"Baby Doe" Regs Thrown Out by Court

Judge calls regulation that established a federal handicapped infant hotline "arbitrary and capricious"

Last month, the Secretary of Health and Human Services (HHS) ordered some 6400 hospitals around the country to post a notice about the care and feeding of handicapped babies. The notice, which Secretary Margaret M. Heckler directed be hung in a "conspicuous" place in delivery rooms and nurseries said: "Discriminatory failure to feed and care for handicapped infants in this facility is prohibited by federal law."

The notice also included the toll-free number of a new HHS "handicapped infant hotline" open 24 hours a day. "Any person having knowledge that a handicapped infant is being discriminatorily denied food or customary care" should phone Washington immediately, it said.

Angered by what they saw as an unwarranted and unreasonable federal intrusion, the American Academy of Pediatrics, joined by the National Association of Children's Hospitals and Related Institutions, and the Children's Hospital National Medical Center sued the government. On 14 April they won a stunning victory when United States District Judge Gerhard A. Gesell concluded that "haste and inexperience have resulted in agency action based on inadequate consideration" of the regulation's consequences. ". . . the public interest requires that the regulation not continue in effect," Gesell declared. Although HHS has vowed to appeal to the Supreme Court, the notices are coming down. As of 18 April the hotline was still open but, an HHS spokesman says, it is likely to be disconnected within days.

The government's involvement in the care of handicapped infants stems from the case of "Baby Doe," who was born in Bloomington, Indiana, a little more than a year ago. The baby, whose name has not been revealed, had Down's syndrome and a surgically correctable blockage of his digestive tract which precluded normal feeding. His parents refused permission to operate, the court in Indiana refused to intervene, and at 6 days old Baby Doe died.

The case, which attracted a lot of publicity, struck a nerve with President Reagan who asked HHS to invoke in future cases laws prohibiting discrimination against the handicapped. The Baby Doe case is, in its relative medical simplicity, atypical of the more complex cases it has come to symbolize.

In response to a memo from the President, then HHS Secretary Richard S. Schweiker sent a notice to all hospitals on 18 May 1982 stating that section 504 of the Rehabilitation Act of 1973 makes it unlawful to deny life-saving care to a handicapped baby. That notice provoked little outcry. But provisions of the March notice-posting and hotline regulation brought federal officials into the nursery in an unprecedented way. "The posting of such signs creates a clear implication of past and present mistreatment by nursery staffs in treating infants," Gordon Avery, chairman of neonatology at Children's Hospital National Medical Center in Washington, D.C., said in an affidavit to the court.

The idea that the government had set out to encourage hotline calls from people who could remain anonymous also rankled. Noting that neonatal intensive care nurseries are invariably highly stressful, Avery said, "Multiple calls for investigation from ill-informed bystanders, perhaps parents of other children in the unit, perhaps dissatisfied employees of the hospital, could create a very nontherapeutic atmosphere of hysteria, defensiveness, and suspicion."

Across the country hospitals posted the notice with great reluctance. At the University of California at San Francisco, chancellor Julius Krevans openly said he was "infuriated and enraged." A sign was posted above the HHS notice that called the government's warning "an affront to our staff's professional commitment and performance."

The March regulation demanded that hospitals make their records available to federal investigators at any time of day or night. Likewise, those investigators were instructed to respond to Baby Doe calls like firemen to a fire. In a memo from a deputy director of the HHS office of civil rights to the heads of the country's regional civil rights districts, directions to the "special assignment Baby Doe squad team" were spelled out. Team members were to drop plans for vacations or other personal activities if a Baby Doe call came in. Instructed to be armed with a credit card, they were also told to be sure they knew how to make airline reservations or secure a government car to travel to the hospital. Each region was to identify for medical consultation a specialist, "hopefully one who is a neonatal specialist," and an alternate.

During the approximately 4 weeks of the hotline's operation upward of 400 calls were logged in. According to Patricia Mackey of the HHS office of civil rights, some of them were "informational," some were "hang-ups," and many were "cranks." For instance, Mackey told *Science*, someone called in and said, " 'There's a baby in the hospital with no mouth and they're not feeding him.' That's a crank." In some cases, HHS could not verify the existence of the allegedly maltreated infant.

But four of the 400 calls were real, insofar as they did refer to a seriously ill newborn, and HHS duly dispatched a Baby Doe squad in those cases. No violations were found. One squad went to Strong Memorial Hospital at the University of Rochester, New York, where physicians were treating Siamese twins, joined at the trunk, who had been flown in from a smaller hospital in southern New York State. Paul Rosenberg, attorney for the hospital, told *Science* that on 29 March he received a call from HHS officials in Washington who reported that a hotline call had been received about the twins. Rosenberg was told the call had come from someone in Binghamton, a town east of Rochester, who had read about the twins in the newspaper. Their father had been quoted as saying that the babies were so hopelessly conjoined that "no surgery was planned."

Within hours, two civil rights investigators from New York and one from Washington were on the scene, where they were given hospital records with the patients' names deleted. They talked to Rosenberg and to the babies' physician. The infants were being fed intravenously, given antibiotics, and were on respirators. Later that night, the Baby Doe squad's consultant arrived from Norfolk, Virginia. Neonatologist Frederick Wirth examined the records and asked to see the twins. "The parents," Rosenberg says, "were adamant in their refusal to let anyone else examine the babies. They absolutely refused." The hospital stood behind the parents. Wirth and the squad members departed, having found no evidence that the babies were getting anything other than good medical care. But the case officially remains open and, Rosenberg says, he can find no one in New York or Washington who is prepared to say when it will be formally concluded.

According to Rosenberg, the descent of the Baby Doe squad in this case not only caused anguish to the parents of the twins but also upset parents of other children hospitalized at Strong Memorial. "The parents of one critically ill patient signed the child out of the hospital against medical advice" for fear their child was not being well cared for, Rosenberg says.

In light of the 1982 reminder notice about care of the handicapped, why did HHS decide last month to issue the new regulation which Judge Gesell described as "novel and far-reaching"? The answer is not entirely clear, although there are indications that it was the President himself, not HHS officials, who wanted something highly visible done to satisfy right-to-life constituents. What is clear is that Gesell found that HHS had insufficient reason to proceed in the manner it did, which included halving the usual 30-day period for public comment that the law prescribes between the date a regulation is published in the *Federal Register* and the date it goes into effect. HHS tried to justify the March regulation as an emergency. "The action of HHS was undertaken to save the lives of children in jeopardy," said Surgeon General C. Everett Koop, a pediatric surgeon. "Americans have been shocked and appalled at the reported deaths of handicapped infants who have been deliberately allowed to die by denial of treatment." Koop declared the regulation "supported by law" and "justified by basic human morality."

At an 8 April hearing in Gesell's court, government attorney Neil Koslowe argued that the HHS Secretary was acting as "the protector of last resort," so that considerations about the quality of the infant's life, cost of life-support, or the effect of a seriously handicapped child on a marriage or siblings could not enter into decisions about medical treatment. Said Gesell in his opinion, "It is clear that a primary purpose of the regulation is . . . to prevent parents from having any influence upon decisions as to whether further medical treatment is desirable."

Arguing on behalf of the Academy of Pediatrics, Stephan E. Lawton, an attorney with the Washington firm of Pierson, Ball & Dowd, urged the court to overturn the regulation on several grounds, among them that reducing time for public comment from 30 to 15 days violated laws governing administrative procedure and that the legally required "factual basis" for promulgating the regulation did not exist. Lawton demonstrated that the government's own files failed to support its contention that handicapped infants are being allowed to die needlessly.

HHS's records, Lawton said, contained no serious memoranda about the pros and cons of the regulation as might be expected. They did show, however, that in the months between the May 1982 reminder notice and the March 1983 regulation, HHS had completed investigations of neonatal care practices at six centers where special interest groups alleged violations were taking place. No violations were found.

Judge Gerhard Gesell

HHS acted in "haste and inexperience"

The record also showed that in promulgating the regulation, HHS officials relied on newspaper clips, including some on euthanasia, and on a handful of articles from professional journals. They also had before them the tape of a television news series called "Death in the Nursery," that ran on WNEV-TV in Boston the last week in February. In a memo dated 1 March, the head of HHS's office of civil rights said that an HHS official in Boston who had seen the show characterized it as "very much sensationalized."

Lawton also noted that the regulation was timed to take effect the day before the President's ethics commission issued a study on "Deciding to Forego Life-Sustaining Treatment." HHS apparently chose to ignore that report which, Gesell said in his opinion, "counsels different approaches to the issue."

Gesell overturned the regulation as a violation of "well-established" standards for rulemaking. The law "requires that all regulations shall issue only after the rulemaker has considered relevant factors to prevent arbitrary and capricious decisionmaking and to assure rational consideration of the impact of the contemplated regulatory action. The instant regulation offends these established precepts to a remarkable extent . . . ," he wrote. ". . . the record reflects no consideration whatsoever of the disruptive effects of a 24-hour, toll-free 'hotline' upon ongoing treatment of newborns. . . . In a desperate situation where medical decisions must be made on short notice by physicians, hospital personnel and often distraught parents, the sudden descent of 'Baby Doe' squads on the scene, monopolizing physician and nurse time and making hospital charts and records unavailable during treatment, can hardly be presumed to produce higher quality care for the infant," he observed.

Further, Gesell said, "The Secretary did not appear to give the slightest consideration to the advantages and disadvantages of relying on the wishes of the parents who . . . in many ways are in the best position to evaluate the infant's best interests. . . . None of these sensitive considerations touching so intimately on the quality of the infant's expected life were even tentatively noted. No attempt was made to address the issue of whether termination of painful, intrusive medical treatment might be appropriate where an infant's clear prognosis is death within days or months or to specify the level of appropriate care in such futile cases," he said.

Although Gesell confined his legal ruling to procedural issues, his opinion did touch on a broader question that could arise in future cases. Can section 504 of the handicapped rights act be properly interpreted as giving HHS authority to monitor individual medical treatment or establish standards for preserving a particular quality of life? Without resolving the matter, Gesell did say, "Many would argue that had Congress intended section 504 to reach so far into such a sensitive area of moral and ethical concerns it would have given some evidence of that intent."

For now, HHS is concentrating on its appeal of Gesell's decision but may well decide to seek congressional action if that fails. The signs in the nursery are down but the fight is not yet settled.

—BARBARA J. CULLITON