NIELSEN v. THE REGENTS: CHILDREN AS PAWNS OR PERSONS?

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Preface

The degree of enlightenment of any civilization may be measured in part by its vigilance in protecting the rights of children. The status of children in the United States has progressed from chattel toward legal individual through extensive litigation of issues so basic as to have been protected for adults since the signing of the Constitution. Crusaders for children's rights have attempted to elicit decisions from the Supreme Court which recognize that the Constitution does not distinguish fundamental freedoms on the basis of age; indeed, that the Constitution recognizes no second-class citizenship.[1] Laws designed to deal with the inherent differences between people have, in fact, resulted in the continuation of distinctions that constitutional amendments were meant to destroy.[2]

This note reviews a case currently pending in California, *Nielsen v. The Regents of the University of California*.[3] The case develops a new area of children's rights in an attempt to establish the principle that the rights and privileges enumerated in the Constitution and guaranteed to all persons are violated when children are the subjects of human experimentation with no expectation of personal benefit.[4]

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* Member, third year class.

1. *See* J. TENBROEK, EQUAL UNDER LAW (1965).

2. *See* Stanton v. Stanton, 95 S. Ct. 1373 (1975); Reed v. Reed, 404 U.S. 71 (1971).

3. Civil No. 665-049 (S.F. Super. Ct., filed Sept. 11, 1973). The complaint was amended to establish the plaintiff's standing as a taxpayer. The present note is based on the First Amended Complaint, filed December 19, 1973, and only reviews the First Cause of Action. The Second Cause of Action challenges another study conducted by the defendant researcher, that of experimenting upon unconscious persons admitted to a local emergency hospital.

4. First Amended Complaint for Injunctive Relief at First Cause of Action XIX, XXI, Nielsen v. The Regents, Civil No. 665-049 (S.F. Super. Ct., filed Dec. 19, 1973). "Nonbeneficial" as used throughout this note refers to the impact of the treatment procedure upon the particular research subject rather than implying the treatment is nonbeneficial *per se*. However, many medical situations termed nonbeneficial may, at a

The test case was filed by James Robert Nielsen, an attorney and specialist in drug law.[5] The defendants are the University of California Regents and the members of the university's Committee on Human Experimentation. Nielsen, who is a member of that committee, charges that the use of children as control subjects in experimental research is unlawful.[6] The charge is based on an experiment proposed by a University of California Medical Center specialist to research the developmental processes of allergic diseases. Although the protocol has been approved by the experimentation committee, use of control subjects is awaiting the outcome of this case. This experiment is but one of many approved over the years by the committee with Nielsen's vote recorded as the only dissent.[7]

The complaint alleges that parents have no right to consent to their child's participation in experiments which in no way will benefit the subjects (at least as can be contemplated at the time of consent). The complaint also alleges undue influence.[8]

This experiment is a longitudinal study; that is, the subjects will submit to the procedure every three to six months over a period of five years. The youngest subjects accepted for participation will be three months old. Children of families with histories of allergic diseases comprise the initial subject group. If the study should expand as pro-

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future point in time, prove to be beneficial to the subject as a result of information gathered regarding early detection of disease.

5. Nielsen is on the faculties of the University of California Medical School, School of Pharmacy and the University of California Hastings College of the Law. He bases his standing to sue on his taxpayer status and seeks injunctive relief. The challenged experiment is to be conducted with public funds.

6. First Amended Complaint for Injunctive Relief at First Cause of Action IV, XXVI, Nielsen v. The Regents, Civil No. 665-049 (S.F. Super. Ct., filed Dec. 19, 1973).

7. *Id.* at XXIV.

8. *Id.* at XXI.

"An apparent consent is not real or free when obtained through:

1. Duress;
2. Menace;
3. Fraud;
4. Undue influence; or,
5. Mistake."

CAL. CIV. CODE § 1567 (West 1954).

"Undue influence consists:

1. In the use, by one in whom a confidence is reposed by another, or who holds a real or apparent authority over him, of such confidence or authority for the purpose of obtaining an unfair advantage over him;
2. In taking an unfair advantage of another's weakness of mind; or,
3. In taking a grossly oppressive and unfair advantage of another's necessities or distress."

CAL. CIV. CODE § 1575 (West 1954).

posed and approved by the university, a control group of "normal" children (those from families with no history of allergic diseases) will be chosen to constitute a base. The complaint challenges the use of those control group children.

Nielsen's allegation of undue influence is based on two aspects of the approved protocol. First, a stipend of $300.00 is offered to the families of all subjects to absorb the cost of inconvenience and baby-sitting. That sum is to be paid directly to the subjects' parents. The complainant alleges that such an offer of money to the prospective subjects' parents takes advantage of the family's possible economic distress. It is necessarily a factor in the parents' decision to consent on behalf of their child. Second, the children contemplated for the control group are to be chosen largely from the families of the staff and students at the University of California medical facility. The complainant views the primary use of those children as an exertion of undue influence over junior medical personnel by stronger and more powerful senior supervisors. Such an influence would negate any consent by the parents made on behalf of their children, even if such consent were otherwise lawful.

History

A. Parens Patriae

The concept of children's rights is contemporary. In eighteenth century English law, it was virtually nonexistent. The right of inheritance was generally recognized; yet, the law made provision for disinheritance in several specific instances.[9] Blackstone, in his commentaries on English law, emphasized the duties of children rather than their rights.[10] Such duties were based on a premise of subjection to the parents and called for obedience during minority, honour and reverence ever after, protection of the parents in their old age and support when in need of assistance.[11]

This attitude generally was accepted by the early American courts[12] which stressed duties of children to their parents.[13] Although a later commentator on American law criticized as barbaric the early views of children as chattel, the parents' absolute control over their children was not set aside to make way for rights of children as persons.[14] The law respected the basic integrity of the family and only recognized a need for state intervention when parents seriously abused

9. *See* 2 W. BLACKSTONE, COMMENTARIES 446-47 (St. G. Tucker ed. 1803).
10. *Id.* at 453.
11. *Id.*
12. *See* 2 J. KENT, COMMENTARIES ON AMERICAN LAW *207-08 (14th ed. 1896).
13. *Id.*
14. *Id.* at *205.

the absolute control they possessed over their children's lives.[15] This recognition took the form of the parens patriae theory.[16]

An early California case held that a child was not to be regarded as property but rather as a citizen of the state and as such "peculiarly under its guardianship and subject to its supervisory control."[17] Yet, in the interest of family integrity, courts and legislatures continued their reluctance to intervene. Their basic assumption seems to have been that parents by nature act in the best interests of their children.[18]

The parens patriae theory was of prime concern when the first juvenile court was established in Illinois in 1899.[19] The Illinois court recognized a difference between the state's responsibility to adult and to child offenders.[20] The court based its theory on the state's concern for the development of its children as responsible citizens.[21]

All states now have statutes providing for child welfare.[22] The courts have recognized that neither parents nor the state have an absolute right of control over a child.[23] The orientation of the parens patriae theory is benevolent. Use of the theory within the court system finds judges attempting to keep children out of the legal framework with the thought that any wrongdoing at such a young age probably is due to environmental factors rather than to an established response to society.[24]

Given the courts' paternal attitude, it is not surprising that few children's rights cases have been considered of sufficient import to reach the Supreme Court of the United States. The most significant of the few decisions to have been litigated before the Court is *In re Gault*.[25] In that

15. *See* Pierce v. Society of Sisters, 268 U.S. 510 (1925).

16. *See* Lippincott v. Lippincott, 97 N.J. Eq. 517, 128 A. 254 (1925); People v. Wilcox, 22 Barb. 178 (N.Y. Sup. Ct. 1854); Mack, *The Juvenile Court*, 23 HARV. L. REV. 104 (1909) [hereinafter cited as *The Juvenile Court*]. *See also* Applic. of Pres., 331 F.2d 1000, 1008 (D.C. Cir.), *cert. denied*, 377 U.S. 978 (1964).

17. Anthony v. Tarpley, 45 Cal. App. 72, 79, 187 P. 779, 782 (1919).

18. *See* Pierce v. Society of Sisters, 268 U.S, 510 (1925); Meyer v. Nebraska, 262 U.S. 390 (1923).

19. *The Juvenile Court, supra* note 16, at 107. *See generally In re* Gault, 387 U.S. 1 (1967); Poe v. Ullman, 367 U.S. 497 (1961).

20. *The Juvenile Court, supra* note 16, at 107.

21. *Id.*

22. *E.g.*, CAL. WELF. & INST'NS CODE §§ 600-02, 625 (West 1972); N.Y. SOC. WELF. LAW § 395 (McKinney 1966). *See* People v. Lawrence, 141 Cal. App. 2d 630, 297 P.2d 144 (1956); In the Matter of Sampson, 65 Misc. 2d 658, 317 N.Y.S.2d 641 (Family Ct. 1970). *But see In re* Seiferth, 309 N.Y. 80, 127 N.E.2d 820 (1955).

23. "[T]he admonition to function in a 'parental' relationship is not an invitation to procedural arbitrariness." Kent v. United States, 383 U.S. 541, 555 (1966). *See also* Odell v. Lutz, 78 Cal. App. 2d 104, 177 P.2d 628 (1947).

24. *The Juvenile Court, supra* note 16, at 107.

25. 387 U.S. 1 (1967).

case, the Court held that such procedural due process rights as that of counsel,[26] adequate notice,[27] confrontation and examination,[28] and the privilege against self-incrimination in proceedings which would be termed criminal if the defendant were adult,[29] were applicable to children placed in a position to lose their liberty.

Gault was a landmark decision in its recognition of the limitations of the parens patriae theory and acknowledgment of children's rights. Since that decision, other rights and freedoms have been made applicable to children by the Court. They include the right to a guarantee against double jeopardy in a juvenile proceeding;[30] to notice and hearing prior to suspension from school;[31] to voting privileges in national elections at age eighteen;[32] to proof beyond a reasonable doubt in a juvenile delinquency adjudicatory hearing;[33] to the First Amendment freedom of speech and due process;[34] to standing for illegitimate children in claiming wrongful death benefits on the death of the mother;[35] to be advised of constitutional rights prior to questioning;[36] to discovery aids prior to waiver of juvenile court jurisdiction;[37] to counsel in a jurisdictional hearing;[38] to education within a nonsegregated public school system;[39] and to the First Amendment freedoms of conscience and speech.[40]

Other cases have limited the application of adult rights to minors. For example, in *McKeiver v. Pennsylvania* the Supreme Court held that a child has no right to a jury in a trial which would be termed criminal if it involved an adult.[41]

B. Early Experimentation

Although experimental science has been present since 200 A.D., case law involving medical experimentation on human subjects emerged

26. *Id.* at 41.
27. *Id.* at 33.
28. *Id.* at 56.
29. *Id.* at 55.
30. Breed v. Jones, 95 S. Ct. 1779 (1975).
31. Goss v. Lopez, 419 U.S. 565 (1975).
32. Oregon v. Mitchell, 400 U.S. 112 (1970).
33. *In re* Winship, 397 U.S. 358 (1970).
34. Tinker v. Des Moines School District, 393 U.S. 503 (1969).
35. Levy v. Louisiana, 391 U.S. 68 (1968).
36. Miranda v. Arizona, 384 U.S. 436 (1966).
37. Kent v. United States, 383 U.S. 541, 557 (1966).
38. *Id.* at 558.
39. Brown v. Board of Educ., 347 U.S. 483 (1954). The Court in *Brown* decided that black children would suffer psychological harm and thus be denied equal protection if not guaranteed equal education within the public school system.
40. West Va. Bd. of Educ. v. Barnette, 319 U.S. 624 (1943).
41. McKeiver v. Pennsylvania, 403 U.S. 528 (1971).

slowly.[42] When research problems came to the attention of the law, the cases usually involved the propriety of consent to therapeutic procedures.[43]

The first children chosen for use as experimental subjects were foundlings and orphans.[44] Because nineteenth century infant mortality rates were so high, scientists felt a great need to study the reasons for childhood deaths.[45] The subjects of study were quite naturally infants. Given the predominance of child labor at that time, researchers easily obtained experimental subjects for their studies.[46] It was not until 1875 that an organization was established for the protection of children. Prior to that time, the Society for the Prevention of Cruelty to Animals was empowered by the courts to act in cases of cruelty to children.[47]

As technology advanced and research methods became more sophisticated,[48] medical science became increasingly aware of the long-range benefits of longitudinal studies.[49] Increased research brought with it an increase in conscience and after 1900 consent to experimental procedures emerged as an issue.[50]

C. Informed Consent

Initially, reports mentioning consent to experimental procedures

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42. *See generally* Comment, *Non-Therapeutic Medical Research Involving Human Subjects*, 24 SYRACUSE L. REV. 1067 (1973).

43. *E.g.*, Bonner v. Moran, 126 F.2d 121 (D.C. Cir. 1941) (regarding skin graft between cousins); Hoener v. Bertinato, 67 N.J. Super. 517, 171 A.2d 140 (1961) (regarding unborn children); Carpenter v. Blake, 60 Barb. 488 (N.Y. Sup. Ct. 1871), *rev'd on other grounds* 50 N.Y. 696 (1872) (regarding negligent medical treatment); Slater v. Baker, 95 Eng. Rep. 860 (K.B. 1767) (regarding negligent setting of a leg).

44. Mitchell, *The Child and Experimental Medicine*, in EXPERIMENTATION WITH HUMAN BEINGS 963 (J. Katz ed. 1972) [hereinafter cited as *Mitchell*].

45. *Id.* Childhood deaths and diseases require special research. One student of the problem has written: "Children cannot be regarded simply as 'little people' pharmacologically. Their metabolism, enzymatic and excretory systems, skeletal development and so forth differ so markedly from adults' that drug tests for the latter provide inadequate information about dosage, efficacy, toxicity, side effects, and contraindications for children." Capron puts forth the suggestion that if children are excluded from the groups available for research purposes, they may in the end be termed "therapeutic orphans." Capron, *Legal Considerations Affecting Clinical Pharmacological Studies in Children*, 21 CLINICAL RESEARCH 141, 142 (1973) [hereinafter cited as *Legal Considerations*].

46. *Mitchell, supra* note 44, at 963.

47. *Id.*

48. *Id.*

49. By observing a child over a number of years, the researcher can see developmental processes at work with full knowledge of all extrinsic factors that may be contributing to such development. The results take longer to accumulate, but are believed to be more accurate than piecing together bits of information from a greater number of individuals, each with peculiar environmental situations which must be considered.

50. *Mitchell, supra* note 44, at 963-64.

alluded only to consent obtained from the physician in charge of the subject patient. Medical journals credited the medical staff with providing patients for use in experimental procedures.[51]

When research developed to the point that persons other than patients and foundlings were used as experimental subjects, the issue of consent became important. Experimentation by a physician in the absence of consent was likely to result in an action for battery[52] or negligence.[53]

Informed consent requires capacity, knowledge and voluntariness.[54] An infant generally does not have the capacity to consent to medical procedures.[55] Therefore, parents or guardians may, in most instances, consent on behalf of a child.[56] The capacity to consent for another is based on the assumption that the parents or guardian will act in the best interests of the child.[57] However, the law recognizes that provision must be made for the failure to act in conformity with that assumption.[58] The knowledge necessary for valid consent to medical treatment means that the person consenting must have available sufficient information with which to make an informed choice.[59] Voluntariness requires that consent be given without fraud, duress or undue influence.[60]

In spite of these sound legal principles which underlie the doctrine of informed consent, courts have found justification to support parents'

51. *Id.*

52. *See generally* W. PROSSER, TORTS 104 (4th ed. 1971).

53. *Id.* at 165.

54. *See generally* Frankel, *Medico-Legal Communication*, 6 WILLAMETTE L.J. 193 (1970); Plante, *An Analysis of "Informed Consent,"* 36 FORDHAM L. REV. 639 (1968).

55. *See generally* W. PROSSER, TORTS 102 (4th ed. 1971). *See also* Zoski v. Gaines, 271 Mich. 1, 260 N.W. 99 (1935). The outer limits of the consent issue with respect to children is examined in the current debate over fetal research. *See* S.F. Chronicle, Feb. 15, 1975, at 10, cols. 7-8; Studies: *Fetal Research*, 5 THE HASTINGS CENTER REP. 11 (June, 1975).

56. *See* People v. Pierson, 176 N.Y. 201 (1903); Shaw, *Dilemmas of "Informed Consent" in Children*, 289 N. ENG. J. MED. 885 (1973). The strict view of the English law appears to be that parents cannot consent to nonbeneficial treatment on behalf of their children. *Mitchell, supra* note 44, at 974; Curran & Beecher, *Experimentation in Children*, 210 J. AM. MED. ASS'N 77, 80-81 (1969). *See also Legal Considerations, supra* note 45, at 143.

57. *See generally* Comment, *Non-Therapeutic Medical Research Involving Human Subjects*, 24 SYRACUSE L. REV. 1067, 1075 (1973).

58. CAL. PEN. CODE § 273(a) (West 1970); N.Y. PEN. LAW § 260.10 (McKinney Cum. Supp. 1974).

59. *See* Cobbs v. Grant, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972). *See generally* Tunkl v. Regents of Univ. of Calif., 60 Cal. 2d 92, 383 P.2d 441, 32 Cal. Rptr. 33 (1963); Natanson v. Kline, 186 Kan. 393, 350 P.2d 1093, *rehearing denied*, 187 Kan. 186, 354 P.2d 670 (1960); Note, *Physicians' Use of Exculpatory Provisions in Contracts Executed with Patients: Tunkl-Belshaw Cases*, 6 WILLAMETTE L.J. 341 (1970).

60. *See generally* W. PROSSER, TORTS 105 (4th ed. 1971).

decisions to subject their children to nonbeneficial medical procedures which seriously endanger life. Often the procedure involves the transplant of organs between siblings or twins.[61] As a rule, courts have held that a parent is capable of consenting to such a transplant between his or her children.[62] The ill child is expected to benefit from the new organ and, therefore, the parent's decision to consent is proper. However, that parent's decision necessarily requires that the healthy child give up an organ. Courts have justified the validity of parental consent for that child on a psychological harm basis concluding that the transplant is proper because, if it were prohibited, and the ill child died, the sibling who did not give the lifesaving organ would suffer overwhelming guilt.[63]

Generally, a court will interview the prospective donor to determine the expectation of psychological harm to the child if not allowed to donate the organ. Evidence is sought that would render the child competent to consent to the particular operation. Knowledge of the procedure and its consequences, and the child's ability to understand fully the attendant risks are some of the factors considered by the court in determining the child's competency.[64]

Even in situations in which medical treatment would benefit the child, state statutes have recognized that it is sometimes necessary to intervene when there is a possible discrepancy between parental interest and the best interest of the child.[65] Probably the most publicized cases are those concerning the question of a parental right to refuse lifesaving treatment for a child.[66] In such cases, the hospital or attending physician

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61. *See* Strunk v. Strunk, 445 S.W.2d 145 (Ky. 1969) (donation by incompetent to normal brother); Nathan v. Farinelli, No. 74-87 (Eq., Mass. Sup. Jud. Ct., July 3, 1974) (bone marrow transplant between siblings). *See generally* Curran, *A Problem of Consent: Kidney Transplantation in Minors*, 34 N.Y.U.L. REV. 891 (1959) [hereinafter cited as *A Problem of Consent*].

62. *See* Hart v. Brown, 29 Conn. Sup. 368, 289 A.2d 386 (1972). *See generally A Problem of Consent, supra* note 61, at 892.

63. According to *A Problem of Consent, supra* note 61, at 892-93, the three unreported opinions combined in Masden v. Harrison, No. 68651 (Eq., Mass. Sup. Jud. Ct., June 12, 1957), were based on psychological harm to the well twin resulting from the court's refusal to accept the donation of his or her organ. The same justification was used in Brown v. Board of Educ., 347 U.S. 483 (1954), wherein the Court found that black children would suffer psychological harm if not offered equal education in the public school system. *See generally Mitchell, supra* note 44, at 964-72 regarding the court procedure in deciding transplant cases between minors.

64. *See generally A Problem of Consent, supra* note 61.

65. CAL. WELF. & INST'NS CODE §§ 739, 1755.3 (West 1972); N.Y. FAMILY CT. ACT § 232 (McKinney Cum. Supp. 1974).

66. *E.g.*, John F. Kennedy Mem. Hosp. v. Heston, 58 N.J. 576, 279 A.2d 670 (1971); State v. Perricone, 37 N.J. 463, 181 A.2d 751 (1962). *See generally* S.F. Examiner & Chronicle, Nov. 17, 1974, § A, at 6, col. 1.

frequently refers the case to a court for appointment of a guardian who will execute the required consent or for the court's intervention sua sponte.[67]

There have been cases, however, where court intervention was not sought and express nonconsent to treatment apparently accepted.[68] One well-published case involving a refusal of medical treatment occurred at Johns Hopkins Hospital in 1963.[69] The principals were a hospital nurse, her attorney husband and their premature baby boy. The child was born with multiple problems: Downs syndrome (mongolism) and a duodenal atresia (a blockage of the small intestine). Without surgery the child could not live because it was impossible for food to pass from the stomach to the rest of the digestive tract. After considerable thought, the parents chose the mental and emotional health of their two healthy children over the life of the newborn. They were not prepared to rear a severely retarded child, so they instructed the hospital staff to avoid any extraordinary measures to save the baby's life. The staff respected the decision of the parents and placed the child in a side room where he starved to death within two weeks. As far as this author is aware, this case never resulted in criminal action against the child's parents or the hospital staff.

D. Diversity of Interests

In deciding cases involving nonbeneficial medical treatment of children, courts have not implied that the parents exercised their right to consent in bad faith.[70] However, individuals make decisions by calling upon a panoply of experiences, interests, education and biases which form their personalities and their personal viewpoints. A parent's decision to allow his or her child to take part in nonbeneficial experimentation is also subject to that parent's viewpoint and prejudices. Yet, when the actual life or health of a child is at issue, every effort should be made to elicit and consider the child's viewpoint.[71] In the complete absence of capacity to consent as, for example, in the case of a three-month-old

67. *See* John F. Kennedy Mem. Hosp. v. Heston, 58 N.J. 576, 279 A.2d 670 (1971); State v. Perricone, 37 N.J. 463, 181 A.2d 751 (1962).

68. *See* Kelsey, *Which Infants Should Live? Who Should Decide?*, 5 THE HASTINGS CENTER REP. 5 (April 1975). *See also* Krugman & Giles, *Viral Hepatitis - New Light on an Old Disease*, in EXPERIMENTATION WITH HUMAN BEINGS 633 (J. Katz ed. 1972); Note, *Studies with Children Backed on Medical, Ethical Grounds*, in EXPERIMENTATION WITH HUMAN BEINGS 633 (J. Katz ed. 1972).

69. Lecture by H. Krever, Q.C., University of Toronto, March 18, 1974 [hereinafter cited as Krever].

70. Hart v. Brown, 29 Conn. Sup. 368, 289 A.2d 386 (1972); Nathan v. Farinelli, No. 74-87 (Eq., Mass. Sup. Jud. Ct., July 3, 1974).

71. *See generally A Problem of Consent, supra* note 61.

child, it is customary for an objective third party to represent the child's interest, particularly when bodily integrity is at issue.[72]

The Johns Hopkins case referred to above[73] is representative of the difficult decisions parents must face. Evidence indicated that the parents' decision was aided by opinions solicited from their pastor and doctors and, therefore, that a variety of considerations were a part of the final decision.[74]

Even if a parent's decision is based on humanitarian motives, the justification of a child's sacrifice is still questionable. One such case involved a seven-year-old blind boy who was expected to die within one year of an inoperable brain tumor.[75] The child's mother gave her consent for the hospital to subject her son to endocrine studies that in no way could benefit him. The justification offered was that such studies might possibly aid medical science in detecting brain tumors at an earlier age. The doctor wrote:

> The mother's motives in giving her consent for the studies were complex. She told the staff that she felt Charles' life would have been worthwhile if, through the studies, it led to knowledge that would benefit other children. This statement implied that her consent was partly a way of dealing with Charles' impending death (although Charles would die, the knowledge gained through him would live on) and partly a way of compensating for his loss (Charles would die so that other children might live). However, the statement also implied the existence of unconscious anger toward Charles, since it disregarded the severe stress to which the child would be subjected.
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> The psychological stress proved to be particularly severe since the medical procedure heightened the fears commonly experienced by a child at Charles' developmental stage—concern about body intactness and manipulation. Frequent venipunctures, necessary for the research, led to acute panic states in the child.[76]

72. There is a threshold question in this respect which must be considered. Prior to the time that a third party would intervene in a decision to allow a child to participate in human experimentation, a question arises as to how the family reaches the point of facing a decision to subject that child to experimental procedures. Capron suggests a selection of fit subjects might be made by those who work with large numbers of children. *Legal Considerations, supra* note 45, at 146-47. Nielsen goes further in suggesting that equality in selection would be achieved only by a national lottery, much like present selective service procedures.

73. Krever, *supra* note 69.

74. *Id.*

75. Lewis, McCollum, Schwartz & Grunt, *Informed Consent in Pediatric Research*, in EXPERIMENTATION WITH HUMAN BEINGS 961 (J. Katz ed. 1972) [hereinafter cited as *Informed Consent in Pediatric Research*]. *See also* Kaplan, *Experimentation—An Articulation of a New Myth*, 46 NEB. L. REV. 87 (1967) [hereinafter cited as *Articulation of a New Myth*].

76. *Informed Consent in Pediatric Research, supra* note 75, at 961; Kaplan suggests that children may be particularly prone to trauma from experimentation simply because they are children. An undeveloped ego often is unable to withstand external

The conflict of interest between parent and child has been of sufficient import in the past to justify the enactment of statutes dealing specifically with children's problems. In California and other states, minors may consent, without parental approval, to certain necessary medical procedures; for example, treatment of pregnancy,[77] general medical care in certain instances[78] and communicable diseases.[79] Courts and legislatures, in interpreting such statutes, have based their decisions on such constitutional considerations as the right to privacy.[80] When a situation could be termed life or death, as in *Nielsen,* the use of guidelines and perhaps state intervention would be necessary to protect the child's interests.

The International Response

Interest in medical research grew so rapidly after 1900 that abuse was inevitable.[81] Specific guidelines were not drafted to protect human subjects and their dignity in experimentation until public outcry arose over the World War II atrocities which were litigated at Nuremberg.[82] Prior to that time, it appears that the accepted guidelines were of a general medical nature, such as those set forth in the Oath of Hippocrates.[83] That oath emphasized broad humanitarian goals rather than enumerating specific requirements for responsible experimentation.[84]

During the Nuremberg Trials twenty-five "dedicated and honored medical men"[85] were accused of committing war crimes against involuntary human subjects.[86] The investigations for which they were prosecut-

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pressure, even allowing for sufficient insight in the case of a mature child. Such fantasies or fears as a child may experience as part of the developmental process would, therefore, be accentuated, or at least brought into conscious thought, through participation in experimental procedures. One must then question the justification when the outcome is not expected to be of any particular benefit to that child. *Articulation of a New Myth, supra* note 75, at 105.

77. Ballard v. Anderson, 4 Cal. 3d 873, 484 P.2d 1345, 95 Cal. Rptr. 1 (1971); *In re* Smith, 16 Md. App. 209, 295 A.2d 238 (Md. Ct. of Special Appeals 1972); CAL. CIV. CODE § 34.5 (West 1954).

78. CAL. CIV. CODE § 34.6 (West Supp. 1975). *See also* S.F. Chronicle, Sept. 20, 1975, at 2, col. 6, wherein it was reported that California Governor Jerry Brown recently signed a bill which will permit girls under eighteen years of age to obtain contraceptive devices without parental permission.

79. CAL. CIV. CODE § 34.7 (West Supp. 1975).

80. *In re* P.J., No. 922976 (D.C. Super. Ct., Feb. 6, 1973).

81. Veressayev, *The Memoirs of a Physician,* in EXPERIMENTATION WITH HUMAN BEINGS 284-91 (J. Katz ed. 1972) [hereinafter cited as *Veressayev*].

82. *See generally* Nuernberg Military Tribunals, United States v. Brandt, 1-2 TRIALS OF WAR CRIMINALS BEFORE THE NUERNBERG MILITARY TRIBUNALS (1950).

83. 2 *id.* at 82-86.

84. *Veressayev, supra* note 81, at 311.

85. *Articulation of a New Myth, supra* note 75, at 87.

86. Not all defendants were found guilty. Nuernberg Military Tribunals, United

ed included, *inter alia*, researching the limits of human endurance and existence at extremely high altitudes and in freezing temperatures, the contraction and treatment of malaria, epidemic jaundice and spotted fever, and the human response to various poisons.[87] The triers of fact in that case were not swayed by the "advance of medical knowledge" defense argument.[88] Although certain human responses were discovered as a result of the research, little information proved useful to the world of civilized medicine.[89]

Apparently, only such dramatic situations as those exposed at Nuremberg could shock the public sufficiently to prompt the drafting of specific guidelines for medical research. A portion of the opinion set up requirements for responsible experimentation, formally called the Nuremberg Code.[90] The code was compiled by the United States Military Tribunal which operated under American procedural rules and was comprised primarily of American jurists.[91] It was considered to be the most forceful formulation of ethical rules of conduct developed to that date and was specifically drawn to regulate human experimentation.[92]

The Declaration of Helsinki[93] was formulated by the World Medical Association in the 1960's amidst criticism of the Nuremberg Code. Researchers had complained that the Nuremberg Code "separated right from wrong more easily than can be done with the nuances of modern research."[94] By 1967, numerous well-known and highly regarded American professional medical organizations had adopted the Declaration of Helsinki as their standard of research.[95]

States v. Brandt, 2 TRIALS OF WAR CRIMINALS BEFORE THE NUERNBERG MILITARY TRIBUNALS 171-301 (1950).

87. 1 *id.* at 92-738.

88. The defense argument was based on the necessity of advancing medical knowledge claimed to have arisen out of the wartime and emergency situations. 2 *id.* at 5-12.

89. The Opening Statement of the Prosecution by Brigadier General Telford Taylor, 1 *id.* at 73, indicated that researchers found that phenol or gasoline injected intravenously will kill a man inexpensively within sixty seconds.

90. 2 *id.* at 181-84.

91. The tribunal was composed of the chief justice of the Supreme Court of Washington, an associate justice of the Supreme Court of Florida, a former justice of the district court of Oklahoma and a former special assistant to the attorney general of the United States. 1 *id.* at 5, 24-26.

92. Comment, *Non-Therapeutic Medical Research Involving Human Subjects*, 24 SYRACUSE L. REV. 1067, 1078 (1973).

93. *Veressayev*, *supra* note 81, at 312-13.

94. Editorial, *The Ethics of Human Experimentation*, 270 N. ENG. J. MED. 1014 (1964).

95. These included, *inter alia*, the American Medical Association, the American Federation for Clinical Research, the Central Society for Clinical Research, the American College of Physicians, the American College of Surgeons, the Society for Pediatric Re-

The principles espoused by the two codes are identical. However, the Helsinki Declaration, designed especially for the researcher's guidance, is much more detailed than the Nuremberg Code. The declaration encourages the use of guidelines in the field of research while acknowledging the importance to the world of the need to advance medical knowledge.

The codes speak, *inter alia*, to the necessity of a voluntary consent to experimentation free of coercion or fraud; to researching other methods which yield the same expected results before resorting to experimentation on humans; to avoiding unnecessary suffering and injury; to a balancing of risk with results expected to be gained from the experimentation; to the necessity of proper safeguards and of providing an opportunity for the subject to withdraw from the experiment at any time.

Even with the acceptance of these codes, abuses continue to occur[96] and other guidelines constantly are being devised.[97] The Department of Health, Education and Welfare issued a policy statement which was adopted by the University of California Medical School on March 29, 1972, and which governs the protocol challenged in *Nielsen*.[98]

Children as Legal Entities

The dignity of the individual, so cherished by modern civilization, has been dealt with extensively by western philosophers.[99] Yet, even the

search and the American Academy of Pediatrics. Comment, *Non-Therapeutic Medical Research Involving Human Subjects*, 24 SYRACUSE L. REV. 1067, 1079 (1973).

96. *See, e.g.*, Hyman v. Jewish Chronic Disease Hosp., 15 N.Y.2d 317, 206 N.E.2d 338, 258 N.Y.S.2d 397 (1965), *rev'd* 21 App. Div. 2d 495, 251 N.Y.S.2d 818, *rev'd per curiam*, 42 Misc. 2d 427, 248 N.Y.S.2d 245 (Sup. Ct. 1964). *See also* New York State Assoc. for Retarded Children, Inc. v. Rockefeller, 357 F. Supp. 752 (1973); Wyatt v. Stickney, 344 F. Supp. 373, *modified sub nom.* Wyatt v. Aderholt, 503 F.2d 1305 (1972) and 344 F. Supp. 387, *modified sub nom.* Wyatt v. Aderholt, 503 F.2d 1305 (1972). The first *Wyatt* case was filed on behalf of all mentally ill persons in the state of Alabama alleging inhumane treatment and deprivation of constitutional rights. By a motion to amend, the class was expanded to include all mentally retarded persons in the state. The two companion cases were published separately. *See generally Legal Considerations, supra* note 45.

97. The experiment in question is subject to the guidelines set out by the Department of Health, Education and Welfare, 38 Fed. Reg. 27882 (1973).

98. *Id. See* Food Drug & Cosmetic Act, 21 U.S.C.A. § 355 (1966). Prior to 1962, the Food and Drug Administration had set only lax standards for use of investigational drugs. The thalidomide babies revealed the inadequacies of those standards and led to the Kefauver-Harris amendment to the Food Drug & Cosmetic Act, placing more emphasis on responsible testing of drugs prior to their being put on the market. *Legal Considerations, supra* note 45, at 142. *See also* Nielsen v. The Regents, Civil No. 665-049 (S.F. Super. Ct., filed Sept. 11, 1973); Schreiner, *Liability in Use of Investigational Drugs*, 185 J. AM. MED. ASS'N 259 (1963); Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947 (1964).

99. *See, e.g.*, "Every man is to be respected as an absolute end in himself, and it

basic proposition that the word "persons" in the United States Constitution also means "children" has required judicial recognition. Court opinions discussing constitutional guarantees of the rights of minors have generally been limited to a discussion of the particular constitutional guarantee in question.[100]

In re Gault[101] discussed the applicability of the Constitution to children. Justice Fortas wrote for the majority:

> [W]hile these cases relate only to restricted aspects of the subject, they unmistakably indicate that, whatever may be their precise impact, neither the Fourteenth Amendment nor the Bill of Rights is for adults alone.[102]

Although the meaning of Justice Fortas' statement seems clear, later cases concerning minors' constitutional rights have limited the opinions to the problem litigated.

In *Tinker v. Des Moines School District*,[103] the United States Supreme Court reversed a federal district court decision which had sustained a school regulation prohibiting public school students from protesting the government's policy in Vietnam by wearing black armbands to school. The Court noted that the right of free speech was not limited to adults:

> Students in school as well as out of school are "persons" under our Constitution. They are possessed of fundamental rights which the State must respect, just as they themselves must respect their obligations to the State.[104]

The majority in *McKeiver v. Pennsylvania*,[105] discussing the constitutional right of trial by jury in criminal cases, however, held that such a right was not applicable to children who had committed an act which would be a crime if committed by an adult. The majority was of the opinion that separation of juvenile and criminal systems should continue despite obvious shortcomings.[106] Therefore, they declined to adopt the

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is a crime against the dignity that belongs to him as a human being to use him as a mere means for some external purpose . . . ." F. PAULSEN, IMMANUEL KANT, HIS LIFE AND DOCTRINE 339-40 (1963).

100. *See, e.g.*, Stanton v. Stanton, 95 S. Ct. 1373 (1975); McKeiver v. Pennsylvania, 403 U.S. 528, 533-34 (1971).

101. 387 U.S. 1 (1967).

102. *Id.* at 13.

103. 393 U.S. 503 (1969).

104. *Id.* at 511.

105. 403 U.S. 528 (1971).

106. The Court stated:

"The juvenile concept held high promise. We are reluctant to say that, despite disappointments of grave dimensions, it still does not hold promise, and we are particularly reluctant to say, as do the Pennsylvania appellants here, that the system cannot accomplish its rehabilitative goals. So much depends on the availability of resources, on the interest and commitment of the public, on willingness to learn, and on understanding as to cause and effect and cure." *Id.* at 547.

argument that all constitutional guarantees are applicable to children. In so holding, they followed opinions issued in six prior children's rights cases.[107]

Justice Douglas, disagreeing with the majority in *McKeiver*, argued:

> The Fourteenth Amendment, which makes trial by jury provided in the Sixth Amendment applicable to the States, speaks of denial of rights to "any person," not denial of rights to "any adult person . . . ."[108]

Justice Douglas did not disregard the differences between adults and children. However, he felt those differences should be considered in a juvenile case without denying constitutional protections.[109] Douglas thought that McKeiver could be tried by jury without denying him the benefits of a parens patriae focus.

Justice Douglas also dissented in part in *Wisconsin v. Yoder*.[110] In that case he concluded that the freedom of religion protected by the Constitution encompassed the freedom of the Amish child to practice a religion, rather than solely the right of the parents to bring up their children in their own religion. The majority had addressed itself only to the interests of the state in relation to the interests of the Amish parents.[111]

It is noteworthy that all of the above situations involve basic adult freedoms which have required decisions by the highest court in the land before they were applied to children.

Extension of Certain Constitutional Rights to Children

A. Due Process Considerations

The rights to life and liberty are guaranteed by the due process clause of the Fourteenth Amendment.[112] The court in *People v. Gillson*

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107. Prior children's rights cases following the parens patriae theory included: *In re* Winship, 397 U.S. 358 (1970); DeBacker v. Brainard, 396 U.S. 28 (1969); *In re* Gault, 387 U.S. 1 (1967); Kent v. United States, 383 U.S. 541 (1966); Gallegos v. Colorado, 370 U.S. 49 (1962); Haley v. Ohio, 332 U.S. 596 (1948).

108. 403 U.S. 528, 560 (1971).

109. Justice Douglas stated: "[W]here a State uses its juvenile court proceedings to prosecute a juvenile for a criminal act and to order 'confinement' until the child reaches 21 years of age or where the child at the threshold of the proceedings faces that prospect, then he is entitled to the same procedural protection as an adult." *Id.* at 559.

110. 406 U.S. 205, 241 (1972) (Douglas, J., dissenting).

111. *Id.* at 213-14.

112. "No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law . . . ." U.S. CONST. amend. XIV, § 1.

easily found the concept of bodily integrity to be within the definition of due process:

> The term "liberty," as used in the constitution, is not dwarfed into mere freedom from physical restraint of the person of the citizen, as by incarceration, but is deemed to embrace the right of man to be free in the enjoyment of the faculties with which he has been endowed by his Creator, subject only to such restraints as are necessary for the common welfare.[113]

Nielsen alleges that the experimental procedures involved might result in serious injury or death.[114] The procedure involves injections of epinephrine, a drug often used in treatment of allergy patients. Its side effects are well-known. Two researchers studying the use of epinephrine in children wrote:

> Every allergist knows that epinephrine may occasionally cause disturbing symptoms. . . . [W]hen we use sympathomimetic drugs for asthma we "buy the whole package." We must expect to encounter certain undesirable cardiovascular side effects. These include dizziness, tremor, pallor, and palpitation.[115]

Any injection may cause side effects which should not be disregarded without justification. There is always the risk of venipuncture and infection, a hematoma at the puncture site or, where there is an undiagnosed aneurysm, a thrombosis and resulting stroke.[116] The possibility of death, albeit remote, is also present.[117]

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113. 109 N.Y. 389, 398-99, 17 N.E. 343, 345 (1888).

114. First Amended Complaint for Injunctive Relief at First Cause of Action XVI, *Nielsen v. The Regents*, Civil No. 665-049 (S.F. Super. Ct., filed Dec. 19, 1973). Complainant Nielsen relies on California Penal Code § 273(a) which makes it a misdemeanor to unjustifiably cause or permit the infliction of physical pain or mental suffering upon a child or consent to such an unjustifiable act. The statute is relevant to to the issue of a violation of the due process rights of the control group children through the following reasoning process. If the conduct is illegal because of a legislative determination that it is unhumane, it is also unconstitutional and invades the guarantee of liberty in the Fourteenth Amendment. *See also* N.Y. PEN. LAW § 260.10 (McKinney Cum. Supp. 1974). Further support for the argument that there has been an abuse of right is CAL. CIV. CODE § 3513 (West 1970) which provides: "Any one may waive the advantage of a law intended solely for his benefit. But a law established for a public reason cannot be contravened by a private agreement." In Friedman v. Pacific Outdoor Adv. Co., 74 Cal. App. 2d 946, 952-53, 170 P.2d 67, 71 (1946), the court held the doctrine of *volenti non fit injuria* not applicable when the injury arises from the violation of a municipal ordinance.

115. Speer & Tapay, *Syncope in Children Following Epinephrine*, 28 ANNALS OF ALLERGY 50 (1970). Syncope means fainting.

116. *See generally* THE MERCK MANUAL OF DIAGNOSIS AND THERAPY 1729 (C. Lyght, M.D. ed. 1956); Lecks, Wood & Donsky, *The metabolic, circulatory, and bronchomotor responses of asthmatic children to epinephrine infusion*, 44 J. OF ALLERGY 261 (1969).

117. Ten percent of all pulmonary aneurysms are asymptomatic. J. KEITH, R. ROWE, & P. VLAD, HEART DISEASE IN INFANCY AND CHILDHOOD 889 (2d ed. 1967). The injection of epinephrine usually results in a temporary increase in the blood pressure. If a child

It is impossible to predict the reaction of any child, or adult, to the injection of an experimental drug. Furthermore, current standards of research which require the termination of a project upon any indication of injury or harm or upon request of the subject are not sufficient in most longitudinal studies such as that challenged in *Nielsen*. Normally, longitudinal studies look to the gradual development of symptoms related to the particular syndrome studied. They usually require children as subjects. In *Nielsen* the youngest subjects contemplated are only three months old, and the plan is to continue the studies of allergic reactions for a period of five years. An infant would have considerable difficulty in communicating to the researcher a wish to terminate the experiment or discomfort resulting from the injection. Although such a young child always has available the aid of vocal protest, it would be almost impossible to determine what, specifically, was the basis for the outburst. If a child cannot speak out and request termination of the experiment, it would appear that the guidelines provide inadequate protection.

This experiment involves significant risks to life and health due to unknown effects of an injection. Since experimental guidelines are ineffective to protect those children who cannot express a wish to terminate the procedures, the due process rights of those control children are violated.

No doubt, the argument will be raised that parental consent would operate as a waiver of the due process rights of the children generally. As noted above, however, the university may be unfairly taking advantage of parents' conflicting interests in order to obtain a control group of healthy children.[118] *Nielsen* alleges that the offer of money to the prospective subjects' parents takes advantage of the family's possible economic distress. The primary use of children from families of the staff and students at the medical facility is challenged as an exertion of undue influence over junior medical personnel. If *Nielsen* succeeds in establishing that any consent given by the prospective subjects' parents is inherently invalid, the experiment could not proceed with a control group. If the allegation is not proved, it would still seem incumbent upon the court to determine whether the Fourteenth Amendment allows a state to take advantage of the legal fiction of parental consent in order to perform nonbeneficial experimentation on healthy children. Therefore, whether considering only the children unable to speak for themselves or

had an undiagnosed aneurysm and the injection of the drug caused an increase in blood pressure, it is conceivable that the blood vessel might burst and that it would result in the child's death. *See also* Burns & Manion, *Sudden Unexpected Death of a Two-year-old Child from Thrombosis of Both Coronary Arteries with Aneurysmal Dilatation of the Vessels*, 38 MED. ANNALS OF THE DIST. OF COLUM. 381 (1969); Rebhun, *Pulmonary Embolism in Asthmatics*, 28 ANNALS OF ALLERGY 586 (1970).

118. See text accompanying note 8 *supra*.

all of the healthy control group children, *Nielsen* is seeking to prove an unconstitutional deprivation of rights.

B. Right to Privacy

The right to privacy, "to be let alone,"[119] is one of the most comprehensive and important of our constitutional freedoms.

> [T]he protection of a person's *general* right to privacy—his right to be let alone by other people—is, like the protection of his property and of his very life, left largely to the law of the individual States.[120]

Although the right to privacy is not expressly set forth in the United States Constitution,[121] courts have recognized certain zones of privacy under the Constitution. These include the right to procreate,[122] to contraception,[123] to child rearing and education[124] and to terminate pregnancy.[125]

As stated previously, case law in certain instances has regarded children as persons under the provisions of the United States Constitution.[126] It should follow, then, that children, like adults, are entitled to the implied constitutional right to privacy.[127]

In *Huguez v. United States*, the Ninth Circuit Court of Appeals held that the body was deserving of protection from unwarranted intrusions. The court stated:

> [T]he intimate internal areas of the physical habitation of mind and soul [are not] any less deserving of precious preservation from unwarranted and forcible intrusions than are the intimate internal areas of the physical habitation of wife and family. Is not the

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119. Katz v. United States, 389 U.S. 347, 350-51 (1967). *See generally* Warren & Brandeis, *The Right to Privacy*, 4 HARV. L. REV. 193 (1890).

120. Katz v. United States, 389 U.S. 347, 350-51 (1967).

121. Justice Douglas' opinion in Griswold v. Connecticut, 381 U.S. 479, 483 (1965), spoke of penumbral rights—those not specifically stated in the Constitution but nonetheless protected from governmental intrusion.

122. Skinner v. Oklahoma, 316 U.S. 535, 541 (1942).

123. *See* Eisenstadt v. Baird, 405 U.S. 438, 453 (1972).

124. *See* Pierce v. Society of Sisters, 268 U.S. 510, 534-35 (1925).

125. Roe v. Wade, 410 U.S. 113, 143 (1973).

126. *In re* Gault, 387 U.S. 1 (1967); Kent v. United States, 383 U.S. 541 (1966).

127. *In re* P.J., No. 922976 (D.C. Super. Ct., Feb. 6, 1973). *See also* Salaices v. Superior Ct., 1 Civil 36088 (First App. Dist., Dec. 11, 1974). A Petition for Prohibition was filed seeking recognition of the wishes of three children whose parents had been divorced. The petition asserted the children's right to privacy in not wanting to comply with parental visitation rights set out in the judgment of dissolution. The appellate court denied the petition and the California Supreme Court denied a rehearing. Such cases signal an awakening to the rights of children separate and apart from those of their parents.

> sanctity of the body even more important, and, therefore, more to be honored in its protection than the sancity of the home . . . ?[128]

The use of drugs as, for example, the injection challenged in *Nielsen*, is an intrusion into the body. As medical science advances and accepted medical and surgical procedures are either abandoned as too drastic or sanctioned only as last resort measures,[129] the medical profession is expanding its use of drugs.[130]

Senator Sam Ervin recently wrote in a report issued by his Subcommittee on Constitutional Rights that use of mind-altering drugs is so potentially threatening to our basic freedoms that the government seriously should question their use at all.[131]

Although we are somewhat protected from the general misuse of drugs by enforced safety standards,[132] typical testing situations, usually including a normal or control group in order to get a base reaction, constitute an unwarranted invasion for some subjects. As in *Nielsen*, where no personal benefit is contemplated for those in the control group, the privacy issue cannot be ignored. If integrity of the mind and body are to be preserved, such an intrusion into the body by injection would constitute a denial of the constitutional right to privacy of those children.

C. Tangential Equal Protection Considerations

Inclusion of the contemplated control group in *Nielsen* suggests not only an unconstitutional deprivation of liberty and invasion of privacy but also raises related questions with respect to a violation of equal protection.

The Fourteenth Amendment to the Constitution demands that equal protection of the laws be extended to all persons similarly situated.[133] Traditionally, courts have given broad discretion to state legisla-

128. 406 F.2d 366, 382 n.84 (9th Cir. 1968), *rehearing en banc denied* (Feb. 12, 1969).

129. *See* Kaimowitz v. Department of Mental Health, 13 Crim. L. Rep. 2452 (Mich. 1973).

130. *See, e.g.*, Mackey v. Procunier, 477 F.2d 877 (9th Cir. 1973). Drugs have been used quite extensively in calming hyperkinetic children. Researchers are now investigating the causes of hyperactivity rather than merely masking its symptoms. It has been too easy to prescribe mind-affecting drugs to help a child "adjust." *See* Divoky, *Toward a Nation of Sedated Children*, LEARNING, March 1973, at 37; Keogh, *Hyperactivity and Learning Disorders: Review and Speculation*, EXCEPTIONAL CHILDREN, Oct. 1971, at 101. *See also* Wyatt v. Stickney companion cases, 344 F. Supp. 373, *modified sub nom.* Wyatt v. Aderholt, 503 F.2d 1305 (1972) and 344 F. Supp. 387, *modified sub nom.* Wyatt v. Aderholt, 503 F.2d 1305 (1972).

131. S.F. Examiner, Dec. 1, 1974, at 1, col. 8.

132. Food, Drug & Cosmetic Act, 21 U.S.C.A. § 355 (1972).

133. *See* Skinner v. Oklahoma, 316 U.S. 535, 540 (1942). *See also* Tussman & ten-

tors to enact statutes utilizing classifications reasonably related to permissible state objectives.[134] However, when the classification infringes on a fundamental constitutional right or on the rights of a "suspect class,"[135] a "compelling state interest" test is applied.[136] Under this test, a necessary relation between the state interest and the classification must be shown.

Arguably, the compelling state interest test could be applied in this case both because the classification of children contains certain of the indicia which have made other classifications suspect (race[137] and alienage[138]) and because the right to privacy is a fundamental right within the scope of the Fourteenth Amendment protections.[139]

Hillary Rodham, a leading advocate for children's rights, has examined the changing status of children under the law[140] and advanced the proposition that the general class of children should be considered suspect, thus triggering the compelling state interest test:

> The strictures of the new equal protection theory should apply to children, i.e., classifications of children *qua* children, or of certain classes of children, should be considered suspect, and needs which from a developmental standpoint are fundamental should be protected as fundamental interests under the Constitution.[141]

The basis for this proposition is that age classifications involve arbitrary notions of capacity which are easily disproved in either individual or group experiences.[142] Additionally, children are a discrete minority, powerless to protect their own interests through the political processes.[143]

The control group children in *Nielsen* represent a minority without political standing. Unlike children from families with a history of allergic diseases, the healthy children in the control group stand to gain no personal benefit from the experiment. Also, unlike healthy adults who might choose to subject themselves to medical experiments, for instance prisoners, the control group children have no recognized right to weigh personal risks against humanitarian contributions before giving consent.

Broek, *The Equal Protection of the Laws*, 37 CAL. L. REV. 341 (1949).

134. *See* Gulf, Colo. & Santa Fe Ry. v. Ellis, 165 U.S. 150, 165-66 (1897).

135. *See* United States v. Carolene Products Co., 304 U.S. 144, 152 n.4 (1938).

136. Shapiro v. Thompson, 394 U.S. 618, 634 (1969). *See also id.* at 658-62 (discussion of "compelling interest" doctrine by Harlan, J., dissenting).

137. *See* Brown v. Board of Educ., 347 U.S. 483 (1954).

138. Graham v. Richardson, 403 U.S. 365, 376 (1971).

139. *See* Griswold v. Connecticut, 381 U.S. 479, 483 (1965).

140. Rodham, *Children Under the Law*, 43 HARV. EDUC. REV. 487 (1973).

141. *Id.* at 507.

142. *Id.* at 512.

143. *See* United States v. Carolene Products Co., 304 U.S. 144, 152 n.4 (1938).

It is doubtful that finding a cure for allergies and advancing medical science would satisfy the rigorous scrutiny of the compelling state interest test. Even if such reasons satisfied the test, it would seem that where less drastic alternatives could lead to the same end, the use of healthy children would be unnecessary.[144]

At the very least, the university appears to be taking unfair advantage of one small and powerless group, subjecting them to the risk of physical harm and to invasion of their privacy simply because their parents, perhaps out of a conflict of interest, have given consent. Use of the legal fiction of parental consent to the disadvantage of the child shocks the conscience. The Constitution requires more.

Conclusion

The foregoing medical and constitutional considerations have been advanced to illustrate the need for an ethical and legal scheme for continuing necessary research on children while preserving the dignity and integrity of the individual.

Suggestions for resolution of the problem are numerous. They include auto-experimentation,[145] refusal to publicize results of experiments acquired through unethical practices,[146] use of ombudsmen,[147] provision for significant compensation of injured subjects[148] and the requirement of a review board to authorize all experiments.[149]

144. *See generally* Gunther, *The Supreme Court 1971 Term*, 86 HARV. L. REV. 1 (1972) wherein Professor Gunther discusses a means versus ends approach to equal protection.

145. Altman, *Auto-Experimentation—An Unappreciated Tradition in Medical Science*, 286 NEW ENG. J. MED. 346 (1972). In an interview with Science magazine, Chester Southam, director of the cancer research team at Sloan-Kettering Institute for Cancer Research, was asked his opinion on auto-experimentation. Southam was being questioned on the Institute's practice of injecting human beings with live cancer cells to study human immunity to cancer. Southam answered, "I would not have hesitated . . . if it would have served a useful purpose. But . . . to me it seemed like false heroism, like the old question whether the General should march behind or in front of his troops. I do not regard myself as indispensable—if I were not doing this work someone else would be—and I did not regard the experiment as dangerous. But, let's face it, there are relatively few skilled cancer researchers, and it seemed stupid to take even the little risk." Southam preferred to rely on a group of volunteers at the Ohio State Penitentiary. *Human Experimentation: Cancer Studies at Sloan-Kettering Stir Public Debate on Medical Ethics*, 143 SCIENCE 551 (1964).

146. Beecher, *Ethics and Clinical Research*, 274 N. ENG. J. MED. 1354, 1360 (1966).

147. Cooper, *Creative Pluralism—Medical Ombudsman*, in EXPERIMENTATION WITH HUMAN BEINGS 991 (J. Katz ed. 1972) [hereinafter cited as *Cooper*].

148. Havighurst, *Compensating Persons Injured in Human Experimentation*, 169 SCIENCE 153 (1970).

149. Melmon, Grossman & Morris, *Emerging Assets and Liabilities of a Committee on Human Welfare and Experimentation*, 282 N. ENG. J. MED. 427 (1970) [hereinafter cited as *Emerging Assets*].

The recommendation most frequently followed has been that of a review board. The project challenged by *Nielsen* is funded by a grant from the Department of Health, Education and Welfare and, as such, is subject to its guidelines,[150] which are similar to those of the Nuremberg Code[151] and the Declaration of Helsinki.[152] In an attempt to carry out responsible research, since 1966 the Department of Health, Education and Welfare has required a Human Experimentation Committee to review proposed protocols, to make recommendations and ultimately to approve or disapprove the projects.[153] Such a committee is active on the University of California Medical School campus reviewing all protocols, whether or not subject to funding.[154] This committee approved the experiment in question. The University of California policy with regard to consideration of the proposed protocols is quite elaborate. Committee members represent diverse medical fields on the school campus. The group's only attorney in the past few years has been the plaintiff Nielsen.[155]

A possible solution to the dilemma is that the peer group review committee be replaced by a committee composed of or including representatives from the lay community. Lay community representation would aid the committee in ridding itself of its inevitable self-serving attitude. Quite naturally, university doctors and scientists on the committee are influenced, though perhaps indirectly, by the favorable publicity likely to flow from a successful experiment.

There are obvious obstacles to implementing such a solution. The committee at the University of California now uses ad hoc committees within specific areas of expertise to facilitate turnover of the highly scientific protocols they are called upon to evaluate. A committee representative from the lay community would require countless hours of medical background preparation to be in a position to rule on a particular protocol. If the objective of a review committee is to provide an evaluation by persons disinterested in the outcome of the experiment, the increased evaluation time might prove advantageous. The addition of one lay member has not changed the outcome of the vote in the years Nielsen has been a member of the committee. Perhaps more lay members are needed to tip the scale toward greater consideration of the patient subject's needs and rights.

150. See text accompanying note 98 *supra.*

151. See text accompanying notes 90-92 *supra.*

152. See text accompanying notes 93-95 *supra.*

153. *See Emerging Assets, supra* note 149, at 427.

154. *Id.*

155. First Amended Complaint for Injunctive Relief at First Cause of Action IV, Nielsen v. The Regents, Civil No. 665-049 (S.F. Super. Ct., filed Dec. 19, 1973).

This author views the concept of a review board as a positive approach, but including peers who have even an indirect interest in the outcome of the research defeats the entire purpose of a board intended to evaluate and criticize procedures. While the most acceptable solution would be to discontinue all nonbeneficial research on children, it is unlikely that such a step would ever be taken or, indeed, that it would be followed even if judicially decreed. Researchers have acknowledged the need for an alternative to the questionable use of children, incompetents and prisoners as subjects.[156] The study challenged in *Nielsen* would simply demand the use of a greater number of children from families with a history of allergic diseases. Receiving the information as a by-product of therapeutic treatment certainly would require more time before medical conclusions could be reached, but the procedure would pose fewer legal problems.[157]

Absent such a voluntary move by researchers, a possible solution to the problem of preserving the infant subjects' constitutional rights might lie in judicial intervention, with a weighing of the risks and benefits anticipated as a result of a study.

One scientist concerned with the ethical problems of human experimentation has argued:

> Any one solution, such as some independent ombudsman or office of review in the executive or legislative branches, would be insufficient. Rather, we need a return to old-fashioned scientific pluralism. We need open, constructive conflict of ideas from which truth may emerge. We should not discourage advocacy, dissidence, and special pleading. One approach is to dilute the concentration of advisory sources. The same people or program sources should not at once guide legislative and executive branches, from within and without, while also dominating voluntary and professional society channels. Let us round out our pluralisms and at least occasionally have some spirited debates over both ends and means, right out in the open.[158]

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156. *See Legal Considerations, supra* note 45, at 145-46.

157. "In our haste to win the medical wars—society's haste—and to enjoy promised fruits of conquest, we are adventuring beyond prudent limits of risk. The hope becomes the theory which leads to selective discovery of evidence to support the wish, while contrary evidence which might slow the pace is ignored or rationalized away. This naturally stems from single-minded advocacy which sometimes has led to great gains, but more often has blocked or retarded action along other avenues of progress.

What is wrong is the absence of mechanisms for obliging proponents of action to offer evidence, in reasonable depth, to independent judges who do not have causes to espouse. Consequently, it has been too easy for bold new programs in the medical sector to come into being without scientific bases for promises or hope that benefits could or would materialize. Once activated these new programs become irreversibly committed because of public promises, dependence of program personnel or continuity of support, and force of legislation." Cooper, *supra* note 147, at 987.

158. *Id.* at 991.

Such an independent and unbiased viewpoint presently is utilized in cases involving child neglect[159] or consent to minor marriages.[160] It seems a small and yet constitutionally required step to expand utilization of a third party viewpoint to embrace the field of nonbeneficial experimentation on children. While implementation of this suggestion might seem an overwhelmingly large task, adoption of other recommendations advanced would reduce the number of situations requiring judicial review.

For instance, Hillary Rodham has suggested three different strategies to further recognition of legal rights for children.[161] They include: (1) abolishing the legal status of infancy or minority to the extent of reversing the presumption of incompetency; (2) application of *all* procedural rights now guaranteed to adults under the Constitution to children whenever the state or a third party moves against them, judicially or administratively; and (3) rejection of the presumption of identity of interests between parents and their children whenever the child has interests demonstrably independent of those of his or her parents with an opportunity for the competent child to assert his or her own interests.[162]

The suggestions are not new. The *Restatement of Torts* for many years has encouraged abolishing rigid age standards for determination of competency.[163] Likewise, Justice Douglas, although dissenting in *Wisconsin v. Yoder*,[164] affirmed the majority decision with respect to one of the children based on a consideration of that child's testimony and obvious competency.[165]

Abolition of the parens patriae theory is not necessarily required if children are given all adult rights. The Juvenile Court movement was designed to approach a child's problems paternalistically rather than to determine guilt or innocence. However, it would be difficult to accept the view that the framers of the movement, in establishing a benevolent approach to rehabilitation of children, meant to deny to those same children the constitutional rights which are guaranteed to all persons.[166] In the field of experimentation, the state could retain an interest in the physical and mental growth of its children without wielding so much power as to deny those children their constitutional rights.

159. *See* CAL. WELF. & INST'NS CODE §§ 600-02, 625 (West 1972); N.Y. SOC. SERV. LAW §§ 385, 397 (McKinney Cum. Supp. 1974); N.Y. SOC. WELF. LAW § 395 (McKinney 1966).

160. *See* CAL. CIV. CODE § 4102 (West 1973).

161. Rodham, *Children Under the Law*, 43 HARV. EDUC. REV. 487 (1973).

162. *Id.* at 506-07.

163. RESTATEMENT OF TORTS § 59 (1934).

164. 406 U.S. 205, 241 (1972).

165. *Id.* at 242-43.

166. *See In re* Gault, 387 U.S. 1, 15-16 (1967).

As to the identity of interests, Rodham suggests that the only way to rid the courts of the problem of presumptions is to resort to extrafamilial decisions, taking into account all interested parties. The courts now treat such an identity of interests as to the parent and child as a legal presumption or at least a permissible presumption.[167] Ideally, it should be treated only as an assumption to be discarded where consequences based on that assumption appear to be irreversible.[168]

Nielsen v. The Regents[169] as a test case could have far-reaching ramifications in casting yet another vote for children's rights. Just as courts heretofore have held in specific instances that the United States Constitution is applicable to children, it is time a general statement be advanced to guarantee for children the full range of protections guaranteed to all persons under the United States Constitution. The instant case is a prime example of the abuse that up to now has been visited upon children simply due to their legal incapacity—a justification for wide-ranging abuse that should not be allowed to continue. One judicial decree alone will not solve the problems of nonbeneficial experimentation on children. The time has come for legislation and specific legal guidelines outlining the rights of children. It well may be that researchers will have to discontinue research on those incompetent to give their informed consent. Whatever the outcome, automatically allowing parents to consent to such experimentation on their children denies those children their constitutional rights. In the words of Earl Warren: "A little freedom for some people will no longer suffice."[170]

Children are one of our most precious national resources. If we are to preserve that resource, the protection extended must be real not illusionary.[171]

167. Rodham, *Children Under the Law*, 43 HARV. EDUC. REV. 487, 510 (1973).

168. *Id.*

169. Civil No. 665-049 (S.F. Super. Ct., filed Sept. 11, 1973).

170. Warren, "*All Men are Created Equal*," 25 RECORD 351, 355-56 (1970).

171. Since this note was written, the plaintiff in *Nielsen* moved for a summary judgment on the First Cause of Action. The facts are not in dispute, although they are viewed quite differently by the opposing parties. The following statements illustrate the defendants' position:

"I believe we all have obligations to one another and to society which some will choose to express by charitable contributions, volunteer work, etc. Another opportunity, another way to make a social contribution is to participate and to permit the participation of one's children in investigations which represent significant opportunities for helpfulness and minimal opportunities for harm. I believe that many parents directly feel that this is a good thing to do for mankind: they can be at peace with their own consciences in placing their children in that small degree of jeopardy given the substantial nature of the benefits that might accrue to children in particular, and adults too." Points and Authorities in Opposition to Preliminary Injunction for Defendants, Exhibit "C" at 5, lines 26-32, *Nielsen v. The Regents*, Civil No. 665-049 (S.F. Super. Ct., filed Dec. 19, 1973).

"It is perhaps reasonable to expect that people have to contribute to the society

> Parents may be free to become martyrs themselves. But it does not follow they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves.[172]

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in which they live. All privileges tend to be associated with responsibility and the fact that small children are unaware of this does not mean they do not fall subject to the same rule of nature." Points and Authorities in Opposition to Preliminary Injunction for Defendants, Exhibit "B" at 10, lines 16-20, *Nielsen, supra.*

172. Prince v. Massachusetts, 321 U.S. 158, 170 (1944). *See* Raleigh Fitkin-Paul Morgan Mem. Hosp. v. Anderson, 42 N.J. 421, 201 A.2d 537 (1964) *cert. denied,* 377 U.S. 985 (1964) (regarding protection of the unborn child).