

Boston University School of Law

Scholarly Commons at Boston University School of Law

Faculty Scholarship

Fall 1977

Scientific Research with Children: Legal Incapacity and Proxy Consent

Leonard H. Glantz

George J. Annas

Barbara Katz

Follow this and additional works at: https://scholarship.law.bu.edu/faculty_scholarship

 Part of the [Health Law and Policy Commons](#)





DATE DOWNLOADED: Tue Apr 25 21:24:44 2023

SOURCE: Content Downloaded from [HeinOnline](#)

Citations:

Please note: citations are provided as a general guideline. Users should consult their preferred citation format's style manual for proper citation formatting.

Bluebook 21st ed.

Leonard H. Glantz, George J. Annas & Barbara F. Katz, Scientific Research with Children: Legal Incapacity and Proxy Consent, 11 FAM. L.Q. 253 (1977).

ALWD 7th ed.

Leonard H. Glantz, George J. Annas & Barbara F. Katz, Scientific Research with Children: Legal Incapacity and Proxy Consent, 11 Fam. L.Q. 253 (1977).

APA 7th ed.

Glantz, L. H., Annas, G. J., & Katz, B. F. (1977). Scientific research with children: legal incapacity and proxy consent. Family Law Quarterly, 11(3), 253-296.

Chicago 17th ed.

Leonard H. Glantz; George J. Annas; Barbara F. Katz, "Scientific Research with Children: Legal Incapacity and Proxy Consent," Family Law Quarterly 11, no. 3 (Fall 1977): 253-296

McGill Guide 9th ed.

Leonard H. Glantz, George J. Annas & Barbara F. Katz, "Scientific Research with Children: Legal Incapacity and Proxy Consent" (1977) 11:3 Fam LQ 253.

AGLC 4th ed.

Leonard H. Glantz, George J. Annas and Barbara F. Katz, 'Scientific Research with Children: Legal Incapacity and Proxy Consent' (1977) 11(3) Family Law Quarterly 253

MLA 9th ed.

Glantz, Leonard H., et al. "Scientific Research with Children: Legal Incapacity and Proxy Consent." Family Law Quarterly, vol. 11, no. 3, Fall 1977, pp. 253-296. HeinOnline.

OSCOLA 4th ed.

Leonard H. Glantz, George J. Annas & Barbara F. Katz, 'Scientific Research with Children: Legal Incapacity and Proxy Consent' (1977) 11 Fam LQ 253

Please note: citations are provided as a general guideline. Users should consult their preferred citation format's style manual for proper citation formatting.

Provided by:

Fineman & Pappas Law Libraries

-- Your use of this HeinOnline PDF indicates your acceptance of HeinOnline's Terms and Conditions of the license agreement available at

<https://heinonline.org/HOL/License>

-- The search text of this PDF is generated from uncorrected OCR text.

-- To obtain permission to use this article beyond the scope of your license, please use:

[Copyright Information](#)

Scientific Research with Children: Legal Incapacity and Proxy Consent*

LEONARD H. GLANTZ[†]
GEORGE J. ANNAS[‡]
BARBARA F. KATZ[§]

Before an investigator can use any person as a subject in biomedical or behavioral research, he must obtain that person's informed consent. This consent must be voluntary, competent, and understanding.¹ There are two questions that arise in regard to experimentation on children. First, is a child legally capable of giving an informed and understanding consent? Second, do parents have the legal capacity to consent to the performance of research on their children? This article will attempt to answer both of these questions.

More than a decade ago, the renowned legal scholar, Paul Freund, wrote, ". . . the law cannot now be expected to yield precise answers to the ethical problems of human experimentation."² Unfortunately, in regard to the law respecting research on children, this statement is equally true today.

*Reprinted with permission from INFORMED CONSENT TO HUMAN EXPERIMENTATION: THE SUBJECT'S DILEMMA. Copyright 1977, Ballinger Publishing Company, Cambridge, MA. The research for this article was conducted by the authors for the National Commission for the Protection of Human Subjects of Bio-Medical and Behavioral Research under N.I.H. Contract No. N01-HU-6-2120.

[†]Staff Attorney, Center for Law and Health Sciences, Boston University School of Law; Assistant Professor, Boston University School of Medicine.

[‡]Director, Center for Law and Health Sciences, Boston University School of Medicine; Member, Massachusetts Bar.

[§]Instructor, Boston University School of Law.

1. United States of America v. Karl Brandt, in KATZ, EXPERIMENTATION WITH HUMAN BEINGS, 305-306 (1972). See Appendix I.

2. Freund, *Ethical Problems in Human Experimentation*, 273 NEW ENG. J. MED. 687 (1965).

Research on children has provided society with substantial benefits. Studies of normal mineral and water composition of healthy infants have led to effective parenteral fluid therapy and regimens with which to combat serious complications of diarrheal diseases.³ Research on healthy children is the only method by which one can establish normal patterns of growth and metabolism.⁴ In addition, the Kefauver-Harris amendments to the Food, Drug and Cosmetics Act⁵ require that drugs to be distributed in interstate commerce for use in children be tested in children to determine their safety and efficacy. Due to the fact that children are not simply "little people," drug testing on adults does not provide adequate information regarding dosage, contraindications, toxicity, efficacy, or side effects for children.⁶

The beneficial nature of research on children does not, however, establish its legality. Before going on to examine the law regulating therapeutic medical procedures that are performed on minors, we should first examine the issue of how the law has come to define minority.

Who Is a Minor?

Under both American and English common law an individual was a minor until he reached the age of twenty-one.⁷ Recently, almost all the states have lowered the age of majority to eighteen.⁸ It is not entirely clear how it was originally determined that the attainment of twenty-one years of age should be the dividing line between minority and adulthood.

In Roman law at the time of Justinian there were three age groups that determined legal capacities and incapacities. First, *infantia*, where the child was incapable of speech, but by 407 A.D.

3. Lowe, Alexander and Mishkin, *Non-Therapeutic Research in Children: An Ethical Dilemma*, 84 J. PED. 468 (1974).

4. *Id.* at 469.

5. 21 U.S.C. 5301 *et seq.*

6. Capron, *Legal Considerations Affecting Clinical Pharmacological Studies in Children*, 21 CLIN. RES. 141, 142 (1972).

7. 1 BLACKSTONE, COMMENTARIES at *463; *Bardwell v. Purrington*, 107 Mass. 419, 425 (1871).

8. TIME, November 25, 1974 at 92.

this was fixed at below seven years of age. Second, *tutela impuberes* ceased at puberty, as a tutor was no longer required when a child could have children. At later law this was fixed at fourteen for males and twelve for females. Third, *cura minoris* was the reaching of adulthood, and was later set at twenty-five years of age.⁹

Among the barbarian tribes fifteen was both the age of majority and the age of combat. In thirteenth-century France if either the challenger or the challenged in judicial combat (the forerunner of dueling) was under fifteen years of age, there could be no combat.¹⁰ Between the ninth and eleventh centuries, fifteen seemed to be the age of majority in Northern Europe.¹¹ The basis on which the age of majority was adopted was quite different in Europe and in Rome. In Rome the question was: Had the male "pupil" both understanding and judgment as to acts in law, particularly in relation to property rights? It was presumed these capacities arose at puberty, later set at fourteen. In Europe, the choice of age fifteen seems to be connected to the capacity to bear arms.¹² Apparently, the raising of the age of majority from fifteen to twenty-one was due to the increase in weight of arms. It was not until the late eleventh century that a military revolution involving a mounted knight occurred, and knighthood became a social distinction. In the twelfth century, knights began riding horses into battle and by the thirteenth century, armor became very heavy. The combination of the heavy armor and the use of horses in combat required a stronger and better trained knight, thus requiring extra years of training and physical development.¹³

During this time, however, socage tenants (those who owned and worked land) recognized fifteen as the age of majority, which was later reduced to fourteen. In socage tenure, one came to majority when he was capable of "attaining to husbandry and 'of conducting his rustic employes.'"¹⁴

9. James, *The Age of Majority*, 4 AM. J. OF LEG. HIST. 22, 24 (1960).

10. *Id.*

11. *Id.* at 25.

12. *Id.*

13. *Id.* at 26-28.

14. *Id.* at 30.

Until 1753 when the Marriage Act was passed, a minor could marry at the age of fourteen without the consent of his parents. After the passage of the Marriage Act, this age was raised to twenty-one for males. A statute of Phillip and Mary raised the age when a female could marry without consent from fourteen to sixteen. It seems that this is responsible for fixing the woman's age of consent to sexual intercourse at sixteen.¹⁵

A commentator who wrote over a hundred years ago acknowledged the fact that setting any one age for the termination of infancy was inequitable, but states that twenty-one years of age is as good as any other.¹⁶ He points out that human life is divided into four periods, each of which is a multiple of seven.

Natural infancy ends at seven years, puberty begins at fourteen, legal infancy ends at twenty-one years, and the natural life of man is three-score years and ten.¹⁷

It is generally believed that the legal status of minority offers children certain protections. As Blackstone put it:

Infants have various privileges, and various disabilities; but their very disabilities are privileges; in order to secure them from hurting themselves by their own improvident acts.¹⁸

From an historical perspective, this is not readily apparent. Under ancient Roman law a father had the power of life and death over his children until they reached adulthood. He could kill, mutilate, sell or offer his child in sacrifice.¹⁹ Such was also the case in ancient Greece.²⁰

In feudal law if a tenant died leaving a minor heir, the lord was allowed the profitable rights of wardship and marriage. The lord had full use of the child's land and had no obligation to render an account to the minor. Upon obtaining majority, the ward had to sue the lord for possession and pay a half year's profit to the lord to receive his own land. Although the minor is protected from

15. *Id.* at 31-32.

16. Tyler, *LAW OF INFANCY AND COVERTURE*, 34 (1868).

17. *Id.*

18. BLACKSTONE, *supra* note 7, at *464.

19. Thomas, *Child Abuse and Neglect, Part I: Historical Overview, Legal Matrix, and Sociological Perspectives*, 50 N. CAR. L. REV. 293, 295 (1972).

20. *Id.* at 294.

squandering his inheritance, it is a rather expensive means of protection.²¹

It has also been argued that a minor's reduced capacity to contract was not for the minor's protection. Under the common law a father was entitled to all the earnings of his child. One way of assuring the father's receipt of these earnings was to prevent the minor from spending them. This was accomplished by rendering the minor incapable of entering into a binding contract. It also protected the father's goods in that the minor could not sell any of his father's property and convert the proceeds to his own use.²²

According to Blackstone,²³ at common law, minors were given the power to enter into a number of serious endeavors. A male at the age of twelve could take the oath of allegiance; at fourteen, he reached the age of discretion and, as discussed above, could consent to or disagree to marriage, could choose his guardian, and, if discretion was actually proved, could make a testament of his personal estate; and at seventeen he could be an executor. A female could be given in marriage or betrothed at seven; at nine she was entitled to dower; at twelve she could consent to or disagree to marriage, and, if found to have sufficient discretion, could bequeath her personal estate; and at seventeen she could be an executrix.

A three-judge Federal District Court in deciding that some minor women are capable of consenting to abortions stated:

[W]hatever may be the value of conclusive presumptions making the 18th birthday a turning point for such matters as voting, the purchase of liquor, and entering into contracts other than certain contracts for necessities, . . . we can attach no such factual magic to that birthday.²⁴

This short review of how we have come to adopt an age of majority not only demonstrates that one cannot attach any "factual magic" to that age, but that our choice of an age of majority is based on feudal law and custom with no relevance to the needs of a modern society.

As a result of this fact some courts have taken a more operative

21. Edge, *Voidability of Minors Contracts: A Feudal Doctrine in a Modern Economy*, 1 GA. L. REV. 205, 220 (1966-67).

22. *Id.* at 221-222.

23. BLACKSTONE, *supra* note 7, at *463.

24. *Baird v. Bellotti*, 393 F. Supp. 847, 855 (1975), *vacated*, 44 U.S.L.W. 5221 (June 29, 1976).

approach to resolving age of consent problems in certain specific circumstances. Thus, in another case dealing with a minor woman's capacity to consent to an abortion, the Washington Supreme Court held that:

The age of fertility provides a practical minimum age requirement for consent to abortion, reducing the need for a legal one.²⁵

One commentator writing about the criminal responsibility of children also pointed to the arbitrary ages set for determining their criminal responsibility. The general rule is that a child younger than seven is conclusively presumed to be incapable of committing a crime.²⁶ Between the ages of seven and fourteen a child is presumed to be incapable of committing a crime, but this presumption is rebuttable by the state.²⁷ The author then discussed the psychological research that has been conducted concerning the development of moral judgment and a sense of justice in children.²⁸ She concludes that at approximately the age of twelve

a juvenile should have reached a sufficient degree of maturation when he is able to assume the consequences of his acts. He has then reached a subjective responsibility and acquired consideration of equity, internalized orientation of right and wrong as well as distributive justice. The child younger than twelve years of age should not be presumed to possess a moral development sufficient to be considered as legally responsible.²⁹

Whether or not one agrees with this conclusion, this paper has taken a giant step in its approach to rationally setting an age of criminal responsibility. Instead of basing the choice of an age of responsibility on the weight of armor, she attempted to use modern psychological research for some guidance. Basically, the paper states that one cannot commit a crime until one understands the meaning of moral responsibility, and one does not reach this stage until about the age of twelve.

One attempt has been made at rationally setting an age limit on participation in a particular experimental procedure. Proposed Massachusetts regulations state:

25. *State v. Koome*, 1 F.L.R. 2236, 2237 (Feb. 18, 1975).

26. Cote-Harper, *Age, Delinquent Responsibility and Moral Judgment*, 11 LES CAHIERS DE DROIT 480, 496 (1970).

27. *Id.*

28. *Id.* at 500-505.

29. *Id.* at 506.

Psychosurgery shall not be performed on the following categories of patients; a) all patients under the age of thirty [30] years old where there is still the possibility of developmental maturation.³⁰

The physiological fact that developmental maturation continues until the age of thirty was used as the criterion for setting this age limit.

Unfortunately, no such analysis exists in regard to consent of a minor to a medical treatment. It would be most helpful to know at what age a child obtains a true sense of his body and mind, knows what it means to take risks, knows what it means to be harmed or suffer discomfort, knows how to balance risks and benefits, and so forth. If we had this knowledge it might be possible to rationally determine an age at which most people could give an informed consent to medical treatment and experimentation. In the absence of such an analysis the courts have constructed their own rules, as we shall now examine.

Consent to Therapeutic Treatment

As a general rule, "a surgeon who performs an operation without his patient's consent commits an assault and battery for which he is liable in damages."³¹ The law of battery is designed to protect the individual's interest in freedom from intentional unpermitted contacts. In proving battery, hostile intent need not be shown. One is only required to prove the absence of consent to the contact.³² The problem of providing medical treatment to children is that they are deemed to be legally incapable of giving such consent.³³ Thus, prior to conducting a therapeutic procedure on a child, the consent of the parent is generally obtained. There is case law that would indicate that the giving of such consent is a parental right that is not tied to any protective function. In the only case that analyzes the basis for the parental consent requirement it is said:

This rule [that a minor cannot consent to medical treatment] is not based upon the capacity of the minor to consent, so far as he is personally con-

30. Proposed Mass. Dept. of Mental Health Reg. § 220.18, 5 Mass. J. of Ment. Health 53 (1975).

31. *Schloendorff v. Society of N.Y. Hosp.* 211, N.Y. 125, 105 N.E. 92, 93 (1914).

32. PROSSER, *LAW OF TORTS*, 34-36 (4 ed. 1971).

33. *Id.* at 102.

cerned, within the field of the law of torts or law of crimes, but is based upon the right of parents whose liability for support and maintenance of their child may be greatly increased by an unfavorable result from the operational procedures upon the part of the surgeon. . . . [S]ince the parents of such a child are responsible for his nurture and training and are liable for his maintenance and support, others will not be permitted to interfere with such relationship or with matters touching the child's personal welfare.³⁴

The court in effect is stating that since the parent of a child might be financially damaged as a result of a procedure performed on his child, he must consent before such a result may occur.

In another case³⁵ an eleven-year-old child died after an operation to remove her tonsils and adenoids. Although there was no parental consent to the operation, the operation was consented to by the child's adult sister. The court held that only the parent could give such a consent and therefore the doctor committed an assault and battery. What is especially interesting here is that the adult sister was in her third year of training as a nurse, and could probably better understand the necessity for, and risks inherent in, the operation, thereby being better able to protect the child's interest. The court was clearly not concerned with protecting the child's interests but in protecting the parents' prerogatives.

It must be noted that the parental prerogative to consent to medical care for the child is not without its limitations. Where it appears that the parents' decision not to consent to medical treatment will cause the child serious injury, the court will intervene to protect the child's interest. Thus, in *In re Clark*,³⁶ the parents would not consent to blood transfusions that were necessary in order to treat their three-year-old child who was suffering from second and third degree burns over forty percent of his body. The court found that:

[The child] has rights of his own—the right to live and grow up without disfigurement.

The child is a citizen of the State. While he "belongs" to his parents, he belongs also to the State. Their rights in him entail many duties. Likewise the fact that the child belongs to the State imposes upon the State many duties. Chief among them is to protect his right to live and grow up with a sound mind in a sound body, and to brook no interference with that right by any person or organization.³⁷

34. *Lacey v. Laird*, 166 Ohio St. 12, 139 N.E.2d 25, 30 (1956).

35. *Moss v. Rishworth*, 222 S.W. 225 (Texas, 1920).

36. 185 N.E.2d 128 (Ohio, 1962).

37. *Id.* at 132.

The recent lower court cases, *Maine Medical Center v. Houle*³⁸ and *In the Matter of Karen Quinlan*,³⁹ hold that parents may not order the termination of treatment that is required to keep their children alive, even when the parents believe that such action would be in the best interests of their child. The protective role courts take is amply demonstrated by the *Houle* case where the doctors, agreeing with the parents, stated that withholding treatment would be in the child's best interests.⁴⁰ However, as is discussed in detail in the section on proxy consent, the appeals court in the *Quinlan* case has reduced the protective role of the court.

Moreover, where the courts are not presented with a life-threatening situation, the refusal of a parent to give consent will not be overruled by the courts. For example, in *In re Seiferth*,⁴¹ a parent would not consent to an operation on a fourteen-year-old boy that was needed to repair a harelip and cleft palate. Although physicians and social workers claimed that it was important for this child to undergo such procedures, the court refused to overrule the parental judgment.

However, there is some indication from more recent cases that courts are beginning to take a more protective role even where the situation does not threaten the child's life. In *In re Sampson*,⁴² a fifteen-year-old boy suffered from Von Recklinghausen's disease which caused a "massive deformity" of the right side of his face. Although he was excused from school as a result of his deformity and had no friends, this condition did not threaten his physical well-being. Neither his sight nor his hearing was affected. Physicians testified that they could not cure the problem, although it could be alleviated, and that the surgery that would take from six to eight hours to perform was "risky." One physician stated that the risk of the procedure would decrease as the child became older because the relative blood loss would be smaller. He suggested that the court wait until the child reached twenty-one years of age so he

38. Maine Sup. Ct. Civ. No. 74-145 (Feb. 14, 1974).

39. New Jersey Sup. Ct. Chancery Div. No. C-201-75 (Nov. 10, 1975).

40. *Supra* note 38, at 3.

41. 309 N.Y. 80, 127 N.E.2d 820 (1955).

42. 317 N.Y.S.2d 641 (1970), *aff'd*, 29 N.Y.2d 900 (1972).

could make his own decision, and that nothing would be lost by waiting. The court, finding that psychological harm would result from not performing the procedure now, overruled the mother's refusal to give her consent. This decision is some indication of how far a court will go in protecting the interests of the child by limiting the prerogative of the parent.

The Child's Consent to Medical Care

While somewhat limiting the parents' ability to make decisions regarding their child's health care, courts and legislatures are at the same time expanding the child's capacity to give consent to such care. A number of doctrines have developed that enable a child to receive health care services without parental consent. First, if an emergency exists, a physician need not wait to receive consent prior to the commencement of treatment. This rule applies to minors as well as adults.⁴³ However, determining whether or not an emergency exists requires, in at least some cases, a subjective judgment, and if the physician is wrong in his determination, he may be liable for damages.⁴⁴

Second, an emancipated minor may, in some jurisdictions, consent to medical treatment.⁴⁵ Children become emancipated by marriage, judicial decree, consent of the parent, or failure of the parents to meet their legal responsibilities.⁴⁶ In addition, a minor who is self-supporting and lives separate and apart from his parents is often deemed to be emancipated.

It is noteworthy that although some courts and legislatures allow emancipated minors to consent to health care, emancipation does not generally give a minor the rights of an adult. Generally, a minor is emancipated against his parents and not the whole world. That is to say, he is no longer under their control and guidance, and they are no longer obligated to support and nurture the child. When a California court ruled that "an emancipated child is in all respects

43. PROSSER, *supra* note 32, at 103; MASS. GEN. LAWS. ANN.ch. 112 § 12F; ANN. CODE OF MD. Art. 43 § 135.

44. *Roger v. Sells*, 61 P.2d 1018 (Okla. 1936).

45. Pilpel, *Minors' Right to Medical Care*, 36 ALB. L. REV. 462, 464 (1972).

46. *Id.* at 465; See, Katz, Schroeder and Sidman, *Emancipating Our Children—Coming of Legal Age in America*, 7 FAM. L.Q. 211 (1973).

his own man . . . with the same independence as though he had attained the age of majority,"⁴⁷ a commentator wrote that this case made a "radical departure" from the general rule.⁴⁸ The general rule is readily stated in the ancient Massachusetts case of *The Inhabitants of Taunton v. The Inhabitants of Plymouth*,⁴⁹ wherein it was held that the emancipation of a son "did not give him capacity to make binding contracts, beyond other infants; or any political or municipal rights, which do not belong by law to minors."⁵⁰

Some statutes merely state that an emancipated minor may consent to medical care.⁵¹ Some statutes are more explicit, stating, for example, that a minor who is fifteen years of age or older, and who is living apart from his parents regardless of duration, and who is managing his own financial affairs, regardless of the source of income, may consent to medical and surgical treatment.⁵²

In the absence of a statute some courts have adopted the emancipated minor rule. Thus an eighteen-year-old (the age of majority in this case being twenty-one) who was married, employed, self-supporting and a father, was held to be legally capable of consenting to a vasectomy.⁵³ The court looked to the age, intelligence, maturity, training, experience, economic independence, and general conduct as an adult in determining the emancipated status of this minor.

Courts and legislatures in adopting the emancipated minor rule have responded creatively to a specific problem. If a minor is living separate and apart from his parents, requiring parental consent would be a serious barrier to the minor's receiving medical treatment. Additionally, since the parent of an emancipated child is no longer responsible for the maintenance and support of that child, a bad result will not increase that parent's obligation.

Finally, the last exception to the general rule is that "mature minors" can consent to receiving medical treatment. In one

47. *Jolicoeur v. Mihaly*, 5 Cal. 3d 565, 96 Cal. Rptr. 697, 488 P.2d 1 at 10 (1971), cited in *Katz, et al., supra* note 46, at 231.

48. *Katz, et al., supra* note 46, at 231.

49. 15 Mass. 203 (1818).

50. *Id.*

51. *See, e.g.*, NEV. REV. STAT. § 12.030(1).

52. *See, e.g.*, CA. CIV. CODE § 34.6.

53. *Smith v. Seibly*, 431 P.2d 719 (Wash. 1967).

seventy-year-old case,⁵⁴ a seventeen-year-old boy who was accompanied to the hospital by an adult aunt and adult sister, died during a surgical procedure to remove a tumor from his ear. Although his father had not consented to the procedure, the court held that no battery was committed since he was accompanied by adult relatives, and since the boy, who was almost grown into manhood, gave his consent.

In *Lacey v. Laird*,⁵⁵ an eighteen-year-old underwent plastic surgery on her nose without parental consent. One judge in a concurring opinion found that since she was a minor she could not legally consent to the procedure, and therefore a technical battery occurred. However, since the battery was of a merely technical nature only nominal damages, one dollar or less, could be awarded.⁵⁶ Another judge, also concurring in the outcome of the case, said that an eighteen-year-old could consent to simple surgical procedures.⁵⁷

In *Bishop v. Shurly*,⁵⁸ a court found that a nineteen-year-old could consent to the administration of a local anesthetic although his mother requested the use of a general anesthetic. And in *Younts v. St. Francis Hospital*,⁵⁹ a seventeen-year-old intelligent minor was allowed to consent to a skin transplant to treat a seriously damaged finger. The court found that she was of sufficient age and maturity to know and understand the nature of the procedure.⁶⁰

Several states have legislatively adopted the mature minor doctrine to a greater or lesser degree.

In Oregon, any person fifteen years of age or older may consent to medical or surgical care.⁶¹ In Alabama, the age of consent to medical care is fourteen.⁶² Mississippi has what may be the most liberal statute which states that:

Any unemancipated minor of sufficient intelligence to understand and ap-

54. *Bakker v. Welsh*, 144 Mich. 632, 108 N.W. 94 (1906).

55. *Supra* note 34.

56. *Id.* at 30-31.

57. *Id.* at 34.

58. 237 Mich. 76, 211 N.W. 75 (1926).

59. 205 Kan. 292, 469 P.2d 330 (1970).

60. *Id.* at 338.

61. ORE. REV. STAT. ch. 381 § 1-3.

62. Code of Ala. ch. 22 § 104(15).

preciate the consequences of the proposed surgical or medical treatment or procedures [may consent to such procedures].⁶³

Basically, the mature minor rule states that anyone who is mature and intelligent enough to give informed consent to a procedure can undergo that procedure without parental consent. Or to put it another way, if you can understand the risks you can consent to them.

The Supreme Court of the United States has, to some extent, validated the mature minor rule, at least insofar as abortion is concerned. The Missouri legislature responded to the Supreme Court's 1973 *Roe v. Wade*⁶⁴ decision that required the liberalization of state abortion laws, by passing a statute that prohibited minors from obtaining abortions unless one of the minor's parents consented to the procedure.⁶⁵ This requirement was challenged in the case entitled *Planned Parenthood of Central Missouri v. Danforth*.⁶⁶ The Court held that the parental consent requirement was unconstitutional, stating,

Constitutional rights do not mature and come into being magically only when one attains the state defined age of majority. Minors, as well as adults, are protected by the Constitution and possess constitutional rights.⁶⁷

However, the Court did not find that "every minor, regardless of age or maturity may give effective consent for termination of pregnancy."⁶⁸ This statement does indicate that if a minor is sufficiently mature then that minor is capable of consenting to an abortion. The determination of maturity must be made on a case by case basis.

The Court decided a similar case⁶⁹ on the same day concerning a Massachusetts statute prohibiting abortions on minors unless both parents consented to it. Unlike the Missouri statute, if one or both parents refused to consent, consent could be obtained by order of a judge of superior court for "good cause shown."⁷⁰

The Massachusetts Attorney General argued that this statute did

63. MISS. CODE ANN. § 41-41-3(h).

64. 410 U.S. 113 (1973).

65. H.C.S. House Bill No. 1211 § 3(4).

66. 44 U.S.L.W. 5198 (June 29, 1976).

67. *Id.* at 5204.

68. *Id.*

69. *Bellotti v. Baird*, 44 U.S.L.W. 5221 (June 19, 1976).

70. MASS. GEN. LAWS ch. 112 § 12P.

not give parents a veto power over a minor's decision to have an abortion. If the parents refuse to consent the minor has recourse to the courts, and, according to the Attorney General, if the court finds that a minor is "capable of giving an informed consent" it must permit the abortion.⁷¹ This retains the mature minor rule and merely requires a court to determine the minor's maturity. The state also argued that a minor could petition the court regardless of whether the parents had been consulted or had withheld consent.

The Court strongly implied that if this interpretation of the statute, which indicates a preference for parental consultation and consent but gives the parents no veto power, and deems mature minors as being legally capable of giving consent, is correct, then the statute would be constitutional. However the Court decided that it would not decide the case until the Massachusetts Supreme Judicial Court had a chance to interpret the statute.

For our purposes it is enough to say that in both of these cases the Supreme Court found that mature minors were capable of giving a valid informed consent to undergo a serious medical procedure.

The Child's Consent to Take Risks

Under our legal system the capacity of a child to consent to risky undertakings is not novel. Indeed, the doctrine of "assumption of risk" has been applied to minors a number of times. Assumption of risk is a defense in a negligence action. It means that the plaintiff, in advance, has expressly given his consent to relieve the defendant of an obligation of conduct toward him, and to accept the chance of injury from a known risk arising out of the defendant's actions. This doctrine is summarized in the Latin phrase, *volenti non fit injuria*—to one who is willing no wrong is done.

To successfully invoke the assumption of risk defense the defendant must show that the plaintiff knew and understood the risk he was incurring, and that his choice to incur the risk was entirely free and voluntary.⁷² The defendant must not only know the facts that created the danger, but must comprehend and appreciate the

71. *Id.* at 5224.

72. Prosser, *supra* note 32, at 447.

danger itself.⁷³ If one cannot comprehend the risk because of his age, he will not be taken to have consented. Aside from the most exceptional cases, courts do not hold that children cannot assume the risks of certain activities. For example, a California court held that as a matter of law a three-and-a-half-year-old child could not assume risks.⁷⁴ But for the most part whether or not a child can assume the risk inherent in a certain situation is a question of fact.

In one Massachusetts case, a ten-year-old child was struck on the head with a golf ball while he was in the process of collecting golf balls that had been hit from practice tees.⁷⁵ The court found that the boy had caddied six or eight times before and had been collecting golf balls for about half an hour prior to being struck. With the knowledge derived from this experience, the court found that this child voluntarily exposed himself to a known and appreciated risk, and therefore could not recover damages.

In *Porter v. Toledo Terminal Railway Co.*,⁷⁶ a thirteen-year-old was injured when he rode his bicycle over rotted railroad tracks, and in *Centrello v. Basky*,⁷⁷ a ten-year-old boy fell and caught his hand in a cement mixer while playing near a construction site. In both of these cases the defendants successfully utilized the assumption of risk defense. In another case, a fifteen-year-old high school freshman had his neck broken in a football game.⁷⁸ He sued the school system which entered a defense based, among other things, on assumption of risk. The court held:

One who enters into a sport, game or contest may be taken to consent to physical contact consistent with the understood rules of the game.⁷⁹

Thus, whether or not a child is capable of understanding the risks inherent in undertaking a dangerous endeavor, and whether or not those risks were voluntarily incurred are questions of fact, and the courts do not find that children are never capable of assuming such risks.⁸⁰

73. *Id.*

74. *Greene v. Watts*, 21 Cal. App. 2d 103, 26 Cal. Rptr. 334 (1962).

75. *Pouliot v. Black*, 341 Mass. 531 (1960).

76. 152 Ohio St. 463, 90 N.E.2d 142 (1950).

77. 164 Ohio St. 41, 128 N.E.2d 80 (1955).

78. *Vendrell v. School District No. 26c*, 23 Ore. 1, 376 P.2d 406 (1962).

79. *Id.*

80. *Aldes v. St. Paul Ball Club*, 88 N.W.2d 94, 251 Minn. 440 (1958).

In an unrelated line of cases, courts have also found that minors may waive certain constitutional rights. In the Supreme Court case of *Haley v. Ohio*,⁸¹ which involved a fifteen-year-old, and *Gallegos v. Colorado*,⁸² which involved a fourteen-year-old, the question presented to the Court was the validity of confessions made by these minors. The Court did not hold that fourteen- and fifteen-year-old children could not give their consent, but held that such confessions would be valid where the minor had the counsel of a lawyer, parent, or adult friend. In a 1971 Pennsylvania case the court found that "a fifteen-year-old boy with an I.Q. of 76 and a mental age of eight to eleven-and-a-half was held to have the required understanding of his constitutional rights to render his confession obtained after four hours of interrogation admissible."⁸³

In summary, certain points can be made regarding how courts view parental and children's rights to make decisions concerning risk-taking.

1. The general rule concerning majority and the age of consent is not based on a scientific or logical rationale. It is the result of generally irrelevant feudal law doctrine.
2. Parents can consent to therapeutic medical care for their young children.
3. The trend is that older children who can understand the consequences of a therapeutic medical procedure can consent to that procedure.
4. In the area of consent to therapeutic medical treatment courts require either the consent of the minor or of the parent, but not of both.
5. In areas outside the field of medical treatment, courts find that children may consent to take risks or waive rights, but base their decisions on the factual circumstances of the specific case.

Nontherapeutic Experimentation on Minors

It has been stated that a resolution of the legal problems surround-

81. 332 U.S. 596 (1948).

82. 370 U.S. 49 (1962).

83. Note, *The Admissibility of Juvenile Confessions: Is an Intelligent and Knowing Waiver of Constitutional Rights Possible Without Adult Guidance?*, 34 U. OF PITT. L. REV. 321, 324 (1972), citing *Commonwealth v. Darden*, 441 Pa. 41, 271 A.2d 257 (1971).

ing nontherapeutic experimentation on minors is made extremely difficult due to the fact that statutory law is nonexistent and case law is largely irrelevant.⁸⁴ Unfortunately, this observation is correct. Two questions are presented that must be dealt with. First, since it is generally understood that the law allows a parent to consent to the invasion of his child's body only if such invasion is for the child's benefit or welfare,⁸⁵ can the parent consent to the conducting of nonbeneficial experimentation on the child? Second, at what point must the child give his consent (or assent) to a nontherapeutic procedure as a precondition to its performance?

In trying to answer these questions, Professor Paul Freund has explained how the law approaches novel questions.⁸⁶ Law is a basically conservative field—no Nobel Prize is awarded for the most revolutionary judicial decision of the year. The law fears setting a bad precedent. To expand on this point Freund cites F.M. Cornford's book, *Micro-Cosmographia Academica* where it stated in a somewhat tongue-in-cheek fashion:

The principle of the dangerous precedent is that you should not now do an admittedly right action for fear that you or your equally timid successors should not have the courage to do right in some future time, which *ex hypothesi* is substantially different but superficially resembles the present one. Every public action which is not customary is either wrong or, if it is right, is a dangerous precedent. It follows that nothing should ever be done for the first time.⁸⁷

Law also tends to generalize on the basis of balancing risks and is deeply protective of human integrity and life. Finally, law is creative and responsive—if the reason for a rule of law ceases to exist, the rule of law should also cease to exist.⁸⁸

With this as a background, we can examine how the problems set forth above have been dealt with.

Codes of conduct that are often referred to for guidance in this area of human experimentation do not directly confront this issue. The Nuremberg Code's first principle is that:

The voluntary consent of the human subject is absolutely essential.

This means that the person involved should have legal capacity to give con-

84. Lowe, *et al.*, *supra* note 3, at 468.

85. Freund, *supra* note 2, at 671.

86. Freund, *supra* note 2.

87. *Id.* at 687-688.

88. *Id.* at 688.

sent . . . and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.⁸⁹

As the previous examination of the law has demonstrated, minors are generally deemed legally incapable of giving their consent to medical treatment. For emancipated and mature minors, courts and legislatures have decided that they may consent to medical treatment that is rendered for their benefit. It is not all clear that such minors could consent to nontherapeutic procedures. But assuming that minors are legally competent to give such a consent, they must have "knowledge and comprehension of the elements of the subject matter involved" in order to give such consent. This sounds very much like the mature minor rule discussed earlier. Some argument could be made that under the Nuremberg Code, older minors can and must consent to nontherapeutic research in order for such research to be conducted on them.

It also appears that the Nuremberg Code outlaws proxy consent. It is the consent of the "human subject" that is required, not the consent of a guardian or representative.

The Helsinki Declaration, on the other hand, states that a subject must give his free consent, but "if he is legally incompetent the consent of the legal guardian should be procured."⁹⁰ It is not clear, however, whether or not the guardian's consent is in addition to the incompetent's consent, or if it acts as a substitute for the subject's consent.

The *only* case that exists which deals with this issue is *Bonner v. Moran*.⁹¹ Because it is quoted so often we will explore it in some detail. At the time of the incident involved, John M. Bonner was a fifteen-year-old junior high student. His cousin, Clara Howard, had been so severely burned that she was a "hopeless cripple." Her aunt (who was also Bonner's aunt) took her to a charity clinic in Washington, D.C. that specialized in plastic surgery. It was decided that a skin graft was required, and a donor with the same blood type as Clara's was sought. After a number of unsuccessful

89. *United States of America v. Karl Brandt*, *supra* note 1.

90. See, Mitchell, *Experimentation on Minors: What Ever Happened to Prince v. Massachusetts?*, 13 DUQUESNE L. REV. 919, 925 (1975).

91. 126 F.2d 121 (D.C. Cir. 1941).

attempts at finding a qualified donor, the aunt persuaded Bonner to go to the hospital for a blood test where it was discovered that he had the same blood type as his cousin. At this time the physician, Dr. Robert Moran, performed the first operation on the boy's side. His mother, with whom he lived, was ill and knew nothing about the procedure. After the operation he returned home and told his mother he was going back to the hospital to get "fixed up." However, once in the hospital more operations were done in order to cut and form a "tube of flesh" from his armpit to his waist. After the tube was surgically formed, it was attached to his cousin forming a literal flesh and blood bond between them. The results were unsatisfactory because of improper blood circulation in the tube, and it was severed after Bonner had lost so much blood he required transfusions. From beginning to end he was hospitalized for two months.

Bonner sued the physician who performed the surgery for assault and battery. The trial court adopted section 59 of the *Restatement of the Law of Torts* which then stated that if a child were capable of appreciating the nature, extent, and consequences of the invasion, he could consent to the medical procedure. Judgment was accordingly rendered by the trial court in favor of the physician, which means that it had to find that the child understood the nature of the procedure and consented to it.

The appeals court began its analysis by noting that the general rule was that a minor could not consent to undergoing a medical procedure, but that there were exceptions to this rule when a minor was emancipated or close to maturity.

But in all such cases [in which the exceptions apply] the basic consideration is whether the proposed operation is for the benefit of the child and is done with the purpose of saving his life or limb. The circumstances of the instant case are wholly without the compass of any of these exceptions. Here the operation was entirely for the benefit of another and involved sacrifice on the part of the infant of fully two months of schooling, in addition to serious pain and possible results affecting his future life. This immature colored boy was subjected several times to treatment involving anesthesia, blood letting, and the removal of skin from his body, with at least some permanent marks of disfigurement.⁹²

92. *Id.* at 123.

The appeals court held that the trial court should have instructed the jury that the consent of the parent was also necessary. The court went on to find that during her son's confinement in the hospital his mother may have learned of what was transpiring, and by doing nothing about it may have ratified her son's consent. If his mother learned about the procedure and publicly expressed pride in her son's courage, such action would have been "tantamount to consent by implication; and that, in the circumstances, would be sufficient."⁹³

The court's opinion is both confused and confusing on this point. Clearly the mother could not give her implied consent after the battery occurred. Consent must occur before the fact. The court must be basing its opinion on the mother's ratification of the child's consent, which was given before the second procedure was performed to form the tube of flesh. As a result the appeals court had to agree with the finding of the trial court that Bonner did consent to the procedure.

There is some dispute over the meaning of this case. Curran and Beecher⁹⁴ argue that the case holds that nonbeneficial procedures "can be legally permitted as long as the parents (or other guardians) consent to the procedure."⁹⁵

Professor Alexander Capron argues that the interpretation "casts more weight onto the opinion than it can bear."⁹⁶ Capron suggests that the outcome of the case is based on the court's finding that Bonner was too immature to understand the complications involved, with the issue of lack of benefit "thrown in as a mere addition."⁹⁷ He goes on to say that the case is really one of ratification of the minor's consent by the parent, but that it nowhere suggests a parent has independent authority to give consent for a nonbeneficial intervention in which a child refuses or is too young to give his consent.⁹⁸

Regardless of scholarly speculation about the meaning of this

93. *Id.*

94. Curran and Beecher, *Experimentation in Children*, 210 J.A.M.A. 77, (1969).

95. *Id.* at 79.

96. Capron, *supra* note 6, at 889.

97. *Id.*

98. *Id.*

case, two statements can be made with authority. First, the trial court found as a matter of fact that Bonner understood and consented to the procedure discussed. Second, the appeals court found that as a matter of law, Bonner's mother could ratify his consent. The only conclusion that one can reach with any element of certainty is that if a child *and* his parent consent to a procedure that does not provide the minor with any benefits, and, indeed, may cause him harm, the procedure may be performed.

One must remember, however, that this case was decided before the Nuremberg Trials were held, and it is conceivable that the outcome would have been different if this case had arisen after the promulgation of the Nuremberg Code. The Nuremberg Code makes no provision for proxy consent, and if the court viewed this as a proxy consent case and found the Nuremberg Code to be controlling, it could have decided that this procedure could not be done under any circumstances.

There is no case that even suggests that children can consent to nonbeneficial research without parental consent. However, the British Medical Research Council, in its statement on children, does suggest that such is the case in England.⁹⁹ The statement starts with the premise that in the strict view of English law parents of minors may not, on behalf of the minor, consent to any procedures which carry some risk of harm and do not benefit the minor. It goes on to say that it may "safely be assumed" that no court would regard a child of younger than twelve years of age as having the capacity to consent to "any procedure that may involve him in an injury."¹⁰⁰ Above this age the reality of a purported consent by the minor would be a question of fact, and one would have to show the person involved fully understood the procedures. However

[e]ven when true consent has been given by a minor. . . . Considerations of ethics and prudence still require that, if possible, the assent of parents or guardians or relatives, as the case may be, should be obtained.¹⁰¹

In the English view one cannot perform nontherapeutic pro-

99. Curran and Beecher, *supra* note 94, at 80.

100. *Id.* at 81.

101. *Id.*

cedures that involve risk on any minor under the age of twelve, or on any minor over the age of twelve, unless he can give "true consent." In cases in which such consent is obtained, parental consent is not required by law, although it might be prudent and ethically desirable.

In a limited way the Michigan legislature had adopted a variation of this rule, Section 27.3178(19b) of the Michigan Code states:

A person of fourteen years of age or older may give one of his two kidneys to a father, mother, son, daughter, brother, or sister for a transplantation needed by him, when authorized by order of the probate court.

If the court determines that the prospective donor is sufficiently sound of mind to understand the needs and probable consequences of the gift to both the donor and donee and agrees to the gift, the court may enter an order authorizing the making of the gift.

Thus, the only determination the probate court must make is whether or not the minor can give "true consent" to the procedure. If he can, then the minor will be allowed to consent and the transplant can go forward. There is no mention of the need for parental consent, and the statute would seem to ban organ donation by younger children. This procedure has one advantage over the English rule. In England it would appear that the determination of the existence of a valid consent would occur after the experiment had been performed, whereas in Michigan the before the fact determination better protects all the parties involved.

One transplant surgeon has adopted elements of both the English rule and the Michigan statute. He does not use children under the age of twelve as kidney donors because they are too young to understand the possibility of physical and psychological harm to themselves in the future and are unable to evaluate the present and future state of their health. However he believes children in their teens are acceptable to use as kidney donors.¹⁰²

The Kidney and Bone Marrow Transplantation Cases

The Michigan statute is the result of the existence of a body of case law that deals with the problems of organ transplantation in a con-

102. MOORE, *TRANSPLANT: THE GIVE AND TAKE OF TISSUE TRANSPLANTATION* 107 (Simon & Schuster, 1972).

fusing and ambiguous manner. Although, as discussed below, these cases are not strictly analogous to the nontherapeutic research situation, they do offer some insights into how courts tend to resolve the issue of proxy consent to nonbeneficial procedures.

Kidney transplantation has been conducted with adults since 1954, with the first case involving minors arising in 1957.¹⁰³ This case¹⁰⁴ involved nineteen-year-old twins. Although the healthy twin, Leonard, and his parents consented to the procedure, the physicians refused to operate because of the uncertainty concerning the validity of the parents' and the minor's consent to undergo a surgical procedure not for his benefit. To resolve this problem, an action for declaratory judgment was brought before a single justice of the Massachusetts Supreme Judicial Court. During the hearing, psychiatric testimony was offered to the effect that if the sick twin, Leon, died, it would have a "grave emotional impact" on the healthy twin. A finding was made that the operation was required to save the life of Leon and that Leonard had been fully informed and understood the consequences of the procedure and consented. Unfortunately, the court did not stop here and specifically adopt the mature minor rule in this situation. Instead, it went on to find that the emotional disturbance resulting from his brother's death could affect the health and emotional well-being of Leonard for the rest of his life. Therefore the operation was

necessary for the continued good health and future well-being of Leonard and that in performing the operation the defendants are conferring a benefit upon Leonard as well as upon Leon.¹⁰⁵

By finding "benefit" to Leonard, the court was able to circumvent the hard issue, since if the healthy donor received a "benefit" the validity of parental consent would no longer be a problem.

This "benefit" theory was used two more times the same year in cases that involved kidney transplants between fourteen-year-old identical twins.¹⁰⁶ In both of these cases the court found that the

103. See, Curran, *A Problem of Consent: Kidney Transplantation in Minors*, 34 N.Y.U.L. REV. 891 (1959).

104. *Masden v. Harrison*, No. 68651 Eq., Mass. Sup. Jud. Ct. (June 12, 1957).

105. Curran, *supra* note 94, at 893, citing *Masden v. Harrison*, at 4.

106. *Huskey v. Harrison*, 68666 Eq., Mass. Sup. Jud. Ct. (Aug. 30, 1957); *Foster v. Harrison*, 68674 Eq., Mass. Sup. Jud. Ct. (Nov. 20, 1957).

fourteen-year-olds understood the probable consequences and risks of the procedures, and gave their consent free of pressure or coercion. But the court still went on to use the psychological benefit theory, thereby avoiding the true issue. In all these early Massachusetts cases the courts found that the minors consented, the parents consented, and there was psychological benefit to the donor. If any one of these elements was missing the outcomes might have been different.

Several cases concerning kidney transplants between siblings have arisen since 1957. Perhaps the most discussed is *Strunk v. Strunk*.¹⁰⁷ In this case the donor, Jerry Strunk, was not a minor but a twenty-seven-year-old incompetent with an I.Q. of 35 and a mental age of six, who was committed to a state institution. The donee, Tommy Strunk, was twenty-eight years old, married, employed and a part-time university student who was suffering from chronic glomerulus nephritis. No other member of the family qualified as a donor due to blood type incompatibility. Because of the apparent lack of benefit to Jerry a court action was instituted, and a guardian *ad litem* (a guardian appointed for the purposes of litigation) was appointed. The guardian questioned the authority of the state to approve the transplant. Psychiatric testimony was offered that alleged Tommy's death would have an "extremely traumatic effect"¹⁰⁸ on Jerry, and that "Tom's life is vital to the continuity of Jerry's improvement"¹⁰⁹ at the state hospital. The court also found that renal transplantation was becoming relatively common and that over 2500 transplants had been done up to the date of the trial. It found that the chances of the transplant being successful increase when the donor and donee are genetically related and that the risk of transplantation to the donee is small, 0.05 to 0.07 percent. The court then adopted the doctrine of "substituted judgment" in which a court acts in a manner it believes the incompetent would act if he had his faculties. The seriously divided court (4-3) allowed the transplant to go forward, becoming the first case in which such an operation was done without the consent of the donor.

107. 445 S.W.2d 145 (Ky. 1969).

108. *Id.* at 146.

109. *Id.*

In a strong dissent Judge Steinfeld stated "My sympathies and emotions are torn between a compassion to aid an ailing young man and a duty to fully protect unfortunate members of society."¹¹⁰ The dissenters, recalling the experiments in Nazi Germany, found that guardians must act to "protect and maintain the ward."¹¹¹ They found that opinions concerning psychological trauma are "most nebulous," that it is well known that transplants are frequently rejected, and that the life of the incompetent is not in danger but that the surgical procedure creates some peril.¹¹² According to the dissenters, the ability to fully understand and consent is a prerequisite to the donation of a body part and a transplant should not be done on an incompetent until it can be "conclusively demonstrated that it will be of significant benefit to the individual."¹¹³

Several years later the case of *Hart v. Brown*¹¹⁴ was decided in Connecticut. This case dealt with a kidney transplant between identical twins who were seven years, ten months old. The court found that although Kathleen, the sick twin, was undergoing regular hemodialysis, she could not do so indefinitely and a kidney transplant was required to sustain her life. It also found that, since immunosuppressive drugs would not be required because the twins were identical, such a transplant would be much less risky for Kathleen than a transplant from a different donor, and that there was substantially a 100 percent chance that both twins would live out a normal life upon following the procedure. The family's clergyman felt the decision was morally and ethically sound and a psychiatrist found that a successful operation would be of "immense benefit to the donor in that the donor would be better off in a family that was happy than in a family that was distressed. . . ."¹¹⁵ The donor was informed of the procedure and "insofar as she may be capable of understanding"¹¹⁶ desired to donate her kidney. The

110. *Id.* at 149.

111. *Id.*

112. *Id.* at 150.

113. *Id.* at 151.

114. 29 Conn. Sup. 368, 289 A.2d 386 (1972).

115. *Id.* at 289 A.2d at 389.

116. *Id.*

guardian *ad litem* also consented. The court specifically noted the limited value of the psychiatric testimony but instead found that

[i]t would appear that the natural parents would be able to substitute their consent for that of their minor children after a close, independent and objective investigation of their motivation and reasoning. This has been accomplished in this matter by the participation of a clergyman, the defendant physicians, and attorney guardian *ad litem* for the donee, and indeed, this court itself.¹¹⁷

It was also found that this procedure was not "clinical experimentation but rather medical treatment."¹¹⁸ The court held that

natural parents of a minor should have the right to give their consent to an isograft kidney transplantation procedure when their motivation and reasoning are favorably reviewed by a community representation which includes a court of equity.¹¹⁹

The right to consent on behalf of a minor was given to the parent as long as the parents' motivation was proper.

In a Georgia case, the court substituted its judgment for a moderately mentally retarded fifteen-year-old girl who was to serve as a donor for her dying mother, and permitted the transplant.¹²⁰

There are two recent cases in which organ donation by a minor was not permitted. In the first, *In re Richardson*,¹²¹ the prospective donor was a seventeen-year-old mental retardate with a mental age of three or four, and the prospective donee was his thirty-two-year-old sister, Beverly. An examination of the court's use of the facts in this case is instructive. It found that although a kidney transplant would be beneficial, it was not immediately necessary to preserve Beverly's life. In the first place, there was evidence that she could be sustained indefinitely by kidney dialysis. Second, although Roy would be the best donor available, as there was only a 3-5 percent chance of rejection with his kidney, there were other donors that could donate with a 20-30 percent chance of rejection. And if these were rejected, other transplant procedures could be done. Thus, a transplant from Roy might be the best alternative for Beverly, but there were other, if less desirable, options open to her. The court

117. *Id.* at 390.

118. *Id.*

119. *Id.* at 391.

120. *Howard v. Fulton-DeKalb Hosp. Authority*, 42 U.S.L.W. 2322 (Ga. Sup. Ct., Fulton, Nov. 29, 1973).

121. 284 S.2d 185 (La. App. 1973).

discussed the *Strunk* case but found that Louisiana law differs from Kentucky law in that the law of Louisiana “is designed to promote and protect the ultimate best interests of the minor.”¹²² Under Louisiana’s statutes, a minor is not allowed to make any *inter vivos* transfers of property and a parent is absolutely prohibited from transferring a minor’s property. The court reasoned that if the law affords such protection against intrusion into a “comparatively mere” property right, it was inconceivable that the minor’s right to be free from bodily intrusion would be any less protected.¹²³ The argument that Roy would benefit from the procedure because Beverly could care for him after his parents died was rejected as “highly speculative . . . and highly unlikely.”¹²⁴ The fact that the transplant was the most desirable course of action for Beverly was not enough to convince the court of equity to permit the transplant, since less detrimental alternatives were available. But from the legal analysis performed by the court, even if a transplant from Roy was the only way to keep Beverly alive, it would not have had the authority to permit such a transplant.

In the second case, the Wisconsin Court resolved the problem in a similar manner. In this case, *In re Pescinski*,¹²⁵ a petition was filed with the court asking it to permit a kidney transplant from Richard, a thirty-nine-year-old catatonic schizophrenic who had been institutionalized for sixteen years and who had a mental age of twelve, to his thirty-eight-year-old sister who was the mother of six minor children. The physician involved said he would not use her parents, who were aged seventy and sixty-seven, since “as a matter of principle”¹²⁶ he would not do the operation on a person over sixty. The physician also refused to use a kidney from any of her minor children as a matter of his “own moral conviction.”¹²⁷

122. *Id.* at 187.

123. *Id.*

124. *Id.*

125. 67 Wis. 2d 4, 226 N.W.2d 180 (1975).

126. *Id.* at 181.

127. *Id.* at 182. When the physician was asked to explain his moral stance he replied: Sir, there are many difficult moral judgments in the field of transplantation to make and each transplant surgeon has to build his own philosophy. That just happens to be mine. I don’t care to defend it. It just happens to be my personal philosophy, sir.

Robertson, Incompetent Organ Donors and the Substituted Judgment Doctrine, 44 (unpublished manuscript, 1975).

Another brother forty-three-years-old who owned a dairy farm and had ten children refused to be a donor because there would be no one to take care of his farm. Additionally, he said he had a stomach problem that required a special diet, and a rupture on his left side. The court's opinion implied that there were a number of competent, healthy potential donors, who were excluded for "moral reasons" or for personal reservations, and who were not asked or did not volunteer to donate their kidneys because of the existence of Richard.

The court held that since Richard did not consent to the procedure, it could not be done.¹²⁸ Additionally, a guardian must act "loyally in the best interests of his ward"¹²⁹ and there was absolutely no evidence here that any interests of the ward would be served. The concept of substituted judgment was forthrightly rejected.¹³⁰ In summarizing its opinion the court stated:

An incompetent particularly should have his own interests protected. Certainly no advantage should be taken of him. In the absence of real consent on his part, and in a situation where no benefit to him has been established, we fail to find any authority for the county court, or this court, to approve the operation.¹³¹

Following this line of kidney transplant cases, a separate but similar line of cases resulted from the advent of bone marrow transplantation procedures.¹³² The bone marrow cases provide less of a physical intrusion into the donor's body as no body cavity is opened, and unlike kidneys, the bone marrow regenerates itself. The donor is subjected to as many as 200 aspirations of the pelvic bone with a needle specially designed to remove bone marrow.¹³³ The Attorney General of the state of Washington has determined that written consent of the guardian is sufficient to authorize a bone marrow donation by a minor.¹³⁴

The practice in Massachusetts, however, is still to acquire a court decree prior to the transplant. The court that created the

128. 226 N.W.2d at 181.

129. *Id.*

130. *Id.*

131. *Id.* at 182.

132. See, Baron, Botsford and Cole, *Live Organ and Tissue Transplants from Minor Donors in Massachusetts*, 55 B.U.L. REV. 159 (1975).

133. *Id.* at 164 n.20.

134. *Id.* at 162 n.16.

“psychological benefit” mischief is currently dealing with the problem in a more straightforward manner. Thus in *Rappeport v. Stott*,¹³⁵ a bone marrow transplant case, the judge held that a seventeen-year-old was “capable of consenting to the proposed procedure,” and did not bother to find that he received psychological benefit.

The most illuminating bone marrow transplant case is probably *Nathan v. Farinelli*,¹³⁶ because of its forthright approach. Toni Farinelli was a healthy six-year-old and her ten-year-old brother, William, was suffering from aplastic anemia, which, left untreated, is fatal in eighty-five percent of the cases. The parents consented to a bone marrow transplant but the physicians refused to operate in the absence of a court authorization. The court found that the risk to Toni was minimal, but also found that she would receive no benefit. The petitioners took the standard approach and called a psychiatrist as a witness. Surprisingly, she testified that she would be speculating if she ventured any opinion about the psychological effect of either allowing or preventing the intended donor from furnishing the bone marrow.¹³⁷ The court appreciated her honesty and found that

[t]o require a finding of benefit to the donor, and particularly to accept a psychological benefit as sufficient, often seems to invite testimony conjured to satisfy the requirement by words but not by substance.¹³⁸

The court also rejected the “substituted judgment” theory as being irrelevant in these situations.¹³⁹

It is the court’s opinion that a better approach to the issue involved in this case is to consider that the primary right and responsibility for deciding the delicate question of whether bone marrow should be taken from Toni and transplanted in William is that of the parents with reference to both children.¹⁴⁰

The requirement that the parents’ decision be reviewed arises out of the possible conflict between the parents’ responsibility for the care and custody of one child, and their similar responsibility for the other. In what can serve as a summary of all these cases, the

135. Civ. No. J74-57 (Mass. Aug. 28, 1974).

136. Civ. No. 74-87 (Mass. July 3, 1974).

137. *Id.* at 7.

138. *Id.*

139. *Id.* at 8-9.

140. *Id.* at 10.

court wrote, "It would be more truthful to recognize that the parents themselves are making decisions for their children,"¹⁴¹ and are not substituting their judgment for that of the child. Finding that the parents' decision was "fair and reasonable" the court permitted the procedure to be done.¹⁴²

The reason for setting out these cases so extensively is that, with the exception of *Bonner*, they are the only cases that deal with consent to nonbeneficial procedures. But we can learn a number of lessons from these cases, as diverse as they may be, that are applicable to research conducted on children.

Although never explicitly stated, courts will permit parents to consent to therapeutic research on children, even where the risks are high, if the benefits are great. In the bone marrow transplant cases, the transplanted bone marrow might cause adverse reactions in the recipient's body. This condition, called graft-versus-host disease, can lead to an agonizing death.¹⁴³ However, since the experimental procedure might save the life of a doomed child, no question is raised as to the ability of the parent to consent on his behalf.¹⁴⁴

As to these cases' importance in regard to nontherapeutic experimentation, we must look at the differences between the transplant cases and nontherapeutic research. First, the procedures that were performed on the donors in the transplant cases were not experimental. Neither the removal of a kidney nor bone marrow aspiration is considered an innovative procedure.

Second, in the average nontherapeutic research setting, parents will not have to struggle with the conflict of interest problem. One commentator has pointed out that one reason why experimentation must be more closely regulated than therapy, is that during therapy

141. *Id.*

142. It is noteworthy that this court ordered both parties to try to procure insurance that would compensate the donor for any harm that might come to her. *Id.* at 12. The court must have realized that although the requirement of informed consent serves to protect the child, there are other mechanisms which would offer additional protection.

143. See, Baron, *et al.* *supra* note 132, at 159-160 n.4, citing Bach and Bach, *Immunogenetic Disparity and Graft-Versus-Host Reactions*, 11 SEMINARS IN HEMATOLOGY 291 (1974).

144. Although at least one Massachusetts Probate Court judge appoints a guardian *ad litem* for the donee child as well as for the donor child, the role of the donee's guardian is not clear. See, Baron, *et al.* *supra* note 132, at 163 n.19.

the doctor sees the patient as an end and not a means, and in non-therapeutic experimentation the subject is seen as the means and not the end.¹⁴⁵ In the transplant cases the parent must also view the donor child as a means, and the cure of the ill child as the end. As a result, the parent's role as the protector of the donor child might be negatively influenced. Courts should be especially aware of this in cases in which the donor is mentally ill or retarded and it may be suspected that parents and physicians may not value the life of the donor as highly as the life of the donee. This is made all the more apparent by the fact that in all the transplant cases involving mentally ill or retarded adults or children, all the mentally ill or retarded individuals were donors, never recipients. Indeed, during the hearings in the *Strunk* case, the Director of the Renal Division, University of Kentucky Medical Center, testified that if something should later happen to the retarded donor's remaining kidney, based on selection criteria at the Medical Center, the donor would not be eligible for either hemodialysis or transplantation.¹⁴⁶ Because of the possibility of exploitation, it is not surprising that the two cases in which the courts denied permission to conduct the transplant involved a mentally retarded and a mentally ill individual.

In the absence of such a conflict, parents should be better able to protect the interests of their child when an investigator asks their permission to use their child as a subject in nontherapeutic research. It might be presumed that parents could put all their energies into protecting their healthy child, because they need not be concerned about the welfare of a sick child.

Both parents and children might be better able to make protective decisions concerning the child's welfare in nontherapeutic research than in the transplant situation because no duress should exist. When a transplant is needed by a sick child, and the healthy child is the only available donor, one essentially communicates the point to both the parent and the child that unless consent is received from all concerned, the child or sibling will die. Truly volun-

145. See, Freund, *supra* note 2, at 689.

146. Savage, *Organ Transplantation with an Incompetent Donor: Kentucky Resolves the Dilemma of Strunk v. Strunk*. 58 KEN. L.J. 129, 146 (1970).

tary consents are hard to imagine in such a situation.¹⁴⁷ But where neither the parent nor child receives any benefit, duress should be entirely absent.

From this analysis it would appear that children involved in non-therapeutic research need *less* outside protection than transplant donors.

But if one looks behind the logic involved in these cases one can see why these cases are resolved the way they have been. The transplant cases revolve around the power of the family to protect its own members. When a child is sick the family as a unit is permitted to use its resources and make sacrifices to help the sick member. All the courts agree on one point, however—the general rule is that parents must act in the best interests of their children and not subject them to harmful situations. The courts that permit transplants have gone through incredible feats of mental gymnastics, such as finding benefit where none exists, to overcome the general rule. The *Farinelli* case, tired of these maneuvers, directly confronted the issue and held that the family could protect its members, and made its decision on that basis.

In addition, as discussed above by Freund, in the transplant cases the courts are balancing risks and being deeply protective of life. Where the risks are relatively minimal and a life hangs in the balance, the courts will decide in favor of life.

Proxy Consent

All the transplant cases have had to struggle with the problem of proxy consent to nonbeneficial procedures. As has been demonstrated by the cases, the issue of who can consent to nonbeneficial procedures that are to be conducted on another person is far from resolved. Part of the problem springs from the fact that the very term “proxy consent” is a contradiction in terms. If the major purposes of the doctrine of informed consent are to protect *self* autonomy and *self* determination, it is difficult to conceptualize how these very personal rights can be exercised by a third party. The courts have confused the matter even more by not clearly

147. See. Sharpe, *The Minor Transplant Donor*, 7 OTTAWA L. REV. 85, 98 (1975).

setting forth the grounds upon which they have validated the exercise of proxy consents.

There are three tests courts have used in determining whether or not proxy consent on behalf of an incompetent organ donor is valid—the “substituted judgment” test, the “best interests of the donor” test, and the “fair and reasonable” test.¹⁴⁸

The substituted judgment concept has a lengthy history that predates *Strunk*, the first transplant case to adopt the doctrine. It appears to have originated in the 1816 English case of *Ex parte Whitbread*,¹⁴⁹ in which it was held that a portion of the money in the estate of a “lunatic” could be given to his next-of-kin to rescue them from poverty. In deciding that such a use of the incompetent’s resources was permissible although he did not directly benefit from the use of funds, the court looked “at what it is likely the lunatic himself would do, if he were in a capacity to act. . . .”¹⁵⁰ The court merely placed itself in the position of the incompetent and determined how it thought he would act if he were competent. There was apparently no evidence as to how this specific individual truly desired to have his funds used in this circumstance, but the court decided he would have acted in the same fashion as would a reasonable person.

More recent American opinions have required courts to actually try to determine how the particular incompetent would act in a given situation. In so doing, courts have imputed to incompetents motives of charity, altruism, self-interest, and the desire to reduce estate taxes in upholding gifts from their estates.¹⁵¹ Courts have also taken into account evidence that the incompetent had previously made gifts to a particular person or persons, or had stated an intention to make such gifts prior to becoming incompetent.¹⁵² In addition, it has been inferred by courts that the incompetent would have made such transfers to his immediate family, and sometimes has

148. See Baron, *et al.*, *supra* note 132, at 169-181. A fourth test would be to determine if the donor is sufficiently mature to personally consent. Since this does not involve proxy consent it is not discussed here.

149. 2 Mer. 99 (1816).

150. *Id.* at 102.

151. Robertson, *Organ Donations by Incompetents and the Substituted Judgment Doctrine*. 76 COL. L. REV. 48, 58 (1976).

152. *Id.* at 59-60.

extended this inference to more distant relatives.¹⁵³

Thus, the historical basis for the substituted judgment test is a line of cases dealing with the transfers of property from an incompetent to a family member who was in need of funds. The question that presents itself is whether or not this principle should be transferred to the organ donation and nontherapeutic research situation. Certainly the court in the *Strunk* case had no problem making this conceptual leap. However, an invasion of a person's body is a more serious undertaking than the invasion of a person's property under our system of jurisprudence. Additionally, determining what a "reasonable person" would do when confronted with the decision to donate an organ is not an easy task. In the *Pescinski* case, it was noted that a number of possible donors did not volunteer to donate a kidney to a relative. However, in the cases of competent donors, we do see relatives readily donating their organs to members of their immediate families who suffer from kidney disease. In one study of kidney donors, it was discovered that fourteen out of the twenty questioned stated that their decision to donate was made in a "split second" or "instantaneously" after learning of the need for the donation.¹⁵⁴ It appeared that their decision-making process was "irrational" and could not be said to meet the requirements of informed consent.¹⁵⁵ If this is an accurate indication of how "reasonable people" make their decision to donate their kidneys to relatives, a court substituting its judgment on behalf of an incompetent could use this information as guidance in determining how a "reasonable person" would act in a similar situation. Thus, if a court found that "reasonable people" act irrationally when faced with the decision to donate an organ, and often agree to donate an organ without taking the risks into account, it could use this finding to permit the donation by the incompetent. Although the Wisconsin¹⁵⁶ and Louisiana¹⁵⁷ courts have rejected the use of the substituted judgment test in regard to kidney dona-

153. *Id.* at 60-61.

154. Fellner and Marshall, *Kidney Donors—The Myth of Informed Consent*, 126 AM. J. PSYCHIATRY 1245 (1970).

155. *Id.*

156. *Supra* note 125.

157. *Supra* note 121.

tions, one commentator has suggested that such an approach deprives the incompetent of the benefits that might be derived from donation.¹⁵⁸

Regardless of the validity of the substituted judgment doctrine as applied to the organ transplant situation, it would seem to have no bearing in the nontherapeutic research situation. Both the historical basis for the doctrine and its recent applications indicate that the doctrine is only to be used to benefit a close relative in need of either funds or a body organ. Nontherapeutic research is usually conducted to benefit society in general at some future date, and therefore the doctrine would not seem to be applicable. In addition, it is far from clear that "reasonable people" generally consent to undergo, for the benefit of society as a whole, nontherapeutic experimental procedures that carry a risk of harm.

The second test under consideration, the "best interests" test, is closely allied with the substituted judgment doctrine. Under this test, one has to demonstrate that the donor will directly benefit from the donation of an organ. This is the test that was utilized in the first three kidney donation cases involving minors.¹⁵⁹ In these cases, it was found that the donors would receive a "psychological benefit" as a result of donating a kidney to their sick twin. By establishing the presence of a benefit, the court was able to avoid the difficult issue of the validity of proxy consent to nonbeneficial procedures. Once a benefit to the donor was established, there was no question that the parents could give their consent. In the *Strunk* case, the court found that the survival of the sick sibling was necessary for the "treatment and eventual rehabilitation" of the incompetent and institutionalized donor.¹⁶⁰ In the *Richardson* case, it was argued that the transplant was in the best interests of the donor because, if the sick sibling survived, she could care for the incompetent after the deaths of their parents.¹⁶¹ The court rejected the argument as being both "highly speculative" and "highly unlikely."¹⁶² The best interests doctrine would also appear to have

158. Robertson, *supra* note 151, at 70.

159. See, Curran, *supra* note 94.

160. *Supra* note 107, at 147.

161. *Supra* note 121, at 187.

162. *Id.*

no applicability to the nontherapeutic research situation. It is difficult, if not impossible, to think of how subjecting a child to nontherapeutic research that carries a risk of harm could be in that child's best interests. This doctrine, would, of course, apply to therapeutic research.

Finally, the "fair and reasonable" test has been adopted by one court in Massachusetts in the case of *Nathan v. Farinelli*.¹⁶³ As discussed earlier, the court found that the parents of a minor donor have the primary responsibility in deciding whether or not their child can serve as a donor in a bone marrow transplantation procedure. The only determination the court made was to decide whether or not the parents' decision was fair and reasonable in the particular circumstances.¹⁶⁴

This test would be applicable in the nontherapeutic research setting. It is conceivable that the parents' decision to subject their child to a nontherapeutic research procedure that did not involve any risk or involved a very minimal amount of risk could be deemed to be fair and reasonable. The problem with this test is that it is very subjective, since what may appear to be fair and reasonable to one person might be considered unfair or unreasonable by another.

The most recent, and perhaps the most drastic, proxy consent case involves the right of a parent to terminate medical procedures that are required to sustain the life of his comatose adult child. In this case, *In the Matter of Karen Quinlan*,¹⁶⁵ Joseph Quinlan, Karen's father, petitioned the lower court to appoint him guardian of the person and property of his comatose daughter, with the specific authority to order cessation of life-sustaining procedures. The lower court denied this petition¹⁶⁶ but was reversed by the New Jersey Supreme Court. The Supreme Court found that Karen's right to privacy would enable her to order cessation of extraordinary life-sustaining procedures if she were competent to do so.¹⁶⁷ It went on to find that she was grossly incompetent to assert this right, but that such a right could be asserted on her behalf by a guardian.¹⁶⁸

163. *Supra* note 136.

164. *Id.* at 10-11.

165. Sup. Ct. of New Jersey, A-116 (1976).

166. *Supra* note 39.

167. *Supra* note 165, at 33-38.

168. *Id.* at 38.

The court reasoned that not to permit such action by the guardian would be to deprive Karen of her right to privacy. The court found:

The only practical way to prevent destruction of the right [to privacy] is to permit the guardian and family of Karen to render their best judgment, subject to the qualifications hereinafter stated, as to whether she would exercise it in these circumstances. If their conclusion is in the affirmative this decision should be accepted by a society the overwhelming majority of whose members would, we think, in similar circumstances, exercise such a choice in the same way for themselves or for those closest to them.¹⁶⁹

This would seem to be an acceptance of the substituted judgment doctrine. The court also seems to accept the fact that it must evaluate the "interests" of the patient as seen by her guardian.¹⁷⁰ This would appear to be some recognition of the best interests test. Finally, the court seems compelled to examine the "motivation and purpose" of the guardian, which might indicate that it is concerned with whether or not he would act in his ward's best interest, and in a fair and reasonable manner. Thus, the court touched on all the tests, although it seemed to adopt the substituted judgment test. As an additional precaution, the court requires the incompetent's physician and an "ethics committee" to be in agreement with the guardian's decision.¹⁷¹ Regardless of these additional safeguards, the *Quinlan* case would seem to expand the power of a parent or guardian to substitute his judgment for his child or ward. However, the facts of this case are very different from either the organ transplant situation or the nontherapeutic research situation, and therefore the holding cannot be applied to those instances.

We should not expect that courts will permit nontherapeutic research on children without their consent, where there is a chance that harm will occur. At this point one must recall the pronouncement in *In re Clark* that:

[T]he fact the child belongs to the state imposes upon the state many duties. Chief among them is to protect his right to live and to grow up with a sound mind in a sound body, and to brook no interference with that right by any person or organization.¹⁷²

Although someday we might all benefit from the results, no specific life will be immediately prolonged by such participation.

169. *Id.* at 38-39.

170. *Id.* at 37.

171. *Id.* at 58-59.

172. 185 N.E.2d at 132.

One commentator has pointed out that allowing nonbeneficial procedures to be performed on minors without their consent, but requiring the consent of adults prior to such procedures being performed on such adults, enables us to force children to participate in activities that may harm them, but not force adults to participate in similar programs.¹⁷³ One might compare this to lowering the age of conscription to include only those from birth to eighteen. It can be concluded that neither parents nor courts can consent to non-therapeutic research on minors who have not also given informed and voluntary consent. The consent of the minor to nontherapeutic research that puts him at risk of harm is essential.

Hopefully, the question of the limits of parental proxy consent to nontherapeutic research on children will be resolved by a case now pending in California, *Nielsen v. Board of Regents*.¹⁷⁴ In this case, the plaintiffs are seeking to bar the use of normal, healthy infants, ranging in age from two months to four years, as controls in an asthma research project. Blood samples were to be drawn and drugs injected to determine the children's tolerance to such substances and stresses.¹⁷⁵ The study was to last five years and the parents were to be paid \$300 per year for their children's participation.¹⁷⁶ There is no question that the children cannot give their consent due to their young age, and the complaint alleges that California law prohibits parents from consenting to such research. California Penal Code § 273(a) states:

(1) Any person who, under circumstances or conditions likely to produce great bodily harm or death, willfully causes or permits any child to suffer, or inflicts thereon unjustifiable physical pain or mental suffering, or having the care or custody of any child, willfully causes or permits such child to be placed in such situation that its person or health is endangered, is punishable by imprisonment in the country jail not exceeding one year, or in the state prison for not less than one year nor more than 10 years.

(2) Any person who, under circumstances or conditions other than those likely to produce great bodily harm or death, willfully causes or permits any child to suffer, or inflicts thereon unjustifiable physical pain or mental suffering or having the care or custody of any child, willfully causes or permits the person or health of such child to be injured, or willfully causes or permits such child to be placed in such situation that its person or health may be endangered, is guilty of a misdemeanor.

173. Baron, *et al.*, *supra* note 132, at 176.

174. Civ. No. 665-049 (Super. Ct. San Francisco, Cal., filed Aug. 23, 1973).

175. *See* Mitchell, *supra* note 90 at 929.

176. *See* Lowe, *et al.*, *supra* note 3, at 470.

One writer argues that the complaint does not go far enough.¹⁷⁷ The experimental group consists of children who are “at-risk” of becoming asthmatics, as indicated by their family medical histories. The complaint does not allege that parents cannot consent to the participation of these children. These children are not now ill, and the drugs given to them are not designed to cure them of a present illness. If they do become ill this research may be of help to them at that future time, but, it is argued, at the moment it must be deemed nontherapeutic, and therefore parents may not give consent to their child’s participation.

The difference between therapeutic and nontherapeutic research is not obvious. In testing the polio vaccine which was supposed to prevent a clinically rare disease, but could, and sometimes did, cause the disease, one might ask, “Were these children subject to therapeutic or nontherapeutic procedures?” None were being treated for an existing condition, and the large majority would never contract the disease. Or were the controls who did not receive the vaccine the ones who were put at risk?¹⁷⁸

Some research may have elements of both therapeutic and nontherapeutic procedures. In one study of phenylketonuria (PKU) and diet, a two-year-old child who could not stand, walk or talk, and who spent her time crying, groaning and banging her head as a result of PKU, was given an experimental diet. Within a few months she improved greatly. This was clearly therapeutic. To establish that the improvement was due to the special diet rather than to natural development, the investigators added five grams of L-phenylalanine to the diet without telling the child’s mother, so that her observations would not be biased. The child rapidly deteriorated. Could the determination that the diet made the difference in the developmental progress be considered therapeutic? The diet is both expensive and restrictive and it would be an injustice to keep the person on the diet forever if it wasn’t required.¹⁷⁹

177. Mitchell, *supra* note 90, at 930-931 n.49.

178. See. Lasagna, *Special Subjects in Human Experimentation*. 98 DAEDALUS 449, 458 (1969).

179. Bickel, Garrard and Hickmans, *Influence of Phenylalanine Intake on Phenylketonuria*, 2 THE LANCET 812-813 (1953), reprinted in KATZ, *EXPERIMENTATION WITH HUMAN BEINGS*. 958-959 (1972).

Summary

1. The general rule is that one must obtain the informed and voluntary consent of the subject prior to his participation in biomedical or behavioral research.

2. There are no decided cases or statutes that specifically deal with the problem of the validity of the consent of the parent or child to participation in nontherapeutic research.

3. The one case that comes closest to confronting this problem, *Bonner v. Moran*, held that if the trial court found that both a fifteen-year-old and his mother consented to his undergoing a procedure that posed serious risks to his health, while offering him no benefits, that such consent would free the physician from liability.

4. Although in the kidney and bone marrow transplantation cases courts permit parents to consent to nonbeneficial procedures on behalf of the minor donors, the cases are factually distinguishable from the nontherapeutic research situation. In the transplantation cases, one family member acts to save the life of another family member. Even in these cases, courts generally require some sort of consent from the donor, and require prior court review of the parents' decision to permit the transplant.

5. Courts have not questioned the right and ability of parents to consent to the performance of therapeutic research on their sick child.

6. Courts are expanding their role as the protectors of the best interests of the child.

7. Courts will closely scrutinize the facts of a particular situation to ensure that one who is not capable of protecting his own interests is not being exploited.

8. Parents have the legal duty to protect the health, well-being and best interests of their children.

9. Courts have found that with adequate safeguards children are capable of waiving important rights, and can consent to incurring serious risks.

Conclusions and Recommendations

Therapeutic Research • Where research is designed to cure a specific disease or condition from which the child is suffering, and no other drug or procedure is available to treat such condition or

disease, or the existing procedure is more dangerous or produces greater discomfort than the proposed procedure, such therapeutic research should be allowed to be conducted with the informed consent of both parents, or one parent if both are not available.

In such a case the parents are consenting to therapy. Or to put it another way, they are consenting to a procedure that is carried out with the purpose of furthering the best interests of the child. As such, the law will enable parents to consent to such procedures. Although the consent of one parent would probably be sufficient, because of the experimental nature of the procedure it would be prudent to allow both parents to decide that the standard procedure is not to be used, since the new procedure might not be efficacious.

Nontherapeutic Research • For nontherapeutic research that carries a risk of harm, such procedures should only be done when the risks are extremely small and the benefits to society are very great. When it has been determined that the risk-benefit ratio of a certain procedure falls into this category, courts, performing their own balancing test, would probably uphold the parental right to consent to their child's participation in such a study. What constitutes a high-risk procedure is not readily determined. Is a high-risk procedure that which has a one-in-a-million chance of causing death, or one that has a fifty percent chance of causing a headache? Though no definitive answers are available, the Ethical Review Board, the Institutional Review Board and the Consent or Protection Committees should all be given the authority to make an independent determination of this issue regarding any proposed research.

When a minor is capable of understanding these procedures his consent should also be required. Or, in other words, he should have the absolute right to refuse to participate in such nontherapeutic procedures. The problem is setting an age at which a minor has such understanding of risk-taking, benefits and harm, and is able to weigh these factors, so that he can give a truly informed consent. One can establish a subjective rule and say that a minor of sufficient intelligence and maturity to understand the consequences of the proposed experimental procedure may consent to such procedures. Investigators would probably be unhappy with this because they would have to make such a determination, and if they

are wrong, liability might result. However, investigators must also make this determination in adults. If an adult is incapable of understanding the risks inherent in undergoing an experimental procedure, an investigator cannot get his informed consent.

Alternatively, one could have all minor subjects of this type of research screened by a protection committee which would make the determination. Or we could ask the courts to make such a finding, as is the case in Michigan in regard to kidney transplants.

The advantage of setting a specific age at which a child can participate or refuse to participate is its objective nature. But it must not be set too low. Draft proposed federal regulations state that research cannot be done on a child above the age of six without his consent.¹⁸⁰ A child of this age will probably agree to do almost anything an authority figure requests. Although it gives the child the right to say no, it is probably a right that will not be forcefully exercised. The age should be set higher, hopefully on a scientific basis with the help of experts in child development. The Michigan statute uses the age of fourteen, Professor Curran suggests fourteen,¹⁸¹ and the British Medical Research Council suggests twelve.¹⁸²

The consent of both parents should be required if both are alive. Since their child might be injured, they should be able to veto his decision since such an injury would have a negative impact on them and would not benefit their child in any way. In addition, since it can be presumed that they will protect the interests of their child when no conflict exists, their counsel should be sought, and their protective role utilized. Children who have no parents and institutionalized children should not be allowed to participate in such studies. The institutionalized child has the dual burden of his minority and the effects of institutionalization.

Children below the age of consent who have been selected, or who are too young to understand the nature and consequences of a procedure, may be subjects in nontherapeutic research when there is no chance of harm occurring, or, as discussed above, the risks are

180. 38 Fed. Reg. 31746 § 46.27(e), Nov. 16, 1973.

181. Curran and Beecher, *supra* note 94, at 82.

182. *Id.* at 80.

minimal. When harm cannot occur, the need for consent declines considerably, and one need not worry about the exploitation of the child. Of course, the consent of the parents should still be required.

Federal regulation of research can only add to the protections already required by state law. Thus, if California outlaws all non-therapeutic research on minors, federal regulations cannot permit such activities in that state.

We believe these recommendations are fair. They protect the children-subjects as well as the parents of these children, but do not unduly burden the research community. Such regulation of research will permit it to continue without exploiting the children who deserve our utmost protection.

