Supreme Court, Appellate Division, First Department, New York. In re Application of Carlotta Rosa ALVARADO, etc., et al., Petitioners–Appellants,

v.

The CITY OF NEW YORK, et al., Respondents–Respondents, and
New York State Department of Health, Intervenor–Respondent.
Jan. 25, 1990.

Parents of brain dead infant brought action to prevent hospital from removing life support system. The Supreme Court, New York County, <u>Freedman</u>, J., <u>145 Misc.2d 687</u>, <u>547 N.Y.S.2d 190</u>, entered judgment for hospital, and parents appealed. The Supreme Court, Appellate Division held that the order was required to be vacated, on consent of hospital, upon hospital's determination that condition of infant did not constitute brain death as statutorily defined.

Ordered vacated, appeal dismissed.

*354 B.W. Subin, New York City, for petitioners-appellants.

A.G. Krams, New York City, for respondents-respondents.

J.E. Kaufman, for intervenor-respondent. Before KUPFERMAN, J.P., and CARRO, ASCH, KASSAL and SMITH, JJ.

MEMORANDUM DECISION.

Order, Supreme Court, New York County (Helen Freedman, J.), <u>547 N.Y.S.2d 190</u>, entered on November 3, 1989 which, *inter alia*, rejected petitioners' constitutional challenge to the New York State Department of Health regulation governing determination of death, <u>10 NYCRR §</u> <u>400.16</u>, and held that the infant petitioner, Luis Alvarado, was brain dead pursuant to the criteria established therein, thereby permitting respondents to remove life support systems, unanimously vacated, on consent of respondents, and the appeal therefrom is dismissed as academic, without costs.

Subsequent to the issuance of the order appealed from, the municipal respondents determined, on the basis of new medical findings, that the condition of the infant petitioner does not constitute brain death as defined in 10 NYCRR § 400.16(a)(2), and have consented to vacatur of the order. In addition, respondents have agreed to seek judicial review before conducting further tests for the purposes of determining whether the infant petitioner is brain dead and before disconnecting life support systems based upon any such determination.

Accordingly, the order appealed from is vacated on consent of respondents, respondents are directed to seek judicial review as indicated, and the appeal is dismissed as academic.

145 Misc.2d 687, 547 N.Y.S.2d 190

Supreme Court, New York County, New York, IAS Part 30.

In the Matter of the Claim of Luis Alfonso ALVARADO, infant by his m/n/g Carlotta Rosa ALVARADO and Carlotta Rosa Alvardo and Luis A. Alvarado, individually, Petitioners, v

NEW YORK CITY HEALTH & HOSPITALS CORPORATION, Elmhurst Hospital and the City of New York, Respondents.

Oct. 18, 1989.

Parents of brain dead infant brought action to prevent hospital from removing life support system. The Supreme Court, Freedman, J., held that court had no authority to intervene in hospital's decision because infant fit within definition of death in Department of Health regulation, regulation was based on sound medical criteria, and regulation was both constitutionally and validly promulgated.

So ordered.

Order vacated and appeal dismissed, 550 N.Y.S.2d 353.

*687 **191 Bert Subin, Frank Melendez, Subin Associates, New York City, for alvarados.

Peter L. Zimroth, Corp. Counsel, New York City (Norma Kerlin, Alan Harris, of counsel), for City of New York.

Salvatore Russo, New York City, for Health & Hospitals.

Robert Abrams, Atty. Gen., New York City (Howard L. Zwickel, Judith E. Kaufman, Barbara Hathaway, of counsel), for State of N.Y.

*688 HELEN E. FREEDMAN, Justice:

In this tragic case, the Court is asked to prevent Elmhurst Hospital from removing a newborn infant from a respirator. The infant's brain ceased to function within hours of birth, although sophisticated mechanical devices have maintained heart and lung function.FN1

FN1. Perinatal deprivation of oxygen appears to have caused this unfortunate situation.

The Hospital claims that life support equipment should be withdrawn because **192 the infant, Luis Alvarado, is dead. The Hospital relies upon the New York State Department of Health ("DOH") regulation entitled "Determination of Death", 10 N.Y.C.R.R. § 400.16 ("the Regulation"). The child's parents challenge both the application of the regulation to this case and its validity.

The issues before this Court are: (1) whether the infant is "dead" within the meaning of the Regulation, (2) whether the Regulation is consistent with current medical knowledge, and (3) whether the Regulation is otherwise consistent with law. If the answer to all three questions is

yes, the law does not permit this Court to interfere with Hospital's decision to remove the respirator.

I Application of the Regulation to this Case The Regulation provides:

- (a) An individual who has sustained either:
- (1) irreversible cessation of circulatory and respiratory functions; or
- (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead.FN2
- FN2. The balance of the Regulation provides:
- (b) A determination of death must be in accordance with accepted medical standards.
- (c) Death, as determined in accordance with paragraph (a)(2) of this section, shall be deemed to have occurred at the time of the completion of the determination of death.
- (d) Prior to the completion of a determination of death of an individual in accordance with paragraph (a)(2) of this section, the hospital shall make reasonable efforts to notify the individual's next of kin or other person closest to the individual that such determination will soon be completed.
- (e) Each hospital shall establish and implement a written policy regarding determination of death in accordance with paragraph (a)(2) of this section. Such policy shall include:
- (1) A description of the tests to be employed in making the determination.
- (2) A procedure for the notification of the individual's next of kin or other person closest to the individual in accordance with subdivision (d) of the section; and
- (3) A procedure for the reasonable accommodation of the individual's religious or moral objection to the determination as expressed by the individual or by the next of kin or other person closest to the individual.

*689 Luis Alvarado was born September 6, 1989, at Elmhurst Hospital. He was transferred to Mount Sinai Hospital where on September 8, he was diagnosed as clinically brain dead. He was then returned to Elmhurst.

The Hospital Chart Progress Record discloses the following information. On September 15, 1989, the staff at Elmhurst met with Mr. and Mrs. Alvarado to explain in Spanish that the infant was clinically and irreversibly brain dead and that his heart and lungs functioned only with the

aid of the respirator and medication. The parents expressed a desire to continue life support systems.

On September 19, 1989, a Dr. Lescano, the attending neonatologist at Elmhurst, suggested to Mrs. Alvarado that she obtain an independent neurological evaluation and offered to meet with the parents and members of their church (Jehovah's Witnesses) to explain the baby's condition to them. She again indicated that she wished to have the life support systems maintained.

On September 21, 1989, Mrs. Alvarado met with a Hospital social worker, and on September 22, 1989, Dr. Lescano again explained to Mrs. Alvarado that the infant's condition was irreversible and that the Hospital would be obliged to remove the respirator unless she obtained a court order.

The Alvarados then commenced this action. On September 28, 1989, the City of New York petitioned the Court to appoint an independent pediatric neurologist to determine whether Luis Alvarado had suffered an irreversible cessation of all functions of the entire brain, including the brain stem. After a number of experts sought by the Court proved unavailable or unacceptable to petitioners' counsel, the Court **193 accepted a recommendation of petitioners' counsel and appointed Dr. Lydia Eviatar, the Chief of Pediatric Neurology at Long Island Jewish Medical Center.

Dr. Eviatar performed two independent neurological examinations, including two Electroencephalograms, on October 3rd *690 and on October 5th, 1989, in accordance with the protocols established pursuant to the Regulation, 10 N.Y.C.R.R. 400.16(e)(1). The parents, the hospital administrator, the Intensive Care Unit personnel, and on the second occasion the family's lawyer, were present.

On October 10, 1989, Dr. Eviatar testified that the infant had sustained irreversible cessation of all functions of the brain, including the brain stem, that there was no possibility of recovery and that all of the tests she performed confirmed these facts. Her tests demonstrated that the baby was comatose with no spontaneous activity or motion of the extremities in reaction to painful stimuli and at all times the baby's pupils remained in mid-position, dilated and unresponsive to light or sound. The baby exhibited no response to irrigation of both ear canals with 20 cc's of ice cold water and there was no ocular response to the oculocephalic maneuver. There were no rooting, sucking, coughing or corneal reflexes present. An apnea (breathing) test was performed with the baby given 100% oxygen via catheter directly into the endotracheal tube. After removal of the respirator, no spontaneous respirations were recorded, and both Electroencephalograms showed complete and total electrocerebral silence. The level of phenobarbital in the blood had been reduced below five for each set of tests so that there were no substances altering the level of consciousness.

Testing by the pediatric neurologists at Elmhurst Hospital and at Mount Sinai Hospital, and by Dr. Eviatar, conclusively demonstrated that there was no function in any part of the brain. Respiration and control of blood pressure normally performed by the lowest part of the brain stem are maintained solely by machinery and medication.

Petitioners have submitted no evidence contradicting the findings of the doctors here.FN3 Under the Regulation the Hospital's determination of death is therefore correct. Accordingly, the Court must address the validity of the regulation.

FN3. Counsel for petitioners argues that Dr. Eviatar found that there were some brain cells alive in the medulla, the part of the base of the brain stem which joins the spinal cord. In response to cross-examination, Dr. Eviatar speculated that the cardio-respiratory functions that had been maintained by artificial means had in turn kept some of the cells in the medulla alive. She said that without the artificial respiration those cells would die. She unequivocally maintained the position throughout cross-examination that all of her tests demonstrated complete irreversible brain death, including the brain stem.

*691 II The Definition of Death under the Regulation is Consistent with Current Medical Knowledge

The traditional legal and medical standard for determining death was based upon cessation of cardiopulmonary function. Since breathing and circulation may now be maintained artificially by sophisticated medical technology in cases where the brain has ceased to function entirely and irreversibly and where the ability to breathe depends completely upon artificial support, the traditional standard has had to be modified.

A definition of death which provides that death has occurred when there is irreversible cessation of all brain function has been accepted by the legal and medical professions and has been unanimously adopted by the Court of Appeals of the State of New York.

In 1968 a Harvard Medical School Committee developed criteria for determining brain death.FN4 Further refinements were published in 1972 and 1977. FN5 During the 1970's, the American Bar Association and **194 American Medical Association both considered and adopted model bills.FN6

FN4. Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death, A Definition of Irreversible Coma, 205, J.A.M.A. 337 (1968). See In Re Welfare of Bowman, 94 Wash.2d 407, 617 P.2d 731, 737 (1980).

FN5. In Re Welfare of Bowman, 617 P.2d at 737.

FN6. Id. 617 P.2d at 738.

In 1978 Congress established the President's Commission of the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research and charged it, inter alia, with studying "the advisability of developing a uniform definition of death." FN7 The Commission, chaired by Morris B. Abram, a New York lawyer, found that current technology permits physicians to "generate breathing and heart beat where the capacity to breathe spontaneously has been irretrievably lost;" and thus, the formerly accepted standard for determining death of 'cessation of cardiopulmonary function'" was too limited.

FN7. 42 U.S.C. § 300v-1(a)(1)(B) (1978).

The Commission issued an 84 page report which recommended legislation adopting the following standard for the determination of death:

"An individual who has sustained either 1) an irreversible cessation of circulatory and respiration functions or 2) irreversible cessation of all functions of *692 the entire brain, including the brain stem, is dead". (1980 Report of President's Commn. for Study of Ethical Problems in Med. and Biomedical and Behavioral Research.)

The Commission specifically rejected a standard of death involving cessation of higher brain (cerebral) function as too radical a departure from traditional religious and philosophical definitions of life and death.

Having reached this conclusion, the Commission worked with the American Bar Association, the American Medical Association and the National Conference of Commissioners on Uniform State Laws to develop statutory language.FN8 In 1980 the Conference approved and recommended that all states enact the Uniform Determination of Death Act which would provide:

FN8. Report of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, p. 2 (1980).

An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards.FN9
FN9. Id.

In New York the legal standard for death was set out in court decisions, not statutes or regulations. Based upon medical advances, the courts of this state were considering persons dead when brain function had ceased irreversibly. This position was affirmed in People v. Eulo (Bonilla), 63 N.Y.2d 341, 482 N.Y.S.2d 436, 472 N.E.2d 286 (1984) upholding two separate lower courts that had used that standard. The Eulo Court recognized that respirators or ventilators could substitute for the lower brain's failure to maintain breathing and that artificial respiration combined with chemical regimen could sustain continued operation of the heart. It found that the heart beat is independent of the brain and with medication, operates as long as blood containing oxygen circulates to the heart. Id. at 351, 482 N.Y.S.2d 436, 472 N.E.2d 286.

The Court noted "It is widely understood that the human brain may be anatomically divided, generally, into three parts: the cerebrum, the cerebellum, and the brain stem. The cerebrum, known as the 'higher brain,' is deemed largely to control cognitive functions such as thought, memory, and consciousness. The cerebellum primarily controls motor coordination. The brain stem, or 'lower brain', which itself has three parts *693 known as the midbrain, pons, and medulla, controls reflexive or spontaneous functions such as breathing, swallowing and sleepwake cycles." Id.

Eulo also discussed the fact that the first legal recognition of irreversible cessation of brain function as a criterion for determining death came in the form of a Kansas Statute enacted in 1970. (Kan.Stats.Ann.**195 § 77.202.) Since that time the President's Commission, the American Bar Association, the American Medical Association and numerous other states had established either through legislation or court decision that the ordinary and accepted meaning of death included "irreversible and complete cessation of the functioning of the entire brain, including the brain stem." Id. at 354–355, 482 N.Y.S.2d 436, 472 N.E.2d 286.

Governor Cuomo then established the New York State Task Force on Life and the Law ("Task Force") based upon the following findings:

- "... major advances in medical science and technology have not been accompanied by a sufficiently thorough evaluation of their ethical, legal and public policy implications; and
- "... as a result, society has, with increasing frequency, been confronted by complex issues of life and death that elude simple answers; and
- "... the challenges posed by these issues require thoughtful debate and consideration, aimed at elevating public understanding of these issues and at developing recommendations as to the appropriate policies to pursue;" FN10

FN10. Executive Order No. 56 (9 NYCRR § 4.56) dated December 17, 1984.

The twenty-six members of the Task Force, which included religious leaders, social service administrators, attorneys, physicians and members of the academic community, held public hearings across the state, heard presentations from experts in the fields of law, religion and medicine, and deliberated for an eighteen month period. The Task Force reviewed the medical and legal literature that had been developed during the previous twenty years.

In 1987, the Task Force concluded that New York should adopt the standard recommended by the President's Commission and already accepted in People v. Eulo on the ground that it "is sound public policy for the State and conforms to existing legal and medical standards". (Task Force Report at 6.)

*694 The Task Force spelled out its reasons for recommending this standard: "First, it establishes a uniform determination and pronouncement of death. Second, it makes the determination of death in this State consistent with the determination in the majority of other states in the nation. Third, it eliminates confusion for the decedent's family and marks the end of what would otherwise be a painful and ultimately futile waiting period before the pronouncement of death ...".

The Task Force concluded that legislative action was unnecessary since Eulo had judicially adopted the standard but that DOH should promulgate a regulation to assure uniform application of that standard. The Task Force also recommended that the regulation address additional issues, suggesting that procedures for informing family members be developed by hospitals and that

accommodation be made for religious and moral objections without establishing a right to continued treatment.

DOH responded to the Task Force's recommendations by proposing a regulation to establish uniform brain death standards for hospitals and other facilities licensed under Article 28 of the Public Health Law.

The language of the Regulation (which tracks the model statute) has been approved by the American Bar Association, the American Medical Association, the American Academy of Neurology, and the American Electroencephalographic Society.FN11 It is currently recognized by 49 states, including New York and that is thus consistent with the current state of medical knowledge. FN12

FN11. Commission Report, p. 73.

FN12. Affidavit of Thomas W. Hartman, Director of Health Care Standards and Analysis, Office of Health Systems Management, New York State Department of Health; New York Times, October 17, 1989, p. B6 quoting Dr. Arthur Caplan, Director of the Center for Bio–Ethics at the University of Minnesota.

It is significant to note that the President's Commission include cessation of higher brain (cerebral) function as too radical a departure from traditional religious and philosophical definitions of life and death. People who have lost higher brain function, are in a persistent vegetative state. While they have lost all cognitive functions, they respond to visual and auditory stimuli and often breathe on their own. Under the New York standard such persons are alive. In the familiar case of Karen Ann Quinlan, the family sought removal of life support systems because Ms. Quinlan had lost higher brain *695 (neocortical) function and was in a persistent vegetative state. FN13 The Court complied with the wishes of the family but her respiratory functions continued for a number of years without the aid of mechanical devices. Unlike Ms. Quinlan, the Alvarado baby has no brain function and does not breathe when the respirator is removed.

FN13. In Re Quinlan, 70 N.J. 10, 355 A.2d 647 cert. den. sub nom. Georger v New Jersey 429 U.S. 922, 97 S.Ct. 319, 50 L.Ed.2d 289 (1976). For a comprehensive discussion of the legal implications of loss of neocortical function see, 71 Cornell Law Review 850 Smith, Legal Recognition of Neocortical Death.

This case differs from the usual "right to die" case in that typically family members seek court authorization to have life support systems terminated where there is a loss of higher brain function, that is, when the patient is in a persistent vegetative state. Therefore, most case law discusses the difference between cognitive and motor function and presumes that there will be no issue should there be no brain function at all.

This Court has found only two cases where relatives or a court appointed guardian sought to prevent termination of life support for young children whom doctors had determined to be brain dead. In re Welfare of Bowman, 94 Wash.2d 407, 617 P.2d 731 (1980) and Dority v. Superior

Court of San Bernardino, 145 Cal.App.3d 273, 193 Cal.Rptr. 288 (4th Dist.1983). In both cases, brain death was found and termination of life support systems authorized. Both courts recognized the wrenching emotional circumstances surrounding these decisions but found no basis for court intervention.

Therefore, even if no Regulation had been adopted, the infant would be dead under modern medicine and law.

III The Legality of the Regulation

Authority of DOH to promulgate the Regulation

Petitioners do not challenge the procedure used by DOH in promulgating the regulation, for it appears to have complied with all lawful requirements. DOH responded to the Task Force's recommendations by proposing for public comment in the State Register on May 13, 1987, a regulation to establish uniform standards for determining death for hospitals and other facilities licensed under Article 28 of the Public Health Law. The regulation was adopted by the State Hospital Review and Planning Council (the "Council"), the body authorized by the legislature to adopt and amend rules and regulations to effectuate Article 28, approved by the Commissioner of *696 Health as required by law, and filed with the Secretary of State on August 25, 1987. FN14

FN14. Public Health Law 2803(2); Hartman Affidavit, par. 5, 14. Subdivisions (d) and (e), which had not been included in the original proposed regulation, were added as an amendment the same day. The proposed regulation had also been "shared" with the legislature's Administrative Regulation Review Commission, which reviews all regulatory proposals, and no objection was raised. Hartman Affidavit, par. 13.

Petitioners claim, however, that DOH usurped a legislative function in promulgating a rule of this nature. DOH responds that it acted under the authority provided by Public Health Law § 2800 which states that: "Hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health". This statute was held to be constitutional in Levine v. Whalen, 39 N.Y.2d 510, 384 N.Y.S.2d 721, 349 N.E.2d 820 (1976). DOH is charged with having "central comprehensive responsibility for development and administration of the State's policy with respect **197 to hospital and related services ..." Regulatory power to implement this mandate is vested in the Council as noted above.

It is well established that regulatory agencies have broad discretion to promulgate rules consistent with their enabling legislation Nicholas v. Kahn, 47 N.Y.2d 24, 416 N.Y.S.2d 565, 389 N.E.2d 1086 (1979). Moreover, "remedial statutes and regulations designed to promote the public good should be liberally construed." Festa v. Leshen, 145 A.D.2d 49, 537 N.Y.S.2d 147 (1st Dept.1989). In Consolidated Edison Co. v. Department of Environmental Conservation, 71 N.Y.2d 186, 192, 524 N.Y.S.2d 409, 519 N.E.2d 320 (1988), the Court of Appeals found that in areas of regulation requiring technical expertise, regulations within the "traditional agency role of applying technical expertise to implement legislative goals," should be upheld.

[1] The regulation at issue falls well within DOH's discretionary powers. This agency has the responsibility of addressing complicated bio-medical issues confronting hospitals and related medical facilities. Since the law of the state had already been confirmed by the Court of Appeals, DOH acted responsibly in codifying that law for hospitals and providing guidance in how to proceed in this area.

The Constitutionality of the Regulation

Petitioners claim that the Regulation is unconstitutional in that it is so "vague and overly broad" that there could be *697 2,000 different criteria for brain death in 2,000 different hospitals. (Melendez affidavit, p. 4)

[2] There has been no showing that the Regulation has created any confusion or inconsistency. Under the Regulation, as before, any determination of death "must be made in accordance with accepted medical standards" 10 N.Y.C.R.R. § 400.16(b). The Regulation merely codified the existing medical definition and suggested implementation procedures. Moreover, the President's Commission and the National Conference of Commissioners on Uniform State Laws concluded that the language contained in the Regulation gave adequate guidance.

The Court further notes that the standards in effect at Elmhurst Hospital, adopted pursuant to the Regulation, were quite specific. Those standards, in four single-space pages, describe a variety of tests which must be performed, specify additional criteria that must be applied in the case of children under three years of age (including repetition of tests 72 hours apart), require that at least two doctors must concur, and provide that if any uncertainty exists, death may not be found.

Petitioners also claim that the Regulation violates the Due Process Clause of the Fourteenth Amendment to the United States Constitution by "infring(ing) upon a person's right to live" while making "(n)o allowance for due process to challenge the finding of the hospital ..."

[3] To determine whether there has been a deprivation of a right without due process, a protected right must be established. If a person is dead, there is no life to be deprived of, with or without due process of law. From time immemorial, physicians have determined when persons are dead and have ceased giving medical treatment. See Matter of Perricone, N.Y.L.J. April 2, 1985, p. 13, col. 3 (Sup.Ct. Nassau County). It is not a denial of due process to have physicians, rather than parents or next of kin or close friends, determine that death has occurred.

The State concedes that petitioners do have a protected right: they have "the right to participate in decisions concerning the medical care of family members and ... in assuring that necessary medical care is not improperly withheld."

Under the Regulation, a hospital must have a procedure for notifying next of kin or another person closest to the individual that a determination of death will soon be completed, and a procedure for the reasonable accommodation of a religious or moral objection to the determination.

*698 **198 [4] In the instant case, the Alvarados were notified before a determination was made, were given an opportunity to obtain an independent medical evaluation, and were offered a chance to have the matter discussed with religious leaders and friends. Therefore, it cannot be said that the family was deprived of its due process rights to participate in the medical care of the child.

[5] For all of the reasons discussed above, the definition of death in the Regulation has been satisfied, the Regulation is based on sound medical criteria and the Regulation was both constitutionally and validly promulgated. Thus, the Court has no authority to intervene in what is a wrenching and heart rending decision to be made by the Hospital.

However, given the emotional impact of a decision to terminate on the family as well as the major medical and legal issues raised, the order restraining the hospital from discontinuing life support systems shall be continued until Monday October 23, 1989 at 5 p.m. during which time the family may make arrangements to move the child to another facility or appeal this decision.