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FEDERAL REGULATION OF FETAL RESEARCH: TOWARD A PUBLIC POLICY FOUNDED ON ETHICAL REASONING

KATHLEEN MARKEY*

The 1975 federal regulations on fetal research reflect the recommendations of a national study commission which formulated a policy based upon broad ethical considerations. The fetus is now accorded comprehensive protection in medical experimentation—protection so comprehensive that necessary and valuable benefits to future fetuses must be given up. This article suggests that the regulations be carefully modified to permit greater latitude in conducting research on drug pharmacology in aborted fetuses.

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Medical research on aborted fetuses has engendered significant controversy in recent years. Fetal research is not new. It was central in the development of the Salk polio vaccine in the 1950's for example, but with widespread legal abortion its scope has greatly expanded. This increased scope has enlarged the controversy surrounding fetal research.¹

The increased number of fetal subjects available would appear to have engendered concern from two groups: anti-abortionists who cannot reconcile themselves to the Supreme Court's decision legalizing early abortions² and who oppose any activity that builds on the rights to abortion; and ethicists and concerned professionals with

* Articles and Comments Editor, *University of Miami Law Review*.

1. Recent literature on fetal research includes: Martin, *Ethical Standards for Fetal Experimentation*, 43 *FORDHAM L. REV.* 547 (1975); Comment, *Fetal Research: A View from Right to Life to Wrongful Birth*, 52 *CHI.-KENT L. REV.* 133 (1975); Note, *Fetal Experimentation: Moral, Legal and Medical Implications*, 26 *STAN. L. REV.* 1191 (1974).

2. *Roe v. Wade*, 410 U.S. 113 (1973).

knowledge of fetal research who fear large-scale abuse of the rights of fetuses. The approaches to controlling fetal research had been diverse until the federal government, through the Department of Health, Education and Welfare (HEW), which funds most medical research in this country, proposed regulation of fetal research.³ The regulations enacted in 1975⁴ are the result of recommendations made to HEW by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research,⁵ created to represent the interests of the diverse community. The Commission was mandated to survey the field and identify basic ethical principles upon which regulations could be formulated. The result has been some clarification of the subject matter and a public policy grounded in ethical reasoning.

After a brief review of the benefits and costs of fetal research, this paper discusses some of the problems with defining the nature and status of the fetus, and the legal and ethical rights accorded this unborn being. Protection of the rights of the fetal being in experimentation is the objective of the 1975 federal regulations in the area. The extensive changes in these regulations are analyzed with a view to their impact upon fetal research. In conclusion specific recommendations are proffered which more realistically reconcile the competing interests involved in fetal research.

I. BACKGROUND TO THE CONTROVERSY

Some of the controversy surrounding fetal research involves the meaning of terms because lack of precision in terminology has had a tendency to obfuscate the issues. Although not entirely settling the controversy over the meaning of terms, the definitions set forth in the regulations are used here.

(c) "Fetus" means the product of conception from the time of implantation until a determination is made, following expulsion or extraction of the fetus, that it is viable.

(d) "Viable" as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of indepen-

3. 39 Fed. Reg. 30,648 (1974); 38 Fed. Reg. 31,738 (1973).

4. 45 C.F.R. §§ 46.201-.211 (1975). The regulations remain substantively unchanged in 1976.

5. National Research Service Award Act of 1974, Pub. L. No. 93-348, 88 Stat. 342.

dently maintaining heart beat and respiration. . . .

(e) "Nonviable fetus" means a fetus *ex utero* which, although living, is not viable.⁶

In addition, "nontherapeutic research," as used here, refers to research not designed with the intention of benefiting this fetus, but rather of gaining scientific or medical knowledge which may benefit future lives.

Few areas of medical research have proved to be more productive for medical progress than fetal research. Fetal cell tissue cultures were used to grow viruses in the development of measles⁷ and polio⁸ vaccines. Experiments on live, nonviable, aborted fetuses have contributed to the development of treatment for asphyxiated newborns⁹ and methods to increase the chances of survival of extra-uterine fetuses, which at the present level of medical technology are nonviable.¹⁰

Research on the fetus prior to abortion led to the development of techniques for intra-uterine blood transfusions for Rh factor incompatibility, and to the development of amniocentesis to diagnose genetic problems prior to birth.¹¹ Results of *in utero* studies with vaccines and drugs to ascertain substances which cross the placenta and affect the fetus also have been significant. In the 1960's a vaccine was developed for rubella which was found safe for adults and children, but whose safety for pregnant women was unknown. Tests on rhesus monkeys showed the vaccine would not have the same effects on pregnant women as the infection would. However, when the vaccine was administered to women about to undergo an abortion, the experiment revealed that the vaccine crossed the placenta and infected the human fetus.¹²

6. 45 C.F.R. §§ 46.203(c)-(e) (1976).

7. See Webb, Illavia & Laurence, *Measles-Vaccine Viruses in Tissue-Culture of Non-Neuronal Cells of Human Fetal Brain*, 2 LANCET 4 (1971).

8. See Plotkin, *Vaccine Production in Human Diploid Cell Strains*, 94 AM. J. EPIDEMIOLOGY 303 (1971).

9. See Chamberlain, *An Artificial Placenta*, 100 AM. J. OBST. & GYNEC. 615 (1968).

10. See Goodlin, *Cutaneous Respiration in a Fetal Incubator*, 86 AM. J. OBST. & GYNEC. 571 (1963).

11. See generally Levin, Oxman, Moore, Daniels & Scheer, *Diagnosis of Congenital Rubella in Utero*, 290 N.E.J.M. 1187 (1974).

12. See Vaheri, Vesikari, Oker-Blom, Speppala, Parkman, Veronelli & Robbins, *Isolation of Attenuated Rubella-Vaccine Virus from Human Products of Conception & Uterine Cervix*, 286 N.E.J.M. 1071 (1972). See also Biro, Iván, Elek & Árr, *Data on the Tissue Concentration of Antibiotics in Man. Tissue Concentration of Semi-Synthetic Penicillins in*

It is well established that some experimentation on human beings is required if medical progress is to be made. Fetal research is vital in order to gain insights into mental retardation,¹³ prematurity, and many types of diseases and birth deformities. One very strong argument for promoting fetal research *in utero* on fetuses about to be aborted is that advances in fetal medicine, particularly in accelerating fetal lung maturity *in utero* and sampling fetal blood mid-pregnancy, can only be accomplished through the use of fetal subjects.¹⁴ Furthermore, although anatomic studies and chemical analyses of completely dead fetal tissues continue to yield important information, living tissues, organs, and intact fetal bodies are still the core of new biomedical research.¹⁵

A third major argument is that performing studies of new procedures and new drugs on fetuses which will be or have been aborted, can prevent damage to fetuses who will be carried to term and bear the burden of prenatal damage throughout their lifetimes.¹⁶ This argument belies any justification for discarding aborted nonviable fetuses without utilizing them to help future infants to be free from defects. In addition, it has been argued that if there is "no research on unwanted aborted fetuses, it will be done on wanted fetuses,"¹⁷ because every new drug, procedure, and vaccine must be tested for the first time on a human being.¹⁸ The value and benefits of fetal research then are great.

On the cost side, it is posited that the question and related controversy is not whether medical knowledge of pregnancy and fetal development ought to be expanded, but rather how far fetal research should go without violating ethical principles. Opponents of fetal research who stress this issue include those who are unwill-

the Fetus, 3 INT'L J. CLIN. PHARMACOL. 321 (1970); Marx, *Drugs During Pregnancy: Do They Affect the Unborn Child?* 180 SCI. 174 (1973).

13. See generally Milunsky, *Medico-Legal Issues in Prenatal Genetic Diagnosis*, in GENETICS AND THE LAW 53 (A. Milunsky & G. Annas eds. 1976).

14. See Mahoney, *Implications of Restrictions on Fetal Research for Biomedical Advance*, AM. FED'N FOR CLINICAL RESEARCH, May 3, 1975, 210, 229-30.

15. *Id.* at 229. But cf. Steinfelds, *Ethics & Fetal Research*, 102 COMMONWEAL 109, 110 (1975) (It is arguable that similar knowledge might be attainable through alternative approaches).

16. Walters, *Fetal Research & the Ethical Issues*, 5 HASTINGS CENTER REP., June 1975, at 13, 16.

17. Gaylin & Lappe, *Fetal Politics*, 235 ATLANTIC, May 1975, at 66, 71.

18. "Since [researchers] did not test thalidomide on unwanted fetuses, [it was] tested unwittingly on wanted ones." *Id.*

ing to accept the *Roe* decision and its consequences.

A larger group of opponents, however, contend that benefit to the health of others is not as valuable as protecting from physical invasion and exploitation involuntary subjects whom this group views as human beings upon conception.¹⁹ Although consideration of the greater social good is sometimes used to justify the exclusion of individual interest,²⁰ it is a basic ethical principle that genuine gains are not sufficient justification for questionable activity.²¹

The emphasis on research and experimentation has produced some studies that have created significant controversy.²² Thus the medical "good" of experiments may not necessarily be equated with the social good. Studies considered legitimate in their inception may later arouse public outcry for strong measures to limit research. This was illustrated by a recent grand jury indictment of four doctors for grave-robbing for their part in studying post-abortion fetuses whose mothers had been given antibiotics.²³ It is essential that independent ethical judgment be used in examining the controversy over the use of fetal subjects.

II. STATUS OF THE FETUS

The crucial issue in the fetal research controversy is the status of the fetus. However, it is an issue surrounded by uncertainties, because in law, philosophy, and religion the status of the fetus is unsettled. Should it be treated as a person, as human tissue, akin to a laboratory animal, or in a unique category of its own?

The Commission did not resolve the issue of the nature of the

19. There are conflicting positions on when the fetus becomes human and entitled to the rights and protections of human beings. The postures range from the point of conception (Roman Catholic Church position) to the point of viability (the legal position of *Roe*).

20. Moffat, *The Indispensable Role of Independent Ethical Judgment*, 21 U. FLA. L. REV. 477, 481 (1969).

21. Steinfels, *supra* note 15, at 110.

22. In one study researchers decapitated eight live aborted fetuses to study oxidation in the brain. Adam, Raiha, Rahiala, & Kekomäi, *Cerebral Oxidation of Glucose & d-butyrate by the Isolated Perfused Human Fetal Head*, 7 PED. RES. 309 (1973).

23. On April 11, 1974, a Boston grand jury indicted four doctors for grave-robbing because they had not secured consent from next of kin for examining dead fetuses. Culliton, *Grave-Robbing: The Charge Against Four from Boston City Hospital*, 186 SCI. 420 (1974). The doctors conducted research whereby women about to abort consented to taking antibiotics. Post-abortion, the fetus was studied to ascertain whether, and in what amounts, the antibiotics crossed the placenta and entered the fetus. Philipson, Sabath & Charles, *Transplacental Passage of Erythromycin and Clindamycin*, 288 N.E.J.M. 1219 (1973).

fetus. In its *Deliberations and Conclusions*²⁴ it reviewed some of the complex problems in the area, but nowhere did it try to define status; it described the fetus under the heading of "human subject." Nor did the Supreme Court in *Roe v. Wade*²⁵ resolve the issue. The Court did not find a direct conflict between the right of the mother's privacy and the right of the fetus to life; it worked out a compromise where the potential life of the fetus ripens at the point of viability.²⁶ While the Court did "not resolve the difficult question of when life begins,"²⁷ it did hold that the constitutional meaning of "person" does not include the unborn.²⁸ However, the dicta in *Roe* cannot be conclusive in the fetal research area because the Court in *Roe* was faced with very different issues than the rights of a fetus to protection from experimentation after the abortion decision has been made. The extent of the constitutional rights of this being in the context of the post-abortion decision then, is not fully resolved.

The nature of the fetus remains the crux of the problem. The nonviable fetus does not appear to be identical with a human being. *Ex utero* it has no independent life system. On the other hand, categorization of the fetus as part of the mother's body, like a tooth or a tumor "is a trivialization of the grandeur of human potential."²⁹ The fetus is indeed a part of the mother's body, but is a unique part—the only part destined to leave the mother's body, and take up an individual and independent existence as a human being.³⁰

The potential for life makes the fetus qualitatively different from being living tissue or a subhuman animal. Its potential for becoming a person places it in its own distinct class of entities. This class should be defined in relation to other categories by searching

24. *Commission Report: Deliberations and Conclusions*, 5 HASTINGS CENTER REP., June 1975, 41 [hereinafter cited as *Commission Report*]. In the preface to its deliberations, the Commission stated:

Although the Commission has not addressed itself directly to the issues of the personhood and the civil status of the fetus, the members of the Commission are convinced that moral concern should extend to all who share human genetic heritage, and that the fetus, regardless of life prospects, should be treated respectfully and with dignity.

Id.

25. 410 U.S. 113 (1973).

26. *Id.* at 163.

27. *Id.* at 159.

28. *Id.* at 157-58.

29. Gaylin and Lappé, *supra* note 17, at 67.

30. Siegel, *A Bias for Life*, 5 HASTINGS CENTER REP., June 1975, 23, 24.

out similarities and dissimilarities which would justify differences in the protection and rights of the fetus.³¹

III. THE LEGAL AND ETHICAL RIGHTS OF THE FETUS

A. Legal

The legal rights of the fetus are those which the common law tradition endeavors to guarantee and protect. Anglo-American law has displayed a certain ambivalence with regard to the fetus by according it some, but not all, of the legal rights of a person.³² In most instances society has required live birth for the rights and protections of personhood to mature. It has been noted that this use of the concept of live birth as the trigger for asserting the right to legal protection probably arose because of judicial skepticism about the reliability of other means of ascertaining life, rather than because of any fundamental notion about when human life begins.³³

There are some exceptions, however, to the live birth requirement of law. In the common law of torts the unborn child was considered a part of the mother and had no independent rights of recovery.³⁴ In recent years courts have rejected this rule and permitted recovery by the child for prenatal injury. The earliest cases so holding established viability as the test for recovery,³⁵ but later courts have permitted recovery without regard to whether the child was viable at the time of injury.³⁶ Furthermore, courts have begun to allow parents to maintain wrongful death actions for fetuses which are stillborn as a result of the act of the defendant.³⁷

31. Steinfels, *supra* note 15, at 110. *But see* Wasserstrom, *The Status of the Fetus*, 5 HASTINGS CENTER REP., June, 1975, 18, 19-20. This view of the status of the fetus as a distinct entity goes a long way toward making experimentation on nonviable fetuses *ex utero* less troublesome. But it also makes abortion a morally worrisome act because it involves destruction of an entity with the potential to be a person.

32. See Louisell, *Abortion, the Practice of Medicine and the Due Process of Law*, 16 U.C.L.A.L. REV. 233 (1969); Note, *The Law and the Unborn Child: The Legal and Logical Inconsistencies*, 46 NOTRE DAME LAW. 349 (1971).

33. Capron, *A Legal Analysis of Definitions of Fetal Status*, AM. FED'N FOR CLINICAL RESEARCH, May 3, 1975, at 223.

34. *E.g.*, *Dietrich v. Inhabitants of Northampton*, 138 Mass. 14 (1884) (Holmes, J.).

35. *E.g.*, *Bonbrest v. Kotz*, 65 F. Supp. 138 (D.D.C. 1946).

36. *E.g.*, *Daley v. Meier*, 33 Ill. App. 2d 218, 178 N.E.2d 691 (1961); *Torigian v. Watertown News Co.*, 352 Mass. 446, 225 N.E.2d 926 (1967); *Kelly v. Gregory*, 282 App. Div. 542, 125 N.Y.S.2d 696 (1953).

37. *E.g.*, *Simmons v. Howard Univ.*, 323 F. Supp. 529 (D.D.C. 1971); *Hatala v. Markiewicz*, 26 Conn. Supp. 358, 224 A.2d 406 (1966); *O'Neill v. Morse*, 385 Mich. 130, 188

The property rights of the child *in ventre sa mere* are very old in the common law. In most jurisdictions the unborn child is recognized as a living heir for the purpose of taking an estate,³⁸ and thus his legal life begins at conception. It should be noted, however, that the primary reason for this rule is to fulfill the donor's intent that children not born at the time of the gift have a share. In equity it has been held that an unborn child, through a guardian, can maintain an action to compel the father to support him or her prior to birth.³⁹

In the context of constitutional law, the Supreme Court in *Roe* stated that the "word 'person', as used in the Fourteenth Amendment, does not include the unborn."⁴⁰ The Court did not define the time at which life begins, but it did rely on viability as the point at which the fetus' potential for life becomes a compelling interest to be protected. The Court focused on the point of viability because it is the point at which the growing organism is potentially able to live outside of the mother.⁴¹ The Court offered no guideline as to how the nonviable fetus was to be treated once outside of the womb. Under *Roe* then, the fetus has no protectible legal rights prior to viability because its existence and survival can be terminated by an abortion: during the pre-viable stage the maternal interests, particularly privacy, predominate over potential life. It would seem, therefore, that if fetal life before viability is so totally unprotected by the constitution, any restriction on fetal experimentation must find grounds other than fetal humanity and concomitant constitutional rights.⁴²

B. *Ethical*

The judicial withholding of legal rights from the fetus does not by itself resolve the question under what conditions the fetus is entitled to ethical considerations. Such considerations are not ap-

N.W.2d 785 (1971). All cases involved fetuses deemed viable at time of injury.

38. *Hall v. Hancock*, 32 Mass. (15 Pick.) 255 (1834); *Mackie v. Mackie*, 230 N.C. 152, 52 S.E.2d 352 (1949).

39. *Kyne v. Kyne*, 38 Cal. App. 2d 122, 100 P.2d 806 (1940).

40. 410 U.S. at 158.

41. One problem with using the point of viability is that it will change as technology improves; new devices and procedures will reduce the age of viability.

42. See McCormick, *Fetal Research, Morality and Public Policy*, 5 HASTINGS CENTER REP., June 1975, 26, 30.

appropriately defined in specific terms. They encompass the entire spectrum of moral and societal concerns valued by our culture. Doctors Willard Gaylin and Marc Lappé of the Institute of Society, Ethics and Life Sciences have asserted that permitting abortion but drawing the line at fetal experimentation is irrational. They argue that since abortion is going to dismember, destroy, and discard the fetus, research on the fetus beforehand (as in pre-abortion drug studies) is a small indignity.⁴³ Furthermore, they assert that "[fetal research] endows the process of abortion with human values it will not otherwise have."⁴⁴

On the other hand, this view seems predicated on a notion that since the worst will be done to the fetus, lesser acts beforehand are justified by the clear benefit to others of such experiments. It has been argued that this approach offends basic canons of ethics and substitutes a "net-benefits" utilitarianism for protection of the individual.⁴⁵ Furthermore, such appeal to benefit to society is based upon a hypothetical good to indeterminate interests in the future.⁴⁶ These hypothetical future benefits are not considered sufficient to outweigh the risks to the fetal subject.

Another argument concerning deleterious consequences of research on nonviable fetuses to be aborted is that it reflects a judgment that the valuations of "human dignity" may be changed if the subject's life expectancy is certain rather than indefinite. Thus it would seem that a subject becomes less a protectible human as death nears, an approach not in accord with the ethical principles regarding the treatment of dying or condemned subjects.⁴⁷ The argument continues that such an attitude could result in society becoming less sensitive to the value of human life. This is specious reasoning in that it is dependent upon the nonviable fetus being accorded the status of a human individual. A valid distinction can be made where fetal subjects and fully human subjects are concerned. A violation of the fetus' integrity might be justified on the ground that it will not have a significant effect on society's protection of the

43. Gaylin & Lappé, *supra* note 17, at 70.

44. *Id.* at 71.

45. P. RAMSEY, *ETHICS OF FETAL RESEARCH* (1975); Tiefel, *The Cost of Fetal Research: Ethical Considerations*, 294 N.E.J.M. 85, 89 (1976).

46. See Toulmin, *Exploring the Moderate Consensus*, 5 HASTINGS CENTER REP., June 1975, 31, 36-37.

47. Martin, *Ethical Standards for Fetal Experimentation*, 43 FORDHAM L. REV. 547, 568-69 (1975).

vulnerable. Experimentation on a twelve-week fetus is so clearly distinguishable from experimentation on a one year old child or a comatose person that such an effect is not significant.⁴⁸

The question of whether, in cases where abortion and death are imminent, different standards for fetal research are justified, was the most difficult for the Commission to resolve.⁴⁹ After taking extensive testimony and after much deliberation, the Commission left the question for further study by recommending that a national ethics review board should rule on special problems related to the interpretation or application of its guidelines.⁵⁰

C. Consent

The ethical problem regarding consent in fetal experimentation is a thorny issue. Proxy consent is usually deemed sufficient in research involving minors, although there is a growing trend against proxy consent for children in nontherapeutic research.⁵¹ There is strong sentiment in the fetal experimentation area that maternal proxy consent for the fetus is morally questionable. Since the pregnant woman refuses to carry the fetus, the normal assumption on which proxy consent is based, that the proxy has the subject's best interests at heart, is weakened.⁵² This view holds that consent, therefore, is unobtainable and condemns all fetal experimentation as unethical.

Another view sees proxy consent by the parents, or mother alone, although not required as a means of looking after the best interests of the fetus, as required because the parents retain a normal psychological stake in their issue,⁵³ and because of the close relationship between the mother and the fetus. Parental consent is

48. See *id.* at 565.

49. *The National Commission and Fetal Research: Introduction*, 5 HASTINGS CENTER REP., June 1975, 11, 12 [hereinafter cited as *National Commission*].

50. *Commission Recommendations* Nos. 5 & 6, 5 HASTINGS CENTER REP., June 1975, 45-46. In the course of deliberation some of the commissioners agreed that a planned abortion did alter the definition of "minimal risk" to the fetus, if not the "status of the fetus *per se*." *Commission Report*, *supra* note 24, at 42-43.

51. See, e.g., Burger, *Reflections on Law & Experimental Medicine*, 15 U.C.L.A.L. REV. 436, 438 (1968); Mishkin, *Multidisciplinary Review for the Protection of Human Subjects in Biomedical Research: Present & Prospective HEW Policy*, 54 B.U.L. REV. 278, 281-83 (1974).

52. P. RAMSEY, *supra* note 45, at 98; Tiefel, *supra* note 45, at 88.

53. See Toulmin, *supra* note 46, at 39; Wasserstrom, *supra* note 31, at 22.

not then a sufficient condition for research on the fetus, but it should be a necessary condition. The Commission⁵⁴ and the regulations⁵⁵ adopt this view.

Requiring consent of both parents does not completely resolve the problem; it does not fully meet the need of the fetal being for protection. In order to accord that more complete protection, it is suggested that an advocate for the fetus be provided, an independent individual who would represent the fetus and have authority to decide the question of consent to experimentation.

IV. REGULATION OF FETAL RESEARCH

A. Background

It is clear that some limits must exist to the quest for medical knowledge; the issue is where to set those limits. In the wake of the *Roe* decision and the increase in the supply of aborted fetuses as research subjects, there arose an increased concern with fetal experimentation. Several state legislatures reacted immediately, in part as a result of anti-abortion sentiment, fears of Frankensteinian experiments, as well as concerns for human dignity, and enacted statutes severely regulating or prohibiting fetal experimentation, particularly experimentation on aborted fetuses.⁵⁶ At that time various bills and amendments restricting fetal research were passed by the House of Representatives.⁵⁷ It seemed, however, that HEW, as the source of more than 80 percent of the funding of medical research in the United States,⁵⁸ was the logical agency to promulgate regulations. In 1973⁵⁹ and 1974,⁶⁰ after lengthy deliberations aimed at forming a sound ethical foundation upon which the regulations could rest, HEW published proposed regulations of experiments on human subjects including fetuses.

In July of 1974, Congress imposed a moratorium on fetal re-

54. *Commission Report*, *supra* note 24, at 43.

55. 45 C.F.R. §§ 46.208(b), 46.209(d) (1976).

56. See, e.g., CAL. HEALTH & SAFETY CODE § 25956 (West Supp. 1975); IND. ANN. STAT. § 35-1-58.5-6 (1975); LA. REV. STAT. ANN. § 14: 87.2 (1974); ME. REV. STAT. ANN. tit. 22 § 1574 (Supp. 1975); MINN. STAT. § 145.422 (Supp. 1975).

57. *National Commission*, *supra* note 49, at 11.

58. Goldstein, *Fetal Research in the Balance*, 10 TRIAL, July 1974, 53; see S. Rep. No. 381 93d Cong. 1st Sess. (1973).

59. 38 Fed. Reg. 31,738 (1973).

60. 39 Fed. Reg. 30,648 (1974).

search involving live, whole fetuses before and after induced abortion and created the Commission for the Protection of Human Subjects to investigate the entire area of research on human subjects.⁶¹ The Commission's first task was to focus upon fetal research, develop guidelines for all federally funded research and make recommendations to HEW for final regulations. The Commission operates in public and is composed of nonresearchers. It has conducted extensive ethical deliberations to come up with ethical principles upon which a policy of regulation should be based.

Although many researchers resent "outside" interference with their work, an independent Commission has several advantages. First, each profession has certain institutionalized values which represent the best interests, as the profession sees them, of both the profession and society. These strong internal values raise questions concerning the right of a profession to make partial judgments for society.⁶² Second, technical competence in a given area is not sufficient to assure that a person is an expert in evaluating a system to make policy decisions for that area.⁶³ Third, although experience in a given area does, in many cases, increase awareness and sensitivity to the humanitarian and social problems in the area, the same experience can also harden the professional into insensitivity and alienate him from society's frame of reference.⁶⁴ Therefore, although the professional does have immediate responsibility for his subject, this does not put him in the best position to make the policy decisions necessary to resolve the ethical problems.

B. *The 1975 Regulations*

The 1975 regulations⁶⁵ of research involving fetuses and pregnant women substantially adopt the Commission's recommendations. Thus they represent a moderate consensus advocating a system of social controls designed to limit the scope and prevent the

61. National Research Service Award Act of 1974, Pub. L. No. 93-348, 88 Stat. 342, 348.

62. Moffat, *supra* note 20.

63. Veatch, *Medical Ethics: Professional or Universal?* 65 HARV. THEOLOGICAL REV. 531, 546-48 (1972).

64. *Id.*

65. 45 C.F.R. §§ 46.201-.211 (1975). The regulations, as did the Commission, recognize that research involving the dead fetus and fetal materials is governed by applicable state or local law, such as the Uniform Anatomical Gift Act. 45 C.F.R. § 46.210 (1975). As previously noted, the regulations remain substantially unchanged in 1976.

abuse of fetal experimentation.⁶⁶ The regulations recognize the fetus as a human subject deserving of care and respect regardless of its life prospects. They also recognize that some use of the fetus as a research subject is in the public interest as it is the only subject through which specific significant advances in health care can be attained. While mutually limiting, these two perspectives are not incompatible.

The regulations apply to all research and related activities supported or conducted by HEW.⁶⁷ All research directed toward fetuses and pregnant women is first subjected to general limitations: (1) the necessary completion of appropriate animal studies; (2) minimal risk to the fetus in nontherapeutic research; (3) separation of researchers from decisions regarding the timing or method of abortion or regarding the viability of the fetus *ex utero*; (4) no introduction of significant changes into the abortion procedure solely in the interests of research where such changes may cause greater than minimal risk to either the fetus or the pregnant woman; and (5) no inducements offered to abort for purposes of research.⁶⁸ These limitations require that the research be important and obtainable by no other means, and subject the human fetus to minimal risk.

Furthermore, prior to commencement of research, informed consent must be sought and obtained in order for the research to be ethically acceptable. Informed consent is a necessary prerequisite for all types of research, but review of adequate consent usually has consisted of checking consent forms. The Commission recommended,⁶⁹ and the regulations⁷⁰ adopt, a new and far stricter form of consent. Provision is made for active monitoring of the entire consent process by Institutional Review Boards⁷¹ set up by indi-

66. Toulmin, *supra* note 46, at 31.

67. 45 C.F.R. § 46.201 (1976).

68. 45 C.F.R. § 46.206 (1976).

69. *Commission Recommendations*, *supra* note 50, No. 8 at 46.

70. 45 C.F.R. § 46.205 (1976).

71. 45 C.F.R. § 46.205(a)(2) (1976) provides for the additional duties of Institutional Review Boards:

(2) Determine that adequate consideration has been given to the manner in which potential subjects will be selected, and adequate provision has been made by the applicant or offeror for monitoring the actual informed consent process (e.g., through such mechanisms, when appropriate, as participation by the Institutional Review Board or subject advocates in: (i) Overseeing the actual process by which individual consents required by this subpart are secured either by approving induction of each individual into the activity or verifying, perhaps

vidual institutions who are applicants for research grants from HEW. These boards must be composed of at least five members with varying backgrounds. No board member may be involved in review of an activity in which he has a conflicting interest, nor may the board consist entirely of people who are associated with the institution or who are members of a single professional group.⁷² The boards review applications and have the responsibility for implementing HEW regulations for the protection of human subjects.⁷³

Monitoring will consist of overseeing the actual consent process and intervening where unanticipated risks arise. This provision marks a major change in policy for it establishes active monitoring of the consent procedure for the first time. This policy assures adequacy of the consent process and prevents unfair discrimination in the selection of research subjects.⁷⁴ The provision for review of the consent process in research conducted on fetal subjects and pregnant women may presage the establishment of similar requirements for other types of research. The Commission is continuing its work in other areas of research and it seems likely that overseeing consent procedures for other subjects, particularly children, may be recommended to HEW in the future.

The new regulations distinguish between research on the pregnant woman as the primary subject and research primarily directed toward the fetus.⁷⁵ The Commission further distinguished between therapeutic and nontherapeutic research, recommending that therapeutic research directed toward these two subjects should be encouraged.⁷⁶ The regulations do not specifically endorse therapeutic research, but seem to do so impliedly in specifying guidelines for research directed primarily toward meeting the health needs of the subject. These guidelines consist of the general preconditions discussed above and consent of the mother and the father.⁷⁷

through sampling, that approved procedures for induction of individuals into the activity are being followed, and (ii) monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen).

72. 45 C.F.R. § 46.106(b)(1976).

73. See 40 Fed. Reg. 33,526 (1975).

74. *Commission Recommendations*, *supra* note 50, No. 8 at 46.

75. *Id.* Nos. 1-7 at 45-46.

76. *Id.* Nos. 1 & 2 at 45.

77. 45 C.F.R. §§ 46.207-.208 (1976). The regulations require parental consent (with rea-

Research directed toward the pregnant woman to meet her health care needs is recognized as the preeminent right. Except for the requirement that she consent, there are no restrictions on therapeutic research upon her as long as the risks to the fetus are minimized as much as possible. The consent of the father is not required here.⁷⁸ This is consistent with the *Roe* decision and most moral and ethical disciplines because the benefits to the mother outweigh the potential risks to the fetus. With respect to nontherapeutic research on the pregnant woman, it is restricted to experimentation which imposes minimal or no risk to the fetus. Such research, furthermore, requires the consent of both mother and father.⁷⁹

Research on the fetus *in utero*, both therapeutic and nontherapeutic, is permissible only if both parents consent and the risk to the fetus is minimal.⁸⁰ That is, no research is permitted upon fetuses *in utero* prior to abortion that would not also be permitted on a fetus carried to term. The regulation incorporates the Commission's view that all fetuses *in utero* are deserving of care and respect whatever their age, their life expectancy, or the circumstances.⁸¹ In substantially incorporating the Commission's recommendations on this highly controversial point, HEW noted that since the Commission was created to represent the best judgment of the community and had conducted extensive deliberations, it was reasonable to accept its findings as the best possible judgment on the matter.⁸²

The use of a minimal risk standard is problematic because there is no indication in the regulations what that means. The Commission in its recommendations did affirm that manifest risks imposed upon nonconsenting subjects were not tolerable, and thus only minimal risks were permissible. It also affirmed that the

sonable exceptions for the father's consent) while the Commission had recommended that maternal consent is sufficient as long as the father does not object. In making the change, HEW

concluded that implementation of a provision for absence of objection might present serious problems. Since the absence of objection can best be verified by requesting consent, the Department . . . retained the requirement for parental consent when the father's identity and whereabouts can reasonably be ascertained, and if he is reasonably available.

40 Fed. Reg. 33,526, 33,527 (1975).

78. 45 C.F.R. §§ 46.207(a)(1), (b)(1) (1976).

79. *Id.* at §§ 46.207(a)(2)-(b)(4) (1976).

80. *Id.* § 46.208 (1976).

81. See *Commission Recommendations*, *supra* note 50, Nos. 4 & 5 at 45.

82. 40 Fed. Reg. 33,526, 33,528 (1975).

woman's decision for abortion did not change the fetus' status regarding minimal risk. However, differences of interpretation regarding what is risk to the fetus expected to be carried to term and what is risk to the fetus about to be aborted did arise. Therefore, the Commission recommended a national review board to resolve problems in interpreting what constitutes risk to the about-to-be aborted fetus.⁸³ The regulations adopt this recommendation and provide for a national Ethical Advisory Board⁸⁴ which HEW will utilize to review research proposals that require further evaluation of the definition of risk.⁸⁵ This, however, does not fully resolve the dilemma for researchers trying to ascertain what constitutes minimal risk to the fetus about to be aborted.

One commissioner stressed a further complexity in determining minimal risk where the research is a first trial. In first trials on a fetal subject the risks are almost always unknown because of the differences in physiology and pharmacology in human and mammalian fetuses. Unknown risk then is very difficult to determine and should not be classified as minimal risk.⁸⁶

A definition of minimal risk remains unclear. Likewise, the question whether the impending abortion alters the degree of risk to the fetus remains unresolved. Several commentators have argued that while a woman's decision for abortion does not change the fetus' status per se, the impending death of the fetus is a morally relevant fact which may justify greater latitude in determining risk.⁸⁷ Similarly it has been argued that even if the nonviable fetus is categorized separately as a being with the potentiality of becoming a person, once abortion or impending abortion removes that factor of potentiality, greater latitude in research can be justified.⁸⁸

On the other hand, strong objection is made to any change in the protection of the fetus who is about to be aborted for two reasons. It is first argued that change in determination of risk because the fetus is about to die violates the autonomy and integrity of the

83. *Commission Report*, *supra* note 24, at 42-43.

84. 45 C.F.R. § 46.204 (1976).

85. 40 Fed. Reg. 33,526 (1975).

86. Lebacqz, *Important Elaborations in Fetal Research: Response to the Recommendations*, 5 HASTINGS CENTER REP., Oct. 1975, 11.

87. See, e.g., McCormick, *supra* note 42; Toulmin, *supra* note 46.

88. See Steinfels, *supra* note 15, at 111.

fetus.⁸⁹ "A woman's decision to have an abortion, however, protected by *Roe* . . . in the interests of her privacy or freedom of her own body, does not change the nature or quality of fetal life."⁹⁰ The second reason given is the woman's right to change her mind about the abortion. If the mother does change her mind after pre-abortion experimentation has begun, the possibilities may be increased of giving birth to an unnecessarily injured child. Moreover, the fact that potentially damaging experiments have been performed on her fetus may constitute an inducement not to change her mind, thereby interfering with her freedom of choice.⁹¹ It is also argued that research on the fetus prior to abortion may be a source of grief and guilt to the mother⁹² against which she should be protected. The regulations do not fully clarify whether the risk factor is modified when the fetal subject is about to be aborted, leaving final resolution on this issue to the Ethical Advisory Board.

Research on the fetus during the abortion procedure itself was dealt with by the Commission in its recommendation on research on the nonviable fetus *ex utero*,⁹³ but no separate provision for this is contained in the regulations.⁹⁴ However, the recommendation included a precondition that no procedural change be introduced into the abortion procedure in the interest of the research alone. The regulations substantially incorporate this precondition into the general limitations on all research directed toward pregnant women and fetuses by qualifying the restriction of procedural changes to those which impose no greater than minimal risk.⁹⁵

Once the fetus is outside the womb, an independent party must determine the viability of the fetus.⁹⁶ If viable it will be treated as a premature infant.⁹⁷ If the fetus might possibly be viable, it is afforded the minimal risk standard. That is, no additional risk to

89. Louisell, *Compelled to Disagree in Fetal Research: Response to the Recommendations*, 5 HASTINGS CENTER REP., Oct. 1975, 9.

90. *Id.* at 10.

91. Wasserstrom, *supra* note 31, at 22.

92. Toulmin, *supra* note 46, at 35.

93. *Commission Recommendations*, *supra* note 50, No. 6 at 45-46.

94. See 45 C.F.R. § 46.209 (1976).

95. 45 C.F.R. § 46.206(a)(4) (1975): "No procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity."

96. *Id.* § 46.206(a)(3)(ii) (1976).

97. *Id.* § 46.203(d) (1976).

the possibility of viability can be imposed upon the fetus. If that standard is met, it is further required that the research be important and obtainable through no other means.⁹⁸ This assures that a fetus with even the smallest chance of viability is accorded due care and dignity.

Research directed toward the nonviable fetus *ex utero* is permitted if the activities do not, of themselves, terminate the heart-beat or respiration of the fetus, the research is important for biomedical knowledge and cannot be obtained by other means, and parental consent is obtained.⁹⁹ In adopting this regulation, HEW incorporated for the most part the Commission's recommendations for the same reasons as it followed the recommendations regarding research on the fetus *in utero*—the Commission represents the best judgment of the community.¹⁰⁰ Thus the regulations adopt the viewpoint that the dying of the nonviable fetus alters the situation in two ways. First, since the dying fetus cannot be injured for life and cannot be saved, the question of risk becomes less relevant. Second, since the abortion is completed, there is no risk of the mother changing her mind which will result in a living but possibly injured child.¹⁰¹ However, even though the risk factor is less relevant, considerations of respect for the dignity of the fetus remain and require that the fetus be accorded the respect of the dying. Therefore, the only nontherapeutic research permitted on the nonviable fetus is that which does not alter the duration of the fetus' life.¹⁰²

In the commentary on the Commission's recommendations, two commissioners noted that scientific opinion is divided upon whether or not the nonviable fetus feels pain. If it is ascertained that the fetus does feel pain, it is argued that respect for the dignity of the subject may require, on humanitarian grounds, that its pain be minimized even to the extent that its lifespan is shortened.¹⁰³

The regulation of research on nonviable fetuses *ex utero* does contain one major exception to the Commission's recommendations. The Commission had recommended the prohibition of any change

98. *Id.* § 46.209(a) (1976).

99. *Id.* §§ 46.209(b)(2)-(3), (d) (1976).

100. 40 Fed. Reg. 33,526, 33,528 (1975).

101. *Commission Report*, *supra* note note 24, at 43.

102. *Id.*

103. Lebacqz, *supra* note 86, at 11-12 (Commissioner Jonsen concurs with Lebacqz' point of view).

in the duration of the fetus' life.¹⁰⁴ However the regulations permit research whereby "[v]ital functions of the fetus . . . [can] be artificially maintained . . . where the purpose of the activity is to develop new methods for enabling fetuses to survive to the point of viability."¹⁰⁵ HEW excepted to the Commission's view on this point because the Secretary was "persuaded by the weight of scientific evidence that research performed on the nonviable fetus *ex utero* has contributed substantially to the ability of physicians to bring to viability increasingly small fetuses."¹⁰⁶ Thus the regulation recognizes that it is in the public interest to continue this vital research. Some support for this position can be found in the principle which holds that research is ethically more acceptable the more closely it approximates the interests of the subject. It would not be unreasonable, then, to suggest that the dying nonviable fetus, just as any other dying subject, would have an interest in the development of technology which is aimed at allowing others like it to survive.¹⁰⁷

Objection to this exception, which allows the duration of the fetus' life to be altered, stresses that the nonviable fetus loses both its dignity in dying and the protection from violation of its integrity. It is argued that permitting this alteration violates the convictions of the regulations and the Commission that the fetus should be treated respectfully and with dignity regardless of its life expectancy.¹⁰⁸

Finally, the regulations recognize the difficulty of applying all the regulations to special research problems, and therefore set up a mechanism for waiver or modification of specific requirements.¹⁰⁹ The waiver or modification can only be made by HEW after a request is made by the applicant and approved by the Ethical Advisory Board which should encourage public participation in the review. Decision is to be made after weighing all the risks to the subject against any benefits to the subject and the importance of the knowledge to be gained. This provision is laudable because it does

104. *Commission Recommendations*, *supra* note 50, No. 6 at 46.

105. 45 C.F.R. § 46.209(b)(1) (1976).

106. 40 Fed. Reg. 33,526, 33,528 (1975).

107. Lebacqz, *supra* note 86, at 12.

108. Tiefel, *supra* note 45, at 88. *Accord*, McCormick & Walters, *A Good Beginning in Fetal Research: Response to the Recommendations*, 5 HASTINGS CENTER REP., Oct. 1975, 13; see Ramsey, in 40 Fed. Reg. 33,526, 33,539 (1975) (summary of paper submitted to the Commission).

109. 45 C.F.R. § 46.211 (1976).

permit the regulations to be adapted to different circumstances,¹¹⁰ but it is also strongly opposed. The opposition sees the provision as an escape hatch from human experimentation principles simply by employing the decision of a fallible national review board. According to this view, the provision does not provide the unborn with the protection of recognized limits on human experimentation.¹¹¹

The regulations have not solved all the problems related to fetal research nor provided protection of the fetus which is acceptable to everyone in terms of being neither too restrictive nor too liberal. However:

[T]he overall protective thrust of the [regulations] is a major step in the right direction. What is perhaps more important than the . . . conclusions themselves is the way in which this problem was faced, not only by legislation or political tradeoffs, or judicial fiat, but by a representative public commission that elicited the views of persons from differing backgrounds, competences and convictions, conducted public discussions, and deliberated openly and candidly on the problem and its implications.¹¹²

V. CONCLUSION: RECOMMENDATIONS

This paper has indicated that the 1975 federal regulations of fetal research go far in acknowledging fetal dignity and providing the fetus *in utero* and the nonviable fetus *ex utero* with comprehensive protection. The greater protection, however, necessarily diminishes the benefits accruing to society from fetal research. In one major area of research, that directed toward understanding the factors which modify placental transfer of drugs and their subsequent movement into the fetus, too much potential benefit may have been given up for a small amount of protection.

There are frequent references in the medical literature to the potential effects on the fetus of drugs administered to the mother, but only a few drugs have been positively identified as teratogenic whereas many have shown the potential for being teratogenic.¹¹³ It is extremely difficult to predict what types of effects a drug

110. See *Commission Report*, *supra* note 24, at 44.

111. See Louisell, *supra* note 89.

112. McCormick & Walters, *supra* note 108, at 13-14.

113. Mirkin, *Impact of Public Policy on the Development of Drugs For Pregnant Women and Children*, AM. FED'N FOR CLINICAL RESEARCH, May 3, 1975, at 233, 235.

necessary for the mother's health is going to have on the fetus unless its actions have been tested in other fetuses. The only way new drugs can be tested on the fetus today is when the mother needs them; the situation then becomes a balancing between the interests of the mother's health care and the interests of the fetus in protection. "[T]his type of 'after the fact' investigative approach is inefficient and least likely to yield the information required to develop a rational therapeutic framework."¹¹⁴

The regulations do not permit nontherapeutic research relating to drug pharmacology on the fetus *in utero* unless there is no risk or minimal risk. Since the unknown actions of new drugs and vaccines on the fetus do not fall within acceptable risk, biomedicine must wait to ascertain the information from the later-born children whose mothers needed the drug. Such an approach seems to provide a small degree of protection to a subject about to expire at a cost of losing vital information about the action of drugs in the fetus. It constitutes a loss of knowledge which would be of significant benefit to fetuses carried to term and not just some hypothetical good that may occur in the indefinite future.

Therefore, it is submitted that this type of research be conducted within carefully constructed guidelines on fetuses about to be aborted. The research would be ethically permissible since the impending death of the fetus is a morally relevant factor which changes the situation.¹¹⁵ A possible harmful effect on the fetus about to die from an abortion is very different from that which constitutes harm in the fetus expected to be carried to term.

Moreover, safeguards can be maintained regarding the risk of the mother changing her mind about the abortion. It is possible to ascertain a group of women where change of mind is a minimal risk; these women have compelling social and psychological pressures which would tend to prevent any change of mind. An additional safeguard can be implemented in the research design by providing for an advocate for the fetus. The advocate would be an independent person appointed to represent the fetus and thereby help to insure that the final decision represents a balance between the interests of the fetus with those of the researcher and society. It is suggested that the cost of the advocate for the fetus be written into the original

114. *Id.* at 236.

115. See text accompanying notes 87-88 *supra*.

research application for funding.

Permitting drug pharmacology research on fetuses about to be aborted may in some instances fall into the minimal risk area and thus require no special modification or waiver of the regulations. Many more drugs, however, will fall into the category of possible risk exceeding the minimal level and will require waiver or modification because of the special circumstances. A third group of drugs will possess unknown risk. In this situation the change in the fetus' status because of the impending abortion does not completely justify extending the latitude to the risk of teratogenic effects. Administration of the drug to the fetus in this situation can only be justified as the lesser of two evils—the fetus about to die is subjected to possible teratogenic effects weighed against experimentation unwittingly done on fetuses carried to term as in the thalidomide tragedies.

In conclusion, the regulations do represent an important step forward in policymaking in the medical-legal area by relating ethical reasoning to the formulation of public policy. Such a policy seeks to institutionalize ethics. Unless it realistically assesses society's interest in improving the health care of pregnant women and fetuses carried to term, it will not resolve the dilemmas of fetal research.