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THE FUTURE OF FETAL RESEARCH IN CALIFORNIA: A PROPOSAL FOR CHANGE

The rapid rise in medical technology has resulted in the promulgation of restrictive research regulations at both state and federal levels. The statutory treatment of fetal research illustrates the trend to regulate experimentation through legislation. The California fetal research statute is used as a model of state legislative efforts. This statute is examined both for legislative intent and for its effect on the research community. Alternatives to resolution of the fetal research controversy at the state level are discussed, followed by a recommendation for the best solution to this medical-ethical dilemma.

Science and medicine, like kings, presidents and parliaments must remain below, but let us hope not immobilized by, law.¹

The balance between scientific progress through innovative experiments and the reluctance of the general public to accept shifts in traditional ethical norms must eventually be resolved within the American legal system. Chief Justice Warren Burger, in his article on experimental medicine, predicted that the law with regard to the "new biology" would emerge slowly through the courts by an application of traditional common law precepts.² Because he concluded that the evolution of law need not keep pace with scientific developments, he foresaw no need for rapid legislative action.³ Within a few years after publication of Chief Justice Burger's article, legislators began to discover that the courts were not quick enough in dealing with many major bioethical dilemmas. Consequently, a rash of legislation regulating scientific research emerged at both state⁴ and federal levels.⁵ These statutes have caused an effective curtail-

1. Burger, *Reflections on Law and Experimental Medicine*, 15 U.C.L.A. L. REV. 436, 442 (1968).

2. *Id.* at 439.

3. *Id.* at 438.

4. Areas of the "New Biology" now subject to legislation at the state level include sterilization, fetal experimentation, transplantation, organ donation, and behavior control. See C. LEVY, *THE HUMAN BODY AND THE LAW* (1975).

5. Federal regulations, enforced through control of funding or distribution of drugs, have reached into many areas of human experimentation. For example, the Food and Drug Administration regulates pharmacological studies while the Department of Health, Education and Welfare (HEW) regulates such areas as research on the fetus, research on prisoners, and research on pregnant

ment of research in certain controversial areas due both to conflicting provisions between governmental levels and to ambiguities within the terms of particular statutes.

Fetal research highlights this conflict between science and ethics. Although physicians have been able to use some of the results of fetal experimentation to develop treatment for fetal disorders, and the potential for future benefits is promising, many segments of society find some or all types of fetal research morally objectionable. State⁶ and federal⁷ legislatures, reluctant to await judicial solutions to fetal research problems, have enacted regulatory statutes. This Comment focuses upon California legislation as an illustration of the difficulties faced by other legislative bodies. The problems encountered with the California regulations are examined, followed by a proposal for a uniform legislative resolution of the fetal research controversy.

OVERVIEW OF FETAL RESEARCH

Although fetal research is used as a definitive term in itself, it actually encompasses many types of experimental techniques, each of which has unique potential benefits that must be balanced against concomitant ethical costs. Hence, clarification of the terminology at the outset is crucial to meaningful legislative analysis.

women. *See* N. HERSHEY & R. MILLER, *HUMAN EXPERIMENTATION AND THE LAW* 105-152 (1976).

6. Seventeen states have enacted regulations regarding fetal research: CAL. HEALTH & SAFETY CODE § 25956 (West Supp. 1977); ILL. ANN. STAT. ch. 38, §§ 81-26, 81-32 (Smith-Hurd 1977); KY. REV. STAT. ANN. § 436.026 (Baldwin 1975); LA. REV. STAT. ANN. § 14:87.2 (West 1974); ME. REV. STAT. tit. 22, § 1574 (Supp. Pamphlet 1975); MASS. GEN. LAWS ANN. ch. 112, § 12j (West Supp. 1977-1978); MINN. STAT. ANN. § 145.422 (West Supp. 1978); MO. ANN. STAT. § 188.035 (Vernon Cum. Annual 1978); MONT. REV. CODES ANN. § 94-5-617 (Crim. Code Supp. 1977); NEB. REV. STAT. § 28-4,161 (Reissue 1975); N.Y. PUB. HEALTH LAW § 2445 (McKinney 1977); N.D. CENT. CODE § 14-02.2-01 (Supp. 1977); OHIO REV. CODE ANN. § 2919.14 (Baldwin Current Service 1976); 35 PA. CONS. STAT. ANN. § 6605 (Purdon Supp. 1977-1978); S.D. COMPILED LAWS ANN. § 34-23A-17 (Rev. 1977); UTAH CODE ANN. § 76-7-310 (Crim. Code Supp. 1977).

7. The United States Congress placed a moratorium on fetal research until guidelines could be proposed to regulate research in this area. *See* National Research Act, Pub. L. No. 93-348, § 213, 88 Stat. 353 (1974) (codified in 42 U.S.C. § 2891-1). The moratorium was lifted following an extensive study of fetal research conducted by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission). *See* NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, *REPORT AND RECOMMENDATIONS: RESEARCH ON THE FETUS* (DHEW Pub. No. (OS) 76-127, 1975), *reprinted in* 40 Fed. Reg. 33,530 (1975) (partially codified in 45 C.F.R. §§ 46.101-301 (1976)) [hereinafter cited as *COMMISSION'S REPORT*]. *See also* NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, *REPORT AND RECOMMENDATIONS: RESEARCH ON THE FETUS (APPENDIX)* (DHEW Pub. No. (OS) 76-128, 1975) [hereinafter cited as *APPENDIX*].

Research on the fetus after death includes studies of the deceased fetus or of living tissue cultures grown from recently deceased fetuses.⁸ Anatomical and chemical studies are performed on completely dead fetal tissue with the objects of improving methods of disease detection and of reducing hazards confronted during induced abortions.⁹ Living fetal tissue has multifarious uses, including aiding studies of developmental genetic problems, growth regulation, and discovery of the early antecedents of human disease.¹⁰

Traditionally, this type of experimentation has not been subjected to the regulations and prohibitions that govern fetal research. Most jurisdictions have traditionally treated the deceased fetus as any other deceased person; hence, the Uniform Anatomical Gift Act governing the donation of tissue determines the appropriate procedure to be followed in utilizing this type of fetal material.¹¹

Research on the fetus *in utero* refers to experimentation within the womb at any time from the point of fertilization until delivery.¹² Because the uterus is the natural environment of the fetus, *in utero* research is a logical method for studying maternal-fetal interactions. Such studies can provide normative data for the development of diagnostic and therapeutic procedures to aid detection and treatment of fetal disorders.¹³ Specific examples of this type of research include diagnosis of genetic defects from amniotic fluid,¹⁴ studies of placen-

8. See Note, *Fetal Experimentation: Moral, Legal, and Medical Implications*, 26 STAN. L. REV. 1191, 1198 (1974).

9. See Mahoney, *Implications of Restrictions on Fetal Research for Biomedical Advance*, 23 CLINICAL RESEARCH 229, 229 (1975). See also APPENDIX, *supra* note 7, at 1-3, 13-4.

10. APPENDIX, *supra* note 7, at 1-29.

11. "The Uniform Anatomical Gift Act (UAGA), which has been adopted in all fifty states and the District of Columbia, permits research on the dead fetus and the products of conception, provided consent has been given by either parent and the other parent has not objected." COMMISSION'S REPORT, *supra* note 7, at 25, reprinted in 40 Fed. Reg. 33,536 (1975) (parenthetical original). In addition to the UAGA, some states have passed varying degrees of restrictions on research with deceased fetuses. See APPENDIX, *supra* note 7, at 13-6 to -8.

12. See Martin, *Ethical Standards for Fetal Experimentation*, 43 FORDHAM L. REV. 547, 550 (1975).

13. For a general discussion of *in utero* experimentation, see COMMISSION'S REPORT, *supra* note 7, at 7-8, reprinted in 40 Fed. Reg. 33,532-33 (1975); P. RAMSEY, *THE ETHICS OF FETAL RESEARCH* 51-57 (1975); Walters, *Fetal Research and the Ethical Issues*, HASTINGS CENTER REP., June, 1975, at 13. See also Mirkin, *Impact of Public Policy on the Development of Drugs for Pregnant Women and Children*, 23 CLINICAL RESEARCH 233 (1975).

14. Amniotic fluid is the fluid in which the fetus is bathed while in the womb. See BLACK'S MEDICAL DICTIONARY 35 (31st ed. 1976) (defined under "amnion").

tal transfer,¹⁵ and intrauterine therapy.¹⁶

When a fetus scheduled for abortion is removed from the uterus and separated from its mother, it is called an abortus.¹⁷ Research involving a living abortus, classified as *ex utero*, is uniquely suited for studying human development because the fetus is so accessible to experimentation. Examples of *ex utero* research include studies of fetal physiology and metabolism,¹⁸ retrieval of organs for use in investigating biosynthesis,¹⁹ and studies directed toward prolongation of fetal life.²⁰

Both *in utero* and *ex utero* experiments can be conducted for the benefit of the particular experimental subject involved. Such work is generally denoted therapeutic.²¹ Nontherapeutic work includes

The amniotic fluid contains cells sloughed from the fetus' skin, which is helpful in genetic diagnosis. See COMMISSION'S REPORT, *supra* note 7, at 8, reprinted in 40 Fed. Reg. 33,532-33 (1975); Note, *Fetal Research: A View from Right to Life to Wrongful Birth*, 52 CHI.-KENT L. REV. 133 (1975). See also APPENDIX, *supra* note 7, at 15-25.

15. Studies of placental transfer include analysis of the effect on the developing fetus of antibiotics or vaccines administered to the mother and, at some stages, transmission of compounds introduced into the fetus. Walters, *supra* note 13, at 14. See COMMISSION'S REPORT, *supra* note 7, at 11, reprinted in 40 Fed. Reg. 33,533 (1975); Note, *Fetal Research—The Legislative Answer*, 78 W. VA. L. REV. 230, 231-32 (1976).

16. Intrauterine therapy is used to treat the fetus while it is still within the uterus. Some techniques employed to ensure normal development include transfusions for Rh incompatibility and administration of compounds found lacking in the fetus. See Walters, *supra* note 13, at 13. See also COMMISSION'S REPORT, *supra* note 7, at 10-12, reprinted in 40 Fed. Reg. 33,532-33 (1975); APPENDIX, *supra* note 7, at 1-5 to -21.

17. The term *abortus* has been eliminated from some fetal research regulations. For example, the National Commission extended the meaning of *fetus* to include the fetus *ex utero* until viability has been reached. The effect was to delete the term *abortus* and substitute in its place the term *fetus ex utero*. See 40 Fed. Reg. 33,526 (1975).

18. These studies are performed on the abortus that continues to live following an abortion procedure. Such studies provide information on circulation, enzymatic composition, and oxidation of nutritional substances. See COMMISSION'S REPORT, *supra* note 7, at 12-15, reprinted in 40 Fed. Reg. 33,532 (1975); Ramsey, *supra* note 13, at 59; Walters, *supra* note 13, at 13.

19. Walters, *supra* note 13, at 13.

20. Studies on life prolongation are used to develop methods by which premature infants may be raised to maturity. Incubation, oxygenation, and the use of artificial placentas are the most widespread techniques now undergoing development. See COMMISSION'S REPORT, *supra* note 7, at 13, reprinted in 40 Fed. Reg. 33,533-34 (1975); Walters, *supra* note 13, at 13. See also Note, *Fetal Experimentation: Moral, Legal, and Medical Implications*, 26 STAN. L. REV. 1191, 1195-97 (1974).

21. Fetal research is generally permitted for therapeutic research, and thus it becomes crucial to understand the full meaning of what will be defined as therapeutic. The medical profession has claimed that there is no realistic way to categorize research as either therapeutic or nontherapeutic, and such attempts at distinction engender confusion. See text accompanying notes 149-150 *infra*. See also P. RAMSEY, *THE PATIENT AS A PERSON* 11-13 (1970); Levine, *The Impact*

studies designed to garner general scientific knowledge and those directed toward development of procedures which may prove therapeutic for future fetuses, although of no benefit to the particular fetus involved in the experiment.

Fetuses are often further classified as viable or nonviable. Medically, a fetus is considered viable if it is capable of maintaining an independent existence outside the womb.²² As designated in *Roe v. Wade*, viability is the point at which the state develops a compelling interest in the life of the fetus.²³ However, a clear set of criteria for determining when a fetus may be categorized as viable has not yet been established.²⁴ Thus, the determination often becomes a matter of professional judgment on the part of the individual physician involved in either the abortion or the experiment.²⁵

EMERGENCE OF THE FETAL RESEARCH CONTROVERSY

The emergence of the fetal research controversy in the United States is most frequently attributed to the Supreme Court's decision in *Roe v. Wade*. Although fetal experimentation was being performed well before 1973, the legalization of demand abortions greatly increased the number of fetuses available for research and therefore has brought the issue of fetal research before the public eye.²⁶ In addition, the refusal of the Supreme Court in this decision to

on *Fetal Research of the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*, 22 VILL. L. REV. 367, 377-82 (1977).

22. See BLACK'S MEDICAL DICTIONARY 904 (31st ed. 1976).

23. 410 U.S. 113, 163 (1973).

24. According to the Supreme Court in *Roe v. Wade*, a fetus is viable when it is capable of a meaningful life outside the mother's womb. *Id.* The National Commission has defined the term "viable infant" similarly: "likely to survive to the point of sustaining life independently, given the support of available medical technology." COMMISSION'S REPORT, *supra* note 7, at 5, *reprinted in* 40 Fed. Reg. 33,531 (1975). The National Commission gave a more concrete guideline for the determination of a "possibly viable" infant—20 to 24 weeks gestational age and a weight from 500 to 600 grams. *Id.* For a discussion of the problems in defining viability, see Martin, *Ethical Standards for Fetal Experimentation*, 43 FORDHAM L. REV. 547, 564-68 (1975). See also COMMISSION'S REPORT, *supra* note 7, at 53-59, *reprinted in* 40 Fed. Reg. 33,542-44 (1975).

25. COMMISSION'S REPORT, *supra* note 7, at 5, *reprinted in* 40 Fed. Reg. 33,532 (1975).

26. Note, *Fetal Experimentation: Moral, Legal, and Medical Implications*, 26 STAN. L. REV. 1191, 1191 n.2 (1974). *But see* Levine, *supra* note 21, at 370, for an argument that even before the *Roe* decision the supply of fetuses for research exceeded demand, and the effect of the decision was only to change the type of fetus available for research.

recognize any rights of the fetus may have contributed to a conclusion that use of this unprotected entity was not violative of ethical canons, thereby encouraging further experimentation.²⁷

Opponents to the Supreme Court's stance in *Roe v. Wade* tend to regard fetal research as inextricably tied to the abortion issue and therefore have denounced it as morally repugnant.²⁸ Although the precise motivation behind the right-to-life groups is unclear, their position is related to the philosophical presumption that personhood begins at conception. One author has even suggested that the organized opposition to fetal research has been motivated by a desire to override the *Roe* decision with a constitutional amendment.²⁹ In order to facilitate passage of this amendment, these groups may believe it is necessary to neutralize possible societal gains from the abortion procedure, one of which is the potential of fetal research to save future lives.

Regardless of the actual impact of *Roe v. Wade* upon the performance of fetal research, the decision was responsible for heightened public awareness of the ethical dilemmas associated with the issue of whether fetal rights should be recognized.³⁰ Following the *Roe* decision on January 22, 1973, the *Washington Post* published a series of articles on fetal research which highlighted some of the questionable experimental procedures being performed in United States laboratories.³¹ These articles, combined with increasing public protest over the abortion decision, prodded the United States Congress into action. In July, 1974, a congressional moratorium³² was imposed on all fetal research until the newly formulated National Commission for the Protection of Human Subjects of Biomedical and Behavioral

27. "Little wonder that intelligent people are asking: how can one who has no right to life itself have the lesser right of precluding experimentation on his or her person?" COMMISSION'S REPORT, *supra* note 7, at 78, reprinted in 40 Fed. Reg. 33,549 (1975) (dissenting statement of Commissioner David Louisell).

28. See, e.g., COMMISSION'S REPORT, *supra* note 7, at 46, reprinted in 40 Fed. Reg. 33,541 (1975) (testimony of Chris Mooney before the Commission indicating a fear that researchers might induce women to undergo abortions and that the desire of researchers to utilize fetuses might hinder developments of alternatives to abortion).

29. Nathan, *Fetal Research: An Investigator's View*, 22 VILL. L. REV. 384, 386 (1977).

30. See McCormick, *Fetal Research, Morality, and Public Policy*, HASTINGS CENTER REP., June, 1975, at 26, 29-30, for a discussion of the effect of abortion policy on experimentation policy. But see Ramsey, *supra* note 13, at 37, for a discussion of the need to sever abortion issues from the formulation of fetal research policy.

31. Cohn, *Considering Ethics—Live Fetus Research Debated*, Wash. Post, Apr. 10, 1973, § A, at 1, col. 5, reprinted in 119 CONG. REC. 17,472 (1973); Cohn, *NIH Vows Not to Fund Fetus Work*, Wash. Post, Apr. 13, 1973, § A, at 1, col. 4, reprinted in 119 CONG. REC. 17,472-73 (1973).

32. National Research Act, Pub. L. No. 93-348, § 213, 88 Stat. 353 (1974) (codified in 42 U.S.C. § 2891-1).

Research (National Commission) could propose recommendations to guide researchers in this area.³³

LEGISLATIVE RESPONSE IN CALIFORNIA

The California response to the fetal research controversy followed quickly in the wake of federal activity. Less than two weeks after publication of the *Washington Post* articles, the State Senate introduced a bill relating to research on the fetus.³⁴ A similar bill was introduced to the members of the California Assembly just one day later.³⁵ The Senate bill was drafted as an urgency statute which was to take effect immediately for the preservation of public health and safety.³⁶ In addition, the proposed legislation was explicitly formulated to conform California law to the federal moratorium prohibiting experimentation on the fetus.³⁷

The bill that originated in the State Senate was subjected to numerous amendments before its final enactment. Intended originally for incorporation into the Penal Code as a felony violation, the bill was later transferred to the Health and Safety Code, with a corresponding reduction of the penalty to an act of unprofessional misconduct.³⁸ An early revision of the bill limited permissible research solely to tissue specimens obtained from dead fetuses, thereby preventing experimentation on the intact deceased fetus or its organs.³⁹ This restrictive amendment was later liberalized in the final bill to include the whole deceased fetus as well as tissue specimens as suitable research materials.⁴⁰ A third modification supported this liberalizing trend by applying fetal research restrictions only to human fetuses.⁴¹ However, this limitation was not incorporated into the

33. *Id.* § 202(b) (Congress created the National Commission and directed it to develop guidelines to govern fetal research).

34. S.B. 1046 (enacted 1973, repealed 1975).

35. A.B. 1724 (enacted 1973).

36. The declaration of emergency was added as an amendment to S.B. 1046 on June 13, 1973.

37. S.B. 1046 (as amended in the Senate on June 13, 1973).

38. S.B. 1046 (as amended in the Assembly on Sept. 6, 1973). One hypothesis for this reduction in penalty is that pressure from lobbying groups favoring research overcame the initial legislative judgment. "Representatives of Stanford, the University of California, the American Civil Liberties Union, and Zero Population Growth did succeed in getting the California bill amended." *'Live' Abortus Research Raises Hackles of Some, Hopes of Others*, MED. WORLD NEWS, Oct. 5, 1973, at 32, 32.

39. S.B. 1046 (as amended in the Senate on June 22, 1973).

40. *Id.* (as amended in the Assembly on Aug. 23, 1973).

41. *Id.* (as amended in the Senate on June 13, 1973).

final version of the bill, thus seemingly prohibiting experimentation upon animal as well as human fetuses. This surprising reversal clearly does not conform to relatively lax regulations found in other areas of animal research and may simply represent an oversight during the final formulation of the bill.⁴²

The bill that originated in the State Assembly went through a very similar metamorphosis from restrictive to more permissive legislation. The transition from a criminal penalty to a violation of professional conduct mirrored the activity in the State Senate.⁴³ Furthermore, a later amendment included a provision permitting research designed to protect the life of the particular fetus involved in the experiment.⁴⁴ The final version limited the restriction of fetal research only to human products of conception and further defined what would be considered a lifeless fetus for experimental purposes.⁴⁵

Both the Assembly and Senate versions of the fetal research statute were unanimously passed and signed into law in September, 1973.⁴⁶ Although very similar, several differences exist between the

42. The Senate clearly intended to permit research on animal fetuses. On June 13, 1973, the Senate bill was amended to provide for this contingency. On September 7, 1973, the Senate also amended the counterpart bill that originated in the Assembly to permit animal research. Only after the extensive revision of the complete Senate bill by the Assembly on September 6, which resulted in the change of penalty from criminal to unprofessional conduct, was the term *human* left out of the bill.

43. A.B. 1724 (as amended in the Assembly on June 18, 1973).

44. *Id.*

45. *Id.* (as amended in the Senate on Sept. 7, 1973).

46. *Id.* (as enacted on Sept. 30, 1973):

SECTION 1. Section 25956 is added to the Health and Safety Code, to read:

25956. (a) It is unlawful for any person to use any aborted product of human conception, other than fetal remains, for any type of scientific or laboratory research or for any other kind of experimentation or study, except to protect or preserve the life and health of the fetus. "Fetal remains," as used in this section, means a lifeless product of conception regardless of the duration of pregnancy. A fetus shall not be deemed to be lifeless for the purposes of this section, unless there is an absence of a discernible heartbeat.

(b) In addition to any other criminal or civil liability which may be imposed by law, any violation of this section constitutes unprofessional conduct within the meaning of the State Medical Practice Act, Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code.

SEC. 2. No appropriation is made by this act, nor is any obligation created thereby under Section 2164.3 of the Revenue and Taxation Code, for the reimbursement of any local agency for any costs that may be incurred by it in carrying on any program or performing any service required to be carried on or performed by it by this act.

S.B. 1046 (as enacted on Sept. 24, 1973):

SECTION 1. Section 25956 is added to the Health and Safety Code, to read:

25956. (a) It is unlawful for any person to use any aborted product of conception, other than fetal remains, for any type of scientific or laboratory research or for any other kind of experimentation or study,

two versions. The Senate version was expressly drafted as an urgency statute designed to conform California law to federal law; the Assembly bill contained no such qualification. Only the Assembly bill contained a definition of a lifeless fetus. Finally, the Assembly bill applied the research regulations only to human fetuses while the Senate bill extended them to "any aborted product of conception."⁴⁷

Until 1975, the California Health and Safety Code reflected the provisions of the Assembly act but contained references to the Senate version as well.⁴⁸ In 1975, two separate bills were introduced in the State Senate with the express intent of repealing all or part of the fetal research legislation.⁴⁹ Senate Bill 679 was intended to repeal both the Senate and the Assembly acts regarding research on the fetus, thus completely removing the statute from the Code. Approximately one week after its introduction, the bill was passed to the Committee on the Judiciary and was returned one year later to the Secretary of the Senate where it was permanently rejected pursuant to Joint Rule 56.⁵⁰

Senate Bill 736, introduced by State Senator Song two days after the introduction of Senate Bill 679, was intended only to repeal the Senate's version of fetal research regulation. The Song Bill included many other minor changes in various statutes and was enacted later that year.⁵¹ The practical effect of repealing only one version is very limited because the Assembly act remains part of the California Code today.⁵²

except to protect or preserve the life and health of the fetus. "Fetal remains," as used in this section, means a lifeless product of conception regardless of the duration of pregnancy.

(b) In addition to any other criminal or civil liability which may be imposed by law, any violation of this section constitutes unprofessional conduct within the meaning of the State Medical Practice Act, Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code.

SEC. 2. This act is an urgency statute necessary for the immediate preservation of the public peace, health or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting such necessity are:

In order to conform California law to federal law prohibiting experimentation on aborted products of conception, it is necessary that this act go into effect at the earliest possible date.

47. See note 46 *supra*.

48. CAL. HEALTH & SAFETY CODE § 25956 (Deering 1975).

49. S.B. 679 (introduced on Apr. 1, 1975); S.B. 736 (introduced on Apr. 3, 1975).

50. CAL. LEGIS., SENATE FINAL HISTORY 339 (Regular Sess. 1975-1976).

51. *Id.* at 368.

52. CAL. HEALTH & SAFETY CODE § 25956 (West Supp. 1977).

INTENT BEHIND THE CALIFORNIA LEGISLATION

Because the California Legislature does not keep records of most debates, legislative intent must be ascertained from the drafting changes embodied in successive versions of the bill. From the history described in the foregoing paragraphs, a clear trend toward modifying the very restrictive initial prohibitions becomes manifest. Modifications have included permitting fetal research in animal systems and permitting use of total human fetal remains. A substantial reduction in the severity of the penalty for violating the statute was present in the final version of both the Assembly and Senate bills. This trend indicates a recognition of, and sympathy toward, the medical researcher's potential dilemma.

Conflicts may be involved in attempting to differentiate experimentation from application of new but unproven therapeutic techniques. Despite these potentially obscure areas, it appears that the legislative intent was to stop experimentation upon aborted human fetuses but not to hinder utilization of treatment designed to prolong fetal life.

Because California's statute was enacted to conform to federal law, a further guide to the legislative intent is the United States *Congressional Record* reflecting debates upon fetal research that preceded enactment of the federal moratorium. Representative Angelo Roncallo introduced an amendment to the National Science Foundation's (NSF) authorization bill for the fiscal year 1974, purporting to bar the use of NSF funds for research upon any aborted fetus with a beating heart.⁵³ Mr. Roncallo specifically stated that the amendment was neither intended as an antiabortion bill,⁵⁴ nor was it in any way to restrict the use of experimental therapeutic procedures designed to save the fetus.⁵⁵

A major impetus behind the amendment was the series of articles which appeared in the *Washington Post* in April, 1973. The author, Victor Cohn, indicated in his second article that the National Institutes of Health (NIH) had vowed not to fund research upon live aborted fetuses.⁵⁶ House representatives subsequently wrote the acting director of the NIH in an attempt to clarify the Institutes'

53. H.R. 7724, 93d Cong., 1st Sess., 119 CONG. REC. 17,468 (1973): "The secretary may not conduct or support research in the United States or abroad on a human fetus which is outside the uterus of its mother and which has a beating heart."

54. *Id.* But see *id.* at 17,475 (statement by Mr. Hogan indicating a desire to restore rights to unborn children, with this amendment operating as a "step in that direction").

55. *Id.* at 17,468.

56. Cohn, *NIH Vows Not to Fund Fetus Work*, Wash. Post, Apr. 13, 1973, § A, at 1, col. 4, reprinted in 119 CONG. REC. 17,472-73 (1973).

policy on fetal research. The NIH indicated that it knew of no circumstances which would justify support for research on a live aborted fetus.⁵⁷ This statement was deemed inadequate by the House representatives who thought that the door remained open for future discoveries of circumstances that would justify such "morally repugnant research."⁵⁸ Consequently, the Roncallo amendment to the NSF funding legislation passed the House with a strong majority of votes: 354 to 9.⁵⁹

Approximately five months later Senator James Buckley, Jr. introduced a similar amendment in the United States Senate.⁶⁰ Although the wording of the amendment was somewhat different from the House version, it was clearly comparable. In fact, Mr. Buckley stated that Mr. Roncallo's office "assures me that it is fully in keeping with the intention of his amendment."⁶¹ The new rider, to be attached to the NIH funding authorization bill, incorporated a prohibition on funding of research performed before as well as after an induced abortion and thus was substantially more restrictive than its predecessor in the House.

Underlying the Buckley amendment was a concern over appropriate consent procedures for research on the fetus and a fear that the justification of "social utility" would become incorporated into the canons of medical ethics.⁶² Although not expressly stated by Senator Buckley, an examination of the legislative history indicates that some of the proponents of the more restrictive complete ban on federal funding of fetal research were motivated by a desire to return to the fetus some basic rights which they believed had been denied by the Supreme Court in *Roe v. Wade*.⁶³

Senator Kennedy, acknowledging similar concerns over the consent problem, cited potential medical advances as motivation for

57. 119 CONG. REC. 17,470-71 (1973) (exchange of letters between members of Congress and NIH).

58. *Id.* at 17,471 (statement of Mr. Mazzoli).

59. *Id.* at 17,476.

60. "The Secretary may not conduct or support research or experimentation in the United States or abroad on a living human fetus or infant, whether before or after induced abortion, unless such research or experimentation is done for the purpose of insuring the survival of that fetus or infant." *Id.* at 29,225 (proposed Senate Amendment to H.R. 7724, 93d Cong., 1st Sess., 119 CONG. REC. 17,468 (1973)).

61. 119 CONG. REC. 29,225 (1973).

62. *Id.* at 29,227-28.

63. *Id.* at 17,475 (statement of Rep. Hogan).

a less restrictive amendment.⁶⁴ He proposed that Mr. Buckley's permanent ban on funding fetal experimentation be modified by placing a moratorium on fetal research only until the National Commission for the Protection of Human Subjects could study the problems and propose suitable guidelines for researchers in this area.⁶⁵ This amendment proposing a moratorium was unanimously passed by the Senate and later became law as part of the National Research Act of 1974.⁶⁶

The congressional intent underlying the federal moratorium is clear. The need for medical research, due to its potential benefits for all fetuses, is justification for permitting carefully regulated research on the fetus. A commission composed of experts in the legal, medical, and ethical fields was to study the issues involved and develop appropriate guidelines.⁶⁷ Until such time as directives and regulations were formulated, research was temporarily halted.

Although the motivation for research regulations at both the state and federal level was similar, a comparison of the California fetal research legislation with the federal moratorium causes certain differences to surface.⁶⁸ The California statute is a permanent addition to the state's legal system. In 1975, after the federal moratorium was lifted, the State Senate's version of the fetal research regulations, which was explicitly enacted to conform to the federal moratorium, was selectively repealed,⁶⁹ leaving intact the Assembly version of the bill which had not been enacted as an urgency measure and did not purport to conform to federal law.⁷⁰ In addition, the California restrictions upon research found in both Assembly and Senate versions would seemingly apply only to research performed upon an aborted fetus,⁷¹ while the federal moratorium prohibited experimentation both before and after an induced abortion.⁷²

64. *Id.* at 29,228-29.

65. *See id.* at 29,229.

66. National Research Act, Pub. L. 93-348, § 202, 88 Stat. 350 (1974) (codified in 42 U.S.C. § 2891-1) (expressly gives the National Commission four months from the date it convenes to formulate its recommendations on fetal research). In actuality, incorporating delays in the swearing in of National Commission members, the moratorium extended for a period of ten months. *See Levine, supra* note 21, at 373.

67. 40 Fed. Reg. 33,530 (1975) (listing members of the National Commission).

68. It is important to keep in mind that the federal regulations apply only to federally funded research. When a California laboratory receives federal funding, it is subject to both state and federal regulations. However, in cases of conflict between the restrictions, the state regulations are to be followed so long as they are at least as protective of fetal rights as are federal regulations. *See* 45 C.F.R. § 46.201(b) (1976).

69. *See* text accompanying note 49 *supra*.

70. *See* text accompanying note 52 *supra*.

71. CAL. HEALTH & SAFETY CODE § 25956 (West Supp. 1977).

72. National Research Act, Pub. L. 93-348, § 213, 88 Stat. 353 (1974) (codified in 42 U.S.C. § 2891-1).

Despite the differences reflected in the final legislation, the California and federal regulations are analogous, and the intention of the legislatures at both levels is essentially the same. Both the California law and the federal moratorium contain special exceptions permitting research that is intended to protect or to preserve the life of the fetus.⁷³ Thus, both legislative bodies accepted experimentation designed to benefit the experimental subject but rejected work which might potentially benefit other fetuses but was of no therapeutic value to the particular subject.

EFFECTUATION OF LEGISLATIVE INTENT

The immediate question is whether the suggested intent of the California legislation has been effectuated by the fetal research regulations. The statute expressly limits research upon aborted products of human conception but makes no reference to any other stage of fetal development. By implication, therefore, the statute fails to regulate research on a fetus prior to abortion.

This omission in the statute permits some of the more controversial types of fetal research.⁷⁴ First, it is conceivable that a researcher could conduct experiments upon a fetus prior to, but in anticipation of, abortion. Provided the analysis of the fetus following abortion is restricted to fetal remains, no technical violation of the statute would have occurred.⁷⁵ Clearly, the lack of any restrictions upon *in utero* research controverts legislative intent. If the California Legislature had planned to permit continuation of only *in utero* diagnostic procedures, this intention could have been effectively handled while still regulating nontherapeutic procedures.

Second, depending upon the definition of "aborted," the statute may possibly be interpreted as permitting experimentation during the interim period between removal of the fetus from the womb and severance of the umbilical cord. This research raises very sensitive ethical issues because the fetus may be considered a dying subject at

73. *Id.*; CAL. HEALTH & SAFETY CODE § 25956 (West Supp. 1977).

74. Some of the experiments which have stirred the greatest public outrage involve *in utero* studies. See, e.g., Philipson, Sabath, & Charles, *Transplacental Passage of Erythromycin and Clindamycin*, 288 NEW ENG. J. MED. 1219 (1973) (the Philipson experiment resulted in prosecution of the researchers for grave-robbing (see text accompanying notes 103-06 *infra*)).

75. CAL. HEALTH & SAFETY CODE § 25956 (West Supp. 1977) (permits research on fetal remains). Although there has not been a technical violation of the California statute, a possible violation of federal regulations may have occurred if the laboratory receives federal funding. See note 68 *supra*.

this point.⁷⁶ Once again the controversial nature of this type of experimentation would indicate that the California Legislature did not impliedly intend to permit such work.

Thus, the only explicitly prohibited procedure in California is *ex utero* research upon a living fetus. The determination of whether *ex utero* experimentation may be conducted will hinge upon whether it can be classified as therapeutic. There is no bright-line test for making this distinction. The effect is to place the physician in the precarious position of deciding whether to employ a potentially therapeutic procedure based on his or her determination of its possible benefit to the particular fetus involved.

If the legislature intended only to prohibit *ex utero* experimentation on a live fetus, the fetal research regulations could now be totally repealed without repercussion. The California Health and Safety Code already requires that a fetus "prematurely born alive in the course of an abortion" be accorded the same rights to medical treatment as any other infant.⁷⁷ Thus, it can be argued that a physician is already required to perform any potentially therapeutic procedures and similarly may not negatively interfere with the fetus' chance for survival by experimenting with a nontherapeutic research technique.

THE EFFECT OF FETAL RESEARCH REGULATIONS UPON CALIFORNIA RESEARCH

Despite the inherent ambiguities within the statute which might easily have been exploited, research in California has not been extended into questionable areas. Precisely because ambiguities exist, such research runs a high risk of subjecting the physician to charges of unprofessional conduct and thus is best left to laboratories in other states.

Some California laboratories continue to work toward development of therapeutic, diagnostic procedures.⁷⁸ As the experiments

76. "But there can be no obligation—indeed, it would be positively wrong—to obtain those results by means of abortuses who are hovering between life and death precisely because for them no such rescue or remedies were wanted." Ramsey, *supra* note 13, at 34-35 (it should be noted that Ramsey includes all fetuses scheduled for abortion in his analogy of a fetus to a dying adult).

77. CAL. HEALTH & SAFETY CODE § 25955.9 (West Supp. 1977).

78. For example, Dr. Louis Gluck, a professor at the University of California at San Diego, is continuing to work on diagnosis and treatment for respiratory distress syndrome, a common cause of death in premature infants. His technique involves analysis of amniotic fluid to determine the lecithin/sphingomyelin ratio which indicates lung maturity. See Gluck, *Fetal Maturity and Amniotic Fluid Surfactant Determination*, in MANAGEMENT OF THE HIGH-RISK PREGNANCY 189 (W. Spellacy ed. 1976).

progress and skills become more sophisticated, animal systems will become unsatisfactory and the procedures will need to be tested upon human fetuses. At this point the confusion and misinterpretations generated by the California legislation may hinder the final step in development and thus indirectly defeat legislative intent.

ALTERNATIVES TO REGULATION AT THE STATE LEVEL

Given the problems inextricably tied to state legislative efforts, alternate resolutions to the fetal research controversy need to be considered.

Resolution Within the Medical Community

An alternative to policy formulation by state legislators would be to return control over fetal research to the medical profession.⁷⁹ England has opted for this course of action. An advisory group was formed in response to reports that a commercial sale of fetuses for medical purposes was being conducted.⁸⁰ The English Advisory Group concluded that clinical decisions would best be made by clinicians and that ethical decisions should be made by the medical profession as a whole.⁸¹ Consequently, research is governed by a set of guidelines outlining professional conduct. These guidelines are formulated by the medical community and approved by the Department of Health and Social Security.⁸² No legislation has as yet been passed.

The United States' medical community has not ignored the ethical problems of its profession.⁸³ As far back as March, 1972, the advisory council in the Human Embryology and Development study section of the National Institute of Child Health and Human Development had proposed regulations for fetal research.⁸⁴ The council agreed that

79. See Note, *Fetal Research: A View from Right to Life to Wrongful Birth*, 52 CHI.-KENT L. REV. 133, 142 (1975) (advocates returning control of certain types of fetal research to physicians).

80. *Research on the Fetus*, 2 BRIT. MED. J. 550, 551 (1972).

81. The Use of Fetuses and Fetal Material for Research, Report of the Advisory Group, chaired by Sir John Peel (London, 1972) reprinted in APPENDIX, *supra* note 7, at 19-1.

82. For a general discussion of the Peel Report, see Ramsey, *supra* note 13, at 1-3.

83. For a discussion of the medical profession's activities in similar ethical problem areas, see Note, *Fetal Research: A View from Right to Life to Wrongful Birth*, 52 CHI.-KENT L. REV. 133, 146-151 (1975).

84. Ramsey, *supra* note 13, at 3-4.

fetal research should be encouraged, but only through planned scientific studies that conformed to acceptable safeguards. These policy proposals were not implemented because of the intervening emergence into public view of the fetal research controversy and subsequent legislative resolution.⁸⁵

Clearly, the medical profession should have some input into the regulation of fetal research. Physicians are more directly affected by limitations on experimentation than are members of other professions and, consequently, are more sensitive to the professional dilemma tied to the ethical considerations. In addition, the medical profession is best equipped to balance the probative worth of a proposed experiment with scientific need. An individual examination of proposed experiments by a peer group would be invaluable, and perhaps indispensable, to a meaningful determination of the permissibility of an experiment.

However, the medical profession should not be the sole source of regulation. The zeal for scientific advancement should be tempered by input severed from the influence of the research world. Furthermore, the sanctions available to the medical community without benefit of legislative intervention are limited.⁸⁶ For example, one physician has proposed that experimental procedures be policed by prohibiting publication of the experimental results, or in the alternative, by publication accompanied by stern editorial comment.⁸⁷ Finally, the resolution of the fetal research controversy concerns all members of the community because it touches upon vital ethical questions with far-reaching repercussions. Therefore, no truly acceptable solution can emerge without consideration of as many different perspectives as possible. The issues tied to fetal research extend beyond the boundaries of the medical profession and therefore cannot be resolved with the research community in isolation.

Physicians have some input into state legislation through various lobbying groups.⁸⁸ However, the state level prohibition on certain types of research precludes a meaningful individual analysis of these

85. The study and subsequent proposals became the impetus for the *Washington Post* articles that served to initiate the fetal research controversy in the United States. See Ramsey, *supra* note 13, at 5. See also text accompanying note 56 *supra*.

86. CAL. BUS. & PROF. CODE §§ 2360-2411 (West 1974) (allows physicians to police their profession by suspending or revoking licenses to practice). California physicians could interpret violation of fetal research regulations as a morally reprehensible act that falls within the Code. Historically, this deterrent has seldom been used.

87. Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354, 1360 (1966). See also Ingelfinger, *The Unethical in Medical Ethics*, 83 ANNALS INTERNAL MED. 264 (1975).

88. See note 38 and accompanying text *supra*.

types of experiments for scientific need. Physician input is greater at the federal level. The federal regulations as promulgated by the National Commission are structured in such a way as to encourage peer review of each proposed experiment before a decision as to its permissibility is made.⁸⁹ Further physician input is available at the federal level through membership on the National Commission itself.⁹⁰

Massachusetts Legislation

Lauded as a compromise between scientist and legislator, the Massachusetts statute has been in force since 1974.⁹¹ Although this statute has been labeled as more liberal than legislation in other states,⁹² its restrictions are greater than those found in California.⁹³ The physician may not conduct *in utero* or *ex utero* experimentation unless the procedure will not "substantially jeopardize the life or health of the fetus."⁹⁴ This exception was incorporated to ensure that certain diagnostic procedures which entail little threat to the fetus could be continued.⁹⁵

However, no research may be performed on a fetus scheduled for abortion.⁹⁶ This complete restriction on utilization of fetuses prior to abortion can produce anomalous results. If taken literally, this would imply that when a woman with a high risk of bearing children with a particular diagnosable genetic defect comes into a clinic for an abor-

89. See 45 C.F.R. §§ 46.204, 46.205 (1976) (duties of the Institutional Review Board with respect to fetal research). For an analysis of the responsibilities of the Institutional Review Board and its relationship to the individual investigator, see N. HERSHEY & R. MILLER, *HUMAN EXPERIMENTATION AND THE LAW* (1976).

90. Three out of the initial 11 National Commissioners were members of the medical community. See 40 Fed. Reg. 33,530 (1975).

91. 1974 Mass. Adv. Legis. Serv. ch. 421 (codified at MASS. GEN. LAWS ANN. ch. 112, § 12j (West Supp. 1977-1978)). See Culliton, *Fetal Research: The Case History of a Massachusetts Law*, 187 SCIENCE 237 (1975); Culliton, *Fetal Research (II): The Nature of a Massachusetts Law*, 187 SCIENCE 411 (1975) (reports on the controversy between scientist and legislator lying behind the legislation).

92. Culliton, *Fetal Research: The Case History of a Massachusetts Law*, 187 SCIENCE 237, 241 (1975).

93. For example, Massachusetts law still imposes a criminal penalty for violation of the statute. MASS. GEN. LAWS ANN. ch. 112, § 12j (West Supp. 1977-1978).

94. *Id.*

95. See Culliton, *Fetal Research: The Case History of a Massachusetts Law*, 187 SCIENCE 237, 240-41 (1975).

96. "No person shall use any live human fetus, whether before or after expulsion from its mother's womb, for scientific, laboratory, research . . ." MASS. GEN. LAWS ANN. ch. 112, § 12j (West Supp. 1977-1978).

tion, she may not undergo amniocentesis to determine whether the child she is carrying is afflicted.⁹⁷

The struggle in Massachusetts is far from finished. Many physicians are still attempting to convince the legislature that such restrictive regulations are not necessary.⁹⁸ Furthermore, prior to enactment of the fetal research statute, an investigation of Boston City Hospital for possible violations of the abortion statute culminated in the initiation of two criminal prosecutions against physicians.⁹⁹ The first of these criminal prosecutions was the case of *Commonwealth v. Edelin*.¹⁰⁰ This case involved a manslaughter charge against a physician who had failed to employ life-saving techniques to prolong the life of an aborted fetus.

Although the *Edelin* case does not involve fetal research per se, it affects fetal research in two ways. First, it solidifies the fears of physicians who may have felt that the threat of prosecution would be wielded as a political weapon.¹⁰¹ Second, it tends to create an affirmative duty to employ all available life-prolongation methods to a fetus who is estimated to have reached the gestational age of at least twenty-four weeks.¹⁰² Thus, on the one hand, the physician is forbidden from performing any experimentation on the fetus, while on the other hand, the physician faces prosecution if he fails to do whatever is in his power to prolong the infant's life. The doctor must therefore make a split-second decision as to whether a particular procedure may be classified as therapeutic for that particular fetus.

97. "[I]f I could diagnose sickle cell anemia . . . and thalassemia and other disorders in utero, I'd be preventing more abortions . . ." Culliton, *Fetal Research: The Case History of a Massachusetts Law*, 187 SCIENCE 237, 238 (1975) (quoting Massachusetts physician Dr. Nathan).

98. "[I have been] becoming involved with the physicians and legislature in trying to develop some kind of reasonable case to present to the legislature, as to why we should not have such restrictive experimentation legislation." GENETICS AND THE LAW 46 (A. Milunsky & G. Annas eds. 1976) (statement by Mr. Chayet, attorney for the Massachusetts physicians charged with grave-robbing (see text accompanying note 103 *infra*)).

99. For a history of these cases, see Culliton, *Abortion and Manslaughter: A Boston Doctor Goes on Trial*, 187 SCIENCE 334 (1975); Culliton, *Grave-Robbing: The Charge against Four from Boston City Hospital*, 186 SCIENCE 420 (1974).

100. — Mass. —, 359 N.E.2d 4 (1976).

101. "Why is Kenneth Edelin being prosecuted for manslaughter? Many Boston doctors and lawyers are convinced it is for political reasons. They point out that this is an election year, that long time district attorney Garrett H. Bryne was in a tough primary race and needed publicity." Culliton, *Manslaughter: The Charge against Edelin of Boston City Hospital*, 186 SCIENCE 327, 328 (1974). See also Ingelfinger, *The Unethical in Medical Ethics*, 83 ANNALS INTERNAL MED. 264 (1975).

102. "This judgment could lead to extraordinary efforts to sustain life against all odds of a successful outcome of an intact human being." APPENDIX, *supra* note 7, at 14-5 (quoting Dr. Mary Avery, chief physician at Children's Hospital Medical Center in Boston).

The second case, *Commonwealth v. Berman*,¹⁰³ may have an even greater impact upon fetal research. The physicians in this case were attempting to determine whether particular antibiotics orally administered to pregnant women would reach the fetus in therapeutic levels.¹⁰⁴ Abortions by hysterotomy were performed on women scheduled for abortion following administration of the drug. An assay for antibiotic levels in the fetus was performed upon the amniotic fluid, fetal liver, spleen, kidney, lung, brain, and muscle. Consent had been obtained for the experiment from the women prior to abortion.¹⁰⁵ Nevertheless, charges of grave-robbing were brought against the physicians who participated in the experiment.¹⁰⁶ The case has not yet been brought to trial, and thus its full impact cannot be ascertained. Because fetuses scheduled for abortion were the experimental subjects, under the present Massachusetts statute the Berman experiment would be found illegal.

Although the Massachusetts statute clarifies some of the ambiguities found in California law,¹⁰⁷ the conflict between compliance with federal and state regulations is still present. A physician receiving federal funds must ascertain the feasibility of each experimental procedure under the regulations at both the federal and state level. Further, although therapeutic research is permitted in Massachusetts, physicians remain reluctant to risk the possibility of criminal prosecution, and thus the potential benefits of fetal research are still not being realized.¹⁰⁸

103. Crim. No. 81821 (Super. Ct. Suffolk Cty., Mass., filed Apr. 17, 1974). See also Culliton, *Grave-Robbing: The Charge against Four from Boston City Hospital*, 186 SCIENCE 420 (1974).

104. Philipson, Sabath, & Charles, *Transplacental Passage of Erythromycin and Clindamycin*, 288 NEW ENG. J. MED. 1219, 1219 (1973).

105. The women consented to participate in the study; however, the researchers failed to obtain the mother's consent for the analysis to be performed on the aborted fetus. See Culliton, *Grave-Robbing: The Charge against Four from Boston City Hospital*, 186 SCIENCE 420, 420 (1974).

106. The grave-robbing statute states: "Whoever conveys away without being lawfully authorized the remains of a human body may be sentenced to a term of years in the state prison and fined." MASS. GEN. LAWS ANN. ch. 272, § 71 (West 1968). The argument against the physicians goes as follows: The abortus was transported from the delivery room to the laboratory for analysis and thus there was a conveyance of a human body. Because the doctor had no burial permit, a violation of the statute had occurred. GENETICS AND THE LAW 46 (A. Milunsky & G. Annas eds. 1976) (statement by Mr. Chayet, attorney for the defendants).

107. The Massachusetts legislation is much more explicit on regulation of *in utero* research—it leaves nothing open for implication.

108. "Researchers who wish to do investigative studies in fetal development in Massachusetts will be in very uncertain territory where a wrong step may

Regulation at the Federal Level

Along with the moratorium on fetal research, the United States Congress established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission).¹⁰⁹ The National Commission was instructed to investigate the nature and extent of fetal research and to recommend policies under which some research might be conducted or supported.¹¹⁰ The moratorium was to extend only until the National Commission's recommendations were formulated.¹¹¹

The final report of the National Commission, entitled "Research on the Fetus," is a comprehensive evaluation of the ethical problems associated with fetal research and a guide to research protocol which best complies with the National Commission's resolution of ethical questions. The National Commission determined that prerequisites to any fetal research should include evidence that pertinent investigations had been conducted in animal models and nonpregnant humans, an assessment of the risks and benefits of the project, and compliance with procedures to insure that informed consent had been sought and granted under proper conditions.¹¹²

The National Commission unanimously agreed that therapeutic research complying with the appropriate prerequisites was permissible.¹¹³ Nontherapeutic research involving a fetus going to term, or a fetus scheduled for abortion, may be conducted provided the risk of fetal harm is minimal.¹¹⁴ In cases presenting special problems, approval of a national ethical review board is required before any funding may be considered.¹¹⁵ In addition, questionable research is subject to the proviso that the knowledge to be gained is of medical importance, cannot be obtained in another way, and does not offend community sensibilities.¹¹⁶

California could follow the step taken by New York and incorpo-

result in egregious criminal prosecution and a ruined career." Curran, *Experimentation Becomes a Crime: Fetal Research in Massachusetts*, 292 *NEW ENG. J. MED.* 300, 301 (1975). *But cf.* Culliton, *Fetal Research (II): The Nature of a Massachusetts Law*, 187 *SCIENCE* 411, 412 (1975) (a drafter of the legislation argues that the criminal nature of the statute is really a protection because it puts a difficult burden of proof on the prosecution).

109. National Research Act, Pub. L. 93-348, § 202, 88 Stat. 350 (1974) (codified in 42 U.S.C. § 2891-1).

110. *Id.*

111. *Id.* § 213, 88 Stat. 353.

112. COMMISSION'S REPORT, *supra* note 7, at 64, reprinted in 40 Fed. Reg. 33,545 (1975).

113. *Id.*

114. *Id.*, reprinted in 40 Fed. Reg. at 33,546.

115. *Id.*, reprinted in 40 Fed. Reg. at 33,547.

116. *Id.*

rate the provisions of the federal regulations into its state statutes.¹¹⁷ This step would certainly benefit those researchers who accept both federal and state funds because it would require conformance with only one set of regulations. Further advantages would accrue to all members of the research community from the greater clarity of the federal regulations. The discussion which surrounded the adoption of each regulation is available to public inspection through the *Federal Register*, and the rationale behind each regulation is clearly articulated.

In addition to simplifying paperwork procedures and providing greater certainty for researchers, the adoption of uniform federal regulations would ease present pressures on the state legislature. The federal regulations undergo periodic reviews and are subject to modification.¹¹⁸ This procedure should allow greater flexibility and greater speed in changing regulations to conform to scientific need and public demand than does a formal repeal or revision of a state statute. Any person may file objections or opinions on policies with the National Commission, and thus the public is guaranteed a mechanism for input.¹¹⁹

Finally, and perhaps of the greatest benefit, the National Commission is composed of eleven members representing experts in a diversity of fields.¹²⁰ The same National Commission also investigates and proposes regulations in other areas of ethical controversy.¹²¹ Thus, the composition of the National Commission is infinitely better suited to deal with complex interdisciplinary ethical issues because the members have more time to debate issues and are less susceptible to media pressure than are individual state legislators.

117. N.Y. PUB. HEALTH LAW § 2445 (McKinney 1976-1977). New York law regulates human research, but research covered by federal regulations is exempted from compliance with state regulations.

118. For example, following publication of its regulations, HEW received numerous criticisms directed toward 45 C.F.R. § 46.209 (1976) and has accordingly changed the regulation. See 42 Fed. Reg. 2792 (1977). See also text accompanying notes 151-54 *infra*.

119. The initial hearings of the National Commission were open to the public where views of concerned citizens could be discussed. Once the recommendations were complete and HEW had promulgated its regulations, the public was invited to comment in writing. These comments have not gone unheeded. See note 118 *supra*.

120. 40 Fed. Reg. 33,530 (1975).

121. National Research Act, Pub. L. 93-348, § 202(a), 88 Stat. 349 (1974) (codified in 42 U.S.C. § 2891-1) (authorizes the National Commission to study and to formulate recommendations to guide experimentation in many areas, including research on prisoners, the mentally infirm, and pregnant women).

The argument against adoption of federal regulations at the state level is largely based on an objection to formulation of controversial ethical policies by a National Commission that may be isolated and beyond the reach of the public. There is some concern that the National Commission's hearings are not as accessible to the public as perhaps they might have been because "[m]ore than written comments should have been invited."¹²² Furthermore, there is some question about the propriety of formulating medical policy by a process that "terminates in the Secretary of Health, Education, and Welfare."¹²³

A further objection to the National Commission as a policy-making body involves a concern that crucial decisions will be determined on the basis of a bare majority: "[W]ill eternal ethical verities be determined by six to five votes?"¹²⁴ This argument is possibly countered by a reminder that numerous Supreme Court decisions involving highly controversial issues are resolved by the swing of a single vote.

The medical community has voiced numerous complaints against attempts to regulate experimentation. One major complaint has been with the bureaucracy and the increased number of hours required to comply with the National Commission's regulations and review committees.¹²⁵

If the National Commission is accepted as an appropriate body for proposing regulations that will be implemented on the state level, will the present regulations regarding fetal research effectuate the intent of the California Legislature? This Comment has previously analogized the intent of the United States Congress and the state legislature, concluding that both legislative bodies were motivated by similar intentions.¹²⁶

The effectiveness of the federal regulations can in part be measured by the request for fetal research funding. There has been a sharp decline in grant requests from the NIH since the controversy began.¹²⁷ This decline can be explained by several factors other than a deficiency in the proposed regulations.

122. Ramsey, *supra* note 13, at 14.

123. *Id.* at 12.

124. Ingelfinger, *The Unethical in Medical Ethics*, 83 ANNALS INTERNAL MED. 264, 267 (1975). *But see* Ingelfinger, *Ethics of Human Experimentation Defined by a National Commission*, 296 NEW ENG. J. MED. 44 (1977) (the author concedes that his fears about the National Commission have not been realized).

125. Ingelfinger, *The Unethical in Medical Ethics*, 83 ANNALS INTERNAL MED. 264 (1975). For a discussion of specific objections to the federal regulations from a medical perspective, see *Position Statement of the American Federation for Clinical Research on the DHEW Proposed Rules on Protection of Human Subjects*, 23 CLINICAL RESEARCH 53 (1975).

126. *See* text accompanying note 73 *supra*.

127. Levine, *supra* note 21, at 367-69.

The moratorium on research at the federal level spanned a period of approximately ten months.¹²⁸ When the moratorium began, those laboratories engaged in fetal research were forced to abandon ongoing projects for an uncertain length of time.¹²⁹ The establishment of a laboratory is an expensive and time-consuming endeavor. A team of specialized personnel can take years to organize. Once such a moratorium is lifted, several years of lag-time may be required to revitalize laboratories, test the new regulations, and bolster confidence in the future of fetal research before numerous requests for grants can be expected.

In addition, the National Commission's regulations specify that in areas of conflict state laws will govern provided that minimum protections are maintained.¹³⁰ Thus, the paucity of grant requests can in part be attributed to restrictive legislation at the state level. California and Massachusetts, both major centers of medical research, have legislation restricting research. The NIH cannot expect to fund a great number of experiments in these jurisdictions.

A prediction has been made that fetal research will regain momentum within the next few years under the present set of National Commission regulations.¹³¹ Thus, in time, the federal regulations may be able to replace California's statute and serve better to effectuate California's legislative intent in regulating fetal research.

UNRESOLVED PROBLEMS WITH FEDERAL REGULATIONS

Despite the attraction of adopting the federal regulations at the state level, there are serious ethical problems that have not yet been satisfactorily resolved by the National Commission. Among these problems are questions regarding efficacious consent procedures, the distinction between therapeutic and nontherapeutic research, and proper treatment of a particular category of fetus, namely the nonviable fetus *ex utero*.

Consent

A determination of whether consent should be required for fetal research, and if so, from whom and under what conditions, is perhaps

128. See note 66 *supra*.

129. Levine, *supra* note 21, at 373.

130. See 45 C.F.R. § 46.201(b) (1976).

131. Nathan, *Fetal Research: An Investigator's View*, 22 VILL. L. REV. 384, 394 (1977).

the most complex issue underlying fetal research. Consent is a pre-requisite for human experimentation—to require efficacious consent on behalf of the fetus implies a presumption that human qualities may be attributed to the fetus and that the fetus is a legal person.

In order to surmount the initial barrier of a decision to require consent, one must make two initial suppositions.¹³² First, the status of the fetus must be resolved in such a way as to make the fetus an entity to whom definite rights may be accorded.¹³³ Clearly, for those who regard the fetus as a mass of tissue, no consent for experimentation should be necessary. The National Commission declined to assert affirmatively the civil status of the fetus or to resolve the issue of personhood but was convinced that the fetus, because it shares in human genetic heritage, should be treated with respect and dignity.¹³⁴

A second presupposition to requiring consent for fetal experimentation is a conclusion that *Roe v. Wade* was not an affirmative denial of fetal rights in all instances.¹³⁵ This supposition can be reached by focusing on the Supreme Court's limited denial of fetal rights. During the first trimester, if a conflict exists between the mother's right to privacy and the fetus' right to life, the mother may choose to have the fetus removed from her body. However, if no conflict exists, *Roe v. Wade* does not necessarily require that the mother's decision with regard to care and treatment of the fetus should govern. Fetal research was not an issue in *Roe v. Wade*, and thus the Court's decision does not mandate the nonexistence of human rights prior to birth when the maternal right to privacy is not involved.¹³⁶

Given that the fetus is a legal person and that consent may be required for fetal research, from whom should it be obtained? When research is being conducted on both mother and fetus, maternal consent clearly is necessary for the portion of research to be performed on the mother. However, the fetus is not capable of consenting on its own behalf, and thus some form of proxy consent is necessary. The regulations published by the HEW require the consent of both parents.¹³⁷ If the father is not available, or if the pregnancy resulted from rape, the necessity of obtaining his consent may be dispensed with.¹³⁸

132. See Tiefel, *The Cost of Fetal Research: Ethical Considerations*, 294 NEW ENG. J. MED. 85, 87 (1976).

133. *Id.*

134. COMMISSION'S REPORT, *supra* note 7, at 62, reprinted in 40 Fed. Reg. 33,544 (1975).

135. Tiefel, *The Cost of Fetal Research: Ethical Considerations*, 294 NEW ENG. J. MED. 85, 87 (1976).

136. See *id.* See also Horan, *Fetal Experimentation and Federal Regulation*, 22 VILL. L. REV. 325, 338 (1977).

137. 45 C.F.R. §§ 46.208, 46.209 (1976).

138. *Id.* This exception is another example of an alteration in the National

In cases where the research is to benefit either the mother, the fetus going to term, or the spontaneously aborted fetus, maternal consent is appropriate. Therefore, problems with the HEW consent requirements arise only in very specific situations. For example, some commentators argue that a mother's decision to abort will generally disqualify her from consenting to experimentation on behalf of the unborn child and that proxy consent from an advocate or guardian should be required.¹³⁹ Another position is that the mother has not abandoned her interest in the fetus' well-being by consenting to an abortion. However, if the fetus is scheduled for abortion and the proposed research is designed to prolong the life of the fetus after abortion, a conflict of interest could arise between the mother's decision to terminate the life of the fetus and the life-saving potential of the research.¹⁴⁰ Although this problem would arise infrequently, its resolution is extremely difficult. A deprivation of the mother's right to consent in a situation where she plans an abortion may be considered an unconstitutional penalty under *Roe v. Wade* because it differentiates between a spontaneous and an induced abortion.¹⁴¹

Another situation in which consent problems arise is when non-therapeutic *in utero* research is planned. Some commentators believe that a parent never has the right to consent to nontherapeutic experimentation.¹⁴² Others feel that because a decision to abort poses a difficult moral dilemma for the parents, the option to reverse the decision should be available until the procedure is performed.¹⁴³ However, if a mother consents to experimentation prior to abortion,

Commission's recommendations by HEW. The National Commission suggested that maternal consent alone be enough to permit *in utero* experimentation subject to a veto from the father. COMMISSION'S REPORT, *supra* note 7, at 74, reprinted in 40 Fed. Reg. 33,547-48 (1975).

139. Ramsey, *supra* note 13, at 89-99.

140. See generally COMMISSION'S REPORT, *supra* note 7, at 26, reprinted in 40 Fed. Reg. 33,537 (1975); McCormick, *Fetal Research, Morality, and Public Policy*, HASTINGS CENTER REP., June 1975, at 26, 28-29.

141. "Since the Supreme Court has declared in *Roe v. Wade* that women have a constitutional right to abortion, basing maternal disqualification on the exercise of that right may be an unconstitutional penalty." COMMISSION'S REPORT, *supra* note 7, at 26, reprinted in 40 Fed. Reg. 33,537 (1975).

142. Ramsey, *supra* note 13, at 92.

143. Wasserstrom, *The Status of the Fetus*, HASTINGS CENTER REP., June, 1975, at 18, 22. But see *Position Statement of the American Federation for Clinical Research on the DHEW Proposed Rules on Protection of Human Subjects*, 23 CLINICAL RESEARCH 53, 56 (1975) (the probability of a woman changing her mind about an abortion is slight and therefore should not be a relevant factor in determining consent procedure).

her decision to abort may become irrevocable in a practical sense through fear of potential birth defects resulting from the experiment.

Further, because the mother may change her mind after the experiment has begun, the father, who may eventually bear the financial responsibility for raising the child, should be able to assert his interest in the unborn child.¹⁴⁴ Thus, unless consent for nontherapeutic research is tied to an agreement to abort, the father's consent should also be required.¹⁴⁵

The federal requirement of paternal consent when the father is available may be subject to constitutional objections. In *Planned Parenthood v. Danforth*,¹⁴⁶ the Supreme Court held that statutory provisions requiring paternal consent to first-trimester abortions were unconstitutional. If the father may not prevent termination of the pregnancy, has he the lesser right to determine whether a particular procedure may be performed prior to termination of this pregnancy?¹⁴⁷ The resolution of this question is particularly difficult because there is a clash between two policies. On the one hand, a woman should be able to consent to any *in utero* research on her own because it involves control over her own body. Conversely, the father may eventually bear the financial burden of raising the child if the mother should later change her mind about the abortion.

Therapeutic v. Nontherapeutic Research

A second source of conceptual difficulty with the National Commission's recommendations involves the categorization of research as either therapeutic or nontherapeutic. Many commentators feel that this distinction is artificial and therefore should be abandoned.¹⁴⁸ The confusion in attempting to classify research as either one or the other may obscure important moral issues which should be implemented into the decision of whether to conduct the research at all. There are some indications that the National Commission is willing to accept new terminology.¹⁴⁹

144. COMMISSION'S REPORT, *supra* note 7, at 28, reprinted in 40 Fed. Reg. 33,537 (1975).

145. It has been suggested that such an agreement would be unenforceable. *Id.*

146. 428 U.S. 52 (1976).

147. For a discussion of why the father should still have input into the experimentation decision, see Wilson, *Fetal Experimentation: Rights of the Father and Questions of Personhood*, 22 VILL. L. REV. 403, 409 (1977).

148. See Lebacqz, *Reflections on the Report and Recommendations of the National Commission: Research on the Fetus*, 22 VILL. L. REV. 357, 361-66 (1977); Levine, *supra* note 21, at 377-82.

149. Levine, *supra* note 21, at 379.

Research on the Non-Viable Fetus Ex Utero

One hotly contested decision made by the National Commission is the permissibility of utilization of the nonviable fetus *ex utero*. The nonviable fetus *ex utero* is a living abortus who cannot survive to childhood even when aided with the most advanced modern medical techniques.¹⁵⁰ Any research performed on such a subject is by definition nontherapeutic. The National Commission recommended that such research be permitted, provided that the fetus was less than twenty weeks gestational age and that no significant procedural changes were introduced into the abortion procedure.¹⁵¹ These recommendations were adopted by HEW in its regulations.¹⁵² However, the National Commission initially included a further restriction on such research by requiring that no intrusion into the fetus be made that would alter the duration of its life. Although this restriction was omitted by HEW in its regulations as promulgated in 1975, a 1977 amendment adopted the limitation upon research.¹⁵³

Strenuous objection to this type of research is based on two arguments: The fetus is at this point technically an infant and should be accorded equivalent rights, and the dying fetus should be treated in the same manner as a dying adult.¹⁵⁴ Under either analogy the nonviable fetus *ex utero* is a person under the law and should be accorded the same rights as other persons.

However, the recent Supreme Court decision in *Planned Parenthood v. Danforth* contains some language which may indicate that a physician's duty to care for a live fetus resulting from an abortion may not arise until the fetus has reached the stage of viability.¹⁵⁵ If this conclusion is reached, the fetus may not appropriately be analogized to an infant until it has reached the point of viability.

150. COMMISSION'S REPORT, *supra* note 7, at 6, reprinted in 40 Fed. Reg. 33,532 (1975).

151. *Id.* at 33,548.

152. 45 C.F.R. § 46.209 (1976).

153. See 42 Fed. Reg. 2793 (1977) for the HEW amendment to 45 C.F.R. § 46.209 (1976).

154. See Horan, *Fetal Experimentation and Federal Regulation*, 22 VILL. L. REV. 325, 339 (1977).

155. Section 6(1) [of the Missouri statute in question] requires the physician to exercise the prescribed skill, care, and diligence to preserve the life and health of the fetus. It does not specify that such care need be taken only after the stage of viability has been reached. As the provision now reads, it impermissibly requires the physician to preserve the life and health of the fetus, whatever the stage of pregnancy.

428 U.S. 52, 83 (1976) (emphasis original).

Consequently, it may be impossible to extend the same protection from nontherapeutic research to a nonviable fetus as would be extended to an infant or dying adult.

CONCLUSION

Fetal experimentation involves a conflict between the need for medical research to improve the quality of fetal care and the rights of the fetus as the research subject. No solution can be reached that will satisfy all facets of possible ethical positions. Thus, a compromise is required between opposing ends of the spectrum.

Individual states have attempted to resolve the ethical dilemma by proscribing certain types of research. This Comment has focused on California legislation and has concluded that the present statute has not satisfactorily effectuated legislative intent and that the state legislature is not properly equipped to deal with the subtleties presented by the moral issues involved. Alternatives to legislation on the state level have been examined. Despite unresolved problems, the federal regulations based upon recommendations of the National Commission for the Protection of Biomedical and Behavioral Research Subjects are currently the most satisfactory means of resolving medical-ethical dilemmas. It is therefore recommended that the individual states regulate fetal research by incorporating the federal regulations into their state codes.¹⁵⁶

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156. New York has taken a step in this direction. *See* N.Y. PUB. HEALTH LAW 2445 (McKinney 1977) (exempts federally regulated research from state regulations).

A model statute would apply the federal regulatory mechanism and its rules to all research conducted within the state. Because the federal regulations have not yet been promulgated in all areas of human research, a state should retain its general, protective legislation, as New York has done, but apply federal regulations to each type of research for which federal rules have already been promulgated. For example, a statute might read as follows:

All research on the fetus conducted within this state shall be governed by the policies and regulations promulgated by any agency of the federal government for the protection of human subjects.