in Washington D.C. is out of touch with reality.

This is merely one of the many facets in which medical technology has moved faster than the ability of society to accommodate and to reach a reasonable consensus. Time will tell.

Meanwhile, Baby Doe died with little suffering after a few days. A family which probably would have been destroyed by the situation has not only been preserved, but they have had another very healthy child, which almost certainly would never have been born, had the pediatricians been able to enforce treatment to preserve Baby Doe's life.

My conscience is clear. I am proud to have stood up for what I and a large percentage of people feel was right. I have asked my children to make sure that my grandchildren know of their grandfather's role in this case and that he had the honor of a personal denunciation by Ronald Reagan.

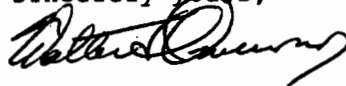
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WILLIAM R. ANDERSON, M.D.  
LELAND R. MATTHEWS, M.D.  
BRANDT L. LUDLOW, M.D.  
DWIGHT L. STAUFFER, M.D.  
ALICE B. WOOD, M.D.  
MADREAN SCHOBBER, R.N.C.  
NURSE PRACTITIONER  
SUELLEN MOYNIHAN  
OFFICE MANAGER

(812) 336-0168  
421 WEST FIRST STREET  
BLOOMINGTON, INDIANA 47401

Meanwhile, I hope that you and the commission members may have the privilege of living in blissful isolation from the hard decisions of real life.

Sincerely yours,



Walter L. Owens, M. D.

WLO/sm

*Suellen T. Moynihan*  
Suellen T. Moynihan

County of residence: Monroe  
Date of expiration: 5/15/92



## The Right to Life

BY GEORGE CRILE, JR., M.D.

THE LAW NOW STATES that in obstetrical units, babies must be fed and given full support, regardless of how extensive and hopeless their congenital malformations.

Despite the law, the debate about the "right to life" continues, involving not only newborn babies but the morality of contraception and abortion, the question of capital punishment, and in patients with damaged brains, the problem of when, if ever, to "pull the plug." These must be viewed not only in the light of the individual's right to life, but in that of society's right for its members to have productive and pleasant lives, not to be lived mainly to support the growing numbers of hopelessly disabled, often unconscious people whose costly existence is consuming so much of the gross national product.

Let's start at the beginning. In the days before vaccination and antibiotics, infectious diseases, like smallpox and diphtheria, killed so many children, and so many more died as young adults of tuberculosis that there was little reason to consider contraception as a means of controlling population. The church opposed birth control and abortion because then there was no threat of overpopulation and it was good to have the members have children to rear in the principles of the church.

In the last 80 years, most of the old rules have changed. Life expectancy in America has increased from 47.3 years in 1900 to 73.3 years in 1980. The population of the world has similarly increased from 1,200,000,000 in 1900, to 4,269,000,000 in 1978. Most of this increase occurred since 1950.

Nature has endowed healthy adults with an inextinguishable sexual desire. Therefore, it seems obvious that the results of sexual activity must be controlled or within a century the exponential growth of the population will result in disaster. Most of the world has recognized this fact and has approved of or even enforced contraception and abortion. Today, in most of China, only one child per couple is allowed. The economic penalties for more (except for twins) are severe. In view of current worldwide trends, there is little need to argue the cause of birth control. Whether we like it or not, it is a fact and, legally or illegally, will continue.

Next in the sequence of disasters is the baby born with incurable defects that make it unable, ever, to support itself or to be anything but a sorrow to its parents and a drain on the economy. I am not referring to defects that can be treated—harelips, spina bifida, or deformities of the extremities, all of which can be corrected or compensated for by surgery. I am concerned about the disposition of those babies who have irreversible brain damage or totally incurable and accurately diagnosable brain defects such as Down's syndrome. No

child with Down's syndrome ever grew up to be self-sustaining. Twenty years ago the diagnosis was a matter of clinical judgment; sometimes it was wrong. Today, the diagnosis is accurate, made on the basis of the chromosomes. As a result, parents can be told that their child has no chance of growing up to be able to take care of itself. If the parents still want to rear their child, that should be their decision, but there should be no support from the community or the state.

I wish to emphasize that I do not believe that existence is necessarily unhappy for the child with Down's nor that such a child cannot be a joy to its parents. That is why the parents should make the final decision.

It remains that a child with Down's syndrome, proven by examination of the chromosomes, will not grow up to be self-sustaining or able to contribute to the economy. Neither the community nor taxpayers should be obliged to support the child.

A different situation exists in respect to babies born with severe brain damage. There is no certain test to show the extent

or reversibility of the damage; therefore a period of observation would be necessary before withdrawal of support could be advised. Several qualified consultants would have to agree before any decision was made. But again, if the decision was to withdraw support, there should be no further obligation for state or community to care for the child. If this were the decision, no medicine would be given the child, no intravenous or artificial feeding.

### The Totally Incompetent

Oldsters, with mental deterioration from stroke or Alzheimer's disease, often become totally incompetent to care for themselves or even to feed themselves. These people do not recognize their friends or relatives and are not aware of their surroundings; to live is merely to ex-

ist. There should be no reason to support life artificially in these cases or of those who have been unconscious for weeks and whose existence is maintained by heart-lung machines. Again, unanimous approval of qualified consultants could result in withdrawal of artificial support.

At the present time, an unsupportably high proportion of all Blue Cross and Medicare funds are spent on a small group of helpless patients who require constant and expensive care. Although there are many ways that the cost of health care could be reduced, one of the simplest would be, in professionally approved cases, to let nature take its course.

*Dr. Crile, Jr., is emeritus consultant and former head, department of general surgery, Cleveland Clinic, Cleveland, Ohio.*

George Crile, Jr., M.D.  
2060 Kent Road  
Cleveland Hts., OH 44106

September 15, 1988

William J. Howard  
US Commission On Civil Rights  
1121 Vermont Avenue  
Suite 800  
Washington, D.C. 20425

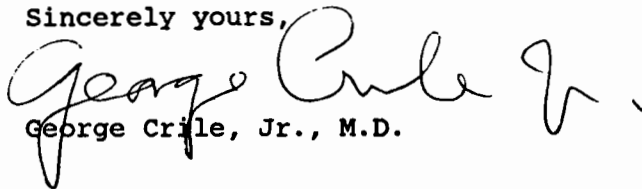
Dear Mr. Howard:

The quotation that was used to indicate that I do not approve of the rehabilitation of disabled persons was lifted out-of-context and for this reason it gives a false impression of my stand. I have never stood against rehabilitation of any one with a brain that was functional or a body that was salvageable. I clearly state in my article that I am referring to people who are hopelessly disabled, and that means disabled to the extent that rehabilitation could not help them to improve or recover. I also state that there is no use in prolonging the lives of those who are unconscious as a result of prolonged coma from which there is no chance of recovery.

If the authors of this treatise do not 1) Omit the out-of-context quotation from my article or 2) Reprint all of my article or 3) Publish this criticism of their out-of-context quote, I will be forced to discuss this misrepresentation with my attorney.

Again, may I emphasize that it is not rehabilitation that I stand against, it is the costly attempts to rehabilitate those for whom there is no hope.

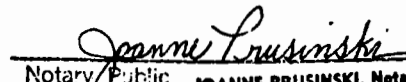
Sincerely yours,

  
George Crile, Jr., M.D.

GC/eg

Sworn to before me and subscribed in  
my presence this 15th day of  
September, 1988. My Commission  
expires \_\_\_\_\_

RECEIVED  
9-19-88

  
Notary Public JOANNE PRUSINSKI, Notary Public  
State of Ohio  
My commission expires Aug. 13, 1993  
Recorded in Cuyahoga County

**Yale New Haven**  
**1826 Hospital**

20 York Street, New Haven, CT 06504

JOHN E. FENN, M.D.  
CHIEF OF STAFF

October 6, 1988

William J. Howard, Esq.  
General Counsel  
United States Commission on Civil Rights  
1121 Vermont Avenue, N.W.  
Washington, D.C. 20425

Dear Mr. Howard:

Thank you for your letter of September 13, 1988.

The allegations you mention about the withholding of treatment to newborns, including references to articles by Dr. Duff written in the 1970s and newspaper stories in the Hartford Courant in 1981, were thoroughly investigated by the Hospital, the U.S. Department of Health and Human Services (HHS), and the Connecticut Department of Health Services, and resolved in favor of the Hospital.

These allegations, moreover, are obviously quite dated. We provide what I believe to be outstanding services to newborns; it is our mission to treat children, not to withhold treatment. It would be unfortunate to rehash these old allegations -- proven not to have substance -- and thereby damage the reputation of the Hospital and its physicians.

It might be helpful to begin by relating to you the history of the investigations.

Beginning in June, 1981, the Hartford Courant ran a series of articles about newborn care. On June 23, 1981, the Connecticut Department of Health Services announced its investigation of the Hospital. On June 24, 1981, former Connecticut State Senator Regina Smith filed a complaint with HHS. On July 27, 1982, the Hospital received a letter from HHS announcing a civil rights compliance review of the Hospital.

The first federal investigators arrived on September 14, 1982. During the

fall of 1982, HHS personnel reviewed over one hundred charts of deaths between January and June, 1981, and March through August, of 1982. They subsequently reviewed 110 charts of babies with specified conditions admitted between October, 1979, and December, 1982. They also conducted extensive interviews with Hospital physicians, nurses, social workers, administrators, and others. On November 10, 1982, the Pediatrics Department Guidelines, which already were in place and which implicitly rejected Dr. Duff's personal views, were adopted by the Board of Trustees as official Hospital policy. In March, 1983, OCR Investigator Peter Chan returned to the Hospital for additional interviews with physicians. On July 21, 1983, Investigator Chan again met with representatives of the Hospital requesting additional information.

On February 1, 1983, the investigation broadened into an investigation of whether or not any of the policies of the Hospital violated Section 504 of the Rehabilitation Act of 1973, as amended. From approximately that time on, the matter was referenced as HHS OCR Compliance Review No. 01-82-7002.

On August 16, 1984, HHS's Office for Civil Rights (OCR) proposed a "Compliance Plan" to finally resolve the entire matter. It was viewed by the government as a "voluntary action plan." During the next several months, details of this settlement were successfully worked out by the government and the Hospital.

On December 5, 1984, Ms. Chang, the OCR Regional Manager, wrote to the Hospital, concluding that during the on-site review, OCR concluded, inter alia, that:

Yale-New Haven Hospital's policies and procedures regarding patient admissions, room assignments and transfers, and the granting of staff privileges were in compliance with Title VI. Contacts with community and advocacy groups did not disclose any allegations of violations; and

YNHH had designated a Section 504 coordinator pursuant to 45 C.F.R. §84.7(a).

OCR also determined several minor problem areas involving, in its view, inadequate notice and grievance policies, and the need for more specific policies with regard to sign language interpreters. YNHH has adopted a Nondiscrimination Plan signed by its Chief of Staff, dated November 19, 1984.

With respect to handicapped infants, Ms. Chang indicated that the matter would not be pursued further because of legal considerations. She

concluded her letter by thanking the Hospital for its cooperation and the assistance rendered to her investigators.

It should be noted that the State investigation also had been resolved in favor of the Hospital. From the beginning of the investigations, the Hospital denied allegations of any wrongdoing, and pointed out that the Pediatric Department had not accepted Dr. Duff's point of view, but had rejected it and adopted its own guidelines.

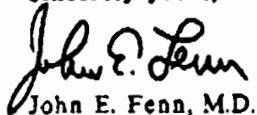
During the course of the investigations, the government and the Hospital spent thousands of hours working on the matter, at a substantial cost to the parties both in terms of manpower and money.

I hope that I have adequately responded to your inquiry. It would be unfortunate if the same stale and fully explored territory were to be revisited after so much time and effort have been devoted to resolving the issues involved, hopefully forever. We are proud of our outstanding newborn special care unit, which over the years has saved thousands of lives. To reopen this matter not only would be unfair and inappropriate, but could damage the reputation of the Hospital and its physicians.

We hope that, based on the information provided in this letter, you will decide not to include any reference to Yale-New Haven Hospital (or any of its physicians or former physicians) in your report or in any other document(s). If, however, such reference is made, we request that this letter also be incorporated in order to provide readers with the full story.

Thank you very much for your consideration of this information.

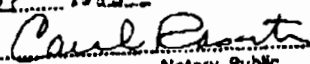
Sincerely yours,

  
John E. Fenn, M.D.

JEF:pm

cc: Mr. C. Thomas Smith



Subscribed and Sworn to before me, a Notary Public, in and for County of Newtown and State of Connecticut, this 7<sup>th</sup> day of October, 1988.  
  
Notary Public

My Commission Expires Mar. 31, 1993



**UNITED STATES  
COMMISSION ON  
CIVIL RIGHTS**

1121 Vermont Avenue, N.W.  
Washington, D.C. 20425

October 7, 1988

John E. Fenn, M.D.  
Chief of Staff  
Yale New Haven Hospital  
20 York Street  
New Haven CT 06504

Dear Dr. Fenn:

Thank you for your letter of October 6, 1988.

It would be very helpful to the Commission, in assessing whether the tentative material to which you responded should be modified, to have copies of four items referenced in your letter.

These are:

The Pediatric Department Guidelines adopted by the hospital Board of Trustees on November 10, 1982.

The "Compliance Plan" proposed by the HHS Office for Civil Rights on August 16, 1984.

The final settlement based on this compliance plan "worked out by the government and the Hospital."

The December 5, 1984 letter from Ms. Chang, OCR Regional Manager.


Finally, does the hospital regard the final settlement referred to in your letter as currently in effect and binding on the hospital? Is the hospital now in fact in compliance with all aspects of the settlement?

To ensure that the final report will fully reflect consideration of this information, it would be helpful if you could supply it as soon as conveniently possible, preferably by October 14, 1988.

The Commission will give very careful consideration to the information contained in your letter and to the material you send in response to this request in determining whether and in what manner to modify the text on which you have commented

Thank you very much for your cooperation in this matter.

Sincerely,



WILLIAM J. HOWARD  
General Counsel

**Yale New Haven**  
**1826 Hospital**

20 York Street, New Haven, CT 06504

JOHN E. FENN, M.D.  
CHIEF OF STAFF

October 18, 1988

William J. Howard, Esq.  
General Counsel  
United States Commission on Civil Rights  
1121 Vermont Avenue, N.W.  
Washington, D.C. 20424

Dear Mr. Howard:

This is in response to your letter of October 7, 1988, and in supplement to my letter to you of October 6, 1988.

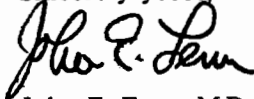
First, as previously indicated, all of the matters at issue have been resolved in favor of the Hospital. We respectfully repeat our request that no reference to the Hospital or its physicians be made in your report or in any other document, and that, if such reference is made, my letter of October 6, 1988, and this letter, be incorporated into the report or other document in order to provide readers with the full story.

I enclose copies of the four documents requested in your letter of October 7, 1988.

In answer to your question, the Hospital continues to exercise its best effort to be in compliance with all requirements of law and its final settlement agreement.

Finally, I emphasize that to reopen a matter which has been explored fully and resolved to the satisfaction of the Hospital, the Connecticut Department of Health Services, and the U.S. Department of Health and Human Services, could serve only to damage the reputation of the Hospital and its physicians and could impede our ability to continue in the provision of outstanding service to newborns. As previously indicated, it is our mission to treat children, not to withhold treatment.

Sincerely yours,



John E. Fenn, M.D.

JEF:pm  
Enclosures

cc: C. Thomas Smith





**GUIDELINES FOR DECIDING  
CARE OF CRITICALLY ILL PATIENTS**

These guidelines are designed to provide direction in the management of critically ill children at Yale-New Haven Hospital. They will be made available to all members of the medical, nursing, and social work staffs.

They are predicated on the assumption that every child treated in this hospital will have maximal efforts utilized to maintain life and health, except in those unusual circumstances where such effort is not indicated or justified. They are also predicated on the assumption that everyone caring for sick children in this institution is well aware that "active euthanasia," any active intervention which will inevitably result in the death of a patient, is illegal, contrary to medical ethics, and intolerable.

The Attending Physician and the parents have the primary responsibility for making decisions about the care of a child. Various other care providers and family counsellors can, and should, contribute to these decisions when appropriate, but the final authority rests with the Attending Physician and the parents to formulate and implement management. Any concerned person involved in the care of the child who disagrees with that decision may appeal to the Chief of the Department of Pediatrics who will attempt to resolve the differences of opinion.

To clearly define patient care, three categories of clinical management have been established:

**Class A:** Maximal therapeutic effort with no reservations.

This group will include most children in Yale-New Haven Hospital, including patients for whom there are significant uncertainties about diagnosis or prognosis. All patients will be assigned to this category unless specified otherwise. For patients in this category, all available efforts will be extended to preserve life and to restore the patient to health.

**Class B:** Selective limitation of therapeutic measures.

For patients in this category, all usual components of therapy will be employed but heroic, extensive, and highly sophisticated measures to prolong life will be withheld because the ultimate prospects for recovery are negligible.

The clearest example of a patient in this category is the decision not to perform extensive resuscitation in a terminal situation (i.e. a child with end stage leukemia refractory to therapy who may have respiratory arrest may be assigned to Class B - do not resuscitate). However, should the child's parents not agree to this decision, classification would still be A.

**Class C:** Discontinuance of life sustaining therapy.

Patients are assigned to this category whose continued survival is wholly dependent on highly sophisticated life support systems. Dying patients with negligible prospect of recovery and patients with brain death are usual instances of where this classification would be employed. However, should the child's parents not agree to this decision, classification would still be A or B.

It is the responsibility of the Attending Physician to note clearly in the chart the assignment of a child to Class B or C. Houseofficers do not have the authority

to write a classification B or C note, although in emergency situations, if a child shows unexpected improvement, a houseofficer does have the authority to revoke orders not to resuscitate. The Attending Physician's classification note should give the base for the decision in some detail. The concurrence of the parents should also be noted.

The Chief of Pediatrics or the Directors of the Intensive Care Units should be informed as appropriate of all patients classified in Group C.

In cases where the Attending Physician is of the opinion that a decision made by the parents will adversely affect the interests of the child, the Chairman of the Department will be notified. If he concurs, recourse will be had to the courts.

Approved by the Board of Trustees at its meeting of  
November 17, 1982

EXHIBIT 1

NONDISCRIMINATION GRIEVANCE PROCEDURE

It is the policy of YNHH to comply voluntarily with Section 504 of the Rehabilitation Act of 1973, Title VI of the Civil Rights Act of 1964, and HHS regulations pertaining thereto. The Yale-New Haven Hospital therefore has adopted this internal grievance procedure to provide prompt and equitable resolution of complaints alleging any claim of unlawful discrimination.

The following rules apply to complaints filed under this procedure:

1. A complaint shall be in writing, contain the name and address of the person filing it, and briefly describe the action alleged to be discriminatory.
2. A complaint shall be filed in the office of the Hospital's coordinator, Richard Burford, within a reasonable time after the person filing the complaint becomes aware of the action alleged to be discriminatory.
3. The Hospital shall conduct such investigation of a complaint as may be appropriate to determine its validity. These rules contemplate informal

but thorough investigations, affording all interested persons and their representatives, if any, an opportunity to submit evidence relevant to a complaint.

4. The Hospital shall issue a written decision determining the validity of the complaint no later than 30 days after its filing.
5. The Hospital shall maintain the files and records relating to complaints filed hereunder. Mr. Burford may assist persons with the preparation and filing of complaints, participate in the investigation of complaints, and advise the Hospital concerning their resolution.
6. The right of a person to prompt and equitable resolution of a complaint filed hereunder shall not be impaired by the person's pursuit of other remedies, and utilization of this grievance procedure is not a prerequisite to the pursuit of other remedies. A person may at any time file a complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, Room 2403, John F. Kennedy Federal Building, Boston, Massachusetts 02203, Tel. (617) 223-0247, TTY (617) 223-4000.

7. These rules shall be liberally construed to protect the substantial rights of interested persons and to assure compliance by the Hospital with Federal statutes and regulations prohibiting unlawful discrimination.

NONDISCRIMINATION NOTICE

It is the policy of Yale-New Haven Hospital to comply voluntarily with Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, as amended, and the Age Discrimination Act of 1973, as amended, and the U. S. Department of Health and Human Services regulations (45 C.F.R. Parts 80, 84, and 91, respectively) pertaining thereto.

Yale-New Haven Hospital does not, on the basis of race, color, national origin, handicap, or age, unlawfully discriminate in admission or access to, or treatment or employment in, its programs or activities that receive Federal financial assistance.

For further information about this policy and Yale-New Haven Hospital's grievance procedure for resolution of complaints, contact Richard B. Burford, Assistant Administrator, 20 York Street, New Haven, Connecticut 06510, Telephone (203) 785-2600.

YALE-NEW HAVEN HOSPITAL (YNHH)

NONDISCRIMINATION PLAN

1. It is the policy of YNHH to comply voluntarily with Section 504 of the Rehabilitation Act of 1973, Title VI of the Civil Rights Act of 1964, and regulations of the U. S. Department of Health and Human Services pertaining thereto.

2. The grievance procedure attached as Exhibit 1 to this Plan will be furnished to each person who files, or inquires about filing, a complaint alleging any unlawful discrimination.

3. YNHH will continue to include nondiscrimination notices in its publications including employee handbooks, recruitment materials, public information booklets, etc. These will be revised in the form annexed hereto. Such notices also shall be prominently posted and maintained in appropriate YNHH administrative offices and service locations and furnished to any unions or professional organizations engaged in bargaining or having contractual relationships with YNHH.

4. YNHH will provide appropriate auxiliary aids to hearing impaired persons where necessary to afford such persons an equal opportunity to benefit from the service in question. Currently, YNHH's auxiliary aids for the hearing impaired

include flash cards, use of paper, pencil and clipboard, telephone amplification devices, and sign language interpreters deemed qualified by the Connecticut Commission for the Deaf. YNHH will not require a patient to provide or pay for the services of a sign language interpreter. YNHH will continue to provide to its nursing and clerical staffs appropriate courses in basic sign language skills. YNHH will not rely on family members or friends of hearing impaired patients to serve as sign language interpreters except where a patient expressly requests such an arrangement. YNHH has installed a telecommunication device for the deaf (TTY) which is located at the Emergency Room control desk. All clerical staff members are trained in the use of the TTY and it is accessible 24 hours a day. YNHH will utilize sign language interpreters and its TTY, as appropriate, to provide effective notice to hearing impaired persons concerning benefits, services, waivers of rights, or consent to treatment.

5. YNHH will provide appropriate auxiliary aids to visually impaired persons where necessary to afford such persons an equal opportunity to benefit from the service in question. Currently, YNHH's auxiliary aids include the provision of readers at no cost to the patient. YNHH has a policy which allows guide dogs access to all areas of the hospital that are open to the general public and for employees



to use them in areas appropriate to perform their duties. YNHH is prepared to draw upon a full range of communication options (auxiliary aids) in order to ensure that visually impaired persons are provided with effective access to health care services. To this end, YNHH will develop the use of taped or braille materials where appropriate.

6. YNHH's Section 504 Coordinator and Patient Representative will be responsible for informing all staff in patient contact positions in regard to these policies and procedures and the availability of auxiliary aids.

Yale-New Haven Hospital

November 19, 1984  
Date

John E. Lunn, MD  
Its President/Chief of Staff



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office for  
Civil Rights

Region 1  
Room 2403  
John F. Kennedy Federal Bldg.  
Government Center  
Boston, MA 02203

August 16, 1984

J. Michael Eisner, Esquire  
Wiggin & Dana  
Counsellors at Law  
195 Church Street  
P.O. Box 1832  
New Haven, Connecticut 06508

Re: Compliance Review No. 01-82-7002

*Michael*  
Dear Mr. Eisner:

Pursuant to our recent telephone conversation, I am enclosing for your review and consideration a proposed "Compliance Plan" which would enable the Office for Civil Rights (OCR) to close the above-referenced review.

Please note that I am flexible as to the format of this Plan. For example, it may be labelled as "Voluntary Action Plan." Or, it may be in the form of a letter from President Smith, or Dr. Fenn, or from you as counselor for Yale-New Haven Hospital (YNHH), incorporating the substance of the Plan. In regards to the auxiliary aid areas, YNHH may already have most, if not all of the requirements in place; if so, you may rewrite or modify that section or attach YNHH documents.

Assuming we have general agreements on the substance of the Plan and OCR receives the written commitment from YNHH, we will issue a letter of compliance. This letter will contain the following elements: Specifically, we will find YNHH, at the time of the review, compliance with the following issues: patient admissions, room assignments and transfers, and the granting of staff privileges under Title VI. We will also find YNHH, by taking voluntary action, to be in compliance with the following issues: nondiscrimination notice under Title VI and Section 504, and grievance procedure and auxiliary aids under Section 504. The letter will state that the issue of handicapped infant is being addressed by Complaint No. 01-83-1001 and the courts have issued injunctions against OCR from making findings. The letter will also recommend that YNHH, in accordance with 45 C.F.R. §80.6(b), maintain racial and ethnic data showing the extent to which members of minority groups are beneficiaries of and participants in its federally assisted programs.

Page 2 - Mr. Eisner  
Review No. 01-82-7002

I hope that the above clarifications will be helpful and look forward to expeditiously resolving the outstanding issues of the compliance review. I am available to discuss the matter with you over the phone or at our meeting on September 18, 1984.

Thank you for your cooperation and assistance. Should you have any questions, please call me at (617) 223-0247.

Sincerely yours,



Peter K. Chan  
Equal Opportunity Specialist  
Office for Civil Rights  
Region I

Enclosures

Yale-New Haven Hospital (YNHH)

Compliance Plan for YNHH under 45 C.F.R. §§84.7(b), 84.8 and 84.52 of the U.S. Department of Health and Human Services Regulation Implementing Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. §794).

1. The grievance procedure attached as Exhibit 1 to this Plan will be utilized to comply with 45 C.F.R. §84.7(b). YNHH shall, without cost, furnish a copy of the grievance procedure and a copy of 45 C.F.R. Part 84 to each person who files, or inquires about filing, a complaint alleging any action prohibited by the regulations.

2. The form of notice attached as Exhibit 2 to this Plan will be utilized to comply with 45 C.F.R. §84.8. The notice will be included in employee handbooks and training manuals, recruitment materials and other publications containing general information that YNHH makes available to the public, participants, beneficiaries, applicants or employees, including those with impaired vision or hearing. The conditions of the preceding sentence may be met either by including appropriate inserts in existing materials and publications or by revising and reprinting the materials and publications. The notice shall also be prominently posted and maintained in every YNHH administrative office and service location and furnished to any unions or professional organizations holding collective bargaining or professional agreements with YNHH.

3. In accordance with 45 C.F.R. §84.52(d), YNHH will provide appropriate auxiliary aids to hearing impaired persons where necessary to afford such persons an equal opportunity to benefit from the service in question. Currently, YNHH's auxiliary aids for the hearing impaired include flash cards, use of paper, pencil and clipboard, telephone amplification devices, and sign language interpreters deemed qualified by the Connecticut Commission for the Deaf. YNHH will not require a patient to provide or pay for the services of a sign language interpreter. YNHH will continue to provide to its nursing and clerical staff appropriate course in basic sign language skills. YNHH will not rely on family members or friends of hearing impaired patients to serve as sign language interpreters except where a patient expressly requests such an arrangement. YNHH has installed a telecommunication device for the deaf (TTY) which is located at the Emergency Room control desk. All clerical staff members are trained in the use of the TTY and it is accessible 24 hours a day. In accordance with 45 C.F.R. §84.52(b), YNHH will utilize sign language interpreters and its TTY, as appropriate, to provide effective notice concerning benefits, services, waivers of rights, or consent to treatment to hearing impaired persons.

4. In accordance with 45 C.F.R. §84.52(d), YNHH will provide appropriate auxiliary aids to visually impaired persons where necessary to afford such persons an equal opportunity to benefit from the service in question. Currently, YNHH's auxiliary aids include the provision of readers, at no cost to the patient. YNHH has a policy which allows guide dogs access to all areas of the hospital that are open to the general public and for employees to use them in areas appropriate to perform their duties.

YNHH is prepared to draw upon a full range of communication options (auxiliary aids) in order to ensure that visually impaired persons are provided with effective access to health-care services. To this end, YNHH will develop the use of taped or braille materials, where appropriate.

5. YNHH's Section 504 Coordinator and Patient Representative will be responsible for informing all staff in patient contact positions of these policies and procedures and the availability of auxiliary aids.

YNHH's submission of this Compliance Plan does not constitute an admission that its past policies or practices have violated Section 504 or 45 C.F.R. Part 84.

Yale-New Haven Hospital

\_\_\_\_\_  
Date

\_\_\_\_\_  
Its President/Chief of Staff

Exhibit 1

NONDISCRIMINATION GRIEVANCE PROCEDURE

The Yale-New Haven Hospital has adopted this internal grievance  
(name of recipient)

procedure to provide prompt and equitable resolution of complaints alleging any action prohibited by the U.S. Department of Health and Human Services regulations implementing Federal statutes that prohibit discrimination on the basis of race, color, national origin, sex, handicap, age and religion, in programs and activities receiving Federal financial assistance, including, as applicable: 45 C.F.R. Part 80, implementing Title VI of the Civil Rights Act of 1964 (42 U.S.C. §2000d et seq.); 45 C.F.R. Part 83, implementing Sections 704 and 855 of the Public Health Service Act (42 U.S.C. §§292d and 298b-2); 45 C.F.R. Part 84, implementing Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. §794); 45 C.F.R. Part 86, implementing Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §1681 et seq.); 45 C.F.R. Part 91, implementing the Age Discrimination Act of 1975, as amended (42 U.S.C. §6101 et seq.); and 45 C.F.R. Part 92, implementing block grant provisions of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. §§300w-7, 300x-7, 300y-9, 708, 8625 and 9906. Copies of these statutes and regulations may be obtained from \_\_\_\_\_,

(name, title, office address and telephone number)

who has been designated to coordinate the efforts of the Yale-New Haven  
(name of

Hospital to comply with the regulations.  
recipient)

The following rules apply to complaints filed under this procedure:

1. A complaint should be writing, contain the name and address of the person filing it, and briefly describe the action alleged to be prohibited by the regulations.

2. A complaint should be filed in the office of the \_\_\_\_\_  
(title of above-  
\_\_\_\_\_ within a reasonable time after the person filing  
named coordinator)  
the complaint becomes aware of the action alleged to be prohibited by the regulations.

3. The \_\_\_\_\_ or his/her  
(title of recipient's chief executive officer)  
designee, shall conduct such investigation of a complaint as may be appropriate to determine its validity. These rules contemplate informal but thorough investigations, affording all interested persons and their representatives, if any, an opportunity to submit evidence relevant to a complaint.

4. The \_\_\_\_\_ shall  
(title of recipient's chief executive officer)  
issue a written decision determining the validity of the complaint no later than 30 days after its filing.

5. The \_\_\_\_\_ shall maintain the files  
(title of above-named coordinator)  
and records of the \_\_\_\_\_ relating to complaints filed  
(name of recipient)  
hereunder. The \_\_\_\_\_ may assist  
(title of above-named coordinator)  
persons with the preparation and filing of complaints, participate in the investigation of complaints, and advise the \_\_\_\_\_  
(title of recipient's chief  
\_\_\_\_\_ concerning their resolution.  
executive officer)

6. The right of a person to prompt and equitable resolution of a complaint filed hereunder shall not be impaired by the person's pursuit of other remedies, and utilization of this grievance procedure is not a prerequisite to the pursuit of other remedies. A person may at any time file a complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, Room 2403, John F. Kennedy Federal Building, Boston, Mass. 02203, Tel. (617) 223-0247, TTY (617) 223-4000.

7. These rules shall be liberally construed to protect the substantial rights of interested persons, to meet appropriate due process standards and to assure compliance by the \_\_\_\_\_ with Federal statutes and regulations.  
(name of recipient)



Exhibit 2

NONDISCRIMINATION NOTICE

In accordance with Title VI of the Civil Rights Act of 1964 (42 U.S.C. §2000a et seq.). Sections 704 and 855 of the Public Health Service Act (42 U.S.C. §§292d and 298b-2), Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. §794), Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §1681 et seq.), the Age Discrimination Act of 1975, as amended (42 U.S.C. §6101 et seq.), and block grant provisions of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. §§300w-7, 300x-7, 300y-9, 708, 8625 and 9906), the Yale-New Haven Hospital  
(name of recipient)

does not discriminate on the basis of race, color, national origin, sex, handicap, age or religion in admission or access to, or treatment or employment in, its programs or activities. The person whose name appears below has been designated to coordinate the efforts of the Yale-New Haven  
(name of

Hospital to comply with the U.S. Department of Health and Human recipient)

Services regulations (45 C.F.R. Parts 80, 83, 84, 86, 91 and 92) implementing these Federal laws. For further information about the regulations and our grievance procedures for resolution of discrimination complaints, contact

\_\_\_\_\_  
(name and title of designated coordinator, office address and telephone number).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office for  
Civil Rights

Region 1  
Room 2403  
John F. Kennedy Federal Bldg.  
Government Center  
Boston, MA 02203

December 5, 1984

Mr. C. Thomas Smith  
President  
Yale-New Haven Hospital  
New Haven, Connecticut 06504

Re: Compliance Review No. 01-82-7002

Dear Mr. Smith:

In 1982, the Office for Civil Rights (OCR) selected Yale-New Haven Hospital (YNHH) as one of four teaching hospitals for review regarding compliance with Title VI of the Civil Rights Act of 1964 (42 U.S.C. §2000d et seq.) and Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. §794), implemented by U.S. Department of Health and Human Services (HHS) regulations found at 45 C.F.R. Parts 80 and 84, respectively.

As a recipient of Federal financial assistance from HHS, YNHH is required to comply with these statutes and regulations. In addition, YNHH has also signed Assurances of Compliance with HHS under Title VI (Form 441) and Section 504 (Form 641).

Title VI prohibits discrimination against individuals on the basis of race, color, or national origin. The compliance review examined whether YNHH is in compliance with 45 C.F.R. §§80.3(b), 80.5(e), and 80.6(d) with respect to the following issues:

- ° patient admissions
- ° patient room assignments and transfers
- ° granting of staff privileges, and
- ° the adoption and dissemination of a nondiscrimination policy and notice.

Section 504 prohibits discrimination against qualified handicapped persons in the provision of services and employment. The compliance review examined whether YNHH has met the following procedural requirements:

- ° adoption and dissemination of a nondiscrimination policy and notice (45 C.F.R. §84.8)
- ° designation of a Section 504 coordinator (45 C.F.R. §84.7(a)), and

- adoption and dissemination of grievance procedures (45 C.F.R. §84.7(b)).

OCR also examined whether YNHH has implemented policies and procedures regarding the effective communication with, and the provision of auxiliary aids to, hearing and visually impaired persons (45 C.F.R. §84.52).

At the time of the on-site review in 1982, OCR found that:

- YNHH's policies and procedures regarding patient admissions, room assignments and transfers, and the granting of staff privileges were in compliance with Title VI. Contacts with community and advocacy groups did not disclose any allegations of violations; and
- YNHH had designated a Section 504 coordinator pursuant to 45 C.F.R. §84.7(a).

OCR also found that:

- YNHH had not provided or disseminated notice of its nondiscrimination policy pursuant to Title VI and Section 504 requirements;
- YNHH did not have a grievance procedure that meets the requirement of 45 C.F.R. §84.7(b); and
- Although YNHH had installed a TTY in its Emergency Room and has made arrangements for the use of qualified sign language interpreters, there was a lack of specific policies or procedures regarding effective communication with and the provision of auxiliary aids to hearing or visually impaired persons.

Since the on-site, YNHH has taken voluntary actions to resolve the identified deficiencies. Productive negotiation between OCR and YNHH has culminated in a Nondiscrimination Plan signed by John E. Fenn, M.D., Chief of Staff, dated November 19, 1984.

The Plan commits YNHH to utilize and disseminate a nondiscrimination notice and grievance procedure acceptable under the HHS regulations. In the area of effective communication with and auxiliary aids to visually and hearing impaired persons, YNHH will continue to draw upon a full range of communication options to ensure that these persons are provided with effective access to health care services. These include 24 hour access to the TTY, use of sign language interpreters deemed qualified by the Connecticut Commission for the Deaf, training of staff in basic sign language skills and the use of TTY, provision of readers, and the development of tapes or braille materials where appropriate. In addition, YNHH's Section 504 Coordinator and Patient Representative will be responsible for informing all staff in patient contact positions in regard to these policies and procedures and the availability of auxiliary aids.

With our acceptance of the Plan, OCR now determines YNHH to be in compliance with Title VI and Section 504 with respect to those issues specifically examined in the compliance review.

45 C.F.R. §80.6(b) Requirement

During the review, YNHH's inability to provide OCR with readily retrievable racial/ethnic data prevented OCR from making statistical comparisons. We therefore wish to notify you of the requirement, in accordance with 45 C.F.R. §80.6(b), to maintain racial and ethnic data showing the extent to which members of minority groups are beneficiaries of and participants in federally assisted programs. YNHH should take immediate action to collect racial/ethnic information with respect to its patients, clients, participants, employees, and applicants for staff privileges.

The following five categories should be used for identification and collection purposes:

Black, not of Hispanic Origin. A person having origin in any of the black racial groups of Africa.

Hispanic. A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.

Asian or Pacific Islander. A person having origins in any of the original people of the Far East, Southeast Asia, the Indian Subcontinent, or the Pacific Islands. This area includes, for example, China, Japan, Korea, the Philippine Islands, and Samoa.

American Indian or Alaska Native. A person having origins in any of the original people of North America, and who maintains cultural identification through tribal affiliation or community recognition.

White, not of Hispanic Origin. A person having origins in any of the original people of Europe, North Africa, or the Middle East.

Handicapped Infant Issue

As part of the review, OCR conducted factfinding at YNHH to determine if handicapped infants were being discriminated against in the provision of treatment or services. After the compliance review was begun, OCR received a separate complaint against YNHH alleging noncompliance with Section 504 in the treatment and care of handicapped infants. Because of the complaint, OCR conducted additional factfinding in this area.

Decisions from the United States Court of Appeals for the Second Circuit have barred HHS from applying Section 504 and the implementing

Page 4 - Mr. C. Thomas Smith  
Compliance Review No. 01-82-7002

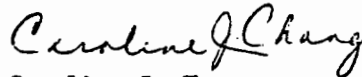
regulations to health care for handicapped infants. OCR will address this issue when this bar is removed.

Under the provisions of the Freedom of Information Act, as amended, 5 U.S.C. §552, and its pertinent regulation, 45 C.F.R. Part 5, the contents of this letter and/or other information received during the review/investigation may be released upon request from the public. However, if such a request is made, we will maintain the confidentiality of information that, if released, would constitute an unwarranted invasion of privacy.

OCR greatly appreciates your cooperation and the assistance extended by your staff to our investigators. We would like to especially thank Dr. John E. Fenn, Chief of Staff; J. Michael Eisner, Legal Counsel; Edward Dowling, Vice President of Human Resources; Virginia Roddey and Angela Holder of the Risk Management/Medical Legal Office.

Should you have any questions, please contact Mr. Peter K. Chan of my staff at (617) 223-0247.

Sincerely yours,



Caroline J. Chang  
Regional Manager  
Office for Civil Rights  
Region I

cc: Dr. John E. Fenn, Chief of Staff  
✓ J. Michael Eisner, Esq.

November 7, 1988

William J. Howard  
General Counsel  
United States Commission on Civil Rights  
1121 Vermont Ave. N.W.  
Washington, D.C. 20425

RE: Commission Report on Medical Treatment of Handicapped  
Infants

Dear Mr. Howard:

My office is in receipt of the second set of revised excerpts to your forthcoming report relating to medical treatment of handicapped infants. You have invited a response to such excerpts without the benefit of any contextual information which may indicate the manner in which such excerpts will be used. The objections raised below relate not only to the abusive substantive material of your report, but also to the gross inadequacy and insufficiency of your investigation process. Such procedural objections are part and parcel of this response and shall not be carved out by your editing from the below material relating to this issue as we receive our due process in the appendix of your "Report". We find it abhorrent that your Commission, as a governmental entity, could be so deficient in it's duty to investigate and protect the civil and constitutional rights of all parties. We believe it is a fundamental defect undermining your report that neither the Department of Human Services or Children's Hospital of Oklahoma (formerly known as Oklahoma Children's Memorial Hospital) have ever received any requests or contact by your Commission regarding any of the practices, issues, etc. discussed in your excerpts. This is incredible considering the fact that you first held hearings on this issue in June of 1985, yet the first notice this hospital has received is an opportunity to respond to draft excerpts of your report. (We have been advised that Dr. Gross was invited to testify, but only after a lawsuit regarding this situation had been filed.) It is more incredible upon noting the drastic changes which have taken place in excerpts received one month apart (September 14th and October 19th, 1988). Therefore, and assuming the attached revisions to be final, we have several observations to make.

1. REPORT AUTHORITY. For interpretative authority, the report repeatedly relies upon apparent law review articles written by Sharon Paulus and Martin Gerry in "Issues of Law and Medicine".



A component of the Department of Human Services and affiliated  
with the University of Oklahoma Health Sciences Center

However, you fail to note that both Ms. Paulus and Mr. Gerry are attorneys of record of plaintiffs in the lawsuit against Children's Hospital of Oklahoma. Furthermore, the journal "Issues in Law and Medicine" is the self-serving creation of the National Legal Center for the Medically Dependent and Disabled, Inc., - a plaintiff in the lawsuit. When has your office reviewed the court records or the medical records of Carlton Johnson?

2. THE FORMULA. In the new excerpt beginning "OKLAHOMA CASE", your reference of information (footnote #1) is the Paulus article. In your second paragraph, you state:

In this evaluation, the [meningomyelocele] team members wrote, they were "influenced" by a quality of life formula:  $QL=NE \times (H+S)$ .

This a clever but deceitful statement. Your implication that the quality of life formula was used in the evaluation of children is a distortion of what is stated in the article and otherwise totally denied. The repeated assertion by the disability groups and now your Commission that a "quality of life formula" served as a basis for denying treatment is an unadulterated lie. The original statement by Robert Fulton and Antonio Padilla on behalf of the Oklahoma Department of Human Services and Children's Hospital emphasizes the formula's non-use, which has also been publicly refuted by Dr. Gross. Furthermore, the assertion that a quality of life formula was used as a basis for determining treatment has been unequivocally refuted by the meningomyelocele team and clinic staff as noted in the attached affidavit (See attachment, originally attached to Fulton and Padilla statement, May 23, 1985.). The formula was simply used as an illustration device and was not even discovered by Dr. Gross until 1981 when he was writing the paper. After describing the formula you continue your excerpt with "based on the assessment, the team recommended to the parents the infant be given either vigorous or supportive care". This continued representation that the team made a recommendation based upon an assessment which included the formula is simply irresponsible. The article clearly states the criteria that were used to evaluate these newborn and it doesn't include such formula.

Along the same line, you later state:

The team members acknowledged that "treatment for babies with identical [degree of mental and physical disability] could be quite different, depending on the contribution from home and society".

This statement is made with the discussion of the formula and did not relate to the management by the team.

3. CARLTON JOHNSON. The Department and Hospital will not discuss treatment of individuals, including Carlton Johnson, who

continues to be treated at the hospital clinic. Suffice it to say, that you have relied upon the Paulus article which has quoted a journalist, who has quoted the plaintiff, etc.

4. DENIAL OF TREATMENT. This excerpt states:

There have been isolated instances in which denial of treatment was publicly announced in medical journal articles, most notably those reporting decisions to withhold lifesaving treatment from a number of newborn children with disabilities at \* \* \* and similar decisions at Oklahoma Children's Memorial Hospital in the 1980's. 1/ In those cases the physician's involved were deliberately crusading for open acceptance of denial of treatment practices by their fellow professionals.

It is absolutely inaccurate to state that treatment was denied any infant by the physicians or hospital at Children's Hospital of Oklahoma. As Dr. Gross made very plain in his article, the decision was made by the parents after full disclosure of the child's condition and treatment option by the physicians.

5. ECONOMIC DISCRIMINATION. In your excerpt from "Chapter 12", wherein you attempt to summarize the article written by Gross et al, you state:

"In addition the criteria used by the team included an assessment of 'contibution from home and family' so that those families who had greater resources might receive a recommendation for treatment and those families with fewer resources would be more likely to receive a recommendation against it, even though the severity of the disability might be the same in both cases."

This is a reckless distortion of the discussion by Dr. Gross of the formula. Nowhere in the article is there any indication that higher income families received treatment and poorer families did not. In the article's discussion of the Shurtleff criteria (which were relied upon), criteria (6) states "a family with economic and intellectual resources who lived within reach of an appropriate medical facility, or a commitment by a social agency to provide needed resources such as foster home or medical care costs". The actual resource/reimbursement facts are as follows:

1. 100% of patients on public assistance without insurance were aggressively treated.
2. 69% of patients qualifying for medical assistance (medicaid or state crippled children's program) were aggressively treated.
3. 58% of the patients with private insurance, including Champus were aggressively treated.



4. 50% of persons with private insurance but who also qualify for medical assistance were aggressively treated.

These statistics clearly belie your unfounded accusations and generalizations.

6. REPORT BIAS. Throughout the excerpt titled "Chapter 12", the author's bias is repeatedly displayed. For example:

- A. The article does not describe an "experiment", but is a retrospective case review.

- B. In describing the process used by the hospital team on page 1, you state "For those infants born with high lesions and who were suspected of having hydrocephalus or other anomalies a formal meeting was convened to make a treatment recommendation to the family." (Emphasis added.) The use of the word "suspected" is an inflammatory addition which is in complete variance with the radiography and CT scans described in the evaluation.

- C. To describe the sac as the size of a "basketball" is outrageous. You have the CNN video tape, look at it.

- D. It is a distortion to state the "families of five children 'demanded' treatment" when it was simply the option they chose after presentation of the child's condition.

- E. Likewise, "at the end of the 'experiment' twenty four families had 'finally agreed' to the non-treatment regimen..." reflects your editorial bias.

7. SURGEON GENERAL C. EVERETT KOOP. The excerpt states:

\*\*\* Subsequent to May 30, 1984, Surgeon General C. Everett Koop was to make 'an indirect approach to the University of Oklahoma \*\*\* to see what current practices are being utilized by the University of Oklahoma in their determinations of who should be treated'. 13/ Physicians at the hospital refused to give the Surgeon General assurances that the practices had ceased. 14/

In the "Background Information" attached to the statement by Robert Fulton and Antonio Padilla of May 23, 1985, this issue was thoroughly explained as follows:

Involvement of U. S. Surgeon General Koop

When the attorneys who authored the May 8, 1985, letter were asked by the news media whether they had contacted officials at DHS or OCMH prior to making their allegations, they reportedly stated that OCMH had continuously rebuffed attempts by C. Everett Koop, Surgeon General of the U.S.

Public Health Service, to clarify OCMH's current position on this subject. To date, neither the Hospital nor the Department of Human Services have been contacted by the Surgeon General.

We do understand that Surgeon General Koop spoke informally on two occasions with an acquaintance at OCMH, Dr. E. Ide Smith, Chief of Pediatric Surgery -- once during a telephone conversation last summer [1984] and once during an incidental meeting at a medical conference in the fall. (See attached affidavit.) On both occasions, Dr. Smith assured Koop of complete compliance by OCMH with the federal regulations and repudiated any allegation that OCMH physicians used a selection formula to determine the type of treatment given to the newborn. Dr. Koop suggested to Smith that OCMH should clear the air with disability groups regarding its policies and Smith related the information to the OTH administration. At Dr. Koop's request, Dr. Smith relayed this information as coming from "good authority". (It should be noted that Fulton had by this time extended his invitation to Mr. Gerry.) [Martin H. Gerry, co-counsel for the National Legal Center for the Medically Dependent and Disabled, Inc.]

These contacts were never considered by Dr. Smith or OCMH to be more than friendly advice and certainly were never considered as formal requests for clarification of OCMH policies. Had Surgeon General Koop made such a request, DHS and OCMH would have been eager to provide him with information and assurances with respect to treatment of children. To extrapolate from casual conversations between professional colleagues that OCMH has "rebuffed" requests by the Surgeon General to clarify OCMH's position is unfair to Surgeon General Koop as well as the Hospital.

While Surgeon General Koop had informal contact with a member of the medical staff at OCMH, the authors of the May 8th letter and their clients made absolutely no effort to obtain information on OCMH policy or practice. Dr. Koop's informal contacts do not excuse their failure to make inquiry at OCMH, especially in light of the invitation extended to Martin Gerry. If they didn't want to bother with coming to Oklahoma, they could have a least written or called. Moreover, DHS and OCMH's policies on this subject are a matter of public record which could have been procured and reviewed by local counsel, Mr. Fairbanks, with a minimum of effort.

As indicated by the above statement issued in 1985, with the accompanying affidavit of Dr. Smith, your conclusion suffers from the inexcusable lack of inquiry and investigation by your office. Dr. Smith, one of many hospital service chiefs, was an acquaintance of the Surgeon General and could hardly be labeled a "hospital official" by virtue of his service position.

Obviously, no further communication was required with his acquaintance since appropriate assurances were provided.

8. LAWSUIT AND INVESTIGATION. The excerpt states:

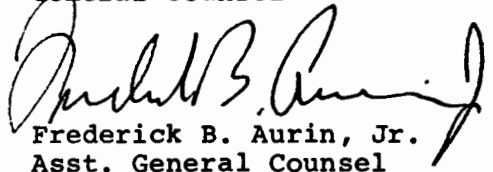
\*\*\* In October, 1985, the American Civil Liberties Union and the National Center for the Medically Dependent and Disabled (a Legal Services Corporation funded National Support Center) filed suit against a number of physicians at Oklahoma Children's Memorial Hospital on behalf of Sharon Johnson (Carlton Johnson's mother), Carlton Johnson himself, the parents of another child with disabilities who had died after allegedly being denied lifesaving treatment at Oklahoma Children's Memorial Hospital, the Spina Bifida Association of America, and the Association for Persons with Severe Handicaps. 15/

The Director of this Department, Robert Fulton (also a former secretary of welfare at HEW) personally invited Martin H. Gerry, an attorney for the National Legal Center for the Medically Dependent to investigate with medical experts in the summer of 1984. No response or even the slightest inquiry was received by Mr. Gerry, the so-called National Legal Center, or the ACLU until James Bopp, Jr., acting on behalf of the National Legal Center held his well-staged press conference in a U.S. Senate office building which demanded the department and hospital submit to a consent order or otherwise face a class action lawsuit. There was no independent investigation but across the street from the press conference was the United States Supreme Court which was then deciding whether or not to grant certiorari on the "Stoneybrook Case" which later resulted in the Bowen decision. Incidentally, more than half of the lawsuit has been dismissed with very little discovery accomplished.

In conclusion, it is difficult for the agency and hospital to place much credence in your report based upon the above reasons. Thank you for this opportunity to respond.

Very truly yours,

Charles L. Waters  
General Counsel


  
Frederick B. Aurin, Jr.  
Asst. General Counsel

ATTESTATION


STATE OF OKLAHOMA )  
 ) ss:  
COUNTY OF OKLAHOMA )

I, Frederick B. Aurin, Jr., of lawful age, being first duly sworn upon oath, state:

That the foregoing letter is written on behalf of the Department of Human Services and Children's Hospital of Oklahoma (formerly Oklahoma Children's Memorial Hospital) and in my capacity as Assistant General Counsel.

  
\_\_\_\_\_  
Frederick B. Aurin, Jr.  
OBA# 379  
Assistant General Counsel  
Department of Human Services

Subscribed and sworn to before me this 7<sup>th</sup> day of November, 1988.

  
\_\_\_\_\_  
Notary Public

My Commission Expires:  
10-8-89



COMMISSION  
FOR HUMAN SERVICES

State of Oklahoma  
Department of Human Services

Sequoyah Memorial Office Building  
P.O. Box 25352  
Oklahoma City, Oklahoma 73125

May 23, 1985



ROBERT FULTON  
Director of Human Services

Thomas J. Marzen  
National Legal Center  
for the Medically Dependent  
and Disabled, Inc.  
P. O. Box 441069  
Indianapolis, Indiana 46204

Dear Mr. Marzen:

This is in response to the letter of May 8, 1985, to the undersigned and several other individual addressees from your organization regarding a potential lawsuit. Your letter relates to compliance by Oklahoma Children's Memorial Hospital (OCMH) with Constitutional and statutory requirements pertaining to the handicapped.

The presentation of your concerns before a national news conference two days before our receipt of your letter and without the courtesy of giving us an opportunity to respond was unorthodox and unprofessional.

Several months ago, Robert Fulton, Director of the Oklahoma Department of Human Services (DHS) and one of the addressees of your May 8th letter, personally invited Mr. Martin H. Gerry, one of your co-counsel, to visit OCMH, bringing whatever medical or legal experts he cared to bring. Mr. Fulton assured Mr. Gerry that the visitors would be allowed to interview physicians and administrators, observe procedures and ask any questions they thought relevant to the care of severely handicapped infants. Unfortunately, you never responded.

In view of your behavior, it is clear that your organization is more interested in publicity than truth. It is sad that you have gained this publicity by vilifying OCMH — one of the finest child care institutions in this nation.

The litigation you are threatening is misguided and inappropriate. No children are "threatened" with lack of care or with improper treatment at OCMH. Children are not being "allowed to die" as alleged in your letter nor have the hospital or physicians engaged in human experimentation. "Quality of Life" or "contributions" anticipated from home, family and/or society are not considered in determining the type of treatment to provide to severely handicapped infants. An affidavit to this effect signed by current staff of the Myelomeningocele Clinic at OCMH and by hospital administrators is enclosed.

May 23, 1985

As explained in the enclosed background paper, OCMH is in full compliance with all federal and state laws on the matter of care of severely handicapped infants. In addition, OCMH established over a year ago an Infant Care Review Committee composed of physicians, nurses, attorneys and representatives of the lay community. The committee reviews medical treatment of newborns on a prospective and retrospective basis for the very purpose of assuring that medical treatment is provided for all infants regardless of handicap or anticipated physical or mental impairments. OCMH is in complete compliance with all of the so called "Baby Doe" requirements.

OCMH, like many other institutions caring for children with spina bifida, is today achieving a much higher survival rate for such children, as compared with the experience of only a few years ago because of increased knowledge and medical advances. Specifically, 25 newborn children with spina bifida have been treated at OCMH since January 1, 1983. Of the 25, 3 died within a very short time after birth of massive complications accompanying spina bifida. Since January of 1984, all 12 infants born with spina bifida and treated at OCMH have survived. The hospital has been able to accomplish these excellent results through the use of surgery and other intensive therapies.

We cannot, of course, agree to the proposed consent judgment forwarded with your May 8th letter. The proposed agreement would have us confirm allegations that are simply not true. Such an agreement is not appropriate. Children treated at OCMH are safe; indeed, those children with birth defects who are born at OCMH or referred there from elsewhere receive care equivalent to that available in other prominent medical institutions throughout the nation.

We do, however, renew the invitation extended earlier that you send a team of medical and legal experts to review current policies and procedures and interview physicians with respect to care and treatment of severely handicapped infants at OCMH. We believe it would be appropriate that experts chosen by you be joined by a few equally expert individuals chosen by us so that there will be maximum confidence that a thorough, unbiased and conclusive review is completed.

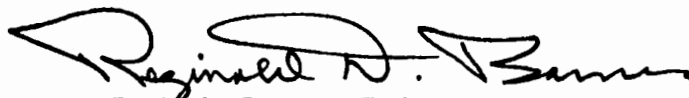
The enclosed background paper sets forth relevant information and comments on allegations contained in your letter of May 8th and the proposed consent agreement you transmitted.

Your public vilification of OCMH when it in fact has complied fully with the law and established medical standards is irresponsible. There can be little doubt that the trust and confidence that patients and their families have placed in the hospital have been jeopardized by your defamatory statements. You can be certain that your conduct has contributed to the grief and suffering of families already seriously overburdened by the tragedy of spina bifida.

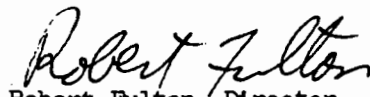
May 23, 1985

We shall await with interest further communications from you, your associates and your clients. Please contact Roger Stuart, Assistant General Counsel for the Oklahoma Department of Human Services, if you need additional information or wish to convey information to us.

Sincerely,



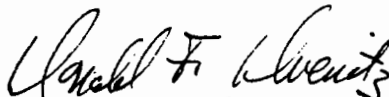
Reginald Barnes, Chairman  
Oklahoma Commission for Human Services



Robert Fulton, Director  
Department of Human Services



Antonio Padilla, Chief Executive  
Officer, Oklahoma Teaching Hospitals



Donald Doenitz, Administrator  
Oklahoma Children's Memorial Hospital



Owen Rennert, M.D., Chief of Staff  
Oklahoma Children's Memorial Hospital

Additional Background Information and Responses to  
Allegations Regarding Care of Children with Spina  
Bifida at Oklahoma Children's Memorial Hospital

Evolution of Federal and State Legislation and Regulations

Legal issues relating to the medical treatment of children born with severe deformities and disabilities have only recently been addressed by the courts and legislators. Not until this past year has Congress acted decisively to address the issues of the so-called "Baby Doe" situation. However, before the recent federal legislation was enacted the Oklahoma Department of Human Services (DHS), Oklahoma Teaching Hospitals (OTH) and Oklahoma Children's Memorial Hospital (OCMH) were in full compliance with regulations promulgated by the Federal Department of Health and Human Services in January, 1984. Despite the fact that those regulations have been held invalid by federal court action, OCMH has continued to strictly conform to their letter and spirit.

The first federal regulatory involvement in this issue began when the United States Department of Health and Human Services issued a notice on May 18, 1982, which informed affected parties of that Department's view that Section 504 of the Rehabilitation Act of 1973 applied to the medical care of handicapped infants. This was followed by the publication of "Interim Final Rules" on March 7, 1983, which required health care providers receiving federal financial assistance to post notices throughout their institutions and to create infant care review committees. Before compliance could be achieved, the Interim Final Rules were declared invalid on April 14th, 1983, in the case of the American Academy of Pediatrics vs. Heckler 561 F. Supp. 394 (D.D.C. 1983).

Subsequently, revised federal rules were initiated in January of 1984. The Oklahoma Department of Human Services and Oklahoma Children's Memorial Hospital immediately implemented the requirements and recommendations for voluntary action which accompanied the rules. On February 9, 1984, the Infant Care Review Committee of Oklahoma Children's Memorial Hospital, a voluntary committee, began operating in the spirit of the new rules.

The January, 1984, rules were set aside on February 23, 1984, by the Federal Court of Appeals, in U.S. v. University Hospital, State University of New York at Stonybrook, 729 F.2d 144 (2nd Cir. 1984). In spite of that decision, on March 27th, 1984, the Oklahoma Human Services Commission, the governing body of the Department of Human Services and Oklahoma Children's Memorial Hospital, approved an amendment to the Department's child protective services procedures providing for investigation of any purported denials of treatment of children in hospitals anywhere in the state. On the same date, the Commission gave initial approval to a statement of purposes and operating procedures for the OCMH Infant Care Review Committee.

Moreover, Oklahoma's legislature took two separate actions in this area during 1984. House Bill 1133, enacted into law on April 10, 1984, added denial of needed medical treatment to the definition of child neglect contained in Oklahoma's statutes. In addition, the appropriations bill for DHS for FY-1985 (House Bill 1522), contained a provision directing the Commission for Human Services to implement policies and procedures providing added assurance that handicapped children receive proper treatment at OCMH. DHS supported both of these measures.

Thus, in spite of the Second Circuit's decision repudiating the January, 1984, federal regulations, Oklahoma chose to honor the letter and spirit of



those rules. As the attachments indicate, these actions are a matter of public record.

The January, 1984, federal rules, and the federal statute enacted in October, 1984 (Public Law 98-457) were the result of a consensus reached by medical organizations and disability groups some of which are now represented by the authors of the May 8, 1985, letter. These attorneys and their clients have totally and irresponsibly failed to review what Oklahoma and its agencies have done. Moreover, their action has been launched despite the personal invitation to make an on-site review of OCMH and of spina bifida patients extended to Martin H. Gerry, Co-counsel for the plaintiffs, by the Director of the Oklahoma Department of Human Services, Robert Fulton. (This invitation is further discussed in the cover letter.) Instead the attorneys and their clients have decided to proceed in a manner which defames the State of Oklahoma and the dedicated physicians and staff at OCMH. This grandstanding has ignored Oklahoma's good faith compliance with proposed federal statutes and regulations.

In addition, while the Courts have uniformly rejected any connections between Section 504 of the Rehabilitation Act of 1973 and the treatment of handicapped infants, the May 8th letter maintains that the State of Oklahoma is violating that statute. This is simply not the case.

Federal District Judge Gerhard Gesell in the American Academy of Pediatrics case threw out the original federal regulations as "arbitrary and capricious" and stated in his opinion that the rules failed to consider many highly relevant factors on "one of the most difficult and sensitive medical problems facing our society". Judge Gesell further pointed out:

Traditionally, the difficult decision of when to withhold life-sustaining treatment of a defective newborn has been one within the privacy of the physician-patient relationship, without interference by State or Federal authorities.

Yet, the May 8, 1985, letter attempts to revive rules which were twice found invalid by Federal Courts and apply them retroactively to the 1977 to 1982 period.

Congress acted decisively with respect to the right to care of the handicapped in Public Law 98-457 (enacted October 9, 1984) and implementing regulations made final on April 15, 1985. The Department of Human Services has now responded with diligence to insure compliance with yet another set of regulations. However, as indicated, Oklahoma's compliance with stricter standards was achieved long before the federal statute was enacted and the implementing rules became final, and more than a year before the May 8, 1985, grandstand press conference in Washington, D.C..

#### OCMH Experience in Treating Newborn Children with Spina Bifida

To support allegations contained in the May 8, 1985, letter, numerous references are made to an article written by Dr. Richard Gross, a former faculty member of the University of Oklahoma, which was published in the October, 1983, issue of "Pediatrics" journal. In this article Dr. Gross

retrospectively describes the experiences he and his associates had with children born with spina bifida from 1977 to 1982. The authors of the May 8th letter attempt to distort Dr. Gross' article by alleging that he selected treatment for patients through the use of a formula and that such a practice also represents past and present hospital policies. Those allegations are simply not true.

It is important to put Dr. Gross' article in a proper perspective. The article did not report on an "experiment", a research study nor a hospital policy. Rather, the article simply reported retrospectively on data collected between 1977 and 1982 on the treatment of newborn children with spina bifida.

The birth of a child with multiple congenital anomalies, with or without a poor prognosis for survival, is obviously a traumatic event for the family. The early and continuous treatment and care of such children evokes, for society as a whole, medical, philosophical, ethical and theological considerations. Although the problem of birth defects is not new, dramatic advances in neonatal care make it possible to sustain life in infants who would have died only a few years ago. At the heart of this matter is, as Judge Gesell noted, "one of the most difficult and sensitive problems facing our society -- the question of what sort of life-sustaining treatment, if any, should be utilized to preserve the lives of severely mentally or physically defective infants".

The general approach to physician - family interaction described in Dr. Gross' article is common with many types of serious health care problems. Members of a team of health care professionals worked closely with each other in diagnosing patients' conditions and in presenting medical information to the families of children with spina bifida in order that the families could decide the nature and extent of medical intervention. This same approach was recently described in an article written by physicians at Children's Hospital of Philadelphia and reported in "Pediatrics" journal in January of this year. Those physicians describe a team similar to the one at OCMH which advised parents with respect to the likely result of surgical intervention so that they could make informed decisions with respect to their children. The fact that this method apparently represents that Hospital's present approach, while OCMH currently utilizes a review procedure endorsed by the very organizations attacking OCMH, makes threats of a lawsuit even more puzzling.

In any event, while it is not appropriate for OCMH to speak for Dr. Gross, he was recently contacted in order to discuss issues raised with respect to the October, 1983, article. Two significant facts emerged from the conversation. First, none of the attorneys nor their clients have ever spoken with or attempted to contact Dr. Gross to review with him their allegations and assumptions. Second, had they done so, they would have been assured that the so-called "quality of life" formula was never a part of the team's approach. Indeed, Dr. Gross stated that he was unaware of the formula until he began writing his paper. While he included the formula in the article for illustrative purposes, it was never applied to children within his care.

Moreover, the entire thrust of the approach Dr. Gross described was to allow parents to make informed decisions with respect to medical treatment. As in

any other medical situation, it was necessary to relate to the parents the known disabilities and prospects of life for the children with and without surgical intervention. Therefore, to the extent that factors such as hydrocephalus, retardation, loss of bladder and bowel function, ambulation, and general survival prognosis were involved, parents were given such facts for the sole purpose of allowing them to make informed decisions regarding treatment.

The on going medical and societal debate in this country regarding the extent of parental rights on this sensitive issue have not yet been resolved. During the period dealt with in Dr. Gross' article, and in fact since the onset of modern medicine, decisions with regard to life-sustaining treatment of a child with multiple birth defects were made within the privacy of the physician-patient relationship. The approach described by Dr. Gross was representative of practices across the nation. Only recently has the government attempted to establish regulations which would govern decisions which were traditionally left to the family with advice from physicians and often clergy.

Finally, the 1977-1982 approach was not an "experiment". Neither the Hospital nor physicians have in the past or present performed experiments on these children. To that end, federal and state regulations regarding experimentation have always been rigorously followed at OCMH.

#### Alleged Racial Discrimination

The May 8th letter asserts that treatment provided by Dr. Gross and his colleagues was racially motivated and had the net result of discriminating against Blacks and "Indians". Apparently this allegation is based upon the assumption that, if the quality of life formula were used in making medical judgments, it would militate against medical treatment for minorities. As already noted, the quality of life formula referred to by Dr. Gross was never applied to his patients.

However, since it was specifically asserted that Blacks and "Indians" were discriminated against, a review has been made of the racial composition of the children with spina bifida referred to in Dr. Gross' paper. The racial composition of those receiving immediate surgical intervention, shunts and other aggressive therapies is as follows:

<u>Black</u>	<u>White</u>	<u>Hispanic</u>	<u>Native American</u>
100%	57%	83%	55%

These findings hardly support the assertion that Dr. Gross and his associates engaged in racial discrimination. Indeed, Dr. Gross' article does not indicate that race was ever a criterion. It appears that injection of the allegation of racial discrimination was only an attempt to inflame emotions, interest the media and discredit OCMH.

#### The Provision of Medical Treatment after Hospitalization

The implication that children with spina bifida are or have been placed in interim care facilities where antibiotics for active infection were purposefully withheld is incorrect. The Children's Shelter referenced in

Dr. Gross' article was a private facility which ceased operation in January, 1984. The placement of children at that facility was a decision made by a parent when home care was not possible. According to the former Medical Director of Children's Shelter, neither the Hospital nor physicians directed that antibiotics to control active infections be withheld. Indeed, children were supplied antibiotics and when illness presented itself, they were taken to OCMH for appropriate treatment. With respect to sedatives, the use of such medications for spina bifida patients has been highly criticized in the medical literature because of problems in their use in European countries. While sedatives were not normally given in these cases, analgesics were used for the control of pain according to the former Medical Director of Children's Shelter.

#### Involvement of U.S. Surgeon General Koop

When the attorneys who authored the May 8, 1985, letter were asked by the news media whether they had contacted officials at DHS or OCMH prior to making their allegations, they reportedly stated that OCMH had continuously rebuffed attempts by C. Everett Koop, Surgeon General of the U.S. Public Health Service, to clarify OCMH's current position on this subject. To date, neither the Hospital nor the Department of Human Services have been contacted by the Surgeon General.

We do understand that Surgeon General Koop spoke informally on two occasions with an acquaintance at OCMH, Dr. E. Ide Smith, Chief of Pediatric Surgery -- once during a telephone conversation last summer and once during an incidental meeting at a medical conference in the fall. (See attached affidavit) On both occasions, Dr. Smith assured Koop of complete compliance by OCMH with the federal regulations and repudiated any allegation that OCMH physicians used a selection formula to determine the type of treatment given to the newborn. Dr. Koop suggested to Smith that OCMH should clear the air with disability groups regarding its policies and Smith related the information to the OTH administration. At Dr. Koop's request, Dr. Smith relayed this information as coming from "good authority". (It should be noted that Fulton had by this time extended his invitation to Mr. Gerry.)

These contacts were never considered by Dr. Smith or OCMH to be more than friendly advice and certainly were never considered as formal requests for clarification of OCMH policies. Had Surgeon General Koop made such a request, DHS and OCMH would have been eager to provide him with information and assurances with respect to treatment of children. To extrapolate from casual conversations between professional colleagues that OCMH has "rebuffed" requests by the Surgeon General to clarify OCMH's position is unfair to Surgeon General Koop as well as the Hospital.

While Surgeon General Koop had informal contact with a member of the medical staff at OCMH, the authors of the May 8th letter and their clients made absolutely no effort to obtain information on OCMH policy or practice. Dr. Koop's informal contacts do not excuse their failure to make inquiry at OCMH, especially in light of the invitation extended to Martin Gerry. If they didn't want to bother with coming to Oklahoma, they could have at least written or called. Moreover, DHS and OCMH's policies on this subject are a matter of public record which could have been procured and reviewed by local counsel, Mr. Fairbanks, with a minimum of effort.

As indicated in the cover letter, DHS and OCMH are quite prepared to undergo a full review by outside experts.

A F F I D A V I T

STATE OF OKLAHOMA    )  
                                  )ss,  
COUNTY OF OKLAHOMA)

I, E. Ide Smith, M.D., the undersigned, do state and affirm that during 2 recent conversations with C. Everett Koop, M.D., the Surgeon General of the United States, I advised Dr. Koop that Oklahoma Children's Memorial Hospital was in compliance with the Federal Baby Doe regulations with an active Infant Care Review Committee. I further advised Dr. Koop that there was no practice in which newborn handicapped children were selected for a particular treatment by use of a quality of life formula or any other non-medical considerations. Our conversations took place, first by phone during the summer of 1984 and, second, during an incidental meeting at a medical conference in Chicago in the fall of 1984.

E. Ide Smith  
E. Ide Smith, M.D.  
Chief of Pediatric Surgery  
Oklahoma Children's Memorial Hospital,

Signed and sworn before me this 22<sup>nd</sup> day of May, 1985.

Shirley Dents, NOTARY PUBLIC  
My commission expires April 5, 1986

A F F I D A V I T

STATE OF OKLAHOMA )  
                          ) ss.  
COUNTY OF OKLAHOMA )

We, the undersigned, are currently members of the Myelomeningocele Team or the Administration at Oklahoma Children's Memorial Hospital. The purpose of this team is to provide a multi-disciplinary approach in order to facilitate and provide the optimal level of care for newborns and permanent follow-up of myelomeningocele patients. As part of this approach the team assists the family with understanding and preparing for the consequences of this condition. The team is always available for any type of consultation.

By providing this approach, the Myelomeningocele Team is best able to be of service to the family. Unless a newborn child is so profoundly ill that to provide treatment would only prolong the act of dying, then the full spectrum of medical treatment is aggressively provided. This team does not now nor to any members' knowledge have they ever made any recommendation to a family on the basis of a quality of life formula, race, economic status, or any other non-medical considerations.

Michael Pollay  
Michael Pollay, M.D.  
Myelomeningocele Team Member

Signed and sworn before me this 20<sup>th</sup> day of May, 1985.

Shirley Dent, NOTARY PUBLIC  
My commission expires April 5, 1986

David A. Yngve  
David A. Yngve, M.D.  
Myelomeningocele Team Member

Signed and sworn before me this 20<sup>th</sup> day of May, 1985.

Shirley Dent, NOTARY PUBLIC  
My commission expires April 5, 1986

William F. Barnes  
William F. Barnes, M.D.  
Myelomeningocele Team Member

Signed and sworn before me this 22<sup>nd</sup> day of May, 1985.

Shirley Dent, NOTARY PUBLIC  
My commission expires April 5, 1986

Harriett Cousins  
Harriett Cousins, M.D.  
Myelomeningocele Team Member

Signed and sworn before me this 21<sup>st</sup> day of May, 1985.

Shirley Dent, NOTARY PUBLIC  
My commission expires April 5, 1986

Laura Fok, PA-C  
Laura Fok, PA-C  
Myelomeningocele Team Member

Signed and sworn before me this 20<sup>th</sup> day of May, 1985.

Shirley Hunt, NOTARY PUBLIC  
My Commission expires April 5, 1986

Ruth Tatyrek, MSW  
Ruth Tatyrek, MSW  
Myelomeningocele Team Member

Signed and sworn before me this 21<sup>st</sup> day of May, 1985.

Shirley Hunt, NOTARY PUBLIC  
My commission expires April 5, 1986

Owen M. Rennert, M.D.  
Owen M. Rennert, M.D.  
Chief of Staff  
Oklahoma Children's Memorial Hospital

Signed and sworn before me this 22<sup>nd</sup> day of May, 1985.

Shirley Hunt, NOTARY PUBLIC  
My commission expires April 5, 1986

Donald F. Goeritz  
Donald F. Goeritz  
Administrator  
Oklahoma Children's Memorial Hospital

Signed and sworn before me this 20<sup>th</sup> day of May, 1985.

Shirley Hunt, NOTARY PUBLIC  
My commission expires April 5, 1986

Antonio A. Fazilla  
Antonio A. Fazilla  
Chief Executive Officer  
Oklahoma Teaching Hospitals

Signed and sworn before me this 20<sup>th</sup> day of May, 1985.

Shirley Hunt, NOTARY PUBLIC  
My commission expires April 5, 1986

OKLAHOMA CHILDREN'S MEMORIAL HOSPITAL  
INFANT CARE REVIEW COMMITTEE

I. MEMBERSHIP:

The membership of this committee will be appointed by the OCMH Chief of Staff and the OTH Executive Chief of Staff. The committee membership will include, at a minimum, the following:

- (1) at least two physicians who practice pediatrics, pediatric surgery, or a surgical subspecialty practice serving primarily pediatric patients and who are members of an OTH medical staff;
- (2) a member of the legal profession (other than the primary OTH legal counsel);
- (3) a hospital administrator;
- (4) a practicing pediatric registered nurse (R.N.);
- (5) a doctoral level specialist in developmental disabilities;
- (6) a representative of the lay public.

A physician member will be appointed as chairman by the chief of staff.



## II. PURPOSES:

The purposes of the committee will be the following:

- \*\*\*\*\* (A) to develop and implement standards, policies, and procedures for the Oklahoma Teaching Hospitals to assure that potentially medically beneficial treatments and/or nourishment be provided for all infants regardless of handicap or anticipated physical or mental impairments.

### Amendment

Submitted to and  
approved by the  
Governing Body  
12-04-84

These standards will be designed to respect reasonable medical judgements and will be directed by the principles stated in:

- (1) 45CFR 84.55 and Appendix C of 45CFR Part 84 (published in the Federal Register, January 12, 1984).
- (2) House Bill No. 1133 (1984 Okla. Sess. Laws Serv., Ch. 120, p.390) (West)(to be codified as 10 O.S. §1101) and Section 18, House Bill No. 1528 (effective July 1, 1984).
- (3) "The Principles of Treatment of Disabled Infants", published by the American Academy of Pediatrics on November 29, 1983, where  
\*\*\*\*\* not inconsistent with the federal and state provisions above.

- (B) to provide emergency review of selected cases in which withdrawal or withholding of life-sustaining therapy is contemplated, particularly those cases in which there is concern by the patient's caretakers or parents that the infant's rights to care are in jeopardy. Such emergency review may be sought on a 24 hour basis at the request of the ICRC or the hospital staff, or the infant's parent or guardian.
- (C) to review regularly and retrospectively records involving withholding or withdrawal of therapy from infants to assure compliance with the established standards for care.

### III. DETAILS OF COMMITTEE FUNCTION:

- (A) Regular meetings will be held at a monthly interval.
- (B) A quorum will be determined by attendance of 51% of the membership and must include at least 2 physician members in attendance.
- (C) A majority shall consist of 51% of the membership present and voting.
- (D) Each committee member will designate an alternate, who will be available on an ad hoc basis in the regular member's absence.
- (E) Emergency meeting of the committee to review specific cases will be convened by the chairman as needed, within 24 hours notice to the membership.
- (F) All deliberations of the committee shall be kept confidential, and shall be released to government authorities only as required by law or court order or after clearance by the hospital's legal counsel.
- (G) All guidelines and policies of the ICRC will be reviewed by the hospital's legal counsel to assure conformity with the hospital's by-laws, rules, and regulations.
- (H) All guidelines and policies must be approved by the respective hospital's Chief of Staff and Executive Committees, by the OTH

Executive Chief of Staff, by the Director of the Department of Human Services, and by the governing body of the Department of Human Services.

IV. GENERAL PRINCIPLES GOVERNING CARE OF THE SEVERELY HANDICAPPED INFANT:

- (A) Beneficial medical therapy for a life-threatening condition shall be provided for all infants regardless of mental or physical handicap.
- (B) The determination of "medically beneficial" therapy shall be made on the basis of a total evaluation of each patient's medical status.
- (C) Appropriate care shall be provided to all infants regardless of financial or social resources.
- (D) All infants will be provided with warmth, nourishment, and routine care.
- (E) Medical care beyond basic nourishment and sustenance is not required for dying infants.
- (F) Patients judged to be dead ("brain dead") by currently accepted medical criteria need receive no further medical care.
- (G) In all instances, parents and legal guardians of all infants must be informed of their infant's condition and must be informed of and

involved in all decisions concerning the appropriateness of the withholding or withdrawal of care from the infant.

- (H) Specific standards for the care of specific conditions will be made consistent with the principles noted above in II.A., and after consultation with appropriate medical specialists within the hospital and after review of the collective medical knowledge and experience with these conditions.

Approved Infant Care Review Committee

March 15, 1984

Approved by Medical Care Committee	4/09/84
Approved by Executive Committee	4/30/84
Approved by Governing Body	7/12/84 (OCMH Exec. Cmte. Minutes)
Approved by Governing Body	9/25/84
AMENDMENT approved by Governing Body	12/04/84

ATTEST:

(SEAL.)

Sharon Sharp  
Sharon Sharp, Secretary to Commission

EXCERPT FROM MINUTES:

MEETING OF OKLAHOMA COMMISSION FOR HUMAN SERVICES

February 28, 1984

ATTEST:

(SEAL)

  
Sharon Sharp, Secretary to Commission

REGULATIONS ON HEALTH CARE FOR HANDICAPPED INFANTS

Mr. Fulton discussed a memorandum mailed in advance to the Commission concerning Federal "Baby Doe" Regulations. This memo sets out the recommendations of a task force which was formed by the Department and headed by Dickye Mines to develop policies and procedures for consideration by the Commission. Item c of the memorandum still requires work and the detailed procedures will come back to the Commission for further review. The Director recommended the Commission to approve the three procedures set out in the memorandum as the components of the implementation process on the understanding that there is still work to be completed on item c. The policy must be in effect by April 13th.

Commissioner Gilbert made a motion to approve the procedures as recommended by the Director. Commissioner Ward seconded the motion.

Voting aye: Commissioners Farha, Furr, Gilbert, Hartley,  
Walters, Ward, Way, Chairman Barnes.  
Unanimously adopted.

Chairman Barnes then recessed the meeting for a short break.

STATE OF OKLAHOMA  
DEPARTMENT OF HUMAN SERVICES

To: Commission for Human Services      Date: February 21, 1984

From: Robert Fulton      Attention:  
Director

Subject: Federal "Baby Doe"      In Reply—Address to  
Regulations      Attention: \_\_\_\_\_  
Non-Discrimination in Programs  
and Activities Receiving or  
Benefiting from Federal Financial  
Assistance--Handicapped Infants  
Effective Date: February 13, 1984

The final Federal rules regarding medical treatment for handicapped infants (also known as the "Baby Doe" regulations) have recently been passed. The major elements of the final rules are:

- 1) The Federal government encourages hospitals to establish review procedures regarding life and death decisions affecting seriously ill newborns.
- 2) Informational notices regarding the legal rights of handicapped infants must be posted in hospitals.
- 3) State child protective services agencies must have established procedures for applying their own state laws protecting children from medical neglect.
- 4) Interpretive guidelines require that health care providers not withhold nourishment or medically beneficial treatment from the handicapped infant solely on the basis of present or anticipated physical or mental impairments. However, it does not interfere with reasonable medical judgements nor require provision of futile treatment.
- 5) Guidelines are also set for HHS investigations of alleged civil rights violations relating to health care for handicapped infants.

State child protective services agencies have 60 days and hospitals have 30 days within which to establish and maintain methods of administration and procedures.

A task force was formed to set Department's policies and procedures to be approved by the Commission. Following are the three major procedures which will need Commission approval:

a) Infant Care Review Committee:

This was not required but it was encouraged. OTH will follow the recommended guidelines. A review committee, headed by Doctor Mary Anne McCaffree, has been appointed. When a case is reviewed by this Committee, the Protective Services Unit of DHS will also be notified. If the Protective Services Unit is notified first, they will contact the hospital review committee.

b) Posting of Informational Notice:

The Federal Government has sent to each hospital receiving Federal funds a copy of the final regulations. It will be their responsibility to post the notices as outlined in the regulations. The Department is sending to each hospital the phone number of the DHS county office to which calls of alleged child abuse or neglect should be reported, the statewide child abuse hotline number, and the Federal hotline number which is already listed in the regulations. The DHS Audit and Review Division makes a yearly inspection for compliance with Federal civil rights of the handicapped requirements and will add checking of the Baby Doe postings to its inspections.

c) Responsibilities of DHS for Child Protective Services:

There is already in place in each county a procedure for receiving of reports of child abuse as required by State and Federal Law. This added responsibility will be handled in the same manner as all other child abuse incidents with the exception that as soon as a possible incident is reported the county staff will call the State Office Child Abuse Unit. It will be the State Office's responsibility to assure that the Federal Office of Civil Rights is notified of each incident. Written policies and procedures will be issued prior to the deadline date of April 13, 1984.

Fritz Aurin and Deborah Rothe have been in touch with Ms. Eleanor Hadad with the Office of Civil Rights in the HHS Regional Office in Dallas. There are questions regarding the definition of "infant" which she plans to clear through the HHS office in Washington. She has also assured the Department that they (HHS) have been responsible for notifying all hospitals. She further clarified that the rules applied only to hospitals and not individual doctors or local health clinics.

With the policies and procedures described above, it is our opinion DHS will be able to make an assurance to HHS that all aspects of the regulations will be implemented.

Thank you for consideration of this request.

*Robert Felton*



EXCERPT FROM MINUTES:

MEETING OF OKLAHOMA COMMISSION FOR HUMAN SERVICES

March 27, 1984

ATTEST:

(SEAL)

  
Sharon Sharp, Secretary to Commission

REGULATIONS ON HEALTH CARE FOR HANDICAPPED INFANTS

The Director discussed briefly the procedures approved at the last meeting regarding the Federal "Baby Doe" Regulations. He reviewed the original memo to the Commission which stated that written policies and procedures would be issued at a later date. had informed the Commission at the last meeting that such policies and procedures would be presented at this meeting. The Commission was furnished in advance with a copy of the proposed policies and procedures regarding alleged medical neglect of handicapped infants (attached).

Commissioner Way made a motion to approve the policies and procedures as presented by the Director. Commissioner Farha seconded motion.

Voting aye: Commissioners Farha, Furr, Gilbert, Greer,  
Hartley, Ward, Way, Chairman Barnes.  
Unanimously adopted.

Re: Federal "Baby Doe" Regulations-

These procedures will be issued by 04-06-84 in the protective Services Handbook and incorporated in Manual Section 620 when it is reissued.

CHILD WELFARE PROCEDURE - ALLEGED MEDICAL NEGLECT OF HANDICAPPED INFANTS

Every report alleging denial of medically beneficial treatment to a handicapped infant shall be promptly investigated and preventive services offered.

Referrals will generally be made to CWU via the county office (as in the case of most other abuse/neglect referrals) or via the statewide child abuse hot line. These phone numbers are required to be posted by the medical provider along with the HHS toll-free number (800-368-1019.)

When such referrals are received, the county office shall immediately notify State Office, Child Abuse Section. The state office is responsible for statewide tracking and notifying the Federal Office of Civil Rights.

Generally, the investigative and post-investigative procedure in these cases will be the same as in other investigations of reported abuse/neglect. The investigation shall be conducted as expeditiously as possible and the Report To The District Attorney, CSU-14-A, submitted promptly as usual.

In the event court intervention is felt to be warranted, appropriate steps should be taken as in other abuse/neglect cases. However, State Office, Child Abuse Section shall also be immediately advised. In the event it becomes necessary to apprise the Office of Civil Rights of the situation prior to completion of the investigation, this shall be the responsibility of the State Office.

Although it is recognized that protective services workers do not usually have the medical expertise necessary to make a determination regarding appropriate medical care, it is also recognized that the workers do have the necessary knowledge and skill to investigate and draw a conclusion based on interviews with and statements taken from qualified medical care providers.

In many hospitals, Infant Care Review Committee (ICRC) will be established for the purpose of reviewing the care provided to critically ill handicapped infants. The establishment of the ICRC is a recommendation rather than a requirement, however. Where there is an ICRC, the protective services worker shall consult with the ICRC as a part of the investigation. In situations where there is not an ICRC, other appropriate medical personnel shall be interviewed.

Generally, the investigation shall include interviewing the complaintant; the parents; obtaining the infant's diagnosis, prognosis, and recommended course of treatment from the attending physician; and interviewing either an ICRC representative and/or other medical personnel as appropriate to the individual case.

## Appendix E

### Federal Affected Agency Answers



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

OCT 12 1988

Mr. William J. Howard  
General Counsel  
United States Commission  
on Civil Rights  
1121 Vermont Avenue, N.W.  
Washington, D.C. 20425

Dear Mr. Howard:

We have received your letter of September 20, 1988, with portions of the draft report on medical discrimination against handicapped infants prepared by the U.S. Commission on Civil Rights. Based on our review of the draft chapters, it appears that you have misinterpreted the purpose and intent of the Office of Inspector General (OIG) inspection on the baby doe program. Our comments are as follows:

Chapter 12, The Role and Performance of the Federal Government

- o Your statement on page two that the OIG study was conducted "in response to the requirement of the Child Abuse Amendments..." is incorrect. The study was conducted in response to a request from the U.S. Surgeon General and the Office of Human Development Services, Administration for Children, Youth and Families.
- o Also, your statement on page two that Inspector General personnel did not understand the requirements of the child abuse amendments and did not make appropriate inquiries to determine whether they are being carried out, indicates your lack of understanding of the purpose and intent of our study. Our next comment reinforces this point.
- o On page three, you state that the OIG failed to review the facts in unreported cases considered by hospital infant care review committees. The purpose of our hospital visits was to determine how hospital committees

are structured and functioning to deal with potential baby doe situations. It was never our intent to review individual case files. As you know, while the Department of Health and Human Services did publish model guidelines for infant care review committees, there is no Federal requirement regarding the establishment, structure or functioning of such committees in hospitals.

- o Your statement on page four about our description of the infant bioethical review committees at four affiliated hospitals in New York is misleading. The purpose of this portion of the report was simply to serve as a reference to other hospitals considering the establishment of similar committees.

Chapter 10, Child Protective Service Agencies

- o Your statements on pages 12 and 16 regarding the "official" nature of comments from respondents from State Child Protective Service (CPS) agencies are incorrect. The comments made by respondents in this study were the personal opinions of professional staff familiar with the baby doe program and how it fits into the State's entire range of child protective services. They did not represent the "official and public position" of State CPS agencies.

We appreciate the opportunity to comment. If your staff have questions, they may contact Ta Zitans at 245-2456.

Sincerely yours,



Richard P. Kusserow  
Inspector General



U.S. Department of Justice

Civil Rights Division

Office of the Assistant Attorney General

Washington, D.C. 20530

OCT 26 1988

William J. Howard, Esquire  
General Counsel  
United States Commission On  
Civil Rights  
1121 Vermont Avenue, N.W.  
Washington, D.C. 20425

Dear Mr. Howard:

I have reviewed the September 19, 1988, draft report of the United States Commission on Civil Rights on medical discrimination against handicapped infants. The description of the activities of the Civil Rights Division with respect to the matters discussed in the report appears accurate. I would note, however, that in 1983 the Department of Health and Human Services referred a matter to the Division involving possible discrimination against a newly born handicapped infant at a hospital in Stoneybrook, New York. We sought to obtain certain medical records, but were blocked in our efforts by a federal district court in New York. If you believe information relating to the Stoneybrook situation would be useful to include in your report, I will have the appropriate records retrieved and provide you with whatever details you need.

If I can be of any further assistance, please feel free to contact me.

Sincerely,

Wm. Bradford Reynolds  
Assistant Attorney General  
Civil Rights Division



NOV 31 1988

Assistant Secretary  
Washington DC 20201

William J. Howard  
General Counsel  
United States Commission  
on Civil Rights  
1121 Vermont Avenue, N. W.  
Washington, D.C. 20425

Dear Mr. Howard:

I am writing in response to your request for comment on Chapter Ten of the Draft Report of the U.S. Civil Rights Commission, entitled "Child Protective Services Agencies and Their Enforcement of the Child Abuse Amendments of 1984." This chapter concerns State implementation of the provisions of the 1984 amendments to Public Law 100-294 concerning medical neglect of handicapped infants.

We are extremely concerned about your findings which indicate that a number of State Child Protective Service (CPS) agencies may fail to meet the requirements for Federal funding as provided for in 45 CFR 1340.15, and your statement that the Department of Health and Human Services has incorrectly certified them as eligible. The issues you raise are indeed serious.

Your report also makes clear that in addition to the possible deficiencies of specific State programs, there are larger societal attitudes and practices which may complicate the fulfillment of Congressional intent in this matter. These include the ambivalence of some CPS agency staff about whether the withholding of medically indicated treatment from disabled infants with life-threatening conditions is appropriately a CPS responsibility; the possible ambivalence on the part of some social work and medical professionals about whether this rightfully should be a decision made by a child's parents with advice from a physician; and as also noted in the report, societal attitudes which often view disabled children as a burden to their parents and communities.

In 1985, when the first grants were awarded to protect infants from medical neglect, the Department followed the procedures set forth in Section 45 1340.15 of the Code of Federal Regulations for certifying the eligibility of States to receive funds. This involved the review of State statutes, programs, policies and procedures for compliance with the requirements of the legislation. Each year following 1985, States have been asked to submit any changes in any of these documents and to certify that they remain eligible. Each year the Regional Administrators of the Office of Human Development Services, working with other regional office staff and the regional counsel, have had the responsibility for reviewing the materials submitted by the States and forwarding to the Commissioner of the Administration for Children, Youth and Families their opinion as to whether the States are in compliance. Funds are awarded by the regional offices to those States that are in compliance based on that verification. In any instance of denial, the Assistant Secretary makes the final determination of ineligibility. So far as we know, only States in compliance have been funded.

Because of the information compiled in your report, we will take two actions. First, we will convene a staff workgroup in the Office of Human Development Services, which includes the Administration for Children, Youth and Families and the Administration on Developmental Disabilities. These agencies have a particular interest, responsibility and expertise in this subject. This group will review our current policies and instructions to determine if there are ways in which we can improve the administration of the Federal program and the use of Federal funds to accomplish its purposes. As part of this effort we will consult with selected States, individuals and organizations outside the government who have a particular interest or expertise. We especially would seek advice on how we can help States encourage and strengthen information, education and training programs so that all appropriate cases of medical neglect are identified and services provided.

These efforts may assist us in obtaining more accurate data about the actual number of cases of medical neglect of handicapped infants, and developing strategies for more effectively serving this population.


Second, we will review the eligibility of each State cited in your report, paying special attention to those areas of concern that you have identified.

Page 3 - William J. Howard

Our efforts will be facilitated if we can review the complete draft of your report and all supporting documentation of your findings, including reference materials such as citations from State laws, regulations, manuals and protocols. We will appreciate your sharing this additional information with us.

Please be assured of our commitment to ensure that all States which receive child abuse State grants meet all of the requirements of Federal law and regulations.

Sincerely,

  
Sydney Olson  
Assistant Secretary for  
Human Development Services



## Appendix F

### *In re Infant Doe*

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# *Declaratory Judgment in the Infant Doe Case*

In the Circuit Court of the County of Monroe  
State of Indiana

In the Matter of the Treatment  
and Care of Infant Doe

Cause No. GU 8204-004A

### Declaratory Judgment

This matter came to be heard by the Court under certain extraordinary conditions concerning the emergency care and treatment of a minor child born at the Bloomington Hospital.

The Court was contacted at his residence by representatives of the Bloomington Hospital. On the basis of representations made by those representatives, the Court quickly determined that an extreme emergency existed.

The Court further determined that the Judge of the Monroe Circuit Court had been contacted concerning this matter and was unable to attend the emergency hearing, and the Court personally contacted the judge of the Monroe Circuit Court who directed this Court to proceed with hearing. Thereafter, hearing was held on the Sixth Floor of the Bloomington Hospital at approximately 10:30 P.M., Saturday, the 10th day of April, 1982.

The following persons were present: John Doe, natural father of Infant Doe, with counsel, Andrew C. Mallor, Esquire; Maggie Keller, Gene Perry, Administrative Vice-Presidents of Bloomington Hospital; Dr. Walter L. Owens, Dr. William R. Anderson, Dr. Brandt L. Ludlow, obstetricians admitted to practice in the State of Indiana with privileges at Bloomington Hospital, Doctor Owens being the obstetrician in attendance at delivery at Infant Doe; Dr. Paul J. Wenzler, family practitioner with pediatric privilege at Bloomington Hospital and who has attended to Mr. and Mrs. Doe's other two children after their birth; Dr. James J. Schaffer and Dr. James J. Laughlin, pediatricians holding pediatric privileges at Bloomington Hospital. (Mrs. Doe was physically unable to attend.)

The Court thereafter heard evidence. Doctor Owens spoke for and on behalf of the obstetric group that delivered the Infant Doe, advising the Court that at approximately 8:19 P.M. on the evening of April 9, Infant Doe was born to Mary Doe in an uneventful delivery, but that shortly thereafter it was very apparent that the child suffered from Down's syndrome, with the further complication of trachioesophageal fistula, meaning the passage from the mouth to the stomach had not appropriately developed and, in fact, were the child to be fed orally, substances would be taken into the lungs and the child most likely would suffocate.

Doctor Owens further stated that he had been previously advised that Doctor Wenzler would serve as practitioner for Infant Doe and that he was further advised that Doctor Wenzler, when faced with extraordinary cases, routinely consulted with Doctor Schaffer. Doctor Schaffer was at the Bloomington Hospital at that time and was called by Doctor Owens and was requested to examine the baby. Doctor Wenzler was notified. Doctors Owens, Schaffer and Wenzler consulted; Doctors Wenzler and Schaffer indicated that the proper treatment for Infant Doe was his immediate transfer to Riley Hospital for corrective surgery. Doctor Owens, representing the concurring opinions of himself, Doctors Anderson and Ludlow, recommended that the child remain at Bloomington Hospital with full knowledge that surgery to correct trachioesophageal fistula was not possible at Bloomington Hospital and that within a short period of time the child would succumb due to inability to receive nutriment and/or pneumonia.

His recommended course of treatment consisted of basic techniques administered to aid in keeping the child comfortable and free of pain. Doctor Owens testified that, even if surgery were successful, the possibility of a minimally adequate quality of life was non-existent due to the child's severe and irreversible mental retardation.

Doctor Schaffer testified that Doctor Owens' prognosis regarding the child's mental retardation was correct, but that he believed the only acceptable course of medical treatment was transfer to Riley Hospital in Indianapolis for repair of trachioesophageal fistula.

Doctor Wenzler concurred in Doctor Schaffer's proposed treatment. Doctor Laughlin testified that he concurred in the opinions of Doctors Schaffer and Wenzler, and he differed with Doctor Owens' opinion in that he knew of at least three instances in his practice where a child suffering from Down's syndrome had a reasonable quality of life. However, he related no knowledge of treatment of children with co-existent maladies of Down's syndrome and trachioesophageal fistula.

Doctor Owens testified that he presented Mr. and Mrs. Doe with the two recommended courses of treatment and requested that they come to a decision. Doctor Owens understood that Doctors Schaffer and Wenzler also discussed their recommendations with Mr. and Mrs. Doe.

Mr. Doe testified that he had been a licensed public school teacher for over seven years and had on occasion worked closely with handicapped children and children with Down's syndrome and that he and his wife felt that a minimally acceptable quality of life was never present for a child suffering from such a condition. Mr. Doe was lucid and able to make an intelligent, informed decision.

Mr. Doe testified that, after consulting with Doctors Owens, Schaffer, Wenzler and Laughlin, he and his wife have determined that it is in the best interest of the Infant Doe and the two children who are at home and their family entity as a whole, that the course of treatment prescribed by Doctor Owens should be followed, and at approximately 2:45 P.M., he and his wife, in the presence of each other and witnesses, signed a statement directing Doctor Owens to proceed with treatment of the infant, the content of said statement, omitting names and dates, is as follows:

The undersigned being the parents of Infant \_\_\_\_\_, born \_\_\_\_\_, at Bloomington Hospital, have had explained to them and they acknowledge that they understand, the course of this treatment for Infant \_\_\_\_\_ as indicated appropriate for Infant \_\_\_\_\_ by Doctors Walter L. Owens, James J. Laughlin, James J. Schaffer and Paul J. Wenzler.

Acknowledging their understanding and the consequences of all of the above proposals made by all of the above four physicians, that they direct that the course of treatment shall proceed as directed by Dr. Walter Owens, M.D., who does not have privilege to practice pediatrics at Bloomington Hospital.

Mr. Len E. Bunger, on behalf of Bloomington Hospital, made a statement that it was the hospital's primary function to reduce morbidity and mortality and that the hospital did not have the knowledge or the authority to make diagnoses or to prescribe treatment and, for that reason, had requested the Court to make a ruling in this matter.

The Court, having heard evidence, recesses and thereafter determines as follows:

1. All qualified persons available to present evidence in this matter were present and thus appointment of a guardian ad litem for Infant Doe was not required to proceed further in this hearing.

2. The Court appeared solely as a representative of the State of Indiana and the laws of the State of Indiana require that the parents be sufficiently informed, as they are in this instance, and any personal feelings of the Court should not intervene.

#### **Issue**

Do Mr. and Mrs. Doe, as the natural parents of Infant Doe have the right, after being fully informed of the consequences, to determine the appropriate course of treatment for their minor child?

#### **Conclusion**

It is the opinion of this Court that Mr. and Mrs. Doe, after having been fully informed of the opinions of two sets of physicians, have the right to choose a medically recommended course of treatment for their child in the present circumstances.

#### **Order**

The Court, being sufficiently advised, now directs the Bloomington Hospital to allow treatment prescribed by Dr. Walter Owens, as directed by the natural parents, Mr. and Mrs. Doe, for the Infant Doe.

The Court further directs that the Clerk of this Court assign a cause number and enter this cause upon the guardianship docket and fee book of this Court.

The Court further appoints the Monroe County Department of Public Welfare as guardian ad litem for the Infant Doe to determine whether the judgment of this Court should be appealed.

Dated this 12th day of April, 1982.

JOHN G. BAKER  
Judge, Monroe Superior Court  
Division III, and as  
Special Judge, Monroe Circuit Court

**Appendix G**

**Section 504 Final Rule**

**Federal Register**

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**Thursday  
January 12, 1984**

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**Part III**

**Department of  
Health and Human  
Services**

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**Office of the Secretary**

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**45 CFR Part 84  
Nondiscrimination on the Basis of  
Handicap; Procedures and Guidelines  
Relating to Health Care for Handicapped  
Infants; Final Rule**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### 45 CFR Part 84

#### Nondiscrimination on the Basis of Handicap; Procedures and Guidelines Relating to Health Care for Handicapped Infants

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Final rules.

**SUMMARY:** These are final rules on procedures and guidelines relating to nondiscrimination on the basis of handicap in connection with health care for handicapped infants. These rules are issued under the authority of section 504 of the Rehabilitation Act of 1973, which prohibits discrimination on the basis of handicap in programs and activities receiving Federal financial assistance.

**EFFECTIVE DATE:** February 13, 1984.

**FOR FURTHER INFORMATION CONTACT:** Susan Shaloub, Office for Civil Rights, Department of Health and Human Services, 330 Independence Avenue, SW., Room 5514, Washington, D.C. 20201; telephone (202) 245-6585. TDD No. (202) 472-2916.

#### SUPPLEMENTARY INFORMATION:

##### I. Synopsis

These rules are the product of a careful analysis of nearly 17,000 comments submitted to the Department during the comment period provided by the proposed rules of July 5, 1983. On the basis of this analysis, the Department has made significant modifications to the proposed rules. These modifications are designed to establish a framework under which the substantial controversy that has attended the Department's efforts to strengthen enforcement of section 504 in this area can be replaced by a more cooperative effort involving the Federal Government, the medical community, private advocacy groups and state governments.

These final rules continue the Department's efforts to put in place an effective mechanism for enforcing section 504 in connection with health care for handicapped infants.

But they also initiate new efforts to make unnecessary the use of those Federal enforcement mechanisms by encouraging hospitals to establish policies and procedures to implement the principle that treatment decisions for handicapped infants be based on reasonable medical judgments, and medically beneficial treatment not be withheld solely on the basis of an

infant's present or anticipated mental or physical impairments.

In seeking to forge a cooperative approach, the Department is encouraged by the recent development of "Principles of Treatment of Disabled Infants" by the following major medical and disability organizations: American Academy of Pediatrics, National Association of Children's Hospitals and Related Institutions, Association for Retarded Citizens, Down's Syndrome Congress, Spina Bifida Association of America, American Coalition of Citizens with Disabilities, The Association for the Severely Handicapped, American Association on Mental Deficiency, and American Association of University Affiliated Programs for the Developmentally Disabled. Announced November 29, 1983, in Washington, D.C., these principles state:

When medical care is clearly beneficial, it should always be provided. \* \* \* Considerations such as anticipated or actual limited potential of an individual and present or future lack of available community resources are irrelevant and must not determine the decisions concerning medical care. The individual's medical condition should be the sole focus of the decision. These are very strict standards.

It is ethically and legally justified to withhold medical or surgical procedures which are clearly futile and will only prolong the act of dying. However, supportive care should be provided, including sustenance as medically indicated and relief of pain and suffering. The needs of the dying person should be respected. The family also should be supported in its grieving.

In case where it is uncertain whether medical treatment will be beneficial, a person's disability must not be the basis for a decision to withhold treatment. \* \* \* When doubt exists at any time about whether to treat, a presumption always should be in favor of treatment.

In the issuance of these final rules, the Department seeks to build upon the spirit of cooperation underlying this landmark statement of principles. The major elements of the final rules are as follows:

First, the Department adopts the recommendation of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research that the Federal government encourage hospitals to establish review procedures concerning life and death decisions affecting seriously ill newborns. The rules include a model Infant Care Review Committee to assist hospitals in this effort.

Second, the rules require the posting in hospitals of an informational notice regarding the legal rights of handicapped infants. The notice

requirements have been revised to permit hospitals to highlight their own policies and internal review procedures, in addition to the federal law and government contact points.

Third, the rules require that state child protective services agencies have established procedures for applying their own state laws protecting children from medical neglect.

Fourth, the appendix to the rules sets forth interpretative guidelines for applying the law in these cases. These guidelines restate the Department's interpretation that section 504 requires that health care providers not withhold nourishment or medically beneficial treatment from a handicapped infant solely on the basis of present or anticipated physical or mental impairments, but it does not interfere with reasonable medical judgments, nor require the provision of futile treatments.

Fifth, the appendix to the rules sets forth guidelines for HHS investigations of alleged civil rights violations relating to health care for handicapped infants. These guidelines provide for the participation of hospital Infant Care Review Committees, the avoidance of unnecessary investigations, the involvement of qualified medical consultants, and the protection of confidential information.

The Department hopes the issuance of these rules, which become effective in 30 days, will end the controversy that has surrounded their development. But more importantly, it is hoped the rules will foster a new process of cooperative efforts and sensible approaches to advance the principle that life and death medical treatment decisions be based on informed judgments of medical benefits and risks, and not on stereotypes and prejudices against handicapped persons.

##### II. Background

On April 30, 1982, President Reagan instructed the Secretary of Health and Human Services:

to notify health care providers of the applicability of section 504 of the Rehabilitation Act of 1973 to the treatment of handicapped patients. That law forbids recipients of federal funds from withholding from handicapped citizens, simply because they are handicapped, any benefit or service that would ordinarily be provided to persons without handicaps. Regulations under this law specifically prohibit hospitals and other providers of health services receiving federal assistance from discriminating against the handicapped.

Our nation's commitment to equal protection of the law will have little meaning

if we deny such protection to those who have not been blessed with the same physical or mental gifts we too often take for granted. I support federal laws prohibiting discrimination against the handicapped, and remain determined that such laws will be vigorously enforced.

The President's instructions followed reports of the death, in Bloomington, Indiana, of an infant with Down's syndrome, from whom available surgical treatment to repair a detached esophagus was withheld.

On May 18, 1982, HHS issued to approximately 7,000 hospitals a notice stating:

Under section 504 it is unlawful for a recipient of federal financial assistance to withhold from a handicapped infant nutritional sustenance or medical or surgical treatment required to correct a life-threatening condition if: (1) the withholding is based on the fact that the infant is handicapped; (2) the handicap does not render the treatment or nutritional sustenance medically contraindicated.

Soon after this notice, the HHS Office for Civil Rights (OCR) established expedited investigative procedures to deal with any case of a suspected discriminatory withholding of lifesustaining nourishment or medical treatment from a handicapped infant.

On March 7, 1983, HHS issued, with a scheduled effective date of March 22, 1983, an interim final rule requiring recipient hospitals to post "in a conspicuous place" in pertinent wards a notice advising of the applicability of section 504 and the availability of a telephone "hotline" to report suspected violations of the law.

On April 14, 1983, the Honorable Gerhard Gesell, United States District Judge for the District of Columbia, declared the interim final rule invalid on the grounds that it was "arbitrary and capricious" and that there was inadequate justification for waiving a public comment period prior to issuance of the regulation. *American Academy of Pediatrics v. Heckler*, 561 F. Supp. 395 (D.D.C. 1983). Judge Gesell declined to order the Department to discontinue use of the hotline.

On July 5, 1983, HHS issued a proposed rule in which the notice requirement was revised; provisions were added concerning state child protective service agencies; an appendix of standards and examples was added; and a 60-day comment period was provided. 48 FR 30846.

The Department received 16,739 comments, of which 16,331 (97.5%) supported the proposed rule, and 406 (2.5%) opposed it. Other aggregate descriptions are:

- Of 322 nurses, 314 (97.5%) supported, and 8 (2.5%) opposed it.
- Of 141 pediatricians or newborn care specialists, 39 (27.7%) favored, and 102 (72.3%) opposed it.
- Of 253 physicians, not including pediatricians or newborn care specialists, 140 (55.3%) favored, and 113 (44.7%) opposed it.
- Of 137 comments from hospital officials and medical, hospital, nursing and other health related association, 31 (22.6%) supported and 106 (77.4%) opposed it.
- Of 77 comments from associations representing the handicapped, all supported the proposed rule.
- Of 100 parents of handicapped persons, 95 (95%) supported and 5 (5%) opposed it.

In addition to the written comments received, a number of meetings were held after issuance of the proposed rule with representatives of interested groups. The principal HHS officials involved in these meetings were the Under Secretary and the Surgeon General. Minutes of these meetings were kept and have been included in the public comment file.

Every comment was read and analyzed. Readers determined whether the commenter was in favor of, or opposed to, the proposed rule and identified particular points made by the commenter. The decisions made by the Department in connection with the rule are based not on the volume of comments advancing any point, but on thorough consideration of the merits of the comments submitted.

### III. Provisions of the Final Rules

#### A. INFANT CARE REVIEW COMMITTEES

The March 1983 report of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research included the following recommendation:

The Commission concludes that hospitals that care for seriously ill newborns should have explicit policies on decisionmaking procedures in cases involving life-sustaining treatment for these infants. . . . Such policies should provide for internal review whenever parents and the attending physician decide that life-sustaining therapy should be foregone. . . .

Such a review could serve several functions and the review mechanism may vary accordingly. First, it can verify that the best information available is being used. Second, it can confirm the propriety of a decision that providers and parents have reached or confirm that the range of discretion accorded to the parents is appropriate. Third, it can resolve disputes among those involved in a decision, if necessary, by siding with one party or

another in a dispute. Finally, it can refer cases to public agencies (child protection services, probate courts, or prosecuting attorneys) when appropriate.

In response to a question included in the preamble, the Department received many comments regarding hospital review boards. Many commenters who expressed opposition to the rule, particularly health care providers, expressed a strong preference for the hospital review board approach over the proposed rule or any implementation or enforcement of section 504. Others opposed hospital review boards, particularly as an alternative to the proposed rule and existing HHS procedures.

The American Academy of Pediatrics, which submitted the most detailed proposal, suggested, as an alternative to the proposed rule, that all hospitals, as a condition of participation in the Medicare program (not as a requirement of section 504), establish a review committee. Under this proposal (also endorsed by the National Association of Children's Hospitals and Related Institutions, and in concept, the American Hospital Association) the committee would have three functions: (1) To develop hospital policies and guidelines for management of specific types of diagnoses; (2) to monitor adherence through retrospective record review; and (3) to review, on an emergency basis, specific cases when the withholding of life-sustaining treatment is being considered. When the committee disagreed with a parental or physician decision to withhold treatment, the case would be referred to the appropriate court or child protective agency, and treatment would be continued pending a decision.

Committee membership would include a hospital administrator, a representative of a disability group, a lay community member, a member of the hospital's medical staff, and a practicing nurse.

Among the arguments advanced in favor of the creation of hospital review boards, as a substitute for the approach set forth in the proposed rule, were:

- (a) They would represent a cooperative approach between the government and the health care community, rather than a confrontational approach.
- (b) They would provide a vehicle by which facility "self-evaluations" can be conducted.
- (c) They would assure an indepth review by persons of varied perspectives of individual, complex cases involving critically ill infants.
- (d) They would provide a mechanism for ensuring that hospitals, physicians

and parents are informed of the most recent medical information concerning treatment of handicapped infants and of community services, counselling, parent support groups, and such alternative care options as adoption, foster care, and other out-of-home placements.

(e) They would lead to the involvement of child protective agencies and of the courts where it is indicated that the interests of the child are not being served.

Many commenters who expressed support for the proposed rule also expressed strong opposition to the alternative approach of hospital review boards because:

(a) Such boards cannot replace State and federal government responsibilities to protect the rights of citizens. The use of review boards would not assure that all individuals with disabilities would receive nondiscriminatory treatment as guaranteed by section 504.

(b) Such boards are virtually untested as a viable mechanism to protect handicapped infants from discriminatory practices.

A number of commenters, including the American Medical Association, the Catholic Health Association, the Federation of American Hospitals, the American College of Hospital Administrators, the American College of Physicians, the American Nurses Association, and other medical groups, expressed support for the concept of review boards, but opposed any mandate that review boards be established. The AMA added:

While we do not support federal intervention in treatment decisions concerning seriously ill newborns, the attention brought about by the government's action should provide a continued stimulus to develop mechanisms to deal with these sensitive matters without the intrusion of the federal government into an area where it does not belong.

#### Response

The Department believes there is much merit in many of the comments submitted both in favor of, and in opposition to, utilization of hospital review boards to assist in the development of standard policies and protocols and to review individual cases. The Department's conclusions are as follows.

First, the Department believes review committees cannot be given an exclusive role in reviewing medical decisions concerning the withholding or withdrawal of medical or surgical treatments from handicapped infants, and thus, cannot accept the proposal of hospital review boards as a *substitute* for mechanisms to enforce section 504.

The Department does not seek to take over medical decisionmaking regarding health care for handicapped infants.

HHS agrees that the best decisionmakers are generally the parents and the physicians directly involved. However, there is, and must be, a framework within which the decisionmakers, the parents and physicians, operate.

That framework is established by laws. With respect to health care professionals providing services under programs or activities receiving federal financial assistance, the framework includes section 504, which prohibits discrimination on the basis of handicap in programs or activities receiving Federal financial assistance. With respect to parents, the laws are state laws establishing limitations on parental authority. With respect to both the federal law and the respective state laws, each specifically provides implementation mechanisms involving government agencies.

The fundamental issue involved in deciding whether review boards should be a substitute for enforcement of section 504 is whether the legal framework within which the decisionmaking parents and physicians are supposed to function (and generally do function) will be utilized.

Under the proposal that review boards act in lieu of government, whether physicians or hospital review boards adhere to the principles of section 504 would be determined by those physicians and boards alone. Whether parents, physicians, or review boards adhere to state laws on the limitations of parental authority would be decided by the same physicians and boards. Whether they ever utilize the implementation schemes established by law to ensure that those principles are adhered to would also be decided by those parents, physicians, and review boards.

The Department concludes that the essential element of this alternative proposal—that it separates the process from the established legal framework governing decisionmaking by parents and physicians, with no meaningful provision to ensure that they function in accord with this framework—makes the proposal unacceptable as a substitute for the proposed rule. This alternative proposal simply does not provide sufficient safeguards that the requirements of section 504 will be met. Because section 504 is applicable to the provision of health care services to handicapped infants in programs and activities receiving Federal financial assistance, the Department believes it would not be justifiable for the

Department to refrain from exercising a regulatory role to enforce the statute.

Second, the Department concludes that, although unacceptable as a substitute, review boards can be very valuable. The Department agrees with the rationale of the President's Commission and many commenters that input from a committee that includes individuals with medical expertise and people with non-medical perspectives and that is guided by proper standards and protocols can be very helpful in bringing about informed, enlightened and fair decisionmaking regarding these difficult issues. The Department, therefore, adopts the recommendation of the President's Commission that the government encourage establishment of hospital review boards.

Third, the Department concludes that the creation of hospital review boards should not be mandated by the Federal government. The Department agrees with the President's Commission that because review boards are "largely untried", they are not so demonstrably effective as to justify making them mandatory for nearly 7,000 hospitals nationwide. Also, there would be very substantial practical problems in seeking to enforce such a mandate with respect to so many hospitals. To make such a mandate viable, it would have to be accompanied by detailed standards on how to organize and operate the committee. The Department agrees with the President's Commission that flexibility is needed for each hospital to consider the best approach for itself. For example, the review board procedures may be unnecessary for small or rural hospitals that rarely encounter cases involving severely impaired newborns and that handle such cases by immediately transferring the infant to the appropriate specialty hospital.

In addition, in view of the strong opposition by major medical organizations to mandatory committees, there would likely be protracted legal proceedings challenging the regulation, whether adopted pursuant to section 504 or pursuant to authority under the Social Security Act to establish conditions of participation and standards for the Medicare and Medicaid programs.

For these reasons, the Department has concluded that Infant Care Review Committees should be encouraged, but not mandated by the federal government.

Fourth, the Department concludes that the establishment of review boards will be facilitated by the development of a model committee. Therefore, § 84.55(f) of the rules sets forth a model Infant Care Review Committee (ICRC). This model

calls for broad representation and significant involvement of the ICRC in developing standard policies and protocols for the hospital and in promptly reviewing specific cases. The model is based substantially on comments submitted by the American Academy of Pediatrics.

The Department has revised the Academy's model somewhat to underscore that the purpose of the ICRC is to advance the basic principles embodied in section 504, the recommendations of the President's Commission and the landmark "Principles of Treatment of Disabled Infants." The Department has also revised the Academy's model to provide, in connection with review of specific cases, for the designation of one member of the ICRC as "special advocate" for the infant. While recognizing that all members of the ICRC should be advocates for the best interests of the infant, the role of the special advocate will be to ensure that all considerations in favor of the provisions of life-sustaining treatment are fully evaluated and considered. As the President's Commission stated, "it is all too easy to undervalue the lives of handicapped infants." The special advocate feature of the model ICRC provides a mechanism to counteract this tendency.

This model is also consistent with the recommendations of the President's Commission and the comments of the American Hospital Association and other medical organizations. The Department also acknowledges the comment of the American Medical Association that the government's actions provide "a continued stimulus" for the medical community "to develop mechanisms to deal with these sensitive matters." HFIS strongly encourages medical organizations to follow through on their suggestions and provide all possible assistance to their member institutions and medical professionals in establishing and operating these ICRC's.

#### B. INFORMATIONAL NOTICE

The proposed rules required that recipient hospitals post "in a conspicuous place in each nurse's station" of appropriate wards a notice stating:

DISCRIMINATORY FAILURE TO FEED AND CARE FOR HANDICAPPED INFANTS IN THIS FACILITY IS PROHIBITED BY FEDERAL LAW.

Any person having knowledge that a handicapped infant is being discriminatory denied food or customary medical care should immediately contact:

#### Handicapped Infant Hotline

Failure to feed and care for infants may also violate the criminal and civil laws of your state.

A number of commenters expressed a concern that the posting of the required notice would itself have a disruptive effect on the provision of health care to newborn infants by creating the impression to an infant's parents, already in a very stressful situation, that the physician, nursing staff, and hospital should not be trusted to provide proper care to their child. In connection with this point, the Catholic Health Association suggested that hospitals be permitted to use an alternative notice allowing the hospital to state its agreement with the policy of nondiscrimination and indicate the appropriate hospital contact person. Another comment suggested alternatives to posting, such as placing the notice on the admitting document or on consent forms used by the hospital.

Some commenters considered the wording of the notice very ambiguous in its references to "discriminatory failure" and "customary medical care" and in its failure to make reference to futile treatments, deference to legitimate medical judgments, the nonapplicability of section 504 to parental decisions, and many distinctions and nuances relating to the applicability of section 504 in this context.

Other criticisms were that the words "should immediately contact" improperly implied a legal obligation to report; the reference to "this facility" implied prior misconduct by that facility; and the reference to violations of "the criminal and civil laws of your state" is inappropriate because it does not relate to the purpose of the notice to inform people about civil rights protections.

A number of commenters suggested additions to the notice, including: a reference to the sanctions for noncompliance; express inclusion of handicapped infants born alive after abortions; reference to physical, mental, or emotional abuse or injury or withholding of fluids, oxygen, medications, warmth, and routine nursing care; and a statement that callers are not required to identify themselves.

Other commenters urged that hospitals be required to notify HHS that the notice has been posted.

#### Response

In an effort to accommodate many of these concerns, the Department has made a number of changes regarding the wording of the informational notice and

the locations where it is to be posted. However, the Department remains convinced of the need for a notice to advise individuals in a position to know about potentially discriminatory conduct of the requirements of the law and of the mechanisms available to report suspected violations expeditiously so that, should a violation be occurring, corrective action can be taken in time to save the infant's life.

In many other contexts of civil rights enforcement and enforcement of scores of other statutes, speed is not essential because the victim of discrimination can be essentially "made whole" through reinstatement in a job, admission to a school or hospital, retroactive benefit payments, or the like. However, in the context of life and death medical decisions, the matter must be handled with the utmost urgency. For this reason, the Department continues to believe that it is essential to meaningful implementation of the requirements of section 504 to have a mechanism for immediate reports of suspected violations.

However, the Department has concluded that it can, without detracting from this overriding objective, eliminate the unintended adverse effects of the notice many commenters perceived. Therefore, the informational notice requirements set forth in § 84.55(b) reflect significant modifications from those set forth in the proposed rules.

First, the Department has adopted the suggestion of the Catholic Health Association that hospitals be permitted to post a notice reflecting that the hospital's policy is consistent with the nondiscrimination requirements of section 504 and that the hospital also has a mechanism to review suspected noncompliance with this policy. This change eliminates any perception that the notice implies improper conduct by the hospital.

The only requirement contained in the rule for the use of this notice (identified in the regulation as "Notice A") is that the content of the notice be truthful as it relates to that hospital. To be truthful, the hospital must have a policy that nourishment and medically beneficial treatment, as determined with respect for reasonable medical judgments, should not be withheld from handicapped infants solely on the basis of their present or anticipated mental or physical impairments. Furthermore, the hospital must have a procedure for review of treatment deliberations and decisions concerning health care for handicapped infants. Also, so that potential callers will be assured that the hospital's procedures will be

implemented in good faith, the hospital's policies must provide for the confidentiality of the identity of, and prohibitions of retaliation against, potential callers who, in good faith and nonmaliciously, provide information about possible noncompliance. A hospital need not, in order to post Notice A, have an Infant Care Review Committee in conformance with the model ICRC, nor forego management prerogatives with respect to anyone who might abuse the hospital's procedures by, for example, willfully making false or malicious calls. Hospitals for which the content of "Notice A" is not truthful must post the notice identified as "Notice B."

Second, the requirement regarding the location where copies of the notice must be posted has been changed. Consistent with the Department's intent to target the notice to nurses and other health care professionals, the proposed rule required that the notice be posted at the nurses' stations of appropriate wards, rather than more generally in the wards as had been stated in the March interim final rule. In view of the concern expressed by a number of commenters that posting in the nurses' stations would continue to make the notice conspicuous to distressed parents, the final rules do not require that copies of the notice be posted at nurses' stations. Rather, the notice is to be posted at any location(s) where nurses and other medical professionals who are engaged in providing health care related services to infants will be aware of the content of the notice. Locations such as locker rooms and lounge areas will suffice as long as placement in these locations ensures that the appropriate personnel will see the notice. Under these circumstances the notice would not have to be posted at nurse's stations or any other location where posting would have adverse effects on parents. The number of copies which must be posted in the hospital is similarly determined on the basis of ensuring that the appropriate personnel will see it.

Third, in view of this more specific targeting, the size of the notice has been reduced from the 8 1/2 x 11 inches requirement in the proposed rule (and the 17 x 14 inch notices distributed in connection with the March rule) to 5 x 7 inches.

Fourth, the wording of the informational notice has been revised in connection with the language which attempts to convey in simple terms the basic protection of the law. The new language reflects the law's deference to reasonable medical judgments, refers to "medically beneficial treatment" and

clarifies that the concept of handicapped discrimination relates to decisions made solely on the basis of present or anticipated mental or physical impairments. The reference in the text of the notice and elsewhere in the rules to "present or anticipated mental or physical impairments" is based on the definition of "handicapped person" in existing regulations, 45 CFR 84.3(j). The Department believes this phrase conveys a better understanding than use of the word "handicap."

The Department has also changed the heading of the notice to eliminate what many perceived to be a negative statement. The revised notice adopts the same heading, "Principles of Treatment of Disabled Infants", adopted by the coalition of leading disability and medical organizations in their landmark statement of principles.

In seeking to compose the wording of the notice, the Department has sought to set forth a simple, understandable, and accurate description of the requirement of the law. To a significant degree, the application of section 504 in this context defies a simple and precise restatement. The wording of the notice, however, does not establish a legally mandated rule of conduct; it merely conveys information. In recognition of the impossibility of setting forth a statement that covers all possible dimensions and nuances of the statute, the notice advises that callers may obtain further information by calling the designated contact points.

The Department believes this statement resolves many of the concerns regarding ambiguity of the prior version of the notice without becoming so cumbersome and complicated that it confuses more than it informs.

Concerning other comments, the Department is not adopting the suggestion that hospitals be required to notify HHS that the notice has been posted. There are insufficient benefits accruing from establishing a mechanism for checking off approximately 7,000 unverified notifications of posting to justify the administrative burden on the Department and recipients.

In addition, consistent with the objective of targeting the notice to nurses and other medical professionals, and in view of concerns about frightening parents, the Department is not adopting the suggestion that the nondiscrimination notice be required on hospital admission or consent forms. However, the Department encourages hospitals and Infant Care Review Committees to consider seriously developing some written information for parents with respect to hospital policies

and procedures in connection with this issue. Such information could include an explanation of rights and responsibilities of parents, infants, and hospitals, the operation of the ICRC, available social services, and other pertinent information.

The Department is also not adopting numerous suggestions for additions to the notice because they are unnecessary and would make the notice cumbersome and possibly confusing. Statements concerning the existence of sanctions for noncompliance, the applicability of section 504 to infants born alive after abortions, the lawfulness of withholding futile treatments, and the applicability of section 504 to a wide range of aspects of medical care are all quite correct, but their inclusion in the notice is unnecessary.

The Department is not adopting the suggestion that the notice state that callers are not required to identify themselves. Although the Department will take appropriate follow-up action on anonymous calls that convey credible and specific information, the Department does not wish to encourage callers to remain anonymous because there is great value in having the ability to recontact the complainant as the inquiry or investigation progresses. The Department believes the statements contained in the notice regarding confidentiality of the identity of callers and prohibitions against retaliation are adequate to overcome the understandable reluctance a sincere potential complainant may have.

Finally, although the statement is correct, the Department adopts the suggestion that the reference to violations of state criminal and civil laws be deleted because it is unnecessary and potentially inflammatory.

### C. RESPONSIBILITIES OF CHILD PROTECTIVE SERVICES AGENCIES

A number of commenters addressed the provision of the proposed rule requiring that state child protective services agencies establish and maintain written methods of administration and procedures to ensure full utilization of their authorities pursuant to state law to prevent instances of medical neglect of handicapped infants.

Several child protective services agencies and their representatives opposed this provision. As stated by the National Council of State Public Welfare Administrators:

While the NCSPPWA agrees there is a need to establish additional protections for infants born with handicapping conditions. . . . we

believe the child protective services agency is not, as a rule, the appropriate authority to establish standards for medical treatment, to police the medical profession, or to make the kinds of medical/ethical judgments required in this area.

The State of Nebraska Department of Public Welfare expressed support for increased involvement of state child protective services agencies:

We feel that the agency with primary responsibility for investigation and enforcement of this law should be the State Protective Services Agency. We further would suggest that hospital administration be charged with the responsibility for reporting any possible violations of this law to the State Protective Services Agency. . . . The State Protective Services Agency should be responsible for reporting to the Office of Civil Rights the results of any actions taken as a result of the report. . . .

Some commenters urged deletion of the requirement that state agencies report cases to OCR because it conflicts with the confidentiality requirements of state child abuse and neglect statutes and presents an unnecessary administrative burden. Other commenters suggested that this requirement be expanded to require reports to OCR at each step of an agency's investigation. Other commenters suggested that state child protective services agencies be required to involve state protection and advocacy systems for the developmentally disabled in all of its activities related to this issue.

#### Response

Section G, below, includes a discussion of the applicability of section 504 in cases where a refusal to provide medically beneficial treatment is a result, not of decisions by a health care provider, but of decisions by parents. As explained in that section, it is the responsibility of the hospital in such a case to report the circumstances to the state child protective services agency. If that agency receives Federal financial assistance in its child protective services program, it may not fail, solely on the basis of the infant's present or anticipated physical or mental impairments, to utilize its full authority pursuant to state law to protect the infant. Although there are some variations among state child protective statutes, all have the following basic elements: a requirement that health care providers report suspected cases of child abuse or neglect, including medical neglect; a mechanism for timely receipt of such reports; a process for administrative inquiry and investigation to determine the facts; and the authority and responsibility to seek an

appropriate court order to remedy the apparent abuse and neglect, if it is found to exist.

Consistent with the applicability of section 504 to child protective services agencies and with the typical elements of state child protective statutes, the proposed rule included a subsection requiring that, within 60 days of the effective date, "each recipient state child protective services agency shall establish and maintain written methods of administration and procedures to assure that the agency utilizes its full authority pursuant to state law to prevent instances of medical neglect of handicapped infants."

This provision was modeled after an existing provision in the Department's regulation implementing title VI of the Civil Rights Act of 1964, 45 CFR 80.4(b), which requires all continuing state programs to have "such methods of administration for the program as are found by the responsible department official to give reasonable assurance" of compliance.

The proposed rule went on to specify several elements which must be included in the agency's methods of administration and procedures. Four of these elements precisely mirror the common fundamental components of state child protective statutes.

The proposed rule also called for immediate notification to the Department of each report of suspected medical neglect of a handicapped infant, the steps taken by the agency to investigate such report, and the agency's final disposition of such report. This requirement was also based upon an existing regulation, 45 CFR 80.6(b), which requires compliance reports "in such form and containing such information" as the Department may require. Therefore, the proposed rule's requirement for notification to OCR is simply a specification of a type of compliance report the Department deems necessary to monitor the recipient's compliance.

With respect to the comments concerning the potential conflict between this notification requirement and the confidentiality provisions of state child abuse and neglect statutes, this provision is entirely consistent with existing regulatory requirements of recipient child protective services agencies under 45 CFR 80.6(c), which includes the statement: "Asserted considerations of privacy or confidentiality may not operate to bar the Department from evaluating or seeking to enforce compliance with this part."

In addition, HHS regulations requiring, as a condition of receiving

Federal funds, state child protective services agencies to protect the confidentiality of child abuse and neglect information also make clear that HHS and the Comptroller General of the United States must have access to documents and other records "pertinent to the HHS grant." 45 CFR 1340.14, 74.24.

The Department has not adopted the suggestion that more detailed requirements be established for state child protective services agencies because the requirements should be flexible enough to be easily incorporated into existing agency procedures.

Section 84.55(c)(1) of the final rules adopts the corresponding provision of the proposed rules without substantive change. In summary, it simply restates existing section 504 responsibilities of recipient state child protective services agencies; requires standard procedures to assure compliance (as has been long required for continuing state programs under title VI); specifies the basic elements of those procedures (which precisely mirror the standard components of state statutes); and specifies a form of compliance reports required under existing agency responsibilities. Consistent with the Department's investigative guidelines, § 84.55(c)(2) encourages state agencies to involve Infant Care Review Committees in connection with the agencies' actions pursuant to its state law and procedures.

#### D. EXPEDITED ACCESS TO RECORDS

The final rules create a limited exception to the Department's existing regulations pertaining to access to sources of information. The existing regulation, 45 CFR 80.6(c), made applicable to section 504 cases by 45 CFR 84.61, states:

Each recipient shall permit access by the responsible Department official or his designees during *normal business hours* to such of its books, records, accounts, and other sources of information, and its facilities as may be pertinent to ascertain compliance with this part. (Emphasis supplied.)

The proposed rules included a modification to specify that access to pertinent records and facilities of a recipient "shall not be limited to normal business hours when, in the judgment of the responsible Department official, immediate access is necessary to protect the life or health of a handicapped individual." The final rules adopt this change in § 84.55(d).

A number of commenters expressed support for this provision as essential to efforts to save lives. Others objected on the grounds that investigations are

highly disruptive, the OCR officials are not qualified to make a judgment regarding the degree of danger to the life or health of a handicapped individual and that the rule should specify circumstances warranting access and procedures applicable to investigations after normal business hours.

#### Response

The Department views this as a minor, technical clarification. Access to recipient facilities and sources of information is required by existing regulations and is essential for the Department to carry out its statutory obligation to determine whether recipients are in compliance with civil rights laws. The provision in existing regulations regarding "normal business hours" is nothing more than a recognition that many recipients conduct their federally assisted programs and activities only during those hours.

The furnishing of inpatient medical services, however, is not a 9:00 a.m. to 5:00 p.m., Monday through Friday undertaking. Rather, the "normal business hours" for nurseries and neonatal intensive care units are 24 hours a day, seven days a week. The Department, therefore, has the authority to seek pertinent records at any time even in the absence of this revision. Nonetheless, the Department adopts this change to clarify its authority and recipients' obligations. The objections expressed regarding this provision are substantially the same as objections to investigative procedures generally, and are discussed in section H, below.

This modification makes clear where the circumstances indicate a risk of imminent, irrevocable harm due to suspected noncompliance, the Department will, as it must, initiate immediate action to determine compliance.

#### E. EXPEDITED ACTION TO EFFECT COMPLIANCE

The final rules include a slight revision to existing regulatory procedures concerning remedies for noncompliance. Existing regulations, 45 CFR 80.8(a) and (d) (made applicable to section 504 cases by 45 CFR 84.61), provide:

If there appears to be a failure or a threatened failure to comply with this regulation . . . compliance with this part may be effected by the suspension or termination of or refusal to grant or to continue Federal financial assistance or by any other means authorized by law. Such other means may include . . . a reference to the Department of Justice with a recommendation that appropriate proceedings be brought to

enforce any rights of the United States under any law of the United States . . . or any assurance or other contractual undertaking. . . .

No action to effect compliance by any other means authorized by law shall be taken until (1) the responsible Department official has determined compliance cannot be secured by voluntary means, (2) the recipient or other person has been notified of its failure to comply and of the action to be taken to effect compliance, and (3) the expiration of at least 10 days from the mailing of such notice to the recipient or other person.

The proposed rule included a provision that the normal requirement of providing 10-days notice "shall not apply when, in the judgment of the responsible Department official, immediate remedial action is necessary to protect the life or health of a handicapped individual." The final rule, in § 84.55(e), adopts this revision.

A number of commenters expressed support for this provision as essential to efforts to save lives; others objected because the rule did not identify standards for waiving the 10-day notice or alternate procedure to be followed.

#### Response

The Department considers this a minor, technical change. The 10-day notice was designed to facilitate pursuit of informal compliance in circumstances where noncompliance did not imminently threaten lives. The failure to provide nourishment or treatment to a handicapped infant, however, may have such a consequence.

As a matter of legal interpretation, the Department believes the normal 10-day notice rule would, even absent the proposed change, be inapplicable in a case where the government seeks a temporary restraining order to sustain the life of a handicapped infant in imminent danger of death. Such actions would often be for the purpose of preserving the status quo, such as by continuing the provision of nourishment and routine care, pending a more definitive determination of compliance or noncompliance with section 504, rather than "to effect compliance" following a determination of noncompliance. In addition, the Department believes federal judges would be appropriately loathe to allow minor procedural technicalities to defeat totally the accomplishment of the statutory purpose. Nonetheless, the Department proposed this limited exception to the normal 10-day notice rule to clarify its authorities and corresponding recipient responsibilities.

The determination of the need to waive the 10-day notice will be made in accordance with the standard

investigative procedures, explained in section H, below. Concerning alternate notice procedures, the final rule provides that oral or written notice will be provided as soon as practicable.

#### F. GUIDELINES RELATING TO HEALTH CARE FOR HANDICAPPED INFANTS

Most of the comments submitted during the comment period dealt with issues well beyond the specific provisions of the proposed rules, such as the applicability of section 504 to this subject matter and the Department's section 504 enforcement process.

Like the proposed rules, the final rules contain four discrete requirements applicable to recipients of Federal financial assistance. First, hospitals must post an informational notice. Second, the normal 10-day notice before initiating action to effect compliance can be waived when immediate action is necessary. Third, access by the Department to pertinent records and facilities can be obtained after "normal business hours" when immediate access is necessary. Fourth, state child protective services agencies must establish procedures to utilize their full authority under state law to prevent medical neglect of handicapped infants.

To bring these specific provisions further back into focus, it is useful to note what the final rules, like the proposed rules, do not do. They do not establish the applicability of section 504 to the provision of health care to handicapped infants. The applicability of section 504 is already established by the statute and the existing HHS regulations. They do not establish the authority or procedures of HHS to investigate reports of suspected noncompliance with section 504. Authority and procedures are already established by the statute, existing regulations and administrative practices. They do not establish a toll-free telephone number, which has been established and is in operation. Although most of the controversy concerning the rules relates to the broader issues, the mandatory aspects of the final rules deal only with several discrete points.

Nonetheless, many of the comments relating to the broader issues were highly relevant and valuable. Other comments on the broader issues reflected a lack of understanding of how the Department interprets the applicability of section 504 in this area and the Department's compliance procedures. To clarify these issues, the final rules include an appendix, which sets forth guidelines relating to health

care for handicapped infants. This appendix includes interpretative guidelines relating to the applicability of section 504 and guidelines for HHS investigations in this area. These guidelines do not independently establish rules of conduct or substantive rights and responsibilities, which are established by the statute and existing regulations. The Department will apply these guidelines flexibly to take into account the circumstances presented in each case regarding both the determination of compliance or noncompliance and the conduct of the investigation. These guidelines are set forth as an appendix to the final rules simply to assist recipients and the public in understanding the Department's general interpretations and procedures. This appendix becomes a part of the permanent Code of Federal Regulations.

#### G. INTERPRETATIVE GUIDELINES RELATING TO THE APPLICABILITY OF SECTION 504

##### Medically Beneficial Treatment

As stated in the preamble to the proposed rules, the Department interprets section 504 as requiring that medically beneficial treatment not be withheld, solely on the basis of handicap, from a handicapped infant.

Three of the questions on which the July 5 notice of proposed rulemaking specifically solicited comments concerned the issue of medically beneficial treatment as the standard to guide treatment decisions, including further explanations that would assist health care providers and the public in understanding the requirements of Section 504, implications concerning cost and the allocation of medical resources, and the impact of perceived economic, emotional and marital effects on parents.

Among commenters supporting the standard of providing medically beneficial treatment was the Down's Syndrome Congress:

Some children may be unwanted by their parents. . . . The Down's Syndrome Congress does not seek to judge those parents who do not feel that they can adequately parent because of the handicap. Rather, we seek to make available those adoption homes that want children who have Down's syndrome.

Also typical of comments in support of the standard of providing medically beneficial treatment was the comment of the Association for Retarded Citizens:

No quality of life or other such considerations are acceptable to the ARC. Although we are primarily a parent organization and many ARC members have had significant difficulty (financial, emotional, etc.) raising their mentally

retarded child, we come down strongly on the side of the child.

Available medical and other technology is not able to fully predict the future capacity of most mentally retarded children, especially in the first days and weeks of life. Our members can cite numerous examples of improper and wrong advice given to them by physicians about the future capacities of their children.

A number of commenters argued that the medically beneficial treatment standard is inappropriate. For example, the Department received the following comment from a Texas physician:

[N]ot only is the "very strict standard" advocated by the President's Commission "not being uniformly followed," [as stated in the HHS July 5 NPRM] it is probably close to *uniformly not* being followed. The "very strict standard" the Secretary of Health and Human Services is trying to foist on the medical community is contrary to the usual practices of that community. (Emphasis in original.)

Similarly, the following comment was submitted by an Alabama physician:

Recently I have treated a 13-month old black child who has congenital heart disease, spastic encephalopathy, vomiting, repeated bouts of bilateral pneumonia, internal squint of the left eye, and mental deficiency. He is one of the thousands of children who are the victims of the neonatal intensive care units located in every medical center. He was born premature, weighing two pounds and ten ounces. With modern treatment and instruments he survived. These children have no future and are a terrible burden on their parents and this nation.

. . . What good is it treating these premature babies? Will it not be better if they are left to die? . . . We are compounding our problems by bringing into life thousands of congenitally sick babies which nature has rejected.

A number of commenters, particularly medical organizations, suggested different articulations of standards. For example, the American Medical Association combines a number of notions in articulating the standard to be applied, including consideration of "quality of life", and deference to parental decisions unless there is "convincing evidence to the contrary." The full text of the AMA position is as follows:

**QUALITY OF LIFE.** In the making of decisions for the treatment of seriously deformed newborns or persons who are severely deteriorated victims of injury, illness or advanced age, the primary consideration should be what is best for the individual patient and not the avoidance of a burden to the family or to society. Quality of life is a factor to be considered in determining what is best for the individual. Life should be cherished despite disabilities and handicaps, except when prolongation would be inhumane and unconscionable. Under these circumstances, withholding or removing life

supporting means is ethical provided that the normal care given an individual who is ill is not discontinued. In desperate situations involving newborns, the advice and judgment of the physician should be readily available, but the decision whether to exert maximal efforts to sustain life should be the choice of the parents. The parents should be told the options, expected benefits, risks and limits of any proposed care; how the potential for human relationships is affected by the infant's condition; and relevant information and answers to their questions. The presumption is that the love which parents usually have for their children will be dominant in the decisions which they make in determining what is in the best interest of their children. It is to be expected that parents will act unselfishly, particularly where life itself is at stake. Unless there is convincing evidence to the contrary, parental authority should be respected.

Another articulation of standards, submitted by the Biomedical Ethics Committee of the University of Minnesota Hospitals, includes the following ethical principles:

When the burden of treatment lacks compensating benefit or treatment is futile, the parent(s) and attending physician need not continue or pursue it.

Therapies lack compensating benefit when: (a) they serve merely to prolong the dying process; (b) the infant suffers from intolerable, intractable pain, which cannot be alleviated by medical treatment; (c) the infant will be unable to participate even minimally in human experience.

Probably the most poignant comments regarding the standard which should be applied relating to the provision of medical care to handicapped infants were submitted by parents of handicapped children. Of 100 commenters who identified themselves as parents of handicapped persons, 95 supported the proposed rule and five opposed it. From a Montana mother:

My daughter Keough was born in November 1980 with Down's syndrome and a host of birth defects in her digestive system similar to Baby Doe's problems . . . Twenty minutes after her birth our then pediatrician offered to let her starve in the hospital nursery . . .

. . . There are times when I am getting up for the tenth time during the night to suction my daughter's trach tube so she can breathe that I would give anything not to have to deal with the situation, but I will never regret having her as part of the family.

From a mother and father, both physicians, in California:

[A]s the parents of an eight-year-old boy with Down's Syndrome, who suffers from marked retardation and a severe cardio-pulmonary condition, we do appreciate both the deep anguish and the countless joys that derive from caring for and caring about a



severely handicapped child. There is no limit set on the strength, the growth and the fulfillment that his love continues to bring us every day. For his sake and for the sake of all the handicapped newborn, it is urgent that safeguards be enacted. Let merciful caring, not mercy-killing, be our answer to their needs.

Another dimension of the comments concerning the interpretation of section 504 as requiring that medically beneficial treatment not be withheld solely on the basis of handicap relates to the difficulty of determining the "medically beneficial treatment." As stated by the Children's Hospital of Boston:

[The NPRM] states that the denial of treatment where there is no medical benefit to the individual would not be discriminatory because the individual would not be a "qualified handicapped person" within the meaning of section 504. . . . [A problem with this analysis is that] it relies on outcome which cannot always be predicted or, even if predicted is not always accurate, may be affected by other factors, and may not even be known for an indeterminate time. If section 504 is to provide guidance in treatment situations, its applicability should be known at the outset. Otherwise staff will be subjected to an after-the-fact scrutiny which may well be inaccurate and oppressive.

Another comment regarding the role of medical judgements was submitted by presiding Judge John G. Baker, Monroe Superior Court, Division III, the Judge who decided the Bloomington Infant Doe case:

The question in the Infant Doe case was, when parents are confronted with two competent medical opinions, one suggesting that corrective surgery may be appropriate and the other suggesting that corrective surgery and extraordinary measures would only be futile acts, does the law allow the parents to select which medical course to follow? It was the decision of the Indiana Court that the law provided the parents with the responsibility of choosing which medical course to follow without governmental intervention.

#### Response

The Department's position remains unchanged. Section 504 provides:

No otherwise qualified handicapped individual shall, solely by reason of his handicap, be excluded from participation, be denied the benefits of, or be subject to discrimination under any program or activity receiving Federal financial assistance. . . .

The statute defines a "handicapped individual" as:

Any person who (i) has a physical or mental impairment which substantially limits one or more of such person's major life activities, or (iii) is regarded as having such an impairment.

A key issue in applying section 504 in any context is that the handicapped individual who is allegedly excluded from participation in, denied the benefits of, or subject to discrimination under a federally assisted program or activity be "otherwise qualified" to participate in, or benefit from, the program or activity, in spite of his or her handicap. In the context of receiving medical care, the ability to benefit for a handicapped person is the ability to benefit medically from treatment or services. If the handicapped person is able to benefit medically from the treatment or service, in spite of the person's present or anticipated physical or mental impairments, the individual is "otherwise qualified" to receive that treatment or service, and it may not be denied solely on the basis of the handicap.

Therefore, the analytical framework under the statute for applying section 504 in the context of health care for handicapped infants is that health care providers may not, solely on the basis of present or anticipated physical or mental impairments of an infant, withhold treatment or nourishment from the infant who, in spite of such impairments, will medically benefit from the treatment or nourishment.

Not only is this analytical framework directed by the statute, the Department believes the medically beneficial treatment standard is the appropriate guiding principle for providing health care services to handicapped infants. The Department agrees with the President's Commission that "it is all too easy to undervalue the lives of handicapped infants," and that it is "imperative to counteract this" by excluding "consideration of the negative effects of an impaired child's life on other persons" and to treat handicapped infants "no less vigorously than their healthy peers."

The Department also agrees with the essential principle contained in the joint statement of November 29, 1983, by the coalition of medical groups and disability organizations, including the American Academy of Pediatrics, the National Association of Children's Hospitals and Related Institutions, the association for Retarded Citizens, the Spina Bifida Association of America, and others:

When medical care is clearly beneficial, it should always be provided. . . . The individual's medical condition should be the sole focus of the decision.

Consistent with the recommendations of the President's Commission and the principles agreed to by the coalition of medical and disability groups,

paragraphs (1), (2) and (3) of section (a) of the appendix state the basic interpretative guidelines of the Department for applying section 504 in this context. These interpretative guidelines make clear that health care providers may not, solely on the basis of present or anticipated physical or mental impairments of an infant, withhold treatment or nourishment from the infant, who, in spite of such impairments, will medically benefit from the treatment or nourishment. They also made clear that futile treatments or treatments that will do no more than temporarily prolong the act of dying of a terminally ill infant are not required by section 504, and that, in determining whether certain possible treatments will be medically beneficial to an infant, reasonable medical judgments in selecting among alternative courses of treatment will be respected. The principle of respecting reasonable medical judgments reflects the Department's recognition that in many cases the process of medical decisionmaking is not mechanical and precise. Analyses of medical risks, medical benefits, possible outcomes, complications, and the like require experience and judgments. Most of all, they must be specifically based on the actual circumstances presented in any given case. The statutory framework does not provide for, nor will the Department seek to engage in, second-guessing of reasonable medical judgments regarding medically beneficial care.

The principle of respecting reasonable medical judgments in the context of applying section 504 is also consistent with analogous case law. For example, the Supreme Court has made it clear that the application of constitutional protections do not interfere with *bona fide* medical judgments so as to authorize a court "to specify which of several professionally acceptable [treatment] choices should have been made." *Youngberg v. Romeo*, 457 U.S. 307, 321 (1982).

However, the Department also recognizes that not every opinion expressed by a doctor automatically qualifies as a reasonable medical judgment. For example, a doctor's opinion that available corrective surgery to save the life of a Down's syndrome infant should be withheld is contrary to the opinion of the President's Commission and comments submitted to the Department by the American Academy of Pediatrics, the National Association of Children's Hospitals and Related Institutions, and other medical organizations. It is not within the

bounds of reasonable medical judgment and is not entitled to deference.

#### Parental Decisions

A number of commenters argued that the Department's analysis of section 504's applicability fails to take into account the lack of authority hospitals and physicians have to perform treatment to which the parents have not consented. Some commenters expressed a belief that the Department purports to require physicians and hospitals unilaterally to overrule parental decisions. As stated by the American Medical Association:

If section 504 is applied as the Department claims it should be, physicians and hospitals will be required to treat a handicapped infant in all cases, regardless of parental consent, for fear of sanctions allegedly authorized by section 504.

Similarly, the National Association of Children's Hospitals and Related Institutions stated:

Nor does the rule recognize that, in lieu of indications to the contrary, decisions of care of the infant made by these parents, based on their determination of the child's best interest, are theirs to make, a right and responsibility assigned to them universally by state statute.

Also in connection with the issue of a recipient's section 504 responsibilities in cases where parents refuse to consent to medically beneficial treatment, a number of commenters criticized a statement included in the Department's May 18 notice to health care providers that:

Health Care providers should not aid a decision by the infant's parents or guardian to withhold treatment or nourishment discriminatorily by allowing the infant to remain in the institution.

The criticism was that to discharge the infant, as the statement implied the hospital should do, would be unlikely to advance the objective of assuring that the infant receive medically beneficial treatment.

#### Response

The Department's position has been, and continues to be, that the lack of parental consent does have an impact on a recipient hospital's section 504 responsibilities, but that the lack of parental consent to provide particular treatment does not remove from hospitals the obligation to operate other aspects of their program without discrimination.

Although the need may not arise frequently, it is an accepted part of the operation of hospitals to contest the denial of parental consent when such a decision is not in the best interest of a

child. Most hospitals have established procedures to petition courts to order medical care when parents do not provide consent for treatment that is medically needed and appropriate.

In addition to the internal hospital procedures, state laws generally establish responsibilities of health care professionals where treatment is being withheld because of improper denial of parental consent. Health care professionals are generally required by state law to report cases of abuse, neglect, or other threats to a child's health. These laws, whether explicitly or implicitly, include the denial of needed medical treatment as an event requiring reporting.

The requirement that health care providers report instances of improper denial of medical care is no less a part of their program than is the provision of care itself. Both arise from the recipients's program of administering to the medical interests of its patients. Section 504 prohibits discrimination on the basis of handicap in the operation of federally assisted programs and activities. Thus, a recipient that, as a matter of practice or law, reports to State authorities the withholding of needed medical treatment from an infant may not deny the same service or benefit to a qualified handicapped infant because the infant is handicapped.

Section 504 applies only to programs or activities receiving federal financial assistance; it does not apply to decisions made by parents. Where a non-treatment decision, no matter how discriminatory, is made by parents, rather than by the hospital, section 504 does not mandate that the hospital unilaterally overrule the parental decision and provide treatment notwithstanding the lack of consent. But it does require that recipient hospitals not fail, on the basis of handicap, to report the apparently improper parental decision to the appropriate State authorities, or to seek judicial review itself, so as to trigger the system provided by State law to determine whether the parental decision should be honored. Action by hospitals to seek judicial review is not uncommon in cases where, for example, parents have objected on religious grounds to a medically necessary blood transfusion for their child.

The Department agrees with the criticism of the sentence in the May 18, 1982 notice. This statement reflected a recognition by the Department that section 504 does not require hospitals unilaterally to overrule parental decisions, and that hospitals cannot provide treatment without parental consent. The point should have been

better stated that a recipient hospital may not blindly implement improper and discriminatory parental decisions. Rather, the hospital should resort to the system provided by state law to determine whether a parental decision should be implemented.

Therefore, the proper analysis of the applicability of section 504 in cases where the failure to provide medically indicated treatment is due to a lack of parental consent is that a recipient hospital is not required to seek to unilaterally overrule the parents, but it must adhere to the standard practice, as required by state law, to make a report to the state agency charged under state law with responsibility to initiate the determination as to whether the parental decision was proper, or to seek judicial review itself. This interpretative guideline is set forth in section (a)(4) of the appendix.

Rather than representing an improper Federal government attempt to "question and overturn the decisions of parents concerning their children's medical treatment," the Department is simply requiring that the long-standing requirements and mechanisms of state law for defining the limits of parental authority not be rendered, through discriminatory actions of recipient hospitals, *de facto* inoperative.

#### Examples

The July 5 proposed rule was accompanied by an appendix explaining the manner in which section 504 applies to the provision of health care services to handicapped infants and providing several examples of its applicability to particular factual situations. A number of commenters criticized statements contained in that appendix. Criticisms and comments were as follows: (a) Use of phrases such as "futile therapies", "services generally provided", and "dubious medical benefit" are ambiguous. (b) The characterization of the infants with intracranial hemorrhage as analogous to anencephaly is incorrect. Intracranial hemorrhages vary greatly in severity, and are generally treatable and treated. (c) The American Society for Parenteral and Enteral Nutrition stated that although there are no circumstances justifying "withholding oral feeding through a working digestive tract in any patient capable of digesting food, in whole or in part," there may be "limited circumstances" in which not providing nourishment through intravenous means "may be appropriate." (d) The appendix does not indicate the appropriate care for infants who have conditions with prognoses worse than Down's syndrome

but less severe than anencephaly, such as Trisomy 18, Trisomy 13, Holoprosencephaly, Hydranencephaly, Cornelia de Lange Syndrome, and many others.

(e) "It would be impossible to develop a complete list of handicaps to which the regulations apply. The limited ability to predict outcomes, and the rapid changes in diagnostic and therapeutic modalities make such a goal wholly impracticable."

#### Response

The application of constitutional and statutory civil rights protections in scores of contexts is difficult. A glance at the Supreme Court's docket confirms this, as every year difficult issues are presented to the Court for resolution. These cases often produce split decisions and multiple opinions.

Therefore, it is to be expected that definitive statements on various dimensions of the applicability of the handicapped discrimination law in connection with health care for handicapped infants, a subject no less difficult than many other aspects of civil rights law, would be few. The imprudence of seeking to speculate on the outcome of applying section 504 in a wide variety of specific factual circumstances was underscored by some of the comments received.

Keeping in mind the utility of providing some examples to assist in understanding the analytical framework of the statute, but also the need to allow individualized attention to specific factual circumstances, the guidelines included in the appendix (section (a)(5)) set forth examples dealing with Down's syndrome, spina bifida, anencephaly, and extreme prematurity.

The Department agrees with the comment that it would be impossible to establish a specific list of all handicapping conditions and the proper treatment in each case. None of the commenters who perceived ambiguities had convincing answers to the questions they raised.

It is appropriate that the law (and thus the government) does not prospectively and unequivocally answer every hypothetical question. In many cases, the law, like medical treatment, can only be applied on a case-by-case basis with a full appreciation for the facts presented.

But it is also appropriate that the law and government have an analytical framework for approaching the issue and a procedural framework for seeking, in cooperation with the medical community and advocacy groups, to narrow the "gray area." The final rules

seek to do no more, and importantly, no less.

#### H. GUIDELINES FOR HHS INVESTIGATIONS RELATING TO HEALTH CARE FOR HANDICAPPED INFANTS

##### Conduct of Investigations

The July 5 notice of proposed rulemaking solicited comments on HHS investigative procedures. A number of commenters argued that OCR complaint investigations are highly disruptive. The primary concerns expressed in this regard were:

(a) Due to the complexity of the subject matter, there are many erroneous complaints, either by well-intentioned, but ill-informed, persons or by disgruntled employees.

(b) Anonymous calls are not reliable.

(c) Investigations monopolize the time of physicians, nurses and other hospital staff, and make medical records, while under review by OCR investigators, unavailable.

(d) Investigations carry with them the potential for sensational media coverage, which can unjustly damage the good reputations of parents, hospitals and health care professionals.

(e) The presence of OCR investigators is likely to frighten other infants' parents who will assume that, because investigators are present, the hospital must be guilty of improper conduct.

##### Response

Although some potential for inconvenience or disruption exists in connection with any type of law enforcement investigation, because of the traumatic circumstances of an infant's illness, the potential for sensationalistic media coverage, and other factors, the Department is very sensitive to the special nature of "Infant Doe" investigations. As HHS has gained experience in conducting these investigations, revisions to investigative procedures have been implemented to minimize any disruptive effects. It is the policy of the Department to do everything possible, consistent with its statutory obligation to investigate effectively all complaints of violations of section 504, to minimize any disruptions that may be caused by OCR investigations.

OCR has made adjustments to investigative procedures. It now undertakes a careful screening of complaints in an effort to avoid unnecessary on-site investigations. This screening consists of immediately initiating a preliminary inquiry with the hospital to obtain information regarding the infant in question. The information

initially received from the complainant and that received from the hospital is then evaluated to determine whether there is a need for an on-site investigation. Particular factors taken into account are the source of the complainant's information (first-hand knowledge, overheard a discussion, etc.), the complainant's position to have reliable information (a nurse in the ward where the infant is being treated, a friend of a friend, etc.), the specificity of the information provided by the complainant and hospital, whether there is any indication of a lack of parental consent for the provision of all medically beneficial treatment, the analysis of the ICRC, whether the hospital is cooperative in connection with the inquiry, and other pertinent factors.

None of these factors considered in evaluating the information provided by the complainant and the hospital is, by itself, determinative. For example, the Department prefers that the complainant provide his or her name. Not only does it corroborate that the complainant takes the matter seriously and reflects some degree of confidence the complainant has in the accuracy of the information being conveyed, having the complainant's name also permits follow-up communications to seek clarification of the information gathered. However, the Department recognizes that a complainant may not be willing to provide his or her name due to fear of retaliation, and that anonymity does not necessarily suggest that the complaint is not valid, particularly if the specificity of the information provided and other factors support the credibility of the complaint. Therefore, the determination as to whether an on-site investigation is needed is made on the totality of the information available to OCR from the complainant, the hospital, and any other source consulted (such as an OCR medical consultant and the state child protective services agency).

HHS believes this procedure, if hospitals cooperate in its implementation, can avoid unnecessary on-site investigations, which inherently have a potential for some inconvenience. Although hospital officials may be properly reluctant to provide information over the telephone, they can confirm the credentials of the OCR investigator making the telephone contact by calling the toll-free telephone number to verify that the caller is, in fact, an OCR investigator.

Where, as a result of this preliminary inquiry, there appears to be no need for an immediate on-site investigation, none will be conducted. However, to assure

that HHS is adequately meeting its statutory responsibility, where there is a significant question as to compliance with section 504, doubt will be resolved in favor of initiating an on-site investigation.

This preliminary inquiry process is undertaken by OCR in an effort to accommodate the special circumstances presented in connection with "Infant Doe" complaints. This procedure should not be construed as suggesting that the Department believes there are any limitations to its legal authority to investigate all complaints or to otherwise collect information regarding recipient compliance in accordance with the Department's existing section 504 regulations. Nor does this preliminary inquiry process establish any legally enforceable procedural right or precondition to the conduct of on-site investigations.

When on-site investigations are conducted, OCR's procedures minimize any potential inconvenience or disruption. Every effort is made, consistent with the need to obtain prompt information, to accommodate the busy schedules of health care professionals to avoid diverting them from their important duties. Similarly, OCR has never had a problem working out access to medical records to avoid their being unavailable to health care professionals who also need access to them.

With respect to media interest, OCR has a firm policy of providing no comment to the press on the details of any open investigation. HHS believes organizations or individual complainants concerned about proper patient care should be extremely sensitive to threats to proper care inherent in making premature and unsupported comments to the media. Similarly, the media should be attentive to OCR's admonition, regularly given in response to media questions, that the fact that an investigation is being conducted does not imply that an allegation is true.

Section (b)(1) through (5) of the appendix spell out the basic guidelines, including the preliminary inquiry process, applicable to HHS investigations in this area. These guidelines make specific reference to the role of Infant Care Review Committees. Whenever a hospital has an ICRC, established and operated substantially in accordance with the suggested model, the Department will consult closely with the ICRC in connection with a preliminary inquiry or investigation and will give careful consideration to the analysis and recommendations of the ICRC.

The Department believes OCR procedures, including the initial inquiry process, minimize the potential for disruption. HHS will, on the basis of further experience gained, such as with ICRCs, continue to evaluate its procedures consistent with the policy of effective enforcement with a minimum of disruption. The Department also notes that there is probably an irreducible level of inconvenience associated with any effort to provide safeguards to prevent the fatal consequences of discriminatory decisions. It must be recognized, however, that the risks of a certain amount of inconvenience or disruption are significantly preferable to the risks of tragic loss of life due to discriminatory decisionmaking.

#### *Use of Medical Consultants*

Another concern expressed by commenters relates to the qualifications of the individuals involved in the administrative fact finding process to evaluate correctly the medical circumstances present in any particular case. For example:

The Alabama Hospital Association strongly feels that the [investigative] team should be comprised of highly trained and licensed medical personnel. Under no circumstances should anyone less than licensed medical personnel be allowed to intrude in this area of medical decisionmaking and impose alternative judgments or conclusions.

The Spina Bifida Association of America made a similar comment from a different perspective:

The key to effective enforcement is securing an independent medical examination of children allegedly being denied treatment, by a physician or medical team both skilled in modern treatment techniques and committed to the equal treatment principle. Such physicians do exist, particularly at expertise centers that have specialized in the care of children with spina bifida. The only way to ensure effective enforcement is to give disability rights groups like SBAA the ability to recommend which expertise centers and expert consultants are used by the regional OCR offices to conduct the independent medical examinations.

#### *Response*

HHS agrees that OCR investigators do not have the medical expertise to make independent judgements concerning difficult medical issues. For this reason, the Office for Civil Rights has made arrangements with qualified physicians to serve as medical consultants to OCR in "Infant Doe" investigations. This process is noted in section(b)(6) of the appendix.

The role of the OCR medical consultants is to provide OCR with an

analysis of the medical issues present in any particular case, and an opinion as to whether medically beneficial treatment was provided. Based on this analysis, OCR makes a determination as to whether any medically beneficial treatment may have been discriminatorily denied solely on the basis of the infant's handicap.

The extent of the involvement of the OCR medical consultant has varied depending upon the circumstances of particular cases. In all cases the OCR medical consultant reviews the pertinent medical records. In some cases the OCR medical consultant and the attending physician have discussed a case by telephone. HHS believes the experience to date with OCR medical consultants demonstrates the effectiveness of their involvement. HHS is aware of no case in which a recipient has challenged the quality of the medical consultant's evaluation or the OCR findings based upon it.

It is important that all interested groups understand the precise and limited role of the OCR medical consultants. Their function is *not* to take over the medical management of particular cases, to conduct a personal, independent examination of the infant, to make independent treatment recommendations to parents, or to otherwise engage in any direct practice of medicine concerning the infant.

The Department has no authority to compel unilaterally an independent medical examination of a child who is the subject of a section 504 complaint. Under applicable requirements of law, physicians may not practice medicine on an infant patient without the consent of the parents or an order of a court of competent jurisdiction.

In any given case, any of a wide variety of circumstances may be present regarding the actions of parents and health care providers. Regardless of the circumstances, the first step is to determine the facts. Only if the facts demonstrate that there is a need for governmental action can that action be pursued. A court will only issue an order if there is a showing of a need for the order, such as evidence that the hospital is out of compliance with section 504 or showing that the parents are medically neglecting the infant. Such a showing cannot be made on the basis of the bare allegations of a complaint or without a determination of the facts.

OCR's function in an investigation is to determine the facts, and the function of the medical consultant is to assist OCR in this effort. The process of determining the facts typically involves a review of medical records and

discussions with health care providers involved. The OCR medical consultants assist in this process by providing identification and expert analysis of the medical issues involved. These consultants do not, and may not under applicable law, take over the medical management of the case.

With respect to the suggestion that HHS give disability groups the opportunity to recommend qualified physicians to serve as OCR medical consultants, the Department would welcome such suggestions from all interested groups.

The Department is unable to commit itself to having a medical consultant participate in person in every on-site investigation. However, the guidelines contained in the appendix state that, to the extent practicable, the OCR medical consultant will discuss the case with the hospital's ICRC or appropriate medical personnel by telephone.

#### *Prompt Report of Investigative Findings*

Another complaint made by a number of commenters regarding OCR enforcement procedures concerns the sometimes lengthy delay between completion of the on-site investigation and receipt by the hospital of notification of the outcome of the investigation. Commenters expressed concern that, particularly in connection with investigations that may have attracted local media attention, where the OCR investigation found no evidence of a violation, the hospital should have the ability to reassure the public promptly that it was involved in no improper activity.

#### *Response*

The point is well taken. Office for Civil Rights procedures pertaining to all investigations require that before the office makes an official finding, whether it is of compliance or noncompliance, a thorough record is compiled and reviewed by supervisory officials. Experience in connection with "Infant Doe" cases is that formal findings have been made in less time than is typical in connection with other civil rights investigations. However, there is generally a need for careful review by an OCR medical consultant, an HHS attorney, and supervisory officials.

The Department recognizes that there are special circumstances in connection with Infant Doe cases, and is instituting a special notification to recipient hospitals in cases where an emergency on-site investigation has been conducted. As a matter of practice, on-site investigation of complaints alleging that an infant's life is in peril due to the discriminatory withholding of medically

beneficial care are conducted immediately for the primary purpose of determining whether there is a need to ask the Department of Justice to seek immediate injunctive relief to compel compliance with section 504. Generally, during the course of the investigation, when sufficient information has been obtained and discussed with the OCR medical consultant, a decision is made on whether there is such a need.

The new procedure is that, when a decision is made that there is no need to make an immediate referral to the Justice Department, the recipient hospital will be immediately notified of that decision. The investigator will, if still on-site, personally notify hospital officials. A letter to the same effect will then promptly be sent by OCR. This letter will notify the recipient hospital of the decision made concerning immediate referral to the Justice Department. It will not provide a formal finding concerning the investigation, which cannot be made until all information is analyzed and reviewed. (It may be, for example, that, although there is no emergency requiring immediate legal action by the Justice Department, there is, or was, noncompliance.)

The Department believes this immediate notification procedure, stated in section (b)(?) of the appendix, will provide a basis for the hospital to assure the press and public that OCR's initial conclusion in connection with the investigation is that no infant is in imminent peril due to discriminatory withholding of medically beneficial treatment.

#### *Confidentiality of Records*

A number of commenters criticized the enforcement process on the grounds that it infringes on the confidentiality of the physician-parent relationship and the privacy of medical records. Some of these commenters referred to the confidentiality requirements of state law and professional ethical standards.

As stated by the Federation of American Hospitals:

The physician may be required to inform the parents that anything they may say or decide must be disclosed to federal or state authorities if an investigation results. [P]arents will find that they have a choice between sharing vital information and counseling with their physician and having their thoughts and emotions revealed to a stranger or, alternatively, withholding information.

A suggestion for an additional confidentiality safeguard, submitted by the director of nursing of a Butte, Montana hospital, was to limit review of

records to one investigator, on-site, with no copies made.

#### *Response*

HHS believes there is no sound legal basis to challenge the Department's right to access to medical records for the purpose of determining compliance with section 504, and that adequate safeguards exist to protect the confidentiality of records obtained by OCR in the course of civil rights investigations.

With respect to legal authority, a state law, such as one restricting access to certain records, cannot, under the Supremacy Clause of the United States Constitution, be used to prevent accomplishment of the full congressional purpose of a Federal law. Similarly, standards of particular professional groups may not frustrate or defeat a Federal statutory duty.

Section 504 establishes certain responsibilities of recipients and authorizes and directs Federal agencies to enforce the law. Existing regulations, 45 CFR 80.6(c) (made applicable to section 504 by 45 CFR 84.61), require:

Each recipient shall permit access by the responsible Department official or his designee during normal business hours to such of its books, records, accounts, and other sources of information, and its facilities as may be pertinent to ascertain compliance with this Part. . . . Asserted considerations of privacy or confidentiality may not operate to bar the Department from evaluating or seeking to enforce compliance with this Part. Information of a confidential nature obtained in connection with compliance evaluation or enforcement shall not be disclosed except where necessary in formal enforcement proceedings or where otherwise required by law.

The requirement that recipients provide access to records necessary to determine compliance is essential to accomplishment of the congressional purpose in enacting section 504.

HHS has adequate safeguards to protect the confidentiality of medical records obtained during the course of a section 504 investigation. In addition to the regulatory provision (quoted above) protecting confidentiality, OCR does not release confidential information in connection with any Freedom of Information Act request. Nondisclosure is permitted under that Act for records, the release of which would constitute a clearly unwarranted invasion of personal privacy. As further protection, OCR permits deletion of the patient's and parents' names and other identifying information to the extent deletion will not impede OCR's ability to determine compliance.

The argument that the possibility that investigators will seek access to a medical file will cause parents to withhold vital information from the infant's physician is not persuasive. Courts and legislatures have repeatedly rejected arguments that exceptions to the principle of confidentiality of medical records and the physician-patient privilege would result in the withholding of information necessary to facilitate proper treatment. There are many established exceptions in the law to the principle of doctor-patient confidentiality in connection with criminal and civil proceedings where the effective administration of justice requires access to information in medical records or provided to physicians. It is also noteworthy in this regard that the Federal Rules of Evidence do not include an express doctor-patient privilege.

With respect to the suggestions for additional safeguards submitted by a commenter, OCR has in some cases been able to limit review of records to one individual at the hospital, without the need to obtain copies. However, no assurances can be made that OCR can meet its responsibility to conduct a thorough investigation under these conditions. Also, in many cases it may be preferable for the hospital to send OCR the pertinent records (with identifying information deleted), perhaps avoiding the need for any on-site investigation.

#### IV. Related HHS Activities

HHS has undertaken several other initiatives in cooperation with the medical community and disability organizations to improve the delivery of health care services to handicapped infants. Recently, a contract was awarded by the Office of Human Development Services, HHS to the John F. Kennedy Institute in Baltimore to develop a model for a working nationwide referral network for the developmentally disabled. Such a network, using today's sophisticated technology, will make it possible for the physician, parents, or care-takers of a developmentally disabled individual to query a single source for information about that disability and pinpoint the best or most appropriate places to get help any where in the country for that individual.

Under the terms of this award, the strong features of two important information systems are to be combined and regionalized. One is a data retrieval system for the particular use of practicing physicians. The other is accessible by the general public. The data base for the physician-oriented

system was developed by the Kennedy Institute in Baltimore, using data supplied by the 38 HHS supported university-affiliated facilities around the country. The American Medical Association has a contract with the Kennedy Institute to include the Institute's data as an additional offering of the A.M.A.'s nationwide medical information network, or "MINET." It is available to every "MINET" subscriber who has a desk-top computer and a telephone.

This enterprise pulls together government, the private nonprofit sector, and organized medicine, in this case, the A.M.A., to make information available to physicians concerning access to specialized care for their patients and as well as to a broad variety of support services in the community.

The more consumer-oriented data system is now functioning in South Carolina to benefit the citizens of that state. The system carries information on access to care and community support services within the state. Any individual or family member can gain access to the system merely by dialing a toll-free "800" number.

The Kennedy Institute has an excellent concept of how such a network will function. Under the contract recently awarded, it is hoped the South Carolina Model will be expanded to seven other states in the region. The next step should then be to extend the system nationally and thus make available to all citizens the best information and the most appropriate resources relative to handicapping conditions.

The availability of such a resource should do much to take the insecurity out of one effort to rally support services for the handicapped newborn.

In addition to this nationwide referral network, HHS and the Department of Education, in cooperation with the coalition of medical and disability organizations who signed the "Principles of Treatment of Disabled Infants," are organizing an effort to develop teaching models for health care professionals on improving infant care, aiding the decision-making process and use of the nationwide referral network.

The Department believes that informational and educational efforts of this kind are also of great importance in advancing the principles underlying the final rules.

#### V. Additional Analysis of Comments

Section III above includes an explanation of the provisions of the final rules, including an analysis of pertinent comments submitted to the Department during the comment period on the

proposed rules. This section is an analysis of other comments not directly related to specific provisions of the final rules.

#### A. LEGAL ISSUES

A significant number of commenters addressed legal issues relating to the application of section 504 to matters concerning health care for handicapped infants.

##### *Statutory Construction of Section 504*

A number of commenters argued that, as a matter of statutory construction, section 504 of the Rehabilitation Act of 1973 is inapplicable to matters concerning health care for handicapped infants. The arguments advanced by these commenters were:

(a) The statute does not specifically mention handicapped infants, and the statutory definition of "handicapped individual" should be construed as inapplicable to infants because its reference to substantial limitations on major life activities has no application to infants since all infants are dependent on the efforts of others for performance of all external life activities.

(b) The legislative history makes no mention of handicapped infants and indicates that the primary focus of Congress in enacting the Rehabilitation Act was matters relating to vocational rehabilitation, rather than medical matters; and although the statutory definition of handicapped individual was amended in 1974 to broaden its scope beyond vocational rehabilitation, including access to services such as medical care, there was no indication that the statute, as amended, was intended to cover medical judgments about the type of treatment given any handicapped individual. As stated by one commenter:

There is not even a hint in the legislative history of the Act or its amendments that would indicate Congressional intent to apply section 504 to medical treatment of severely handicapped infants. Rather, it is clear that Congress intended the Act to foster fruitful and independent living for handicapped individuals.

(c) The rulemaking history of the Department's section 504 regulations reveals previous HHS interpretations that section 504 is inapplicable.

##### *Response*

The Department's position remains unchanged. Section 504 clearly applies to matters concerning the provision of health care to handicapped infants, and nothing in the legislative history of the statute or rulemaking history of the

Department's regulations suggests a credible interpretation to the contrary:

**Section 504 provides:**

No otherwise qualified handicapped individual . . . shall, solely by reason of his handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. . . .

The statute defines a "handicapped individual" as

any person who (i) has a physical or mental impairment which substantially limits one or more of such person's major life activities. . . . or (iii) is regarded as having such an impairment.

An infant is a person. If an infant has a physical or mental impairment which substantially limits major life activities, or is regarded as having such an impairment, the infant is a "handicapped individual" within the meaning of the law. If a hospital engages in a program or activity which provides medical services to infants and if that program or activity receives Federal financial assistance, it is a "program or activity receiving Federal financial assistance" within the meaning of the law.

If an infant who is a "handicapped individual" is "otherwise qualified" to receive the benefits of a medical services program or activity receiving Federal financial assistance, and is denied, solely by reason of his handicap, the benefits of those medical services, that infant is within the protection of section 504.

A key issue, therefore, in applying section 504 in any context is that the handicapped individual who was allegedly excluded from participation in, denied the benefit of, or subjected to discrimination under, a federally assisted program or activity be "otherwise qualified" to participate in, or benefit from, the program or activity. To be "otherwise qualified," the handicapped individual must, in spite of his or her present or anticipated physical or mental impairment, be able to meet the essential requirements for participation in the program or activity.

In the context of receiving medical care, the ability to benefit for a handicapped person is the ability to benefit medically from treatment or services. If the handicapped person is able to benefit medically from the treatment or service, in spite of the person's handicap, the individual is "otherwise qualified" to receive that treatment or service, and it may not be denied solely on the basis of the handicap.

Therefore, the analytical framework under the statute for applying section 504 in the context of health care for handicapped infants is that medically beneficial treatment and services not be withheld from a handicapped infant solely on the basis of the handicap.

The legislative history makes clear that by enacting section 504 Congress intended to eliminate all of the "many forms of potential discrimination" against handicapped people through "the establishment of a broad governmental policy." S. Rep. No. 1297, 93d Cong., 2d Sess. 38 (1974). The statute applies to all federally funded programs or activities, specifically including those that provide "health services." *Id.*

The rulemaking history related to the 1977 promulgation of the Department's section 504 regulations explained that the Department was not seeking to regulate with respect to the highly controversial issue of the rights of institutionalized persons to receive treatment for the condition which led to their institutionalization. Additionally, the regulation specifies that the provision of health care services generally to handicapped persons is a matter covered by the Act and the Department's rules. 45 CFR 84.52.

It is difficult to understand the theory of statutory construction that would distinguish the provision of health care services to qualified handicapped infants from the provision of other federally assisted benefits and services to qualified handicapped individuals.

The Department cannot subscribe to the theory that the definition of "handicapped individual" should be construed as inapplicable to infants because infants are dependent upon others for all major life activities. This argument appears to be based on a much too narrow view of what constitutes "major life activities." The Department's section 504 regulations define "major life activities" at 45 CFR 84.3 (j)(2)(ii), as: "functions such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working." Infants undertake at least some of these major life activities from the moment of birth.

Moreover, if this is the theory, the Department is unaware of the basis to be used in determining at what age the protections of section 504 would begin to apply.

In summary, the Department can find no clue in any bit of legal analysis or rational policy analysis to commend the notion that there is or should be a distinction in the application of section 504 based on the age of the handicapped individual.

It appears the real basis for the contention that section 504 is inapplicable in this context is that medical care is involved, rather than what some may perceive as much less complicated matters like distributing welfare benefits, developing transportation systems, administering housing programs, delivering social services, providing educational services, making employment decisions, and the like.

The Department agrees that matters relating to the provision of medical care are in some ways different from other aspects of applying section 504. For one thing, the consequences of discriminatory treatment may be much higher—a matter of life and death. Also, the analysis involved in determining whether discrimination exists may, in some cases, be much more subtle and difficult. But one aspect that appears the same in all applications of section 504 is that decisions regarding whether handicapped persons will receive the services and benefits of programs and activities receiving Federal financial assistance are sometimes made, not on the basis of the individual's actual qualifications for, and ability to benefit from, those activities, but rather on stereotypes and prejudices concerning the limitations on major life activities faced by handicapped persons. Section 504 was enacted to eliminate these considerations from such decisions. And although the section 504 analysis may be more subtle (at least in some cases), it is an anomalous and bizarre theory that section 504 can properly be used to require that a ramp be built in a hospital to assure that handicapped persons not be denied access to medical services solely on the basis of their handicaps, but that statute may not properly be used to prevent the intentional act of allowing other handicapped persons to die in that hospital, solely because of their handicaps. The Department cannot subscribe to this theory.

In summary, the Department's position is unchanged. Section 504 clearly applies to the provision of health care for handicapped infants.

*Separating the "Handicap" from the Condition Requiring Treatment*

A number of commenters expressed views that the section 504 analysis summarized above is incapable of application in many or most cases because the handicapping condition and the condition requiring treatment are one and the same. This fact, the commenters argue, results in an inability to separate "medical judgments" from judgments relating to social, emotional,

economic, or other non-medical issues, concerning which unreasonable prejudices have often caused discrimination against handicapped individuals.

#### Response

Although perhaps subtle, the analysis required by the statutory framework is just as applicable in a case where the handicapping condition and the condition requiring treatment are the same as it is to the "simpler" case where two distinct conditions are involved.

In the "simple" case involving two distinct conditions, such as Down's syndrome and an intestinal obstruction, the Down's syndrome does not present a medical contraindication to surgical correction of the intestinal obstruction. There is no valid medical reason (assuming no other indications) for treating the Down's syndrome infant differently than an infant with the same intestinal obstruction and no Down's syndrome.

The same analysis applies where the handicapping condition and the condition to be treated are the same. In such a case the "handicap" is the physical or mental impairment the infant has or will have (or "is regarded as having") after completion of the treatment under consideration. In the case of an infant born with myelomeningocele, for example, the treatment which must be considered is surgery to close the protruding sac to prevent infection and other potentially fatal consequences. The "handicap" is the physical and/or mental impairment the infant is regarded as likely to have in future life. To the extent the myelomeningocele itself or other complications (such as respiratory problems, infection, anesthetic risk, or other factors) present, in the exercise of reasonable medical judgment, contraindications to the surgery, the infant is not able to benefit, in spite of his or her handicap, from the surgery. However, if the surgery would be medically beneficial, in that it would be likely, in the exercise of reasonable medical judgment, to bring about its intended result of avoiding infection or other fatal consequences, then failure to perform the surgery because of the anticipated impairments in future life offends section 504, as the withholding of surgery is *because of* the handicap and *in spite of* the infant's being qualified to receive the surgery.

In both the Down's syndrome and myelomeningocele examples, this analytical framework accomplishes precisely what Congress intended in enacting section 504: to overcome stereotypes and prejudices against

handicapped persons who are, in spite of their handicaps, able to participate in, and benefit from, activities and services supported by Federal funds.

All of this is not to say that application of this analytical framework in every case will be easy. Nonetheless, in spite of the difficulties which may arise in case-by-case applications, the analytical framework focusing on the provision of medically beneficial treatment to handicapped infants is the correct one under the statute, and is capable of application.

#### Applicability of Section 504 When Hospital Is Incapable of Providing Treatment

A number of commenters questioned the applicability of section 504 in cases where the hospital, due to lack of sophisticated equipment, medical specialists, or other factors, is incapable of providing the treatment needed by a particular infant. These commenters appeared to suggest that the Department would find such a hospital to be in violation of section 504 because it did not provide the medically beneficial treatment it was unable to provide.

#### Response

The answer on the applicability of the law in such a case is as clear as the applicability of common sense. Common sense indicates that if a patient needs treatment which a hospital cannot provide, the hospital will try to refer the patient to a facility that can provide it. If the patient is handicapped, the common sense response is the same. The failure of the hospital to itself provide the treatment is not "on the basis of the handicap"; rather, nontreatment is based on the fact that the hospital is incapable of providing the treatment.

Similarly, if the medically indicated course of action for any individual with a condition the facility is incapable of treating is to arrange for that individual to be transferred to a facility where the treatment can be provided, then this transfer cannot be denied to a qualified handicapped person (one who will benefit medically from it) on the basis of the person's handicap.

#### Responsibilities of Hospitals as Opposed to Physicians

Another challenge to the Department's application of section 504 to health care for handicapped infants was submitted by the Federation of American Hospitals:

... A hospital cannot practice medicine. In fact, many state laws prohibit and punish the unauthorized practice of medicine. Nevertheless, the proposed rules place the responsibility for the physician's decision on

the hospital. Moreover, assuming that discrimination on the basis of handicap exists, it is *not* discrimination on the part of the hospital, it is the discrimination of the physician and/or parents who are not recipients of federal financial assistance as that term is defined under the Rehabilitation Act. Therefore, insofar as they apply to hospitals, not physicians and parents, the proposed rules are also totally misdirected.

#### Response

The Department disagrees with the comment's implications that the law in any way requires hospitals to engage in the unauthorized practice of medicine, and that hospitals have no authority to prohibit discrimination by physicians.

It is the Department's view that a hospital has the authority to condition a physician's staff membership or renewal of membership on an agreement to abide by the hospital's policy of nondiscrimination. Indeed, the Department's conditions for hospital participation in the Medicare program require that a hospital have "an effective governing body legally responsible for the conduct of the hospital as an institution." 42 CFR 405.1021. Those conditions also require that a hospital have:

a medical staff organized under bylaws approved by the governing body, and responsible to the governing body of the hospital for the quality of all medical care provided patients in the hospital and for the ethical and professional practices of its members.

#### 42 CFR 405.1023.

Under those conditions the medical staff is also "responsible for support of . . . hospital policies." 42 CFR 405.1023(a). Standards set forth in the accreditation manual for hospitals, published by the Joint Commission on Accreditation of Hospitals, also recognize the responsibility of the governing body to adopt and approve bylaws consistent with all applicable laws and regulations. The accreditation manual also emphasizes that the governing body has the responsibility for the conduct of the hospital's operation and that the medical staff is responsible to the governing body.

It is the Department's position therefore that a hospital has the right to establish and implement a policy of nondiscrimination among its employees and medical staff, and that this does not constitute an unauthorized practice of medicine by the institution.

#### Applicability of Section 504 to Adults

Several commenters raised the issue whether section 504 would also be applicable to issues relating to medical care provided to adults. For example,



the Department received the following comment from a doctor in San Antonio, Texas:

As a doctor who practices on adult patients, what I find most worrisome about this whole sorry affair is that the reasoning behind the proposed rules applies at least as well to adults as to infants with congenital defects. Should every patient, no matter how old or ill, be forced to receive the "benefits" of cardiopulmonary resuscitation? Should a ninety-year-old man with a stroke which has caused him to develop pneumonia be subjected to weeks on a respirator in hopes of getting him well enough to go to a nursing home, where the same basic problem is sure to lead to another bout of pneumonia? Should a senile, combative eighty-year-old lady with a breast mass have a biopsy and mastectomy? Certainly a stroke and senility are handicaps if Down's syndrome is.

#### Response

Although section 504 is, of course, applicable to issues relating to health care provided to adults, the unique issues relating to health care for handicapped infants significantly affect the application of the law and justify the special procedures established by the final rules.

The special needs of infants and minors have long been recognized by most states, as its evidenced by the enactment of child abuse and neglect statutes. These statutes, in most instances, specifically reference the failure to provide necessary medical care to minors as constituting child abuse or neglect, and establish special remedial authorities.

In contrast, most adult patients are viewed by courts as being competent to give or withhold consent regarding medical treatment for themselves. In the case of adults incapable of making decisions, due to senility, mental retardation, or the like, courts have applied the "substituted judgment" doctrine to try to ascertain the incompetent patient's own wishes through available evidence and by asking what a reasonable person in the patient's situation would do.

The circumstances which give rise to the special procedures established by every state to protect children are the same circumstances which give rise to the special procedures established by the final rules to apply section 504 to matters relating to health care for handicapped infants.

#### Limitations on Obligations Imposed By Section 504

A number of commenters called attention to judicial decisions indicating limitations on the extent to which section 504 mandates that recipients of Federal financial assistance undertake

substantial changes in their programs or activities.

As stated by the American Academy of Pediatrics:

Case law interpreting section 504 suggests the existence of limitations beyond which the statute cannot reach, giving rise to the question of whether HHS' rule would impose on providers unwarranted affirmative action burdens. In *Southeastern Community College v. Davis*, 442 U.S. 397 (1979), the Supreme Court considered the claims of a licensed practical nurse that her denial of admission to a college nursing program on the basis of her hearing disability violated section 504. The college had determined that Davis's impairment was such that, even with a hearing aid, she would be unable to participate fully in the program and function effectively as a nurse. According to the plaintiff, however, the college should not have taken her handicap into account in determining whether she was "otherwise qualified" for the program, but, rather, should have confined its inquiry to her academic and technical qualifications. The Court rejected this argument, finding that section 504 "by its terms does not compel educational institutions to disregard the disabilities of handicapped individuals. . . ." 442 U.S. at 405.

Davis argued further that HHS regulations implementing section 504 required that the nursing program be modified to accommodate her, to which the Court replied:

If these regulations were to require substantial adjustment in existing programs beyond those necessary to eliminate discrimination against otherwise qualified individuals, they would do more than clarify the meaning of § 504. Instead, they would constitute an unauthorized extension of the obligations imposed by that statute. *Id.* at 410. . . .

#### Response

The only affirmative step required of recipient hospitals by the final rules is to post an informational notice. As explained in the preamble, the Department has sought to tailor the notice, with respect to both its wording and the locations for its posting, so as to avoid any disruptive or administratively burdensome effects. The posting of notices to advise individuals of protections provided by Federal laws is very common in connection with a wide range of civil rights, health and safety, consumer protection, labor standards, and other Federal laws. The posting of this notice cannot be credibly argued to constitute the kind of excessive regulation prohibited by the *Davis* doctrine.

The other provisions of the final rule which affect hospitals, the clarification regarding access to records and the narrow exception to the ten-day notice rule, similarly impose no appreciable administrative burdens on hospitals. The provision of the final rules relating to state child protective services

agencies also, as explained in the preamble, imposes no significant burdens.

The case-by-case application of section 504 and existing regulations, entirely separate from any mandatory provision of the final rules, is, of course, subject to the *Davis* limitations. However, as clearly evidenced by the guidelines set forth in the appendix to the final rules, these limitations have been fully complied with in connection with the Department's interpretations of the application of section 504 and in its enforcement processes.

Section 504, as the *Davis* decision recognized, requires the operation of a recipient's program in a nondiscriminatory fashion. The Department's interpretations and procedures applicable in this context require no more. The guidelines in the appendix make clear the Department interprets section 504 as not requiring the provision of futile treatments and as respecting reasonable medical judgments. Further, they make clear that investigative procedures have been specially crafted to avoid substantial administrative burdens. The basis of the Supreme Court's decision in *Davis* was that because the Court found it unlikely that the plaintiff could benefit ultimately from the nursing program, the college's refusal to make substantial modifications to its educational program to accommodate the plaintiff was not discriminatory. The appendix guidelines make clear that the Department's interpretation of section 504 in this context carefully adheres to this ability to benefit requirement.

The *Davis* decision did not authorize the evasion of section 504 obligations under the guise that adhering to the nondiscrimination mandate may require some attention. However the courts ultimately refine the doctrine that there are limitations on the scope of section 504, it is the Department's firm position that those limitations are in no way touched by the mandatory requirements of the final rules, nor will they be touched by case-by-case application of the law consistent with the guidelines set forth in the appendix to the final rules.

#### Medicare and Medicaid as "Federal Financial Assistance"

A number of commenters also disputed the Department's legal authority for the rules on the grounds that participation by hospitals in the Medicare and Medicaid programs did not bring them within the coverage of section 504 on the grounds that Medicare and Medicaid are not

"Federal financial assistance" within the meaning of the Act.

#### Response

The Department's position, consistently held since the Medicare and Medicaid programs were originally enacted in 1965, that Medicare Part A payments to hospitals and Medicaid constitute Federal financial assistance for purposes of applicability of Title VI of the Civil Rights Act of 1964 and the nondiscrimination statutes modeled after it, including section 504, is unchanged.

Because the rules do not specifically refer to the Medicare or Medicaid programs, the validity of the rule is not dependent upon the Department's long-standing interpretation. However, hospital officials who believe their hospitals are not subject to these civil rights laws may wish to inform themselves of the Department's position and the substantial legal support for it.

The Department's position has been clear, unequivocal, and consistent. The appendix to the Department's title VI regulations lists Medicare and Medicaid as programs of Federal financial assistance. 45 CFR Part 80, Appendix A, Part 1, No. 121, and Part 2, No. 30. The appendix to HHS's section 504 regulations makes clear HHS's interpretation that the scope of jurisdiction of section 504 is the same as that for title VI. 45 CFR Part 84, Appendix A, Subpart A, No. 2.

The legislative history of the Medicare statute makes clear that Medicare payments to hospitals were intended to constitute Federal financial assistance for purposes of the applicability of title VI of the Civil Rights Act, and thus section 504 as well. Speaking on the floor of the Senate in support of the Medicare bill, Senators Ribicoff and Hart stated unequivocally that title VI was applicable to hospitals participating in Medicare. Senator Ribicoff:

"[H]ospitals and other institutions have . . . to abide by Title VI of the Civil Rights Act." 111 Cong. Rec. 15803 (1965). Senator Hart:

In addition to the new economic independence it will create, I am hopeful that the bill will promote first class citizenship in another fashion also. We decided last year, and wrote into law, that federal tax dollars collected from all the people may not be used to provide benefits to institutions or agencies which discriminate on the grounds of race, color, or national origin. This principle will, of course, apply to hospital and extended care and home health services provided under the social security systems, and will require institutions and agencies furnishing these services to abide by Title VI of the Civil Rights Act of 1964. Id. at 15813 [emphasis supplied].

In addition, the legislative history of the Civil Rights Act supports this position. In the most complete analysis of title VI contained in the House Judiciary Committee's Report, the additional views of seven supporters of the legislation, uncontroverted in any section of the report, specifically made reference to the predecessor program to Medicaid and clearly stated congressional policy underlying title VI:

In a related fashion, racial discrimination has been found to exist in vendor payment programs for medical care of public assistance recipients. Hospitals, nursing homes, and clinics in all parts of the country participate in these programs and, in some, Negro recipients have received less than equal advantage.

In every essential of life, American citizens are affected by programs of Federal financial assistance. Through these programs, medical care, food, employment, education, and welfare are supplied to those in need. For the government, then, to permit the extension of such assistance to be carried on in a racially discriminatory manner is to violate the precepts of democracy and undermine the foundations of government.

H.R. Rep. No. 914, 88th Cong. 2d Sess. (Additional Views on H.R. 7152 of Hon. William M. McCulloch, et al.).

Courts which have dealt with this issue have found Medicare and Medicaid to constitute Federal financial assistance for purposes of establishing civil rights jurisdiction. A recent such case is *United States v. Baylor University Medical Center*, 564 F. Supp. 1495 (N.D. Tex. 1983). Citing HHS regulations indicating that Medicare and Medicaid are Federal financial assistance, case law in which courts "have had little difficulty" in finding that they are Federal financial assistance, the legislative history of the Medicare statute, long-standing agency interpretation, and the broad construction which must be given to remedial civil rights statutes, the court found that Medicare and Medicaid are Federal financial assistance for purposes of section 504 coverage. The court also specifically rejected the medical center's argument that Medicare and Medicaid payments are exempt from the definition of "Federal financial assistance" on the grounds of being under contracts of insurance. The Court distinguished insurance programs, by noting that Medicare is funded by mandatory taxes and Medicaid by general revenues, rather than through a system of risk-based premiums.

Other cases supporting the position that Medicare and Medicaid payments are Federal financial assistance are *NAACP v. Wilmington Medical Center*,

657 F.2d 1332 (3d Cir. 1981) (the court noted its jurisdiction was based on the hospital's receipt of Medicare and Medicaid funding); *United States v. Cabrini Medical Center*, 497 F. Supp. 95, 96, n.1 (S.D.N.Y. 1980); *Cook v. Oschner*, No. 70-1969 (E.D. La., Feb. 12, 1979) (the defendants' argument that Medicare and Medicaid payments did not constitute Federal financial assistance was rejected by the district court during pre-trial motions); *Flora v. Moore*, 461 F. Supp. 1104, 1115 (N.D. Miss 1978); and *Bob Jones University v. Johnson*, 396 F. Supp. 597 (D.S.C. 1974), *aff'd*, 529 F.2d 514 (4th Cir. 1975) (court held that VA benefits to students constituted Federal financial assistance to the university and noted their similarity to Medicaid).

The basic congressional policy underlying title VI, section 504 and related statutes is that federally funded programs and services are to be administered in a nondiscriminatory fashion. The Medicare and Medicaid programs were established for the purpose of providing medical service to people who otherwise might not be financially able to obtain them. The argument that somehow these federally assisted medical services were not intended to be within the reach of the nondiscrimination rule is clearly contrary to the basic congressional policy. Underscoring this is the fact that HHS spends billions of dollars annually for health care services to the aged, disabled, and poor, and virtually all hospitals participate in these programs. According to data of the Health Care Financing Administration (HCFA), HHS, of approximately 6,930 hospitals, 6,737 participate in Medicare and virtually the same number in Medicaid. In fiscal year 1982, total hospital costs in the United States were \$136 billion. Of this, \$47.9 billion were HCFA expenditures (\$36.3 billion, Medicare, \$11.6 billion, Medicaid). Approximately 36 percent of all hospital costs in the United States are financed through the Medicare and Medicaid programs. See *HCFA Statistics* (Publication No. 03155, Sept. 1983).

It should also be noted that there are no persuasive arguments for distinguishing Medicaid and Medicare on the question of whether they constitute Federal financial assistance to hospitals. Although Federal Medicaid funds flow through the states, the states' relationship to the hospitals in Medicaid is essentially the same as that of the Federal government to the hospitals in Medicare. HHS regulations for both title VI and section 504 specify that recipients of Federal financial assistance include all subrecipients

which receive funds from a recipient. 45 CFR 80.13(i), 84.3(f).

In addition, Medicare and Medicaid cannot be considered procurement contracts for purposes of the statutory exemption from civil rights jurisdiction in connection with such contracts. Unlike the relationship that exists under procurement contracts, health care providers promise only that if they serve an eligible beneficiary of the program, they will look to the government for payment of all but specified items. In addition, under Medicare and Medicaid the level of services is determined by providers who are not acting as agents for the government and are not discharging an obligation the government has assumed. Rather they are—with Federal assistance—engaging in activities they have long performed. In this respect Medicare and Medicaid payments are indistinguishable from grants to pay the costs of medical services. Indeed, those payments often cover medical costs of indigent patients that hospitals would otherwise be required to absorb pursuant to their other legal obligations. In contrast, under a procurement contract the government acts on its own account as a consumer of goods, such as typewriters and paper clips, or services, such as hotel accommodations and rental car services for traveling employees. The level of services under procurement contracts is determined by the government and not, as under Medicaid or Medicare, by the provider.

Furthermore, the Medicare and Medicaid programs do not fall within the statutory exemption from the definition of Federal financial assistance for any payments pursuant to "a contract of insurance or guaranty." 42 U.S.C. 2000 d-1, 2000 d-4 (title VI); 45 CFR 84.3(h) (section 504). The principal object of the Medicare and Medicaid programs is to provide service. Medicare and Medicaid programs cannot properly be characterized as, or analogized to, a contract of insurance. Benefits under these programs are not measured by any fixed premium paid by the beneficiary to the government; the government reimburses for the reasonable cost incurred by the provider in rendering services. Missing from both reimbursement plans is that essential element of insurance—the assumption of risk. The Medicare and Medicaid programs do not purport to indemnify for nonpayment by the beneficiary. The hospital, in becoming a provider of services under these programs, agrees to look to the government for payment and to accept the reimbursement from the government as full payment, except for

the deductible and coinsurance. The beneficiary does not incur any obligation to pay for those services which are covered by the agreement between the provider and the government.

Nor do Medicare and Medicaid constitute contracts of guaranty. Essential to a definition of a contract of guaranty is a primary obligation on the part of the individual for whom the guaranty is given. A contract of guaranty is a promise to pay or an assumption of performance of some duty upon the failure of another who is primarily obligated in the first instance. In contrast, the reimbursement provisions of the Medicare and Medicaid programs are not activated by the failure of the individual recipient to pay for the medical services covered by agreement between the government and the hospital.

It is the absence of these elements which distinguishes Medicare and Medicaid from programs that Congress intended to be excluded under the contract of insurance or guaranty exception, such as mortgage guarantees under FHA or VA and depositors' insurance under FDIC, where the role of the government is clearly as an insurer or guarantor and Federal monies are involved only if the private party does not meet his or her obligation. It is also noteworthy that the American Hospital Association apparently concluded in 1966, when Medicare was instituted, that hospitals receiving Medicare were recipients of Federal financial assistance for title VI purposes. The AHA solicited and printed in its journal a question and answer article prepared by the former Department of Health, Education and Welfare to help hospitals understand what they were required to do to comply with title VI to receive Medicare funds. See "Hospitals and Title VI of the Civil Rights Act of 1964, Questions and Answers," *Hospitals*, June 1, 1966. Also, pursuant to 45 CFR 84.5, hospitals which participate in the Medicare and Medicaid programs have submitted assurances to HHS that they would comply with section 504 and the applicable regulations.

Accordingly, as demonstrated by this brief summary of points in support of the Department's long-standing position, hospitals which participate in the Medicare and Medicaid programs are recipients of Federal financial assistance for the purpose of establishing section 504 jurisdiction.

#### *"Program or Activity" Receiving Federal Financial Assistance*

Another argument presented by some commenters to dispute the legal

authority for the proposed rule is that even if Medicare and Medicaid are "Federal financial assistance," they are not "a program or activity" which provides medical care to handicapped infants. The argument appears to be that, purportedly following the analysis of the government's brief to the Supreme Court in the pending case of *Grove City College v. Bell*, 687 F.2d 684 (3d Cir. 1982), cert. granted, 51 USLW 3611, February 22, 1983 (#82-792), the "program or activity" which receives Federal financial assistance in the form of Medicare and Medicaid payments to a hospital is the fiscal accounting office of the hospital.

As stated by the American Academy of Pediatrics:

... to the extent, then, that the government believes that Title IX cannot extend beyond the financial aid office, is difficult to understand how section 504 could extend to nurseries, maternity wards, and neonatal intensive care units simply because the medical expenses of primarily elderly Medicare beneficiaries are reimbursed in the accounting office.

#### *Response*

The Department believes this argument is without merit. The position advanced by the government in *Grove City* is that in determining what constitutes the Federally assisted program, it is necessary to examine both the nature of the Federal program and the organizational practices of the recipient institutions. *Grove City* involves the Basic Education Opportunity Grants program (BEOG), in which grants are made to students and used by the students to pay for tuition, fees, room and board. The recipient institutions operate financial aid programs under the direction of a financial aid office, with a separate budget and a specific purpose, to provide financial aid to students who otherwise could not afford to attend the college. BEOG's are one component of the college's financial aid program. In view of the nature of the Federal BEOG program and the organizational practices of colleges, it is the college's financial aid program that receives the Federal assistance. Although, conceivably, an effort could be undertaken to "trace" the "ripple effects" of the BEOG money throughout the college, the government's position in *Grove City* is that this is not what Congress intended in enacting the program specificity requirement in the applicable civil right statutes.

The circumstances involved in connection with Medicare and Medicaid reimbursements to hospitals are entirely

different from those involved in BEOC's and colleges. Rather than providing assistance to a general financial aid program operated by the recipient, Medicare and Medicaid payments to hospitals are primarily for particular medical services provided to particular patients who received services in particular units of the hospital. It is services provided to particular beneficiaries by the hospital's operating room, x-ray department, laboratory, pediatrics ward, or other organizational units that give rise to the Federal reimbursements. In addition, the hospital's organizational and accounting practices provide for Federal reimbursement for a proportionate share of administrative costs, housekeeping, depreciation of physical plant, and other general expenses, all specifically itemized and specifically eligible for reimbursement.

Also unlike colleges, "tracing" Medicare and Medicaid reimbursements within hospitals is not dependent upon looking for "ripple effects" of the Federal funds. Rather, it is the specific identification of actual services and costs which gives rise to reimbursements based specifically thereon.

Therefore, the Federally assisted program of a hospital is not, as a commenter suggested, the accounting office of the hospital, any more than the Federally assisted program of a college is the accounting office or comptroller. An examination of the applicable Federal programs and the recipient's organizational practices makes clear that the issues presented in the *Grove City* case, and the positions taken by the government in that case, do not undermine the legal basis for the final rules or the application of section 504 to health care for handicapped infants.

It should also be noted that whatever subtleties or twists are ultimately associated with the interpretation of "program or activity," the final rules specifically accommodate the program specificity requirement pertaining to the posting of the informational notice as applicable to each recipient that provides health care services to infants "in programs or activities receiving Federal financial assistance." If, on the basis of the Supreme Court's eventual decision in *Grove City* or other factors, limitations evolve on what programs or activities of hospitals are covered by section 504, those limitations will be accommodated by the text of the rules.

#### *Services vs. Employment as Jurisdictional Limitation*

The Federation of American Hospitals advanced another argument in behalf of

the proposition that the Department has no legal authority to issue the final rules. The Federation commented:

The Rehabilitation Act of 1973 (Pub. L. 93-112) does not apply to hospitals. Federal circuit courts of appeal which squarely address the issue uniformly hold that the Act does not apply to hospitals as recipients of Medicaid or Medicare funds. These courts have held that the Rehabilitation Act applies to recipients of federal financial assistance if, and only if, that assistance has the primary objective of providing employment.

In *United States v. Cabrini*, 639 F.2d 908 (2d Cir. 1981), the Court . . . [held] that the Office for Civil Rights was not authorized to investigate a complaint by a hospital employee that he was discharged for mental disability. . . . *Tragesar v. Libbie Rehabilitation Center, Inc.*, 590 F.2d 87, 89 (4th Cir. 1978), cert. den'd, 442 U.S. 947; *Scanlon v. Atascadero State Hospital*, 677 F.2d 1271, 1272 (9th Cir. 1981); see, also, *Carmi v. Metropolitan St. Louis Sewer District*, 620 F.2d 672, 674-675 (8th Cir. 1980), cert. den'd, 101 S. Ct. 248 (1980) . . .

As there is no legal authority supporting the proposition that the Rehabilitation Act of 1973 applies to hospitals receiving Medicare and Medicaid funds since the primary objective of those programs is not employment; the proposed rules must be withdrawn.

#### *Response*

The Federation's legal argument is incorrect. The *Tragesar/Carmi/Cabrini Scanlon* line of cases holds that section 504 does not provide jurisdiction over employment practices of recipients unless the Federal financial assistance has the primary objective of providing employment. These cases held that section 505(a)(2) of the Rehabilitation Act, making the "remedies, procedures, and rights set forth in title VI of the Civil Rights Act of 1964" applicable to section 504, incorporated the restriction in section 604 of the Civil Rights Act of 1964, which makes title VI inapplicable to employment practices unless the Federal financial assistance has the primary objective of providing employment. Two circuit courts have recently held that the reference to title VI procedures in section 505 did not intend to incorporate the employment restriction. *Jones v. Metropolitan Atlanta Rapid Transit Authority*, 681 F.2d 1376 (11th Cir. 1982), petition for cert. pending, No. 82-1159 (filed January 11, 1983); *LeStrange v. Consolidated Rail Corporation*, 687 F.2d 767 (3d Cir. 1982), cert. granted. The Supreme Court is expected to decide this issue during its present term.

Regardless of the merits of that issue, it has no relevance to the final rules. No case has held, as none could based on the clear statutory language and congressional intent of section 504, that

section 504 applies only to a very narrow segment of employment practices, and has no applicability to the provision of services and benefits under programs and activities receiving Federal financial assistance.

#### *B. ENFORCEMENT PROCESSES*

A prior section of this preamble discusses investigative procedures of the Department applicable in the context of health care for handicapped infants and an analysis of related comments. This section discusses other comments pertinent to this issue.

#### *Sanction for Non-Compliance*

A number of commenters stated objections to the sanction for non-compliance, termination of Federal financial assistance. The basic thrust of these comments was that termination of all or a portion of a hospital's Federal financial assistance would be unfair in the context of difficult treatment decisions, later judged by HHS to be in non-compliance with section 504. As stated by the American Hospital Association:

The penalty for even inadvertent violation would be severe. The Department asserts authority and threatens to terminate all federal financial assistance that the individual or institution may be receiving. Moreover, the threat of such penalties may encourage physicians and others to refuse to participate in programs funded by the Federal government, particularly those supporting specialized treatment facilities for the newborn. In cases where the institution depends for operation on significant federal funds unrelated to handicaps, this policy may, for example, cause the closing of neonatal units to avoid the risk of losing federal funds. Such a result could reduce access to needed care for many infants who could be helped with safe, timely and effective treatment.

#### *Response*

It is correct that under the law, non-compliance with section 504 can result in termination of Federal financial assistance to the particular program or activity, or part thereof, in which the noncompliance has been found. However, the existing procedural and legal requirements applicable to any action to terminate Federal financial assistance are more than adequate to protect against an unfair result.

The Rehabilitation Act provides, in section 505(a)(2), that the remedies, procedures and rights set forth in title VI of the Civil Rights Act of 1964 shall be applicable to actions to enforce section 504. These title VI procedures provide substantial due process protections.

First, before Federal financial assistance can be terminated, the

recipient must have an opportunity for a hearing before a court or administrative law judge, who must expressly find that there has been a failure to comply with the law or applicable regulations.

Second, before Federal financial assistance can be terminated, there must be a finding that compliance cannot be secured by voluntary means. Therefore, a recipient that has been found to have violated section 504 in connection with the health care provided to a handicapped infant will not lose its Federal funding unless it refuses to adopt the standards or procedures necessary to prevent future noncompliance.

Third, in any case, the burden of proof that there has been noncompliance and that it cannot be corrected by voluntary means is on the government. The standards for this determination are those set forth in the appendix to the final rules which includes the guideline regarding deference to reasonable medical judgments.

Fourth, the Department's regulations provide for appeal of adverse administrative law judge decisions to the Department's Civil Rights Reviewing Authority, which is independent from the Office for Civil Rights. Recipients may then seek review by the Secretary of the decisions of the Reviewing Authority. Further, the Department's final decision is subject to judicial review.

Therefore, there is no basis for an assertion that Federal financial assistance can be precipitously terminated on the basis of some subjective determinations by a handful of bureaucrats. In fact, due primarily to the statutory requirement that recipients be given full opportunity to voluntarily comply, the chance, based on all prior governmental experience under title VI and the statutes modeled after it, that any recipient will actually lose its Federal financial assistance is rather remote.

#### *OCR Investigations at Strong Memorial Hospital and Vanderbilt University Hospital*

In support of criticisms of OCR investigations, a number of commenters cited reports of hospitals which were subjects of OCR investigations at the time the interim final rule was put into effect in March. As stated by the American Hospital Association:

The mischief of the federal hotline enforcement mechanism was illustrated graphically during the short life of the March rule by the occurrences at Vanderbilt University Hospital in Nashville and Strong Memorial Hospital in Rochester, NY. In the Vanderbilt case, an anonymous hotline caller

alleged that ten named children at the hospital were not being fed or given proper medical care. A federal "Baby Doe squad" (consisting of lay officials from the regional and national staffs of the Office of Civil Rights and a hired neonatologist) arrived at the hospital that evening and met with the attending physicians for each of the children, the chief of pediatrics, the chief pediatric resident, and the associate director for nursing, after which the neonatologist examined each child. On the following day, the investigative team examined medical records and interviewed nursing staff, hospital administrators, and the chief of pediatrics.

[The investigation] resulted in the delayed discharge of one patient, delayed the transporting of children to scheduled surgery, necessitated the re-ordering of laboratory reports, diverted nurses from patient assignments, delayed nursing shift reports, and consumed, in total, substantial amounts of professional time that otherwise would have been devoted to the care of patients, including the infants who were the subjects of the investigation.

The Strong Memorial experience was strikingly similar and even more disturbing. An unidentified hotline caller, whose only information concerning the case apparently came from a newspaper report, triggered an investigation regarding the treatment of conjoined twins in that facility. An identically constituted investigative squad arrived at the hospital, though without any statement of investigative authority or written requests for hospital records. The hospital complied nonetheless with the investigators' requests, only to have the team disagree as to which of them was entitled to the information. The neonatologist member of the team subsequently departed upon learning that the investigators had failed to obtain the parents' consent to examine the infants.

The effects of the investigation in this case went well beyond the diversion of patient care resources and delays in treatment. The parents of the conjoined infants were subjected to substantial undesired publicity. Parents of other critically-ill children were led by this publicity and the lack of clarification from federal investigators to become apprehensive about the adequacy of care provided at Strong Memorial. Before the investigation concluded, one family removed its seriously-ill child from the facility prior to the completion of treatment, on the belief that the hospital was intentionally harming children.

#### *Response*

The Department strongly disputes the accounts of these investigations provided by personnel affiliated with the two hospitals. The reports referenced by commenters appear to be based upon affidavits prepared in connection with litigation initiated by the American Hospital Association challenging the implementation of the March interim final rule. Contrary to these reports, both of these investigations were conducted very

expeditiously and professionally, and every effort was made to minimize any disruption to the hospitals. In addition, during the course of these investigations (and prior to their being raised in the litigation), officials of neither hospital complained to OCR regarding the conduct of the investigations, nor, in either case, did hospital personnel complain to OCR personnel that the investigations were causing significant disruptions to the patient care activities of the hospital.

With respect to the Strong Memorial Hospital case, the following are the pertinent facts of the investigation:

a. On the morning of March 29, 1983 (seven days after the effective date of the interim final rule), a complaint was received on the hotline about conjoined infants recently born at Strong Memorial Hospital in Rochester, New York.

b. An investigative team consisting of one investigator from the Washington Office and two from the New York Regional Office was sent to the site to investigate. The team arrived at approximately 4:30 p.m. Arrangements were made to have a medical consultant also travel to the site.

c. The team met with a hospital administrative officer and the attending physician. The attending physician reviewed the infants' condition and status. He mentioned that there was a no-resuscitation order in effect for the twins, should cardiac arrest occur.

d. The attending physician told OCR that the parents were concerned about publicity. OCR assured him that OCR would not discuss the case with the media or otherwise publicize OCR's investigation.

e. The OCR team made no request to interview other staff at that time. The administrator produced a copy of the medical records. The Washington Office investigator received it and said it would not be necessary to produce another copy for the Regional Office. Throughout the investigation, the administrator and attending physician were cooperative and helpful. The attending physician asked the team leader to tell the OCR medical consultant that he could be called late and would be glad to come to the hospital and meet with him, show him the medical records, and let him view the infant. The administrator asked to be called when the medical consultant arrived. The OCR team left the hospital at about 7:30 p.m.

f. The OCR medical consultant arrived in Rochester about 9:15 p.m. and met with the investigative team. Apparently based on a misimpression of his role, the consultant stated he would not review

the records or go to the hospital to meet with the physician or view the infants unless the parents consented.

g. On the morning of March 30, 1983, the OCR team and the OCR medical consultant had a telephone conversation with the administrator. He said that he wished the OCR team would not return to the hospital because that investigation was receiving publicity. The team leader decided there was no need to return to the hospital.

h. In summary, the investigative team was on site only three hours in the late afternoon and early evening of March 29.

With respect to Vanderbilt University Hospital, following are the pertinent facts of the case:

a. OCR received a hotline telephone call at 11:45 a.m. on March 23, 1983 (the day after the effective date of the interim final rule), alleging that ten infants at Vanderbilt University Hospital were not receiving treatment and/or nourishment.

b. From 9:30 p.m. to 11:45 p.m. on March 23, 1983, the OCR investigative team, consisting of two investigators from the Atlanta Regional Office, one from the Washington Office, and the OCR medical consultant, met with various members of the hospital staff to discuss the current status of the ten infants.

c. After this meeting, from midnight until 12:30 a.m., the OCR medical consultant physically viewed the infants on the regularly scheduled "rounds" in the company of the Chief Pediatric Resident and the Chief of Pediatrics.

d. From 8:00 a.m. until 2:45 p.m. on March 24, 1983, the OCR investigators and medical consultant reviewed the available medical records of the ten children. Medical records were given to OCR in groups of four and retrieved as needed by the Associate Director of Nursing and other members of the Vanderbilt staff. The Associate Director of Nursing and the hospital staff members were very cooperative, and at no time did they indicate to the investigative team that the review of records was causing any problem. In only one instance did they indicate they needed a chart, and OCR immediately relinquished it. That chart was not subsequently made available for review that day, but a copy of it was mailed to OCR.

e. All records were reviewed with the understanding that if they were needed for patient care they would be retrieved. Computer printouts detailing the admitting diagnosis, age, physician assigned to the case, service area, and the date of admission or transfer for all ten children were given to the OCR

team. The Associate Director of Nursing stated that this printout was readily available because the information was kept on-line for billing purposes and this would not interfere with patient care. The bedside charts were copied and given to OCR at the end of day because they were needed for patient care.

f. Following the OCR review of the medical records, from approximately 2:45 p.m. to 4:00 p.m. on March 24, 1983, the OCR team interviewed the available nurses who were involved in the primary care of the infants. Five nurses were interviewed for approximately 10 to 15 minutes each. The selection of the nurses was left to the discretion of the Associate Director of Nursing; she scheduled them so that patient care would not be disrupted.

g. At no time did the Chief of Pediatrics or Associate Director of Nursing indicate that the OCR investigation was placing patients in jeopardy.

h. The hospital staff asked the OCR team for a preliminary statement of findings. The team leader responded that OCR investigators are not authorized to make findings during an investigation. An investigative report would have to be prepared following the investigation, and this would have to be reviewed before the agency could issue findings.

i. The total time spent on-site to investigate the circumstances relating to all ten infants was approximately eleven hours. The total time occupied of the two Vanderbilt doctors directly involved was seven and one-half hours. Every effort was made to minimize any disruption, and at no time during the investigation did hospital personnel complain to OCR that the investigation was disrupting patient care.

Therefore, contrary to the reports of hospital officials, prepared to support litigation against the Department, these investigations were conducted professionally and every effort was made to minimize any disruptions.

Concerning the report that, according to a hospital official, one family withdrew a seriously ill patient from the Strong Memorial Hospital before completion of treatment due to fears that the hospital was intentionally harming children, caused by their reading of local newspaper accounts of the investigation, the report provided no further details, and the department has no basis to confirm the event or the motivations for it. However, the firm policy of not commenting to the media regarding an open investigation was adhered to strictly in the Strong Memorial Hospital case. Media attention was not provoked by OCR, nor

did OCR make any statement to the media which could have implied any belief by OCR that the allegations of the complaint were substantiated.

#### *Danger of Overtreatment*

Several Commenters expressed the concern that the existence of OCR's enforcement process would cause hospitals and health care professionals to "overtreat" an infant. An example of this is a case in which the attending physician or physicians have concluded on the basis of reasonable medical judgment that treatment would be futile, but, due to a fear that an OCR investigation might come to a contrary conclusion, nevertheless provide futile treatment, which, while prolonging the process of dying, causes suffering to the infant and severe distress to the infant's parents. In connection with adverse ramifications of overtreatment, attention was called to the experiences of one family, as presented in a recent book, *The Long Dying of Baby Andrew* (Little, Brown and Co., Boston, 1983).

#### *Response*

The Department believes that whatever the dangers are that physician misjudgments will lead to "overtreatment" of infants, those dangers are not increased by the existence of section 504 or the determination of the Department to see that it is effectively enforced. As indicated above, section 504 does not require that futile treatments, which will do no more than prolong the act of dying, be provided. Moreover, OCR decisions concerning compliance or noncompliance with section 504, informed by the expert evaluation of qualified medical consultants, do not interfere with reasonable medical judgments. Also, in any case, reviewing whether certain care was medically indicated and denied on the basis of the infant's handicap, there are extensive due process protections to assure accuracy of fact finding. Furthermore, even where there is an ultimate finding, after exhaustion of all due process rights, of noncompliance of section 504, no sanction can be implemented unless the recipient hospital refuses to adopt procedures to bring it into compliance.

The Department agrees that in a "close case" it may be prudent to preserve the status quo pending additional consideration regarding whether certain possible treatments are medically indicated, whether that additional consideration is by specialists at the hospital, by medical professionals at a more specialized facility, by some internal hospital

review board, or by some state or federal agency. In such a case, the usual practice in most hospitals likely would be to continue life-sustaining care until the appropriate analysis has been secured.

### C. ALTERNATIVE APPROACHES

In addition to proposals discussed in the preamble concerning establishment of Infant Care Review Committees, the Department received other suggested alternative approaches.

#### *AMA Proposal: Further Study Prior to Action*

The American Medical Association proposed that, rather than adopting any regulation, the Department should initiate a study to include: compilation of data on the incidences of each type of severe impairment in newborns and of successful treatment, unsuccessful treatment and nontreatment in each category; identification of the issues involved in medical management and of mechanisms currently used by hospitals and states; determination of the availability of facilities, financial resources, and public and private social services; and an assessment of the impact of the various alternative means of responding to situations involving severely impaired newborns, including such factors as the ongoing treatment of newborns, the families of severely impaired newborns, the operation of health care facilities, the confidentiality of patient-physician relationship, the malpractice and disciplinary risks of health care providers, the availability of facilities and resources, and the costs of care.

#### *Response*

The AMA's proposal for an elaborate study prior to taking any action concerning this matter is not acceptable to the Department. The Department does not believe it is necessary—or in some respects, even possible—to generate definitive data, information or conclusions on many of the issues identified in the AMA's study proposal.

Much of the data the AMA proposes be compiled concerning the incidence rates of every classification and degree of serious impairment, of respective modes of treatment, of rates of success, nonsuccess and nontreatment, and of issues, mechanisms, resources and costs is probably impossible to compile. These matters are the subject of an entire discipline of medical practice and study. To suggest that a government study will somehow generate conclusive information on these issues appears naive at best.

The call for a study of the resources available and the costs of care for newborns appears aimed at identifying an aggregate cost to society of putting into practice the principle of providing all handicapped infants with medically beneficial treatment. Because there are no reliable data available on the extent to which handicapped infants are now denied medically beneficial treatment, it would appear impossible to develop even reasonable guesses regarding aggregate costs. Of course, in the overall context of all health care expenditures in the United States, the costs are certain to be relatively small.

In question 6 included in the preamble to the July 5 proposed rule the Department sought input on this cost issue by asking for "examples of cases where medically indicated treatment would, but for the legal requirements of section 504, be withheld." No information was submitted to the Department in response to this question which provides a basis for meaningful cost projections. Although the AMA did not address the issue, other major medical organizations who commented on the cost issue indicated that cost should not be a determinative factor in deciding upon treatment for seriously impaired newborns.

The Department agrees there is utility in assessing the impact of various alternative means of addressing and responding to situations involving severely impaired newborns. Much of this preamble focuses on precisely this issue. Although the AMA did not identify the "various alternative means" it believes to exist to deal with this issue, based on the comments received by the Department, there would appear to be three major approaches: (1) Enforcement of section 504 (hereinafter "the section 504 approach"); (2) review by hospital review boards, such as Infant Care Review Committees (hereinafter "ICRC approach"); and (3) the traditional doctor-parent approach.

Concerning impact on treatment of newborns, the section 504 approach is most directly focused on the provision of medically beneficial treatment. The ICRC approach would be organized to have this as its objective, but lacks a mechanism to assure this as a relatively uniform result among thousands of hospitals. The connection between actual practice and this objective appears most potentially attenuated under the traditional doctor-parent approach, under which there are many thousands of individual decisionmaking units.

With respect to the impact on families to the extent some parents

would not consent to medically beneficial treatment, the traditional doctor-parent approach would appear least likely, given the lack of a mechanism to facilitate uniformity, to resort to the system provided by State law to review the propriety of parental decisions. The ICRC approach appears more likely, and the section 504 approach most likely, to produce this result in that they incorporate standards that the lack of parental consent for medically beneficial treatment must be brought to the attention of the appropriate state agencies.

Concerning the impact on the operation of health care facilities, the traditional doctor-parent approach would appear to have the least impact because the facilities have no formalized involvement in the decisionmaking process. Both the section 504 approach and the ICRC approach would likely result in greater involvement of the health care facility.

With respect to the confidentiality of patient-physician relationships, the traditional physician-parent approach is most protective of confidentiality in that it does not provide for the sharing of information with others. Both the section 504 approach and ICRC approach involve the sharing of information with others, but both incorporate adequate confidentiality safeguards.

With respect to the impact on malpractice and disciplinary risks (assuming that by disciplinary risks, the AMA is referring to revocation of medical licenses, or the like) of health care providers, to the extent physicians have malpractice or disciplinary vulnerabilities relating to incorrect diagnoses or inadequate knowledge of prevailing medical judgments regarding indicated treatments, approaches which facilitate the avoidance of failure to provide medically indicated treatment would appear to reduce those vulnerabilities. Because none of the approaches involve doctors or hospitals overruling parental decisions, and because reports to State agencies of suspected instances of neglect of children are immunized by state law from legal vulnerability, none appear to increase malpractice or disciplinary risks in the context of actions which would be taken when parents refuse consent for medically beneficial treatment.

With respect to the impact on costs, available resources, and available facilities, to the extent the different approaches affect the likelihood that handicapped infants will receive medically indicated treatment, these factors will be correspondingly affected.

However, the Department is unaware of any data base for quantifying these factors.

In summary, the Department believes adequate information is on the record to provide a basis for prudent and informed decisions on this issue. Regarding several of the issues raised by the AMA proposal, the Department agrees there would be advantages in having more detailed information and data. However, obtaining more definitive information on some of these issues is impracticable or impossible due to the lack of a reliable data base and a viable methodology to obtain better data. Therefore, the Department believes there would be very little to be gained from another government study of this issue.

#### D. FACTUAL BASIS FOR FINAL RULES

##### NPRM Explanation

A number of commenters challenged the Department's factual basis for the proposed rule, as set forth in the July 5 notice of proposed rulemaking. The points argued in support of the position that the factual basis did not provide a sufficient foundation for the regulation were:

(a) Judge Gesell questioned the factual basis for the March 7 rule.

(b) The 1973 article by Drs. Duff and Campbell of the Yale New-Haven Hospital documenting that of 299 consecutive deaths occurring in that special care nursery, 45 (14%) were related to withholding treatment, cited in the preamble to the proposed rule, was too old to be reliable.

(c) The several specific cases cited in the preamble had various probative defects.

(d) The 1977 article reporting the results of a survey of pediatricians suggesting discriminatory attitudes was outdated, not statistically valid, and otherwise lacked current probative value.

(e) The findings of the report of the President's Commission for Study of Ethical Problems in Medicine and Biomedical and Behavioral Research entitled *Deciding to Forego Life-Sustaining Treatment* contradict the Department's factual basis.

(f) Because "discrimination against the handicapped in the delivery of health care services does not only involve handicapped newborns," there is "no compelling rationale for a set of rules targeted solely at this population."

##### Response

The Department continues to believe that a substantial factual basis exists for

the proposed rule. First, it should be noted that Judge Gesell, although he found many relevant factors to have been inadequately considered in connection with issuance of the March 7 rule, did not find the factual basis inadequate to support "undertaking a regulatory approach to the problem of how newborns should be treated in government-financed hospitals."

Second, the arguments that the well-documented Duff and Campbell study is outdated are based on the personal opinions of several commenters. These personal opinions, although in some cases those of highly-respected medical professionals, were not backed up by any empirical data even remotely resembling the very detailed evidence of the Duff and Campbell study.

Third, the conclusion of the President's Commission that decision-making about seriously ill newborns "usually adheres" to proper standards cannot be fairly represented as evidence that handicapped newborns should be exempt from basic protections of the law prohibiting discrimination on the basis of the handicap.

Fourth, regardless of the caveats concerning the age of particular cases or the lack of a conclusive finding of illegal discrimination, the several specific cases cited in the preamble to the proposed rule support the proposition that handicapped infants may be subjected to unlawful discrimination.

Fifth, in the absence of any empirical studies or data to bolster their personal opinions, the commenters who suggested that the results, published in 1977, of the survey of pediatricians' attitudes are outdated are not convincing. The article, "Ethical Issues in Pediatric Surgery: A National Survey of Pediatricians and Pediatric Surgeons," 60 *Pediatrics* 588, reported the results of a survey of 400 members of the Surgical Section of the American Academy of Pediatrics and an additional 308 chairpersons of teaching departments of pediatrics and chiefs of divisions of neonatology and genetics in departments of pediatrics. Responses were received from 267 of the former group (66.8%) and 190 of the latter (61.7%). Responses were anonymous. Among the results of the survey were:

—76.6% of the pediatric surgeons and 49.5% of the pediatricians said they would "acquiesce in parents' decision to refuse consent for surgery in a newborn with intestinal atresia if the infant also had Down's syndrome."

—23.6% of pediatric surgeons and 13.2% of pediatricians would encourage parents to refuse consent for treatment of a newborn with intestinal atresia and Down's syndrome. Only 3.4% of pediatric surgeons

and 15.8% of pediatricians would get a court order directing surgery if the parents refused.

—63.3% of the pediatric surgeons and 42.6% of the pediatricians said in cases of infants with duodenal atresia and Down's syndrome, where they "accept parental withholding of lifesaving surgery," they would also "stop all supportive treatment including intravenous fluids and nasal gastric suction."

—62% of all respondents who believe that children with Down's syndrome "are capable of being useful and bringing love and happiness into the home" would nevertheless acquiesce in parents' decisions not to allow surgery for the atresia. Only 7% who so believe indicate that they would go to court to require surgery.

Sixth, there is no requirement in law or policy for the government to prove the magnitude of illegality before establishing basic mechanisms to allow for effective enforcement of a clearly applicable statute.

##### Evidence of Problems Submitted by Commenters

Additional evidence of the risk that handicapped infants may be subjected to discrimination was submitted by commenters. For example, the Spina Bifida Association of America stated:

Unfortunately, the SBAA has direct experience of cases in which this principle [of nondiscrimination] has not been followed—instances in which children with spina bifida have been initially denied appropriate treatment. Pediatric neurosurgeon Dr. David McClone of Chicago Children's Memorial Hospital, a member of SBAA's Professional Advisory Committee, has found that 5% of the children with spina bifida referred to him have been victims of treatment denial. Most of these cases, he believes, resulted from ignorance of current therapies and their impressive outcomes.

The Department received a number of comments from practicing nurses regarding the problem and need for the proposed rule. For example, from a Lexington, Kentucky, nurse:

I am a registered nurse and have worked in the labor and delivery area, newborn nursery and intensive care nursery. . . . I think the average American would be shocked at the decisions that are made regarding "non-perfect" infants. I have personally heard physicians and nurses talk to new parents about their child and persuade the parents to "let the child die and therefore end its suffering"—which really meant "let us starve your child to death"—that is certainly not a humane way to "let a child die."

A nurse in Boca Raton, Florida wrote:

I am an RN with a speciality in maternal-child health. In the past few years I have had to witness the deaths of innocent children in hospitals where a decision was



made not to continue with medical care and assistance.

Another nurse wrote:

As a nurse (RN) in a neonatal ICU, I feel compelled to write and voice my support of the "Baby Doe rule" now proposed. . . . Many doctors and nurses openly support withholding or withdrawing medical care. . . . Due to the ethics of the medical director of the unit, this has only been done once or twice to my knowledge. I would report any cases of neglect I knew of if this number and service were available. . . . An outside third party is needed to police the cases. Please allow some method of reporting and investigating these babies' cases to be available.

From a nurse in San Diego, California came the following comment:

[A]s a practicing registered nurse myself, I believe such regulations permit nurses and staff to act in a patient's best interest—life itself—without fear of harassment and possible job loss.

In addition, some commenters who opposed the proposed rule appeared to acknowledge that there is a risk that handicapped infants will not receive medically beneficial treatment. For example, the American Society of Law and Medicine, a national, nonprofit professional association, stated:

There can be no question that some decisions to end life-sustaining care for newborns have been made inappropriately, even if the frequency of this problem has not been established.

Another example of this is the comment by the chairman of the division of pediatrics of a hospital in Illinois:

We are acutely aware that handicapped individuals (not must handicapped newborns) are systematically discriminated against in our society. We are also acutely aware that we, like virtually all members of our society, are guilty of having prejudicial beliefs and attitudes about the handicapped. That pediatricians and other health care providers have acted on these negative beliefs and attitudes should come as no surprise. That parents, at least in the initial phase of their relationship with a handicapped newborn, should wish to be spared what is perceived as a burden or even wish that the infant had never been born should come as no shock.

We wholeheartedly agree that in the past these obviously critically important decisions have not been accorded the degree of reflection and care they are due. Given the wide range of possible technological interventions now possible; given the changing conception of the appropriate role of physician and parents in such decisions; and given the need for public accountability for such decisions—we support the idea that the manner in which such decisions have been made in the past needs critical re-examination.

Another example is the comment of the American Academy of Pediatrics:

The traditional method of a single physician making such judgment (regarding treatment), without exposure to other persons having additional facts, experience, and points of view, may lead to decisions, which, in retrospect, cannot be justified.

#### Response

The Department believes these comments provide additional support for the Department's conclusions that available evidence indicates there are cases in which handicapped infants are at risk of having life-sustaining, nourishment or medically beneficial treatment withheld solely on the basis of their present or anticipated physical or mental impairments, and that this evidence constitutes a substantial foundation for the establishment of basic procedural mechanisms to facilitate enforcement of section 504.

#### OCR Investigations to Date

Another argument made by a number of commenters to support criticisms of the adequacy of the factual basis for the proposed rule was that the experience of the Office for Civil Rights to date in connection with section 504 enforcement activities relating to health care for handicapped infants indicate there is no significant evidence of a problem that the rule could reasonably be designed to deal with. As stated by the American Hospital Association:

The total absence of verifiable violations, notwithstanding hundreds of hotline calls, also compels the conclusion that either this mechanism is not an effective means to meet any alleged need or, as we believe to be the case, the violations that have been described are not occurring. In either case, a federal regulation is unnecessary.

#### Response

Rather than support the argument that there is no need for section 504 applicability or enforcement in connection with health care for handicapped infants, the OCR experience to date provides additional evidence that the assumption that handicapped infants will receive medically beneficial treatment is not always justified.

First, it must be noted that the vast majority of the several hundred calls made to the Department were not for the purpose of reporting suspected violations of section 504. Rather, the vast majority of calls were for administrative purposes, such as hospital officials asking questions about the provisions of the March interim final rule, individuals acting on their apparent curiosity to see if anyone would answer the telephone, and other peripheral

matters. It should also be noted that the Department's experience under the interim final rule does not provide an adequate basis to make conclusive judgements in any direction because the rule was only in effect for about three weeks, from March 22 until April 14, the day Judge Gesell declared it invalid.

Following is a summary of the Infant Doe cases handled to date, and current as of December 1, 1983.

1. *Bloomington, Indiana*. Investigation into April 1982, death of infant with Down's syndrome and esophageal atresia from whom surgery was withheld on the instructions of the parents. An investigation, delayed due to difficulties in obtaining information sealed by court order, has been conducted. Final administrative action has not yet been taken.

2. *Robinson, Illinois*. May 14, 1982 complaint that hospital (at the parents' request) failed to perform necessary surgery on an infant born with myelomeningocele. Prompt on-site investigation was conducted, involving OCR, the Justice Department and the state child protective services agency. The parents refused consent for surgery; the hospital referred the matter to state authorities, who accepted custody of the infant and arranged for surgery and adoption. The care provided to the infant while these actions were taken was in compliance with section 504. Finding: no violation.

3. *Madison, Wisconsin*. May 7, 1982, complaint that two infant survivors of abortions may have been denied treatment. On-site investigation revealed that two infants, of 26 and 22 weeks gestation, were born alive following abortions; life-saving procedures were applied; neither infant could survive due to extreme prematurity. Finding: no violation.

4. *Kettering, Ohio*. July 26, 1982, complaint that an infant with spina bifida and hydrocephalus was not being treated. Immediate on-site investigation revealed that surgery to correct the spina bifida condition was not performed immediately because the infant had medical complications. Surgery was performed after the infant's condition stabilized. The hospital provided all proper treatment. Finding: no violation.

5. *Barrington, Illinois*. September 17, 1982, complaint that a multi-handicapped infant was not receiving needed treatment. Immediate on-site investigation determined that given the nature and severity of the problems, there were no procedures or services which could have been provided which might have changed or otherwise

influenced the outcome for this infant, who died for days after birth. Finding: no violation.

6. *New Haven, Connecticut*. October 12, 1982, complaint (referred from the Department of Justice) that hospital engaged in a pattern and practice of denying medical treatment to handicapped infants. The complaint was included in a compliance review, already in progress. The investigation has been expanded to include several cases involving other Connecticut hospitals. The investigation, which has included review of hundreds of medical files, has not been completed.

7. *Tulsa, Oklahoma*. December 7, 1982, complaint that a baby was being deliberately dehydrated. Immediate on-site investigation determined that the infant had hydranencephaly (complete or almost complete absence of cerebral hemispheres) and transposition of the great vessels (reversal of main vessels into heart); notwithstanding all proper care, the severity of the anomalies made the prognosis very pessimistic. Finding: no violation.

8. *Duarte, California*. January 10, 1983, complaint that the hospital denied the complainant's son admission to the hospital for a bone marrow transplant solely because of his handicapping condition, Down's syndrome. An investigation has been conducted. Administrative action has not been completed.

9. *Austin, Texas*. January 17, 1983, complaint that newborn babies with serious birth defects have not received proper care. An investigation has been conducted. Administrative action has not been completed.

10. *Lansing, Michigan*. January 24, 1983, complaint that a handicapped infant born to a surrogate mother was treated for a streptococci infection over the objections of the father who had told the hospital not to care for the child. OCR inquiry determined the hospital took immediate steps to obtain an appropriate court order to assure that needed treatment was provided, notwithstanding objections from the father. Finding: no violation.

11. *San Antonio, Texas*. March 2, 1983, complaint that deaths of a number of infants at two hospitals may have been related to discriminatory withholding of care. OCR investigation postponed at request of District Attorney assisting in grand jury criminal investigation.

12. *Houston, Texas*. March 10, 1983, complaint that five infants were denied proper care in a neonatal intensive care unit. The investigation has not been completed.

13. *Jackson, Michigan*. March 14, 1983, complaint from a mother that her son,

who had Down's syndrome, died as a result of improper treatment. An investigation has been conducted. Administrative action not completed.

14. *Odessa, Texas*. March 18, 1983, hotline complaint that the hospital had failed to provide adequate medical care to a premature infant who died in 1982. On-site investigation and review of medical records by OCR medical consultant found that the infant, born March 18, 1982, after a 25-28-week gestation period, suffered from extreme immaturity, and died March 20, 1982. Finding: no violation.

15. *Nashville, Tennessee*. March 22, 1983, hotline complaint that an infant had been denied sustenance for three days. Immediate contact revealed the infant was not a patient at the facility and the alleged attending physician was not a member of the attending or resident medical staff. This was verified by the patient census data, the facility's physician roster, and contact with the county medical society. This case was administratively closed due to an insufficient complaint.

16. *Nashville, Tennessee*. March 22, 1983, anonymous hotline complaint that 10 children were not receiving adequate medical treatment. Immediate on-site investigation, including an OCR medical consultant, determined that no child was in imminent danger; all children were receiving nutritional sustenance; and all children were receiving proper care. Finding: no violation.

17. *Fayette, Alabama*. March 22, 1983, anonymous hotline complaint that a handicapped infant was denied nourishment and allowed to die in an Alabama hospital in December 1982. The caller could provide no other information. Investigation has been conducted. Administrative action awaiting report from medical consultant.

18. *Waxahachie, Texas*. March 23, 1983, anonymous hotline complaint that between Christmas and February, a premature infant was denied treatment and allowed to die at a hospital in Texas. An investigation has been conducted. Administrative action not yet completed.

19. *Baltimore, Maryland*. March 23, 1983, hotline complaint that a premature infant was not being provided nourishment and heat. An immediate on-site investigation determined that the infant, weight 1 lb., ½ ounce at birth, was viable; the infant died several hours after birth; the infant had no congenital malformations or anomalies. Final administrative action on this case has not yet been taken.

20. *Newark, New Jersey*. March 27, 1983, anonymous hotline complaint that a premature infant, born as a result of a

third trimester abortion, was not receiving adequate care. Immediate on-site investigation revealed that the premature infant weighed about 700 grams, and showed few signs of life. The infant was aggressively resuscitated, placed on intravenous feeding, and provided other life supporting treatment. Appropriate care was being provided. Finding: no violation.

21. *Rochester, New York*. March 29, 1983, hotline complaint that Siamese twin infants were being denied treatment. Immediate on-site investigation determined that a team of specialists examined the infants and concluded the conjoined female infant would not survive any attempt to separate them. Full intensive care was provided. The infants were placed on a respirator and given antibiotics, fluid and the necessary nutrition. At the time of the on-site, March 29, 1983, it was determined that there was no basis for seeking emergency remedial action. Final administrative action has not yet been completed.

22. *Seattle, Washington*. March 30, 1983, hotline complaint that an infant was being denied food and water and would not live much longer than a day or two. The caller had no identifying or other information. Immediate on-site inquiry determined there were no infants at the facility meeting the description of the complaint. The case was administratively closed due to insufficient complaint.

23. *Miami, Florida*. April 4, 1983, hotline complaint alleging (based upon information in the newspaper) parents of a premature infant and the attending physician decided not to allow the infant to be resuscitated. Immediate inquiry determined the infant had died prior to receipt of the complaint. The premature infant had multiple catastrophic conditions, including complete liquefaction of the brain. Final administrative action awaiting report of medical consultant.

24. *Decatur, Alabama*. April 6, 1983, hotline complaint from a parent that her child's condition was misdiagnosed by a particular physician during a 2½ year period. Inquiry determined that the child suffers from food allergies; the prognosis is excellent, the child at one time was believed, apparently erroneously, to be retarded. This case was administratively closed because the inquiry failed to reveal information suggesting a possible violation of section 504.

25. *Melrose Park, Illinois*. April 8, 1983, anonymous hotline complaint. The caller provided no details concerning the infant's condition or treatment.

Immediate telephone inquiry discovered no information to suggest a section 504 violation. This case was administratively closed due to an insufficient complaint.

26. *Charlotte, North Carolina*. April 10, 1983, hotline complaint that a premature infant died in July 1979 due to withholding of treatment. The caller could not provide any other information. Due to the length of time since the alleged discriminatory act and the lack of specific information, this case was administratively closed due to an insufficient complaint.

27. *Hyde Park, New York*. April 13, 1983, anonymous hotline complaint that the hospital would have let a baby with Down's syndrome die if the parents had not been aggressive and insisted on care being provided. The caller could provide no identifying information. This case was administratively closed due to an insufficient complaint.

28. *Coquille, Oregon*. April 13, 1983, hotline complaint that parents of a handicapped infant and the attending physician were going to withhold all treatment. Immediate on-site investigation, including medical consultant's review of medical records, determined the infant had a severe congenital central nervous system defect incompatible with life and not amenable to surgical correction; hospital provided supportive care and attempted to provide fluid orally, but did not attempt to provide intravenous fluids or arrange immediate transfer to a tertiary level neonatal intensive care unit for more specialized evaluations. The OCR medical consultant and the specialists at the tertiary care facility to which the infant was transferred three days after birth concluded that no course of treatment which was available would have avoided imminent death of this infant; the most that could have been expected from more aggressive care would have been to prolong the act of dying. The infant died 10 days after birth. Finding: no violation.

29. *Athens, Tennessee*. April 18, 1983, anonymous hotline complaint that an infant born at 28 weeks gestation was denied treatment and nourishment and allowed to die at a Tennessee hospital. The caller could give no identifying information. Investigation has been conducted. Administrative action awaiting report of medical consultant.

30. *Shreveport, Louisiana*. April 20, 1983, hotline complaint that a particular physician at the hospital certified three infants born alive as stillborn and refused to provide care to another infant. Investigation, including medical consultant review, found no medically

beneficial treatment was withheld. Finding: no violation.

31. *Dayton, Ohio*. April 29, 1983, anonymous hotline complaint that an infant, identity unknown, weighing one pound and eight ounces was denied treatment and died. Inquiry revealed the deceased infant was premature (22 weeks gestation) and immature (organs were not developed); the infant had no anomalies; the hospital attempted to administer oxygen but the lungs were too small to function; no medically beneficial treatment was withheld. This case was administratively closed due to the lack of information suggesting possible violation of section 504.

32. *Los Angeles, California*. May 17, 1983, complaint that infant, believed stillborn, lived several hours and may not have received proper care. Administrative action has not been completed.

33. *Daytona Beach, Florida*. May 19, 1983, hotline complaint that an infant with spina bifida may not be receiving medical treatment. Immediate contact with hospital and state agency and prompt on-site investigation indicated that the parents did not consent to surgery for the infant; on May 18, eight days after birth, the state agency obtained a court order to provide surgery, which was performed May 22, 1983. An investigation has been conducted. Administrative action awaits report of medical consultant.

34. *Baton Rouge, Louisiana*. May 23, 1983, hotline complaint that medical services were denied a premature infant, who died soon after birth. Investigation has been conducted. Administrative action has not been completed.

35. *Colorado Springs, Colorado*. June 21, 1983, hotline complaint from a nurse that an infant with myelomeningocele and paralyzed vocal chords was being denied necessary surgery. Immediate on-site investigation indicated substantial uncertainty on whether treatment for the myelomeningocele would be provided immediately; physicians were providing nutrition and supportive care and were awaiting the results of several tests on the infant. During the afternoon, hospital personnel were advised that an on-site investigation would be initiated that evening; that the state child protective services agency would be asked to also investigate; and that OCR would notify the Justice Department of the investigation. Also during the afternoon, the OCR medical consultant discussed the case with the attending physician. That evening corrective surgery was performed on the myelomeningocele. Investigation, including review by medical consultant, determined that no

medically beneficial treatment was withheld on the basis of the infant's handicap. Finding: no violation.

36. *Brooklyn, New York*. June 23, 1983, complaint that premature infant who died in 1981 did not receive proper care. An investigation was conducted. Administrative action awaits report of medical consultant.

37. *Atlanta, Georgia*. June 27, 1983, hotline complaint that an infant, identity unknown, born with multiple anomalies was in a life-threatening situation because the doctors were planning to cease treatment of the infant. On-site investigation, June 28, indicated the premature infant, who weighed 950 grams at birth, received aggressive treatment, but the prognosis was not optimistic. At the time of the on-site investigation, it was determined there was no basis to seek emergency remedial action. Final administrative action is awaiting written report from medical consultant.

38. *Medford, Oregon*. July 7, 1983, anonymous hotline complaint that two infants died in 1962 because of improper medical treatment. The investigation has not been completed.

39. *Pinchurst, North Carolina*. July 21, 1983, hotline complaint that a three-week old infant with spina bifida and hydrocephalus would not live if surgical treatment was not provided. Immediate inquiry determined the appropriate surgery was performed July 8, 1983. Final administrative action has not been concluded.

40. *San Francisco, California*. August 2, 1983, hotline complaint that an infant with a cleft palate and heart defect was allowed to die at a California hospital in May 1979. The caller stated that a malpractice lawsuit is pending. The investigation has not been completed.

41. *Falls Church, Virginia*. August 9, 1983, hotline complaint that a baby, identity unknown, with possible brain damage, no ears or eyes, would not be given nourishment. A meeting with hospital officials failed to identify an infant meeting the description given by the complainant. An infant with somewhat similar circumstances was described; no information concerning this infant suggested a lack of appropriate care. Complainant refused to accept OCR calls seeking further information. This case was administratively closed due to an insufficient complaint.

42. *Wichita, Kansas*. August 11, 1983, complaint that infant whose body was discovered at incinerator site may have been denied proper treatment. An investigation has been conducted.

Administrative action has not been completed.

43. *Lincoln, Nebraska*. August 25, 1983, hotline complaint that two premature infants did not receive appropriate care and died. The investigation has not been completed.

44. *Boynton Beach, Florida*. September 20, 1983, hotline complaint that two handicapped infants were allowed to die immediately following birth. The investigation has not been completed.

45. *Norfolk, Virginia*. September 21, 1983, complaint that infant born alive following an abortion was not being fed or treated. Inquiry determined infant died September 20, 1983. Final administrative action has not been completed.

46. *Boise, Idaho*. September 30, 1983, hotline complaint that an abandoned premature infant with no brain tissue might be withdrawn from life support. Immediate inquiry determined the State child protective services agency had obtained custody of the infant and had no plans to discontinue life support. Final administrative action has not been completed.

47. *Philadelphia, Pennsylvania*. October 16, 1983, hotline complaint that infant, age approximately six weeks, with spina bifida, who received surgery, was not receiving appropriate follow-up care. Inquiry initiated October 16. Decision made that circumstances did not suggest need for immediate remedial action. Final administrative action has not been completed.

48. *Long Island, New York*. October 19, 1983, complaint, based on newspaper article, that infant with spina bifida not receiving surgery due to refusal of parents to consent; legal proceedings has been initiated in State court. Inquiry initiated October 19. On October 27, HHS asked Department of Justice to commence legal action to overcome refusal of hospital to permit review of pertinent records. On November 2, legal action was commenced. On November 17, district court ruled against the government. Appeal filed November 18.

49. *Phoenix, Arizona*. November 7, 1983 anonymous hotline complaint that infant with spina bifida and other conditions not receiving surgery. Immediate inquiry initiated; records obtained; OCR medical consultant discussed case with attending physician and hospital review committee. Decision made not to refer case to Justice Department for emergency remedial action. Final administrative action not yet completed.

The Department believes three of these cases demonstrate the utility of the procedural mechanisms called for in

the final rules. In the Robinson, Illinois case (listed as case 2, above), for example, the involvement of the state child protective services agency, working in cooperation with HHS and the Justice Department, was the most important element in bringing about corrective surgery for the infant. The state agency received a report from the hospital administrator pursuant to the state child protective services statute. Had there been no governmental involvement in the case, the outcome might have been much less favorable. Media reports one year later indicate the child's development was proceeding very well, with leg braces adequately compensating for the child's impairment.

In the Daytona Beach, Florida case (listed as case 33, above), action by the state child protective services agency, like that called for in the final rules, brought about needed corrective surgery. Without this action, the infant might have died or suffered more severe impairments.

In the Colorado Springs, Colorado case (listed as case 35, above) the prompt involvement of HHS, acting upon a complaint from a nurse, may have contributed to the decision to provide corrective surgery. Because the decisionmaking process was in progress at the time the OCR inquiry began, it is impossible to say the surgery would not have been provided without this involvement. However, the involvement of OCR and the OCR medical consultant was cooperatively received by the hospital and apparently constructive.

Although no case has resulted in a finding of discriminatory withholding of medical care, the Department believes these cases provide additional documentation of the need for governmental involvement and the appropriateness of the procedures established by the final rules.

#### E. OTHER ISSUES

##### Self-Evaluation

Among the questions on which the July 5 notice of proposed rulemaking solicited comments was question 1:

Should recipients providing health care services to infants be required to perform a self-evaluation, pursuant to 45 CFR 84.8(c)(1), with respect to their policies and practices concerning health services to handicapped infants?

A number of commenters expressed support for this requirement. Some commenters expressed the view that self-evaluations would be helpful and should be conducted, but they should not be a federal regulatory mandate. Some commenters suggested that if this were to be a requirement, it should be through mechanisms other than section

504, such as voluntary accreditation standards or Medicare conditions of participation.

Some commenters opposed a self-evaluation requirement on the grounds it would likely be unproductive. For example:

Americans United for Life is skeptical of any approach to the enforcement of section 504 that relies on the cooperation of those being regulated. Encouraging hospitals to perform "self-evaluation" is not likely to lead to accurate evaluation.

##### Response

The Department has not adopted a self-evaluation requirement as part of the final rules. The Department believes this function will be most effectively carried out in connection with the activities of Infant Care Review Committees encouraged by the final rules, and therefore will not seek to impose uniform standards for self-evaluations.

##### Information to Parents

Among the questions on which the July 5 notice of proposed rulemaking solicited comments was question 2:

Should such recipients be required to identify for parents of handicapped infants born in their facilities those public and private agencies in the geographical vicinity that provide services to handicapped infants?

A great many commenters expressed support for such a requirement on the ground that before parents are put into a position of having to make very difficult decisions concerning care for their handicapped child, the parents should be aware of the health and social services agencies and organizations and parental support groups available in the community. Other commenters opposed this requirement. Some commenters expressed the view that hospitals should provide this information as part of their own policies and procedures, but that it would be counterproductive to seek to impose rigid, uniform regulatory requirements in this regard.

Among those supporting such a requirement was the Spina Bifida Association of America (SBAA):

The SBAA strongly supports such a requirement; it might be the most important influential aspect of the entire regulation.

Parents of a newborn spina bifida child are expected to make rational life and death decisions when what was expected to be a joyous time has instead become an occasion for confronting the concerns of the unknown. The decisions must be made quickly and under great stress. Dr. Rosalyn Darling, a member of SBAA's Professional Advisory Committee, has written that decisions are often made by physicians and individuals who have very little contact with the

disabled community; consequently, decisions concerning treatment are often "stacked" against the newborn with a problem. Parents naturally turn to their physician for guidance, but he or she may have only outdated and unwarrantedly pessimistic information about spina bifida. Even if the physician is well-informed about the available treatment, he or she is rarely aware of the supportive services in the community or equipped to give the support and counselling that others who have gone through the same experience can't provide.

Clearly, new parents of a disabled child need the names of agencies and support groups available to assist the family unit. Other parents who have gone through the same situation can then share their knowledge of the disability and its treatment and give comfort and assistance.

The American Speech-Language-Hearing Association, which represents 39,000 speech-language pathologists and audiologists nationwide, stated:

[P]arents and physicians are largely unaware of what educational, habilitative, and rehabilitative services are available for handicapped children, how much success handicapped children receiving these services can have, the obligation of states to educate handicapped children, the extent of research now going on regarding handicapped children, and other federal, state and local governmental commitments to the handicapped. Unfortunately, physicians have all that they can do to maintain currency with medical information and are, therefore, frequently ill-informed as to what can be done for handicapped infants.

Recipients should be required to provide complete information to the parent about the appropriate handicap. This would include not only identification of public and private agencies that provide services to handicapped infants, but (1) detailed information on the handicap itself; (2) discussion of the educational and rehabilitation potential; (3) discussion of alternative care options such as foster homes, adoption, etc.; (4) identification of parent support groups; and (5) discussion of expectations for a self-sufficient future life. In providing the required information the recipient should use individuals knowledgeable about the handicap, including professionals, associations and parents of handicapped children. For example, the American Speech-Language-Hearing Association and its consumer affiliate, the National Association of Hearing and Speech Action (NAHSA) maintains a Help line (800-638-8255) that can be used to obtain information on (1) speech-language pathology and audiology services available in any area of the United States, (2) speech, language and hearing disorders, and (3) other agencies serving the communicatively handicapped. NAHSA provides informational brochures. . . . Many professional associations have similar documents that would be helpful to recipients.

Among those opposing a requirement that recipients provide information to

parents was Georgetown University Hospital, Washington, D.C. As an alternative, the hospital proposed:

DHHS should undertake the responsibility of providing a federal office charged with the task of identifying for parents of handicapped children those public and private agencies in the geographical vicinity of the parent's residence that provide service of handicapped infants, and for providing the necessary financial assistance to acquire such services. Hospitals should be required to furnish parents with a telephone number, and/or address of this federal office.

#### Response

The Department believes it is extremely important for parents of handicapped newborn infants to receive detailed information on the availability of health and social services for handicapped children in the communities. However, the Department has concluded the most effective way to advance this goal is not through an attempt to impose detailed regulatory requirements that would be very difficult to monitor and enforce.

Rather, the Department has undertaken several initiatives, discussed above in the preamble, to improve the furnishing of information to parents. In addition, this should be a central focus of the activities of the Infant Care Review Committees, which, under the model set forth in the final rules, include participation by representatives of disability groups or disability experts.

#### VI. Regulatory Information

##### Severability

It is the Secretary's intent that should any subsection, paragraph, clause, or provision of this rule be declared by a court of competent jurisdiction to be invalid, the remainder of the rule, not expressly so declared invalid, shall continue in effect.

##### Regulatory Impact Analysis

This proposed rule has been reviewed under Executive Order 12291. It is not a major rule as defined by the Order because it does not have an effect on the economy of \$100 million or more or meet the other definitional criteria contained in the Order, and thus does not require a regulatory impact analysis.

##### Regulatory Flexibility Analysis

The Regulatory Flexibility Act (Pub. L. 96-354) requires the Federal government to anticipate and reduce the impact of rules and paperwork requirements on small businesses and other small entities. For each rule with a "significant impact on a substantial number of small entities" an analysis must be prepared describing the rule's impact on small entities.

The Secretary certifies that the final rules do not have a significant impact on a substantial number of small entities. As it relates to hospitals, the primary requirement of the final rules is to post an informational notice, which has no significant impact on the hospitals. The requirements concerning expedited access to records and expedited action to effect compliance also, as explained above, have no significant impact. Requirements in the final rules relating to state child protective services agencies have no substantial impact on those agencies, because those requirements, as explained above, are fully consistent with normal procedures of those agencies and existing regulatory requirements.

Matters addressed in the guidelines included in the final rules are not requirements of the rules. They reflect interpretations and procedures of the Department pursuant to the statute, existing regulations, and existing procedures.

Therefore, a regulatory flexibility analysis is not required.

##### Paperwork Reduction Act

Section 84.55(c) of the final rules contains information collection requirements. These requirements were submitted to the Office of Management and Budget for review under section 3504(h) of the Paperwork Reduction Act of 1980, and approved for use through September 30, 1986. The OMB No. is 0990-0114.

##### Department of Justice Review

Pursuant to Executive Order 12250, these final rules have been reviewed and approved by the Department of Justice.

##### List of Subjects in 45 CFR Part 84

Civil rights. Education of handicapped. Handicapped. Physically handicapped.

Dated: December 30, 1983.

Approved:

Margaret M. Heckler,

Secretary.

#### PART 84—[AMENDED]

The authority citation for Part 84 is as follows:

Authority: Sec. 504, Rehabilitation Act of 1973, Pub. L. 93-112, 87 Stat. 394 (29 U.S.C. 794974); sec. 111(a), Rehabilitation Act Amendments of 1974, Pub. L. 93-516, 88 Stat. 1619 (29 U.S.C. 706); sec. 606, Education of the Handicapped Act (20 U.S.C. 1405), as amended by Pub. L. 94-142, 89 Stat. 795; sec. 321, Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and

Rehabilitation Act of 1970, 84 Stat. 182 (42 U.S.C. 4561), as amended; sec. 497, Drug Abuse Office and Treatment Act of 1972, 86 Stat. 78 (21 U.S.C. 1174), as amended.

For the reasons set forth in the preamble:

1. 45 CFR Part 84 is amended by inserting after § 84.54 the following new § 84.55:

**§ 84.55 Procedures relating to health care for handicapped infants.**

(a) *Infant Care Review Committees.* The Department encourages each recipient health care provider that provides health care services to infants in programs receiving Federal financial assistance to establish an Infant Care Review Committee (ICRC) to assist the provider in delivering health care and related services to infants and in complying with this part. The purpose of the committee is to assist the health care provider in the development of standards, policies and procedures for providing treatment to handicapped infants and in making decisions concerning medically beneficial treatment in specific cases. While the Department recognizes the value of ICRC's in assuring appropriate medical care to infants, such committees are not required by this section. An ICRC should be composed of individuals representing a broad range of perspectives, and should include a practicing physician, a representative of a disability organization, a practicing nurse, and other individuals. A suggested model ICRC is set forth in paragraph (f) of this section.

(b) *Posting of informational notice.* (1) Each recipient health care provider that provides health care services to infants in programs or activities receiving Federal financial assistance shall post and keep posted in appropriate places an informational notice.

(2) The notice must be posted at location(s) where nurses and other medical professionals who are engaged in providing health care and related services to infants will see it. To the extent it does not impair accomplishment of the requirement that copies of the notice be posted where such personnel will see it, the notice need not be posted in area(s) where parents of infant patients will see it.

(3) Each health care provider for which the content of the following notice (identified as Notice A) is truthful may use Notice A. For the content of the notice to be truthful: (i) The provider must have a policy consistent with that stated in the notice; (ii) the provider must have a procedure for review of treatment deliberations and decisions to which the notice applies, such as (but

not limited to) an Infant Care Review Committee; and (iii) the statements concerning the identity of callers and retaliation are truthful.

*Notice A:*

**PRINCIPLES OF TREATMENT OF DISABLED INFANTS**

It is the policy of this hospital, consistent with Federal law, that, nourishment and medically beneficial treatment (as determined with respect for reasonable medical judgments) should not be withheld from handicapped infants solely on the basis of their present or anticipated mental or physical impairments.

This Federal law, section 504 of the Rehabilitation Act of 1973, prohibits discrimination on the basis of handicap in programs or activities receiving Federal financial assistance. For further information, or to report suspected noncompliance, call:

[Identify designated hospital contact point and telephone number] or

[Identify appropriate child protective services agency and telephone number] or U.S. Department of Health and Human Services (HHS): 800-368-1019 (Toll-free; available 24 hours a day; TDD capability).

The identity of callers will be held confidential. Retaliation by this hospital against any person for providing information about possible noncompliance is prohibited by this hospital and Federal regulations.

(4) Health care providers other than those described in paragraph (b)(3) of this section must post the following notice (identified as Notice B):

*Notice B:*

**PRINCIPLES OF TREATMENT OF DISABLED INFANTS**

Federal law prohibits discrimination on the basis of handicap. Under this law, nourishment and medically beneficial treatment (as determined with respect for reasonable medical judgments) should not be withheld from handicapped infants solely on the basis of their present or anticipated mental or physical impairments.

This Federal law, section 504 of the Rehabilitation Act of 1973, applies to programs or activities receiving Federal financial assistance. For further information, or to report suspected noncompliance, call:

[Identify appropriate child protective services agency and telephone number] or U.S. Department of Health and Human Services (HHS): 800-368-1019 (Toll-free; available 24 hours a day; TDD capability)

The identity of callers will be held confidential. Federal regulations prohibit retaliation by this hospital against any person who provides information about possible violations.

(5) The notice may be no smaller than 5 by 7 inches, and the type size no smaller than that generally used for similar internal communications to staff. The recipient must insert the specified information on the notice it selects. Recipient hospitals in Washington, D.C. must list 863-0100 as the telephone

number for HHS. No other alterations may be made to the notice. Copies of the notices may be obtained from the Department of Health and Human Services upon request, or the recipient may produce its own notices in conformance with the specified wording.

(c) *Responsibilities of recipient state child protective services agencies.* (1) Within 60 days of the effective date of this section, each recipient state child protective services agency shall establish and maintain in written form methods of administration and procedures to assure that the agency utilizes its full authority pursuant to state law to prevent instances of unlawful medical neglect of handicapped infants. These methods of administration and procedures shall include:

(i) A requirement that health care providers report on a timely basis to the state agency circumstances which they determine to constitute known or suspected instances of unlawful medical neglect of handicapped infants;

(ii) A method by which the state agency can receive reports of suspected unlawful medical neglect of handicapped infants from health care providers, other individuals, and the Department on a timely basis;

(iii) Immediate review of reports of suspected unlawful medical neglect of handicapped infants and, where appropriate, on-site investigation of such reports;

(iv) Provision of child protective services to such medically neglected handicapped infants, including, where appropriate, seeking a timely court order to compel the provision of necessary nourishment and medical treatment; and

(v) Timely notification to the responsible Department official of each report of suspected unlawful medical neglect involving the withholding, solely on the basis of present or anticipated physical or mental impairments, of treatment or nourishment from a handicapped infant who, in spite of such impairments, will medically benefit from the treatment or nourishment, the steps taken by the state agency to investigate such report, and the state agency's final disposition of such report.

(2) Whenever a hospital at which an infant who is the subject of a report of suspected unlawful medical neglect is being treated has an Infant Care Review Committee (ICRC) the Department encourages the state child protective services agency to consult with the ICRC in carrying out the state agency's authorities under its state law and methods of administration. In developing its methods of

administration and procedures, the Department encourages child protective services agencies to adopt guidelines for investigations similar to those of the Department regarding the involvement of ICRC's.

(The provisions of § 84.55(c) have been approved by the Office of Management and Budget pursuant to the Paperwork Reduction Act. The OMB No. is 0990-0114.)

(d) *Expedited access to records.* Access to pertinent records and facilities of a recipient pursuant to 45 CFR 80.8(c) (made applicable to this part by 45 CFR 84.61) shall not be limited to normal business hours when, in the judgment of the responsible Department official, immediate access is necessary to protect the life or health of a handicapped individual.

(e) *Expedited action to affect compliance.* The requirement of 45 CFR 80.8(d)(3) pertaining to notice to recipients prior to the initiation of action to effect compliance (made applicable to this part by 45 CFR 84.61) shall not apply when, in the judgment of the responsible Department official, immediate action to effect compliance is necessary to protect the life or health of a handicapped individual. In such cases the recipient will, as soon as practicable, be given oral or written notice of its failure to comply, of the action to be taken to effect compliance, and its continuing opportunity to comply voluntarily.

(f) *Model Infant Care Review Committee.* Recipient health care providers wishing to establish Infant Care Review Committees should consider adoption of the following model. This model is advisory. Recipient health care providers are not required to establish a review committee or, if one is established, to adhere to this model. In seeking to determine compliance with this part, as it relates to health care for handicapped infants, by health care providers that have an ICRC established and operated substantially in accordance with this model, the Department will, to the extent possible, consult with the ICRC.

(1) *Establishment and purpose.* (i) The hospital establishes an Infant Care Review Committee (ICRC) or joins with one or more other hospitals to create a joint ICRC. The establishing document will state that the ICRC is for the purpose of facilitating the development and implementation of standards, policies and procedures designed to assure that, while respecting reasonable medical judgments, treatment and nourishment not be withheld, solely on the basis of present or anticipated physical or mental impairments, from

handicapped infants who, in spite of such impairments, will benefit medically from the treatment or nourishment.

(ii) The activities of the ICRC will be guided by the following principles:

(A) The interpretative guidelines of the Department relating to the applicability of this part to health care for handicapped infants.

(B) As stated in the "Principles of Treatment of Disabled Infants" of the coalition of major medical and disability organizations, including the American Academy of Pediatrics, National Association of Children's Hospitals and Related Institutions, Association for Retarded Citizens, Down's Syndrome Congress, Spina Bifida Association, and others:

When medical care is clearly beneficial, it should always be provided. When appropriate medical care is not available, arrangements should be made to transfer the infant to an appropriate medical facility. Consideration such as anticipated or actual limited potential of an individual and present or future lack of available community resources are irrelevant and must not determine the decisions concerning medical care. The individual's medical condition should be the sole focus of the decision. These are very strict standards.

It is ethically and legally justified to withhold medical or surgical procedures which are clearly futile and will only prolong the act of dying. However, supportive care should be provided, including sustenance as medically indicated and relief of pain and suffering. The needs of the dying person should be respected. The family also should be supported in its grieving.

In cases where it is uncertain whether medical treatment will be beneficial, a person's disability must not be the basis for a decision to withhold treatment. At all times during the process when decisions are being made about the benefit or futility of medical treatment, the person should be cared for in the medically most appropriate ways. When doubt exists at any time about whether to treat, a presumption always should be in favor of treatment.

(C) As stated by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research:

This [standard for providing medically beneficial treatment] is a very strict standard in that it excludes consideration of the negative effects of an impaired child's life on other persons, including parents, siblings, and society. Although abiding by this standard may be difficult in specific cases, it is all too easy to undervalue the lives of handicapped infants: the Commission finds it imperative to counteract this by treating them no less vigorously than their healthy peers or than older children with similar handicaps would be treated.

(iii) The ICRC will carry out its purposes by:

(A) Recommending institutional policies concerning the withholding or withdrawal of medical or surgical treatments to infants, including guidelines for ICRC action for specific categories of life-threatening conditions affecting infants;

(B) Providing advice in specific cases when decisions are being considered to withhold or withdraw from infant life-sustaining medical or surgical treatment; and

(C) Reviewing retrospectively on a regular basis infant medical records in situations in which life-sustaining medical or surgical treatment has been withheld or withdrawn.

(2) *Organization and staffing.* The ICRC will consist of at least 7 members and include the following:

(i) A practicing physician (e.g., a pediatrician, a neonatologist, or a pediatric surgeon),

(ii) A practicing nurse,

(iii) A hospital administrator,

(iv) A representative of the legal profession,

(v) A representative of a disability group, or a developmental disability expert,

(vi) A lay community member, and

(vii) A member of a facility's organized medical staff, who shall serve as chairperson.

In connection with review of specific cases, one member of the ICRC shall be designated to act as "special advocate" for the infant, as provided in paragraph (f)(3)(ii)(E) of the section. The hospital will provide staff support for the ICRC, including legal counsel. The ICRC will meet on a regular basis, or as required below in connection with review of specific cases. It shall adopt or recommend to the appropriate hospital official or body such administrative policies as terms of office and quorum requirements. The ICRC will recommend procedures to ensure that both hospital personnel and patient families are fully informed of the existence and functions of the ICRC and its availability on a 24-hour basis.

(3) *Operation of ICRC—(i) Prospective policy development.* (A) The ICRC will develop and recommend for adoption by the hospital institutional policies concerning the withholding or withdrawal of medical treatment for infants with life-threatening conditions. These will include guidelines for management of specific types of cases or diagnoses, for example, Down's syndrome and spina bifida, and procedures to be followed in such recurring circumstances as, for example, brain death and parental refusal to consent to life-saving treatment. The

hospital, upon recommendation of the ICRC, may require attending physicians to notify the ICRC of the presence in the facility of an infant with a diagnosis specified by the ICRC, e.g., Down's syndrome and spina bifida.

(B) In recommending these policies and guidelines, the ICRC will consult with medical and other authorities on issues involving disabled individuals, e.g., neonatologists, pediatric surgeons, county and city agencies which provide services for the disabled, and disability advocacy organizations. It will also consult with appropriate committees of the medical staff, to ensure that the ICRC policies and guidelines build on existing staff by-laws, rules and regulations concerning consultations and staff membership requirements. The ICRC will also inform and educate hospital staff on the policies and guidelines it develops.

(ii) *Review of specific cases.* In addition to regularly scheduled meetings, interim ICRC meetings will take place under specified circumstances to permit review of individual cases. The hospital will, to the extent possible, require in each case that life-sustaining treatment be continued, until the ICRC can review the case and provide advice.

(A) Interim ICRC meetings will be convened within 24 hours (or less if indicated) when there is disagreement between the family of an infant and the infant's physician as to the withholding or withdrawal of treatment, when a preliminary decision to withhold or withdraw life-sustaining treatment has been made in certain categories of cases identified by the ICRC, when there is disagreement between members of the hospital's medical and/or nursing staffs, or when otherwise appropriate.

(B) Such interim ICRC meetings will take place upon the request of any member of the ICRC or hospital staff or parent or guardian of the infant. The ICRC will have procedures to preserve the confidentiality of the identity of persons making such requests, and such persons shall be protected from reprisal. When appropriate, the ICRC or a designated member will inform the requesting individual of the ICRC's recommendation.

(C) The ICRC may provide for telephone and other forms of review when the timing and nature of the case, as identified in policies developed by the ICRC, make the convening of an interim meeting impracticable.

(D) Interim meetings will be open to the affected parties. The ICRC will ensure that the interests of the parents, the physician, and the child are fully considered; that family members have

been fully informed of the patient's condition and prognosis; that they have been provided with a listing which describes the services furnished by parent support groups and public and private agencies in the geographic vicinity to infants with conditions such as that before the ICRC; and that the ICRC will facilitate their access to such services and groups.

(E) To ensure a comprehensive evaluation of all options and factors pertinent to the committee's deliberations, the chairperson will designate one member of the ICRC to act, in connection with that specific case, as special advocate for the infant. The special advocate will seek to ensure that all considerations in favor of the provision of life-sustaining treatment are fully evaluated and considered by the ICRC.

(F) In cases in which there is disagreement on treatment between a physician and an infant's family, and the family wishes to continue life-sustaining treatment, the family's wishes will be carried out, for as long as the family wishes, unless such treatment is medically contraindicated. When there is physician/family disagreement and the family refuses consent to life-sustaining treatment, and the ICRC, after due deliberation, agrees with the family, the ICRC will recommend that the treatment be withheld. When there is physician/family disagreement and the family refuses consent, but the ICRC disagrees with the family, the ICRC will recommend to the hospital board or appropriate official that the case be referred immediately to an appropriate court or child protective agency, and every effort shall be made to continue treatment, preserve the status quo, and prevent worsening of the infant's condition until such time as the court or agency renders a decision or takes other appropriate action. The ICRC will also follow this procedure in cases in which the family and physician agree that life-sustaining treatment should be withheld or withdrawn, but the ICRC disagrees.

(iii) *Retrospective record review.* The ICRC, at its regularly-scheduled meeting, will review all records involving withholding or termination of medical or surgical treatment to infants consistent with hospital policies developed by the ICRC, unless the case was previously before the ICRC pursuant to paragraph (f)(3)(ii) of this section. If the ICRC finds that a deviation was made from the institutional policies in a given case, it shall conduct a review and report the findings to appropriate hospital personnel for appropriate action.

(4) *Records.* The ICRC will maintain records of all of its deliberations and summary descriptions of specific cases considered and the disposition of those cases. Such records will be kept in accordance with institutional policies on confidentiality of medical information. They will be made available to appropriate government agencies, or upon court order, or as otherwise required by law.

#### Amendment to Table of Contents

2. The table of contents to 45 CFR Part 84 is amended by striking the designation of "84.55-84.60 [Reserved]" and by inserting in lieu thereof, the following:

Sec.  
84.55 Procedures relating to health care for handicapped infants.  
84.56-84.60 [Reserved]

3. 45 CFR Part 84 is amended by inserting after Appendix B the following new appendix:

#### Appendix C—Guidelines Relating to Health Care for Handicapped Infants.

(a) *Interpretative guidelines relating to the applicability of this part to health care for handicapped infants.* The following are interpretative guidelines of the Department set forth here to assist recipients and the public in understanding the Department's interpretation of section 504 and the regulations contained in this part as applied to matters concerning health care for handicapped infants. These interpretative guidelines are illustrative; they do not independently establish rules of conduct.

(1) With respect to programs and activities receiving Federal financial assistance, health care providers may not, solely on the basis of present or anticipated physical or mental impairments of an infant, withhold treatment or nourishment from the infant who, in spite of such impairments, will medically benefit from the treatment or nourishment.

(2) Futile treatment or treatment that will do no more than temporarily prolong the act of dying of a terminally ill infant is not considered treatment that will medically benefit the infant.

(3) In determining whether certain possible treatments will be medically beneficial to an infant, reasonable medical judgments in selecting among alternative courses of treatment will be respected.

(4) Section 504 and the provisions of this part are not applicable to parents (who are not recipients of Federal financial assistance). However, each recipient health care provider must in all aspects of its health care programs receiving Federal financial assistance provide health care and related services in a manner consistent with the requirements of section 504 and this part. Such aspects includes decisions on whether to report, as required by State law or otherwise, to the appropriate child protective services agency a suspected instance of medical neglect of a child, or to take other



action to seek review or parental decisions to withhold consent for medically indicated treatment. Whenever parents make a decision to withhold consent for medically beneficial treatment or nourishment, such recipient providers may not, solely on the basis of the infant's present or anticipated future mental or physical impairments, fail to follow applicable procedures on reporting such incidents to the child protective services agency or to seek judicial review.

(5) The following are examples of applying these interpretative guidelines. These examples are stated in the context of decisions made by recipient health care providers. Were these decisions made by parents, the guideline stated in section (a)(4) would apply. These examples assume no facts or complications other than those stated. Because every case must be examined on its individual facts, these are merely illustrative examples to assist in understanding the framework for applying the nondiscrimination requirements of section 504 and this part.

(i) Withholding of medically beneficial surgery to correct an intestinal obstruction in an infant with Down's Syndrome when the withholding is based upon the anticipated future mental retardation of the infant and there are no medical contraindications to the surgery that would otherwise justify withholding the surgery would constitute a discriminatory act, violative of section 504.

(ii) Withholding of treatment for medically correctable physical anomalies in children born with spina bifida when such denial is based on anticipated mental impairment paralysis or incontinence of the infant, rather than on reasonable medical judgments that treatment would be futile, too unlikely of success given complications in the particular case, or otherwise not of medical benefit to the infant, would constitute a discriminatory act, violative of section 504.

(iii) Withholding of medical treatment for an infant born with anencephaly, who will inevitably die within a short period of time, would not constitute a discriminatory act because the treatment would be futile and do no more than temporarily prolong the act of dying.

(iv) Withholding of certain potential treatments from a severely premature and low birth weight infant on the grounds of reasonable medical judgments concerning the improbability of success or risks of potential harm to the infant would not violate section 504.

(b) *Guidelines for HHS investigations relating to health care for handicapped infants.* The following are guidelines of the Department in conducting investigations relating to health care for handicapped infants. They are set forth here to assist recipients and the public in understanding applicable investigative procedures. These guidelines do not establish rules of conduct, create or affect legally enforceable rights of any person, or modify existing rights, authorities or responsibilities pursuant to this

part. These guidelines reflect the Department's recognition of the special circumstances presented in connection with complaints of suspected life-threatening noncompliance with this part involving health care for handicapped infants. These guidelines do not apply to other investigations pursuant to this part, or other civil rights statutes and rules. Deviations from these guidelines may occur when, in the judgment of the responsible Department official, other action is necessary to protect the life or health of a handicapped infant.

(1) Unless impracticable, whenever the Department receives a complaint of suspected life-threatening noncompliance with this part in connection with health care for a handicapped infant in a program or activity receiving Federal financial assistance, HHS will immediately conduct a preliminary inquiry into the matter by initiating telephone contact with the recipient hospital to obtain information relating to the condition and treatment of the infant who is the subject of the complaint. The preliminary inquiry, which may include additional contact with the complainant and a requirement that pertinent records be provided to the Department, will generally be completed within 24 hours (or sooner if indicated) after receipt of the complaint.

(2) Unless impracticable, whenever a recipient hospital has an Infant Care Review Committee, established and operated substantially in accordance with the provisions of 45 CFR 84.55(f), the Department will, as part of its preliminary inquiry, solicit the information available to, and the analysis and recommendations of, the ICRC. Unless, in the judgment of the responsible Department official, other action is necessary to protect the life or health of a handicapped infant, prior to initiating an on-site investigation, the Department will await receipt of this information from the ICRC for 24 hours (or less if indicated) after receipt of the complaint. The Department may require a subsequent written report of the ICRC's findings, accompanied by pertinent records and documentation.

(3) On the basis of the information obtained during preliminary inquiry, including information provided by the hospital (including the hospital's ICRC, if any), information provided by the complainant, and all other information obtained, the Department will determine whether there is a need for an on-site investigation of the complaint. Whenever the Department determines that doubt remains that the recipient hospital or some other recipient is in compliance with this part or additional documentation is desired to substantiate a conclusion, the Department will initiate an on-site investigation or take some other appropriate action. Unless impracticable, prior to initiating an on-site investigation, the Department's medical consultant (referred to in paragraph 6) will contact the hospital's ICRC or appropriate medical personnel of the recipient hospital.

(4) In conducting on-site investigations, when a recipient hospital has an ICRC established and operated substantially in accordance with the provisions of 45 CFR 84.55(f), the investigation will begin with, or include at the earliest practicable time, a meeting with the ICRC or its designees. In all on-site investigations, the Department will make every effort to minimize any potential inconvenience or disruption, accommodate the schedules of health care professionals and avoid making medical records unavailable. The Department will also seek to coordinate its investigation with any related investigations by the state child protective services agency so as to minimize potential disruption.

(5) It is the policy of the Department to make no comment to the public or media regarding the substance of a pending preliminary inquiry or investigation.

(6) The Department will obtain the assistance of a qualified medical consultant to evaluate the medical information (including medical records) obtained in the course of a preliminary inquiry or investigation. The name, title and telephone number of the Department's medical consultant will be made available to the recipient hospital. The Department's medical consultant will, if appropriate, contact medical personnel of the recipient hospital in connection with the preliminary inquiry, investigation or medical consultant's evaluation. To the extent practicable, the medical consultant will be a specialist with respect to the condition of the infant who is the subject of the preliminary inquiry or investigation. The medical consultant may be an employee of the Department or another person who has agreed to serve, with or without compensation, in that capacity.

(7) The Department will advise the recipient hospital of its conclusions as soon as possible following the completion of a preliminary inquiry or investigation. Whenever final administrative findings following an investigation of a complaint of suspected life-threatening noncompliance cannot be made promptly, the Department will seek to notify the recipient and the complainant of the Department's decision on whether the matter will be immediately referred to the Department of Justice pursuant to 45 CFR 80.8

(8) Except as necessary to determine or effect compliance, the Department will (i) in conducting preliminary inquiries and investigations, permit information provided by the recipient hospital to the Department to be furnished without names or other identifying information relating to the infant and the infant's family; and (ii) to the extent permitted by law, safeguard the confidentiality of information obtained.

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BOWEN, SECRETARY OF HEALTH AND HUMAN SERVICES *v.* AMERICAN HOSPITAL ASSOCIATION ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

No. 84-1529. Argued January 15, 1986—Decided June 9, 1986

Section 504 of the Rehabilitation Act of 1973 provides that “[n]o otherwise qualified handicapped individual . . . shall, solely by reason of his handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.” In 1984, the Secretary of Health and Human Services (Secretary) promulgated regulations requiring: (1) health care providers receiving federal funds to post notices that because of § 504’s prohibition against discrimination on the basis of handicap, health care should not be withheld from infants on the basis of their mental or physical impairments; (2) state child protective services agencies to establish procedures to prevent unlawful medical neglect of handicapped infants, and when considered necessary, in the judgment of the responsible official of the Department of Health and Human Services, to protect a handicapped infant’s life or health; (3) immediate access to patient records; and (4) expedited compliance actions. In consolidated actions in Federal District Court, respondents sought to declare the regulations invalid and to enjoin their enforcement. The court granted the requested relief on the authority of *United States v. University Hospital*, 729 F. 2d 144 (CA2), and the Court of Appeals affirmed on the basis of that earlier decision.

*Held:* The judgment is affirmed.

794 F. 2d 676, affirmed.

JUSTICE STEVENS, joined by JUSTICE MARSHALL, JUSTICE BLACKMUN, and JUSTICE POWELL, concluded that the regulations in question are not authorized by § 504. Pp. 624-647.

(a) A hospital’s withholding of treatment from a handicapped infant when no parental consent has been given cannot violate § 504, for without the parents’ consent the infant is neither “otherwise qualified” for treatment nor has he been denied care “solely by reason of his handicap.” There is nothing in the administrative record documenting the Secretary’s belief that there exists “discriminatory withholding of medical care” in violation of § 504 which would justify federal regulation. None

of the examples cited by the Secretary as justification for the regulation suggest that the hospitals receiving federal funds, as opposed to parents, withheld medical care on the basis of handicap. Pp. 630-636.

(b) The complaint-handling process the Secretary would impose on unwilling state agencies is totally foreign to the authority to prevent discrimination conferred on him by § 504. While the Secretary can require state agencies to document their *own* compliance with § 504, nothing in § 504 authorizes him to commandeer state agencies to enforce compliance by *other* recipients of federal funds (in this instance, hospitals). Pp. 637-642.

(c) The Secretary’s basis for federal intervention is perceived discrimination against handicapped infants in violation of § 504, and yet the Secretary has pointed to no evidence that such discrimination occurs. The administrative record does not contain the reasoning and evidence necessary to sustain federal intervention into a historically state-administered decisional process that appears—for lack of any contrary evidence—to be functioning in full compliance with § 504. Nothing in § 504 authorizes the Secretary to dispense with the law’s focus on discrimination and instead to employ federal resources to save the lives of handicapped newborns, without regard to whether they are victims of discrimination by recipients of federal funds or not. Section 504 does not authorize the Secretary to give unsolicited advice either to parents, to hospitals, or to state officials who are faced with difficult treatment decisions concerning handicapped children. The administrative record demonstrates that the Secretary has asserted the authority to conduct on-site investigations, to inspect hospital records, and to participate in the decisional process in emergency cases in which there was no colorable basis for believing that a violation of § 504 had occurred or was about to occur. These investigative actions are not authorized by § 504, and the regulations that purport to authorize a continuation of them are invalid. Pp. 642-647.

STEVENS, J., announced the judgment of the Court, and delivered an opinion in which MARSHALL, BLACKMUN, and POWELL, JJ., joined. BURGER, C. J., concurred in the judgment. WHITE, J., filed a dissenting opinion, in which BRENNAN, J., joined and in Parts I, II, IV, and V of which O’CONNOR, J., joined, *post*, p. 648. O’CONNOR, J., filed a dissenting opinion, *post*, p. 665. REHNQUIST, J., took no part in the consideration or decision of the case.

*Deputy Assistant Attorney General Cooper argued the cause for petitioner. With him on the briefs were Solicitor General Fried, Assistant Attorney General Reynolds, Dep-*

uty Solicitor General Wallace, Edwin S. Kneedler, Brian K. Landsberg, and Mark L. Gross.

Richard L. Epstein argued the cause for respondents American Hospital Association et al. With him on the brief were Stuart M. Gerson, William G. Kopit, David H. Larry, and Robert W. McCann. Benjamin W. Heineman, Jr., argued the cause for respondents American Medical Association et al. With him on the brief were Carter G. Phillips, Vincent F. Prada, Newton N. Minow, Jack R. Bierig, Ann E. Allen, and Joseph A. Keyes, Jr.\*

JUSTICE STEVENS announced the judgment of the Court and delivered an opinion, in which JUSTICE MARSHALL, JUSTICE BLACKMUN, and JUSTICE POWELL join.

This case presents the question whether certain regulations governing the provision of health care to handicapped infants are authorized by §504 of the Rehabilitation Act of 1973. That section provides, in part:

\*Briefs of *amici curiae* urging reversal were filed for the American Association on Mental Deficiency et al. by James W. Ellis and Ruth A. Luckasson; for the American Coalition of Citizens with Disabilities et al. by Thomas K. Gilhool, Frank J. Laski, Michael Churchill, and Timothy M. Cook; for the Association for Retarded Citizens of the United States et al. by Martin H. Gerry; for the Disability Rights Education & Defense Fund, Inc., et al. by Barbara M. Milstein; for the Rutherford Institute et al. by W. Charles Bundren, Guy O. Farley, Jr., James J. Knicely, John W. Whitehead, Thomas O. Kotouc, Wendell R. Bird, and William B. Hollberg; for Carlton Johnson by James Bopp, Jr., and Thomas J. Marzen; and for David G. McLone, M. D., et al. by Dennis J. Horan, Victor G. Rosenblum, Edward R. Grant, and Maura K. Quinlan.

Briefs of *amici curiae* urging affirmance were filed for the American Academy of Pediatrics et al. by Stephan E. Lawton, Jack N. Goodman, and John A. Hodges; for the State University of New York by Robert Abrams, Attorney General of New York, Robert Hermann, Solicitor General, Frederick K. Mehlman, Stanley A. Camhi, Paul M. Glickman, Donna Miller, Martha O. Shoemaker, and Jane Levine, Assistant Attorneys General, and Sanford H. Levine; and for George P. Smith II, *pro se*.

James Bopp, Jr., filed a brief for Senator Orrin G. Hatch et al. as *amici curiae*.

"No otherwise qualified handicapped individual . . . shall, solely by reason of his handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance." 87 Stat. 394, 29 U. S. C. § 794.<sup>1</sup>

## I

The American Medical Association, the American Hospital Association, and several other respondents<sup>2</sup> challenge the validity of Final Rules promulgated on January 12, 1984, by the Secretary of the Department of Health and Human Services.<sup>3</sup> These Rules establish "Procedures relating to health care for handicapped infants," and in particular require the posting of informational notices, authorize expedited access to records and expedited compliance actions, and command state child protective services agencies to "prevent instances of unlawful medical neglect of handicapped infants." 45 CFR § 84.55 (1985).

Although the Final Rules comprise six parts, only the four mandatory components are challenged here.<sup>4</sup> Subsection (b)

<sup>1</sup>"Handicapped individual" is defined in § 7(7)(B) of the Act, as amended, as "any person who (i) has a physical or mental impairment which substantially limits one or more of such person's major life activities, (ii) has a record of such an impairment, or (iii) is regarded as having such an impairment." 92 Stat. 2985, 29 U. S. C. § 706(7)(B).

<sup>2</sup>The respondents include the Hospital Association of New York State, the American College of Obstetricians and Gynecologists, the Association of American Medical Colleges, the American Academy of Family Physicians, and certain individual physicians.

<sup>3</sup>Margaret Heckler occupied the position of Secretary throughout the rulemaking period. On December 13, 1985, after certiorari had been granted, Dr. Otis Bowen assumed that position. Despite the fact that Dr. Bowen was not responsible for promulgation of the Final Rules, for the sake of continuity our references assume that he was. For ease of reference we refer to the Secretary, the Department, and HHS interchangeably.

<sup>4</sup>In subsection (a) the Department "encourages each recipient health care provider that provides health care services to infants" to establish an

is entitled "Posting of informational notice" and requires every "recipient health care provider that provides health care services to infants in programs or activities receiving

"Infant Care Review Committee (ICRC)" to assist in the development of treatment standards for handicapped infants and to provide assistance in making individual treatment decisions. 45 CFR § 84.55(a) (1985). In subsection (f), the Department describes its version of a model ICRC.

Subsection (f) also provides that "[t]he activities of the ICRC will be guided by . . . [t]he interpretative guidelines of the Department." 45 CFR § 84.55(f)(1)(ii)(A) (1985). These guidelines, which are "illustrative" and "do not independently establish rules of conduct," pt. 84, appendix C, ¶(a), set forth the Department's interpretation of § 504. Although they do not contain any definition of "discrimination," they do state that § 504 is not applicable to parents and that the regulation applies to only two categories of activities of hospitals: (1) refusals to provide treatment or nourishment to handicapped infants whose parents have consented to, or requested, such treatment; and (2) the failure or refusal to take action to override a parental decision to withhold consent for medically beneficial treatment or nourishment. With respect to the second category, the guidelines state that the hospital may not "solely on the basis of the infant's present or anticipated future mental or physical impairments, fail to follow applicable procedures on reporting such incidents to the child protective services agency or to seek judicial review." 45 CFR pt. 84, appendix C, ¶(a)(4) (1985).

With respect to the first category, the guidelines do not state that § 504 categorically prohibits a hospital from withholding requested treatment or nourishment "solely on the basis of present or anticipated physical or mental impairments of an infant." 45 CFR pt. 84, appendix C, ¶(a)(1). Rather, the substantive guidelines and two of the illustrative examples recognize that the etiology of and prognosis for particular handicapping conditions may justify "a refusal to treat solely on the basis of those handicapping conditions." ¶(a)(2) (§ 504 does not require "futile treatment"); ¶(a)(5)(iii) (§ 504 does not require treatment of anencephaly because it would "do no more than temporarily prolong the act of dying"); ¶(a)(iv) (same with severely premature and low birth weight infants). In general, the guidelines seem to make a hospital's liability under § 504 dependent on proof that (1) it refused to provide requested treatment or nourishment solely on the basis of an infant's handicapping condition, and (2) the treatment or nourishment would have been medically beneficial. See ¶¶(a)(1)-(3), (5).

The guidelines also describe how HHS will respond to "complaints of suspected life threatening noncompliance" with § 504 in this context, progress-

Federal financial assistance"—a group to which we refer generically as "hospitals"—to post an informational notice in one of two approved forms. 45 CFR § 84.55(b) (1985). Both forms include a statement that § 504 prohibits discrimination on the basis of handicap, and indicate that because of this prohibition "nourishment and medically beneficial treatment (as determined with respect for reasonable medical judgments) should not be withheld from handicapped infants solely on the basis of their present or anticipated mental or physical impairments." 45 CFR §§ 84.55(b)(3), (4) (1985). The notice's statement of the legal requirement does not distinguish between medical care for which parental consent has been obtained and that for which it has not. The notice must identify the telephone number of the appropriate child protective services agency and, in addition, a toll-free number for the Department that is available 24 hours a day. *Ibid.* Finally, the notice must state that the "identity of callers will be kept confidential" and that federal law prohibits retaliation "against any person who provides information about possible violations." *Ibid.*

Subsection (c), which contains the second mandatory requirement, sets forth "Responsibilities of recipient state child protective services agencies." Subsection (c) does not mention § 504 (or any other federal statute) and does not even use the word "discriminate." It requires every designated agency to establish and maintain procedures to ensure that

ing from telephone inquiries to the hospital to obtain information about the condition of the infant, to requests for access to records, and finally to on-site investigations and litigation in appropriate cases. ¶(b). The guidelines do not draw any distinction between cases in which parental consent has been withheld and those in which it has been given. Nor do they draw any distinction between cases in which hospitals have made a report of parental refusal to consent to treatment and those in which no report to a state agency has been made. They do announce that the "Department will also seek to coordinate its investigation with any related investigations by the state child protective services agency so as to minimize potential disruption," ¶(b)(4), indicating that the Department's investigations may continue even in cases that have previously been referred to a state agency.

“the agency utilizes its full authority pursuant to state law to prevent instances of unlawful medical neglect of handicapped infants.” 45 CFR § 84.55(c)(1). Mandated procedures must include (1) “[a] requirement that health care providers report on a timely basis . . . known or suspected instances of unlawful medical neglect of handicapped infants,” § 84.55(c)(1)(i); (2) a method by which the state agency can receive timely reports of such cases, § 84.55(c)(1)(ii); (3) “immediate” review of those reports, including “on-site investigation,” where appropriate, § 84.55(c)(1)(iii); (4) protection of “medically neglected handicapped infants” including, where appropriate, legal action to secure “timely court order[s] to compel the provision of necessary nourishment and medical treatment,” § 84.55(c)(1)(iv); and (5) “[t]imely notification” to HHS of every report of “suspected unlawful medical neglect” of handicapped infants. The preamble to the Final Rules makes clear that this subsection applies “where a refusal to provide medically beneficial treatment is a result, not of decisions by a health care provider, but of decisions by parents.” 49 Fed. Reg. 1627 (1984).

The two remaining mandatory regulations authorize “[e]xpedited access to records” and “[e]xpedited action to effect compliance.” 45 CFR §§ 84.55(d), (e) (1985). Subsection (d) provides broadly for immediate access to patient records on a 24-hour basis, with or without parental consent, “when, in the judgment of the responsible Department official, immediate access is necessary to protect the life or health of a handicapped individual.” § 84.55(d). Subsection (e) likewise dispenses with otherwise applicable requirements of notice to the hospital “when, in the judgment of the responsible Department official, immediate action to effect compliance is necessary to protect the life or health of a handicapped individual.” § 84.55(e). The expedited compliance provision is intended to allow “the government [to] see[k] a temporary restraining order to sustain the life of a handicapped infant in

imminent danger of death.” 49 Fed. Reg. 1628 (1984). Like the provision affording expedited access to records, it applies without regard to whether parental consent to treatment has been withheld or whether the matter has already been referred to a state child protective services agency.

## II

The Final Rules represent the Secretary’s ultimate response to an April 9, 1982, incident in which the parents of a Bloomington, Indiana, infant with Down’s syndrome and other handicaps refused consent to surgery to remove an esophageal obstruction that prevented oral feeding. On April 10, the hospital initiated judicial proceedings to override the parents’ decision, but an Indiana trial court, after holding a hearing the same evening, denied the requested relief. On April 12 the court asked the local Child Protection Committee to review its decision. After conducting its own hearing, the Committee found no reason to disagree with the court’s ruling.<sup>5</sup> The infant died six days after its birth.

Citing “heightened public concern” in the aftermath of the Bloomington Baby Doe incident, on May 18, 1982, the director of the Department’s Office of Civil Rights, in response to a directive from the President, “remind[ed]” health care providers receiving federal financial assistance that newborn in-

<sup>5</sup> At the instance of the local prosecutor, the Indiana courts on April 13 held another hearing at which the court concluded that “Baby Doe” had not been neglected under Indiana’s Child in Need of Services statute. Additional attempts to seek judicial intervention were rebuffed the same day. On the following day, the Indiana Court of Appeals denied a request for an immediate hearing. *In re Infant Doe*, No. GU 8204-004A (Monroe County Cir. Ct., Apr. 12, 1982). The Indiana Supreme Court, by a vote of 3 to 1, rejected a petition for a writ of mandamus. *State ex rel. Infant Doe v. Baker*, No. 482 S 140 (May 27, 1982). The infant died while a stay was being sought in this Court, and we subsequently denied certiorari. *Infant Doe v. Bloomington Hospital*, 464 U. S. 961 (1983).

fants with handicaps such as Down's syndrome were protected by § 504. 47 Fed. Reg. 26027 (1982).<sup>6</sup>

This notice was followed, on March 7, 1983, by an "Interim Final Rule" contemplating a "vigorous federal role." 48 Fed. Reg. 9630. The Interim Rule required health care providers receiving federal financial assistance to post "in a conspicuous place in each delivery ward, each maternity ward, each pediatric ward, and each nursery, including each intensive care nursery" a notice advising of the applicability of § 504 and the availability of a telephone "hotline" to report suspected violations of the law to HHS. *Id.*, at 9631. Like the Final Rules, the Interim Rule also provided for expedited compliance actions and expedited access to records and facilities when, "in the judgment of the responsible Department official," immediate action or access was "necessary to protect the life or health of a handicapped individual." *Id.*, at 9632. The Interim Rule took effect on March 22.

On April 6, 1983, respondents American Hospital Association et al. filed a complaint in the Federal District Court for the Southern District of New York seeking a declaration that the Interim Final Rule was invalid and an injunction against its enforcement. Little more than a week later, on April 14, in a similar challenge brought by the American Academy of Pediatrics and other medical institutions, the Federal District Court for the District of Columbia declared the Interim Final Rule "arbitrary and capricious and promulgated in violation of the Administrative Procedure Act." *American Academy of Pediatrics v. Heckler*, 561 F. Supp. 395, 404 (1983). The District Judge in that case "conclude[d] that haste and inexperience ha[d] resulted in agency action based on inadequate consideration" of several relevant concerns

<sup>6</sup>The notice maintained that hospitals would violate § 504 if they "allow[ed] [an] infant" to remain in their care after "the infant's parents or guardian [had withheld consent to] treatment or nourishment discriminatorily." 47 Fed. Reg. 26027 (1982). The Secretary no longer subscribes to this reading of the statute. See 49 Fed. Reg. 1631 (1984).

and, in the alternative, found that the Secretary had improperly failed to solicit public comment before issuing the Rule. *Id.*, at 399-401.

On July 5, 1983, the Department issued new "Proposed Rules" on which it invited comment. Like the Interim Final Rule, the Proposed Rules required hospitals to post informational notices in conspicuous places and authorized expedited access to records to be followed, if necessary, by expedited compliance action. 48 Fed. Reg. 30851. In a departure from the Interim Final Rule, however, the Proposed Rules required federally assisted state child protective services agencies to utilize their "full authority pursuant to State law to prevent instances of medical neglect of handicapped infants." *Ibid.* Mandated procedures mirrored those contained in the Final Rules described above. *Ibid.* The preamble and appendix to the Proposed Rules did not acknowledge that hospitals and physicians lack authority to perform treatment to which parents have not given their consent.<sup>7</sup>

<sup>7</sup>In explaining the need for the Proposed Rules, the preamble, although mentioning "parental rights over their children," insisted that physicians' "acquiescence in nontreatment of Down's children is apparently *because of* the handicap," rather than, it must be supposed, lack of parental consent. 48 Fed. Reg. 30848 (1983).

The effect of parental nonconsent was not even mentioned in the appendix to the Proposed Rules. That section, which set forth the Department's view of "the manner in which Section 504 applies to the provision of health care services to handicapped infants," *id.*, at 30851, declared that § 504 mandated "the basic provision of nourishment, fluids, and routine nursing care." *Id.*, at 30852. The provision of sustenance, according to the Department, was "not an option for medical judgment." *Ibid.* Thus, "[e]ven if a handicapped infant faces imminent and unavoidable death, no health care provider should take upon itself to cause death by starvation or dehydration." *Ibid.*

In addition to its unqualified endorsement of nourishment as required by § 504, the appendix announced that "[a]ny decision not to correct intestinal atresia in a Down's Syndrome child, unless an additional complication medical warrants such decision, *must* be deemed a denial of services based on

After the period for notice and comment had passed, HHS, on December 30, 1983, promulgated the Final Rules and announced that they would take effect on February 13, 1984. On March 12 of that year respondents American Hospital Association et al. amended their complaint and respondents American Medical Association et al. filed suit to declare the new regulations invalid and to enjoin their enforcement. The actions were consolidated in the Federal District Court for the Southern District of New York, which awarded the requested relief on the authority of the decision of the United States Court of Appeals for the Second Circuit in *United States v. University Hospital*, 729 F. 2d 144 (1984). *American Hospital Assn. v. Heckler*, 585 F. Supp. 541 (1984); App. to Pet. for Cert. 50a. On appeal, the parties agreed that the reasoning of the Court of Appeals in *University Hospital*, if valid, required a judgment against the Government in this case.<sup>8</sup> In accordance with its earlier decision, the Court of Appeals summarily affirmed the District Court. 694 F. 2d 676 (1984). Since the judgment here thus rests entirely on the reasoning of *University Hospital*, it is appropriate to examine that case now.

### III

On October 11, 1983, after the Department's Interim Final Rule had been declared invalid but before it had promulgated the Final Rules challenged here, a child with multiple congenital defects known as "Baby Jane Doe" was born in Long

the handicap of Down's Syndrome. The same reasoning applies to a case of Down's Syndrome [infant] with esophageal atresia, and the denial of surgery to correct atresia." *Ibid.* (emphasis added). The Department did not discuss the relevance of parental nonconsent to the hospital's treatment obligation under § 504, presumably because it was irrelevant given its understanding of the provision at that time.

<sup>8</sup>Indeed, although the Government took an appeal from the District Court's judgment, it filed a motion for summary disposition after the Court of Appeals denied its motion for initial consideration en banc. Its motion expressly acknowledged that an affirmance was compelled by the decision in *University Hospital*.

Island, New York, and was promptly transferred to University Hospital for corrective surgery. After consulting with physicians and other advisers, the parents decided to forgo corrective surgery that was likely to prolong the child's life, but would not improve many of her handicapping conditions.

On October 16, 1983, an unrelated attorney named Washburn filed suit in the New York Supreme Court, seeking the appointment of a guardian *ad litem* for the infant who would direct the hospital to perform the corrective surgery. The trial court granted that relief on October 20, but was reversed the following day by the Appellate Division which found that the "concededly concerned and loving parents" had "chosen one course of appropriate medical treatment over another" and made an informed decision that was "in the best interest of the infant." *Weber v. Stony Brook Hospital*, 95 App. Div. 2d 587, 589, 467 N. Y. S. 2d 685, 687 (*per curiam*). On October 28, the New York Court of Appeals affirmed, but on the ground that the trial court should not have entertained a petition to initiate child neglect proceedings by a stranger who had not requested the aid of the responsible state agency. *Weber v. Stony Brook Hospital*, 60 N. Y. 2d 208, 211-213, 456 N. E. 2d 1186, 1187-1188 (*per curiam*).

While the state proceedings were in progress, on October 19, HHS received a complaint from a "private citizen" that Baby Jane Doe was being discriminatorily denied medically indicated treatment. HHS promptly referred this complaint to the New York State Child Protective Service. (The agency investigated the charge of medical neglect and soon thereafter concluded that there was no cause for state intervention.) In the meantime, before the State Child Protective Service could act, HHS on October 22, 1983, made repeated requests of the hospital to make its records available for inspection in order to determine whether the hospital was in compliance with § 504. The hospital refused the requests

and advised HHS that the parents had not consented to a release of the records.

Subsequently, on November 2, 1983, the Government filed suit in Federal District Court invoking its general authority to enforce § 504 and 45 CFR § 84.61 (1985), a regulation broadly authorizing access to information necessary to ascertain compliance. The District Court allowed the parents to intervene as defendants, expedited the proceeding, and ruled against the Government. It reasoned that the Government had no right of access to information because the record clearly established that the hospital had not violated the statute. *United States v. University Hospital, State Univ. of N. Y. at Stony Brook*, 575 F. Supp. 607, 614 (EDNY). Since the uncontradicted evidence established that the hospital “ha[d] at all times been willing to perform the surgical procedures in question, if only the parents . . . would consent,” the hospital “failed to perform the surgical procedures in question, not because Baby Jane Doe [wa]s handicapped, but because her parents ha[d] refused to consent.” *Ibid.*

The Court of Appeals affirmed. In an opinion handed down on February 23, 1984, six weeks after promulgation of the Final Rules, it agreed with the District Court that “an agency is not entitled to information sought in an investigation that ‘overreaches the authority Congress has given.’” 729 F. 2d, at 150 (quoting *Oklahoma Press Publishing Co. v. Walling*, 327 U. S. 186, 217 (1946)). It further held that although Baby Jane Doe was a “handicapped individual,” she was not “otherwise qualified” within the meaning of § 504 because “where medical treatment is at issue, it is typically the handicap itself that gives rise to, or at least contributes to the need for services”; as a result “the ‘otherwise qualified’ criterion of section 504 cannot be meaningfully applied to a medical treatment decision.” 729 F. 2d, at 156. For the same reason, the Court of Appeals rejected the Government’s argument that Baby Jane Doe had been “subjected to discrimination” under § 504: “Where the handicapping condi-

tion is related to the condition(s) to be treated, it will rarely, if ever, be possible to say with certainty that a particular decision was ‘discriminatory.’” *Id.*, at 157. The difficulty of applying § 504 to individual medical treatment decisions confirmed the Court of Appeals in its view that “[C]ongress never contemplated that section 504 of the Rehabilitation Act would apply to treatment decisions involving defective newborn infants when the statute was enacted in 1973, when it was amended in 1974, or at any subsequent time.” *Id.*, at 161. It therefore rejected “the far-reaching position advanced by the government in this case” and concluded that until Congress had spoken, “it would be an unwarranted exercise of judicial power to approve the type of investigation that ha[d] precipitated this lawsuit.” *Ibid.*

Judge Winter dissented. He pointed out that § 504 was patterned after § 601 of the Civil Rights Act of 1964, which prohibits discrimination on the basis of race in federally funded programs, and asserted that a refusal to provide medical treatment because of a person’s handicapping condition is as clearly covered by § 504 as a refusal based on a person’s race is covered by § 601:

“A judgment not to perform certain surgery because a person is black is not a *bona fide* medical judgment. So too, a decision not to correct a life threatening digestive problem because an infant has Down’s Syndrome is not a *bona fide* medical judgment. The issue of parental authority is also quickly disposed of. A denial of medical treatment to an infant because the infant is black is not legitimated by parental consent.” *Id.*, at 162.

The Government did not file a certiorari petition in *University Hospital*. It did, however, seek review of the judgment in this case. We granted certiorari, 472 U. S. 1016 (1985), and we now affirm.



## IV

The Solicitor General is correct that "handicapped individual" as used in § 504 includes an infant who is born with a congenital defect. If such an infant is "otherwise qualified" for benefits under a program or activity receiving federal financial assistance, § 504 protects him from discrimination "solely by reason of his handicap."<sup>9</sup> It follows, under our decision in *Alexander v. Choate*, 469 U. S. 287, 301 (1985), that handicapped infants are entitled to "meaningful access" to medical services provided by hospitals, and that a hospital rule or state policy denying or limiting such access would be subject to challenge under § 504.

However, no such rule or policy is challenged, or indeed has been identified, in this case. Nor does this case, in contrast to the *University Hospital* litigation, involve a claim that any specific individual treatment decision violates § 504. This suit is not an enforcement action, and as a consequence it is not necessary to determine whether § 504 ever applies to individual medical treatment decisions involving handicapped infants. Respondents brought this litigation to challenge the four mandatory components of the Final Rules on their face,<sup>10</sup> and the Court of Appeals' judgment which we review merely affirmed the judgment of the District Court which "declared invalid and enjoined enforcement of [the final] regulations,

<sup>9</sup> As the case comes to us, we have no reason to review the Court of Appeals' assumption that the provision of health care to infants in hospitals receiving Medicare or Medicaid payments is a part of a "program or activity receiving Federal financial assistance." See *Consolidated Rail Corp. v. Darrone*, 465 U. S. 624, 635-636 (1984).

<sup>10</sup> See, e. g., Brief in Opposition for Respondents American Medical Assn. et al. 7-8, n. 8; Record, Doc. No. 4, Memorandum of Points and Authorities in Support of Plaintiffs' Motion for Preliminary Injunction 12 ("The Final Regulation which is challenged in this action contains four mandatory provisions" (citations omitted)); *id.*, at 28 ("After *University Hospital* . . . must fall all of the mandatory obligations imposed by the Final Regulation"). Cf. App. 138-140 (complaint of American Medical Association et al.).

purportedly promulgated pursuant to section 504 of the Rehabilitation Act of 1973, 29 U. S. C. § 794 (1982)." App. to Pet. for Cert. 2a.<sup>11</sup> The specific question presented by this

<sup>11</sup> It is true that the District Court, in addition to declaring "[t]he Final Regulation . . . invalid and unlawful as exceeding" § 504 and enjoining petitioner from "any further implementation of the Final Regulation," also declared invalid and enjoined "[a]ny other actions" of the Secretary "to regulate treatment involving impaired newborn infants taken under authority of Section 504, including currently pending investigation and other enforcement actions." App. to Pet. for Cert. 51a. This language must, however, be given a limited construction. The complaints in this case did not challenge the Department's authority to regulate all treatment decisions, but more precisely the mandatory provisions of the Final Rules and enforcement activity along those lines but undertaken pursuant to the Department's "general authority" to enforce § 504, as occurred in the *University Hospital* litigation and in 41 of the 49 full-scale investigations conducted by the Secretary up to that point in time. See App. 138-139 (complaint of American Medical Association et al.); *id.*, at 145 (same); *id.*, at 159 (complaint of American Hospital Association et al.). See also Record, Doc. No. 4, Memorandum of Points and Authorities in Support of Plaintiffs' Motion for Preliminary Injunction 10-11. From these pleadings, the Court of Appeals apparently interpreted the District Court's use of the word "any" to forbid "[a]ny other actions" resembling the "currently pending investigation and other enforcement actions" specified in the injunction, App. to Pet. for Cert. 51a, rather than all possible regulatory and investigative activity that might involve the provision of health care to handicapped infants. Thus, as will become clear from our analysis of the Final Rules below, the injunction forbids continuation or initiation of regulatory and investigative activity directed at instances in which parents have refused consent to treatment and, if the Secretary were to undertake such action, efforts to seek compliance with affirmative requirements imposed on state child protective services agencies. "Because of the rightly serious view courts have traditionally taken of violations of injunctive orders, and because of the severity of punishment which may be imposed for such violation," *Pasadena City Bd. of Education v. Spangler*, 427 U. S. 424, 439 (1976); see *Longshoremen v. Marine Trade Assn.*, 389 U. S. 64, 76 (1967); *Gunn v. University Committee*, 399 U. S. 383, 389 (1970), the Court of Appeals properly construed the District Court's judgment as pertaining to the regulations challenged in this litigation (and enforcement activity independent of the Final Rules but paralleling the procedures set forth therein). Cf. *Schmidt v. Lessard*, 414 U. S. 473, 477 (1974) (*per curiam*).

case, then, is whether the four mandatory provisions of the Final Rules are authorized by § 504.

### V

It is an axiom of administrative law that an agency's explanation of the basis for its decision must include "a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Assn. v. State Farm Mut. Automobile Ins. Co.*, 463 U. S. 29, 43 (1983) (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U. S. 156, 168 (1962)).<sup>12</sup> Agency deference has not come so far that we will uphold regulations whenever it is possible to "conceive a basis" for administrative action. To the contrary, the "presumption of

(noting desirability of precise construction of injunction orders to facilitate appellate review). It is, of course, the Court of Appeals' judgment that we are called on to review, not the District Court's. See *Union Pacific R. Co. v. Chicago, R. I. & P. R. Co.*, 163 U. S. 564, 593 (1896). Cf. *Davis v. Packard*, 6 Pet. 41, 49 (1832). Accordingly, we give great weight to the Court of Appeals' construction of the judgment it affirmed. Cf. *United States v. Colgate & Co.*, 250 U. S. 300, 301-302 (1919). For purposes of comparison, the dissent's expansive reading of the judgment is supported neither by the Court of Appeals nor by the parties. See Brief for Respondents American Medical Assn. et al. 14, 48, n. 60. Cf. Brief for Respondents American Hospital Assn. et al. 4 (quoting final judgment of the District Court). In view of the fact that we affirm this judgment on reasoning narrower than that employed by the lower courts, it bears repetition that this Court "reviews judgments, not opinions." *Chevron U. S. A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U. S. 837, 842 (1984). See, e. g., *Black v. Cutter Laboratories*, 351 U. S. 292, 297 (1956); *J. E. Riley Investment Co. v. Commissioner*, 311 U. S. 55, 59 (1940); *Williams v. Norris*, 12 Wheat. 117, 120 (1827); *McClung v. Silliman*, 6 Wheat. 598, 603 (1821).

<sup>12</sup> See *Baltimore Gas & Electric Co. v. Natural Resources Defense Council, Inc.*, 462 U. S. 87, 105-106 (1983); *Bowman Transportation, Inc. v. Arkansas-Best Freight System, Inc.*, 419 U. S. 281, 285-286 (1974); *FTC v. Sperry & Hutchinson Co.*, 405 U. S. 233, 249 (1972); *FPC v. United Gas Pipe Line Co.*, 393 U. S. 71, 72-73 (1968) (*per curiam*); *Siegel Co. v. FTC*, 327 U. S. 608, 613 (1946).

regularity afforded an agency in fulfilling its statutory mandate," is not equivalent to "the minimum rationality a statute must bear in order to withstand analysis under the Due Process Clause." *Motor Vehicle Mfrs. Assn. v. State Farm Mut. Automobile Ins. Co.*, 463 U. S., at 43, n. 9. Thus, the mere fact that there is "some rational basis within the knowledge and experience of the [regulators]," *United States v. Carolene Products Co.*, 304 U. S. 144, 152 (1938) (footnote omitted), under which they "might have concluded" that the regulation was necessary to discharge their statutorily authorized mission, *Williamson v. Lee Optical Co.*, 348 U. S. 483, 487 (1955), will not suffice to validate agency decision-making. See *Industrial Union Dept. v. American Petroleum Inst.*, 448 U. S. 607, 639-659 (1980) (opinion of STEVENS, J.); *Burlington Truck Lines, Inc. v. United States*, 371 U. S. 156, 169 (1962). Our recognition of Congress' need to vest administrative agencies with ample power to assist in the difficult task of governing a vast and complex industrial Nation carries with it the correlative responsibility of the agency to explain the rationale and factual basis for its decision, even though we show respect for the agency's judgment in both.

Before examining the Secretary's reasons for issuing the Final Rules, it is essential to understand the pre-existing state-law framework governing the provision of medical care to handicapped infants. In broad outline, state law vests decisional responsibility in the parents, in the first instance, subject to review in exceptional cases by the State acting as *parens patriae*.<sup>13</sup> Prior to the regulatory activity culminat-

<sup>13</sup> The basic pattern of decisionmaking is well summarized in the 1983 report of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research:

"The paucity of directly relevant cases makes characterization of the law in this area somewhat problematic, but certain points stand out. First, there is a presumption, strong but rebuttable, that parents are the appro-

ing in the Final Rules, the Federal Government was not a participant in the process of making treatment decisions for newborn infants. We presume that this general framework was familiar to Congress when it enacted § 504. See *Cannon v. University of Chicago*, 441 U. S. 677, 696–697 (1979). It therefore provides an appropriate background for evaluating the Secretary's action in this case.

The Secretary has identified two possible categories of violations of § 504 as justifications for federal oversight of handicapped infant care. First, he contends that a hospital's refusal to furnish a handicapped infant with medically beneficial treatment "solely by reason of his handicap" constitutes unlawful discrimination. Second, he maintains that a hospital's failure to report cases of suspected medical neglect to a

appropriate decisionmakers for their infants. Traditional law concerning the family, buttressed by the emerging constitutional right of privacy, protects a substantial range of discretion for parents. Second, as persons unable to protect themselves, infants fall under the *parens patriae* power of the state. In the exercise of this authority, the state not only punishes parents whose conduct has amounted to abuse or neglect of their children but may also supervise parental decisions before they become operative to ensure that the choices made are not so detrimental to a child's interests as to amount to neglect and abuse.

"... [A]s long as parents choose from professionally accepted treatment options the choice is rarely reviewed in court and even less frequently supervised. The courts have exercised their authority to appoint a guardian for a child when the parents are not capable of participating in the decisionmaking or when they have made decisions that evidence substantial lack of concern for the child's interests. Although societal involvement usually occurs under the auspices of governmental instrumentalities—such as child welfare agencies and courts—the American legal system ordinarily relies upon the private initiative of individuals, rather than continuing governmental supervision, to bring the matter to the attention of legal authorities." Report, at 212–214 (footnotes omitted).

This summary accords with the Secretary's understanding of the state-law framework, at least in other contexts. See 50 Fed. Reg. 14880 (1985) (final rule implementing Child Abuse Amendments of 1984) ("The decision to provide or withhold medically indicated treatment is, except in highly unusual circumstances, made by the parents or legal guardian").

state child protective services agency may also violate the statute. We separately consider these two possible bases for the Final Rules.<sup>14</sup>

"Rather than address these issues, the dissent would remand to the Court of Appeals. See *post*, at 656. In light of its willingness to address the broader hypothetical question whether § 504 ever authorizes regulation of medical treatment decisions—"even if the judgment below were limited to invalidation of these regulations," *post*, at 650, n. 4—it comes as something of a surprise to read the references to the Solicitor General's argument that "this claim in its current form is not properly in the case," *post*, at 657, n. 9. The procedural objections are plainly without substance. Respondents AMA et al. raised the lack of factual support in their brief in opposition to the petition for certiorari. See Brief in Opposition for Respondents American Medical Association et al. 20 ("First, the fundamental problem with the Secretary's position is that it is based on a situation that has not occurred—and will not occur—in real life. . . . Not surprisingly, the Secretary cites no case where [his hypothetical problem] has occurred"); *id.*, at 20–21; *id.*, at 26 ("B. The Secretary Has Shown No Problem With the Historic State Law Framework That Warrants Direct Federal Investigation and Regulation"); *id.*, at 26–29. The Solicitor General, although responding that such evidence exists, see Reply Memorandum for Petitioner 9, did not raise a procedural bar. As a result, the objection is waived. See *Oklahoma City v. Tuttle*, 471 U. S. 808, 815–816 (1985). Although further discussion of this objection is therefore unnecessary, the dissent is also wrong in suggesting that respondents' complaints did not raise "the lack of a factual basis involving situations in which parents have consented to treatment." *Post*, at 657, n. 9. In fact, the complaint of respondents AMA et al. alleged "COUNT II: Violation of the Administrative Procedure Act," App. 146, and incorporated by reference the allegation that "None of the mandatory provisions of the Final Regulation have a basis in fact or are designed to meet a documented problem," *id.*, at 140. Accord, *id.*, at 158 (complaint of respondents AHA et al.). The fact that our decision rests on grounds narrower than that relied on by the lower courts is surely not an infirmity. We can only add that the lack of factual support for these regulations was fully briefed in this Court, see especially Brief for Respondents American Medical Assn. et al. 39–41; Brief for Respondents American Hospital Assn. et al. 48–49, and the fact that the Solicitor General responds with so little, so late bespeaks the absence of evidentiary support for the regulations, not an inadequate opportunity to direct us to it.

The Solicitor General also contends, for the first time in his reply brief on the merits, see Reply Brief for Petitioner 16, n. 6, that the Final Rules are

## VI

In the immediate aftermath of the Bloomington Baby Doe incident, the Secretary apparently proceeded on the assumption that a hospital's statutory duty to provide treatment to handicapped infants was unaffected by the absence of parental consent. See *supra*, at 617-619. He has since abandoned that view. Thus, the preamble to the Final Rules correctly states that when "a non-treatment decision, no matter how discriminatory, is made by parents, rather than by the hospital, section 504 does not mandate that the hospital unilaterally overrule the parental decision and provide treatment notwithstanding the lack of consent." 49 Fed. Reg. 1631 (1984). A hospital's withholding of treatment when no parental consent has been given cannot violate § 504, for without the consent of the parents or a surrogate decisionmaker the infant is neither "otherwise qualified" for treatment nor has he been denied care "solely by reason of his handicap."<sup>15</sup> Indeed, it would almost certainly be a tort as a matter of state law to operate on an infant without parental consent. This analysis makes clear that the Government's heavy reliance on the analogy to race-based refusals which violate § 601

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"interpretative guidelines" which "merely explained the Secretary's construction of Section 504 in this setting," *ibid.* This assertion was rejected the only occasion on which it was tendered, see *American Academy of Pediatrics v. Heckler*, 561 F. Supp. 395, 401 (DC 1983), is belied by the Secretary's own decision to provide notice and request comment on the regulations, cf. 5 U. S. C. § 553(b), and is patently without merit. To its credit, the dissent does not ultimately rely on either of these arguments. See *post*, at 657, n. 9.

<sup>15</sup> Just as "[t]he failure of the hospital to itself provide the treatment" because of the unavailability of medical equipment or expertise would not be "on the basis of the handicap" but "on the fact that the hospital is incapable of providing the treatment," according to the Secretary's regulations, 49 Fed. Reg. 1637 (1984), it is equally clear that a refusal to provide care because of the absence of parental consent would not be "solely by reason of [the infant's] handicap."

of the Civil Rights Act is misplaced. If, pursuant to its normal practice, a hospital refused to operate on a black child whose parents had withheld their consent to treatment, the hospital's refusal would not be based on the race of the child even if it were assumed that the parents based *their decision* entirely on a mistaken assumption that the race of the child made the operation inappropriate.

Now that the Secretary has acknowledged that a hospital has no statutory treatment obligation in the absence of parental consent, it has become clear that the Final Rules are not needed to prevent hospitals from denying treatment to handicapped infants. The Solicitor General concedes that the administrative record contains no evidence that hospitals have ever refused treatment authorized either by the infant's parents or by a court order. Tr. of Oral Arg. 8. Even the Secretary never seriously maintained that posted notices, "hotlines," and emergency on-site investigations were necessary to process complaints against hospitals that might refuse treatment requested by parents. The parental interest in calling such a refusal to the attention of the appropriate authorities adequately vindicates the interest in enforcement of § 504 in such cases, just as that interest obviates the need for a special regulation to deal with refusals to provide treatment on the basis of race which may violate § 601 of the Civil Rights Act.

The Secretary's belated recognition of the effect of parental nonconsent is important, because the supposed need for federal monitoring of hospitals' treatment decisions rests *entirely* on instances in which parents have refused their consent. Thus, in the Bloomington, Indiana, case that precipitated the Secretary's enforcement efforts in this area,<sup>16</sup> as

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<sup>16</sup> The Secretary's summary of this case makes it clear that the hospital's failure to perform surgery was based on the parents' refusal of consent: "*Bloomington, Indiana*. Investigation into April 1982, death of infant with Down's syndrome and esophageal atresia from whom surgery was

well as in the *University Hospital* case that provided the basis for the summary affirmance in the case now before us,<sup>17</sup> the hospital's failure to perform the treatment at issue rested on the lack of parental consent. The Secretary's own summaries of these cases establish beyond doubt that the respective hospitals did not withhold medical care on the basis of handicap and therefore did not violate § 504; as a result, they provide no support for his claim that federal regulation is needed in order to forestall comparable cases in the future.

The Secretary's initial failure to recognize that withholding of consent by *parents* does not equate with discriminatory denial of treatment by *hospitals* likewise undermines the Secretary's findings in the preamble to his proposed rulemaking. In that statement, the Secretary cited four sources in support of the claim that "Section 504 [is] not being uniformly followed." 48 Fed. Reg. 30847 (1983). None of the cited examples, however, suggests that recipients of federal financial assistance, as opposed to parents, had withheld medical care on the basis of handicap.<sup>18</sup>

withheld on the instructions of the parents." *Id.*, at 1646 (emphasis added).

As recounted earlier, the hospital initiated judicial review to override the parents' decision, but its efforts proved unavailing. The Solicitor General now acknowledges that there was no basis for finding a violation of § 504 in this case. See Tr. of Oral Arg. 12.

<sup>17</sup>Notwithstanding that the Secretary's summary of this case demonstrates both that treatment was withheld because of refusal of parental consent and that state-court proceedings to override the parents' decision had been instituted before the Department intervened, the Department proceeded with its own investigation anyway:

"*Long Island, New York.* October 19, 1983, complaint, based on newspaper article, that infant with spina bifida not receiving surgery due to refusal of parents to consent; legal proceedings ha[d] been initiated in State court. Inquiry initiated October 19. On October 27, HHS asked Department of Justice to commence legal action to overcome refusal of hospital to permit review of pertinent records." 49 Fed. Reg. 1649 (1984) (emphasis added).

<sup>18</sup>The Secretary first cited a 1973 survey by Raymond Duff and A. G. M. Campbell calculating that 14% of deaths in the special nursery of the Yale-

Notwithstanding the ostensible recognition in the preamble of the effect of parental nonconsent on a hospital's obligation to provide care, in promulgating the Final Rules the Secretary persisted in relying on instances in which parents had refused consent to support his claim that, regardless of its "magnitude," there is sufficient evidence of "illegality" to justify "establishing basic mechanisms to allow for effective enforcement of a clearly applicable statute." 49 Fed. Reg. 1645 (1984). We have already discussed one source of this evidence—"the several specific cases cited in the preamble to the proposed rule." *Ibid.* Contrary to the Secretary's belief, these cases do not "support the proposition that handicapped infants may be subjected to unlawful discrimination." *Ibid.* In addition to the evidence relied on in prior notices, the Secretary included a summary of the 49 "Infant Doe

New Haven hospital "were related to withholding treatment." 48 Fed. Reg. 30847 (1983). The Secretary's solitary quotation from this study, accurately illustrating the locus of the treatment decisions reviewed by the authors, involved refusal of parental consent:

"An infant with Down's syndrome and intestinal atresia, like the much publicized one at Johns Hopkins Hospital, was not treated because his parents thought the surgery was wrong for their baby and themselves. He died several days after birth." *Ibid.* (emphasis added) (quoting Duff & Campbell, Moral and Ethical Dilemmas in the Special-Care Nursery, 289 New Eng. J. Med. 890, 891 (1973)).

The Secretary next referred to an incident at Johns Hopkins Hospital which, as the above quotation intimates, also concerned parental refusal of consent. Then followed brief mention of the "Bloomington Baby Doe" incident, in which the parents, as the Secretary now admits, refused consent to treatment despite the hospital's insistence that it be provided. The Secretary's fourth and final example involved "a 1979 death of an infant with Down's syndrome and an intestinal obstruction at the Kapiolani-Children's Medical Center in Honolulu, Hawaii," 48 Fed. Reg. 30847 (1983), which again appears to have resulted from "a lack of parental consent," *id.*, at 30848.

Generalizing from these examples, the Secretary reported the results of a survey of physician attitudes. He faulted "[t]heir acquiescence in non-treatment of Down's children" which he surmised was "apparently because of the handicap represented by Down's syndrome." *Ibid.* See n. 22, *infra*.

cases" that the Department had processed before December 1, 1983.<sup>19</sup> Curiously, however, by the Secretary's own admission *none* of the 49 cases had "resulted in a finding of discriminatory withholding of medical care." *Id.*, at 1649. In fact, in the entire list of 49 cases there is no finding that a hospital failed or refused to provide treatment to a handicapped infant for which parental consent had been given.<sup>20</sup>

Notwithstanding this concession, the Secretary "believes three of these cases demonstrate the utility of the procedural

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<sup>19</sup>The Secretary also reprinted selected quotations from various commenters reporting the existence of "discriminatory" decisions denying sustenance and care to handicapped infants. None of these comments disclosed whether those "discriminatory" decisions were made by parents or by hospitals.

<sup>20</sup>The Secretary's repeated inability to identify a single treatment decision in violation of § 504 lends an aura of unreality to JUSTICE WHITE's criticism of the Court of Appeals' decision in *University Hospital*. In explaining why he believes "the stated basis for the Court of Appeals' holding in *University Hospital* was incorrect," *post*, at 656; see *post*, at 655, n. 8, JUSTICE WHITE completely ignores the fact that the case involved a specific treatment decision made by parents. Since JUSTICE WHITE elsewhere agrees that parental decisions are not covered by § 504, *post*, at 657, n. 10, and that the infant involved in the *University Hospital* case was therefore not "otherwise qualified" for treatment, *post*, at 654, n. 7, he implicitly acknowledges that the *judgment* in *University Hospital* is correct; only by ignoring the actual facts of that case—as well as the actual facts of the 49 cases that were investigated by the Secretary—and speculating about nonexistent hypothetical cases in which a hospital might refuse to provide treatment requested by parents, does the dissent offer any basis for questioning the decision in *University Hospital*.

Indeed, even the dissent's criticism of the *reasoning* of the Court of Appeals' decision is based on a hypothetical situation that the Court of Appeals did not address. That court was concerned with the treatment of cases in which "the handicapping condition is related to the condition(s) to be treated," 729 F. 2d, at 157 (emphasis added); see *id.*, at 147, whereas JUSTICE WHITE has carefully limited his hypothetical discussion to cases in which "the treatment is completely unrelated to the baby's handicapping condition." *Post*, at 655 (emphasis added). Thus, like bishops of opposite colors, the opinions of JUSTICE WHITE and the Court of Appeals do not even touch one another.

mechanisms called for in the final rules." *Ibid.* Accord, *ibid.* ("[T]hese cases provide additional documentation of the need for governmental involvement and the appropriateness of the procedures established by the final rules"). However, these three cases, which supposedly provide the strongest support for federal intervention, fail to disclose any discrimination against handicapped newborns in violation of § 504. For example, in Robinson, Illinois, the Department conducted an on-site investigation when it learned that the "hospital (*at the parents' request*) failed to perform necessary surgery." *Id.*, at 1646 (emphasis added). After "[t]he parents refused consent for surgery," "the hospital referred the matter to state authorities, who accepted custody of the infant and arranged for surgery and adoption," all "in compliance with section 504." *Ibid.* The Secretary concluded that "the involvement of the state child protective services agency," at the behest of the hospital, "was the most important element in bringing about corrective surgery for the infant. . . . Had there been no *governmental* involvement in the case, the outcome might have been much less favorable." *Id.*, at 1649 (emphasis added).<sup>21</sup>

The Secretary's second example illustrates with even greater force the effective and nondiscriminatory functioning of state mechanisms and the consequent lack of support for federal intervention. In Daytona Beach, Florida, the Department's hotline received a complaint of medical neglect of a handicapped infant; immediate contact with the hospital and state agency revealed that "the parents did not consent to surgery" for the infant. *Id.*, at 1648. Notwithstanding this information, which was confirmed by both the hospital and the state agency, and despite the fact that the state agency had "obtained a court order to provide surgery" the day *before* HHS was notified, the Department conducted an

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<sup>21</sup>The preamble repeatedly makes the assumption that evidence showing the need for *governmental* involvement provides a basis for *federal* involvement. See, e. g., 49 Fed. Reg. 1649 (1984).

on-site investigation. *Ibid.* In the third case, in Colorado Springs, Colorado, the Department intervened so soon after birth that “the decisionmaking process was in progress at the time the OCR [Office of Civil Rights] inquiry began,” and “it is impossible to say the surgery would not have been provided without this involvement.” *Id.*, at 1649. “However,” the Secretary added, “the involvement of OCR and the OCR medical consultant was cooperatively received by the hospital and apparently constructive.” *Ibid.*

In sum, there is nothing in the administrative record to justify the Secretary’s belief that “discriminatory withholding of medical care” in violation of § 504 provides any support for federal regulation: In two of the cases (Robinson, Illinois, and Daytona Beach, Florida), the hospital’s refusal was based on the absence of parental consent, but the parents’ decision was overridden by state authorities and the operation was performed; in the third case (Colorado Springs, Colorado) it is not clear whether the parents would have given their consent or not, but the corrective surgery was in fact performed.<sup>22</sup>

<sup>22</sup>JUSTICE WHITE’s dissent suggests that regulation of health care providers can be justified on a theory the Secretary did not advance—a supposed need to curtail discriminatory advice by biased physicians. See *post*, at 658–661. After observing that at least some handicapped infants have not been treated, the dissent identifies physician attitudes as a likely explanation and concludes that mandated informational notices were presumably designed to “foste[r] an awareness by health care professionals of their responsibility not to act in a discriminatory manner with respect to medical treatment decisions for handicapped infants.” *Post*, at 660.

The dissent’s theory finds no support in the text of the regulation, the reasoning of the Secretary, or the briefs filed on his behalf in this Court. The regulations in general—and the informational notices in particular—do not purport to place any constraints on the advice that physicians may give their patients. Moreover, since it is now clear that parental decisionmaking is not covered by § 504, *supra*, at 630–631, the dissent’s theory rests on the unstated premise that the statute may prevent the giving of advice to do something which § 504 does not itself prohibit. It is hardly obvious that the Rehabilitation Act of 1973 prohibits physicians from “aiding and abet-

## VII

As a backstop to his manifestly incorrect perception that withholding of treatment in accordance with parental instructions necessitates federal regulation, the Secretary contends that a hospital’s failure to report parents’ refusals to consent to treatment violates § 504, and that past breaches of this kind justify federal oversight.

By itself, § 504 imposes no duty to report instances of medical neglect—that undertaking derives from state-law reporting obligations or a hospital’s own voluntary practice. Although a hospital’s selective refusal to report medical neglect of handicapped infants might violate § 504,<sup>23</sup> the Secretary

ting” a parental decision which parents admittedly have a right to make. And if Congress did intend this counterintuitive result, one might expect an explanation from the Secretary as to how the hotlines and emergency on-site inspections contemplated by the Final Rules square with the constitutional doctrines on regulation, direct or indirect, of speech in general and of decisionmaking by health professionals in particular.

In reality, the Secretary neither found nor implied that physicians’ predispositions against treating handicapped infants had resulted in parental refusals to consent to treatment. Indeed, he principally relied on attitudinal surveys for the converse proposition that regulation is necessary because parents refuse consent to treatment and physicians will “acquiesce in parental refus[als] to treat.” 48 Fed. Reg. 30848 (1983). To the extent *any* theory may be discerned in the Secretary’s two-column summary of physician surveys, it is that doctors would not *correct* “bad” parental decisions, not that they were responsible for helping them to make such choices in the first place. Moreover, even if the Secretary had relied on this evidence to insinuate that doctors imposed their own value judgments on parents by lobbying them to refuse consent, he never explains that the parental decisionmaking process is one in which doctors exercise the decisive influence needed to force such results. Compare *ibid.*, with *post*, at 658–659. The Secretary, in short, has not even adumbrated a theory of “discrimination” remotely resembling the one invented by the dissent, and therefore has not made the essential connection between the evidence of physician attitudes and the regulatory choice made here.

<sup>23</sup>Of course, § 504 would be violated only if the hospital failed to report medical neglect of a handicapped infant when it would report such neglect of a similarly situated nonhandicapped infant. Because respondents have

has failed to point to any specific evidence that this has occurred. The 49 actual investigations summarized in the preamble to the Final Rules do not reveal *any* case in which a hospital either failed, or was accused of failing, to make an appropriate report to a state agency.<sup>24</sup> Nor can we accept the Solicitor General's invitation to infer discriminatory nonreporting from the studies cited in the Secretary's proposed rulemaking. Even assuming that cases in which parents have withheld consent to treatment for handicapped infants have gone unreported, that fact alone would not prove

challenged the Secretary's regulations on their face, we have no occasion to address the question whether infants with birth defects are similarly situated with infants in need of blood transfusions (the paradigm case in which hospitals have reported or have sought to override parental decisions, according to the Solicitor General, Brief for Petitioner 28, and n. 16), or whether a hospital could legitimately distinguish between the two situations on the basis of the different risks and benefits inhering in certain operations to correct birth defects, on the one hand, and blood transfusions, on the other hand.

<sup>24</sup>To the contrary, the Secretary's case summaries reveal numerous instances in which hospitals have voluntarily reported instances of suspected medical neglect and have even initiated legal proceedings themselves. In the Bloomington, Indiana, case which prompted these regulations, and in the *University Hospital* case which supported the summary affirmance now before us, the parents' decision was the subject of judicial review in the state courts. In the Robinson, Illinois, case on which the Secretary relies as one of three examples illustrating the need for federal regulation, the hospital reported the parents' refusal to consent to state authorities who arranged for surgery and adoption. 49 Fed. Reg. 1646 (1984). Most dramatically, in the Daytona Beach, Florida, case HHS received its hotline complaint the day *after* the state agency had already obtained a court order overriding the parents' refusal to consent to surgery. *Id.*, at 1648. Notwithstanding the Department's "immediate contact" with the hospital *and the state agency*—which surely must have made it clear that the case had already been reported to that agency and that there was no colorable basis for suspecting a violation of § 504—the Department conducted an on-site investigation. *Ibid.* In the third case on which the Secretary placed special emphasis, the Department intervened before the parents had decided whether to authorize treatment or not, so that no reporting obligation could have been triggered. *Ibid.*

that the hospitals involved had discriminated on the basis of handicap rather than simply failed entirely to discharge their state-law reporting obligations, if any, a matter which lies wholly outside the nondiscrimination mandate of § 504.

The particular reporting mechanism chosen by the Secretary—indeed the entire regulatory framework imposed on state child protective services agencies—departs from the nondiscrimination mandate of § 504 in a more fundamental way. The mandatory provisions of the Final Rules omit any direct requirement that hospitals make reports when parents refuse consent to recommended procedures.<sup>25</sup> Instead, the Final Rules command *state agencies* to require such reports, regardless of the state agencies' own reporting requirements (or lack thereof). 45 CFR § 84.55(c)(1)(i) (1985). Far from merely preventing state agencies from remaining calculatedly indifferent to handicapped infants while they tend to the needs of the similarly situated nonhandicapped, the Final Rules command state agencies to utilize their "full authority" to "prevent instances of unlawful medical neglect of handicapped infants." § 84.55(c)(1). The Rules effectively make medical neglect of handicapped newborns a state investigative priority, possibly forcing state agencies to shift scarce resources away from other enforcement activities—perhaps even from programs designed to protect handicapped children outside hospitals. The Rules also order state agencies to "immediate[ly]" review reports from hospitals, § 84.55(c)(1)(iii), to conduct "on-site investigation[s]," *ibid.*, and to take legal action "to compel the provision of necessary nourishment and medical treatment,"

<sup>25</sup>The interpretative guidelines appended to the Final Rules do impose on hospitals and other health care providers the duty not to discriminate against handicapped infants in reporting instances of parental neglect. We do not address the question whether reporting, either as a hospital practice or as a requirement of state law, constitutes a "program or activity receiving Federal financial assistance" under § 504. See *Consolidated Rail Corp. v. Darrone*, 465 U. S., at 635–636. Cf. *Grove City College v. Bell*, 465 U. S. 555, 570–574 (1984).



§ 84.55(c)(1)(iv)—all without any regard to the procedures followed by state agencies in handling complaints filed on behalf of nonhandicapped infants. These operating procedures were imposed over the objection of several state child protective services agencies that the requirement that they turn over reports to HHS “conflicts with the confidentiality requirements of state child abuse and neglect statutes,” 49 Fed. Reg. 1627 (1984)—thereby requiring under the guise of nondiscrimination a service which state law denies to the nonhandicapped.<sup>26</sup>

The complaint-handling process the Secretary would impose on unwilling state agencies is totally foreign to the authority to prevent discrimination conferred on him by § 504. “Section 504 seeks to assure evenhanded treatment,” *Alexander v. Choate*, 469 U. S., at 304; “neither the language, purpose, nor history of § 504 reveals an intent to impose an affirmative-action obligation” on recipients of federal financial assistance, *Southeastern Community College v. Davis*, 442 U. S. 397, 411 (1979).<sup>27</sup> The Solicitor General also recognizes that § 504 is concerned with discrimination and with discrimination alone. In his attempt to distinguish the Secretary’s 1976 determination that it “is beyond the authority of section 504” to promulgate regulations “concerning ade-

<sup>26</sup> JUSTICE WHITE’s dissent, quoting the Secretary’s explanation for these requirements, concludes that they form, in “substance,” a nondiscrimination requirement. *Post*, at 663. This assertion is repetitive, not responsive. The rules governing state child protective services agencies operate independently of any provisions of state law; they go further than them in several respects; they flatly contradict them in others (*e. g.*, confidentiality); and they do not accommodate the revision, modification, or repeal of state laws. To say that the Secretary can give detailed marching orders to state agencies upon discovering that both the agencies and HHS are working toward the same general objective—at least when defined with sufficient abstractness—would countenance a novel and serious intrusion on state autonomy.

<sup>27</sup> See *Southeastern Community College v. Davis*, 442 U. S., at 410 (language and structure of 1973 Rehabilitation Act recognizes “the distinction between . . . evenhanded treatment . . . and affirmative efforts”).

quate and appropriate psychiatric care or safe and humane living conditions for persons institutionalized because of handicap or concerning payment of fair compensation to patients who perform work,” 41 Fed. Reg. 29548, 29559, the Solicitor General explains:

“This conclusion of course was consistent with the fact that, as relevant here, Section 504 is essentially concerned only with discrimination in the *relative* treatment of handicapped and nonhandicapped persons and does not confer any *absolute* right to receive particular services or benefits under federally assisted programs.” Brief for Petitioner 40, n. 33.

See also 48 Fed. Reg. 30846 (1983) (“Section 504 is in essence an equal treatment, non-discrimination standard”).<sup>28</sup>

The Final Rules, however, impose just the sort of absolute obligation on state agencies that the Secretary had previously disavowed. The services state agencies are required to make available to handicapped infants are in no way tied to the level of services provided to similarly situated nonhandicapped infants. Instead, they constitute an “*absolute* right to receive particular services or benefits” under a federally assisted program. Even if a state agency were scrupulously impartial as between the protection it offered handicapped and nonhandicapped infants, it could still be denied federal funding for failing to carry out the Secretary’s mission with sufficient zeal.

It is no answer to state, as does the Secretary, that these regulations are a necessary “‘metho[d] . . . to give reasonable assurance’ of compliance.” 49 Fed. Reg. 1627 (1984) (quoting 45 CFR § 80.4(b), which requires state agencies to

<sup>28</sup> The Secretary notes that “by enacting section 504 Congress intended to eliminate all of the ‘many forms of potential discrimination’ against handicapped people through ‘the establishment of a broad governmental policy.’ S. Rep. No. 1297, 93d Cong., 2d Sess. 38 (1974).” 49 Fed. Reg. 1636 (1984). But no matter how broad the prohibition contained in § 504 may be, what it prohibits is discrimination.

report on their compliance with Title VI). For while the Secretary can require state agencies to document their *own* compliance with § 504, nothing in that provision authorizes him to commandeer state agencies to enforce compliance by *other* recipients of federal funds (in this instance, hospitals). State child protective services agencies are not field offices of the HHS bureaucracy, and they may not be conscripted against their will as the foot soldiers in a federal crusade.<sup>29</sup> As we stated in *Alexander v. Choate*, 469 U. S., at 307, “nothing in the pre- or post-1973 legislative discussion of § 504 suggests that Congress desired to make major inroads on the States’ longstanding discretion to choose the proper mix” of services provided by state agencies.

### VIII

Section 504 authorizes any head of an Executive Branch agency—regardless of his agency’s mission or expertise—to promulgate regulations prohibiting discrimination against the handicapped. See S. Rep. No. 93-1297, pp. 39-40 (1974).<sup>30</sup> As a result of this rulemaking authority, the Secretary of

<sup>29</sup> Important principles of federalism are implicated by any “federal program that compels state agencies . . . to function as bureaucratic puppets of the Federal Government.” *FERC v. Mississippi*, 456 U. S. 742, 783 (1982) (opinion of O’CONNOR, J.).

<sup>30</sup> Twenty-seven agencies, including the National Endowment for the Arts, the Nuclear Regulatory Commission, and the Tennessee Valley Authority, have promulgated regulations forbidding discrimination on the basis of handicap in programs or activities receiving federal financial assistance. The Department of Housing and Urban Development has issued a proposed rulemaking. See Jones & Wolfe, *Regulations Promulgated Pursuant to Section 504 of the Rehabilitation Act of 1973: A Brief History and Present Status* 8-9 (Congressional Research Service, Feb. 28, 1986). There is thus not the same basis for deference predicated on expertise as we found with respect to the Environmental Protection Agency’s interpretation of the 1977 Clean Air Act Amendments in *Chevron U. S. A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U. S., at 842-845, and with respect to the Federal Reserve Board’s construction of the Bank Holding Act in *Board of Governors, FRS v. Investment Company Inst.*, 450 U. S. 46, 56, and n. 21 (1981).

HHS has “substantial leeway to explore areas in which discrimination against the handicapped pos[es] particularly significant problems and to devise regulations to prohibit such discrimination.” *Alexander v. Choate*, 469 U. S., at 304, n. 24.

Even according the greatest respect to the Secretary’s action, however, deference cannot fill the lack of an evidentiary foundation on which the Final Rules must rest. The Secretary’s basis for federal intervention is perceived discrimination against handicapped infants in violation of § 504, and yet the Secretary has pointed to no evidence that such discrimination occurs. Neither the fact that regulators generally may rely on generic information in a particular field or comparable experience gained in other fields, nor the fact that regulations may be imposed for preventative or prophylactic reasons, can substitute for evidence supporting the Secretary’s own chosen rationale. For the principle of agency accountability recited earlier means that “an agency’s action must be upheld, if at all, on the basis articulated by the agency itself.” *Motor Vehicle Mfrs. Assn. v. State Farm Mut. Automobile Ins. Co.*, 463 U. S., at 50 (citations omitted).<sup>31</sup>

The need for a proper evidentiary basis for agency action is especially acute in this case because Congress has failed to indicate, either in the statute or in the legislative history, that it envisioned federal superintendence of treatment decisions traditionally entrusted to state governance. “[W]e must assume that the implications and limitations of our federal system constitute a major premise of all congressional legislation, though not repeatedly recited therein.” *United States v. Gambling Devices*, 346 U. S. 441, 450 (1953) (opin-

<sup>31</sup> Accord, *American Textile Mfrs. Institute, Inc. v. Donovan*, 452 U. S. 490, 539 (1981); *Burlington Truck Lines, Inc. v. United States*, 371 U. S. 156, 168 (1962); *SEC v. Chenery Corp.*, 332 U. S. 194, 196 (1947); *SEC v. Chenery Corp.*, 318 U. S. 80, 87 (1943).

ion of Jackson, J.).<sup>32</sup> Congress therefore “will not be deemed to have significantly changed the federal-state balance,” *United States v. Bass*, 404 U. S. 336, 349 (1971)—or to have authorized its delegates to do so—“unless otherwise the purpose of the Act would be defeated,” *FTC v. Bunte Bros., Inc.*, 312 U. S. 349, 351 (1941).<sup>33</sup> Although the nondiscrimi-

<sup>32</sup> See Frankfurter, *Some Reflections on the Reading of Statutes*, 47 *Colum. L. Rev.* 527, 540 (1947) (“The underlying assumptions of our dual form of government, and the consequent presuppositions of legislative draftsmanship which are expressive of our history and habits, cut across what might otherwise be the implied range of legislation”).

<sup>33</sup> Cf. *Heublein, Inc. v. South Carolina Tax Comm’n*, 409 U. S. 275, 281–282 (1972) (“[U]nless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the Federal-State balance.” (quoting *United States v. Bass*, 404 U. S., at 349); *Davies Warehouse Co. v. Bowles*, 321 U. S. 144, 152 (1944) (“Where Congress has not clearly indicated a purpose to precipitate conflict [between federal agencies and state authority] we should be reluctant to do so by decision” (footnote omitted)); *Penn Dairies, Inc. v. Milk Control Comm’n*, 318 U. S. 261, 275 (1943) (“An unexpressed purpose of Congress to set aside statutes of the states regulating their internal affairs is not lightly to be inferred and ought not to be implied where the legislative command, read in the light of its history, remains ambiguous”); *FTC v. Bunte Bros., Inc.*, 312 U. S., at 354–355 (“The construction of § 5 [of the Federal Trade Commission Act] urged by the Commission would thus give a federal agency pervasive control over myriads of local businesses in matters heretofore traditionally left to local custom or local law. . . . An inroad upon local conditions and local standards of such far-reaching import as is involved here, ought to await a clearer mandate from Congress”); *Apex Hosiery Co. v. Leader*, 310 U. S. 469, 513 (1940) (“The maintenance in our federal system of a proper distribution between state and national governments of police authority and of remedies private and public for public wrongs is of far-reaching importance. An intention to disturb the balance is not lightly to be imputed to Congress”); *United States v. Altobella*, 442 F. 2d 310, 313–316 (CA7 1971); 3 C. Sands, *Sutherland on Statutory Construction* § 62.01, p. 64 (4th ed. 1974) (“[T]he rule of strict construction [of statutes in derogation of sovereignty] serves a quasi-constitutional purpose in our federal system of split sovereignty by helping to secure both levels of sovereign power against encroachment by each other” (footnote omitted)).

The legislative history of the Rehabilitation Act does not support the notion that Congress intended intervention by federal officials into treatment

nation mandate of § 504 is cast in language sufficiently broad to suggest that the question is “not one of authority, but of its appropriate exercise[,] [t]he propriety of the exertion of the authority must be tested by its relation to the purpose of the [statutory] grant and with suitable regard to the principle that whenever the federal power is exerted within what would otherwise be the domain of state power, the justification of the exercise of the federal power must clearly appear.” *Florida v. United States*, 282 U. S. 194, 211–212 (1931). Accord, *Chicago, M., St. P. & P. R. Co. v. Illinois*, 355 U. S. 300, 306 (1958). That is, “it must appear that there are findings, supported by evidence, of the essential facts . . . which would justify [the Secretary’s] conclusion.” *Florida v. United States*, 282 U. S., at 212. The administrative record does not contain the reasoning and evidence that is necessary to sustain federal intervention into a historically state-administered decisional process that appears—for lack of any evidence to the contrary—to be functioning in full compliance with § 504.

The history of these regulations exposes the inappropriateness of the extraordinary deference—virtually a *carte blanche*—requested by the Government. The Secretary’s

decisions traditionally left by state law to concerned parents and the attending physicians or, in exceptional cases, to state agencies charged with protecting the welfare of the infant. As the Court of Appeals noted, there is nothing in the legislative history that even remotely suggests that Congress contemplated the possibility that “section 504 could or would be applied to treatment decisions, involving defective newborn infants.” 729 F. 2d 144, 159 (1984).

“As far as can be determined, no congressional committee or member of the House or Senate ever even suggested that section 504 would be used to monitor medical treatment of defective newborn infants or establish standards for preserving a particular quality of life. No medical group appeared alert to the intrusion into medical practice which some doctors apprehend from such an undertaking, nor were representatives of parents or spokesmen for religious beliefs that would be affected heard.” *Id.*, at 158 (quoting *American Academy of Pediatrics v. Heckler*, 561 F. Supp., at 401).

present reading of § 504 has evolved only after previous, patently erroneous interpretations had been found wanting.<sup>44</sup> The checkered history of these regulations began in 1982, when the Department notified hospitals that they would violate § 504 if they “allow[ed] an infant” to remain in their care after “the infant’s parents or guardian [had withheld consent to] treatment or nourishment discriminatorily.” 47 Fed. Reg. 26027. By the time the Proposed Rules were announced one year later, the Secretary had abandoned that construction. But the Department substituted the equally untenable view that “the basic provision of nourishment, fluids, and routine nursing care” was “not an option for medical judgment” and that “[t]he decision to forego medical treatment of a correctable life-threatening defect because an infant also suffers from a permanent irremediable handicap that is not life-threatening, such as mental retardation, is a violation of Section 504,” insinuating by omission that lack of parental consent did not alter the hospital’s obligation to provide corrective surgery. 48 Fed. Reg. 30852, 30847 (1983). Although the preamble to the Final Rules corrects the prior erroneous signals from the Department that § 504 authorizes it to override parental decisions and to save the lives of handicapped infants, it persists in advocating federal regulation on the basis of treatment denials precipitated by refusals of parental consent and on the ground that its experience with the Baby Doe hotline has demonstrated that “the assumption that handicapped infants will receive medically beneficial treatment is not always justified.” 49 Fed. Reg. 1646 (1984).

This response, together with its previous remarks, makes irresistible the inference that the Department regards its

<sup>44</sup>The fact that the agency’s interpretation “has been neither consistent nor longstanding . . . substantially diminishes the deference to be given to HEW’s [now HHS’s] present interpretation of the statute.” *Southeastern Community College v. Davis*, 442 U. S., at 412, n. 11 (citing *General Electric Co. v. Gilbert*, 429 U. S. 125, 143 (1976)).

mission as one principally concerned with the quality of medical care for handicapped infants rather than with the implementation of § 504. We could not quarrel with a decision by the Department to concentrate its finite compliance resources on instances of life-threatening discrimination rather than instances in which merely elective care has been withheld. Cf. *Heckler v. Chaney*, 470 U. S. 821 (1985). But nothing in the statute authorizes the Secretary to dispense with the law’s focus on discrimination and instead to employ federal resources to save the lives of handicapped newborns, without regard to whether they are victims of discrimination by recipients of federal funds or not. Section 504 does not authorize the Secretary to give unsolicited advice either to parents, to hospitals, or to state officials who are faced with difficult treatment decisions concerning handicapped children. We may assume that the “qualified professionals” employed by the Secretary may make valuable contributions in particular cases, but neither that assumption nor the sincere conviction that an immediate “on-site investigation” is “necessary to protect the life or health of a handicapped individual” can enlarge the statutory powers of the Secretary.

The administrative record demonstrates that the Secretary has asserted the authority to conduct on-site investigations, to inspect hospital records, and to participate in the decisional process in emergency cases in which there was no colorable basis for believing that a violation of § 504 had occurred or was about to occur. The District Court and the Court of Appeals correctly held that these investigative actions were not authorized by the statute and that the regulations which purport to authorize a continuation of them are invalid.

The judgment of the Court of Appeals is affirmed.

*It is so ordered.*

CHIEF JUSTICE BURGER concurs in the judgment.

JUSTICE REHNQUIST took no part in the consideration or decision of this case.

JUSTICE WHITE, with whom JUSTICE BRENNAN joins and with whom JUSTICE O'CONNOR joins as to Parts I, II, IV, and V, dissenting.

Section 504 of the Rehabilitation Act of 1973 forbids discrimination solely on the basis of handicap in programs or activities receiving federal financial assistance. The issue before us is whether the Secretary of Health and Human Services has any authority under the Act to regulate medical treatment decisions concerning handicapped newborn infants. Relying on its prior decision in *United States v. University Hospital*, 729 F. 2d 144 (CA2 1984), the Court of Appeals held that the Secretary was without power in this respect and affirmed a decision of the District Court that § 504 does not extend so far and that the Secretary may not regulate such decisions in any manner.

Although it is my view that we granted certiorari to address this issue, the plurality avoids it by first erroneously reading the decision below as enjoining only the enforcement of specific regulations and by then affirming on the basis that the promulgation of the regulations did not satisfy established principles of administrative law, a matter that the Court of Appeals had no occasion to, and did not, discuss. With all due respect, I dissent.

### I

The plurality's initial and fundamental error is its statement that the only question presented here is the specific question whether the four mandatory provisions of the Final Rules issued by the Secretary are authorized by § 504. This conclusion misconstrues the opinion and judgment of the Court of Appeals. The plurality concedes that the District Court's judgment on its face did not stop with enjoining the

enforcement of the final regulations. *Ante*, at 625–626, n. 11. In fact, the District Court permanently enjoined the Secretary from implementing the final regulations and also from “continuing or undertaking any other actions to investigate or regulate treatment decisions involving impaired newborn infants taken under authority of Section 504, including pending investigation and other enforcement actions.” App. to Pet. for Cert. 51a–52a. This broad injunction ousted the Secretary from the field entirely and granted the precise relief sought by the complaint, which was filed after *University Hospital* and which sought to take full advantage of that decision.<sup>1</sup> The Court of Appeals affirmed and in no way modified the injunction that the District Court had entered. In doing so, the Court of Appeals relied on its previous determination in *University Hospital* that the Secretary had no statutory authority to regulate medical treatment decisions regarding newborn infants. See App. to Pet. for Cert. 2a–3a.<sup>2</sup>

<sup>1</sup> I disagree with the plurality's conclusion that “[t]he complaints in this case did not challenge the Department's authority to regulate all treatment decisions, but more precisely the mandatory provisions of the Final Rules and enforcement activity along those lines but undertaken pursuant to the Department's ‘general authority’ to enforce § 504.” *Ante*, at 625, n. 11. Although focusing most extensively on the regulations and pending HHS investigations, the complaint specifically cited the *University Hospital* holding that “Section 504 [does] not apply to ‘treatment decisions involving defective newborn infants.’” App. 138. The complaint also specifically requested that the District Court “issue a preliminary and permanent injunction prohibiting the defendant from enforcing her final rule embodied in 45 CFR § 84.55, 49 Fed. Reg. 1622, *et seq.* (Jan. 12, 1984), and prohibiting defendant from otherwise acting pursuant to the claimed authority of Section 504 of the Rehabilitation Act of 1973 in regard to the medical treatment of infants with birth defects.” *Id.*, at 159. The complaint thus requested both invalidation of the regulations and an injunction against all other actions by the Secretary in this area.

<sup>2</sup> The Court of Appeals' brief order affirming the District Court's judgment, although characterizing that judgment generally as having struck down the regulations, cited *University Hospital* and made no changes in the broad relief awarded by the District Court. The Court of Appeals

It is true that the regulations themselves were invalidated and their enforcement enjoined. This result, however, was directly compelled by the *University Hospital* conclusion that the Secretary was without power to issue any regulations whatsoever that dealt with infants' medical care, and it did not comprise the whole relief awarded by the District Court and affirmed by the Court of Appeals. I thus see no justification for the plurality's distortion of the Court of Appeals' affirmance of the District Court's all-inclusive injunction, which, like *University Hospital*, now represents the law in the Second Circuit.<sup>3</sup> We should resolve the threshold statutory question that this case and *University Hospital* clearly pose—namely, whether the Secretary has any authority at all under the Act to regulate medical care decisions with respect to the handicapped newborn.<sup>4</sup>

## II

Section 504 of the Act, which was construed in *University Hospital*, provides:

“No otherwise qualified handicapped individual in the United States, as defined in section 706(7) of this title,

gave absolutely no indication that it was construing the District Court's judgment one whit less broadly than that judgment's language indicated. Nowhere, therefore, is there a justification for the plurality's reconstructive reading of the Court of Appeals' judgment.

<sup>3</sup>I note in this regard that the parties as well do not appear to have contemplated the more limited reading of the judgment below adopted by the plurality. See Brief for Petitioner 9; Brief for Respondents American Hospital Association et al. 4; Brief for Respondents American Medical Association et al. 14.

<sup>4</sup>I would not avoid the issue of the validity of *University Hospital* even if the judgment below were limited to invalidation of these regulations. Given that the judgment below, whether it extends as far as *University Hospital* or not, was based on the *University Hospital* view that all regulation of medical treatment decisions is outside the Secretary's § 504 authority because of the nature of those decisions, I believe that the better approach here would be for the Court to determine the correctness of *University Hospital* in any case.

shall, solely by reason of his handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.” 29 U. S. C. § 794.

After determining that § 706(7), which defines handicapped persons, is not limited to adults and includes the newborn, the Court of Appeals in *University Hospital* construed the “otherwise qualified” language of § 504 to limit the reach of the section to situations in which the handicap is “unrelated to, and thus improper to consideration of, the services in question.” 729 F. 2d, at 156.<sup>5</sup> This, concluded the Court of Appeals, would exclude most handicapped newborns because their handicaps are not normally irrelevant to the need for medical services. Furthermore, the Court of Appeals thought that the “otherwise qualified” limitation should not be applied in the “comparatively fluid context of medical treatment decisions” because “[w]here the handicapping condition is related to the condition(s) to be treated, it will

<sup>5</sup>The Court of Appeals first addressed and reserved the question whether the hospital or its functions comprised a program or activity receiving federal financial assistance. Noting that this was a fact-specific inquiry, cf. *Grove City College v. Bell*, 465 U. S. 555 (1984), the Court of Appeals assumed that the entire hospital was covered by § 504 and proceeded to consider “whether, assuming the entire hospital is covered by section 504, the statute authorizes the type of investigation initiated here.” 729 F. 2d, at 151.

I also do not consider whether or under what circumstances hospitals or hospital neonatal programs may constitute programs or activities receiving federal financial assistance. The judgment of the District Court which was affirmed by the Court of Appeals does not set forth guidelines for interpreting this language in this context: It merely enjoins actions directed at such programs or activities. The regulations as well simply adopt the statutory language without interpreting it. Thus, I assume here that the § 504 strictures would be applied only to appropriate programs or activities, and I therefore would leave discussion of this fact-specific issue for further proceedings. I would not now hold that § 504 may never apply on this basis.

rarely, if ever, be possible to say with certainty that a particular decision was 'discriminatory.'" *Id.*, at 156-157.

Having identified these perceived incongruities between the language of § 504 and the potential regulation of medical decisions regarding handicapped newborns, the Court of Appeals concluded that "[b]efore ruling that congress intended to spawn this type of litigation under section 504, we would want more proof than is apparent from the face of the statute." *Id.*, at 157. Thus, the Court of Appeals turned to the legislative history, where it again found nothing to persuade it that Congress intended § 504 to apply to medical treatment of handicapped infants and hence to enter a field so traditionally occupied by the States. Neither did it consider the current administrative interpretation of § 504 to be a longstanding agency construction calling for judicial deference. In the Court of Appeals' view, therefore, the section was inapplicable to medical treatment decisions regarding the newborn absent some further indication of congressional intent.

I disagree with this conclusion, which the Court of Appeals adhered to in the case before us now. Looking first at the language of the statute, I agree with the Court of Appeals' preliminary conclusion that handicapped newborns are handicapped individuals covered by the Act. There is no reason for importing an age limitation into the statutory definition, and this Court has previously stated that "§ 504 protects handicapped persons of all ages from discrimination in a variety of programs and activities receiving federal financial assistance." *Smith v. Robinson*, 468 U. S. 992, 1016-1017 (1984).<sup>6</sup> This leaves the critical question whether a handi-

<sup>6</sup> Although infants with birth defects are clearly handicapped individuals covered by § 504, there is one manner in which they may differ from most other handicapped individuals for § 504 purposes. Specifically, they may have a combination of conditions—some of which are medically correctable and some of which are not. In older handicapped individuals, medically correctable conditions may have been corrected so that only irreparable handicapping conditions remain. In a newborn infant, however, both correctable and incorrectable conditions may exist. Thus, since both of these

capped infant can ever be "otherwise qualified" for medical treatment and hence possibly subjected to unlawful discrimination when he or she is denied such treatment.<sup>7</sup>

may interfere with major life activities, both types of conditions may be considered to be handicaps. In this context, however, it might make more sense to consider as handicaps only those conditions that cannot be medically treated to the point that they will not impair major life activities. For such correctable conditions would not be likely to cause the infant to be regarded as handicapped. In any case, I believe that defining an infant's handicap may well be a delicate problem and one that deserves some consideration.

<sup>7</sup> It would appear that for an infant to be qualified for treatment his or her parents must have consented to such treatment. For the purposes of this discussion of whether the Court of Appeals was correct that medical treatment decisions may *never* be regulated by § 504, I assume that parental consent has been given and that the arguably discriminatory treatment decision is being made by the hospital or doctor. The Court of Appeals in *University Hospital* concentrated on the nature of these decisions in concluding that § 504 may not properly be applied, and I concentrate on that as well. That a situation in which treatment is refused where parental consent has been given may not have been shown to have arisen does not undermine this assumption here. The critical question is whether the operative provisions of § 504 may *ever* apply here given the nature of the decision.

For the purposes of addressing the Court of Appeals' *University Hospital* analysis, the most straightforward fact situation to consider is one in which the benefit provided is the medical treatment itself and in which a hospital refuses treatment in the face of parental consent. In this context, the Court of Appeals' conclusion that the nature of the decisions themselves precludes application of § 504 may be addressed with maximum simplicity. I note, however, that it may well be that the benefits provided by hospitals and doctors and covered by § 504 extend beyond treatment itself. For example, one benefit provided by hospitals and doctors to patients who cannot make their own medical treatment decisions may be medical advice in those patients' best interest to those who must ultimately make the relevant medical treatment decisions. To the extent that the provision of this benefit is a program or activity covered by the statute, I would think that the statute requires that the same advice be given to parents of a handicapped baby as to the parents of a similarly situated nonhandicapped baby. Another benefit provided may be the reporting of nontreatment to the relevant state agency in the case of a parental decision not to treat. Again,

It may well be that our prior consideration of this language has implied that the Court of Appeals' construction is correct. In *Southeastern Community College v. Davis*, 442 U. S. 397, 406 (1979), we held that "[a]n otherwise qualified person is one who is able to meet all of a program's requirements in spite of his handicap." This formulation may be read as implying that where a handicapped person meets all of the requirements normally necessary to receive a program's benefits regardless of his or her handicap, he or she is otherwise qualified because that handicap does not interfere with and is thus irrelevant to his or her qualification for the program. Thus, the Court of Appeals' view—that refusing treatment that is called for only because of the handicapping condition cannot constitute discrimination on the basis of handicap since there will be no similarly situated nonhandicapped newborn, *i. e.*, one who needs the same treatment—draws support from our holding in *Davis* since it turns on the same underlying perception that discrimination occurs only when the handicapping condition is irrelevant to the qualification for the program.

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to the extent that the provision of this benefit is a program or activity covered by the statute, see n. 13, *infra*, I would think that § 504 requires that the hospital or doctor report nontreatment of a handicapped baby when it would report the denial of the same treatment for a nonhandicapped baby.

My conclusions in this regard are buttressed by my view of § 504's coverage in the case of a medical treatment decision regarding a black baby. If a hospital or doctor advised different or less efficacious treatment for a black baby than for a white baby, I believe that this would be discrimination under the statute. Similarly, a failure to report a parental decision not to treat because of race would seem to me to be illegally discriminatory—assuming that this decision otherwise came within the statute.

In sum, although these additional situations present the same issue as to when a handicapped baby is otherwise qualified and when such a baby is subjected to discrimination as does the direct example of a refusal to treat and although it may well be that it would be in these contexts that the statute would most likely be given effect, for simplicity's sake I have centered my discussion of *University Hospital* on the refusal-to-treat example.

Even under the Court of Appeals' interpretation of "otherwise qualified," however, it does not follow that § 504 may never apply to medical treatment decisions for the newborn. An esophageal obstruction, for example, would not be part and parcel of the handicap of a baby suffering from Down's syndrome, and the infant would benefit from and is thus otherwise qualified for having the obstruction removed in spite of the handicap. In this case, the treatment is completely unrelated to the baby's handicapping condition. If an otherwise normal child would be given the identical treatment, so should the handicapped child if discrimination on the basis of the handicap is to be avoided.<sup>8</sup>

It would not be difficult to multiply examples like this. And even if it is true that in the great majority of cases the handicap itself will constitute the need for treatment, I doubt that this consideration or any other mentioned by the Court of Appeals justifies the wholesale conclusion that § 504 never applies to newborn infants with handicaps. That some or most failures to treat may not fall within § 504, that discerning which failures to treat are discriminatory may be difficult, and that applying § 504 in this area may intrude into the traditional functions of the State do not support the categori-

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<sup>8</sup>There are substantial arguments that could be made that the Court of Appeals too narrowly read the statute. It could be argued, for example, that the benefit provided by hospitals is not defined in terms of specific treatments. Rather, the benefit is "general medical care for whatever happens to need treating." If this is the benefit, then a much broader application of the statute in this context is reasonable. Alternatively, even if the benefit is defined more narrowly, "reasonable accommodation" might require more than mere impartial dispensing of identical treatment. See *Alexander v. Choate*, 469 U. S. 287, 299-300, and nn. 19, 20 (1985). I need not resolve this issue of the exact meaning of § 504 and *Davis* in this context, however, because my conclusion that *University Hospital's* broad reasoning was incorrect does not depend on it. Although I do not resolve these issues, I note that while the more expansive interpretations seem consistent with the interpretation adopted by the Secretary in the regulations, the more restrictive one does not. See 45 CFR pt. 84, Appendix C(a) (1985).



cal conclusion that the section may never be applied to medical decisions about handicapped infants. And surely the absence in the legislative history of any consideration of handicapped newborns does not itself narrow the reach of the statutory language. See *Jefferson County Pharmaceutical Assn. v. Abbott Laboratories*, 460 U. S. 150, 159-162, and n. 18 (1983). Furthermore, the broad remedial purpose of the section would be undermined by excluding handicapped infants from its coverage; and if, as the plurality indicates, *ante*, at 642-643, the Secretary has substantial leeway to explore areas in which discrimination against the handicapped poses serious problems and to devise regulations to prohibit the discrimination, it is appropriate to take note of the Secretary's present view that § 504 properly extends to the subject matter at issue here. Thus, I believe that the Court of Appeals in *University Hospital* incorrectly concluded that § 504 may never apply to medical treatment decisions concerning handicapped newborn infants. Where a decision regarding medical treatment for a handicapped newborn properly falls within the statutory provision, it should be subject to the constraints set forth in § 504. Consequently, I would reverse the judgment below.

### III

Having determined that the stated basis for the Court of Appeals' holding in *University Hospital* was incorrect and that the decision below cannot be supported by *University Hospital's* blanket prohibition, I would remand the case to the Court of Appeals. The respondents have, as the plurality's opinion itself demonstrates, raised significant issues aside from the threshold statutory issue presented here. There are, for example, substantial questions regarding the scope of the Secretary's statutory authority in this area and whether these particular regulations are consistent with the statute. I would decline to reach and decide these questions for the first time in this Court without the benefit of the

lower courts' deliberations.<sup>9</sup> The plurality, however, has chosen to reach out and address one of those subsidiary issues. Because the plurality has resolved that issue in a manner that I find indefensible on its own terms, I too address it.

The plurality concludes that the four mandatory provisions of the final regulations are invalid because there is no "rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Assn., Inc. v. State Farm Mutual Automobile Ins. Co.*, 463 U. S. 29, 43 (1983) (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U. S. 156, 168 (1962)). The basis for this conclusion is the plurality's perception that two and only two wholly discrete categories of decisions are the object of the final regulations: (1) decisions made by hospitals to treat or not treat where parental consent has been given and (2) decisions made by hospitals to refer or not to refer a case to the state child protective services agency where parental consent has been withheld.<sup>10</sup>

<sup>9</sup> In addition, although the Secretary did not brief the merits of the respondents' claim that the regulations are invalid because arbitrary and capricious, the Secretary did indicate his view that this claim in its current form is not properly in the case and that it is inadequate on its face. See Reply Brief for Petitioner 16, n. 6.

Specifically, the Secretary first asserts that the respondents' argument as to the lack of factual basis involving situations in which parents have consented to treatment was not raised in the complaint. See App. 146 (challenging lack of showing of instances where "erroneous" parental decisions were made and where medical authorities did not take proper measures under state law). Thus, the Secretary contends that the first major claim addressed and relied on by the plurality was never properly raised. Second, the Secretary contends that these are interpretative regulations that impose no new substantive duties, see 49 Fed. Reg. 1628 (1984), and that no factual basis for their issuance need therefore be given. Cf. 5 U. S. C. § 553(b).

These contentions, although not perhaps representing a procedural bar to our reaching this claim, see *ante*, at 629, n. 14, do provide an additional sign that the plurality's resolution of this case rests on shaky ground.

<sup>10</sup> At this point in the case, as the plurality observes, all parties concerned agree that parental decisions are not included in § 504's application. See *ante*, at 630.

Since the Secretary has not specifically pointed to discriminatory actions that provably resulted from either of these two specific types of decisions, the plurality finds that the Secretary's conclusion that discrimination is occurring is unsupported factually. The plurality's characterization of the Secretary's rationale, however, oversimplifies both the complexity of the situations to which the regulations are addressed and the reasoning of the Secretary.

First, the Secretary's proof that treatment is in fact being withheld from handicapped infants is unquestioned by the plurality. It is therefore obvious that whoever is making them, *decisions* to withhold treatment from such infants are in fact being made. This basic understanding is critical to the Secretary's further reasoning, and the discussion accompanying the proposed regulations clearly indicates that this was the Secretary's starting point. See 48 Fed. Reg. 30847-30848 (1983). Proceeding with this factual understanding, the next question is whether such withholding of treatment constitutes prohibited discrimination under §504 in some or all situations. It is at this point that the plurality errs. In the plurality's view, only two narrow paradigmatic types of decisions were contemplated by the Secretary as potentially constituting discrimination in violation of the statute. See *ante*, at 628-629. The plurality does not explain, however, precisely what in the Secretary's discussion gives rise to this distillation, and my reading of the explanation accompanying the regulations does not leave me with so limited a view of the Secretary's concerns.

The studies cited by the Secretary in support of the regulations and other literature concerning medical treatment in this area generally portray a decisionmaking process in which the parents and the doctors and often other concerned persons as well are involved—although the parental decision to consent or not is obviously the critical one.<sup>11</sup> Thus, the pa-

<sup>11</sup>See, e. g., Duff & Campbell, *Moral and Ethical Dilemmas in the Special-Care Nursery*, 289 N. Eng. J. Med. 890 (1973). See also Gross,

rental consent decision does not occur in a vacuum. In fact, the doctors (directly) and the hospital (indirectly) in most cases participate in the formulation of the final parental decision and in many cases substantially influence that decision.<sup>12</sup> Consequently, discrimination against a handicapped infant may assume guises other than the outright refusal to treat once parental consent has been given. Discrimination may occur when a doctor encourages or fails to discourage a parental decision to refuse consent to treatment for a handicapped child when the doctor would discourage or actually oppose a parental decision to refuse consent to the same treatment for a nonhandicapped child. Or discrimination may occur when a doctor makes a discriminatory treatment recommendation that the parents simply follow. Alternatively, discrimination may result from a hospital's explicit laissez-faire attitude about this type of discrimination on the part of doctors.

Contrary to the plurality's constrained view of the Secretary's justification for the regulations, the stated basis for those regulations reveals that the Secretary was cognizant of this more elusive discrimination. For example, the evidence cited most extensively by the Secretary in his initial proposal of these regulations was a study of attitudes of practicing and teaching pediatricians and pediatric surgeons. See 48 Fed. Reg. 30848 (1983) (citing Shaw, Randolph, & Manard, *Ethical Issues in Pediatric Surgery: A National Survey of Pediatricians and Pediatric Surgeons*, 60 *Pediatrics* 588 (1977)). This study indicated that a substantial number of these doctors (76.8% of pediatric surgeons and 49.5% of pedi-

Cox, Tatyrek, Pollay, & Barnes, *Early Management and Decision Making for the Treatment of Myelomeningocele*, 72 *Pediatrics* 450 (1983).

<sup>12</sup>Presumably, the program or activity that § 504 would apply to in this context would be the hospital's neonatal program of medical care or the hospital's program of medical care generally. In either case, actions of both doctors and hospitals that cause or permit discriminatory decisions that are taken as part of the program or activity would be subject to § 504's constraints.

atricians) would "acquiesce in parents' decision to refuse consent for surgery in a newborn with intestinal atresia if the infant also had . . . Down's syndrome." *Id.*, at 590. It also indicated that a substantial minority (23.6% of pediatric surgeons and 13.2% of pediatricians) would in fact encourage parents to refuse consent to surgery in this situation and that only a small minority (3.4% of pediatric surgeons and 15.8% of pediatricians) would attempt to get a court order mandating surgery if the parents refused consent. In comparison, only a small minority (7.9% of pediatric surgeons and 2.6% of pediatricians) would acquiesce in parental refusal to treat intestinal atresia in an infant with no other anomaly. And a large majority (78.3% of pediatric surgeons and 88.4% of pediatricians) would try to get a court order directing surgery if parental consent were withheld for treatment of a treatable malignant tumor. The Secretary thus recognized that there was evidence that doctors would act differently in terms of attempts to affect or override parental decisions depending on whether the infant was handicapped.

Based on this evidence, the Secretary conceded that "[t]he full extent of discriminatory and life-threatening practices toward handicapped infants is not yet known" but concluded "that for even a single infant to die due to lack of an adequate notice and complaint procedure is unacceptable." 48 Fed. Reg. 30847 (1983). Thus, the Secretary promulgated the regulations at issue here. These regulations, in relevant part, require that a notice of the federal policies against discrimination on the basis of handicap be posted in a place where a hospital's health care professionals will see it. This requirement is, as the Secretary concluded, "[c]onsistent with the Department's intent to target the notice to nurses and other health care professionals." App. 25. The notice requirement, therefore, may reasonably be read as aimed at fostering an awareness by health care professionals of their responsibility not to act in a discriminatory manner with respect to medical treatment decisions for handicapped infants.

The second requirement of the regulations, that state agencies provide mechanisms for requiring and reporting medical neglect of handicapped children, is also consistent with the Secretary's focus on discrimination in the form of discriminatory reporting.<sup>13</sup>

I therefore perceive a rational connection between the facts found by the Secretary and the regulatory choice made. The Secretary identified an existing practice that there was reason to believe resulted from discrimination on the basis of handicap. Given this finding, the amorphous nature of much of the possible discrimination, the Secretary's profession that the regulations are appropriate no matter how limited the problem,<sup>14</sup> and the focus of the regulations on loci where unlawful discrimination seems most likely to occur and on persons likely to be responsible for it, I conclude that these regulations are not arbitrary and capricious and that the Court errs in striking them down on that basis. Although the Secretary's path here may be marked with "less than ideal clarity," we will uphold such a decision "if the agency's path may reasonably be discerned." *Motor Vehicles Mfrs. Assn.*, 463 U. S., at 43 (quoting *Bowman Transportation, Inc. v. Arkansas-Best Freight System, Inc.*, 419 U. S. 281, 286 (1974)).

The plurality also objects to the regulations' requirement concerning the state protective agencies' reporting proce-

<sup>13</sup>The plurality reserves the question whether reporting would be a program or activity receiving federal financial assistance, *ante*, at 639, n. 25, and I follow that course.

<sup>14</sup>The plurality itself says that "regulations may be imposed for preventative or prophylactic reasons," *ante*, at 643, but concludes that the Secretary here proceeded based on the perception of an actual problem rather than a need for prophylactic rules. To me, however, the Secretary's statement that the rules are appropriate if necessary for even one problem situation makes the plurality's distinction in this respect questionable: The line between a prophylactic rule and a rule that draws its justification from the likely existence of even one unlawful action seems to me a very fine one.

dures on another ground. Specifically, the plurality finds that this requirement is in fact a substantive prescription rather than a prohibition of discrimination. The plurality bases this conclusion on the fact that the regulation sets forth specific procedures that must be adopted by state agencies.

The plurality's conclusion disregards the Secretary's explanation for this requirement. In the preamble to the proposed regulations, the Secretary explicitly stated:

"The Department has determined that under every state's law, failure of parents to provide necessary, medically indicated care to a child is either explicitly cited as grounds for action by the state to compel treatment or is implicitly covered by the state statute. These state statutes also provide for appropriate administrative and judicial enforcement authorities to prevent such instances of medical neglect, including requirements that medical personnel report suspected cases to the state child protective services agency, agency access to medical files, immediate investigations and authority to compel treatment." 48 Fed. Reg. 30848 (1983).

This finding was repeated in the statement accompanying the final regulations:

"Although there are some variations among state child protective statutes, all have the following basic elements: a requirement that health care providers report suspected cases of child abuse or neglect, including medical neglect; a mechanism for timely receipt of such reports; a process for administrative inquiry and investigation to determine the facts; and the authority and responsibility to seek an appropriate court order to remedy the apparent abuse and neglect, if it is found to exist." 49 Fed. Reg. 1627 (1984).

The regulations, in turn, require that the State provide these same services with respect to medical neglect of handicapped infants. See 45 CFR § 84.55(c) (1985). The only

additional requirements imposed by the regulations involve provisions enabling the Department itself to review for compliance with the nondiscrimination requirements. Consequently, the regulations simply track the existing state procedures found to exist by the Secretary, requiring that funded state agencies provide those same procedures for handicapped children. The fact that the regulations specify the procedures that are necessary to ensure an absence of discrimination and do not instead speak in "nondiscrimination" terms is irrelevant. The substance of the requirement is nondiscrimination. The plurality's conclusion in this regard, however, apparently rests on a determination that implementation of a nondiscrimination mandate may be accomplished in only one form—even if the same result may be accomplished by another route. See *ante*, at 640, n. 26. I would not elevate regulatory form over statutory substance in this manner. In sum, the plurality's determination that the regulations were inadequately supported and explained as a matter of administrative law does not withstand examination of the Secretary's discussion of the underlying problem and of the contours of the regulations themselves.

#### IV

My disagreement with the plurality in this case does not end here, however. For even under its chosen rationale, I find its ultimate conclusion dubious. Having assiduously restricted its discussion to the validity of the regulations only, the plurality ends up concluding expansively that not only the regulations but also other investigations taken by the Secretary independent of the regulations are invalid. Thus, the Court apparently enjoins the Secretary's on-site investigations as well as "the regulations which purport to authorize a continuation of them." *Ante*, at 647. And the plurality rests this action on the conclusion that the lower courts "correctly held that these investigative actions were not authorized by the statute." *Ibid*.

I am at a loss to understand the plurality's reasoning in this respect. In construing the judgment below, the plurality appears to conclude that, although the injunction entered by the District Court and affirmed by the Court of Appeals did not purport to prohibit *all* actions by the Secretary under the statute, the injunction did in fact extend beyond merely these particular regulations. Thus, the plurality indicates that the judgment below applied as well to actions that "resemble," "parallel," or are "along [the] lines [of]" the regulations. *Ante*, at 625-626, n. 11. The plurality further defines what actions it believes the Court of Appeals and District Court contemplated: "[T]he injunction forbids continuation or initiation of regulatory and investigative activity directed at instances in which parents have refused consent to treatment and, if the Secretary were to undertake such action, efforts to seek compliance with affirmative requirements imposed on state child protective services agencies." *Ante*, at 625, n. 11.

Aside from the fact that I see absolutely nothing in either the District Court's or the Court of Appeals' judgment that would support a constrained reading of the broadly phrased relief awarded by the District Court and affirmed without modification by the Court of Appeals,<sup>15</sup> I have some doubt as to how different the Court's holding today is from a holding that § 504 gives HHS no authority whatsoever over decisions to treat handicapped infants. The plurality's lack of coherence on this crucial point raises substantial doubts as to the reach of the holding and as to the basis for that holding.

Finally, I am puzzled as to how and why the plurality's determination that the regulations are invalid because they are arbitrary and capricious extends to other actions not taken under the regulations. The plurality apparently would enjoin all enforcement actions by the Secretary in situations in which parents have refused to consent to treatment. See *ante*, at 625-626, n. 11. Yet it is not clear to me that the

<sup>15</sup> See nn. 1-2, *supra*, and accompanying text.

plurality's basis for invalidating these regulations would extend to all such situations. I do not see, for example, why the plurality's finding that the Secretary did not adequately support his conclusion that failures to report refusals to treat likely result from discrimination means that such a conclusion will *never* be justified. The Secretary might be able to prove that a particular hospital generally fails to report nontreatment of handicapped babies for a specific treatment where it reports nontreatment of nonhandicapped babies for the same treatment. In essence, a determination that these regulations were inadequately supported factually would not seem to be properly extended beyond actions taken pursuant to these regulations: The fact that the Secretary has not adequately justified generalized action under the regulations should not mean that individualized action in appropriate circumstances is precluded.

#### V

In sum, the plurality today mischaracterizes the judgment below and, based on that mischaracterization, is sidetracked from the straightforward issue of statutory construction that this case presents. The plurality incorrectly resolves an issue that was not fully addressed by the parties, gives no guidance to the Secretary or the other parties as to the proper construction of the governing statute, and fails adequately to explain the precise scope of the holding or how that holding is supported under the plurality's chosen rationale. From this misguided effort, I dissent.

JUSTICE O'CONNOR, dissenting.

I fully agree with JUSTICE WHITE's conclusion that the only question properly before us is whether the Court of Appeals correctly concluded that the Secretary has no power under 29 U. S. C. § 794 to regulate medical treatment decisions concerning handicapped newborn infants. I also agree that application of established principles of statutory construction and of the appropriate standard for judicial review

of agency action leads inescapably to the conclusion that the Secretary has the authority to regulate in this area. Because, however, I see no need at this juncture to address the details of the regulations or to assess whether they are sufficiently rational to survive review under 5 U. S. C. § 706 (2)(A), I join only parts I, II, IV, and V of JUSTICE WHITE's dissent.

# Appendix I

## Child Abuse Amendments of 1984

PUBLIC LAW 98-457—OCT. 9, 1984

98 STAT. 1749

Public Law 98-457  
98th Congress

### An Act

To extend and improve provisions of laws relating to child abuse and neglect and adoption, and for other purposes.

Oct. 9, 1984  
[H.R. 1904]

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Child Abuse Amendments of 1984".*

Child Abuse  
Amendments of  
1984.  
42 USC 5101  
note.

### TITLE I—AMENDMENTS TO CHILD ABUSE PREVENTION AND TREATMENT ACT

#### PART A—PROGRAM IMPROVEMENTS

##### THE NATIONAL CENTER ON CHILD ABUSE AND NEGLECT

SEC. 101. (a) Section 2(a) of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5101(a)) (hereinafter in this title referred to as "the Act") is amended by striking out "Health, Education, and Welfare" and inserting in lieu thereof "Health and Human Services".

(b) Clauses (6) and (7) of section 2(b) of the Act are amended to read as follows:

"(6) study and investigate the national incidence of child abuse and neglect and make findings about any relationship between nonpayment of child support and between various other factors and child abuse and neglect, and the extent to which incidents of child abuse and neglect are increasing in number and severity, and, within two years after the date of the enactment of the Child Abuse Amendments of 1984, submit such findings to the appropriate Committees of the Congress together with such recommendations for administrative and legislative changes as are appropriate; and

Study.

"(7) in consultation with the Advisory Board on Child Abuse and Neglect, annually prepare reports on efforts during the preceding two-year period to bring about coordination of the goals, objectives, and activities of agencies and organizations which have responsibilities for programs and activities related to child abuse and neglect, and, not later than March 1, 1985, and March 1 of each second year thereafter, submit such a report to the appropriate Committees of the Congress."

Reports.

(c) Section 2(c) of the Act is amended by striking out "The Secretary may carry out his functions under subsection (b) of this section" and inserting in lieu thereof "The functions of the Secretary under subsection (b) of this section may be carried out".

(d) Section 2 of the Act is further amended by inserting after subsection (d) the following new subsection:

"(e) No funds appropriated under this Act for any grant or contract may be used for any purpose other than that for which such funds were specifically authorized."

## DEFINITIONS

Post. p. 1752.

## SEC. 102. Section 3 of the Act is amended—

(1) by inserting "(including any employee of a residential facility or any staff person providing out-of-home care)" after "by a person";

(2) by striking out the period at the end thereof and inserting in lieu thereof a semicolon; and

(3) by adding at the end thereof the following new clause:

"(2)(A) the term 'sexual abuse' includes—

"(i) the employment, use, persuasion, inducement, enticement, or coercion of any child to engage in, or having a child assist any other person to engage in, any sexually explicit conduct (or any simulation of such conduct) for the purpose of producing any visual depiction of such conduct, or

"(ii) the rape, molestation, prostitution, or other such form of sexual exploitation of children, or incest with children,

under circumstances which indicate that the child's health or welfare is harmed or threatened thereby, as determined in accordance with regulations prescribed by the Secretary; and

"(B) for the purpose of this clause, the term 'child' or 'children' means any individual who has not or individuals who have not attained the age of eighteen."

## DEMONSTRATION OR SERVICE PROGRAMS AND PROJECTS

Grants.  
42 USC 5103.

SEC. 103. (a) Section 4(b)(2)(E) of the Act is amended by striking out "his" and inserting in lieu thereof "and the child's".

Waiver.

(b) Section 4(b)(3) of the Act is amended to read as follows:

Ante. p. 1749.

"(3)(A) Subject to subparagraph (B) of this paragraph, any State which on the date of enactment of the Child Abuse Amendments of 1984 does not qualify for assistance under this subsection may be granted a waiver of any requirement under paragraph (2) of this subsection—

"(i) for a period of not more than one year, if the Secretary makes a finding that such State is making a good-faith effort to comply with any such requirement, and for a second one-year period if the Secretary makes a finding that such State is making substantial progress to achieve such compliance; or

"(ii) for a nonrenewable period of not more than two years in the case of a State the legislature of which meets only biennially, if the Secretary makes a finding that such State is making a good-faith effort to comply with any such requirement.

Post. p. 1752.

"(B) No waiver under subparagraph (A) may apply to any requirement under paragraph (2)(K) of this subsection."

(c) Section 4 of the Act is further amended—

(1) by redesignating subsection (e) as subsection (f); and

(2) by inserting after subsection (d) the following new subsection:

"(e) The Secretary, in consultation with the Advisory Board on Child Abuse and Neglect, shall ensure that a proportionate share of assistance under this Act is available for activities related to the prevention of child abuse and neglect."



AUTHORIZATION OF APPROPRIATIONS

SEC. 104. (a) Section 5(a) of the Act is amended—

42 USC 5104

(1) by striking out "(a)" after "Sec. 5.";

(2) by inserting after the first sentence the following new sentence: "There are hereby further authorized to be appropriated for the purposes of this Act \$33,500,000 for fiscal year 1984, \$40,000,000 for fiscal year 1985, \$41,500,000 for fiscal year 1986, and \$43,100,000 for fiscal year 1987."; and

(3) in the second sentence by striking out "this section" and all that follows through the end of such subsection, and inserting in lieu thereof "this section except as provided in the succeeding sentence, (A) not less than \$9,000,000 shall be available in each fiscal year to carry out section 4(b) of this Act (relating to State grants), (B) not less than \$11,000,000 shall be available in each fiscal year to carry out sections 4(a) (relating to demonstration or service projects), 2(b)(1) and 2(b)(3) (relating to information dissemination), 2(b)(5) (relating to research), and 4(c)(2) (relating to training, technical assistance, and information dissemination) of this Act, giving special consideration to continued funding of child abuse and neglect programs or projects (previously funded by the Department of Health and Human Services) of national or regional scope and demonstrated effectiveness, (C) \$5,000,000 shall be available in each such year for grants and contracts under section 4(a) for identification, treatment, and prevention of sexual abuse, and (D) \$5,000,000 shall be available in each such year for the purpose of making additional grants to the States to carry out the provisions of section 4(c)(1) of this Act. With respect to any fiscal year in which the total amount appropriated under this section is less than \$30,000,000, funds shall first be available as provided in clauses (A) and (B) in the preceding sentence and of the remainder one-half shall be available as provided for in clause (C) and one-half as provided for in clause (D) in the preceding sentence."

42 USC 5103.

42 USC 5101.

Post, p. 1753.

(b) Section 5(b) of the Act is repealed.

42 USC 5104.

ADVISORY BOARD ON CHILD ABUSE AND NEGLECT

SEC. 105. (a) The first sentence of section 6(a) of the Act is amended by striking out "including" and all that follows thereafter through "Administration."

42 USC 5105.

(b) Section 6(a) of the Act is further amended by inserting at the end thereof the following sentence: "The Advisory Board may be available, at the Secretary's request, to assist the Secretary in coordinating adoption-related activities of the Federal Government."

(c)(1) Section 6(b) of the Act is repealed.

(2) Subsection (c) of section 6 of the Act is redesignated as subsection (b).

COORDINATION

SEC. 106. Section 7 of the Act is amended by striking out "between" and inserting in lieu thereof "among".

42 USC 5106.

## PART B—SERVICES AND TREATMENT FOR DISABLED INFANTS

## NEW DEFINITION

42 USC 5102

## SEC. 121. Section 3 of the Act is further amended—

(1) by striking out “this Act the term ‘child abuse and neglect’” and inserting in lieu thereof the following: “This Act—  
“(1) the term ‘child abuse and neglect’”;

(2) by striking out the period at the end thereof and inserting in lieu thereof a semicolon and the word “and”; and

(3) by adding after clause (2) (as added by section 102(3) of this Act) the following new clause:

“(3) the term ‘withholding of medically indicated treatment’ means the failure to respond to the infant’s life-threatening conditions by providing treatment (including appropriate nutrition, hydration, and medication) which, in the treating physician’s or physicians’ reasonable medical judgment, will be most likely to be effective in ameliorating or correcting all such conditions, except that the term does not include the failure to provide treatment (other than appropriate nutrition, hydration, or medication) to an infant when, in the treating physician’s or physicians’ reasonable medical judgment, (A) the infant is chronically and irreversibly comatose; (B) the provision of such treatment would (i) merely prolong dying, (ii) not be effective in ameliorating or correcting all of the infant’s life-threatening conditions, or (iii) otherwise be futile in terms of the survival of the infant; or (C) the provision of such treatment would be virtually futile in terms of the survival of the infant and the treatment itself under such circumstances would be inhumane.”

## NEW BASIC STATE GRANT REQUIREMENT

## SEC. 122. Section 4(b)(2) of the Act (42 U.S.C. 5103(b)(2)) is amended—

(1) by striking out “and” at the end of clause (I);

(2) by striking out the period at the end of clause (J) and inserting in lieu thereof a semicolon and the word “and”; and

(3) by inserting after clause (J) the following new clause:

“(K) within one year after the date of the enactment of the Child Abuse Amendments of 1984, have in place for the purpose of responding to the reporting of medical neglect (including instances of withholding of medically indicated treatment from disabled infants with life-threatening conditions), procedures or programs, or both (within the State child protective services system), to provide for (i) coordination and consultation with individuals designated by and within appropriate health-care facilities, (ii) prompt notification by individuals designated by and within appropriate health-care facilities of cases of suspected medical neglect (including instances of withholding of medically indicated treatment from disabled infants with life-threatening conditions), and (iii) authority, under State law, for the State child protective service system to pursue any legal remedies, including the authority to initiate legal proceedings in a court of competent jurisdiction, as may be necessary to

Ante, p. 1749.

prevent the withholding of medically indicated treatment from disabled infants with life-threatening conditions.”.

ADDITIONAL STATE GRANTS AND ASSISTANCE FOR TRAINING, TECHNICAL ASSISTANCE, AND CLEARINGHOUSE ACTIVITIES

- SEC. 123. (a) Section 4 of the Act is further amended by—
- 1) redesignating subsection (c) as subsection (d), subsection (d) as subsection (e), and subsection (e) as subsection (f); and
  - 2) inserting after subsection (b) the following new subsection:
 

“(c)(1) The Secretary is authorized to make additional grants to the States for the purpose of developing, establishing, and operating or implementing—

    - “(A) the procedures or programs required under clause (K) of subsection (b)(2) of this section;
    - “(B) information and education programs or training programs for the purpose of improving the provision of services to disabled infants with life-threatening conditions for (i) professional and paraprofessional personnel concerned with the welfare of disabled infants with life-threatening conditions, including personnel employed in child protective services programs and health-care facilities, and (ii) the parents of such infants; and
    - “(C) programs to help in obtaining or coordinating necessary services, including existing social and health services and financial assistance for families with disabled infants with life-threatening conditions, and those services necessary to facilitate adoptive placement of such infants who have been relinquished for adoption.

“(2)(A) The Secretary shall provide, directly or through grants or contracts with public or private nonprofit organizations, for (i) training and technical assistance programs to assist States in developing, establishing, and operating or implementing programs and procedures meeting the requirements of clause (K) of subsection (b)(2) of this section; and (ii) the establishment and operation of national and regional information and resource clearinghouses for the purpose of providing the most current and complete information regarding medical treatment procedures and resources and community resources for the provision of services and treatment for disabled infants with life-threatening conditions (including compiling, maintaining, updating, and disseminating regional directories of community services and resources (including the names and phone numbers of State and local medical organizations) to assist parents, families, and physicians and seeking to coordinate the availability of appropriate regional education resources for health-care personnel).

“(B) Not more than \$1,000,000 of the funds appropriated for any fiscal year under section 5 of this Act may be used to carry out this paragraph.

“(C) Not later than 210 days after the date of the enactment of the Child Abuse Amendments of 1984, the Secretary shall have the capability of providing and begin to provide the training and technical assistance described in subparagraph (A) of this paragraph.”.
- (b) Section 4 of the Act is further amended by adding after paragraph (3) the following new paragraph:
- “(4) Programs or projects related to child abuse and neglect assisted under part B of title IV of the Social Security Act shall

42 USC 5103.

Public information.

Ante, p. 1752.

Contracts with U.S.

42 USC 5104.

Ante p 1749.

42 USC 5103.

42 USC 620

comply with the requirements set forth in clauses (B), (C), (E), (F), and (K) of paragraph (2).”

#### REGULATIONS AND GUIDELINES

42 USC 1303  
note

SEC. 124. (a)(1) Not later than 60 days after the date of the enactment of this Act, the Secretary of Health and Human Services hereinafter in this part referred to as the “Secretary”) shall publish proposed regulations to implement the requirements of section 4(b)(2)(K) of the Act (as added by section 122(3) of this Act).

Ante p. 1752

(2) Not later than 180 days after the date of the enactment of this Act and after completion of a process of not less than 60 days for notice and opportunity for public comment, the Secretary shall publish final regulations under this subsection.

Ante p. 1752.

(b)(1) Not later than 60 days after the date of the enactment of this Act, the Secretary shall publish interim model guidelines to encourage the establishment within health-care facilities of committees which would serve the purposes of educating hospital personnel and families of disabled infants with life-threatening conditions, recommending institutional policies and guidelines concerning the withholding of medically indicated treatment (as that term is defined in clause (3) of section 3 of the Act (as added by section 121(3) of this Act)) from such infants, and offering counsel and review in cases involving disabled infants with life-threatening conditions.

(2) Not later than 180 days after the date of the enactment of this Act and after completion of a period of not less than 60 days for notice and opportunity for public comment, the Secretary shall publish the model guidelines.

#### REPORT ON FINANCIAL RESOURCES

Study.

42 USC 1305.

SEC. 125. The Secretary shall conduct a study to determine the most effective means of providing Federal financial support, other than the use of funds provided through the Social Security Act, for the provision of medical treatment, general care, and appropriate social services for disabled infants with life-threatening conditions. Not later than 270 days after the date of the enactment of this Act, the Secretary shall report the results of the study to the appropriate Committees of the Congress and shall include in the report such recommendations for legislation to provide such financial support as the Secretary considers appropriate.

#### IMPLEMENTATION REPORT

42 USC 5103  
note.

SEC. 126. Not later than October 1, 1987, the Secretary shall submit to the appropriate Committees of the Congress a detailed report on the implementation and the effects of the provisions of this part and the amendments made by it.

#### STATUTORY CONSTRUCTION

42 USC 5101  
note.

29 USC 794.

SEC. 127. (a) No provision of this Act or any amendment made by this Act is intended to affect any right or protection under section 504 of the Rehabilitation Act of 1973.

(b) No provision of this Act or any amendment made by this Act may be so construed as to authorize the Secretary or any other governmental entity to establish standards prescribing specific med-

ical treatments for specific conditions, except to the extent that such standards are authorized by other laws.

(c) If the provisions of any part of this Act or any amendment made by this Act or the application thereof to any person or circumstances be held invalid, the provisions of the other parts and their application to other persons or circumstances shall not be affected thereby.

Provisions held invalid.

#### EFFECTIVE DATES

SEC. 128. (a) Except as provided in subsection (b), the provisions of this part or any amendment made by this part shall be effective on the date of the enactment of this Act.

42 USC 5102 note.

(b)(1) Except as provided in paragraph (2), the amendments made by sections 122 and 123(b) of this Act shall become effective one year after the date of such enactment.

(2) In the event that, prior to such effective date, funds have not been appropriated pursuant to section 5 of the Act (as amended by section 104 of this Act) for the purpose of grants under section 4(c)(1) of the Act (as added by section 123(a) of this Act), any State which has not met any requirement of section 4(b)(2)(K) of the Act (as added by section 122(3) of this Act) may be granted a waiver of such requirements for a period of not more than one year, if the Secretary finds that such State is making a good-faith effort to comply with such requirements.

Waiver.

Ante, p. 1753.  
Ante, p. 1752.

## TITLE II—AMENDMENTS TO THE CHILD ABUSE PREVENTION AND TREATMENT AND ADOPTION REFORM ACT OF 1978

#### FINDINGS AND DECLARATION OF PURPOSE

SEC. 201. (a) The first sentence of section 201 of the Child Abuse Prevention and Treatment and Adoption Reform Act of 1978 (42 U.S.C. 5111) (hereinafter in this title referred to as "the Act") is amended—

(1) by inserting "the welfare of thousands of children in institutions and foster homes and disabled infants with life-threatening conditions may be in serious jeopardy and that some such children are in need of placement in permanent, adoptive homes; that" after "finds that"; and

(2) by inserting "have medically indicated treatment withheld from them, nor" after "should not".

(b) The second sentence of section 201 of the Act is amended—

(1) by inserting a comma and "including disabled infants with life-threatening conditions," after "special needs"; and

(2) by amending clause (2) to read as follows:

"(2) providing a mechanism for the Department of Health and Human Services to—

"(A) promote quality standards for adoption services, pre-placement, post-placement, and post-legal adoption counseling, and standards to protect the rights of children in need of adoption;

"(B) coordinate with other Federal departments and agencies, including the Bureau of the Census, to provide for a national adoption and foster care information data-gathering and analysis system; and

"(C) maintain a national adoption exchange to bring together children who would benefit by adoption and qualified prospective adoptive parents who are seeking such children."

#### MODEL ADOPTION LEGISLATION AND PROCEDURES

42 USC 5112

SEC. 202. (a) Section 202(a) of the Act is amended by striking out "Health, Education, and Welfare" and inserting in lieu thereof "Health and Human Services".

(b) Section 202(c) of the Act is amended by inserting at the end thereof the following new sentence: "The Secretary shall coordinate efforts to improve State legislation with national, State, and local child and family services organizations, including organizations representative of minorities and adoptive families."

(c) Section 202 of the Act is further amended by inserting at the end thereof the following new subsection:

"(d) The Secretary shall review all model adoption legislation and procedures published under this section and propose such changes as are considered appropriate to facilitate adoption opportunities for disabled infants with life-threatening conditions."

#### INFORMATION AND SERVICES

42 USC 5113.

SEC. 203. (a) Section 203(a) of the Act is amended by striking out "Health, Education, and Welfare" and inserting in lieu thereof "Health and Human Services".

(b)(1) Section 203(a) of the Act is further amended by inserting before the period at the end thereof a comma and "including services to facilitate the adoption of children with special needs and particularly of disabled infants with life-threatening conditions and services to couples considering adoption of children with special needs".

(c)(1) Section 203(b) of the Act is amended by striking out in the matter preceding clause (1) "subsection (a) of this section" and inserting in lieu thereof "this title".

(2) Section 203(b)(1) of the Act is amended to read as follows:

"(1) provide (after consultation with other appropriate Federal departments and agencies, including the Bureau of the Census and appropriate State and local agencies) for the establishment and operation of a Federal adoption and foster care data-gathering and analysis system."

(3) Section 203(b) of the Act is further amended—

(A) by striking out "parent groups" in clause (4) and inserting in lieu thereof "adoptive family groups and minority groups";

(B) by striking out "and" at the end of clause (4);

(C) by redesignating clause (5) as clause (7) and by inserting immediately after clause (4) the following new clauses:

"(5) encourage involvement of corporations and small businesses in supporting adoption as a positive family-strengthening option, including the establishment of adoption benefit programs for employees who adopt children;

"(6) continue to study the nature, scope, and effects of the placement of children in adoptive homes (not including the homes of stepparents or relatives of the child in question) by persons or agencies which are not licensed by or subject to regulation by any governmental entity; and"; and

**(D) by striking out "Health, Education, and Welfare" and inserting in lieu thereof "Health and Human Services" in clause (7) (as redesignated by clause (C) of this paragraph).**

**AUTHORIZATION OF APPROPRIATIONS**

**SEC. 204. Section 205 of the Act is amended by striking out "and" after "1978," and by inserting a comma and "and \$5,000,000 for each of the fiscal years 1984, 1985, 1986, and 1987," after "fiscal years".** 42 USC 5115.

**Appendix J**

**Child Abuse Amendments Final Rule**

**Federal Register**

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**Monday  
April 15, 1985**

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**Part VI**

**Department of  
Health and Human  
Services**

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**Office of Human Development Services**

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**45 CFR Part 1340  
Child Abuse and Neglect Prevention and  
Treatment Program; Final Rule  
Model Guidelines for Health Care  
Providers To Establish Infant Care  
Review Committees; Notice**



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Office of Human Development Services**
**45 CFR Part 1340**
**Child Abuse and Neglect Prevention and Treatment Program**
**AGENCY:** Office of Human Development Services, HHS.

**ACTION:** Final rule.

**SUMMARY:** This rule contains a new basic State grant requirement to implement the Child Abuse Amendments of 1984 (Pub. L. 98-457). As a condition of receiving State grants under the Child Abuse Prevention and Treatment Act, States must establish programs and/or procedures within the State's child protective service system to respond to reports of medical neglect, including reports of the withholding of medically indicated treatment for disabled infants with life-threatening conditions.

Other changes in regulations required by these Amendments will be published as a separate NPRM at a later date.

**DATES:** This rule is effective May 15, 1985. However, as specified in Pub. L. 98-457 and the rule, operative requirements become effective October 9, 1985.

**FOR FURTHER INFORMATION CONTACT:** Jay Olson, (202) 245-2859.

**SUPPLEMENTARY INFORMATION:**
**Program Description**

The Child Abuse Prevention and Treatment Act (Public Law 92-247, 42 U.S.C. 5101, *et seq.*) was signed into law in 1974. It established in the Department of the National Center on Child Abuse and Neglect. The National Center is located organizationally within the Children's Bureau of the Administration for Children, Youth and Families in the Office of Human Development Services.

Under this Act, the National Center carries out the following responsibilities:

- Makes grants to States to implement State child abuse and neglect prevention and treatment programs.
- Funds public or nonprofit private organizations to carry out research, demonstration, and service improvement programs and projects designed to prevent, identify and treat child abuse and neglect.
- Collects, analyzes, and disseminates information, e.g., compiles and disseminates training materials, prepares an annual summary of recent and on-going research on child abuse

and neglect, and maintains an information clearinghouse.

- Assists States and communities in implementing child abuse and neglect programs.
- Coordinates Federal programs and activities, in part through the Advisory Board on Child Abuse and Neglect.

The Act has been extended and amended several times since its passage. Regulations for the State grant and discretionary fund programs are found at 45 CFR Part 1340; the most recent revisions were published on January 26, 1983 (48 FR 3698). The fifty States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, and the Trust Territory of the Pacific Islands are eligible to apply for State grants. Fifty-one of the fifty-seven eligible jurisdictions meet the requirements of the Act and the regulations and currently receive State grant funds. We will refer to these jurisdictions as "States" in this preamble discussion.

**State Child Protective Service System**

Funds from the State grant program are used to support the activities of the State Child Protective Service (CPS) system. State CPS agencies are the agencies designated in the State to respond to reports of child abuse and neglect. (All States have a CPS system and CPS agency whether they receive State grant funds under the Act or not.)

The CPS agency responds to reports of abuse and/or neglect, investigates, refers situations to law enforcement officials as appropriate, and provides treatment and services. The focus of the agency's efforts is on the family—to protect the child, preserve the home, prevent separation of the child from the family if at all possible, prevent further abuse or neglect, and alleviate or correct the factors leading to the report. The agency generally regards its contact with the family as a demonstration of community concern and evidence of a desire to be of help to both parents and children.

Anyone in a State may report known or suspected abuse and neglect. Local (city, county) telephone numbers for reporting are found in local telephone directories. States that have a State-wide 24-hour hot line typically give that number wide publicity. The list of CPS agency contacts in the NPRM was provided for general information purposes regarding the overall child protective service system, not for reporting specific instances of abuse or neglect.

Investigations, services, and other activities may be provided by CPS

agency staff, by law enforcement agencies, by multidisciplinary teams (many of which are located in major hospitals), and by utilizing the services of other public and voluntary agencies in the community. Most CPS workers have specialized training, and multidisciplinary fact-finding teams often have some expertise in medicine, law and law enforcement, as well as in social work.

**Notice of Proposed Rulemaking**

On December 10, 1984, the Department published a Notice of Proposed Rulemaking (NPRM) (49 FR 48160) to implement a major new requirement in Pub. L. 98-457, the Child Abuse Amendments of 1984. This requirement, applicable to CPS agencies, is found in a new clause (K) in section 4(b)(2) of the Child Abuse Prevention and Treatment Act. It mandates that, in order to qualify for basic State grants under the Act, States must, by October 9, 1985 (within one year of enactment), have programs or procedures or both in place within the State's CPS system for the purpose of responding to reports of medical neglect, including instances of the withholding of medically indicated treatment (including appropriate nutrition, hydration and medication) from disabled infants with life-threatening conditions.

A definition of "withholding of medically indicated treatment" is given in section 3 of the Act and means the failure to respond to an infant's life-threatening conditions by providing treatment (including appropriate nutrition, hydration, and medication) which, in the treating physician's reasonable medical judgment, will be most likely to be effective in ameliorating or correcting all such conditions. Exceptions to the requirement to provide treatment (but not the requirement to provide appropriate nutrition, hydration, and medication) may be made only in cases in which:

- (1) The infant is chronically and irreversibly comatose; or
- (2) The provision of such treatment would merely prolong dying or not be effective in ameliorating or correcting all of the infant's life-threatening conditions, or otherwise be futile in terms of the survival of the infant; or
- (3) The provision of such treatment would be virtually futile in terms of the survival of the infant and the treatment itself under such circumstances would be inhumane.

The Amendments also required the Department to publish interim model guidelines to encourage hospitals to

establish committees to educate hospital personnel and families of disabled infants with life-threatening conditions, recommend institutional policies and guidelines concerning withholding of medically indicated treatment from such infants, and offer counsel and review in cases involving such disabled infants. Interim Model Guidelines were also published on December 10, 1984 (49 FR 48170).

We received more than 116,000 letters in response to the NPRM and the Interim Model Guidelines from a wide range of associations and individuals. The overwhelming majority of these comments expressed general support for the regulation. Many letters strongly endorsed the requirement that all disabled infants, regardless of their condition, receive appropriate nutrition and hydration, and the Department's interpretation that the law did not permit life and death treatment decisions to be made on the basis of subjective opinions regarding the future "quality of life" of a retarded or disabled person. Many of these commenters recommended the addition of more specific requirements they believed would more effectively protect disabled infants.

A number of commenters disapproved of the proposed rule. Some of them objected to any governmental action that they believed interfered with an individual's right to make personal decisions in this matter. Some commenters urged deletion of specific provisions of the proposed rule they believed were excessive or distorted the intent of Congress. Frequently identified in this connection were the clarifying definitions the Department proposed to support the basic statutory definition.

In addition, during the comment period, we met with representatives of a number of right-to-life, disability rights and medical organizations. A summary of the issues discussed and recommendations made at these meetings is included in the Department's public comment record.

#### Summary of the Final Rule

In the NPRM, the Department sought to adhere closely to the letter and spirit of the legislation. As noted at that time, this legislation was the product of an extraordinary effort on the part of several Senators and Congressmen and representatives of a wide range of medical, right-to-life and disability organizations to forge a substantial consensus on an effective and workable program to assure the provision of appropriate medical care to disabled infants. It was and continues to be of great importance to the Department to

preserve and advance this consensus in order to most effectively implement this program.

It is clear that the legislation represented a careful balance between the need to establish effective protection of the rights of disabled infants and the need to avoid unreasonable governmental intervention into the practice of medicine and parental responsibilities. In the NPRM, the Department's principal objective was to replicate this careful balance achieved in the legislation. Commenters on the NPRM gave the Department "mixed reviews" on how well this objective was accomplished.

Of special significance to the Department were the more than 115,000 letters from concerned citizens who strongly endorsed the compelling objective of assuring the provision of medically indicated treatment to disabled infants with life-threatening conditions. This was an overwhelming outpouring of letters from concerned citizens from all walks of life which significantly contributed to and reinforced the Department's commitment to develop an effective and workable regulation. Several major themes clearly emerged from this extraordinary volume of comments.

First, many of these commenters urged continued emphasis on the basic principle inherent in the statute that medical treatment decisions are not to be made on the basis of subjective opinions about the future "quality of life" of a retarded or disabled person. Many of these comments included personal and positive experiences and anecdotes relating to raising, being raised with, adopting, working with, or teaching disabled individuals. Some of these comments included photographs of natural or adopted disabled children or family members.

Second, these commenters urged adoption of requirements for child protective services agencies to implement program and/or procedures to fully effectuate the compelling statutory purpose. Suggestions were made for additional procedures dealing with access to medical records and the opportunity to obtain an independent medical examination, when necessary.

Third, many commenters strongly endorsed the Department's interpretations of key terms included in the basic statutory definition on the grounds that these clarifications were proper and important supplements to the statutory definition.

The Department also received a number of comments from medical associations whose support was essential to accomplishing the

legislative compromise who argued that the careful balance evident in the statute was distorted by inclusion in the proposed rule of an inflexible catalog of binding definitions that counterproductively constrained the ability of reasonable medical judgment to react thoughtfully to the myriad of real-life problems in intensive care nurseries. These commenters made clear that their support for the legislation was based on inclusion in the compromise of deference to reasonable medical judgment, and that this element was insufficiently reflected in the proposed rule to allow their continued support.

In addition to the large number of comment letters we received, also noteworthy was a letter to Secretary Heckler from the six principal sponsors of the "compromise amendment" that became the provisions of the Child Abuse Amendments of 1984 dealing with services and treatment for disabled infants. This letter from Senators Hatch, Denton, Cranston, Nickles, Dodd and Kassebaum is especially important in reflecting the spirit of the extraordinary consensus reached through what the Senators referred to as the "painstaking negotiations" involving the diverse coalition.

The principal sponsors made several significant points. First, they noted that each word of the statutory definition "was chosen with utmost care" and indicated they were aware that the Department received numerous comments asking that the clarifying definitions be deleted. Although the principal sponsors did not specifically endorse these recommendations, they urged that they be given "every consideration" to ensure that the final rule is crafted with the same degree of care as was the statutory definition.

Second, the principal sponsors strongly urged that the word "imminent" not be used to characterize the proximity in time at which death is anticipated regardless of treatment in the context of situations in which treatment (other than nutrition, hydration, and medication) need not be provided. They stated:

In the negotiations leading to the final language, there was much discussion about whether or not to include the word "imminent" in the statutory definition. It became apparent that "imminent" would create undue confusion both because it was ambiguous and because the expected time of death cannot be predicted with precision. A decision was made, therefore, not to include "imminent", and we urge that it be dropped in the regulations as well. Should the law in its present form prove ineffective, or harmful to infant care, we will seek appropriate legislative remedies.

Third, they urged avoidance of the use of examples of specific medical conditions in a way that would be interpreted as "establishing federally-prescribed medical standards for approved treatment for specific cases."

Fourth, the principal sponsors urged clarifications concerning references to Infant Care Review Committees to "specifically make clear that the use of such committees is voluntary."

Finally, they recommended that the "existing cooperative relationship between state child protective services agencies and hospitals" be advanced by providing that the names, telephone numbers and titles of designated persons in the hospital be made known to the appropriate hospital staff and agency staff.

The Department has considered carefully the recommendations of the many commenters and the principal sponsors. This consideration has led to a number of revisions to the rule. These revisions reflect a reaffirmation of the Department's objective of replicating the careful balance accomplished in the legislation by the six principal sponsors, the diverse coalition of medical, pro-life and disability organizations, and the Congress as a whole between the need for an effective program and the need to prevent unreasonable governmental intervention.

This balancing effort has produced a number of decisions. First, the Department has adopted a recommendation that appeared to be unanimous among all of the medical associations whose endorsement was central to accomplishing the legislative compromise to delete the proposed rule's clarifying definitions from the text of the final rule. Only two of the clarifying definitions, those that appeared in the Conference Committee Report, have been adopted in the final rule.

Second, because the Department continues to believe that guidance relating to interpretations of key terms used in the statutory definition of "withholding of medically indicated treatment" will aid in effective implementation of the statute (a belief shared by many commenters), the Department is stating clearly its interpretative guidelines regarding these key terms in an appendix to the final rule. This appendix will be codified as an appendix to 45 CFR Part 1340. In publishing these interpretative guidelines, the Department is not seeking to establish them as binding rules of law, nor to prejudge the exercise of reasonable medical judgment in responding to specific circumstances. Rather, this guidance is intended to

assist in interpreting the statutory definition so that it may be effectively and rationally applied in specific cases so as to fully effectuate the statutory purpose of protecting disabled infants.

The third conclusion arising from this balancing effort is that the Department's interpretative guidelines included in the appendix to the final rule continue to make clear the Department's interpretation that the statute unambiguously directs reasonable medical judgments to matters regarding treatment (including appropriate nutrition, hydration and medication) which "will be most likely to be effective in ameliorating or correcting" all of the infant's life-threatening conditions, and that it does not sanction decisions based on subjective opinions about the future "quality of life" of a retarded or disabled person.

Fourth, in offering the interpretative guidelines in the appendix and in providing the rationale for the interpretations, the Department will avoid using examples of specific diagnoses to elaborate on meaning. This action should avoid the essential thrust of the interpretative guidelines being lost amidst uncertainty regarding how the addition or subtraction of particular complications or medical nuances might affect the examples. It should also allay concerns that the proposed rule presented what some commenters referred to as a "cookbook approach" to the practice of medicine.

Fifth, the term "imminent" that appeared in the proposed rule in connection with the prognosis that no treatment will prevent death of the infant has been deleted from the Department's interpretative guidelines that appear in the appendix. This revision will assure no deviation from the resolution of a matter specifically decided during the legislative negotiations. The guidelines, however, continue to make clear that treatment may not be withheld solely due to a distant prognosis of death.

Sixth, the Department has adopted the recommendations of many commenters that specific provisions of the rule address child protective services agency procedures to gain access to medical records when necessary, to obtain a court order for an independent medical examination when necessary, and to identify the designated hospital liaison persons to facilitate coordination with the child protective services agency.

The Department believes these revisions will ensure that the final rule reaffirms the legislative commitment to a program that deserves the support of a diverse coalition of associations and individuals. The section-by-section

analysis in this preamble and the appendix to the final rule describe these revisions in greater detail, and discuss the significant comments received by the Department.

In addition, Model Guidelines for Health Care Providers to Establish Infant Care Review Committees are being published elsewhere in today's Federal Register, along with a discussion of the comments received.

#### Section-by-Section Discussion of the Comments

Before beginning the section by section discussion, we would like to respond to some basic questions and concerns expressed in the comment letters. Many commenters asked for clarification regarding who was the decision maker for the treatment of the infant, what was the focus of the CPS agency's concern, and exactly how these new requirements should be implemented.

In the NPRM, we described the new requirements in the context of a discussion of the role and function of the CPS system and its focus on the family. The decision to provide or withhold medically indicated treatment is, except in highly unusual circumstances, made by the parents or legal guardian. Parents are the decision makers concerning treatment for their disabled infant, based on the advice and reasonable medical judgment of their physician (or physicians). The counsel of an Infant Care Review Committee (ICRC) might also be sought, if available. Therefore, if a report is made to the CPS agency, either by a physician, a nurse, the person designated by the hospital/health care facility, or by any other person, the focus of the CPS agency's work will be, as it is in responding to other reports of child abuse or neglect, to protect the child and assist the family.

We want to emphasize that it is not the CPS agency or the ICRC or similar committee that makes the decision regarding the care of and treatment for the child. This is the parents' right and responsibility. Nor is the aim of the statute, regulations, and the child abuse program to regulate health care. The parents' role as decision maker must be respected and supported unless they choose a course of action inconsistent with applicable standards established by law. Where hospitals have an ICRC or similar committee and the review and counsel of the ICRC is sought, it is the role of the ICRC to review the case, provide additional information as needed to insure fully informed decision-making, particularly in difficult cases, and recommend that the hospital

seek CPS agency involvement when necessary to assure protection for the infant and compliance with applicable legal standards.

With respect to reporting, we also want to emphasize that anyone at any time may report cases of known or suspected abuse or neglect to the local CPS agency. Reporting may be required of certain categories of persons by State law, but reporting is not limited to physicians, ICRC members, designated individuals in health care facilities, or any others. We hope this statement will reassure and resolve the concerns of many commenters who appeared to believe that reports could come only from individuals designated by the hospital or health care facility, or other hospital personnel, e.g., an ICRC member.

With respect to how the new requirements are to be carried out, several key points clearly emerge from the statute and the legislative history.

First, procedural requirements should build upon existing mechanisms at the state level, rather than creating a new system and a new bureaucracy to respond to reports of known or suspected instances of the withholding or medically indicated treatment from infants with life-threatening conditions.

Second, in responding to such reports, CPS agencies are to coordinate and consult with individuals designated by and within the hospital in order to avoid unnecessary disruption of ongoing hospital activities.

Third, the legislation was not intended to require child protection workers to practice medicine or second guess reasonable medical judgments. Rather, Congress intended that the child protective agency respond to reports of suspected medical neglect under procedures designed to ascertain whether any decision to withhold treatment was based on reasonable medical judgment consistent with the definition of "withholding of medically indicated treatment."

Finally, if the CPS agency determines there is a withholding of medically indicated treatment from a disabled infant with a life threatening condition(s), the agency is to pursue the appropriate legal remedies provided by State law to prevent the withholding.

The Department is not prescribing any particular process or investigative steps that must be followed by the CPS agency in every case. Under the Act and existing regulations, basic standards are established but detailed procedures are not dictated. Each CPS agency has the flexibility to work out its own internal investigative procedures and develop mechanisms to provide for coordination

and consultation with local health care facilities and other organizations and agencies. Therefore, this rule does not require the CPS agency to consult with State or local agencies representing the disabled or any other organizations or agencies in the development of their programs and procedures or publish the procedures for public comment.

#### *Section 1340.14 Eligibility requirements.*

We have made a technical change in the lead-in sentence in § 1340.14 to include the eligibility requirements in § 1340.15.

#### *Section 1340.15(a) Purpose.*

In response to several comments, we have added, for specificity, the words "with life-threatening conditions" to the end of the sentence in paragraph (a).

#### *Section 1340.15(b) Definitions.*

1. *The term "medical neglect"—§ 1340.15(b)(1).* Paragraph (b)(1) defines the term "medical neglect," used in the final rule. This term is also used in the new section 4(b)(2)(K) of the Act, which requires states to have programs and/or procedures "for the purpose of responding to the reporting of medical neglect (including instances of withholding of medically indicated treatment from disabled infants with life-threatening conditions)." The term "medical neglect" is not defined in the statute, nor in the existing regulation. However, section 3 of the Act, prior to the 1984 amendments, defined "child abuse and neglect" to include "negligent treatment or maltreatment," and the existing regulation (§ 1340.2(d)(3)(i)) defines this latter term to include the "failure to provide adequate food, clothing, shelter, or medical care." The new law and its legislative history make clear that Congress understood and intended that "medical neglect" is a form of "child abuse and neglect" within the meaning of the Act and the present regulations, and that the "withholding of medically indicated treatment from disabled infants with life-threatening conditions" is a form of medical neglect.

Because of these factors, paragraph (b)(1) simply "closes the loop" by defining "medical neglect" as the failure to provide adequate medical care, and by stating that medical neglect includes, but is not limited to, the withholding of medically indicated treatment from disabled infants with life-threatening conditions.

2. *The term "withholding of medically indicated treatment"—§ 1340.15(b)(2).* Paragraph (b)(2) of the final rule defines the term "withholding of medically indicated treatment" with a definition

identical to that which appears in section 3(3) of the Act (as amended by section 121(3) of the Child Abuse Amendments of 1984).

As clearly documented in the legislative history of the Child Abuse Amendments of 1984, this statutory definition was the central element of what was repeatedly referred to as the "compromise amendment" that emerged from lengthy negotiations among senators and representatives of medical, disability and right-to-life organizations. See H. Conf. Rep. No. 1038, 98th Cong., 2d Sess. 40 (1984); 130 Cong. Rec., S. 9312 (Daily Ed., July 26, 1984) (remarks of Sen. Denton). The essence of this compromise was to reach a careful balance between the need for meaningful protections of the rights of disabled infants to receive appropriate medical care with the need to avoid unreasonable governmental intervention into the practice of medicine or parental responsibilities.

In the proposed rule, the Department proposed a number of clarifying definitions of terms used in the statutory definition. Because the Department was not represented in the lengthy negotiations that produced the compromise amendment, the Department specifically solicited comments on these clarifying definitions. Many were received.

A significant number of comments from medical associations that were major participants in the Congressional negotiations argued that the careful balance evident in the compromise amendment they endorsed was insufficiently reflected in the proposed rule. These commenters uniformly argued that the clarifying definitions, taken as a whole, could be construed so as to have the effect of distorting the legislative compromise, which, they said, did not contemplate regulatory elaborations of the definition.

It was not the Department's intent in the proposed rule to deviate from the letter or the spirit of the compromise amendment. HHS believes it is important to the successful implementation of this law to seek to maintain the statute's careful balance and to preserve and advance the substantial consensus that joined to support the legislative compromise. The Department also continues to believe that successful implementation of this statute will be advanced by offering guidance that will assist in understanding the statutory definition. Thus, the clarifying definitions have been deleted from the text of the regulation, except for the two that were adopted by Congress in the Conference

Committee Report. However, as noted above, the Department's interpretations of these terms are set forth and explained in the appendix to the final rule, which will become an appendix to this rule in the Code of Federal Regulations. The Department believes that these interpretative guidelines can and should be referred to by interested parties in understanding, interpreting and applying the statutory definition. Changing the Department's interpretations from regulatory definitions to interpretative guidelines should allay concerns that the proposed rule could have been construed so as to distort the Congressional compromise by establishing binding rules of law that may compound rather than resolve the myriad of real-life problems in intensive care nurseries, while still giving all parties the benefits of very relevant interpretations of the statute by the agency charged with its implementation.

**3. The term "infant"—**  
**§ 1340.15(b)(3)(i).** The Conference Committee Report included a definition of "infant," which has been adopted in very similar terms in paragraph (b)(3)(i). The apparent reason Congress defined the term is that "infant" does not have a single, commonly accepted meaning. *Dorland's Medical Dictionary*, for example, states that infancy is frequently regarded as extending "to the time of assumption of erect posture (12 to 14 months)"; but is also sometimes regarded "to extend to the end of the first 24 months." *Dorland's Illustrated Medical Dictionary* (26th Edition, 1981), p. 663.

The Conference Committee made clear that its principal focus was on infants less than one year of age. However, the Committee made several other points obviously designed to ensure that the one-year definition would not be applied so arbitrarily and rigidly that infants over one year old would not receive appropriate attention from child protective services systems. Thus, the Conference Committee stated that the principal focus on infants less than one year old did not imply "that treatment should be changed or discontinued when an infant reaches one year of age," nor was it intended "to affect or limit any existing protections available under State laws regarding medical neglect of children over one year of age." H. Conf. Rep. No. 1038, 96th Cong., 2d Sess. 41 (1984).

Thus, as a general rule, issues of medical treatment for infants over one year of age are to be considered under the less precisely defined, but clearly applicable, standards of "medical neglect." Issues of medical treatment for

disabled infants under one year of age with life-threatening conditions must be considered under the more precisely defined standards of the definition of "withholding of medically indicated treatment."

One more factor was added by the Conference Committee. For certain infants over one year of age, the Conference Committee believed the more precisely defined standards of the definition of "withholding of medically indicated treatment" might be more appropriate to use in considering the question of medical treatment than the more general standards of "medical neglect." Thus, the Conference Committee stated that the more precisely defined standards "may" be applied to those infants over one year of age "who have been continuously hospitalized since birth, who were born extremely prematurely or who have long-term disabilities." *Id.* The apparent Congressional intent is to recognize that these three categories of infants, although over one year of age, share important characteristics with those infants under one year of age who are the principal focus of the statutory provision.

The Department has incorporated these points into the definition of "infant." On the last point discussed, the definition has been revised somewhat from that which appeared in the proposed rule. The proposed rule stated that the term "infant" always included the three categories of infants over one year of age described above, or in other words, that the standards of the more precise definition of "withholding of medically indicated treatment" would always apply to the consideration of medical neglect of these infants. In response to comments that this deviated from the "may include" standard of the Conference Committee, the provision has been revised to assure consistency with Congressional intent. The Department interprets the "may include" language relating to these categories of infants over one year of age as indicating Congress' intent that the standards of the more precise definition should be consulted thoroughly in the evaluation of any issue of medical neglect regarding these infants. Thorough consideration of these standards will permit an informed judgment on whether these standards in fact constitute the most appropriate basis for evaluation of the medical neglect issue.

A number of other comments were made regarding the definition of "infant," particularly regarding inclusion in the term of the three categories of

infants over one year of age. Some commenters suggested that this provision be expanded, such as to include all children. Other commenters argued that the provision should be revised to prevent the inclusion of adults who, for example, have had a long-term disability since birth. Other commenters suggested specific inclusion of infants born alive after attempted abortions.

The definition of the term "infant" has not been revised in response to these suggestions. As explained above, the Congressional intent was that the standards of "medical neglect," rather than the more precisely articulated standards of the definition of "withholding of medically indicated treatment" apply to older children. The definition does make clear, however, that this shall not be construed to affect or limit any existing protections available under State laws regarding medical neglect of children over one year of age.

In addition, no revision is necessary to clarify that "infant" does not include older children and adults. The potential appropriateness of applying the more precisely stated standards of the definition of "withholding of medically indicated treatment" to certain infants over one year of age is still stated, as it was in the proposed rule and in the Conference Report, in terms of *infants* over one year of age. Older children and adults are not "infants over one year of age."

Finally, no change is necessary to clarify that infancy begins at the point of live birth, regardless of the circumstances of the live birth.

**4. The term "reasonable medical judgment"—**  
**§ 1340.15(b)(3)(ii).** Clause (b)(3)(ii) defines the term "reasonable medical judgment" used in the statutory definition of "withholding of medically indicated treatment." It is identical to the definition contained in the Conference Committee Report. H. Conf. Rep. No. 1038, 96th Cong., 2d Sess. 41 (1984).

#### *Section 1340.15(c) Eligibility*

We have made three additions to paragraph (c). First, many commenters believed that the name, title and telephone number of the person designated by the health care facility should be widely publicized, e.g., made known not only to the CPS agency but to all employees of the facility, to all parents of disabled children being treated in the facility, and to the community at large. We agree that in order for the CPS agency to carry out its responsibilities in paragraph (c)(2) of

this section for coordination and consultation with and receipt of prompt notification from individuals designated by and within appropriate health care facilities, it must at least know the name, title and telephone number of the designated person(s). Therefore, we have added a new paragraph (c)(3) to require that the CPS agency promptly contact each health care facility to obtain the name, title, and telephone number of the individual(s) designated by the facility as responsible for coordinating and consulting with and promptly notifying the State CPS agency of cases of known or suspected medical neglect. We have also required that, at least annually, this information be verified for accuracy.

With respect to the recommendation that we require hospitals to publicize the identification of the designated contact person with the hospital, this is not mandated because matters relating to the internal affairs of hospitals are beyond the scope of this regulation. However, we strongly encourage hospitals to make this information known within the facility as a way of assuring the protection of infants.

Essentially, paragraphs (c)(2)(i) and (ii) require the development of a coordination and communications system whose purpose is to assure that reports of suspected medical neglect are made at optimum speed. This communications system should operate whether the reports are made by the designated individual(s) or by any other person, and whether they are reports requesting CPS agency intervention and legal protection of an infant or reports requesting an initial CPS agency investigation. Under all these circumstances, rapid communication is of the utmost importance. Many letters from health care facilities indicated their plans that the designated individual will also assist the CPS agency staff and/or agency medical consultant in investigating a report and in facilitating other protective actions as needed.

We have not accepted the recommendation that the individual designated by the health care facility must, in all cases, be a member of the ICRC in order to assure that the CPS agency will receive reports of medical neglect. We do not have statutory authority to require ICRCs or similar committees and must adhere to the statutory requirement that the selection of the designated individual be made by the health care facility.

We have not accepted the recommendation that the name, title, and telephone number of persons designated by health care facilities be published annually in the newspaper of

general circulation in the geographic area served by the facility. Commenters appeared to believe that this would enable the public to report suspected instances of medical neglect to the hospital and the hospital could report it to the CPS agency. As we have stated above, anyone may report such cases directly to the CPS agency.

Second, we agree with the many commenters who recommended that the State CPS agency may, in some cases, need access to an infant's medical records and an opportunity to conduct an independent medical examination of the infant. We have added language to paragraph (c)(4) to require that as a part of the development of programs and/or procedures required in paragraph (c), the State child protective system must specify the procedures to be followed, consistent with State law, to carry out these actions. Paragraph (c)(4)(i) requires that procedures be developed, consistent with State law, to obtain access to medical records and/or other pertinent information when such access is necessary to assure an appropriate investigation of a report of medical neglect; paragraph (c)(4)(ii) requires that procedures be developed, consistent with State law, to obtain a court order for an independent medical examination of the infant, or otherwise effect such as examination in accordance with the process established under State law, when necessary to assure an appropriate resolution of a report of medical neglect.

These two additions elaborate on the requirement included in paragraph (3) of the proposed rule that the State's programs and/or procedures must conform with the requirements of section 4(b)(2) of the Act and § 1340.14 of the existing regulations. The Act and existing regulations require States to have procedures for adequate investigations and the provision of protective services. Existing regulations also make reference to medical examinations, the provisions of medical services, and related actions. See section 4(b)(2)(C) of the Act and § 1340.14(d), (f), and (h). These additions to paragraph (c)(4) of the final rule clarify that, in connection with this conformity requirement, the State's programs and/or procedures must make provision, consistent with State laws, for access to medical records and medical examinations when necessary. Although these actions will not be needed in every investigation of reported medical neglect, the specific identification of these procedures for use by agency staff increases the protections for disabled infants.

We have not adopted other recommendations for specific State agency investigative procedures or requirements, e.g., that the CPS agency must obtain a full consultation with the attending physicians and consultants and with an independent medical consultant prior to taking any enforcement action. We believe that any such special limitations would be inconsistent with Congressional intent that existing procedures and methods be utilized.

Other comments regarding § 1340.15(c) and our response are as follows:

*Designation of the CPS Agency.* A few commenters stated that it was not clear whether the intent of the regulations was to expand existing CPS agency programs to include the population defined or whether a parallel system was contemplated. One national professional social service organization recommended that States be mandated to establish an agency or agencies responsible for responding to reports of medical neglect of disabled infants and observed that child welfare agencies traditionally have given lower priority to handicapped children than mental health or mental retardation agencies, for example.

We believe it is the clear intent of Congress that States utilize their existing child protective service system to carry out this new responsibility. As indicated in the legislative history, however, States have the flexibility to determine the specific agency or agencies within their child protective service system to exercise the authority to institute legal proceedings on behalf of the disabled infants referenced in new clause (K) of section 4(b)(2) of the Act. (See H. Conf. Rept. 98-1038, pp 41-2.)

*Requirement for a new State statutory definition.* One commenter suggested that States be required to amend their State statutes to include the definition of "withholding of medically indicated treatment." Neither the statute nor the legislative history indicates that Congress intended that States enact this definition. Rather, the legislative history indicates Congress' understanding that States currently can receive reports concerning, and provide protection to, disabled infants with life-threatening conditions under present statutes and definitions. The documentation requirements in paragraph (d) are designed to be consistent with this understanding.

*Funding.* Several letters raised the matter of funding, not only for treatment costs of disabled infants but also for

CPS agency costs of additional staff, training, medical consultation, and development of procedures.

For FY 1985, Congress provided funds under the Act as follows: the basic State grant funds were increased from \$7 million to \$9 million and new funds totaling \$3 million were appropriated specifically to assist States to implement provisions related to section 4(b)(2)(K). In addition, HDS will make funds available under section 4(c)(2) of the Act to enable States to obtain training and technical assistance to carry out section 4(b)(2)(K) requirements. HDS also plans to award approximately \$2 million in "special grant" funds to assist States in implementing several priority child abuse prevention initiatives, including the provisions of section 4(b)(2)(K).

We do not have statutory authority and decline to require States to assume full financial responsibility for the maintenance and medical costs of all such disabled children.

*Waiver of effective date.* Paragraph (c)(4) of the NPRM (now paragraph (c)(5) of the final rule) stated that the eligibility requirements under § 1340.15 are effective October 9, 1985, the effective date established in the Child Abuse Amendments of 1984. One State social service agency questioned whether it was possible to meet the requirements by October 9, 1985 and asked about the availability of a waiver. The Act, however, does not permit the new waiver provision in section 4(b)(3) of the Act to apply to the section 4(b)(2)(K) requirements.

It should be noted that, consistent with standard agency practice, the final rule becomes effective 30 days from the date of publication in the Federal Register. However, as specified in paragraph (c)(5), the actual effective date for State agency programs and/or procedures to be in place is October 9, 1985. See section 4(b)(2)(K) of the Act and section 128 of Pub. L. 98-457.

*Increased Federal involvement and enforcement.* Because the Act so clearly places the responsibility for implementation on State CPS agencies, the Department does not see a need to establish a Federal hot-line for reporting suspected instances of medical neglect as requested by some commenters. Such a federal reporting system would not be the most effective in assuring the most prompt reporting to State or local CPS agencies. Again, we urge that interested persons note the telephone number of the local agency that receives reports of abuse and neglect.

*Implementation.* Section 4(c)(2)(A)(ii) of the Act requires the Department to provide for the establishment and operation of national and regional

information and resource clearinghouses for the purpose of providing the most current and complete information regarding medical treatment procedures and resources and community resources for the provision of services and treatment for disabled infants with life-threatening conditions. Many letters expressed strong support for these and other educational efforts that may be undertaken by the Department, particularly in the field of neonatology. Currently, we are in the process of determining how best to implement these clearinghouse requirements. Once they are in operation, we will inform the health care community, the State CPS agencies, and the national disability and right to life associations of procedures for accessing the information. Therefore, we do not believe it is necessary or appropriate to require that CPS agencies be responsible for informing health care facilities of the clearinghouses and access procedures. We also decline to require that the CPS agency consult with the clearinghouse (or the ICRC or similar committee consult with the clearinghouse) in every CPS agency investigation or ICRC review. We believe that these decisions are best made based on the circumstances of each individual case.

We understand that in several States the CPS agency and State and local medical associations and other organizations have begun to work together to implement reporting, coordination, and procedural development requirements. As a point of information, the American Bar Association is preparing a series of suggested legal procedures for States, hospitals, physicians, and prosecutors that will assure that investigations and decisions regarding disabled infants will comport with State and Federal law. The results of this project, funded by the National Center on Child Abuse and Neglect, are expected in late summer.

#### *Section 1340.15(d) Documentation.*

Regarding suggestions to amend paragraph (d), several commenters recommended that each hospital or health care facility be required to provide the State CPS agency with a written copy of its internal procedures for responding to internal reports of possible withholding of medically indicated treatment, including procedures for review by ICRCs or similar committees. Other commenters recommended requiring documentation that the State CPS agency routinely review the procedures used by health care facilities to ensure that both hospital personnel and patient families are fully informed of the existence and

functions of any ICRC or other relevant decision-making body established by or operating within the health care facility.

While we encourage hospitals and health care facilities to establish ICRCs, or similar committees, and necessary implementing policies and procedures, we do not believe it is appropriate to require CPS agency review of health care facility procedures or necessary as a documentation requirement. Regulation of internal management procedures of hospitals is not required in the Act, is beyond the scope of the State child protective service system, and thus, is not a proper matter to be dealt with in this rule. Another comment letter on the first point, however, suggested that useful training for CPS and hospital staff might include an introduction to the decision-making processes and procedures within each agency/organization.

#### *Section 1340.15(e) Regulatory construction.*

Paragraph (e) of the final rule sets forth two provisions regarding the impact of this section. Both of these provisions are based on similar provisions contained in section 127 of the Child Abuse Amendments of 1984.

Section 127(a) of the Amendments states:

No provision of this Act or any amendment made by the Act is intended to affect any right or protection under section 504 of the Rehabilitation Act of 1973.

Section 504 of the Rehabilitation Act is the Federal law that prohibits discrimination on the basis of handicap in programs and activities that receive Federal financial assistance. The HHS implementing regulations for section 504 are at 45 CFR Part 84.

Consistent with the statutory provision, paragraph (e)(1) states that no provisions of this regulation will effect any right, protection, procedure or requirement of the HHS regulations implementing section 504, 45 CFR Part 84.

This reference to Part 84 includes 45 CFR 84.55 (48 FR 1622, January 12, 1984), which establishes certain procedures relating to health care for handicapped infants. This regulation is based on the Department's interpretation that under section 504 of the Rehabilitation Act of 1973, health care providers may not, solely on the basis of present or anticipated physical or mental impairments of an infant, withhold treatment or nourishment from the infant who, in spite of such impairments, will medically benefit from the treatment or nourishment.

This regulation establishes certain procedural requirements and guidelines. First, it encourages hospitals to establish Infant Care Review Committees and provides a model committee. Second, it requires each State child protective services agency that receives Federal financial assistance to establish and maintain procedures to assure that the agency utilizes its full authority pursuant to State law to prevent instances of unlawful medical neglect of handicapped infants. Third, it establishes certain procedures relating to the Department's interpretation of its authority to conduct investigations of complaints of alleged discriminatory withholding of treatment from handicapped infants.

In June of 1984, a Federal court invalidated this regulation and enjoined further investigations of alleged discriminatory withholding of medical treatment from handicapped infants under section 504. *American Hospital Association v. Heckler*, et al., 585 F. Supp. 541 (S.D.N.Y.), *aff'd*, Nos. 84-6211, 84-6231 (2d Cir., Dec. 27, 1984), *petition for cert. filed* (Mar. 27, 1985). The Solicitor General, on behalf of the Department, has petitioned the Supreme Court to accept this case for decision.

Consistent with section 127(a) of the Child Abuse Amendments of 1984 and the clear legislative history establishing a Congressional "policy of neutrality" on this legal controversy concerning the applicability of section 504 to health care for handicapped infants, (see *Congressional Record*, Vol. 130, S-12392, daily edition September 28, 1984 (letter from Senators Hatch, Denton, Nickles, Kassebaum, Dodd, and Cranston)), paragraph (e) of this regulation makes clear that this regulation in no way affects the prior regulation under section 504.

The Department received a number of comments regarding this provision of the proposed rule. Some commenters argued that because of the enactment of the Child Abuse Amendments of 1984, HHS should discontinue its efforts to deal with the issue of medical care for disabled infants under the authority of section 504. Other commenters suggested that the Department take some action in the context of this regulation that would establish a direct interrelationship between 45 CFR 1340.15 and 45 CFR Part 84.

The Department believes that the efforts previously undertaken under the authority of section 504 were, and continue to be, necessary and appropriate, both as a matter of law and important national policy. There are substantial similarities between the section 504-based rule and the Child

Abuse Amendments of 1984. Both seek to assure the provision of medically indicated treatment, and incorporate into this goal respect for reasonable medical judgment, exclusion of futile treatments, and the like. Both approaches encourage the formation by hospitals of Infant Care Review Committees. Both approaches also recognize the need for State child protective services agencies to have specific procedures in place to deal with this form of medical neglect.

The major difference between the section 504-based approach and that of the Child Abuse Amendments of 1984 is that the former is implemented and enforced directly by the Federal government, whereas the latter, within the framework of the Child Abuse Prevention and Treatment Act, relies on State implementation and enforcement regarding individual instances of child abuse and neglect (which includes medical neglect, which, in turn, includes the withholding of medically indicated treatment from disabled infants with life threatening conditions). The section 504-based system, thus, is fully compatible with the Child Abuse Amendments of 1984 approach, but has the additional element of a compliance mechanism of direct Federal intervention as a "back-up" to the mechanisms of Infant Care Review Committees (where implemented) and child protective services systems.

The Department believes that the compatibility of these two authorities strongly suggests the utility of assuring, if both are operational, that they are fully coordinated. The Department's goal in pursuing, through litigation, reinstatement of the section 504-based authority, is to clear the way for action to forge such an effective interrelationship between the two authorities.

But the Department also believes that it would conflict with clearly stated Congressional intent to now undertake efforts to establish such an interrelationship in the context of this regulation. The legislative history of the Child Abuse Amendments clearly reflects a "policy of neutrality" concerning the section 504-based program. This final rule is fully in accord with this policy of neutrality. When the controversy regarding the section 504-based program is resolved in the context of the present litigation, the question of the most effective interrelationship between the two authorities will, if the Department's position prevails, then be addressed.

Other commenters questioned why the statutory formulation of disavowing any intent to "affect any right or

protection" under section 504 was expanded in the proposed rule to "affect any right, protection, procedure, or requirement" under the section 504 regulations. The reason is simply that whereas the statute establishes broadly-worded rights and protections, the regulation, in addition to fleshing out those rights and protections, establishes enforceable procedures and requirements. Thus, the transition from the statutory "policy of neutrality" to the regulatory "policy of neutrality" gives rise to the inclusion of these regulatory procedures and requirements. For example, if 45 CFR 84.55 (the section 504-based regulation that established certain procedures relating to health care for handicapped infants, but was invalidated by court order) is reinstated through further litigation, the procedures and requirements included in that section will be back in full force, unaffected by anything in this final rule. (It will then be for the Department to decide whether any changes in § 84.55 should be made to establish the most effective interrelationship between the two authorities.) Nothing more or less is intended or effectuated by paragraph (e)(1).

Paragraph (e)(2) is a new provision; it did not appear in the proposed rule. Similar to paragraph (e)(1), paragraph (e)(2) adopts, for purposes of regulatory construction, a provision corresponding to the Act's statement of statutory construction. Section 127(b) of the 1984 Amendments states:

No provision of this Act or any amendment made by this Act may be so construed as to authorize the Secretary or any other governmental entity to establish standards prescribing specific medical treatments for specific conditions, except to the extent that such standards are authorized by other laws.

In response to suggestions from commenters, paragraph (e)(2) adopts in the regulation the same rule of construction in identical operative terms.

#### Impact Analysis

A number of commenters raised questions about possible costs and related impacts of these rules. Most common was a concern that the definitions created by these rules might lead to large numbers of cases involving costly treatments. Others expressed concern as to who might pay for the costs of expensive treatment. A few pointed out that early treatment could avoid even more costly future treatment in some cases. And a number expressed concerns over administrative aspects of these rules, such as involvement of child abuse agencies or creation of infant care



review committees, which might create substantial administrative or legal costs, including disruption of existing arrangements.

Our view was, and remains, that these rules are not likely to result in an "annual effect on the economy of \$100 million or more", or a "significant economic impact on a substantial number" of health care providers, as provided in Executive Order 12291 and the Regulatory Flexibility Act, respectively. We have, as previously discussed, eliminated many of the definitions which gave rise to these concerns.

More importantly, the role of these rules in the larger context of medical care for infants is minor. Nonetheless, there are large costs involved in medical care of infants with life-threatening conditions and we agree that such costs are in the aggregate quite high. Our point was simply that the costs of a rule include only those costs which the rule itself causes, and aggressive and sometimes quite costly care for such infants is already an established and growing feature of the American health care system, quite apart from passage of the Child Abuse Amendments of 1984.

#### *The Larger Context of Newborn Care*

Early in this century, very large advances in public health measures and medical treatment led to significant reductions in infant mortality and a huge increase in life expectancy. In recent years such advances have continued. From 1970 to 1980, infant deaths per thousand live births dropped from 20 to 13. In the same period, fetal death rates dropped from 14 to 9 per 100,000 live births, and neonatal deaths from 15 to 8 per thousand live births. Similar reductions continue in the 1980's.

These recent advances reflect a variety of factors ranging from generally better nutrition, improved access to medical care both pre and post-partum, advances in diagnosis and treatment, new surgical techniques, and improved organization and management of infant care (as reflected in the creation of "tertiary care" hospital units specializing in intensive neonatal care). Many of these most recent advances do not involve saving the lives of normal infants brought to normal term—those infants were already surviving. Instead, we are now routinely saving infants who would surely have died even a decade ago.

Such improvements are costly. One recent study points out that the great majority of cases (80%) at a tertiary care center are relatively inexpensive (costing an average of \$8,000) but that most of the rest cost \$20,000 or more and

some involve hospital costs in the hundreds of thousands of dollars. Cost of hospital treatment for all these infants averages over \$20,000. Further, some of the infants who now survive will require costly services for the rest of their lives.

About 2½% of all births involve a significant physical defect of some kind. Most of these, however, are not life threatening and do not require immediate, major medical intervention. For example, club foot and cleft lip and palate are among the most common defects, as are a variety of heart defects. Children with birth defects affecting mental functions such as Down Syndrome or Spina Bifida, are much rarer. Indeed, the majority of the most expensive infant care cases come from the 40,000 infants born each year with birth weights of 1500 grams or less who are normal in other respects. In many cases their care will involve life and death decisions, and some fraction of these will pose ethical and medical dilemmas, such as whether a particular child can be treated effectively or without inhumane pain and suffering. The crucial point is that virtually all such infants now, and in the future will, receive "state of the art" medical care, often at great expense, quite irrespective of the new statutory provisions of this rule.

Similarly, the vast majority of these infants have their care paid for by private health insurance or, in a minority of cases, by the Medicaid program.

The Maternal and Child Health Block Grant and other State funds can also pay for care, at State discretion. Some small fraction of parents do not have sufficient insurance coverage, or will face subsequent costs not covered by any medical insurance. Again, these problems exist quite irrespective of the new statutory provision or this rule. (In response to a Congressional mandate, the Department is preparing a special report dealing with financial resources for care of disabled infants with life-threatening conditions.)

#### *Overall Effects of the Statute and Rule*

Against this backdrop, the statute and this rule can readily be placed in perspective. In some unknown but very small fraction of infants, medically indicated treatment may have been or would have been withheld but for the response to the "Baby Doe" cases (including not only the law and this rule, but also public awareness and prior rules). However, the great majority of expensive interventions would occur—and are already occurring at annual

costs in the range of several billion dollars—regardless of this change.

A considerable number of examples were used by commenters asserting that the statute or the rule would force inappropriate medical intervention, would force unnecessary and expensive evaluation by expert physicians and referral to expert facilities (e.g., neonatal tertiary care centers), or even inappropriate care for infants who were dying and for whom attempted treatment would be inhumane. Our response to these allegations is found elsewhere in this preamble. However, even if these assertions had all been correct, the examples involved rare conditions for which the potentially affected population is extremely small. Regardless, the changes made in this final rule should eliminate any doubt on this point.

Other commenters argued that the statute or rule would force use of truly experimental research procedures. Nothing in the statute or rule forces use of experimental procedures. To the contrary, medical ethics, federal regulations, and many State laws require that patients (or their parents) provide "informed consent" based on free choice and without coercion when physicians propose human experimentation. These rules do not require such experimentation.

Some commenters raised the possibility that the potential for legal action would lead to inappropriate "defensive" practices such as treatment of infants who were in fact dying and for whom attempted treatment would be inhumane. Such a possibility clearly exists, simply because human decisions are never perfect. Moreover, prudent persons would take care not to expose themselves to possible governmental or legal challenge and one way to do so is to pursue treatment in cases right on the "margin." However, substantial protection against such challenges arises from the deference provided reasonable medical judgment by the statute; it would be purely speculative to assume that any substantial number of inappropriate interventions would be caused by the statute. Regardless, we do not believe that anything in the rule requires or fosters such a result.

We cannot make a confident estimate as to just how many cases there may be in which either the statute or the rule would make a difference. No comments provided a sound basis for such estimates. However, only a very small fraction of births involve any serious question of survival. Of these, only a fraction would not be treated appropriately under current medical

practice, and would involve even a potential allegation of medical neglect. These considerations suggest that the potential number of cases which the statute might impact is not large. The number differentially affected by any particular wording of the rule itself would be far smaller. Taking into account typical costs of treatment for infants requiring intensive neonatal care, we conclude that the total costs due to the rule would not reach the thresholds of the Executive Order.

#### *Procedural, Legal, and Administrative Costs*

Similar reasoning applies to procedural and administrative costs. Here, we agree that the statute may make a larger relative difference, since it newly involves most States' child abuse agency and procedures, and encourages hospitals to create new Infant Care Review Committees. And here the relevant universe includes not only the cases where decisions are different, but also the potentially far larger number of cases undergoing review as well as the need to train staff and develop procedures.

With respect to the State agencies, real or suspected cases of abuse are already handled routinely. Infant care cases, though involving complex medical issues which may require the use of medical consultants, are no different in principle than other cases. And, as pointed out above, medical neglect is already covered by State laws. Federal grants to State agencies have increased from \$6.7 million in fiscal year 1984 to \$9 million plus \$3 million specifically for implementation of these new requirements in fiscal year 1985. While we do not have a quantitative estimate of incremental costs to State agencies at this time, we do not believe that a serious resource problem exists.

With the emphasis on the voluntary nature of the suggested guidelines for Infant Care Review Committees, most of the specific concerns as to disruption of or overlap with other hospital functions should be eliminated. Many hospitals already have some kind of review process, and the number of committees, though small, has increased in recent years. Others will elect to create a new process, similar if not identical to our guidelines. Because any such process is voluntary, costs are not caused by this rule. Regardless, in the light of extensive parental, medical, and other consultative involvement which almost invariably occurs already in extreme cases, net additional resources need not be large. This is particularly so because the clearinghouses which the

Department is funding will make obtaining expert medical advice and information relatively easy. Relative to both overall hospital revenues and resources devoted to intensive care of infants, these costs should be exceedingly low.

Legal and enforcement costs for cases in controversy will depend largely on the number of violations and suspected violations of the law. Very few cases should require legal action to assure needed treatment, particularly if Infant Care Review Committees or alternative arrangements perform their duties conscientiously.

#### *Conclusion*

In the light of the factors discussed above, the Department has determined that this is not a major rule under E.O. 12291, and certifies that a regulatory flexibility analysis is not required.

#### *Paperwork Reduction Act*

Under the Paperwork Reduction Act of 1980 the Department is required to submit to the Office of Management and Budget (OMB) for review and approval any information collection requirements in a proposed or final rule. The Department did submit § 1340.15 of the NPRM to OMB for their review under section 3504(h) of the Paperwork Reduction Act of 1980, and OMB assigned a control number (0980-0165). However, since the requirements are being revised by adding a new § 1340.15(c)(3) and expanding § 1340.15(c)(4), we are required to resubmit the information collection requirements contained in § 1340.15 to OMB for their approval. A notice will be published in the Federal Register when approval is obtained.

#### *List of Subjects in 45 CFR Part 1340*

Child welfare, Disabled, Family violence, Grants programs-health, Grant programs-social programs.

(Catalog of Federal Domestic Assistance Program No. 13.628, Child Abuse and Neglect Prevention and Treatment)

For the reasons set forth in the preamble, 45 CFR Part 1340 is amended as follows:

1. The Table of Contents is amended by adding a new section, § 1340.15 "Services and treatment for disabled infants," and a new listing "Appendix—Interpretative Guidelines Regarding 45 CFR 1340.15—Services and Treatment for Disabled Infants." As revised, the table of contents reads as follows.

## **PART 1340—CHILD ABUSE AND NEGLECT PREVENTION AND TREATMENT**

### **Subpart A—General Provisions**

- Sec.  
1340.1 Purpose and scope.  
1340.2 Definitions.  
1340.3 Applicability of Department-wide regulations.  
1340.4 Coordination requirements.

### **Subpart B—Grants to States**

- 1340.10 Purpose of this subpart.  
1340.11 Allocation of funds available.  
1340.12 Application process.  
1340.13 Approval of applications.  
1340.14 Eligibility requirements.  
1340.15 Services and treatment for disabled infants.

### **Subpart C—Discretionary Grants and Contracts**

- 1340.20 Confidentiality.

### **Appendix—Interpretative Guidelines Regarding 45 CFR 1340.15—Services and Treatment for Disabled Infants.**

2. The authority citation for Part 1340 is revised to read as follows:

Authority: Child Abuse Prevention and Treatment Act, Pub. L. 93-247, 88 Stat. 4; Pub. L. 95-266, 92 Stat. 205. Sections 609-610; Pub. L. 97-35, 95 Stat. 488; Pub. L. 98-457, 98 Stat. 1749 (42 U.S.C. 5101 et seq. and 42 U.S.C. 5101 note).

3. The introductory text of § 1340.14. Eligibility requirements is revised to read as follows:

#### **§ 1340.14 Eligibility requirements.**

In order for a State to qualify for an award under this subpart, the State must meet the requirements of § 1340.15 and satisfy each of the following requirements:

4. A new § 1340.15 is added to Subpart B—Grants to States, to read as follows:

#### **§ 1340.15 Services and treatment for disabled infants.**

(a) *Purpose.* The regulations in this section implement certain provisions of the Child Abuse Amendments of 1984, including section 4(b)(2)(K) of the Child Abuse Prevention and Treatment Act governing the protection and care of disabled infants with life-threatening conditions.

(b) *Definitions.* (1) The term "medical neglect" means the failure to provide adequate medical care in the context of the definitions of "child abuse and neglect" in section 3 of the Act and § 1340.2(d) of this part. The term "medical neglect" includes, but is not limited to, the withholding of medically indicated treatment from a disabled infant with a life-threatening condition

(2) The term "withholding of medically indicated treatment" means the failure to respond to the infant's life-threatening conditions by providing treatment (including appropriate nutrition, hydration, and medication) which, in the treating physician's (or physicians') reasonable medical judgment, will be most likely to be effective in ameliorating or correcting all such conditions, except that the term does not include the failure to provide treatment (other than appropriate nutrition, hydration, or medication) to an infant when, in the treating physician's (or physicians') reasonable medical judgment any of the following circumstances apply:

(i) The infant is chronically and irreversibly comatose;

(ii) The provision of such treatment would merely prolong dying, not be effective in ameliorating or correcting all of the infant's life-threatening conditions, or otherwise be futile in terms of the survival of the infant; or

(iii) The provision of such treatment would be virtually futile in terms of the survival of the infant and the treatment itself under such circumstances would be inhumane.

(3) Following are definitions of terms used in paragraph (b)(2) of this section:

(i) The term "infant" means an infant less than one year of age. The reference to less than one year of age shall not be construed to imply that treatment should be changed or discontinued when an infant reaches one year of age, or to affect or limit any existing protections available under State laws regarding medical neglect of children over one year of age. In addition to their applicability to infants less than one year of age, the standards set forth in paragraph (b)(2) of this section should be consulted thoroughly in the evaluation of any issue of medical neglect involving an infant older than one year of age who has been continuously hospitalized since birth, who was born extremely prematurely, or who has a long-term disability.

(ii) The term "reasonable medical judgment" means a medical judgment that would be made by a reasonably prudent physician, knowledgeable about the case and the treatment possibilities with respect to the medical conditions involved.

(c) *Eligibility Requirements.* (1) In addition to the other eligibility requirements set forth in this Part, to qualify for a grant under this section, a State must have programs, procedures, or both, in place within the State's child protective service system for the purpose of responding to the reporting of medical neglect, including instances of

withholding of medically indicated treatment from disabled infants with life-threatening conditions.

(2) These programs and/or procedures must provide for:

(i) Coordination and consultation with individuals designated by and within appropriate health care facilities;

(ii) Prompt notification by individuals designated by and within appropriate health care facilities of cases of suspected medical neglect (including instances of the withholding of medically indicated treatment from disabled infants with life-threatening conditions); and

(iii) The authority, under State law, for the State child protective service system to pursue any legal remedies, including the authority to initiate legal proceedings in a court of competent jurisdiction, as may be necessary to prevent the withholding of medically indicated treatment from disabled infants with life-threatening conditions.

(3) The programs and/or procedures must specify that the child protective services system will promptly contact each health care facility to obtain the name, title, and telephone number of the individual(s) designated by such facility for the purpose of the coordination, consultation, and notification activities identified in paragraph (c)(2) of this section, and will at least annually recontact each health care facility to obtain any changes in the designations.

(4) These programs and/or procedures must be in writing and must conform with the requirements of section 4(b)(2) of the Act and § 1340.14 of this part.

In connection with the requirement of conformity with the requirements of section 4(b)(2) of the Act and § 1340.14 of this part, the programs and/or procedures must specify the procedures the child protective services system will follow to obtain, in a manner consistent with State law:

(i) Access to medical records and/or other pertinent information when such access is necessary to assure an appropriate investigation of a report of medical neglect (including instances of withholding of medically indicated treatment from disabled infants with life threatening conditions); and

(ii) A court order for an independent medical examination of the infant, or otherwise effect such an examination in accordance with processes established under State law, when necessary to assure an appropriate resolution of a report of medical neglect (including instances of withholding of medically indicated treatment from disabled infants with life threatening conditions).

(5) The eligibility requirements contained in this section shall be effective October 9, 1985.

(d) *Documenting eligibility.* (1) In addition to the information and documentation required by and pursuant to § 1340.12(b) and (c), each State must submit with its application for a grant sufficient information and documentation to permit the Commissioner to find that the State is in compliance with the eligibility requirements set forth in paragraph (c) of this section.

(2) This information and documentation shall include:

(i) A copy of the written programs and/or procedures established by, and followed within, the State for the purpose of responding to the reporting of medical neglect, including instances of withholding of medically indicated treatment from disabled infants with life-threatening conditions;

(ii) Documentation that the State has authority, under State law, for the State child protective service system to pursue any legal remedies, including the authority to initiate legal proceedings in a court of competent jurisdiction, as may be necessary to prevent the withholding of medically indicated treatment from disabled infants with life-threatening conditions. This documentation shall consist of:

(A) A copy of the applicable provisions of State statute(s); or

(B) A copy of the applicable provisions of State rules or regulations, along with a copy of the State statutory provisions that provide the authority for such rules or regulations; or

(C) A copy of an official, numbered opinion of the Attorney General of the State that so provides, along with a copy of the applicable provisions of the State statute that provides a basis for the opinion, and a certification that the official opinion has been distributed to interested parties within the State, at least including all hospitals; and

(iii) Such other information and documentation as the Commissioner may require.

(e) *Regulatory construction.* (1) No provision of this section or part shall be construed to affect any right, protection, procedures, or requirement under 45 CFR Part 84, Nondiscrimination in the Basis of Handicap in Programs and Activities Receiving or Benefiting from Federal Financial Assistance.

(2) No provision of this section or part may be so construed as to authorize the Secretary or any other governmental entity to establish standards prescribing specific medical treatments for specific conditions, except to the extent that

such standards are authorized by other laws or regulations.

5. 45 CFR Part 1340 is further amended by adding at the end thereof the following Appendix:

**APPENDIX TO PART 1340—  
Interpretative Guidelines Regarding 45  
CFR 1340.15—Services and Treatment  
for Disabled Infants**

This appendix sets forth the Department's interpretative guidelines regarding several terms that appear in the definition of the term "withholding of medically indicated treatment" in section 3(3) of the Child Abuse Prevention and Treatment Act, as amended by section 121(3) of the Child Abuse Amendments of 1984. This statutory definition is repeated in § 1340.15(b)(2) of the final rule.

The Department's proposed rule to implement those provisions of the Child Abuse Amendments of 1984 relating to services and treatment for disabled infants included a number of proposed clarifying definitions of several terms used in the statutory definition. The preamble to the proposed rule explained these proposed clarifying definitions, and in some cases used examples of specific diagnoses to elaborate on meaning.

During the comment period on the proposed rule, many commenters urged deletion of these clarifying definitions and avoidance of examples of specific diagnoses. Many commenters also objected to the specific wording of some of the proposed clarifying definitions, particularly in connection with the proposed use of the word "imminent" to describe the proximity in time at which death is anticipated regardless of treatment in relation to circumstances under which treatment (other than appropriate nutrition, hydration and medication) need not be provided. A letter from the six principal sponsors of the "compromise amendment" which became the pertinent provisions of the Child Abuse Amendments of 1984 urged deletion of "imminent" and careful consideration of the other concerns expressed.

After consideration of these recommendations, the Department decided not to adopt these several proposed clarifying definitions as part of the final rule. It was also decided that effective implementation of the program established by the Child Abuse Amendments would be advanced by the Department stating its interpretations of several key terms in the statutory definition. This is the purpose of this appendix.

The interpretative guidelines that follow have carefully considered comments submitted during the comment period on the proposed rule. These guidelines are set forth and explained without the use of specific diagnostic examples to elaborate on meaning.

Finally, by way of introduction, the Department does not seek to establish these interpretative guidelines as binding rules of law, nor to prejudice the exercise of reasonable medical judgment in responding to specific circumstances. Rather, this guidance is intended to assist in interpreting the statutory definition so that it may be

rationally and thoughtfully applied in specific contexts in a manner fully consistent with the legislative intent.

1. *In general: the statutory definition of "withholding of medically indicated treatment."*

Section 1340.15(b)(2) of the final rule defines the term "withholding of medically indicated treatment" with a definition identical to that which appears in section 3(3) of the Act (as amended by section 121(3) of the Child Abuse Amendments of 1984).

This definition has several main features. First, it establishes the basic principle that all disabled infants with life-threatening conditions must be given medically indicated treatment, defined in terms of action to respond to the infant's life-threatening conditions by providing treatment (including appropriate nutrition, hydration or medication) which, in the treating physician's (or physicians') reasonable medical judgment, will be most likely to be effective in ameliorating or correcting all such conditions.

Second, the statutory definition spells out three circumstances under which treatment is not considered "medically indicated." These are when, in the treating physician's (or physicians') reasonable medical judgment:

- The infant is chronically and irreversibly comatose;
- The provision of such treatment would merely prolong dying, not be effective in ameliorating or correcting all of the infant's life-threatening conditions, or otherwise be futile in terms of survival of the infant; or
- The provision of such treatment would be virtually futile in terms of survival of the infant and the treatment itself under such circumstances would be inhumane.

The third key feature of the statutory definition is that even when one of these three circumstances is present, and thus the failure to provide treatment is not a "withholding of medically indicated treatment," the infant must nonetheless be provided with appropriate nutrition, hydration, and medication.

Fourth, the definition's focus on the potential effectiveness of treatment in ameliorating or correcting life-threatening conditions makes clear that it does not sanction decisions based on subjective opinions about the future "quality of life" of a retarded or disabled person.

The fifth main feature of the statutory definition is that its operation turns substantially on the "reasonable medical judgment" of the treating physician or physicians. The term "reasonable medical judgment" is defined in § 1340.15(b)(3)(ii) of the final rule, as it was in the Conference Committee Report on the Act, as a medical judgment that would be made by a reasonably prudent physician, knowledgeable about the case and the treatment possibilities with respect to the medical conditions involved.

The Department's interpretations of key terms in the statutory definition are fully consistent with these basic principles reflected in the definition. The discussion that follows is organized under headings that generally correspond to the proposed clarifying definitions that appeared in the proposed rule but were not adopted in the

final rule. The discussion also attempts to analyze and respond to significant comments received by the Department.

2. *The term "life-threatening condition."*

Clause (b)(3)(ii) of the proposed rule proposed a definition of the term "life-threatening condition." This term is used in the statutory definition in the following context:

[T]he term "withholding of medically indicated treatment" means the failure to respond to the infant's *life-threatening conditions* by providing treatment (including appropriate nutrition, hydration, and medication) which, in the treating physician's or physicians' reasonable medical judgment, will be most likely to be effective in ameliorating or correcting all such conditions [ , except that] . . . [Emphasis supplied].

It appears to the Department that the applicability of the statutory definition might be uncertain to some people in cases where a condition may not, strictly speaking, by itself be life-threatening, but where the condition significantly increases the risk of the onset of complications that may threaten the life of the infant. If medically indicated treatment is available for such a condition, the failure to provide it may result in the onset of complications that, by the time the condition becomes life-threatening in the strictest sense, will eliminate or reduce the potential effectiveness of any treatment. Such a result cannot, in the Department's view, be squared with the Congressional intent.

Thus, the Department interprets the term "life-threatening condition" to include a condition that, in the treating physician's or physicians' reasonable medical judgment, significantly increases the risk of the onset of complications that may threaten the life of the infant.

In response to comments that the proposed rule's definition was potentially overinclusive by covering any condition that one could argue "may" become life-threatening, the Department notes that the statutory standard of "the treating physician's or physicians' reasonable medical judgment" is incorporated in the Department's interpretation, and is fully applicable.

Other commenters suggested that this interpretation would bring under the scope of the definition many irreversible conditions for which no corrective treatment is available. This is certainly not the intent. The Department's interpretation implies nothing about whether, or what, treatment should be provided. It simply makes clear that the criteria set forth in the statutory definition for evaluating whether, or what, treatment should be provided are applicable. That is just the start, not the end, of the analysis. The analysis then takes fully into account the reasonable medical judgment regarding potential effectiveness of possible treatments, and the like.

Other comments were that it is unnecessary to state any interpretation because reasonable medical judgment commonly deems the conditions described as life-threatening and responds accordingly. HIS agrees that this is common practice followed under reasonable medical judgment, just as all the standards incorporated in the

statutory definition reflect common practice followed under reasonable medical judgment. For the reasons stated above, however, the Department believes it is useful to say so in these interpretative guidelines.

**3. The term "treatment" in the context of adequate evaluation.**

Clause (b)(3)(ii) of the proposed rule proposed a definition of the term "treatment." Two separate concepts were dealt with in clause (A) and (B), respectively, of the proposed rule. Both of these clauses were designed to ensure that the Congressional intent regarding the issues to be considered under the analysis set forth in the statutory definition is fully effectuated. Like the guidance regarding "life-threatening condition," discussed above, the Department's interpretations go to the applicability of the statutory analysis, not its result.

The Department believes that Congress intended that the standard of following reasonable medical judgment regarding the potential effectiveness of possible courses of action should apply to issues regarding adequate medical evaluation, just as it does to issues regarding adequate medical intervention. This is apparent Congressional intent because Congress adopted, in the Conference Report's definition of "reasonable medical judgment," the standard of adequate knowledge about the case and the treatment possibilities with respect to the medical condition involved.

Having adequate knowledge about the case and the treatment possibilities involved is, in effect, step one of the process, because that is the basis on which "reasonable medical judgment" will operate to make recommendations regarding medical intervention. Thus, part of the process to determine what treatment, if any, "will be most likely to be effective in ameliorating or correcting" all life-threatening conditions is for the treating physician or physicians to make sure they have adequate information about the condition and adequate knowledge about treatment possibilities with respect to the condition involved. The standard for determining the adequacy of the information and knowledge is the same as the basic standard of the statutory definition:

reasonable medical judgment. A reasonably prudent physician faced with a particular condition about which he or she needs additional information and knowledge of treatment possibilities would take steps to gain more information and knowledge by, quite simply, seeking further evaluation by, or consultation with, a physician or physicians whose expertise is appropriate to the condition(s) involved or further evaluation at a facility with specialized capabilities regarding the condition(s) involved.

Thus, the Department interprets the term "treatment" to include (but not be limited to) any further evaluation by, or consultation with, a physician or physicians whose expertise is appropriate to the condition(s) involved or further evaluation at a facility with specialized capabilities regarding the condition(s) involved that, in the treating physician's or physicians' reasonable medical judgment, is needed to assure that decisions regarding medical intervention are based on

adequate knowledge about the case and the treatment possibilities with respect to the medical conditions involved.

This reflects the Department's interpretation that failure to respond to an infant's life-threatening conditions by obtaining any further evaluations or consultations that, in the treating physician's reasonable medical judgment, are necessary to assure that decisions regarding medical intervention are based on adequate knowledge about the case and the treatment possibilities involved constitutes a "withholding of medically indicated treatment." Thus, if parents refuse to consent to such a recommendation that is based on the treating physician's reasonable medical judgment that, for example, further evaluation by a specialist is necessary to permit reasonable medical judgments to be made regarding medical intervention, this would be a matter for appropriate action by the child protective services system.

In response to comments regarding the related provision in the proposed rule, this interpretative guideline makes quite clear that this interpretation does not deviate from the basic principle of reliance on reasonable medical judgment to determine the extent of the evaluations necessary in the particular case. Commenters expressed concerns that the provision in the proposed rule would intimidate physicians to seek transfer of seriously ill infants to tertiary level facilities much more often than necessary, potentially resulting in diversion of the limited capacities of these facilities away from those with real needs for the specialized care, unnecessary separation of infants from their parents when equally beneficial treatment could have been provided at the community or regional hospital, inappropriate deferral of therapy while time-consuming arrangements can be affected, and other counterproductive ramifications. The Department intended no intimidation, prescription or similar influence on reasonable medical judgment, but rather, intended only to affirm that it is the Department's interpretation that the reasonable medical judgment standard applies to issues of medical evaluation, as well as issues of medical intervention.

**4. The term "treatment" in the context of multiple treatments.**

Clause (b)(3)(iii)(B) of the proposed rule was designed to clarify that, in evaluating the potential effectiveness of a particular medical treatment or surgical procedure that can only be reasonably evaluated in the context of a complete potential treatment plan, the "treatment" to be evaluated under the standards of the statutory definition includes the multiple medical treatments and/or surgical procedures over a period of time that are designed to ameliorate or correct a life-threatening condition or conditions. Some commenters stated that it could be construed to require the carrying out of a long process of medical treatments or surgical procedures regardless of the lack of success of those done first. No such meaning is intended.

The intent is simply to characterize that which must be evaluated under the standards of the statutory definition, not to imply anything about the results of the evaluation. If parents refuse consent for a particular

medical treatment or surgical procedure that by itself may not correct or ameliorate all life-threatening conditions, but is recommended as part of a total plan that involves multiple medical treatments and/or surgical procedures over a period of time that, in the treating physician's reasonable medical judgment, will be most likely to be effective in ameliorating or correcting all such conditions, that would be a matter for appropriate action by the child protective services system.

On the other hand, if, in the treating physician's reasonable medical judgment, the total plan will, for example, be virtually futile and inhumane, within the meaning of the statutory term, then there is no "withholding of medically indicated treatment." Similarly, if a treatment plan is commenced on the basis of a reasonable medical judgment that there is a good chance that it will be effective, but due to a lack of success, unfavorable complications, or other factors, it becomes the treating physician's reasonable medical judgment that further treatment in accord with the prospective treatment plan, or alternative treatment, would be futile, then the failure to provide that treatment would not constitute a "withholding of medically indicated treatment." This analysis does not divert from the reasonable medical judgment standard of the statutory definition; it simply makes clear the Department's interpretation that the failure to evaluate the potential effectiveness of a treatment plan as a whole would be inconsistent with the legislative intent.

Thus, the Department interprets the term "treatment" to include (but not be limited to) multiple medical treatments and/or surgical procedures over a period of time that are designed to ameliorate or correct a life-threatening condition or conditions.

**5. The term "merely prolong dying."**  
Clause (b)(3)(v) of the proposed rule proposed a definition of the term "merely prolong dying," which appears in the statutory definition. The proposed rule's provision stated that this term "refers to situations where death is imminent and treatment will do no more than postpone the act of dying."

Many commenters argued that the incorporation of the word "imminent," and its connotation of immediacy, appeared to deviate from the Congressional intent, as developed in the course of the lengthy legislative negotiations, that reasonable medical judgments can and do result in nontreatment decisions regarding some conditions for which treatment will do no more than temporarily postpone a death that will occur in the near future, but not necessarily within days. The six principal sponsors of the compromise amendment also strongly urged deletion of the word "imminent."

The Department's use of the term "imminent" in the proposed rule was not intended to convey a meaning not fully consonant with the statute. Rather, the Department intended that the word "imminent" would be applied in the context of the condition involved, and in such a context, it would not be understood to specify

a particular number of days. As noted in the preamble to the proposed rule, this clarification was proposed to make clear that the "merely prolong dying" clause of the statutory definition would not be applicable to situations where treatment will not totally correct a medical condition but will give a patient many years of life. The Department continues to hold to this view.

To eliminate the type of misunderstanding evidenced in the comments, and to assure consistency with the statutory definition, the word "imminent" is not being adopted for purposes of these interpretative guidelines.

The Department interprets the term "merely prolong dying" as referring to situations where the prognosis is for death and, in the treating physician's (or physicians') reasonable medical judgment, further or alternative treatment would not alter the prognosis in an extension of time that would not render the treatment futile.

Thus, the Department continues to interpret Congressional intent as not permitting the "merely prolong dying" provision to apply where many years of life will result from the provision of treatment, or where the prognosis is not for death in the near future, but rather the more distant future. The Department also wants to make clear it does not intend the connotations many commenters associated with the word "imminent." In addition, contrary to the impression some commenters appeared to have regarding the proposed rule, the Department's interpretation is that reasonable medical judgments will be formed on the basis of knowledge about the condition(s) involved, the degree of inevitability of death, the probable effect of any potential treatments, the projected time period within which death will probably occur, and other pertinent factors.

6. *The term "not be effective in ameliorating or correcting all of the infant's life threatening conditions" in the context of a future life-threatening condition.*

Clause (b)(3)(vi) of the proposed rule proposed a definition of the term "not be effective in ameliorating or correcting all the infant's life-threatening conditions" used in the statutory definition of "withholding of medically indicated treatment."

The basic point made by the use of this term in the statutory definition was explained in the Conference Committee Report:

Under the definition, if a disabled infant suffers from more than one life-threatening condition and, in the treating physician's or physicians' reasonable medical judgment, there is no effective treatment for one of those conditions, then the infant is not covered by the terms of the amendment (except with respect to appropriate nutrition, hydration, and medication) concerning the withholding of medically indicated treatment. H. Conf. Rep. No. 1038, 98th Cong., 2d Sess. 41 (1980).

This clause of the proposed rule dealt with the application of this concept in two contexts: first, when the nontreatable condition will not become life-threatening in the near future, and second, when humaneness makes palliative treatment medically indicated.

With respect to the context of a future life-threatening condition, it is the Department's

interpretation that the term "not be effective in ameliorating or correcting all of the infant's life-threatening conditions" does not permit the withholding of treatment on the grounds that one or more of the infant's life-threatening conditions, although not life-threatening in the near future, will become life-threatening in the more distant future.

This clarification can be restated in the terms of the Conference Committee Report excerpt, quoted just above, with the italicized words indicating the clarification, as follows: Under the definition, if a disabled infant suffers from more than one life-threatening condition and, in the treating physician's or physicians' reasonable medical judgment, there is no effective treatment for one of these conditions *that threatens the life of the infant in the near future*, then the infant is not covered by the terms of the amendment (except with respect to appropriate nutrition, hydration, and medication) concerning the withholding of medically indicated treatment; *but if the nontreatable condition will not become life-threatening until the more distant future, the infant is covered by the terms of the amendment.*

Thus, this interpretative guideline is simply a corollary to the Department's interpretation of "merely prolong dying," stated above, and is based on the same understanding of Congressional intent, indicated above; that if a condition will not become life-threatening until the more distant future, it should not be the basis for withholding treatment.

Also for the same reasons explained above, the word "imminent" that appeared in the proposed definition is not adopted for purposes of this interpretative guideline. The Department makes no effort to draw an exact line to separate "near future" from "more distant future." As noted above in connection with the term "merely prolong dying," the statutory definition provides that it is for reasonable medical judgment, applied to the specific condition and circumstances involved, to determine whether the prognosis of death, because of its nearness in time, is such that treatment would not be medically indicated.

7. *The term "not be effective in ameliorating or correcting all life-threatening conditions" in the context of palliative treatment.*

Clause (b)(3)(iv)(B) of the proposed rule proposed to define the term "not be effective in ameliorating or correcting all life-threatening conditions" in the context where the issue is not life-saving treatment, but rather palliative treatment to make a condition more tolerable. An example of this situation is where an infant has more than one life-threatening condition, at least one of which is not treatable and will cause death in the near future. Palliative treatment is available, however, that will, in the treating physician's reasonable medical judgment, relieve severe pain associated with one of the conditions. If it is the treating physician's reasonable medical judgment that this palliative treatment will ameliorate the infant's *overall* condition, taking all individual conditions into account, even though it would not ameliorate or correct *each* condition, then this palliative treatment is medically indicated. Simply put, in the

context of ameliorative treatment that will make a condition more tolerable, the term "not be effective in ameliorating or correcting *all* life-threatening conditions" should not be construed as meaning *each and every* condition, but rather as referring to the infant's *overall* condition.

HHS believes Congress did not intend to exclude humane treatment of this kind from the scope of "medically indicated treatment." The Conference Committee Report specifically recognized that "it is appropriate for a physician, in the exercise of reasonable medical judgment, to consider that factor [humaneness] in selecting among effective treatments." H. Conf. Rep. No. 1038, 98th Cong., 2d Sess. 41 (1984). In addition, the articulation in the statutory definition of circumstances in which treatment need not be provided specifically states that "appropriate nutrition, hydration, and medication" must nonetheless be provided. The inclusion in this proviso of medication, one (but not the only) potential palliative treatment to relieve severe pain, corroborates the Department's interpretation that such palliative treatment that will ameliorate the infant's overall condition, and that in the exercise of reasonable medical judgment is humane and medically indicated, was not intended by Congress to be outside the scope of the statutory definition.

Thus, it is the Department's interpretation that the term "not be effective in ameliorating or correcting all of the infant's life-threatening conditions" does not permit the withholding of ameliorative treatment that, in the treating physician's or physicians' reasonable medical judgment, will make a condition more tolerable, such as providing palliative treatment to relieve severe pain, even if the overall prognosis, taking all conditions into account, is that the infant will not survive.

A number of commenters expressed concerns about some of the examples contained in the preamble of the proposed rule that discussed the proposed definition relating to this point, and stated that, depending on medical complications, exact prognosis, relationships to other conditions, and other factors, the treatment suggested in the examples might not necessarily be the treatment that reasonable medical judgment would decide would be most likely to be effective. In response to these comments, specific diagnostic examples have not been included in this discussion, and this interpretative guideline makes clear that the "reasonable medical judgment" standard applies on this point as well.

Other commenters argued that an interpretative guideline on this point is unnecessary because reasonable medical judgment would commonly provide ameliorative or palliative treatment in the circumstances described. The Department agrees that such treatment is common in the exercise of reasonable medical judgment, but believes it useful, for the reasons stated, to provide this interpretative guidance.

8. *The term "virtually futile".*

Clause (b)(3)(vii) of the proposed rule proposed a definition of the term "virtually futile" contained in the statutory definition.

The context of this term in the statutory definition is:

[T]he term "withholding of medically indicated treatment" . . . does not include the failure to provide treatment (other than appropriate nutrition, hydration, or medication) to an infant when, in the treating physician's or physicians' reasonable medical judgment, . . . the provision of such treatment would be *virtually futile* in terms of the survival of the infant and the treatment itself under such circumstances would be inhumane. Section 3(3)(C) of the Act [emphasis supplied].

The Department interprets the term "virtually futile" to mean that the treatment is highly unlikely to prevent death in the near future.

This interpretation is similar to those offered in connection with "merely prolong dying" and "not be effective in ameliorating or correcting all life-threatening conditions" in the context of a future life-threatening condition, with the addition of a characterization of likelihood that corresponds to the statutory word "virtually." For the reasons explained in the discussion of "merely prolong dying," the word "imminent" that was used in the proposed rule has not been adopted for purposes of this interpretative guideline.

Some commenters expressed concern regarding the words "highly unlikely," on the grounds that such certitude is often medically impossible. Other commenters urged that a distinction should be made between generally utilized treatments and experimental treatments. The Department does not believe any special clarifications are needed to respond to these comments. The basic standard of reasonable medical judgment applies to the term "virtually futile." The Department's interpretation does not suggest an impossible or unrealistic standard of certitude for any medical judgment. Rather, the standard adopted in the law is that there be a "reasonable medical judgment." Similarly, reasonable medical judgment is the standard for evaluating potential treatment possibilities on the basis of the actual circumstances of the case. HHS does not believe it would be helpful to try to establish distinctions based on characterizations of the degree of general usage, extent of validated efficacy data, or other similar factors. The factors considered in the exercise of reasonable medical judgment, including any factors relating to human subjects experimentation standards, are not disturbed.

9. *The term "the treatment itself under such circumstances would be inhumane."*

Clause (b)(3)(viii) of the proposed rule proposed a definition of the term "the treatment itself under such circumstances would be inhumane," that appears in the statutory definition. The context of this term in the statutory definition is that it is not a "withholding of medically indicated treatment" to withhold treatment (other than appropriate nutrition, hydration, or medication) when, in the treating physician's reasonable medical judgment, "the provision of such treatment would be virtually futile in terms of the survival of the infant and the treatment itself under such circumstances would be inhumane." § 3(3)(C) of the Act.

The Department interprets the term "the treatment itself under such circumstances would be inhumane" to mean the treatment itself involves significant medical contraindications and/or significant pain and suffering for the infant that clearly outweigh the very slight potential benefit of the treatment for an infant highly unlikely to survive. (The Department further notes that the use of the term "inhumane" in this context is not intended to suggest that consideration of the humaneness of a particular treatment is not legitimate in any other context; rather, it is recognized that it is appropriate for a physician, in the exercise of reasonable medical judgment, to consider that factor in selecting among effective treatments.)

Other clauses of the statutory definition focus on the expected *result* of the possible treatment. This provision of the statutory definition adds a consideration relating to the *process* of possible treatment. It recognizes that in the exercise of reasonable medical judgment, there are situations where, although there is some slight chance that the treatment will be beneficial to the patient (the potential treatment is considered *virtually futile*, rather than futile), the potential benefit is so outweighed by negative factors relating to the process of the treatment itself that, under the circumstances, it would be inhumane to subject the patient to the treatment.

The Department's interpretation is designed to suggest the factors that should be taken into account in this difficult balance. A number of commenters argued that the interpretation should permit, as part of the evaluation of whether treatment would be inhumane, consideration of the infant's future "quality of life."

*The Department strongly believes such an interpretation would be inconsistent with the statute. The statute specifies that the provision applies only where the treatment would be "virtually futile in terms of the survival of the infant," and the "treatment itself under such circumstances would be inhumane." (Emphasis supplied.)* The balance is clearly to be between the very slight chance that treatment will allow the infant to survive and the negative factors relating to the process of the treatment. These are the circumstances under which reasonable medical judgment could decide that the treatment itself would be inhumane.

Some commenters expressed concern about the use of terms such as "clearly outweigh" in the description of this balance on the grounds that such precision is impractical. Other commenters argued that this interpretation could be construed to mandate useless and painful treatment. The Department believes there is no basis for these worries because "reasonable medical judgment" is the governing standard. The interpretative guideline suggests nothing other than application of this standard. What the guideline does is set forth the Department's interpretation that the statute directs the reasonable medical judgment to considerations relating to the slight chance of survival and the negative factors regarding the process of treatment and to the balance between them that would support a conclusion that the treatment itself would be inhumane.

Other commenters suggested adoption of a statement contained in the Conference Committee Report that makes clear that the use of the term "inhumane" in the statute was not intended to suggest that consideration of the humaneness of a particular treatment is not legitimate in any other context. The Department has adopted this statement as part of its interpretative guideline.

#### 10. *Other terms.*

Some commenters suggested that the Department clarify other terms used in the statutory definition of "withholding of medically indicated treatment," such as the term "appropriate nutrition, hydration or medication" in the context of treatment that may not be withheld, notwithstanding the existence of one of the circumstances under which the failure to provide treatment is not a "withholding of medically indicated treatment." Some commenters stated, for example, that very potent pharmacologic agents, like other methods of medical intervention, can produce results accurately described as accomplishing no more than to merely prolong dying, or be futile in terms of the survival of the infant, or the like, and that, therefore, the Department should clarify that the proviso regarding "appropriate nutrition, hydration or medication" should not be construed entirely independently of the circumstances under which other treatment need not be provided.

The Department has not adopted an interpretative guideline on this point because it appears none is necessary. As noted above in the discussion of palliative treatment, the Department recognizes that there is no absolutely clear line between medication and treatment other than medication that would justify excluding the latter from the scope of palliative treatment that reasonable medical judgment would find medically indicated, notwithstanding a very poor prognosis.

Similarly, the Department recognizes that in some circumstances, certain pharmacologic agents, not medically indicated for palliative purposes, might, in the exercise of reasonable medical judgment, also not be indicated for the purpose of correcting or ameliorating any particular condition because they will, for example, merely prolong dying. However, the Department believes the word "appropriate" in this proviso of the statutory definition is adequate to permit the exercise of reasonable medical judgment in the scenario referred to by these commenters.

At the same time, it should be clearly recognized that the statute is completely unequivocal in requiring that all infants receive "appropriate nutrition, hydration, and medication," regardless of their condition or prognosis.

Dated: March 29, 1985.

Dorcas R. Hardy,  
Assistant Secretary for Human Development Services.

Approved: April 5, 1985.

Margaret M. Heckler,

Secretary.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of Human Development Services**

**Services and Treatment for Disabled Infants; Model Guidelines for Health Care Providers To Establish Infant Care Review Committees**

**AGENCY:** Office of Human Development Services, HHS.

**ACTION:** Model Guidelines for Health Care Providers to Establish Infant Care Review Committees.

**SUMMARY:** These are model guidelines to encourage the establishment within health care facilities, especially facilities with tertiary level neonatal care units, of committees for the purposes of educating hospital personnel and families of disabled infants with life-threatening conditions, recommending institutional policies and guidelines concerning the withholding of medically indicated treatment (including appropriate nutrition, hydration, and medication) from such infants, and offering counsel and review in cases involving disabled infants with life-threatening conditions. The publication of these model guidelines is required by section 124(b) of the Child Abuse Amendments of 1984, Pub. L. 98-457.

**FOR FURTHER INFORMATION CONTACT:** Jay Olson at (202) 245-2859.

**SUPPLEMENTARY INFORMATION:** These model guidelines are being issued in accordance with section 124(b) of the Child Abuse Amendments of 1984, Pub. L. 98-457. Pursuant to this section, these guidelines encourage hospitals that provide health care to infants to establish Infant Care Review Committees (ICRCs).

As required by the Act, interim model guidelines were published for public comment December 10, 1984, 45 FR 48170, and a 60-day comment period was provided. The Department received many comments regarding the interim model guidelines. These comments have been carefully considered. The appendix to the model guidelines is an analysis of significant comments received during the comment period.

The principles, policies and procedures set forth in this model represent the Department's best judgments, informed by a careful review of the comments submitted, regarding the most effective formulation for review committees. The Department encourages hospitals that provide care to infants, especially facilities with tertiary level neonatal care units, to establish ICRC's, and to consider fully

the provisions set forth in the Department's suggested model.

**Infant Care Review Committees—Model Guidelines**

**I. Introduction**

In the past several years there has been substantially heightened public attention to issues relating to treatment and services for disabled infants. This increased attention has fueled, and has been fueled by, controversy regarding existing patterns of medical care decision-making and various proposals and initiatives to affect those patterns.

Amidst this controversy, one proposal that has gained widespread support is the establishment of hospital-based committees as the forum and focal point for efforts to assure that medical treatment decisions are informed, thoughtful and consistent with proper medical standards. The thrust of this proposal was well articulated in the March 1983 report of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research:

The Commission concludes that hospitals that care for seriously ill newborns should have explicit policies on decisionmaking procedures in cases involving life-sustaining treatment for these infants. . . . Such policies should provide for internal review whenever parents and the attending physician decide that life-sustaining therapy should be foregone. . . .

Such a review could serve several functions and the review mechanism may vary accordingly. First, it can verify that the best information available is being used. Second, it can confirm the propriety of a decision that providers and parents have reached or confirm that the range of discretion accorded to the parents is appropriate. Third, it can resolve disputes among those involved in a decision, if necessary, by siding with one party or another in a dispute. Finally, it can refer cases to public agencies (child protection services, probate courts, or prosecuting attorneys) when appropriate.

Subsequent to this report, a broad range of medical and health associations endorsed the concept of hospital review committees to deal with issues relating to medical care for disabled infants. These associations include the American Academy of Pediatrics, the National Association of Children's Hospitals and Related Institutions, the American Hospital Association, the American Medical Association, the Catholic Health Association, the Federation of American Hospitals, the American College of Hospital Administrators, the American College of Physicians, the American Nurses Association, and others. Some of these associations, as well as other

organizations, have developed model guidelines for committees.

Most recently, this proposal was strongly endorsed by the United States Congress in Pub. L. 98-457, the "Child Abuse Amendments of 1984." In addition to provisions in that legislation requiring State child protective services agencies to establish procedures to prevent the "withholding of medically indicated treatment from disabled infants with life-threatening conditions," the law made it a matter of national policy to encourage the establishment of hospital committees. More specifically, this law, which was supported by an extraordinary coalition of medical associations and disability and other advocacy organizations, requires that:

[T]he Secretary [of Health and Human Services] shall publish . . . model guidelines to encourage the establishment within health care facilities of committees which would serve the purposes of educating hospital personnel and families of disabled infants with life-threatening conditions, recommending institutional policies and guidelines concerning the withholding of medically indicated treatment . . . from such infants, and offering counsel and review in cases involving disabled infants with life-threatening conditions.

Pub. L. No. 98-457, section 124.

The Department of Health and Human Services fully endorses the recommendation of the President's Commission and the adoption by Congress of the policy of encouraging the formation of these committees. What follows are the HHS model guidelines for the establishment and operation of Infant Care Review Committees.

The guidelines are purely advisory. They are not mandatory in any way. The establishment of an ICRC is not required by any Federal law, regulation, administrative policy, or condition of participation in any Federal program. Similarly, if a hospital chooses to establish an Infant Care Review Committee, there is no requirement of any kind that follows this model. In addition, the Department offers no legal, regulatory or administrative inducements or rewards for establishing an ICRC and/or following this model. Moreover, no legal responsibilities of the hospital, including those related to child protective services activities of the State, are removed or reduced by the establishment of an ICRC and/or adoption of this model.

Rather, the Department's recommendation that hospitals establish Infant Care Review Committees and consider the elements of this model is based solely on the Department's firm agreement with the various



endorsements, listed above, of the hospital review committee concept and the Department's judgment that the elements of this model are important to make the committee effective. The Department thus strongly encourages hospitals that provide care to infants, especially those with tertiary level neonatal care units, to establish Infant Care Review Committees, and to consider the provisions of these model guidelines.

## II. Establishment and Purpose

HHS recommends that the hospital establish an Infant Care Review Committee (ICRC) or join with one or more other hospitals to create a joint ICRC. The purposes and functions of the Infant Care Review Committee are:

1. To educate hospital personnel and families of disabled infants with life-threatening conditions;
2. To recommend institutional policies and guidelines concerning the withholding of medically indicated treatment from disabled infants with life-threatening conditions; and
3. To offer counsel and review in cases involving disabled infants with life-threatening conditions.

## III. Membership and Administration

**A. Membership of ICRC.**—The Department strongly recommends that the ICRC membership consist of individuals from varied disciplines and perspectives. A multi-disciplinary approach is important for the ICRC to have sufficient expertise to supply and evaluate all pertinent information to assist the committee in effectively carrying out its functions. The committee size should be large enough to represent diverse perspectives, but not so large as to hinder effectiveness. The Department recommends that the ICRC consists of at least the following core members:

1. A practicing physician (e.g., a pediatrician, a neonatologist, or a pediatric surgeon),
2. A practicing nurse,
3. A hospital administrator,
4. A social worker,
5. A representative of a disability group,
6. A lay community member, and
7. A member of the facility's organized medical staff, who shall serve as chairperson.

Consistent with the multi-disciplinary approach, the ICRC should consider supplementing the core membership with other permanent members, or through other formal methods, such as designating certain individuals as "advisors" to the ICRC, or through informal or ad hoc involvement. Among

those that could be considered for such supplementation are: a representative of the clergy, a representative of the legal community (i.e., an attorney or judge), physicians with particular specialties pertinent to a policy or particular case under consideration, individuals with knowledge of issues affecting children and the families of children with certain disabilities, and other individuals with knowledge and perspectives valuable to effective action on particular functions and activities of the ICRC.

**B. Administration of the ICRC.**—The Department makes the following recommendations regarding administration of the ICRC:

1. The hospital should provide staff support for the ICRC, including legal counsel. The ICRC should meet on a regular basis or as recommended below in connection with review of specific cases. It should adopt or recommend to the appropriate hospital official or body such administrative policies as terms of office and quorum requirements.

2. The ICRC should recommend procedures to ensure that both hospital personnel and patient families are fully informed of the existence and functions of the ICRC and its availability to meet on a 24-hour basis.

3. The ICRC should carefully inform itself of all pertinent legal requirements and procedures, including pertinent provisions of State law requiring a report or notification to the appropriate State child protective services agency of known or suspected instances of medical neglect, including the withholding of medically indicated treatment (including appropriate nutrition, hydration, and medication) from disabled infants with life-threatening conditions and related procedures of the State agency.

4. The ICRC should maintain records of all of its deliberations and summary descriptions of specific cases considered and the disposition of those cases. Such records should be kept in accordance with institutional policies on confidentiality of medical information. They should be made available to appropriate government agencies, or upon court order, or as otherwise required by law.

## IV. Educational Activities

**A. Basic Functions.**—The ICRC should act as a resource to hospital personnel and families of disabled infants with life-threatening conditions to provide current and complete information concerning medical treatment procedures and resources in the hospital and in other hospitals with which the hospital has referral agreements or to which patients may otherwise be

referred. The ICRC should also act as a resource concerning available community services which may be needed for the provision of services and treatment for disabled infants with life-threatening conditions.

**B. Specific Activities.**—In order to carry out these functions, the ICRC should determine and make available to hospital personnel and families of disabled infants information regarding:

1. Available national and regional information and resource clearinghouses that provide pertinent information, such as the Computerized Handicapped Assistance Information Network ("CHAIN");

2. Facilities and agencies in the community and area that provide treatment and services, such as rehabilitative services and ongoing support, to disabled infants and children and their families;

3. Public and private programs and activities in the community and area, including organizations and associations that provide counselling and support for disabled children and their families and, when appropriate, adoption placement counselling and services; and

4. Other informational materials regarding medical treatment and rehabilitation procedures and resources and support activities.

## V. Policy Development

**A. Basic Policy.** In recommending institutional policies and guidelines, the basic policy should be to prevent the withholding of medically indicated treatment from disabled infants with life-threatening conditions. The definitions set forth below offer guidance regarding the substance of this basic policy. The definition of the term "withholding of medically indicated treatment" is that set forth in the Child Abuse Amendments of 1984 and specifically referenced by Congress in the provision of that law that encourages establishment of hospital committees.

1. The term "withholding of medically indicated treatment" means the failure to respond to the infant's life-threatening conditions by providing treatment (including appropriate nutrition, hydration, and medication) which, in the treating physician's or physicians' reasonable medical judgment, will be most likely to be effective in ameliorating or correcting all such conditions, except that the term does not include the failure to provide treatment (other than appropriate nutrition, hydration, or medication) to an infant when, in the treating

physician's or physicians' reasonable medical judgment—

(a) The infant is chronically and irreversibly comatose;

(b) The provision of such treatment would—

(1) Merely prolong dying.

(2) Not be effective in ameliorating or correcting all of the infant's life-threatening conditions, or

(3) Otherwise be futile in terms of the survival of the infant; or

(c) The provision of such treatment would be virtually futile in terms of the survival of the infant and the treatment itself under such circumstances would be inhumane.

2. The following are definitions of terms used in the definition of "medically indicated treatment."

(a) The term "infant" means an infant less than one year of age. The reference to one year of age does not imply that treatment should be changed or discontinued when an infant reaches one year of age or to affect or limit proper standards of medical care for children over one year of age. In addition to their applicability to infants less than one year of age, the standards set forth in the definition of "withholding of medically indicated treatment" in paragraph (1) should be consulted thoroughly in the evaluation of any issue of medical treatment involving an infant older than one year of age who has been continuously hospitalized since birth, who was born extremely prematurely, or who has a long-term disability.

(b) The term "reasonable medical judgment" means medical judgment that would be made by a reasonably prudent physician, knowledgeable about the case and the treatment possibilities with respect to the medical conditions involved.

3. HHS recommends that ICRC's also carefully review the Department's interpretative guidelines regarding terms used in the definition of "withholding of medically indicated treatment" (set forth in paragraph (1)) that appear in the appendix to the final rule implementing the provisions of the Child Abuse Amendments of 1984. The final rule will be codified at 45 CFR 1340.15, and the appendix will appear as an appendix to 45 CFR Part 1340.

**B. Development of Specific Policies and Guidelines.** 1. The Department recommends that the ICRC develop prospectively and recommend for adoption by the hospital institutional policies concerning the withholding or withdrawal of medical treatment for infants with life-threatening conditions. These could include guidelines for management of specific types of cases

or diagnoses that are likely to be seen in that facility and might present dilemmas in medical management, and procedures to be followed in such recurring circumstances. The hospital, upon recommendation of the ICRC, may wish to require attending physicians to notify the ICRC of the presence of the facility of an infant with a diagnosis specified by the ICRC.

2. In recommending these policies and guidelines, the ICRC should consult with medical and other authorities on issues involving treatment and services for disabled individuals, e.g., neonatologists, pediatric surgeons, and county and city agencies and disability advocacy organizations which provide services for the disabled. It should also consult with appropriate committees of the medical staff, to ensure that the ICRC policies and guidelines build on existing staff by-laws, rules and regulations concerning consultations and staff membership requirements. The ICRC should also make itself available to assist the hospital in its activities to inform and educate hospital staff on the policies and guidelines adopted by the hospital.

3. The Department recommends that the ICRC review existing procedures used by the hospital and/or recommend the adoption of new procedures to facilitate effective coordination and cooperation between the hospital and the State child protective services system with respect to that system's activities relating to preventing the withholding of medically indicated treatment from disabled infants with life-threatening conditions. These procedures should include: (a) Provisions regarding the responsibilities under State law for the hospital, physicians and other medical professionals to report to the child protective services agency suspected instances of medical neglect (including the withholding of medically indicated treatment from disabled infants with life-threatening conditions); (b) provisions regarding the designation of individuals (hereafter referred to as "designated individuals") within the hospital (who may, but need not be, members of the ICRC) to serve the liaison function with the child protective services agency in connection with the agency's programs and procedures for responding to the reporting of medical neglect (including the withholding of medically indicated treatment from disabled infants with life-threatening conditions); (c) procedures for coordination between the designated individuals and the ICRC in response to consultations initiated by the agency; (d) procedures for prompt notification by

the designated individuals to the agency of suspected medical neglect (including instances of withholding of medically indicated treatment from disabled infants with life-threatening conditions); (e) procedures to facilitate compliance by the hospital and medical personnel of any and all other requirements of State law relating to activities of the child protective services system in connection with the system's programs and/or procedures concerning the withholding of medically indicated treatment from disabled infants with life-threatening conditions; and (f) such other procedures as may be appropriate to facilitate effective coordination and consultation between the hospital and medical personnel and the child protective services agency.

#### *VI. Council and Review in Specific Cases*

A major function of the Infant Care Review Committee is to review and offer counsel in specific cases involving disabled infants with life-threatening conditions. Set forth below are the procedures HHS recommends for carrying out this function in two contexts. The first context is prospective review of cases regarding infant patients concerning whom treatment decisions are being made or about whom there are otherwise issues of present or future treatment. The second context is retrospective review of cases concerning which there is then no issue of present or future treatment.

**A. Prospective Review and Counsel.** In addition to regularly scheduled meetings, emergency ICRC meetings should take place under specified circumstances to permit review of individual cases. The hospital should, to the extent possible, require in each case that life-sustaining treatment be continued, until the ICRC can review the case and provide advice.

1. Because of the need for prompt review and counsel, emergency ICRC meetings may have to be convened within 24 hours (or less if indicated). Such meetings should be convened when there is disagreement between the family of an infant and the infant's physician as to the withholding or withdrawal of treatment, when a preliminary decision to withhold or withdraw life-sustaining treatment has been made in certain categories of cases identified by the ICRC in its specific policies, when there is disagreement between members of the hospital's medical and/or nursing staffs, or when otherwise appropriate.

2. Such emergency ICRC meetings should take place upon the request of

any member of the ICRC or hospital staff or parent or guardian of the infant. The ICRC should have procedures to preserve the confidentiality of the identity of persons making such requests, and such persons should be protected from reprisal. When appropriate, the ICRC or a designated member should inform the requesting individual of the ICRC's recommendation.

3. The ICRC may provide for telephone and other forms of review when the timing and nature of the case, as identified in policies developed by the ICRC, make the convening of an emergency meeting impracticable.

4. Emergency meetings should be open to the affected parties. When appropriate to ensure informed discussion, a physician(s) experienced in the evaluation and treatment of the relevant disability(ies) or life-threatening condition(s) should be invited to attend. The ICRC should ensure that the interests of the parents, the physician, and the child are fully considered; that family members have been fully informed of the patient's condition and prognosis and that appropriate counselling services have been made available to them; and that they have been provided with a listing which describes, and any further information they need to facilitate their access to, the services furnished by parent support groups and public and private agencies in the geographic vicinity to infants with conditions such as that before the ICRC.

5. HHS recommends that to ensure a comprehensive evaluation of all options and factors pertinent to the committee's deliberations, the chairperson designate one member of the ICRC to act, in connection with that specific case, as "special advocate" for the infant. The special advocate should seek to ensure that all considerations in favor of the provision of additional treatment are fully evaluated and considered by the ICRC. The chairperson should make clear to all participants and observers that the designation of a "special advocate" is a standard procedural practice to ensure thorough deliberation, and that it does not imply that any other participant is less concerned about the welfare of the infant.

6. In cases in which there is disagreement on treatment between a physician and an infant's family, and the family wishes to continue life-sustaining treatment, the ICRC should counsel that the family's wishes be carried out, for as long as the family wishes, unless such treatment is medically contraindicated. When there is physician/family disagreement and the family refuses

consent to life-sustaining treatment, and the ICRC, after due deliberation, in accordance with the policies, principles and procedures set forth above, agrees with the family, the ICRC should counsel that the treatment (other than appropriate nutrition, hydration, and medication) be withheld. When there is physician/family disagreement and the family refuses consent, but the ICRC disagrees with the family, the ICRC should counsel that the hospital board or appropriate official immediately refer the matter to an appropriate court or child protective services agency in accordance with applicable reporting requirements and related procedures, and that every effort be made to continue treatment, preserve the status quo, and prevent worsening of the infant's condition until such time as the court or agency renders a decision or takes other appropriate action. The ICRC should also follow this procedure in cases in which the family and physician agree that life-sustaining treatment should be withheld or withdrawn, but the ICRC disagrees.

**B. Retrospective Record Review.** For the purpose of monitoring the effectiveness of policies and procedures of the hospital and ICRC, the Department recommends that the ICRC, at its regularly-scheduled meeting, review all records involving withholding or termination of medical or surgical treatment to infants consistent with hospital policies developed by the ICRC, unless the case was previously before the ICRC for emergency review. If the ICRC finds that a deviation was made from the institutional policies in a given case, it should conduct a review and report the findings to appropriate hospital personnel for appropriate action. If the ICRC finds that revisions to institutional policies are necessary or appropriate, it should develop appropriate recommendations.

Approved:

Dated: April 1, 1985.

C. Everett Koop,  
Surgeon General, U.S. Public Health Service.

Dated: March 29, 1985.

Dorcas R. Hardy,  
Assistant Secretary for Human Development Services.

Dated: April 5, 1985.

Margaret M. Heckler,  
Secretary.

#### Appendix

Analysis of Model Guidelines for Health Care Providers to Establish Infant Care Review Committees and Comments Submitted Regarding Interim Model Guidelines.

#### 1. Introduction

Section I of the model guidelines includes introductory information to lay the foundation for the Department's recommendation that hospitals establish ICRC's. The Department believes the factors identified are particularly pertinent with respect to hospitals with tertiary level neonatal care units, and thus especially recommends ICRC's for such hospitals.

A number of comments submitted in connection with the interim model guidelines expressed concern that although the interim guidelines were identified as advisory, the format, structure and wording could give the impression that they were mandatory or that there were some legal, regulatory or administrative enducements associated with them. Some commenters expressed the view that the interim guidelines were too inflexible to accommodate diversity among hospitals, and suggested that a different type of model, such as one that identified significant concepts and suggested alternative approaches, would be better. Some commenters who indicated misgivings about the potential effectiveness of ICRC's suggested the Department soften the degree to which it recommends ICRC's.

In response to these concerns, the Department has revised some of the introductory material to clarify that the guidelines are *purely* advisory, that establishment of an ICRC and/or adoption of this model does not relieve any legal responsibilities of the hospital (including responsibilities relating to State child protective services activities), and that every hospital is completely free to adopt, adapt, or ignore the model. In short, these model guidelines are accompanied by neither carrots nor sticks.

The comments, however, have not shaken the Department's belief that ICRC's can be very valuable in advancing the objective of assuring the provision of appropriate medical care to disabled infants with life-threatening conditions, and that the Department's legislative charge is to develop a model that includes those principles and procedures the Department believes are important for ICRC's to realize their potential efficacy. The Department recognizes that realization of this potential will require not only dedication to the concept of ICRC's, but also persistence in evaluating and sharing information about experience with ICRC's, including those that are based on different models, to facilitate

informed judgments about possible refinements and improvements.

With all of these considerations in mind, the introductory information continues to recommend strongly ICRC's, especially for hospitals with tertiary level neonatal care units, and to urge careful consideration of all elements of this model.

## 2. Establishment and Purpose

This section of the model guidelines lists the purposes and functions of the ICRC in the terms set forth in the Act. It is not materially changed from the provision included in the interim guidelines. Some commenters suggested a different name for the committee, such as "Infant Bioethics Committee" or some other term that emphasized the committee's function of considering questions of medical ethics. The Department has not changed the title of the committee because nothing in the authorizing statute corroborates the notion that the focus of the committee should be "medical ethics," at least to the extent that term connotes considerations different than those involved in evaluating medical treatment possibilities that "will be most likely to be effective in ameliorating or correcting" all life-threatening conditions. Thus, the Department continues to believe the title "Infant Care Review Committee" best characterizes the purposes and functions of the committee.

## 3. Memberships of the ICRC

Section III-A of the model guidelines recommends the membership of the ICRC. The Department received numerous comments regarding this section of the interim guidelines. Some commenters suggested that no particular membership should be specified to permit more flexibility, such as an option to limit membership to the hospital's medical staff. Some commenters suggested that more specific qualifications and credentials should be required for membership, such as requiring that the nurse be a registered professional nurse, that the physician be a neonatologist, that the social worker have certain credentials, that the representative of a disability group have certain training or professional standing, and the like. Some commenters urged that members from other disciplines should be represented, such as a special education teacher, an ethicist, a family physician, and the like. Some commenters proposed that the ICRC should have a more formal mechanism for advocacy for disabled infants, such as the inclusion of a trained child advocate

appointed by an independent entity, the inclusion of a permanent "special advocate," or the like. Some commenters recommended that the ICRC should have a higher number or percentage of physicians and other medical professionals.

In response to these comments, the Department has made several changes to the model from what appeared in the interim guidelines. First, the model now identifies the key concept that should be the basis for decisions on membership: That the ICRC should consist of individuals from varied disciplines and perspectives. Second, the model now identifies a recommended core membership that is designed to implement this multi-disciplinary approach, and provides further suggestions for supplementing the core membership on a permanent or other formal or informal basis. Third, a representative of the legal profession has been dropped from the recommended core membership and included in the list of individuals to be considered for supplementation of the core membership because legal counsel for the ICRC is elsewhere (in section III-B-1) provided.

The Department believes these revisions strike an appropriate and workable balance between the need for a multi-disciplinary approach and the unworkability of forming a committee with a representative of every discipline, perspective or group that might have a more refined or more general or more expert or different point of view. The use of one or more of the suggested mechanisms for supplementing the disciplines and perspectives represented by the core membership reinforces the prime concept of a multi-disciplinary approach without making the ICRC unworkable.

The Department rejects the argument that no committee membership should be recommended because the Department believes adoption of the multi-disciplinary approach is vital to the effectiveness of the ICRC. However, although the Department recommends the selection of highly qualified individuals, the Department believes it unnecessary to specify certain educational or other credentials for members.

In addition, the Department has not adopted the various suggestions for formal advocacy for disabled infants. In judicial proceedings involving a neglected child, it is vital that the child have a skilled, independent advocate. For this reason, section 4(b)(2)(C) of the Federal Child Abuse Prevention and Treatment Act requires that a guardian

ad litem be appointed to represent the child in all such proceedings. But the Department believes the functions of the ICRC are much different from those of a court. A court makes a binding decision on the rights and responsibilities of the parties before it. In contrast, the function of the ICRC is, as set forth in the statutory directive for HHS to issue these guidelines, to educate hospital personnel and families, to recommend institutional policies, and to "offer counsel and review" in specific cases. Therefore, the Department believes it is neither necessary nor appropriate to replicate a guardian ad litem function on the ICRC.

## 4. Administration of the ICRC

Section III-B of the guidelines addresses several matters regarding the administration of the ICRC. Paragraph two calls for procedures to ensure that both hospital personnel and patient families are fully informed of the existence and functions of the ICRC and its availability on a 24-hour basis. Some commenters suggested this information also be widely publicized to the public to facilitate requests from persons other than hospital personnel and patient families for review of specific cases. The Department has not adopted this suggestion. Although child protective services agencies permit any person to make reports of suspected child abuse and neglect, including suspected medical neglect involving the withholding of medically indicated treatment from disabled infants with life-threatening conditions, HHS does not view the functions of the ICRC in the same light. The ICRC is not designed to be an arm of the State child protective services system, and thus procedures appropriate for that system are not necessarily appropriate for the ICRC. The purpose of the ICRC is to assist the hospital in assuring the provision of medical care and related service that are consistent with good medical standards and the obligations of the hospital and medical personnel under applicable law. Rather than replicate procedures of the child protective services system, the guidelines, in section V-B, call for the ICRC to develop recommended policies to facilitate effective coordination and cooperation between the hospital and the child protective services system.

Paragraph three calls for the ICRC to inform itself of pertinent legal requirements and procedures, including those relating to child protective services agency activities. In response to comments, a sentence in the interim guidelines that called for the ICRC to

consult with the child protective services agency has been deleted from this model. A new provision has been added to section V-B to deal with the issue of the relationship between the ICRC and the State child protective services agency.

Paragraph four relates to maintenance and confidentiality of records. Some commenters suggested a more limited provision concerning the confidentiality of records than the provision in the interim model guideline that records be made available to appropriate government agencies, or upon court order, or as otherwise required by law. Other commenters proposed more detailed record-keeping requirements, such as maintaining taped or detailed written minutes of all meetings, and a provision for regular transmittal of these materials to the State child protective services agency. HHS has made no material change in this provision. Matters regarding the confidentiality of medical records and the availability of those records to courts, administrative agencies, and the like, are already specifically dealt with under the law. The Department does not believe it appropriate to try to establish a new or different set of standards for this purpose. The Department has also not adopted more detailed recordkeeping standards of the ICRC. HHS does not believe the standard procedures applicable to judicial proceedings or certain administrative activities, which may require transcripts or other detailed records, are necessary or appropriate in relation to the purposes and functions of ICRC's.

Some commenters suggested a provision be added to the guidelines to provide immunity or indemnification for the ICRC and its members against any potential civil liability for actions taken by the ICRC. The Department has no power to grant immunity, nor does HHS have sufficient familiarity with the pertinent provisions of State law that might have a bearing on the issue to recommend that hospitals and ICRC's

take any particular action on this question. Hospitals and ICRC's that believe it appropriate to explore this question further should consult with their counsel.

#### 5. Educational Activities

Section IV of the guidelines outlines recommended ICRC activities relating to its function of educating hospital personnel and families of disabled infants with life-threatening conditions. In response to public comments, one change has been made from the interim guidelines, adding that, when appropriate, the ICRC make available to hospital personnel and families information concerning adoption placement counselling and services in the community.

No changes have been made in response to some comments that the educational activities listed exceed the capabilities of ICRC's or would require a full-time staff member, or to other comments that the activities listed are duplicative or other activities already being performed by hospital staff. The Department believes the activities listed are not excessive, and nothing in the model suggests that an ICRC is supposed to isolate itself from the ongoing activities of various units of the hospital that normally engage in social services counselling and assistance, in-house educational activities, the provision of information to patients and their families, and the like.

#### 6. Policy Development

Section V of the model guidelines outlines activities relating to the function of the ICRC to recommend institutional policies and guidelines concerning the withholding of medically indicated treatment from disabled infants with life-threatening conditions. Section V-A sets forth the basic policy that should guide the ICRC.

Some commenters sought clarification of what they viewed as an inconsistency between the reference at some places in the interim guidelines to "developing"

policies and guidelines and the reference at other places in the model to "recommending" policies and guidelines. The statutory provision that directed the Secretary to issue these model guidelines refers to this purpose of the ICRC as "recommending institutional policies and guidelines." Nothing in the interim guidelines was intended to deviate from this standard, and several changes have been made in section V to avoid any lack of clarity on this point.

Some comments suggested that the statement of the ICRC's "basic policy," stated in the model as "to prevent the withholding of medically indicated treatment from disabled infants with life-threatening conditions," was too narrow in that it dealt with only one function of the ICRC, and that it should be made more general. The Department, in making no material change to this statement, is guided by the statutory language, which describes the "policy" purpose of the committee as "recommending institutional policies and guidelines concerning the withholding of medically indicated treatment (as that term is defined in clause (3) of section 3 of the Act . . .)" from disabled infants with life-threatening conditions. The incorporation of the definition of the term "withholding of medically indicated treatment" contained in section 3 of the Child Abuse Prevention and Treatment Act, as amended by the Child Abuse Amendments of 1984, and the context of the 1984 amendments make clear that policies "regarding" the withholding of medically indicated treatment should be guided by the principle that policies and guidelines should be designed "to prevent" such withholding. Thus, the Department believes that in developing recommended institutional policies and guidelines, the guiding principle should be to prevent the withholding of medically indicated treatment from disabled infants with life-threatening conditions.

Paragraph one of section V-A sets forth the statutory definition of "withholding of medically indicated treatment," which, as noted above, is incorporated into the statutory directive that the Secretary issue these model guidelines. Paragraph two sets forth two definitions of terms contained in the basic statutory definition. These two definitions are taken from the Conference Committee Report on the Child Abuse Amendments of 1984.

The interim model guidelines also included provisions relating to definitions of other terms used in the definition of "withholding of medically indicated treatment," provisions that were identical to definitions included in the proposed regulation to implement the Child Abuse Amendments of 1984. In response to comments regarding these provisions in the proposed rule and interim model guidelines, they were not adopted in the final rule, and have similarly not been adopted in these final model guidelines.

The appendix to the final rule, however, includes the Department's interpretative guidelines regarding terms used in the statutory definition. It also includes a detailed discussion of these interpretations, as well as the comments received by the Department. The information contained in the appendix to the final rule may assist the ICRC in understanding dimensions of the definition of "withholding of medically indicated treatment." The Department recommends in paragraph (3) that the ICRC carefully review the appendix to the final rule.

#### *7. Development of Specific Policies and Guidelines*

Section V-B of the model guidelines recommends specific activities of the ICRC relating to its function of recommending institutional policies and guidelines. A new paragraph (three) has been added to the material that appeared in the interim model guidelines. Paragraph three is included in response to many comments that urged revisions or clarifications to the model in connection with the issue of the interaction among: (a) The ICRC; (b) the child protective services system; and (c) other individuals within the hospital

with responsibilities relating to the child protective services system's activities.

This issue involves several factors. First, under the Child Abuse Amendments of 1984, State child protective services agencies must, as a condition of eligibility for Federal assistance, have in place certain programs and/or procedures "for the purpose of responding to the reporting of medical neglect (including instances of withholding of medically indicated treatment from disabled infants with life-threatening conditions)." Second, these programs and/or procedures must provide for "coordination and consultation with individuals designated by and within" hospitals. Third, they must also provide for "prompt notification" by such individuals of suspected medical neglect, including instances of withholding of medically indicated treatment from disabled infants with life-threatening conditions. And fourth, other provisions of State law relating to child protective services activities, including reporting obligations of medical personnel and hospitals, investigative authorities, responsibilities and procedures, and the like, are applicable to reports of suspected medical neglect, including instances of withholding of medically indicated treatment from disabled infants with life-threatening conditions.

The issue, thus, is how the ICRC should relate to these various responsibilities and activities. The model does not provide a specific answer because the procedures implemented in particular hospitals should take into account the pertinent provisions of State law and local agency procedure, which are not necessarily uniform throughout the United States. The model, therefore, calls on the ICRC to look into these matters and to develop, in connection with its other policy development activities, recommended procedures for the hospital to implement in order to facilitate effective coordination with the child protective services system, as well as coordination between the ICRC and other hospital officials in relation to matters of interest to the child protective services agency in connection with the withholding of medically indicated

treatment for disabled infants with life-threatening conditions.

It should be noted that the model does not specifically call for the ICRC chairperson or members to be the "designated individuals" for the liaison function with the child protective services agency. Such a designation, however, might best facilitate effective coordination and cooperation with the child protective services agency. On the other hand, some hospitals might prefer to incorporate this into existing coordination mechanisms applicable to the full range of potential child abuse and neglect issues. Therefore, although there are strong reasons for assigning the ICRC chairperson or other member the liaison function, the model does not specifically call for this, but rather recommends that the ICRC itself address this and the related issues.

A number of other comments were received concerning this section of the interim model dealing with development of specific policies and guidelines. Some commenters argued that the activities called for in the interim model guidelines were excessively prescriptive and would lead to unreasonable interference in medical management. The Department intended nothing unusual or overly prescriptive in suggesting that ICRC's develop recommended guidelines for management of particular types of cases and procedures to be followed in recurring circumstances. Some revisions to the language have been adopted to clarify this intent.

Other commenters suggested that the model provide that all specific policies developed by the ICRC for recommended adoption by the hospital be submitted to and approved by the State child protective services agency prior to adoption by the hospital. This suggestion has not been adopted because the Department does not believe the legislative directive to the Secretary to issue these model guidelines can be construed to support a concept that ICRC's are to be directly regulated by child protective services agencies or that they are to be functionaries of the agencies.

### 8. Prospective Review and Counsel

Section VI-A sets forth recommended procedures for the ICRC to carry out its function of offering prospective review and counsel in cases involving disabled infants with life-threatening conditions. Paragraphs 1 and 2 outline circumstances under which emergency ICRC meetings should be convened. Because of the need for prompt review and counsel, HHS recommends that the ICRC have the capability to convene an emergency meeting within 24 hours (or less if indicated) to consider such cases.

The Department received many comments regarding these paragraphs. Some commenters suggested that in order to avoid unnecessary or excessive meetings, the model not call for emergency meetings when requested by any member of the ICRC or hospital staff or parent or guardian of the infant, and that instead the model should recommend a screening process, such as for the chairperson to decide whether a meeting is appropriate. Other commenters suggested that the model also call for emergency meetings when requested by any interested person on the grounds that some cases that should be reviewed may not come to the attention of the ICRC under the criteria included in the model. HHS has not adopted either suggestion. The Department believes that until each ICRC has gained some experience, it may not adequately be able to judge whether review of certain cases covered by the criteria would actually be unnecessary. Similarly, HHS is unaware at this stage of ICRC experience of the likelihood that cases which should be reviewed would not involve at least one of the seven criteria listed in paragraphs one and two (including when it is "otherwise appropriate"). In the absence of some basis to believe it is necessary, HHS is disinclined to suggest that medical professionals and other ICRC members deal with cases that do not meet any of the criteria upon request of any person with the same urgency and priority as cases that do meet the criteria.

Some commenters suggested that convening meetings on 24-hours notice would be impracticable. Other commenters suggested that the provision in the model (paragraph three) permitting telephone conferences or other methods of review when convening an emergency meeting is impracticable should be deleted because they lack the effectiveness of in-person meetings. HHS has made no material revision to the model in this regard. The Department continues to recommend that ICRC's respond to cases that meet

the criteria identified on an urgent (24 hours, or less if necessary) basis, and to recognize that the timing and nature of a case may in certain circumstances make in-person meetings impracticable.

Two additional provisions have been added, in response to comments, to the version of paragraph four that appeared in the interim guidelines. First, consistent with one of the revisions to section III-A (regarding membership of the ICRC), the model suggests that a physician(s) experienced in the evaluation and treatment of the relevant disability(ies) or life-threatening condition(s) be invited, if appropriate, to the emergency meeting. The second revision recommends the ICRC ensure that parents receive appropriate counselling, as well as full information regarding the patient's condition and prognosis.

The Department received many comments regarding the recommendation in paragraph five that the chairperson designate a "special advocate" to ensure that all considerations in favor of additional treatment are fully considered. Some commenters suggested that the model specify that the "special advocate" must be a trained child advocate independent of the hospital. Other commenters suggested this provision be deleted because it would create an adversarial relationship; it implies other ICRC members are less concerned about the infant's best interests; and it will confuse parents to have someone advocating treatment in every case, even if unjustified.

HHS has made no material change in response to these comments. As noted above in the discussion of section III-A (regarding membership of the ICRC), HHS does not believe the guardian ad litem model is necessary or appropriate for the ICRC. Thus, the model does not recommend formal representation for the infant by a trained advocate. On the other hand, the Department continues to believe that the "special advocate" feature will contribute to a comprehensive evaluation of all options and factors pertinent to the committee's deliberations. It should be noted that the model does not call for the "special advocate" to be a "treatment advocate," if nontreatment is appropriate and permissible under applicable standards. Rather, the special advocate is to ensure that all considerations in favor of additional treatment are fully *evaluated and considered* by the ICRC. This does not require that the special advocate argue, just for the sake of argument, with the judgments of other ICRC members who have fully evaluated and

considered all pertinent factors and who believe nontreatment is not inappropriate. It should also be noted that the model guidelines call for the chairperson to make clear to all participants and observers that the designation of a "special advocate" is a standard procedural practice to ensure thorough deliberation, and that it does not imply that any other participant is less concerned about the welfare of the infant.

Paragraph six suggests the kinds of recommendations the ICRC should make in certain circumstances. Some commenters urged revisions to the wording of this paragraph which they thought could be construed as recommending that the ICRC was to act as a decision maker, rather than perform the function of "offering counsel and review," as it is stated in the legislative provision that required the Secretary to issue these model guidelines. No deviation from the statutory concept of "offering counsel and review" was intended, and several revisions to the wording have been made to avoid any misunderstandings in this regard.

A number of commenters recommended revised or additional provisions in the model guidelines relating to the interaction between the ICRC and the child protective services agency. Some commenters suggested that if life-sustaining treatment is not being provided, the ICRC should make a report to the child protective services agency at the conclusion of its meetings, regardless of whether the ICRC believes "medically indicated treatment" is being withheld, in order to permit an independent review by the agency. Some commenters suggested a similar report as soon as the ICRC learns of a case that it intends to review, in order to permit simultaneous review by the agency or monitoring by the agency of the ICRC's deliberations. Some commenters suggested that consideration by the ICRC should permit a delay in reporting to the child protective services agency.

The Department has made no revisions or additions to the model guidelines in response to these comments. As stated above in the discussion of section V-B (regarding the development of specific policies and guidelines), the existence and activities of the ICRC do not amend the responsibilities under State law of medical professionals and the hospital to report to the child protective services agency suspected instances of medical neglect (including the withholding of medically indicated treatment from disabled infants with life-threatening

conditions). Nor does the existence of the ICRC reduce or affect the rights of other persons to report suspected cases to the agency. Although the child protective services agency and the ICRC are to be guided by similar principles and standards regarding the best interests of the child, the Department believes they have separate and distinct functions. The primary function of the ICRC in this context is to offer counsel to the attending physician(s), the hospital and the family to assure that the parents have the benefit of prudent, knowledgeable and professional evaluations, recommendations and services, consistent with appropriate medical standards, to assist them in making sound decisions regarding the welfare of their child. The function of the child protective services agency is to determine those circumstances in which the power of the State must be invoked to protect the infant, and then to take appropriate action to do so. Linkages between child protective services agencies and health care institutions and professionals are already established in law, and the legislative history of the

Child Abuse Amendments of 1984 makes clear these existing mechanisms are to apply in connection with instances of withholding of medically indicated treatment from disabled infants with life-threatening conditions. In view of these factors, the model does not enlarge, contract, or amend the applicable legal standards for reporting to child protective services agencies.

#### *2. Retrospective Record Review*

Section VI-B of the model guidelines recommends that the ICRC retrospectively review records in certain categories of cases as a method of monitoring the effectiveness of the policies and procedures of the ICRC and hospital.

In response to some comments that the description of this activity in the interim guidelines gave the impression of an unproductive, after-the-fact fault-finding mission, this section has been revised somewhat to clarify its purpose. Some commenters suggested that the model call for ICRCs to report to the child protective services agency any discovered deviations from hospital

policies. Other commenters suggested annual reports to the agency of the results of the ICRC review of all cases, to be followed by compilations by the agency and by HHS for publication. For the reasons set forth in the discussion above regarding section VI-A (concerning prospective counsel and review), the Department has not adopted these suggestions. The reports the ICRC and/or the hospital make to the child protective services agency or any other entity should be those indicated by applicable requirements. With respect to the objective of adding to professional and public knowledge of the potential benefits and difficulties of ICRCs, the Department agrees that activities relating to this objective should be encouraged through the mechanisms of professional and public communications, but believes it is beyond the intended scope of these model guidelines to seek to organize some comprehensive information compilation and distribution system.

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**Appendix K**

***In re Steinhaus***

STATE OF MINNESOTA

COUNTY OF REDWOOD

IN COUNTY COURT

JUVENILE COURT DIVISION

In the Matter of the Welfare of

Lance Tyler Steinhaus, a minor.

O R D E R

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This matter came on before this Court upon the motions of Amy Steinhaus and Dr. David Steinhorn in the courtroom of the Lyon County Courthouse in the City of Marshall, Minnesota on the 14th day of August, 1986, at 9:00 a.m. Mr. David Peterson, 308 North Third Street, Marshall, Minnesota 56258 appeared on behalf of the Redwood County Welfare Department; Ms. Natalie Hauschild, 315 South Washington, Box 377, Redwood Falls, Minnesota 56283 appeared on behalf of petitioner Amy Steinhaus; and Jan D. Halverson, University of Minnesota Hospital and Clinic, Box 708, Harvard Street at East River Road, Minneapolis, Minnesota 55455 appeared on behalf of Dr. David Steinhorn. Present was Mr. Timothy Steinhaus, father of the child, represented by Cecil Naatz, Attorney at Law, Marshall, Minnesota 56258. Present, also, was Mr. Michael Boyle, Attorney at Law, Springfield, Minnesota, representing the child.

The undersigned, upon all the evidence introduced at this hearing and upon all the files and records herein, finds as follows:

## FINDINGS OF FACT

1. Lance Tyler Steinhaus was born on March 20, 1986. On or about April 24, 1986 he received serious injuries, including a fractured skull and fractured ribs. The child became comatose on that date and has never regained consciousness. That the child was the subject of a Neglect Petition in Redwood County, Minnesota. That the child was found to be neglected as the result of the actions of the child's father and that custody was placed in the Redwood County Welfare Department.

2. That the child's mother, Amy Steinhaus, after consultation with the child's doctors agreed that the child should not receive antibiotics and that a "Do Not Resuscitate" order should be placed upon his medical chart.

3. That on the Motion of the Redwood County Welfare Department a temporary restraining order was signed on August 1, 1986 which order restrained medical doctors from removing the child from antibiotic treatment.

4. That this matter has come before the Court upon the motion of Amy Steinhaus and Dr. Steinhorn requesting that this Court (1) dissolve the temporary injunction granted on August 1, 1986, and (2) ordering that personal hygiene, nutrition, hydration and suctioning of oral secretions be continued, but that any aggressive medical treatment including antibiotic treatment, resuscitation efforts, surgical interventions and the use of respiratory devices to treat Lance Tyler Steinhaus be proscribed (not required).

5. Doctor David Steinhorn is a Medical Doctor and an instructor of the Department of Pediatrics at the University of Minnesota Hospital. Until shortly before the hearing he was the treating doctor for the child.

6. Dr. Steinhorn testified that the child's current medical condition is one of a "persistent vegetative state". The testimony indicated that the child was not "brain dead" and there was some activity in the brain, although in his opinion this activity pertained to basic primal instincts. He testified that the child is severely impaired that he is unable to handle oral secretions, that he has an ineffective cough and gag so that he cannot clear his airway effectively. The child is fed by a feeding tube directly into his stomach. Dr. Steinhorn defined a persistent vegetative state as having no interaction with his environment and testified that in his opinion the child had no hope of improvement. Dr. Steinhorn testified also that the child is susceptible to life threatening infections and that without antibiotics that he would probably die of infection within a short period of time.

7. That based upon the testimony introduced at trial that the child is a disabled infant with a life threatening condition.

8. Dr. Steinhorn indicated that he has consulted with other doctors including staff pediatric neurologists at the University of Minnesota Hospital and also the Ethics Committee at the University of Minnesota Hospital. That all he has talked to have concurred that the child should have a given "comfort care"

environment without providing any aggressive intervention in the event his heart stopped or he should stop breathing.

9. The doctor testified that in his opinion it would not be in the best interest of the child to try to prolong his life through any type of ventilatory support or the institution of antibiotic therapy.

10. That Dr. Steinhorn did advocate that the child remain on one type of antibiotic which would prevent seizures. That the doctor testified that he would not strongly object to passive administering of antibiotics by means of the stomach tube but that he would object to more intrusive administration of antibiotics by intervenous means.

From the above findings, this Court makes the following:

#### CONCLUSIONS OF LAW

1. Federal and State law establish a clear and consistent standard for what treatment must be provided disabled infants with life-threatening conditions.

In the wake of considerable public debate over whether and when children with disabilities should receive life-preserving treatment (stimulated by the death of a Bloomington, Indiana child born with Down's Syndrome after surgery, food and water were withheld from him in April, 1982), Congress enacted the Child Abuse Amendments of 1984, Pub. L. No. 98-457, tit. 1, secs. 121-28, 98 Stat. 1749, 1752-55 (codified at 42 U.S.C.A. 5101 to 5103) (Supp. 1986). See generally Bopp & Balch, The Child Abuse Amendments of 1984 and their Implementing Regulations: A Summary,

1 Issues in L. & Med. 91, 95-100 (1985). The law enacted was the product of negotiations among medical, disability rights and pro-life representatives and represented a consensus among a broad range of groups. Groups that supported the final language included, among many others, the American Hospital Association, the National Association of Children's Hospitals and Related Institutions, the American Academy of Pediatrics, the American Nurses Association, the American College of Physicians, the American Association on Mental Deficiency, the Association for Retarded Citizens, U.S., and The Association for Persons with Severe Handicaps. Id. at 100; 130 Cong. Rec. S8951, S8952 (daily ed. June 29, 1984).

The legislation applies to all states that receive federal funds under the Child Abuse Prevention and Treatment and Adoption Reform Act. Minnesota receives Child Neglect & Abuse Basic State Grant No. 05 CA 5388/09-2 in the amount of \$158,521 for the eighteen months commencing September 30, 1985.

As amended by the 1984 act, 41 U.S.C.A. 5103 (b) (2) (K) (Supp. 1986) provides, "In order for a State to qualify for assistance under this subsection, such State shall...have in place... procedures or program...to provide for...(iii) authority, under State law, for the State child protective service system to pursue any legal remedies, including the authority to initiate legal proceedings in a court of competent jurisdiction, as may be necessary to prevent the withholding of medically indicated treatment from disabled infants with life-threatening conditions." In addition, 42 U.S.C.A. 5103 (b)

(2) (C) (1982) requires that "in order for a State to qualify for assistance under this subsection, such State shall...provide that...upon a finding of abuse or neglect, immediate steps shall be taken to protect the health and welfare of the abused or neglected child...".

42 U.S.C.A. 5102 (1982) defines "child abuse and neglect" as including "negligent treatment, or maltreatment of a child..." Under an implementing regulations, 45 C.F.R. 1340.2 (d) (3) (1) (1985) explicitly states, "The term 'medical neglect' means the failure to provide adequate medical care in the context of the definitions of 'child abuse and neglect' in section 3 of the Act [42 U.S.C.A. 5102 (1982)] and 1340.2 (d) of this part. The term 'medical neglect' includes, but is not limited to, the withholding of medically indicated treatment from a disabled infant with a life-threatening condition."

In May, 1985, Minnesota enacted legislation to ensure its compliance with these requirements. As a result, the Juvenile Code now includes in its definition of "neglected child" one "who is medically neglected, which includes the withholding of medically indicated treatment from a disabled infant with a life-threatening condition." Minn. Stat. Ann. 260.015 Subd. 10 (e) (Supp. 1986).

The centerpiece of the Child Abuse Amendments of 1984 is the Act's definition of "withholding of medically indicated treatment." Minn. Stat. Ann. 260.015 (e) (Supp. 1986) also includes a definition of the term that essentially repeats the federal definition.

42 U.S.C.A. 5102 (3) (Supp. 1986) defines "withholding of medically indicated treatment" as:

the failure to respond to the infant's life-threatening conditions by providing treatment (including appropriate nutrition, hydration, and medication) which, in the treating physician's or physicians' reasonable medical judgment, will be most likely to be effective in ameliorating or correcting all such conditions, except that the term does not include the failure to provide treatment (other than appropriate nutrition, hydration, or medication) to an infant when, in the treating physician's or physicians' reasonable medical judgment, (A) the infant is chronically and irreversibly comatose; (B) the provision of such treatment would (i) merely prolong dying, (ii) not be effective in ameliorating or correcting all of the infant's life-threatening conditions, or (iii) otherwise be futile in terms of the survival of the infant; or (C) the provision of such treatment would be virtually futile in terms of the survival of the infant and the treatment itself under such circumstances would be inhumane.

See also 45 C.F.R. 1340.15 (2) (1985).

The Federal Department of Health and Human Services, the agency charged with administering the Act, has succinctly summarized the structure of the mandated standard of care as follows:

[F]irst, all such disabled infants must under all circumstances receive appropriate nutrition, hydration and medication. Second, all such disabled infants must be given medically indicated treatment. Third, there are three exceptions to the requirement that all disabled infants must receive treatment, or, stated in other terms, three circumstances in which treatment is not considered "medically indicated."

Dept. of Health and Human Services, Off. of Human Development Serv., Child Abuse and Neglect Prevention and Treatment Program, 49 Fed. Reg. 4816, 48163 (1984).

It is clear that it is this definition of what medical treatment is and is not required, contained in both federal and Minnesota law, that must guide this court in making decisions about Lance Steinhaus.

2. Lance Steinhaus is a "Disabled Infant With Life-Threatening Conditions" Within the Meaning of Federal and Minnesota Law.

The treatment standards of both the federal act (42 U.S.C.A. 5103 (b) (2) (k) (Supp. 1986) and the Minnesota law (Minn. Stat. Ann. 260.015 Subd. 10 (e) (Supp. 1986) apply to "disabled infant(s) with (a) life-threatening condition(s)." Because the Minnesota law is so similar to the federal one, and because it was obviously passed to ensure Minnesota's compliance with the federal law, it would be illogical to give any different interpretation to the meaning of the terms of the Minnesota law than to those of the federal act.

The regulations issued by the federal Department of Health and Human Services to implement the Child Abuse Amendments of 1984 define "infant" as follows:

The term "infant" means an infant less than one year of age. The reference to less than one year of age shall not be construed to imply that treatment should be changed or discontinued when an infant reaches one year of age, or to affect or limit any existing protections available under State laws regarding medical neglect of children over one year of age. In addition to their applicability to infants less than one year of age, the standards set forth in paragraph (b) (2) of this section should be consulted thoroughly in the evaluation of any issue of medical neglect involving an infant older than one year of age who has been extremely prematurely, or who has a long-term disability.



45 C.F.R. 1340.15 (3) (1) (1985)

Lance is less than one year of age. According to the testimony of Dr. Steinhorn, he is likely to remain in a persistent vegetative state indefinitely. Thus, he has a "long-term disability." It is important to note that the definition makes clear that if particular treatment is required for him now, that treatment should not be discontinued when he reaches one year of age.

Does Lance have a "life-threatening condition"? At the same time it issued the regulations implementing the Child Abuse Amendment of 1984, the Department of Health and Human Services promulgated "interpretative Guidelines Regarding 45 C.F.R. 1340.15 - Services and Treatment for Disabled Infants." Although they were not established "as binding rules of law," the Department explained that "this guidance is intended to assist in interpreting the statutory definition so that it may be rationally and thoughtfully applied in specific contexts in a manner fully consistent with the legislative intent." 45 C.F.R. Part 1340 App. (1985). Guideline 2 discusses the term "life-threatening condition" in a manner that could have been written specifically to address Lance's case:

It appears to the Department that the applicability of the statutory definition might be uncertain to some people in cases where a condition may not, strictly speaking, by itself be life-threatening, but where the condition significantly increases the risk of the onset of complications that may threaten the life of the infant. If medically indicated treatment is available for such a condition, the failure to provide it may result in the onset of complications that, by the time the condition becomes life-threatening in the strictest sense, will eliminate or reduce the potential

effectiveness of any treatment. Such a result cannot, in the Department's view, be squared with the Congressional intent.

Thus, the Department interprets the term "life-threatening condition" to include a condition that, in the treating physician's or physicians' reasonable medical judgment, significantly increases the risk of the onset of complications that may threaten the life of the infant.

Id.

Dr. Steinhorn testified that, because of his condition, Lance is susceptible to life-threatening infections. It is for this reason that antifiotics are necessary. Clearly, this susceptibility is a "life-threatening condition" under the Health & Human Services guidelines.

3. That under the law Lance Steinhaus should receive antibiotic treatment as a part of the appropriate nutrition, hydration and medication to which all disabled infants are entitled.

Dr. Steinhorn testified that the child is susceptible to life threatening infections and that without antibiotics it is very likely that he would die from infection. The doctor testified that administering of most antibiotics was relatively easy and could be given the child through his stomach tube. The doctor in fact testified that he had no great objection to administering antibiotic medicine by this method and would recommend that a certain type of antibiotic be given to prevent seizures as being regarded as inhumane while death by infection as being regarded as humane.

This Court finds that the administering of antibiotic treatment is not a heroic measure, but is appropriate medication to which the child is entitled.

4. The Treatment Requirements Applicable to Lance Steinhaus require that He be given Resuscitation Unless His Condition Fits one of the Three Exceptions set forth in the Statute. It Is Not Clear whether the Child meets the "Chronically and Irreversibly Comatose Exception of the Statute.

In general the standard of care is subject to three exceptions in which only "appropriate nutrition, hydration and medication" is required.

The first exception is when "the infant is chronically and irreversibly comatose." 42 U.S.C.A. 5102 (3) (B) (Supp. 1986); Minn. Stat. Ann. 260.011 Subd. 10 (e) (1) (Supp. 1986). Dr. Steinhorn testified that Lance is in a "persistent vegetative state." It is not clear that this is the same thing as a coma. A November 1985 medical journal article describes differences:

Coma was defined operationally as a sleeplike, unarousable, unresponsive state in which the patient shows no awareness of self or environment. Such patients (1) do not open their eyes either spontaneously or in a response to any verbal stimulus, (2) utter no comprehensible words, and (3) neither obey commands nor move their extremities appropriately to localize or to resist noxious stimuli.

Patients in the PVS [Persistent Vegetative State], however, are awake without being aware. They open their eyes and look about randomly but do not follow objects or respond to verbal command. The eyes open and blink spontaneously and to menace but are unattentive. Patients may sleep at times. Chewing and bruxism (grinding of teeth) are common, and a grasp reflex is often present.

Hansotia, Persistent Vegetative State, 42 Archives of Neurology 1048, 1048 (1985) (footnote omitted).

A standard reference text makes the same distinction:

Coma implies the absence of both arousal and content. In terms of observable behavior, the comatose patient appears to be asleep, but unlike the sleeping, he cannot be aroused from this state...

The patient in the vegetative state appears awake but shows no evidence of content, either confused or appropriate. He often has sleep-wake cycles but cannot demonstrate an awareness either of himself or his environment.

Levy, The Comatose Patient, in I The Clinical Neurosciences 955, 956 (R. Rosenberg ed. 1983) (emphasis in original).

Unless it can be shown that the child is chronically and irreversibly comatose, the exception does not apply. The Court's recollection of the testimony does not support this finding. This matter, however, may be the subject of further testimony and a review of the transcript of the hearing.

5. The Futility Exceptions to the General Requirement of Treatment Do Not Apply to Lance Steinhaus.

The second and third exceptions both relate to treatment which is futile in staving off death for very long. They are:

(B) the provisions of such treatment would (i) merely prolong dying, (ii) not be effective in ameliorating or correcting all of the infant's life-threatening conditions, or (iii) otherwise be futile in terms of the survival of the infant; or (C) the provision of such treatment would be virtually futile in terms of the survival of the infant and the treatment itself under such circumstances would be inhumane.

42 U.S.C.A. 5102 (3) (B) & (C) (Supp. 1986). See also 45 C.F.R. 1340.15 (2) (ii) & (iii) (1985); Minn. Stat. Ann. 260.015 Subd. 10 (e) (2) & (3) (Supp. 1986).

Because Dr. Steinhorn gave undisputed testimony that, with treatment, Lance might survive for "decades", none of the language is applicable.

First, the treatment at issue would not "merely prolong dying". HHS Interpretative Guideline No. 5 addresses the meaning of these words:

The Department interprets the term "merely prolong dying" as referring to situations where the prognosis is for death and, in the treating physician's or physicians' reasonable medical judgment, further or alternative treatment would not alter the prognosis in an extension of time that would not render the treatment futile.

Thus, the Department continues to interpret Congressional intent at not permitting the "merely prolong dying" provision to apply where many years of life will result from the provision of treatment, or where the prognosis is not for death in the near future, but rather the more distant future.

45 C.F.R. Part 1340 App. (1985)

"Decades" are certainly equivalent to "many years of life". Thus, since antibiotics and resuscitation could purchase many years of life, such treatment for Lance would not "merely prolong dying."

HHS Interpretative Guideline Number 6 explicates the meaning of "not be effective in ameliorating or correcting all of the infant's life-threatening conditions."

Under the definition, if a disabled infant suffers from more than one life-threatening condition and, in the treating physician's or physicians' reasonable medical judgment, there is no effective treatment for one of these conditions that threatens the life of the infant in the near future, then the infant is not covered by the terms of the amendment (except with respect to appropriate nutrition, hydration, and medication) concerning the withholding of medically indicated treatment; but if the nontreatable condition

will not become life-threatening; but if the nontreatable condition will not become life-threatening until the more distant future, the infant is covered by the terms of the amendment.

There is no indication from the testimony of Dr. Steinhorn that Lance has any life-threatening condition that cannot be treated and will thus inevitably cause his death in the near future even if treatment is provided for other life-threatening conditions. On the contrary, with treatment Lance could live for "decades." Evidently this second clause of the second exception does not apply.

The third clause of the second exception refers to treatment that would "otherwise be futile in terms of the survival of the infant" and the third exception refers to treatment "virtually futile in terms of the survival of the infant." Under HHS Interpretative Guideline No. 8, "The Department interprets the term "virtually futile" to mean that the treatment is highly unlikely to prevent death in the near future."

It is important to recognize that both clauses discuss futility only in the context of "the survival of the infant," not in terms of recovery from the disability. The plain language of the statutes, however, makes clear that the length of life, rather than its quality, is to be the basis for judgments about futility. In addition, the HHS Interpretative Guidelines flatly state, "[T]he definition's focus on the potential effectiveness of treatment in ameliorating or correcting life-threatening conditions makes clear that it does not sanction decisions based on subjective opinions about the future "quality of life" of a retarded or disabled person. Id.

Since Lance could live for "decades" if treatment is provided, it assuredly cannot be accurately said that the treatment is either "futile" or "virtually futile" in terms of his survival.

The third exception is phrased in the conjunctive; for it to apply, it must be the case both that treatment would be "virtually futile in terms of the survival of the infant" and that "the treatment itself under such circumstances would be inhumane." Since the specifications of the first requirement clearly are not met, treatment could not be withheld even if the second requirement were met.

In Interpretative Guideline No. 9, the Department rejected the view that the statutory language of this exception allows "consideration of the infant's future 'quality of life'."

The Department strongly believe such an interpretation would be inconsistent with the statute. The statute specifies that the provision applies only where the treatment would be "virtually futile in terms of the survival of the infant," and the "treatment itself under such circumstances would be inhumane." (Emphasis supplied.) The balance is clearly to be between the very slight chance that treatment will allow the infant to survive and the negative factors relating to the process of the treatment. These are the circumstances under which reasonable medical judgment could decide that the treatment itself would be inhumane.

Id. (Emphasis in original.)

In light of the uncontested evidence that Lance could survive for "decades" if provided treatment, it is clear that neither the second nor the third exceptions apply.

NOW THEREFORE, IT IS HEREBY ORDERED,

1. That the Motion of the mother, Amy Steinhaus and Dr. Steinhorn are hereby denied.

2. That this Court's Order of August 1, 1986 is made permanent and it is further ordered that until further order of this Court the minor child Lance Tyler Steinhaus shall be provided with "treatment (including appropriate nutrition, hydration, and medication including antibiotics and resuscitation) which, in the treating physician's or physicians' reasonable medical judgment, will be most likely to be effective in ameliorating or correcting all life-threatening conditions.

Dated: September 11, 1986

  
George I. Harrelson  
Judge of County Court

#### MEMORANDUM

ISSUE The issue before this Court is whether medical treatment, including antibiotic treatment and resuscitation efforts, should be continued on behalf of Lance Tyler Steinhaus, an infant child who is in a persistent vegetative state.

A DISTINCTION A distinction to be drawn is that the child is not "brain dead." There was testimony that the child's brain shows the existence of recordable activity, although the treating doctor was of the opinion that such activity was minimal and related to primal instincts, such as control of breathing. It is noted that the child is not on any respirator.

BACKGROUND In earlier times organized society reached out to segregate, confine, sterilize, and otherwise discriminate against



people with disabilities. It was not until the 1960's and 1970's that a significant disability rights movement got under way in the United States. Suits to secure rights were joined by legislative action that resulted in the enactment of such laws as the Education of the Handicapped Act and the Rehabilitation Act.

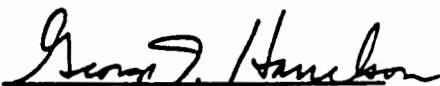
UNDERLYING RATIONALE The unspoken but underlying rationale of the motion before this Court is that this infant child has such a profound disability that he exists in a "vegetative state", that he will never be able to live a normal life and that, therefore, he should be allowed to die. This rationale was openly expressed in the Infant Doe case where nutrition and beneficial medical care were withheld from a Down's Syndrome infant on the ground that there was no possibility of a minimally adequate "quality of life". Adopting this rationale or way of thinking would certainly have some benefits. The child's death would allow the mother to proceed with her life. I am informed that the mother is a good mother and a fine person and spends almost every spare minute with the child. The child's death would also put an end to the extensive medical care which must by this time amount to tremendous expense. Arguably, such medical expense could produce more profitable results if applied to the cases with a better prognosis.

There are some problems, however, with this "quality of life" argument. Who decides whether the "quality of life" is adequate? Where is the line drawn?

APPLICABLE LAW The Child Abusement Amendments of 1984 were enacted in the wake of considerable debate over whether children with disabilities should receive life-preserving treatment. The law is now clear that all infant children with life threatening conditions have a right to medically indicated treatment. Lance Steinhaus meets this definition. As the result of this law the child has the right to comfort care consisting of food, water, personal hygiene, and appropriate medication. Appropriate medication in this case indicates antibiotic treatment which will prevent death by infection.

CONCLUSION In enacting the 1984 Amendments, the "quality of life" rationale was rejected. The child clearly has a right to medically indicated treatment including antibiotic treatment which will prevent death by infection. If the child's condition worsens and it is found that he is either chronically and irreversibly comatose, or that he meets one of the other exceptions in the law, then the law would not require heroic measures such as resuscitation. Based upon the evidence introduced, however, the Court can not make this finding at this time.

Dated: September 11, 1986

  
George F. Harrelson  
Judge of County Court

STATE OF MINNESOTA

IN COUNTY COURT

COUNTY OF REDWOOD

FAMILY DIVISION

In the Matter of the Welfare of

Lance Tyler Steinhaus,

a Minor

AMENDED  
FINDINGS OF FACT AND  
ORDER

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The above matter came before this court upon the motions of Amy Steinhaus and Dr. David Steinhorn in the Courtroom of the Redwood County Courthouse in the City of Redwood Falls, Minnesota on the 6th day of October, 1986. Mr. David Peterson, Marshall, Minnesota 56258 appeared on behalf of the Redwood County Welfare Department, Ms. Natalie Hauschild, 315 South Washington, Box 377, Redwood Falls, Minnesota 56283 appeared on behalf of the petitioner Amy Steinhaus; Jan D. Halverson, University of Minnesota Hospital and Clinic, Box 708, Harvard St. at East River Road, Minneapolis, Minnesota 55755 appeared on behalf of Dr. David Steinhorn; Cecil Naatz, Attorney at Law, Marshall, Minnesota appeared on behalf of Timothy Steinhaus; Michael Boyle, Attorney at Law, Springfield, Minnesota appeared on behalf of the guardian ad litem and the child..

The motion brought by Petitioner Amy Steinhaus is for an order amending the Findings of Fact, Conclusions of Law and Order of this Court dated September 11, 1986 so as to find that the minor child, Lance Tyler Steinhaus is "chronically and irreversibly comatose" so as not to require resuscitation or other heroic measures as set forth in that except in 42 U.S.C.A. 5102 (3) (B) (Supp.1986); Minnesota Statutes 260.015 Subd. 10 (e) (1) (Supp. 1986).

The motion by Dr. David Steinhorn is for an order to amend the Findings of Fact, Conclusions of Law and Order of September 11, 1986 finding that a decision by the legal custodian to withhold treatment other than appropriate nutrition, hydration or medication would not constitute medical neglect or the withholding of medically indicated treatment as defined in Minn. Stat. ss260.015 Subd. (10) e.

The undersigned, upon all the evidence introduced at this hearing and upon all the records and files herein, find as follows:

FINDINGS OF FACT

1. That on August 14, 1986, Dr. David Steinhorn, one of the treating doctors of Lance Steinhaus, testified that the child was in a "persistent vegetative state" and that he also testified that the child was chronically and irreversibly comatose.
2. That on October 6, 1986, the court received the testimony of Doctor Stephen Smith, a pediatric neurologist. That Dr. Smith testified that he had received the medical record of Lance Steinhaus and that he had examined the child on October 1, 2, 4 and 5, 1986. That the Doctor testified that he had received a CAT scan of Lance Steinhaus taken May 20, 1986 and a MR (Magnetic Resonance) Scan taken September 26, 1986.
3. The Court was presented the CAT Scan of Lance Steinhaus' brain which was contrasted with a CAT Scan of a normal brain. That likewise an MR Scan of Lance Steinhaus' brain was contrasted to a MR Scan of a normal brain. That Doctor Smith testified that based upon his examination and an examination of the CAT Scan and MR Scan that both of the hemispheres of the child's brain have been "virtually destroyed". He testified that the normal architecture of the brain is missing and that the major areas of the brain have been replaced by fluid.
4. The doctor testified that only area of the brain not completely destroyed is the brainstem. That the brain stem which controls very basic life control systems such as respiration and temperature shows considerable damage.
5. That the doctor testified that based upon his examination and tests that it is his opinion that while the child has some of the criteria of a "persistent vegetative state" that the child does not have the normal "sleep-wake patterns of that state. The doctor testified that the child in his opinion was chronically and irreversibly comatose. The Doctor further testified that in his opinion there are no foreseeable advances in medical science which could hope to improve the child's condition.

6. That it was the opinion of Dr. Smith at appropriate medical practice would dictate that the child be given nutrition, warmth, cleanliness and medication such as antibiotics to treat infection. The doctor testified that appropriate medical practice would not require resuscitation or intubation or any heroic efforts for the child.

From the above findings the Court makes the following:

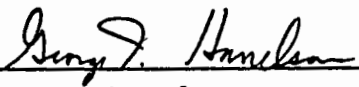
CONCLUSIONS OF LAW

1. That the minor child, Lance Tyler Steinhaus is chronically and irreversibly comatose.
2. That State and Federal law require that the child received "comfort care" consisting of appropriate nutrition, hydration, warmth and medication.
3. That Federal Law, 42 U.S.C.A. 5102 (3) (Supp. 1986) and Minnesota State Law, Minn. State ss 260.015, Subd. 10 (e) under the circumstances of this case do not require treatment other than appropriate nutrition, hydration, warmth and medication.
4. That a decision by the legal custodian of the child to withhold treatment other than appropriate nutrition, hydration or medication would not constitute medical neglect or the withholdings of medically indicated treatment as defined Minn. Stat. <sup>ss</sup>260.015 Subd. 10 (e).

NOW THEREFORE, IT IS HEREBY ORDERED:

1. That the motion of petitioner, Amy Steinhaus is hereby granted.
2. That the motion of petitioner Dr. David Steinhorn is hereby granted.

Dated: October 13, 1986

  
George I. Harrelson  
Judge of County Court

COURT ADMINISTRATOR  
REG. NO. COUNTY, MINN.  
FILED  
10-13-86