Fetal Experimentation: Legal Implications of an Ethical Conundrum

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FETAL EXPERIMENTATION: LEGAL IMPLICATIONS OF AN ETHICAL CONUNDRUM

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I. REGULATING FETAL RESEARCH

A. The Controversy

Research on the fetus embraces a complex mixture of ethical, legal, and medical issues. The effort to regulate it has been characterized by a struggle between doctor-researchers who support fetal experimentation to eliminate or alleviate a variety of ills which afflict mankind, and a lay population which opposes fetal experimentation as an assault on the sanctity of human life.
The controversy has been fueled by the debate on abortion.\textsuperscript{1} Much fetal research has taken place on fetuses scheduled for abortion; and as the number of abortions has increased, this research has become more visible and frequent.\textsuperscript{2} At root, both practices compel a response to a vexing question: When do the full rights of personhood attach to a developing human being?

Many in the research community assert that a fetus is not human, or at least is not protectible in a fully human sense.\textsuperscript{3} They laud the substantial benefits which are accruing from fetal experimentation, pointing out that the general, overwhelming purpose of such experimentation is to improve prenatal care for fetuses which are to be carried to full term. Their detractors, however, view the doctor-researchers as callous, impersonal investigators who place scientific inquiry over regard for human life. They believe a fetus is a fellow human being who should not be subjected to unwarranted scientific manipulation.\textsuperscript{4}

1. Types of Research

To disentangle the threads of this dispute, an understanding of the nature of fetal experimentation is necessary. Medical researchers engaged in fetal experimentation have concentrated on four areas of study: First, research concerning the growth and development of the fetus in utero; second, diagnosis and observation of fetal diseases and genetic disorders; third, improvement of fetal therapy and pharmacology; and fourth, research on the nonviable fetus ex utero. Each of these areas is discussed separately below.

\textsuperscript{1} See N.Y. Times, Apr. 13, 1973, at 20, col. 3.


\textsuperscript{3} See generally, Martin, Ethical Standards for Fetal Experimentation, 43 Fordham L. Rev. 547 (1975).

\textsuperscript{4} Those opposed to fetal research point to the possible "brutalizing" effect such practices can have on community ethical standards. They point to the example of research on children: In the nineteenth century, children from orphanages were used in research projects. It is generally agreed that the effort to protect the fetus is simply an extension of the humanitarian impulse to protect children which resulted in child protection statutes—a relatively recent phenomenon. For a general discussion of the legal protection of children see Paulsen, The Legal Framework for Child Protection, 66 Colum. L. Rev. 679, 680-86 (1966).
a. Growth and development

There is still a paucity of knowledge about the physiological development and the sequential changes in the biochemical growth of the fetus. The study of fetal growth and development in utero is essential, since medical practitioners must first comprehend the intricacies of fetal anatomy, physiology, organ function, sensory capacity, and metabolism in order to meaningfully diagnose and treat fetal disorders before birth.

Much experimentation in this area is conducted on dead fetuses through autopsy or on live fetal tissue or organs excised from dead fetuses. Other experiments have involved the monitoring of fetal response and behavior through ultrasound and by fetal electroencephalogram. To acquire a better understanding of fetal metabolism, researchers have examined both fluid withdrawn from the amniotic sac surrounding the fetus and samples of blood taken from the umbilical cord. Other studies have involved the injection of nonradioactive tracers (such as carbon-13) into the amniotic cavity in order to monitor the dispersal or absorption of those tracers.

b. Diagnosis

Researchers concerned with improving the diagnosis of fetal disorders have considered the problems of genetic defects, neural tube defects, Rh incompatibility, and Respiratory Distress Syndrome. This research has had a largely predictive purpose and is designed to permit physicians to assess the health and development of the fetus in utero.

The diagnostic technique used in most cases is amniocentesis, a procedure which involves withdrawing fluid from the amniotic sac surrounding the fetus for subsequent analysis. First

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7 Id. at 10-11, 23.
8 Id. at 13.
used as a clinical procedure in 1882, this technique, combined with substantial progress in tissue culture research, has greatly expanded the intrauterine diagnosis of chromosomal and metabolic disorders. However, amniocentesis is capable of detecting only the most severe disorders, and there is a slight chance that it may harm the fetus. Fetoscopy and ultrasound may prove to be superior for diagnostic purposes, but both are still in the early stages of development.

Often diagnostic research is undertaken in conjunction with the treatment of prenatal disorders. In the case of Rh incompatibility, Respiratory Distress Syndrome, and neural tube disorders—major causes of infant mortality—intrauterine therapy may be available if the condition is diagnosed. For example, in the case of Respiratory Distress Syndrome, corticosteroids can be administered to correct certain chemical deficiencies which cause lung immaturity in the infant. Diagnostic procedures may also be employed to determine whether the physician should induce premature birth to avert serious harm to the fetus and the mother which could result from certain prenatal disorders if the pregnancy were carried to full term.

Diagnostic research may reveal the presence of such grave abnormalities that abortion would be recommended. However, advances in medical knowledge through further research may actually result in saving many fetuses from abortion. For example, if both parents carry a gene for certain kinds of serious disorders, such as Tay Sachs, there is currently a one-in-four chance of their having a severely defective child. Given these odds, many parents choose to abort. As a result of research on the prenatal diagnosis of blood diseases, however, these parents can find out if their fetus is free of serious defects; and the mother may then decide to carry it to full term.

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11 Id. at 1243. Of more than several hundred disorders, only slightly more than sixty can be diagnosed using amniocentesis; however, virtually all chromosomal abnormalities are potentially detectable with the use of amniocentesis. Id. at 1258. See also Levin, Oxman, Moore, Daniels, & Sheer, Diagnosis of Congenital Rubella In Utero, 290 New Eng. J. of Med. 1187 (1974).

12 Mahoney Report 11.

13 Id. at 10.  
14 Id. at 25.  
15 Id. at 25.  
16 Boston Globe, Feb. 15, 1975, at 24, col. 1. Five women with either sickle cell trait or Cooley's anemia trait elected not to have abortions when fetoscopy—a new technique
c. Fetal therapy and pharmacology

The purpose of pharmacological research is to discover which drugs and agents administered for maternal and fetal care during pregnancy are the safest and most effective. Drug transfer studies are frequently undertaken to determine whether certain drugs will cross the placental barrier and have an impact on the fetus, or will instead affect only the mother. Often drug transfer research involves only an autopsy examination of fetal tissues. Since the average woman takes six drugs or agents during or prior to discovering her pregnancy, researchers have retrospectively examined the impact of those drugs on fetuses following abortions or natural births. The effects of analgesics, hormones, birth control pills, addictive drugs, insulin, anticonvulsants, anesthetics, and drugs taken for maternal disease treatment have all been studied in this manner.

Recently there has been a movement in the research community to expand the scope of pharmacological research. Researchers have sought to concentrate exclusively on fetuses scheduled for abortion, since they are able to utilize experimental drugs without fearing the adverse consequences on research subjects who will survive. While animal experimentation must precede research on human subjects for purposes of eliminating avoidable research risks, there is no alternative to testing on human subjects at some point, because of significant physiological differences between animals and humans. The most notable example of the need for preliminary testing of drugs on human subjects occurred in the development of rubella vaccine. Researchers developed a rubella serum that did not pass through animal placentas and presumably was safe for use by pregnant women. In subsequent testing on human subjects, however, the vaccine passed through the placenta and damaged the fetus. As a result, doctors for examining the fetus in utero—and removal of a sample of fetal blood from the placenta revealed that their fetuses were free from defects. Id.


Forfar & Nelson, Epidemiology of drugs taken by pregnant women: Drugs that may affect the fetus adversely, 14 CLINICAL PHARMACOLOGY AND THERAPEUTICS 632 (1973).

Mahoney Report, Table I at 15.

Id. at 36-39.
were able to caution mothers to refrain from taking rubella vaccine prior to or during pregnancy. Had there been no prior testing on fetuses to be aborted, another thalidomide-type disaster might have occurred.

d. Research on fetal tissue and nonviable fetuses ex utero

The vast majority of reported research on fetuses ex utero is restricted to dead fetal subjects. After the death of a fetus, many tissues can be utilized to study tissue and cell growth as well as metabolic and cellular function. Tissue cultures from human fetuses have become indispensable for the growth of certain viruses and for the development of viral vaccines to combat major illnesses. According to one authority:

[T]he legal prohibition of the investigative use of embryonic and fetal tissues derived from dead human embryos or fetuses . . . will gravely retard the advancement of medical knowledge in many areas. Examples of such areas are: (1) the further understanding of the causes and development of means for the prevention of fetal abnormalities; (2) the alterations in cellular mechanisms underlying transformation of normal human cells to cancer cells and the immunologic factors involved in resistance to cancer; and (3) the development of vaccines not now available against viral and other infectious micro-organisms such as varicella virus, cytomegalovirus and the agents of hepatitis and mycoplasma. Regarding the last-mentioned area of investigation, it should be realized that the development of the prophylactics now generally employed in the prevention of poliomyelitis, measles and German measles stemmed from the results of original studies with human embryonic tissues.

In addition to experimentation involving dead fetuses and fetal tissue, research has been conducted on nonviable ex utero fetuses which exhibit signs of life. This type of research is extremely rare: No more than 20 cases were reported out of 3,000 citations of fetal research throughout the world in the last decade. Experimentation ranges from simple observation and

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20 Mahoney Report 22.

21 Id.


23 Fetal Research Report 33,534.
monitoring of fetuses with instruments such as EEG, X-rays, and radioisotope scans,\(^{24}\) to more invasive procedures designed to artificially maintain fetal life functions for purposes of developing an artificial placenta which would enable doctors to increase the potential for survival of premature infants.\(^ {25}\)

2. Abuses

Despite the minimal risk associated with much, but certainly not all, fetal research and its beneficient objectives, abuses have taken place.\(^ {26}\) Some experiments, such as the administration of drugs of unknown danger to fetuses to be aborted, involve practices about which there might be reasonable disagreement. Similarly, research on the nonviable fetus which involves only measurement or minor invasive procedures is not likely to stir heated debate.

Other experiments on the nonviable fetus, however, raise serious ethical questions. For example, in one preliminary attempt to develop a fetal incubator, 15 fetuses (9-24 weeks' gestation) obtained from induced abortions were immersed in a salt solution containing oxygen at extremely high pressure, in an attempt to provide oxygen for the fetuses through the skin.\(^ {27}\) As the determinants of life were a pulsating umbilical cord or visible heartbeat, the fetuses' chests were opened whenever necessary to observe their hearts. In this experiment, four fetuses were supported artificially, \(i.e.,\) denied death, for 22 hours. In another example, a study to determine fetal brain metabolism of ketone bodies, the heads of eight fetuses (12-17 weeks' gestation) were severed from their bodies after heartbeat had ceased.\(^ {28}\) While death had technically occurred, life at the cellular level continued

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\(^{24}\) Mahoney Report 22.

\(^{25}\) Id. at 24-25.


\(^{28}\) Id.

\(^{29}\) Adam, Raiha, Rahiala, et al., Cerebral Oxidation of Glucose and D-BOH-Butyrate by the Isolated Perfused Human Fetal Head, 7 Pediatric Research 309 (1973).
in the brain, and thus it was possible to measure the extent to which fetal cerebral tissues could metabolize D-BOH-Butyrate as an alternative to glucose.  

B. Regulating Fetal Research

The potential value of fetal research has not stilled the voices of those who view it as an unwarranted assault on the integrity of living human beings. The protest against fetal research has taken several forms, including the use of the criminal process against doctor-researchers and the promulgation of state statutes designed to limit the types of research which may be undertaken.

Two cases have commanded national attention: The Massachusetts "grave-robbing" incident and the trial of Dr. Kenneth C. Edelin. See Boston Globe, Feb. 16, 1975, at 1, col. 4.

The Massachusetts "grave-robbing" cases were triggered by a journal article written by three Boston doctors. See Philipson, Sabath, & Charles, supra note 15. The article described an experiment to determine which of two drugs reaches a fetus in sufficient concentration to prevent congenital syphilis where the mothers are allergic to penicillin. All of the women who participated in the experiment had requested abortions and had provided their written consent to the research. The article came to the attention of the Boston City Council and the Suffolk County District Attorney's Office. Indictments were returned against the three doctors who wrote the article and a pathologist who assisted them in the experiment. Boston Globe, Feb. 16, 1975, at 5, col. 1. The doctors were charged with "grave-robbing" in violation of a state statute. Id. Their cases are still pending.

In the process of investigating the "grave-robbing" incident, a representative of the Suffolk County District Attorney's Office found two dead fetuses in the county mortuary. One was allegedly 24 weeks old; and a certificate listing the cause of its death could not be located. Dr. Kenneth Edelin, the doctor who performed the abortion, was indicted for the manslaughter of the aborted fetus. In his instructions to the jury, the judge stated that a fetus is not a person until birth, that birth is defined as "the process which causes the emergence of a new individual from the body of its mother," and that a person is one who is born, that is, outside the body of the mother. Despite the fact that the only eyewitness for the state testified that the fetus showed no sign of life when it was removed from the mother, the jury convicted Dr. Edelin of manslaughter. Several of the jurors said their guilty finding was based on the belief that Dr. Edelin was negligent in not attempting to save the life of a premature infant while performing an abortion. A picture of the fetus had a powerful effect in moving the jury toward conviction. Boston Globe, Feb. 16, 1975, at 4, col. 6. On appeal the Massachusetts Supreme Court ordered a directed verdict for acquittal. Commonwealth v. Edelin, 359 N.E.2d 4 (Mass. 1976).

There is a wide variation among states as to the limitations their statutes impose on fetal experimentation. Certain statutes, for example, limit experimentation on ex utero fetuses and yet fail to prohibit or regulate in utero experimentation. See, e.g., CAL. HEALTH & SAFETY CODE § 25956 (Supp. 1976); ILL. ANN. STAT. ch. 38, § 81-18 (Smith-Hurd Supp. 1976); NEB. REV. STAT. § 28-4,161 (1975). Other statutes impose a nearly universal ban on fetal experimentation, excluding only those measures designed to preserve the life or
The most pervasive regulation of fetal research, however, has been at the national level. In July 1974, in response to research on fetuses and other subjects who might lack the capacity to consent, Congress passed the National Research Act.\(^{33}\) The act applies to all federally funded fetal research\(^{24}\) and provides for the establishment of regulations governing the limits of permissible research and the procedures to be followed in undertaking such research.\(^{35}\)

As a preliminary step to the promulgation of regulations, the act provided for the establishment of a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.\(^{36}\) The Commission was assigned the responsibility of studying the various kinds of research in progress, and reporting its conclusions and recommendations regarding appropriate research and research protocols to the Secretary of the Department of Health, Education, and Welfare.\(^{37}\) In performing its initial assignment, the Commission held hearings and solicited the oral and written views of experts from a broad range of disciplines.\(^{38}\)
The legislative history of the enabling statute, pre-existing codes, and other materials relating to research on the fetus were consulted, as were the draft rules and policy guidelines of the Department of Health, Education, and Welfare. The final recommendations of the Commission were submitted to HEW and were incorporated in large part into the regulations issued by the Department.

Following a definitional section, the Department's regulations provide for the establishment of two Ethical Advisory Boards, one advisory to the Public Health Service and the other advisory to all other agencies and components of the Department of Health, Education, and Welfare. The function of the boards...

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39 Id. at 33,531. The papers and reports submitted to the Commission are compiled in The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Research on the Fetus: Appendix (1975). The Department's draft rules and policy guidelines emphasize informed consent and prior review as the principal means for protecting human research subjects. They require an extra layering of committees to assess risk, monitor consent, and evaluate the ethical implications of particular research. 39 Fed. Reg. 30,642, 30,653-54 (1974). See notes 190-244 and accompanying text infra.

38 The regulations are found at 45 C.F.R. §§ 46.201-.301 (1976). While the regulations and recommendations are similar in many respects, they differ on the question of whether to permit research on a nonviable fetus ex utero which would alter its duration of life. The Department concluded that the continuation of research to develop an artificial placenta is in the public interest. See note 164 and accompanying text infra. In justifying its decision to permit the research, the Department stated that it 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." 40 Fed. Reg. 33,528 (1975). But see note 184 infra concerning the Department's proposed amendments to the regulations.

37 45 C.F.R. § 46.203 (1976). For the purposes of this article, the relevant definitional sections are:

(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 independently maintaining heartbeat and respiration... If a fetus is viable after delivery, it is a premature infant.

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

(f) "Dead fetus" means a fetus ex utero which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).

Id. § 46.204.
is to render advice concerning the ethical issues present in those classes of proposals which each board determines must be submitted to it.\textsuperscript{43} In addition, the regulations expand the functions of Institutional Review Boards in local hospitals and similar institutions\textsuperscript{44} in connection with activities involving fetuses, pregnant women, or human \textit{in vitro} fertilization.\textsuperscript{45} No research award may be made by the Department of Health, Education, and Welfare until the appropriate reviewing bodies certify the research application.\textsuperscript{46}

General limitations are placed on all research activity.\textsuperscript{47} Prior to commencing fetal research, studies on animals and nonpregnant individuals are required. When nontherapeutic research is conducted, the risk to the fetus must be minimal; if the research is therapeutic and conducted on either the mother or the fetus, the risk to the fetus must be the least possible consistent with achieving the objectives of the research.\textsuperscript{48}

Finally, the regulations also place limits on specific areas of research. These include provisions which relate to research activities directed toward pregnant women as subjects,\textsuperscript{49} activities involving the dead fetus, fetal material, or the placenta,\textsuperscript{50} research carried out in connection with abortion,\textsuperscript{51} \textit{in utero} research,\textsuperscript{52} and experimentation on the nonviable fetus \textit{ex utero}.\textsuperscript{53}

\textsuperscript{43} Id. § 46.204(c), (d). The proposals potentially include any grant or contract sought by the applicant for “supporting research, development, and related activities involving: (1) The fetus, (2) pregnant women, and (3) human \textit{in vitro} fertilization.” Id. § 46.201(a).

\textsuperscript{44} To obtain funding for research involving human subjects, an organization must establish an Institutional Review Board whose function is to review and either approve or disapprove research proposals. In addition, where the research involves risk to human subjects, the Institutional Review Board must conduct continuing review throughout the course of the project; insure that informed consent has been obtained; and determine that the risks to the subject are outweighed both by the benefits to the subject and by the knowledge to be gained through research. Id. § 46.102. See text accompanying notes 232-40 infra.

\textsuperscript{45} Id. § 46.205.

\textsuperscript{46} Id. §§ 46.204(e), 46.205(b).

\textsuperscript{47} Id. § 46.206.

\textsuperscript{48} Id. § 46.206(a)(1)-(2).

\textsuperscript{49} Id. § 46.207.

\textsuperscript{50} Id. § 46.210.

\textsuperscript{51} Id. § 46.206(a)(3)-(4).

\textsuperscript{52} Id. § 46.208.

\textsuperscript{53} Id. § 46.209.
II. LEGAL ISSUES RAISED BY THE REGULATIONS

A. Scope of Analysis

The remainder of this article will analyze the legal issues raised by sections 46.208 and 46.209 of the Department's regulations, i.e., research on the fetus in utero and on the fetus ex utero. These sections of the regulations were chosen partly for reasons of economy in an article of this length, and partly because the most baffling problems are in the areas selected. 5

Initially it may be helpful to clarify some important terms which will be used throughout the analysis. The words fetal experimentation or fetal research provide little clue to the complexity of the topic. Part of the problem is that we are considering a "being" in different environments and stages of growth, and

5 Serious questions are also posed in those areas omitted from discussion. Research on a premature infant (a fetus ex utero ascertained to be viable) is subject to the laws and regulations governing research on children in general; but that area of the law is itself unclear. The new regulation governing research on the dead fetus, fetal material, and the placenta contains vexing definitional questions. It states that such research "shall be conducted only in accordance with any applicable State or local laws regarding such activities." 45 C.F.R. § 46.210 (1976). These statutes, however, leave open perplexing questions. For example, the question of when death occurs, or perhaps, in the case of fetuses, when life occurs, must be answered.

In the case of the fetus, it is not irreversible changes which preclude a return to normal functioning that signal death, but an absence of adequate physiological development which precludes the attainment of normal functioning. Conceptually, however, it is difficult to regard the time before "life" begins as death. For a discussion of this issue and an analysis of state laws bearing on the issue of research on fetal tissue and remains, see Capron, The Law Relating to Experimentation with the Fetus, in THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, RESEARCH ON THE FETUS: APPENDIX (1975) [hereinafter cited as Capron Report].

In addition, research on the pregnant woman presents a plethora of problems, hardly solved by the new regulations. By what calculus, for example, do we measure the degree of therapeutic experimentation permissible on a mother which may cause harm to her unborn child? The regulations bar nontherapeutic research on the mother except where "the risk to the fetus is minimal." 45 C.F.R. § 46.207(a)(2) (1976). But therapeutic research on the mother may be conducted in accordance with her wishes, id. § 46.207(b)(1), with the sole limitation that the fetus be placed at risk to the minimum extent possible. Id. § 46.207(a)(1). Thus the regulations may be a poor guide to doctor-researchers in specific situations. What kind of risks are we talking about? Who measures the probability of harm and magnitude of harm which may be inflicted? If an activity will meet the health needs of the mother but will not provide significant benefit, and if the same activity involves an immeasurable risk to the fetus, are we prepared to say that the research should proceed? If doctors or hospitals refuse to proceed, are we prepared to absolve them from liability if the health needs of the mother are neglected? Is a father's consent irrelevant if he must share the burden of supporting a potentially defective offspring?
these differences may be critically important in defining whether that being has legal personhood. Thus one must distinguish carefully between fetuses in utero and ex utero and between fetuses which are preivable, nonviable, or viable. A fetus in utero before the time of viability is preivable, because it will in the normal course of events grow into viability; on the other hand, a fetus ex utero before the time of viability is nonviable, because, given the current state of technological development, there is no way it will attain viability. Similarly, a careful distinction must be made between therapeutic and nontherapeutic experimentation. If the objective is to benefit the subject, the experimentation is therapeutic; whereas if the main objective is to benefit others through the acquisition of new knowledge, it is nontherapeutic. Even the word experimentation should be defined. It refers to all nonstandard procedures utilized for diagnosis, therapy, or the acquisition

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5 For a definition of viability see note 41 supra. In Planned Parenthood v. Danforth, 96 S. Ct. 2831 (1976), the Supreme Court upheld the constitutionality of a Missouri statutory definition of viability as "that stage of fetal development when the life of the unborn child may be continued indefinitely outside the womb by natural or artificial life-supportive systems." Id. at 2831. For a discussion of the Department's minimum criteria for viability see note 169 infra.

5 Even the free substitution of words such as "experimentation," "research," "test," and the Department's more nebulous "activity" may be confusing. Experimentation, for example, appears to have a more invidious connotation than the word research.

The objectives of experiments on human beings cover a wide spectrum, but may be classified roughly as therapeutic or nontherapeutic. Many experiments are intended to benefit the subject (therapeutic experimentation). Frequently a doctor must treat a patient with an untried method because no "accepted" treatment exists. A doctor may also use a new method of treatment where other procedures are regarded as "standard practice," thinking that the new method will prove more beneficial to his patient or be equally beneficial to his patient but lead to improved treatment for other sufferers of similar disorders. On the other hand, many experiments are not intended to benefit the subject (nontherapeutic experimentation), but are conducted solely in the pursuit of new knowledge. The subject might be a patient under a doctor's care for an unrelated ailment . . . or he might be a healthy volunteer. Different standards should govern therapeutic and nontherapeutic experimentation. The therapeutic purpose itself serves to justify a doctor's exposing a terminal leukemia patient to substantial risk in an effort to prevent or postpone imminent death, while a stronger independent justification should be required for allowing a researcher to expose a healthy volunteer to a similar risk simply to gain new knowledge.

of theretofore unknown information, and all standard procedures performed for the same reasons but not in a context where such procedures would be customary practice.58

Lastly, in considering risk, it is important to assess the probability of harm that may result from an experimental procedure. Is the likelihood one in one thousand, one in fifty, or unknown? In the use of new therapies or the pursuit of new knowledge, physicians or medical researchers may have a general notion of risk; but the very newness of their activity may make a precise calculation impossible. One should also assess the magnitude of harm which may result. For example, is damage, if it occurs, likely to be measured in terms of minor, transient injury or life-long impairment of a vital organ?59 The answer to this question may depend partly upon a consideration of the interests which are put at risk. Are we concerned with protecting “health,” i.e., the physical, mental, or emotional well-being of the research subject or other affected persons, or “human dignity”?60 The latter concept, while nebulous in content, may be our paramount concern; the concept relates not to tangible injury, but to the preservation of values associated with individual human autonomy and worth.

B. Research on the Fetus In Utero

1. Legal Status of the Fetus In Utero

The first issue raised by the Department’s regulation controlling in utero experimentation41 does not go to the regulation itself but to the rationale upon which it is based: What rights does a fetus possess which entitle it to the protection afforded by the regulations? This section will examine different areas of the law which have dealt with the fetus in utero in an attempt to determine when such a fetus acquires certain interests or “rights.”62

58 For another definition, see Martin, supra note 3, at 549.
60 See Martin, supra note 3, at 554-56.
61 The regulation is quoted in the text accompanying note 127 infra.
62 For a more complete discussion of the rights of the fetus in utero in property, criminal, and tort law, see Louisell, Abortion, the Practice of Medicine and the Due Process of Law, 16 U.C.L.A.L. Rev. 233, 236-44 (1969).
a. Property law

Anglo-American property law has long accorded the fetus legal recognition. In an early English case, an unborn child was held to be one of the “children living” at the time of the testator’s demise. Three years later, another English decision rebutted the contention that a fetus is a nonentity:

Let us see, what this nonentity can do. He may be vouched in a recovery, though it is for the purpose of making him answer over in value. He may be an executor. He may take under the Statute of Distributions. He may take by devise. He may be entitled under a charge for raising portions. He may have an injunction; and he may have a guardian.

American law followed the English lead. In 1834, Hall v. Hancock held that a grandchild born almost nine months after the testator’s death was a beneficiary under a bequest to such grandchildren “as may be living at my death.” Most states have followed this Massachusetts opinion. Cases have held that a devise of land vests in an unborn child prior to its birth, and that a child may be an income recipient under a trust before birth. The cases recognize, however, that the property rights of a child in utero are not perfected until and unless the child is born alive.

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65 32 Mass. (15 Pick.) 255 (1834).
67 Deal v. Sexton, 144 N.C. 157, 56 S.E. 691 (1907).
69 G. PATON, A TEXTBOOK OF JURISPRUDENCE 396 (4th ed. 1972). See also Roe v. Wade, 410 U.S. 113, 162 (1973). Liberal construction of fetal property interests apparently stems from an attempt to carry out testator intent (the presumption being that a testator would not wish to exclude any of his issue); but such intent is viewed as applying to live-born children. This point of view is contested by Professor David Louisell, who argues that, in the process of litigation, it is natural that the cases would be decided after a child has been born, and that, under the circumstances, it is “superfluous” and “only dictum” for courts to require a “live birth” in order to establish legal rights:

Such decisions proceed more from a pragmatic sense of fairness and realism than from a philosophic conclusion of the existence in utero of autonomous human life. But this is only speculation. And whatever the motivation for the decisions, they are clear-cut holdings that a child in gestation is a
b. Criminal law

Some legal scholars maintain that the common law refused to recognize feticide as homicide unless the child was fully born and then died as the result of the prenatal injuries. This is disputed by others who believe that the early common law required not birth but quickening, or animation, for a fetus to be protected by the laws against homicide. Whatever the early English law, it is generally agreed that by the mid-seventeenth century the common law had adopted the "born alive" theory.

Most American jurisdictions have followed the "born alive" theory. Some state courts, however, have held that a fetus shall

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human person, hence an autonomous legal entity capable of possessing property.


"Fully born" means that the fetus is entirely separated from its mother, with an entirely independent life, with the umbilical cord cut, and with its own breathing and heart action. Jackson v. Commonwealth, 265 Ky. 295, 96 S.W.2d 1014 (Ct. App. 1936); Morgan v. State, 148 Tenn. 417, 256 S.W. 433 (1922).

"Quickening" is the stage of development "when the motion of the fetus becomes perceptible, usually about the middle of the period of pregnancy." State v. Patterson, 105 Kan. 9, 181 P. 609, 610 (1919).

H. de Bracton, The Laws and Customs of England, III, ii, 4, quoted and translated in Means, supra note 71, at 419, presents a description of 13th century English law: "If there be anyone who strikes a pregnant woman or gives her a poison whereby he causes an abortion, if the foetus be already formed or animated, and especially if it be animated, he commits homicide."

If a woman be quick with childe, and by a potion or otherwise killeth it in her wombe, or if a man beat her, whereby the childe dyeth in her body, and she is delivered of a dead childe, this is a great misprision, and no murder; but if the childe be born alive and dyeth of the potion, battery, or other cause, this is murder; for in law it is accounted a reasonable creature, in rerum natura, when it is born alive.

3 Coke, Institutes 50 (1648), as quoted by Means, supra note 71, at 420.

Singleton v. State, 33 Ala. App. 536, 35 So. 2d 375 (1948); People v. Ryan, 9 Ill. 2d
be regarded as a human being for the purpose of homicide statutes when it has reached viability. Several courts have required only a showing of "quickening" in fetal manslaughter cases. A number of others have extended the definition of "human being" for the purposes of manslaughter to include the fetus from the "moment" of conception.

c. Tort law

Early American tort law, as exemplified by the language of Justice Holmes in Dietrich v. Inhabitants of Northampton, denied recovery for fetal injury on the ground that "the unborn child was a part of the mother at the time of the injury." Until World War II, the Dietrich decision was followed universally. Courts based their opinions on Justice Holmes' erroneous knowledge of biology and on the difficult questions of causation involved in linking tortious conduct to prenatal injury.

467, 138 N.E.2d 516 (1956); People v. Hayner, 300 N.Y. 171, 90 N.E.2d 23 (1949); Harris v. State, 28 Tex. App. 308, 12 S.W. 1102 (1889); Bennett v. State, 377 P.2d 634 (Wyo. 1963). "'Person,' when referring to the victim of a homicide, means a human being who has been born and is alive." N.Y. PENAL LAW § 125.05(1) (McKinney 1975).


71 Evans v. People, 49 N.Y. 86 (1872); Foster v. State, 182 Wis. 298, 196 N.W. 233 (1923).


Roe v. Wade, 410 U.S. 113 (1973), will now, presumably, protect a physician from a charge of murder or manslaughter where the fetus dies in utero as a necessary result of abortion. See text accompanying notes 111-23 infra for a discussion of Roe v. Wade. The recent resolution in the case of Commonwealth v. Edelin, 359 N.E.2d 4 (Mass. 1976), reaffirms this conclusion. Freedom from a charge of homicide is more problematical in the experimentation context where a physician, not knowing the lethal effects of his experiment, injures a fetus which dies as a result. Capron Report, supra note 54, at 17.

The impact of Roe is completely unclear in more generalized situations involving homicide, as in the case of a man who fatally injures a fetus while beating a woman. Boston Globe, Oct. 3, 1975, at 16, col. 1. Depending on the wording of the applicable state statute, a charge might be brought whether the fetus dies before or after birth.

80 138 Mass. 14 (1884).

81 Id. at 17.
In 1946, in *Bonbrest v. Kotz*, a federal district court rejected the rationale and conclusion of *Dietrich* and declared that injuries to a viable unborn child were compensable in an action by the child after birth. The Minnesota Supreme Court extended this reasoning soon afterward, holding that a personal representative could maintain a wrongful death action for fetal injuries to a viable fetus. Other courts quickly followed this trend, leading to "the most spectacular abrupt reversal of a well settled rule in the whole history of the law of torts." Today, virtually every American jurisdiction permits recovery in tort for prenatal injuries. Differences still exist, however, in the requirements for actions by a surviving child and actions under wrongful death statutes; consequently, each area will be explored separately.

1. Action for prenatal injuries by a surviving child

Since such a claim is brought by the child himself, it is apparent that the tortfeasor's liability is prospective, contingent on the unborn child's live birth. Thus, a child who suffers nonfatal prenatal injuries, but who dies *in utero* before birth from independent causes, cannot maintain an action for those injuries. The status of the unborn child in respect to its right of recovery is not that of a legal person capable of asserting an independent right, but that of a separate living entity having a *potentiality* of legal personhood not fully recognized until birth.

A number of courts have implied that recovery for prenatal injuries is limited to cases where the alleged injury occurred at a viable stage of gestation. The principal rationale for this requirement is the difficulty in proving that a defendant's actions were the proximate cause of the child's previable injuries. However,

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82 Verkennes v. Cornies, 229 Minn. 365, 38 N.W.2d 838 (1949).
85 Id. at 337.
86 Cf. *La Blue v. Specker*, 358 Mich. 558, 100 N.W.2d 445 (1960) (holding that the unborn fetus is a "child" and a "person" entitled to bring an action for a parent's death prior to the child's birth).
88 See, e.g., the hypothetical case posed in *Todd v. Sandidge Constr. Co.*, 341 F.2d 75, 80 n.9 (4th Cir. 1964) (Haynsworth, J., dissenting).
the viability requirement has been widely criticized as arbitrary and unsatisfactory in limiting a potential tortfeasor's duty of care. Prosser has argued that compensation for prenatal injuries should not hinge on the stage of fetal development at the time of the injury, since the child sustains the same harm after birth regardless of the time when the injury occurs. In accord with Prosser's view, the current trend has been to eliminate the viability requirement in actions for prenatal injuries. Most jurisdictions which have recently ruled on the issue allow recovery for prenatal injuries even if the injury occurs early in pregnancy, before either viability or quickening.

2. Action for wrongful death

A wrongful death action may be brought in cases where a child does not survive to assert a claim. Neither the difficulty in assessing appropriate damages nor the difficulty in proving causation has been deemed sufficient to bar the action. But while every state permits recovery for wrongful death, there is sharp disagreement with respect to whether a live birth is required in order to maintain a wrongful death action. Courts in several jurisdictions require it, maintaining that there has been no harm to a "person" until the fetus is born alive.

Arrayed against these authorities are more than a score of

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90 W. Prosser, supra note 84, at 337-38.
92 W. Prosser, supra note 84, at 337 n.31, lists seven jurisdictions (California, Georgia, Louisiana, New Hampshire, New Jersey, Pennsylvania, and Rhode Island) as having expressly discarded the viability and quickening requirements.
93 Id. at 337.
jurisdictions which permit an action for the wrongful death of a viable fetus regardless of whether it is born alive.\textsuperscript{5} One state, Georgia, permits such an action for children injured when not yet viable but only “quick.”\textsuperscript{6} In order to permit recovery in these cases, courts have held that the unborn fetus is a “person” or “minor child” as a matter of statutory construction. In a recent case regarding the fetus’ statutory status, \textit{Eich v. Town of Gulf Shores},\textsuperscript{7} the Alabama Supreme Court declared:

   We recognize the cases cited by appellee construing the term “minor child” as not including a fetus, but are not persuaded that such a strict construction here would insure the necessary growth of the law in this vital area and the individual justice of the case before us.\textsuperscript{8}

The court held that the purpose of the Alabama wrongful death statute was to preserve human life, and that therefore a live birth was not a prerequisite to liability.\textsuperscript{9} The court criticized the “live birth” requirement as being illogical, since under such a standard a tortfeasor’s liability depends not on the seriousness of his wrongful conduct, but on whether the injured child is able to survive his injuries for at least a moment after birth. A wrongdoer is thus rewarded if his conduct kills a fetus immediately.\textsuperscript{10}


\textsuperscript{7} Id. at 98, 300 So. 2d at 356 (footnote omitted).

\textsuperscript{8} Id.

\textsuperscript{9} Id. at 97, 99, 300 So. 2d at 355, 357. The Illinois Supreme Court was persuaded to eliminate the “live birth” standard for wrongful death actions on this same rationale. Chrisafogeorgis v. Brandenberg, 55 Ill. 2d 368, 304 N.E.2d 88 (1974). In denying fetal “personhood” in \textit{Roe v. Wade}, Justice Blackmun attempted to reconcile his position with the fact that so many jurisdictions regarded the unborn fetus as a “person” under their
d. **Welfare law**

Until recently, another context in which the law appeared to be in conflict with respect to fetal status was in the definition of a "dependent child" in the Federal Aid to Families with Dependent Children (AFDC) program. The statutory interpretation of "dependent child" had caused much confusion in the courts, because nowhere in the statute was there mention of the unborn. The statute referred simply to needy children "under the age of eighteen." HEW regulations made matching funds available to the unborn, but the regulations were not mandatory, and the Department had approved state plans which made funds available to the unborn as well as plans which did not.

Four out of five federal courts of appeals which have recently considered this issue concluded that an unborn child qualified as a "dependent child" under the Social Security Act, and that a pregnant woman was, therefore, eligible to obtain AFDC benefits prior to her child's birth. The Fifth Circuit, for example, de-

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wrongful death statutes. Permitting parents to recover in tort for the wrongful death of their fetus, he asserted, is not based on the theory that the unborn child is a person in the full sense, but rather is designed to vindicate the parents' interest in the potentiality of human life. 410 U.S. at 162. Blackmun's view is difficult to reconcile with the fact that the wrongful death statutes are not framed in terms of "potential children." In construing the statutes, the courts have struggled to determine whether legislatures intended to include the fetus in the class of "persons" covered by the statutes. Moreover, it does not disprove legal personhood to say that a wrongful death suit for an unborn fetus is designed only to vindicate parental interests, since a wrongful death action always vindicates the interests of the family of the deceased. The fact that parents may recover in tort for the wrongful death of their child in no way diminishes the legal personhood of children.

In Great Britain the recent Law Commission Report on Injuries to Unborn Children considered the question of when parents may bring an action "for loss of their unborn child." The Commission recommended that such an action should be barred unless the fetus survives for at least 48 hours after delivery. Even before presentation of the Report to Parliament the 48-hour requirement was criticized as being illogical, partly on the ground that it might encourage doctors to take extraordinary measures to keep a fetus alive merely to satisfy a technical requirement. The Times (London), Sept. 12, 1975, at 14, col. 1. All attempts at line drawing ignore the fact that biological development lies on a continuum.

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The First, Fourth, Fifth, and Seventh Circuits had upheld fetal eligibility prior to
clared that "[a]n unborn child's lack of status as a 'person' for Fourteenth Amendment purposes does not affect the status of an unborn child as a 'child' within the language of the Act..."\textsuperscript{106} The Seventh Circuit based its finding of eligibility on the administrative practices of the Department of Health, Education, and Welfare and its predecessors, which had permitted prenatal benefit payments since 1941.\textsuperscript{107}

The Supreme Court held, however, that it was not mandatory for states receiving federal assistance under AFDC to provide benefits to pregnant women, since the unborn child did not qualify as a "dependent child" as defined by the Social Security Act.\textsuperscript{108} Because the Court based its holding on statutory construction, it expressly reserved the question of whether HEW has the statutory authority to approve federal participation in state programs which elect to continue payments for unborn children.\textsuperscript{109} Had the Court concluded that the unborn were indeed dependent children, it would have faced a serious equal protection issue in those states which excluded the unborn from coverage.\textsuperscript{110}

e. Roe v. Wade

Although the trend prior to 1973 appeared to be in the direction of expanding legal recognition of fetal interests, in that year the Supreme Court decided Roe v. Wade,\textsuperscript{111} the landmark decision in the area of abortion. The Court held that a woman's right


\textsuperscript{107} The Second Circuit denied fetal eligibility. Wisdom v. Norton, 507 F.2d 750 (2d Cir. 1974).

\textsuperscript{108} In Wisdom v. Norton, the Second Circuit Court of Appeals declared that the Department of Health, Education, and Welfare exceeded its statutory authority in permitting states to confer AFDC benefits upon the unborn child. 507 F.2d 750, 755 (2d Cir. 1974). In Burns v. Alcala, however, the Supreme Court refrained from determining whether HEW exceeded its statutory authority. 420 U.S. at 586.

\textsuperscript{109} Such a holding would have enunciated a view of fetal personhood inconsistent with its holding in Roe v. Wade, 410 U.S. 113 (1973).

\textsuperscript{110} Id. The Court further explicated its position on a woman's constitutional rights to abortion in Planned Parenthood v. Danforth, 96 S. Ct. 2831 (1976) and Bellotti v. Baird, 96 S. Ct. 2857 (1976).
of privacy is protected by the fourteenth amendment,\textsuperscript{112} that the decision to have an abortion falls within this right,\textsuperscript{113} and that the right to an abortion is fundamental and can only be subject to regulation when there is a compelling state interest.\textsuperscript{114} The state has two legitimate interests: maternal health and the protection of the potentiality of human life.\textsuperscript{115} Each interest acquires increasingly greater significance as the fetus develops during pregnancy. This maturing of significance permits limited state regulation to foster maternal health during the second trimester and provides the state with a compelling interest in proscribing abortion in order to protect the potentiality of human life during the third trimester or after viability, except where an abortion is necessary to protect the health of the mother.\textsuperscript{116}

With respect to fetal rights, what did Roe decide? The Court held that “the word ‘person,’ as used in the Fourteenth Amendment, does not include the unborn.”\textsuperscript{117} A fetus \textit{in utero} therefore enjoys no fourteenth amendment rights and, in all probability, no other constitutional rights until after birth, since the Court’s constitutional analysis was not limited to the fourteenth amendment.\textsuperscript{118} A state may choose not to restrict abortions even after viability; and a fetus has no constitutional right to object, despite the harm that might occur.\textsuperscript{119}

\begin{itemize}
  \item \textsuperscript{112} 410 U.S. at 153.
  \item \textsuperscript{113}  Id.
  \item \textsuperscript{114}  Id. at 155, 163.
  \item \textsuperscript{115}  Id. at 162.
  \item \textsuperscript{116}  Id. at 162-65.
  \item \textsuperscript{117}  Id. at 158.
  \item \textsuperscript{118}  Id. at 157. It is unlikely that the Court would be so inconsistent as to deem the fetus a nonperson for purposes of abortion and a person for other purposes.
  \item \textsuperscript{119}  Although Roe may appear to some to be the logical and ultimate extension of the Court’s concern for privacy in matters of sexual conduct enunciated in Griswold v. Connecticut, 381 U.S. 479 (1965) and Eisenstadt v. Baird, 405 U.S. 438 (1972), it has not gone without detractors. Professor John Ely, criticizing the decision as an unjustifiable extension of the constitutionally protected right to privacy and as court-made legislation, said:
    
    What is frightening about Roe is that this super-protected right [a woman’s freedom to choose an abortion] is not inferable from the language of the Constitution, the framers’ thinking respecting the specific problem in issue, any general rules derivable from the provisions they included, or the nation’s governmental structure.


    Certainly the Court in Roe has substantially expanded the notion of privacy. It is one thing to protect the privacy of the home and of those intimate sexual activities between
Although Roe held that the fetus is not a person in the fourteenth amendment sense, this decision does not necessarily mean that the fetus is not entitled to protection. As Roe acknowledged, the state has an “important and legitimate interest in protecting the potentiality of human life.” Whether a previable or viable fetus, as a potential human life, should be accorded protection should depend on a balancing of the interests asserted in a particular context, and those interests may differ in situations other than abortion.

When the mother's fundamental right to privacy is involved, the state may regulate only when its interest is compelling. Roe held that the state's interest in protecting the potentiality of human life becomes compelling when the fetus reaches viability (during the third trimester of gestation); thereafter, the mother's fundamental privacy right to abortion can be subordinated to the state's interest in protecting the viable fetus, except where the mother's life or health is endangered.

However, Roe leaves unanswered the question of the scope of the mother's fundamental privacy right. The decision might be

120 410 U.S. at 162. See note 114 and accompanying text supra. The potentiality concept is inapposite, however, to protection of the nonviable fetus which, by definition, is physiologically incapable of attaining viability. See notes 141-42 infra. Nevertheless, the nonviable fetus may be entitled to protection based on a fundamental “dignity” concept: The fetus, simply because it is a member of the human family, must be accorded certain considerations. See note 135 infra. See also note 100 supra.

121 410 U.S. at 163. The Court defined “viability” as that point of development at which the fetus is “potentially able to live outside the mother’s womb, albeit with artificial aid.” Id. at 160. The Court added: “Viability is usually placed at about seven months (28 weeks) but may occur earlier, even at 24 weeks.” Id.

122 See note 116 supra.
interpreted to confer on the mother an unfettered right to do what
she pleases with her fetus until the third trimester, but it can also
be narrowly construed as a determination of the respective rights
of mother and fetus only in the context of abortion. While Roe
acknowledges a mother's fundamental right to terminate her
pregnancy, it does not expressly grant a right to manipulate
fetal existence in any other context; nor does it expressly grant
the mother a right to consent to in utero experimentation.

If the mother's privacy right in Roe is broadly construed to
ecompass absolute control over the fetus in the first two trimes-
ters, the state might nevertheless assert a compelling interest in
protecting the potentiality of life at a point earlier than viability
when a procedure such as nontherapeutic experimentation,
rather than abortion, is planned. And if Roe is strictly construed
to apply only to abortion, then there is no precedent to assume
the mother's fundamental privacy right includes fetal experimen-
tation, and state regulation to protect the fetus' potentiality for
a full life need not be justified by a compelling interest. The state
would merely have to demonstrate a rational basis for the asser-
tion of its interest. Thus, even though Roe deems the fetus a
nonperson for constitutional purposes, it may nevertheless be en-
titled to protection where the state demonstrates a compelling
interest in the potentiality of life in the nonabortion context, or
where the fundamental rights of the mother are not at issue.

A somewhat analogous situation arises in cases involving the
state's power to restrict experimentation on animals. Animals,
like the fetus, enjoy no constitutional rights. Yet a rational
basis for the statutes banning cruelty to animals in most, if not
all, states can be found in the dehumanizing and brutalizing
effect on society of needless cruelty inflicted on helpless crea-
tures. These statutes, attacked as unconstitutional takings of

123 That the constitutional right of privacy encompasses a woman's right to obtain an
abortion is difficult to square with cases holding that a person has no absolute right to
bodily privacy. E.g., Schmerber v. California, 384 U.S. 787 (1966) (involuntary blood test
for criminal evidence); Buck v. Bell, 274 U.S. 200 (1927) (involuntary sterilization); Jacob-
sen v. Massachusetts, 197 U.S. 11 (1905) (compulsory vaccination). See also note 128
infra.


125 See, e.g., ILL. ANNOT. STAT. ch. 8, § 704 (1975); IOWA CODE ANN. § 717.3 (1946);
MASS. GEN. LAWS ANN. ch. 272, § 77 (Supp. 1976).
property without due process of law, have been upheld as a legitimate exercise of the police power to protect public morality.\textsuperscript{128} If a state or the federal government may regulate animal research, it surely may regulate fetal research to protect the potentiality of human life; and it is inconceivable that the protection accorded to the fetus, even when balanced against the interests of society in the results of fetal experimentation, would not be greater than those accorded to animal research subjects.

2. Regulation of Research on the Fetus \textit{In Utero}

Section 46.208 of the Department’s regulations addresses activities directed toward fetuses \textit{in utero} as subjects.

(a) No fetus \textit{in utero} may be involved as a subject in any activity covered by this subpart unless: (1) The purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.\textsuperscript{127}

One example of research addressed by this section of the regulations is the development of a perfected fetoscope for the diagnosis and amelioration of fetal diseases and defects. Other examples include detection of fetal breathing through ultrasound, fetal heartbeat through electrocardiogram, and fetal vision through light shined transabdominally. The administration of certain drugs to the mother in an effort to determine whether they will cross the placenta and provide therapy to the fetus before birth would also be covered by this section. Some of these procedures involve only minimal violation of bodily integrity and appear to pose little risk. With other procedures, however, the hazards of research are incalculable; and the decision to use the

\textsuperscript{128} Burr, Toward Legal Rights for Animals, 4 Env. AFF. 205, 207 (1975). Of course, as might be expected, in a genuine collision of animal and human interests, the interests of animals have been forced to give way. The Animal Welfare Act, 7 U.S.C. §§ 2131-55 (1970), provides protection for most warm-blooded animals in terms of requirements such as adequate housing, ample food and water, and decent sanitation. But the act in no way authorizes “disruption or interference with scientific research or experimentation.” Similarly, states assign animals quite limited rights in the area of research, barring only “unnecessary” infliction of pain, but permitting the use of animals for “the testing of drugs or medicines.” See, e.g., MASS. GEN. LAWS ANN. ch. 49A, § 2 (1968).

\textsuperscript{127} 45 C.F.R. § 46.208 (1976).
research technique may depend on the anticipated benefit to the fetus.

Despite its sound legal foundation, the regulation raises serious questions because of its (perhaps deliberate) imprecision of language. This imprecision may lead to two situations where possibly unintended results could occur. One situation involves the requirement of consent by both parents before physicians may render even a life-saving, therapeutic, but experimental treatment to their unborn fetus. Apparently therapeutic care may be withheld if either parent objects. Were this situation to arise with respect to a child, however, it is entirely possible that upon petition a court would intervene, declare the child neglected, and order the treatment under its parens patriae power. It is not clear, however, that a court would, or could, intervene if it finds the fetus is not a human person equivalent to a child. The regulation could have been drafted to provide an exception to parental consent in cases of serious, possibly life-threatening illness or injury, although the draftsmen may have believed that a judicially applied common law or statutory remedy would still be available.

There is also reason for concern, in the case of nontherapeutic research, with the requirement that the risk be "minimal." If a procedure is truly experimental, the degree of risk is definitionally unascertainable. Moreover, the word "minimal" disguises the measurement to be used; does it refer to the likelihood of injury, the magnitude of injury, or both? Many would regard even the possibility of minor injury as unacceptable and unnecessary.

128 In a case decided before Roe v. Wade, the New Jersey Supreme Court required that a pregnant woman obtain blood transfusions necessary to save the life of her unborn fetus. The woman had refused the transfusions on religious grounds. (She was a Jehovah's Witness.) The court stated:

We are satisfied that the unborn child is entitled to the law's protection and that an appropriate order should be made to ensure blood transfusions to the mother in the event that they are necessary in the opinion of the physicians in charge at the time.

Raleigh Fitkin-Paul Morgan Mem. Hosp. v. Anderson, 42 N.J. 421, 422, 201 A.2d 537, 538, cert. denied, 377 U.S. 985 (1964). This holding is not necessarily foreclosed by Roe v. Wade, since it involved compulsory prenatal medical care for a "viable" fetus. Since the state may assert a "compelling interest" in the potential life of the fetus during the third trimester of pregnancy, it may arguably require a pregnant woman to obtain certain types of therapeutic care, despite the fact that this requirement might impinge on "fundamental" privacy and religious rights.
when the fetus will receive no benefit, even though others might characterize the risk in such a case as minimal.

More importantly, particularly from a substantive point of view, the notion of what constitutes minimal risk may vary depending on whether or not a fetus will be aborted.\textsuperscript{129} Because the regulations\textsuperscript{130} are not clear on this point, the contention may be raised that a previable fetus is incapable of being subject to risk, because it will necessarily die following abortion. In addition, if it is scheduled to die by techniques which will mutilate it in any event,\textsuperscript{131} why be squeamish about conducting research which may result in lesser degrees of harm?

There are several responses to this assertion. For example, it may be argued that the decision to abort involves the taking of a life. Even if, as a pragmatic matter, that taking is permissible under the law, our instincts should be to preserve and protect life whenever possible.\textsuperscript{132} Therefore, no undue influence should be imposed upon a woman to abort.\textsuperscript{133} Experimentation, if it involves

\textsuperscript{129} There are very valid reasons for conducting fetal research, and it makes good research sense to use a fetus scheduled for abortion in a potentially hazardous but valuable experiment, e.g., in studies concerning drug transfer across the placenta. See note 19 and accompanying text supra.

\textsuperscript{130} See 45 C.F.R. §§ 46.206(2), (4) (1976).

\textsuperscript{131} During the first 12 weeks, or first trimester, of pregnancy, both dilation and curettage ("D and C") and vacuum curettage procedures are employed for abortion. The former involves widening the mouth of the cervix and scraping and emptying the uterus manually. The latter involves the use of a vacuum-powered device to scrape the fetus, placenta, and amniotic sac from the uterine wall, homogenize them, and suck them out of the uterus. Interview with James H. Staton, Executive Director of the Boston Hospital for Women, in Boston, Feb. 19, 1975.

Abortions are generally not performed from the twelfth through the sixteenth week of pregnancy, but between sixteen and twenty weeks, two methods are used: Injection of saline solution into the uterus, or intravenous injection of the drug prostaglandin. In almost all cases, a saline abortion kills the fetus, often deforming it hideously. Interview with Dr. David Nathan, Professor of Pediatrics, Harvard Medical School, Children's Hospital Medical Center, Boston, Mass., in Boston, Feb. 13, 1975. Prostaglandin may not kill the fetus, but at least 90\% of the fetuses aborted by this method are born dead. If a fetus shows some signs of life—a determination made by the delivering physician—it generally dies within minutes, or at most a few hours. Boston Globe, Feb. 13, 1975, at 3, col. 1.

If these methods do not induce an abortion of the fetus, a hysterotomy, or little Caesarian, is performed. This is a surgical procedure in which the fetus is removed intact from the uterus, and it may be the procedure of choice for pregnancies between 20 and 24 weeks. This method poses the smallest health risk to the fetus and the greatest risk to the pregnant woman. Id.

\textsuperscript{132} Fetal Research Report, supra note 19, at 33,539.

\textsuperscript{133} Statement by R. Wasserstrom, id. at 33,540.
a potential hazard of deforming the fetus, will compromise the mother's choice of whether to carry it to full term, since once the decision has been made to have an abortion, subsequent experimentation may preclude the mother from reconsidering that decision.134

More important than the rather utilitarian argument on withdrawal of consent is the contention that nontherapeutic experimentation on a fetus in utero involves an assault on the dignity of a potential human being.135 Until abortion actually occurs, the fetus scheduled for abortion should be treated no differently than the fetus carried to full term.136 Professor Louisell, in his dissent to the Commission's recommendations, states: "The argument that the fetus-to-be-aborted 'will die anyway' proves too much. All of us 'will die anyway.'"137 We should not subject a terminally ill cancer patient to potentially harmful nontherapeutic experimentation simply because the person lacks what most of the rest of us have—an unascertainably long and full future life. Arguably, we should do the same for a fetus, whether or not it has full status as a person.

C. *Research on the Nonviable Fetus* Ex Utero

The regulation governing research on fetuses ex utero, including nonviable fetuses, provides that:

134 A similar withdrawal of consent problem exists in adoptions of newborn children. Frequently a mother, who before giving birth has consented to surrender her child for adoption, wishes to withdraw that consent upon or shortly after birth. To cope with this problem,

[a] number of states have statutes which declare invalid any consent executed by a mother before the birth of the child . . . [T]he British Adoption Act of 1958 . . . absolutely voids any consent unless the infant is at least six weeks old on the date of the execution of the document.


135 Prior to the abortion of the fetus, its protection may be justified on two grounds: First, its potentiality for human existence; and, second, because it should be afforded a measure of human dignity. The term "dignity," as used here, encapsulates those pragmatic, theological, and metaphysical considerations which give worth and value to human existence; it relates to the notion that the fetus is entitled to respect simply because it is a member of the human family.

136 Once abortion occurs, however, the potentiality of continued existence is terminated and can no longer serve as the basis for protection of fetal rights. The fetus should then be treated, with respect to experimentation, like other nonviable fetuses and accorded a measure of dignity, and, hence, protection. See notes 138-84 and accompanying text infra.

137 *Fetal Research Report*, supra note 19, at 33,549 (dissent by D. Louisell).
(a) No fetus *ex utero* may be involved as a subject in an activity covered by this subpart until it has been ascertained whether the particular fetus is viable, unless: (1) There will be no added risk to the fetus resulting from the activity, and (2) the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(b) No nonviable fetus may be involved as a subject in an activity covered by this subpart unless: (1) Vital functions of the fetus will not be artificially maintained except where the purpose of the activity is to develop new methods for enabling fetuses to survive to the point of viability, (2) experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and (3) the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.3

The regulation prohibits any research which may subject a fetus *ex utero* to additional risks until it has been ascertained whether that fetus is viable. If a fetus is found to be viable, it must be treated as a premature infant.1 If, however, the fetus *ex utero* is found to be nonviable, it may be the subject of research to further the development of important biomedical knowledge which cannot be obtained by other means.140

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138 45 C.F.R. § 46.209 (1976). HEW has received criticism of the concept of viability as it applies to the fetus *ex utero*. The Department noted, in response, that both it and the Commission were aware of the medical uncertainty inherent in the term “viability” and that, therefore, the regulations defining a viable fetus used very conservative criteria to insure against medical error in determining viability. Consequently, HEW proposed no changes in the use of the terms “viability” or “fetus *ex utero*.” 42 Fed. Reg. 2792 (1977).

139 45 C.F.R. § 46.203(d) (1976). The regulation specifies that “[i]f a fetus is viable after delivery, it is a premature infant.” Once a fetus attains the status of a premature infant, a legal duty of care arises for both the attending physician and the parents. Generally this duty requires that life-saving therapeutic assistance be rendered so that the premature infant will have the opportunity to survive. For a discussion of this legal duty of care in related areas see Robertson, note 186 infra; Paulsen, supra note 4.

140 The permissible risk associated with such research is not clear. The regulations contain a general provision requiring minimal risk in activities unrelated to fetal health needs. 45 C.F.R. § 46.206(2) (1976). This standard is imprecise and difficult to apply even to fetal experimentation generally. See text accompanying notes 59-60 supra. In the unique situation of the nonviable fetus which cannot be “harmed for life,” however, minimal risk may be a meaningless proposition. See text accompanying note 159 infra. Perhaps for this reason, the regulations pertaining to the nonviable fetus omit any reference to risk, 45 C.F.R. § 46.209, in contrast to the provisions regulating research on the fetus *in utero* where the concept of minimal risk is expressly included, id. § 46.208(a).

The difficulty of defining permissible risk for the fetus *ex utero* raises a potential problem in the application of the Department’s waiver provisions. The regulations provide that the Secretary may modify or waive specific limitations on fetal research after considering:
1. Rights of the Nonviable Fetus

Obviously, the critical distinction in the regulations is between those ex utero fetuses which are viable and those which are not. The regulations define viability as "being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration." A lack of viability does not, however, mean that the fetus is already dead. The nonviable fetus ex utero is similar to any other being which, having lost a vital function, must necessarily die. But, while a nonviable fetus is a fortiori dying and has no potentiality for continued life, it may be regarded as a living person for the duration of its short existence. Is there, then, any scientific or moral justification for conferring fewer of the rights of humanity on the nonviable fetus than are required for the viable fetus? Is the distinction made in the regulations a tenable one?

a. Legal precedent

Legal source materials are of little help in answering this question. While many courts and commentators have struggled to define the status of the fetus in utero, there is a curious void in considering the status of beings born prior to the stage of viability. In tort and homicide cases, for example, most courts will confer human status on an infant who is born alive, without apparent regard to whether the infant is viable or nonviable. The

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whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant such modification or waiver and that such benefits cannot be gained except through a modification or waiver.

Id. § 46.211. Approval by both an Institutional Review Board and an Ethical Advisory Board is required. Despite this significant safeguard, if risk is, in fact, seen as a meaningless concept in the context of research on the fetus ex utero, the waiver provisions might give rise to potentially degrading forms of research on such fetuses, a result which the promulgation of the regulations was originally intended to prevent.

141 45 C.F.R. § 46.203(d) (1976).

142 The regulations define a dead fetus as one "which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached)." Id. § 46.203(f). A nonviable fetus may possess one or more of these attributes; but absent appropriate weight and age, these attributes are not themselves sufficient to indicate viability. FETAL RESEARCH REPORT, supra note 19, at 33,543.

143 See, e.g., People v. Chavez, 77 Cal. App. 2d 621, 176 P.2d 92 (1947); People v. Ryan, 9 Ill. 2d 467, 138 N.E.2d 516 (1956); Jackson v. Commonwealth, 265 Ky. 295, 96
courts will usually confer blanket human status in homicide cases as long as the child has been completely expelled from the mother's body and has a separate and independent existence.\textsuperscript{144} Proof of independent existence frequently depends on a showing of "independent circulation and/or respiration";\textsuperscript{145} but a fetus may be patently nonviable and still be capable of having "independent circulation and/or respiration."\textsuperscript{146} Presumably, the nonviable fetus has a "separate and independent existence" for the duration of its life and, therefore, qualifies as a human person under the homicide statutes.

The point is not clear, however, because case law usually deals with the murder of babies at full term.\textsuperscript{147} In People v. Chavez,\textsuperscript{148} for example, it was held that a viable child, in the process of being born, may be considered a live "human being" within the meaning of the homicide statute. Likewise, in Singleton v. State,\textsuperscript{149} the court, citing People v. Chavez with approval, stated that a baby should be regarded as a human being if it is viable and, after separation from the mother, capable of life if given normal and reasonable care. Neither court expressly decided, however, whether a nonviable, live-born fetus would similarly be regarded as a human being.

Like the judiciary, state legislatures have not addressed the issue directly. Most fetal experimentation statutes prohibit research on live fetuses; and "life" is variously defined.\textsuperscript{150} Their

\textsuperscript{144} See, e.g., Montgomery v. State, 202 Ga. 678, 44 S.E.2d 242 (1947); Logue v. State, 198 Ga. 672, 32 S.E.2d 397 (1944); State v. Winthrop, 43 Iowa 519 (1876); People v. Hayner, 300 N.Y. 171, 90 N.E.2d 23 (1949); State v. Collington, 259 S.C. 446, 192 S.E.2d 856 (1972); Morgan v. State, 148 Tenn. 47, 256 S.W. 433 (1923).

\textsuperscript{145} See, e.g., State v. Winthrop, 43 Iowa 519 (1876); People v. Hayner, 300 N.Y. 171, 90 N.E.2d 23 (1949).

\textsuperscript{146} See note 142 supra.


\textsuperscript{148} 77 Cal. App. 2d 621, 176 P.2d 92 (1947).

\textsuperscript{149} 33 Ala. App. 536, 35 So. 2d 375 (1948).

\textsuperscript{150} In Maine "life" is defined as "beating of the heart, pulsation of the umbilical cord or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached." Me. Rev. Stat. Ann., tit. 22, § 1576 (Supp. 1975). Note that spontaneous respiration is omitted, even though respiratory activity is the \textit{sine qua non} of human life.
language is neither consistent nor sophisticated. One is left with
the impression that most legislatures proceeded on the unarticu-
lated premise that personhood begins at conception. Blocked
from conferring this status on the fetus in utero by Roe v. Wade,\footnote{\textit{Id.} at 161.}
they seized upon any reasonable sign of life as sufficient to confer
personhood once birth or abortion has occurred.

What of \textit{Roe v. Wade}? Unhappily, those who might have
anticipated some illumination by the Supreme Court will be dis-
appointed. At one point the majority opinion remarks that “the
law has been reluctant to endorse any theory that life . . . begins
before live birth.”\footnote{\textit{Id.} at 2848.} “Live birth” is not explained, however; and
in a subsequent opinion, \textit{Planned Parenthood v. Danforth},\footnote{\textit{Id.} at 2855 (White, J., concurring in part and dissenting in part).}
the Court does little to clarify the issue. The majority opinion in
\textit{Danforth} appears to equate personhood with live birth and viabil-
ity; but while both the majority and Justice White employ words
such as “live-born infant”\footnote{See, \textit{e.g.}, L. \textit{Arey, Developmental Anatomy: A Textbook and Laboratory Manual of Embryology} (7th ed. 1965); G. \textit{Flanagan, The First Nine Months of Life} (1962); W. \textit{Hamilton} \& H. \textit{Moseman, Human Embryology} (1972); B. \textit{Patten, Human Embryology} (rev. ed. 1976); G. \textit{Corner, An Embryologist's View, in Abortion in a Changing Society} (1970).} and “live babies”\footnote{\textit{Id.} at 2855 (White, J., concurring in part and dissenting in part).} when discussing fetuses \textit{ex utero}, no distinction is made between viable and nonvi-
able fetuses and no definition is offered.

\paragraph{b. Scientific justification}

In view of the ambiguity in judicial opinions, it is not surpris-
ing that when we turn from law to science, to hoped-for certainty
in the growing body of knowledge concerning fetal growth and
development, we obtain little in the way of clarification. Instead
of firm demarcation lines, we find a continuum, a process in

There is no point of discontinuity, no point at which we can
confidently say in biological terms that \textit{this} fetus is a person and
\textit{that} one is not.

[T]he advance of embryology and medicine over the past century
and a half rendered untenable any notion that the fetus suddenly

\begin{footnotesize}
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\item \textit{non} of viability. See 45 C.F.R. § 46.203(f) (1976).
\item 410 U.S. 113 (1973).
\item \textit{Id.} at 161.
\item 96 S. Ct. 2831 (1976).
\item \textit{Id.} at 2848.
\item \textit{Id.} at 2855 (White, J., concurring in part and dissenting in part).
\end{itemize}
\end{footnotesize}
“came to life” in a physiological sense at a definable point during pregnancy. Once the embryo’s growth had been traced in a continuous line from a single unfertilized ovum through the unbroken processes of fertilization, cell division, segmentation (in the case of identical twins), implantation of the blastocyst in the uterine wall, and a gradual fetal development to the point of birth, those who believed in the sanctity of the fetus from the “moment” of quickening, or from some other “moment”, were deprived of the ability to link their belief to any distinct physical or biological event other than perhaps “conception”, which was itself later revealed as a complex and continuous process.107

c. An ethical view

Clearly, both scientific technology and legal precedent are of little assistance in ascertaining whether the distinction between viable and nonviable fetuses is an appropriate one for determining the existence of human rights. In fact, the sole justification for this distinction may lie in a discussion of the ethical issues involved in research on the fetus ex utero.

In its report to HEW, the National Commission began its analysis with the view that the nonviable fetus “must be considered a dying subject.”158 The Commission then stated that this status alters the situation of the fetus in two ways. “First, the question of risk becomes less relevant, since the dying fetus cannot be ‘harmed’ in the sense of ‘injured for life.’”159 Unlike the previable fetus in utero, its potential for continued existence is gone.

Second, however, while questions of risk become less relevant, considerations of respect for the dignity of the fetus continue to be of paramount importance, and require that the fetus be treated with the respect due to dying subjects. While dying subjects may not be “harmed” in the sense of “injured for life,” issues of violation of integrity are nonetheless central.160

The Department echoes this sentiment, stating that for fetuses ex utero “no procedures will be undertaken which fail to treat the fetus with due care and dignity, or which affront community sensibilities.”161

107 Tribe, supra note 119, at 19-20 (footnotes omitted).
158 Fetal Research Report, supra note 19, at 33,546.
159 Id.
160 Id.
161 Id. at 33,528.
After uttering these protestations, however, both bodies apparently conclude that the nonviable fetus' "dignity" does not preclude all nontherapeutic research, but only such research which alters the duration of fetal life.\(^2\) Thus, where important biomedical knowledge may be gained, the Commission, and the Department by implication, apparently embrace the rationale that they expressly reject: Nontherapeutic research on the nonviable fetus is permissible because the fetus cannot be "harmed" or "injured" for life. In addition, the regulations provide that researchers may artificially sustain the life signs of a nonviable fetus—admittedly an alteration of the duration of life, but arguably therapeutic\(^3\)—if the purpose of the research is the development of artificial life support systems.\(^4\)

In arriving at what seems to be a clear compromise between principle and practice, both organizations may have concluded that there is no completely satisfactory way to balance the demands of medical research against the rights of a being whose status as a legal "person" has not been definitely ascertained. On the basis of biological facts, a categorical assertion that the nonviable fetus either is or is not a "person" entitled to certain rights is unwarranted. Given this uncertainty, however, caution alone suggests that doubts should have been resolved in favor of personhood and that the nonviable fetus should be regarded as a full human being in the research context.

In advocating the permissibility of research on the nonviable fetus, however, both the Commission and the Department may have been influenced by the ethical approach advocated by Dr. Sissela Bok. In reference to the problem of abortion, Dr. Bok has suggested that "[w]e must abandon . . . a definition of humanity capable of showing us who has a right to live,"\(^5\) and examine, instead, the reasons for protecting life. In a paper submitted to the National Commission, Dr. Bok advanced a similar thesis with respect to fetal experimentation. She proposed four reasons for protecting humans from harm: "(1) [T]he victim's anguish, suf-

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\(^2\) See 45 C.F.R. § 46.209 (1976); Fetal Research Report, supra note 19, at 33,546.

\(^3\) See text accompanying notes 178-83 infra.

\(^4\) The issue of artificially sustaining the life signs of a nonviable fetus for the purpose of developing an artificial placenta is a major area of conflict between the Commission and the Department. See note 40 supra.

\(^5\) Bok, Ethical Problems of Abortion, 2 Hastings Center Studies 33, 41 (1974).
ferring and deprivation of continued experience of life; (2) the brutalization of the agent; (3) the grief of those who care about the victim; and (4) the establishment of a pattern that ultimately will harm all of society."

Dr. Bok concluded that none of these reasons was applicable to a fetus in the early stages of gestational life. But this approach poses a new dilemma. Instead of a biological continuum, we are confronted by a continuum of reasons for protecting a fetus ex utero the further along it is in the process of development. Here it may be equally difficult to draw a line. However, in terms of Dr. Bok's ethical analysis, the Department's 20-week minimum age criterion for viability is reasonable, albeit arbitrary. Undeniably, a 19-week-old, nonviable fetus looks human; but according to most medical experts, it cannot feel pain or experience emotional anguish, and certainly cannot apprehend its circumstances. These facts, if known, could avoid possible grief to the parents resulting from experimentation; and the parental consent requirement can effectively prevent research which would offend the feelings of the mother and father. Nor would research on the

166 Fetal Research Report, supra note 19, at 33,538.
167 Id.
168 Id.
169 This difficulty may ultimately require that all "human" dying subjects be protected, regardless of age, expectation of life, or circumstance. P. Ramsey, The Ethics of Fetal Research 33-35 (1975).
170 As minimal criteria to identify viability, the Department requires "an estimated gestational age of 20 weeks or more and a body weight of 500 grams or more." Fetal Research Report, supra note 19, at 33,552. See also notes 41 and 55 supra. These requirements are conservative. The National Commission, on the basis of a study conducted by Dr. Richard Behrman of Columbia University, concluded that a fetus must weigh 601 grams or more and have a gestational age over 24 weeks to sustain independent growth and development. Id. at 33,542-44. The Commission could find no unambiguous documentation that a fetus with weight and age below these limits had ever survived; and the chances of survival of an infant weighing less than 750 grams are extremely small. Id. at 33,543.
171 Note the reaction of the jury in the Edelin trial to pictures of a fetus only slightly older. Boston Globe, Feb. 16, 1975, at 2, col. 1. See note 31 supra.
172 It is highly unlikely that the fetus has the capacity to experience pain prior to 28 weeks. See Scarf, supra note 2, at 93-94. No one actually knows, however, whether this assertion is true. Interview with Dr. David Nathan, Professor of Pediatrics, Harvard Medical School, Children's Hospital Medical Center, Boston, Mass., in Boston, Feb. 13, 1975.
174 The regulations specify that research may be conducted "only if the mother and father are legally competent and have given their informed consent." 45 C.F.R. § 46.209(d)
nonviable fetus be brutalizing for the researcher.

Moreover, it seems highly unlikely that nontherapeutic research on the nonviable fetus will open the door to similar research on persons distinguished by race, religion, or status who have been subjected involuntarily to research in the past.\(^\text{174}\) Because there is almost no likelihood that it experiences pain or discomfort, due to its undeveloped nervous system, the nonviable fetus differs substantially from a more mature subject, even one who is unconscious and dying.\(^\text{175}\) Given these distinctions, it seems unlikely that values we cherish in this society—respect for the dignity and integrity of others—will be affronted by this type of research. Subjecting the nonviable fetus to nontherapeutic experimentation will not cause us to fear, as it might with research on retarded or incarcerated subjects, that such experimentation could be extended without logical break to all others.\(^\text{176}\)

To argue that nontherapeutic research is permissible, however, is not to argue that it should proceed without regulation. Although the nonviable fetus occupies a unique status, as a person it is entitled to substantial protection. Even if its personhood is denied, the dignity it is accorded, while not sufficient by itself to countermand the needs of medical research, should be sufficient to compel elaborate safeguards and to eliminate offensive and degrading forms of research. A number of safeguards are discussed in section III of this paper.\(^\text{177}\)

2. Research Which Artificially Sustains the Life of a Nonviable Fetus

One particular form of experimentation on the nonviable fetus deserves special scrutiny: Research which artificially maintains vital functions in order "to develop new methods for enabling fetuses to survive to the point of viability."\(^\text{178}\) A desire to

\(^{174}\) The "opening wedge" argument is usually employed by those who object to the wedge, but cannot muster sufficient arguments against it; instead, they point to all the dire possibilities that may result from the extension of a principle. The law is replete with line drawing; and there are often dire possibilities on either side of the line.

\(^{175}\) Cf. In re Quinlan, 335 A.2d 647 (N.J. 1976).

\(^{176}\) See Martin, supra note 3, at 565.

\(^{177}\) See notes 190-268 and accompanying text infra.

\(^{178}\) 45 C.F.R. § 46.209(b)(1) (1976). See text accompanying note 244 infra for standards which should govern this type of research.
eliminate offensive and degrading forms of research seems inconsistent with this type of experimental activity. Past research projects, such as the one in which fetuses were submerged in hyperoxygenated saline solution because their lungs were insufficiently developed to permit them to breathe, involve methods which offend and shock a significant segment of society. In view of this reaction, persuasive justification should be required for activities which so substantially assault notions of "human" dignity and bodily integrity.

One such justification might be the argument that research using the nonviable fetus to develop an artificial placenta meets fetal health needs. As a general limitation on fetal experimentation, the Department's regulations require that the risk to the fetus should be minimal and the least possible for achieving the objectives of the activity, "except where the purpose of the activity is to meet the health needs of . . . the particular fetus." It would seem to follow from the regulation that any risk, pain, indignity, or discomfort to a fetus is acceptable, if its health or life even possibly hangs in the balance. The law appears to support this societal objective.

No one would deny, however, that for most fetuses involved in this type of research death is inevitable. Researchers will be able to devise sophisticated techniques which will allow them to sustain a fetus' life signs long after it would die naturally if left undisturbed. There is no chance that the nonviable fetus will benefit in any way as a result of these herculean efforts, other than having its life prolonged. As the research techniques are perfected and the technology comes closer to achieving its objective, the struggle for life may be sustained over a substantial period of time. Can one reasonably analogize these projects to

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177 See note 27 supra.
178 See note 142 and text accompanying notes 59-60 supra for a discussion of the difficulty involved in defining risk.
180 In a recent case, a Maine court declared that a mother and father had "neglected" their defective newborn infant by refusing to obtain "ordinary" medical care. A guardian was appointed for the child and surgery was performed. When the child subsequently died, the parents expressed great anguish at having been brought into court and having the decision to seek surgery taken out of their hands. Maine Medical Center v. Houle, Civil No. 74-145 (Supreme Court of Cumberland County, Feb. 14, 1974), reported in Washington Post, Feb. 25, 1974, at 1, col. 1.
therapeutic attempts to keep a patient alive through extraordinary means, when there is almost no chance for fetal survival, and the primary purpose of the procedures is to accumulate scientific data?

These conflicting considerations make a judgment about the therapeutic or nontherapeutic character of the research extremely difficult. If the possibility of life is the goal, and if any given fetus may achieve this objective for even a limited period of time, then the research may be characterized as therapeutic. On the other hand, if the practical implications of the research are borne in mind, it seems clear that most fetuses used in these experiments will be research subjects with no hope of obtaining a real benefit. By this characterization, clearly the research is nontherapeutic.

It may be argued, however, that this research is therapeutic for the particular fetuses involved. Our values adjure us to preserve life regardless of its quality; and distinctions are not drawn as to whether we should implement this value only if the preservation is for longer than an hour, a day, a week, or some other period of time. Preserving life in all its contexts furthers an important societal objective. It is difficult to argue, moreover, that research designed to preserve life has an intrinsically brutalizing effect or that it opens the door to experimental atrocities on other classes of defenseless subjects. Nevertheless, because of the nature of this research, substantial prior animal testing should be required in the development of an artificial placenta before using human fetal subjects; and the participation of human fetuses should be limited to situations where there is some, even if remote, chance of ultimate survival. These limita-

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183 Because we should generally strive to preserve life, it does not follow that we should be compelled to do so in all circumstances, e.g., "[when] the degree of bodily invasion increases and the prognosis dims." In re Quinlan, 355 A.2d 647, 664 (N.J. 1976). Neither should we be forbidden to do so. Parents of a nonviable fetus should be free to consent or withhold consent to its participation in this form of experimentation.

184 Currently, the regulations provide that "vital functions of the fetus will not be artificially maintained except where the purpose of the activity is to develop new methods for enabling fetuses to survive to the point of viability." 45 C.F.R. § 46.209(b)(1) (1976). See note 138 and accompanying text supra. In response to criticism of this provision by the National Commission, see 42 Fed. Reg. 2792 (1977), HEW has proposed an amendment to "reflect the Department's actual intent . . . to permit artificial maintenance of vital functions only to enable the particular fetus 'to survive to the point of viability.'" Id. The proposed regulation provides that, with respect to an ex utero fetus whose viability has not been ascertained, the purpose of the research must be "to enhance the possibility
tions would insure that nontherapeutic elements, such as the opening of fetal chest walls to observe heartbeat, do not predominate in the research design.

3. A Duty to Experiment?

One final issue is raised by the regulations permitting research which artificially sustains life. If this type of research is characterized as therapeutic, may desperate parents, following premature, spontaneous delivery of a nonviable or possibly viable fetus, resort to legal action to compel experimentation in the hope of obtaining a viable offspring? The answer to this question is probably in the negative, since it is unclear on what theory parents could force physicians to reverse a decision not to experiment. A malpractice action would occur subsequent to the event and would be inapposite because of the customary practice rule.\textsuperscript{185} Specific performance based on a theory of contract between parents and doctor would probably be no more successful; at best, a doctor contracts to render reasonable, ordinary care. When a procedure has no realistic prospect of success, is extraordinary in nature, and requires a willing application of skill in its performance, it is highly unlikely that it could or should be compelled.\textsuperscript{186}

In addition, it is unclear whether an obstetrician attending a mother at an abortion prior to the third trimester must assume the fetus is a patient once "birth" occurs and, in keeping with good medical practice, act to preserve its life and health. The Supreme Court, in \textit{Planned Parenthood v. Danforth},\textsuperscript{187} assumed that criminal statutes would operate to compel treatment for "live-born infants."\textsuperscript{188} The Court struck down, however, a statute

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\textsuperscript{185} See text accompanying notes 255-56 infra.
\textsuperscript{187} 96 S. Ct. 2831 (1976).
\textsuperscript{188} \textit{Id.} at 2848. Paradoxically, the Court refused to sever the provisions of the Missouri statute before it for consideration, and thereby struck down as unconstitutional a requirement that physicians act to preserve the life of an aborted "child."
\end{flushright}
which imposed criminal liability for failure "to exercise that degree of professional skill, care and diligence to preserve the life and health of the fetus which . . . would be required . . . to preserve the life and health of any fetus intended to be born and not aborted." The Court's finding of unconstitutionality appears to have been based on a reading of the statute as applying to all fetuses, even those before the stage of viability, whether in utero or ex utero. Presumably, then, a physician may not be liable for failure to undertake "therapeutic" measures for a nonviable fetus ex utero.

III. PROTECTIVE MECHANISMS

The Department's regulations, in addition to establishing guidelines for experimentation, set forth two principal protective devices for safeguarding fetal rights. One device is a requirement that consent of the parents of the fetus be obtained before research can be conducted. The other device involves review and monitoring by Ethical Advisory Boards at the national level and by Institutional Review Boards at each research institution. This section will examine the legal efficacy of these protective mechanisms and the extent to which they are adequate safeguards. Additional protective mechanisms will then be discussed briefly in conclusion.

A. Controls Established by Federal Regulations


The sections of the regulations relating to experimentation with fetuses in utero and nonviable fetuses ex utero contain nearly identical provisions on consent: The regulation pertaining to ex utero fetuses provides that research

may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if: (1) his identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

\[169\] Id. at 2847.
\[170\] 45 C.F.R. § 46.208 (1976).
\[171\] Id. § 46.209.
\[172\] Id. § 46.209(d). The consent regulation pertaining to in utero fetuses fails to track precisely the quoted language; the word "informed" is omitted from the phrase "father's informed consent." Id. § 46.208(b).
This requirement of parental consent for fetal experimentation appears to have been extrapolated from the requirement that parental consent be obtained prior to utilization of either established or innovative medical procedures on children. Two principles govern this exercise of parental authority. First, as a general proposition, parents in this culture have traditionally possessed substantial independent control over their children. Second, parents in all jurisdictions have an affirmative obligation to provide necessary medical care for their children; and their failure to do so may result in prosecution and the forfeiture of their rights of parenthood. Thus, in a blend of these two principles, parents are given wide latitude in the choice of medical treatment for a child; but they must exercise their power to grant or withhold consent on the basis of the child's best interest. When a child's condition is serious, as when death is imminent, parents may consent to drastic therapeutic measures. Parents do not, however, possess authority to consent to nontherapeutic medical procedures; and, a fortiori, they may not consent to nontherapeutic research.

The Department's regulations require both mother and father to be legally competent. Since males and females in their early teens are capable of conceiving children, this competence limitation may preclude obtaining their consent to fetal research, even in situations where the research is therapeutic. A preferable solution would be to permit therapeutic research after consent has been obtained from other parties, such as the incompetent parents' legal guardians, as well as from the parents themselves.


See note 186 supra.

Cf. Prince v. Massachusetts, 321 U.S. 158 (1944). In Prince, the Supreme Court refused to invalidate a state statute barring minors from selling newspapers and other merchandise. The statute was applied to prohibit a child from selling religious literature. The Court recognized that zealous attempts to distribute propaganda of any type might create an emotional situation harmful to the child. The Court then observed:

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

Id. at 170.
experimentation, since the risks engendered by research are more difficult to assess than those associated with accepted medical procedures.

Nevertheless, courts have permitted nontherapeutic procedures on children, even procedures presenting a substantial hazard, in certain limited situations. The leading case on the subject, Bonner v. Moran, involved a 15-year-old boy who consented to be the donor in a skin transplantation procedure that was necessary to save the life of his cousin. The court held that the consent of the minor alone was not sufficient to compel judgment for the defendant doctor in an action for assault and battery. Inferentially, the case may be read to stand for the proposition that parental consent would have been sufficient to enable the physician to perform the procedure, even though the procedure entailed a substantial risk of injury.

In the late 1950's, the issue of parental consent for a nontherapeutic procedure performed on a minor was placed directly in focus by three Massachusetts cases involving kidney transplantation. In all three cases, the kidney of a healthy child was to be transplanted to his ill sibling; both the minors and their parents had consented. In each of these cases the Massachusetts Supreme Judicial Court decided that, since the donor child would receive a psychological benefit, the parents could consent to the operations. In a similar case, the Court of Appeals of Kentucky permitted the transplantation of a kidney from a mentally retarded 27-year-old man to his dying brother. The court based its opinion on two conclusions: The incompetent would suffer

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197 However, one commentator has suggested that, because of the drastic impediment to medical research on childhood diseases which would occur if experimentation were curtailed, children should be permitted to be subjects of such research "where they are peculiarly suitable and there is no discernible hazard to them." Freund, Introduction to Experimentation with Human Subjects at xvi (P. Freund ed. 1970).


psychological damage from the loss of his brother; and the risk to the incompetent donor was minimal.\textsuperscript{202}

Other courts have rejected the psychological benefit theory, but have permitted nontherapeutic procedures on other grounds. For example, in a 1972 Connecticut case\textsuperscript{203} involving a kidney transplant, the court discounted testimony relating to psychological benefit to the donor. Nevertheless, it permitted the operation to proceed, holding that parents of identical twins could consent to a transplant from one twin to the other when the operation is necessary for the continued life of the donee, the risk is negligible, and the parents’ motives and reasoning have been reviewed by a guardian \textit{ad litem}, clergyman, and the court.\textsuperscript{204} Another court similarly rejected the concept of psychological benefit in the context of bone marrow transplantation.\textsuperscript{205} The court found that, although “the evidence does not permit a finding that the procedure will be of any benefit”\textsuperscript{206} to the donor, it did “not believe that a finding of benefit to the donor is essential . . . .”\textsuperscript{207} The opinion clearly stated that “parents have the right and responsibility to make these decisions”\textsuperscript{208} subject to judicial review to guard against a conflict arising from their responsibility to care for both children. The court must merely decide if the parents’ decision to allow their child to be a donor is “fair and reasonable.”\textsuperscript{209}

Several propositions can be drawn from the transplant cases. First, a striking aspect of these decisions is the fact that the courts never questioned the parents’ right to consent to an experimental (but therapeutic) procedure on behalf of the donee-child. Thus, parents may consent to placing their child at serious risk if exigent circumstances justify drastic therapeutic measures and the child might derive a benefit from them.\textsuperscript{210} Second, parents may consent to a nontherapeutic procedure in which the child

\textsuperscript{202} Id. at 149.
\textsuperscript{204} Id. at 390.
\textsuperscript{206} Id. at 412.
\textsuperscript{207} Id. at 413.
\textsuperscript{208} Id. at 414.
\textsuperscript{209} Id.
\textsuperscript{210} See note 186 supra. If the child will die without the therapeutic procedure, courts will almost invariably grant the parents great latitude of choice.
will be a donor if the risks to the donor are outweighed by the benefits to the donee.\textsuperscript{211} Third, there appears to be some movement away from rationalizing such parental consent to a nontherapeutic procedure on the basis of the contrived notion that the incompetent donor receives a benefit. Finally, courts are deferential to parental authority and appear very reluctant to second-guess parents after they have made a decision concerning their child, even though the parents have a serious conflict of interest when both the donor and the donee children are their own.

In the context of therapeutic research on a fetus \textit{in utero}, the federal regulations embody the first proposition: As in the case of a minor child, the parents of a fetus have broad discretion when they act to further its health needs. In the context of nontherapeutic research on both \textit{in utero} and nonviable \textit{ex utero} fetuses, however, the regulations grant authority to parents significantly beyond that inhering in the other three propositions derived from the transplant cases: Parents may consent to experimentation on the fetus even though it will not provide a life-saving benefit to a sibling.\textsuperscript{212} No benefit, psychological or otherwise, need accrue to the fetus. Moreover, courts do not even have the opportunity to review the parental decision since no judicial approval is necessary under the regulations.

The latitude given to parental authority might be understandable were we to conclude that parents are as protective toward their fetuses as they are toward their minor children. But common sense suggests that this assumption is not warranted; and the number of abortions makes the point doubly clear. The alternative conclusion is that fetuses are not as deserving of pro-

\textsuperscript{211} In the bone marrow and kidney transplant cases, notes 199-209 supra, the benefit (the possibility of saving the donee's life) outweighed the risk of harm to the donor. Only once was parental consent overridden, \textit{In re Richardson}, 284 So. 2d 185 (La. App.), \textit{cert. denied}, 284 So. 2d 338 (La. 1973), in a situation where the transplant was not an "absolute, immediate necessity" to preserve life. \textit{Id.} at 187. The court held that it was inconceivable that a statute absolutely prohibiting donation of a minor's property by his parents afforded "less protection to a minor's right to be free in his person from bodily intrusion to the extent of loss of an organ unless such loss be in the best interest of the minor." \textit{Id.}

\textsuperscript{212} See 45 C.F.R. §§ 46.208(a)(2), .209(a) (1976). The regulations provide, however, that the risk must be minimal to a fetus \textit{in utero}, \textit{id.} § 46.208(a)(2), and that research activities directed toward a viable fetus \textit{ex utero} must conform to regulations respecting experimentation with human subjects, \textit{see id.} § 46.209(c). The utility of this limitation is open to some question, however, since the degree of risk may be impossible to gauge in advance.
tection as minor children, and that parental consent is a sufficient safeguard under the circumstances. In either event, whether parental consent alone suffices to protect fetuses should be determined by analyzing the different contexts in which fetuses may be subject to nontherapeutic research.

b. Fetus in utero

Where both parents desire a child, they acquire a growing emotional attachment to the fetus throughout pregnancy; and, following birth, both parents are responsible for its maintenance and support, including the provision of medical services. They are clearly the parties most concerned about the welfare of their future child; therefore, it makes sense to assume that they will act to safeguard the interests of the maturing fetus in utero, particularly as these interests largely coincide with their own.\(^1\)

c. Previable fetus scheduled for abortion

A distinctly different picture exists in the case of a previable fetus scheduled for abortion. Here it can be argued that, where abortion is not necessary to protect maternal life or health, the parents have consigned the fetus to death. They are hardly the parties who should then be charged with protecting its interests; moreover, any research on it would, by definition, be nontherapeutic. Hans Tiefel has observed:

> [T]he pregnant woman cannot be assumed to be the parental guardian of the fetus when non-therapeutic experiments are proposed in connection with a planned abortion. For when the woman has decided for whatever reasons not to become a parent—and there certainly are reasons which justify an abortion—then rights that depend on the parent-analogy are obviously no longer appropriate.\(^2\)

On the other hand, it can be argued that few abortions are motivated by malice toward the fetus. The absence of a father, a lack of financial resources to support a child, the youth of the parents, or a need to defer childrearing because of career demands

\(^1\) That this assumption is not invariably true, however, is demonstrated by Raleigh Fitkin-Paul Morgan Mem. Hosp. v. Anderson, 42 N.J. 421, 201 A.2d 537, cert. denied, 377 U.S. 985 (1964). See note 128 supra.

\(^2\) Written comments submitted (April 24, 1975) by Hans O. Tiefel, Kennedy Fellow in Medical Ethics at Harvard University, to the Subcommittee of the Massachusetts Legislature on Human Experimentation and Clinical Investigation (in conjunction with Hearings on Mass. Gen. Laws ch. 113, § 12J (1975) held on March 7, 1975) at 8.
are examples of nonmalicious motives. In none of these cases would the parents necessarily be insensitive to the rights of their developing child; and this would be particularly true where an abortion is necessitated by the health needs of the mother.

The issue, then, is not whether maternal consent should be required prior to research on a fetus scheduled for abortion, but whether it is sufficient, standing alone, as a protective device. Approval by an independent review board could be required as an additional measure to guard the interests of the fetus. Alternatively, a procedure similar to that used when a minor donates a kidney might be appropriate: This procedure entails, in addition to parental consent, appointment of a guardian ad litem to obtain the imprimatur of the court.

d. Nonviable fetus ex utero

Similar checks on the consent authority granted to parents by the regulations seem desirable in the case of aborted nonviable fetuses. Supplementing parental consent to research on such fetuses with other protective provisions is both more sensible and more humane than the approach incorporated in several state statutes which terminate parental rights over the fetus should it survive, except when the abortion is performed to preserve the mother's life or health. Under these statutes, parents would be unable to consent even to performance of therapeutic procedures on the aborted fetus.

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211 Review procedures are, in fact, required prior to initiation of fetal research where federal funding is involved. See notes 231-44 and accompanying text infra.


215 See notes 231-44 and accompanying text infra.


219 LA. REV. STAT. ANN. §§ 13:1569-70 (Supp. 1977); Mo. ANN. STAT. § 188.040 (Vernon, Cum. Supp. 1977). The Louisiana statute regards a fetus which survives an abortion as a neglected or dependent child and gives jurisdiction over proceedings involving the child to the juvenile court. Missouri regards the aborted child as an abandoned ward of the state and places it under the jurisdiction of the juvenile court; the mother and the father, if he consented to the abortion, lose all parental rights or obligations vis-à-vis their aborted offspring.

216 These statutes may be open to constitutional attack on due process grounds because parental rights are forfeited automatically without any showing of actual or pending neglect. Cf. Stanley v. Illinois, 405 U.S. 645 (1972). The degree of protection of fetal rights afforded by these statutes is also questionable in that the state-appointed guardian is potentially indifferent.
e. Dual consent

With limited exceptions, the regulations require consent by both parents in order to conduct research on a fetus, whether in utero or ex utero.216 As a means of protecting fetal interests, this dual consent requirement constitutes an important additional safeguard. But, for the fetus in utero, is dual consent justifiable after Roe v. Wade220 and Planned Parenthood v. Danforth?221 Specifically, does the mother's privacy interest give her the sole right to consent?222

In Roe, the Supreme Court confined its discussion of fundamental privacy to the pregnant woman planning an abortion. Once conception has taken place, and the fetus is growing within her, the choice to abort the fetus is her right alone. The Court specifically eschewed any consideration of a father's rights,223 and this primacy of the mother was reaffirmed in Danforth.224 Neither Roe nor Danforth, however, granted a pregnant woman absolute

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216 See note 192 and accompanying text supra.
221 96 S. Ct. 2831 (1976).

Since Skinner v. Oklahoma, 316 U.S. 535, 541 (1942), the Court has slowly carved out a zone of personal liberty which is immune to state intrusion, absent the nearly unattainable showing of a compelling state interest. In general, this zone of privacy encompasses intimate matters associated with marriage, family, and sexual relations. The Supreme Court has enunciated the right in cases dealing with sterilization, id., the use of contraception by married persons, Griswold v. Connecticut, supra, and by unmarried persons, Eisenstadt v. Baird, 405 U.S. 438 (1972), and the choice of marriage partner, Loving v. Virginia, 388 U.S. 1 (1967). But see Doe v. Commonwealth's Atty., 96 S. Ct. 1490, reaffirming 96 S. Ct. 2192 (1976), affg 403 F. Supp. 1199 (E.D. Va. 1975), in which the Supreme Court seemingly narrowed the scope of the privacy right by affirming (without comment) a lower court decision upholding a Virginia sodomy statute which prohibited private consensual homosexual acts between adults. Since the statute patently infringed on intimate sexual matters, the conclusion to be drawn is that the privacy right is restricted to heterosexual relations.
224 96 S. Ct. 2831 (1976). The Court struck down a spousal consent requirement for abortions, holding that a state cannot delegate to a father power which it does not itself possess. Id. at 2841.
bodily autonomy.\textsuperscript{225} Simply because a woman possesses a privacy right in the first two trimesters to retain a fetus or to have it expelled from her womb, it does not follow that she possesses unfettered discretion to do with the fetus as she pleases in any other respect. While her right to refuse an invasion of her body is undoubtedly fundamental,\textsuperscript{224} it is less clear that she possesses a fundamental privacy right to invade the body of her fetus for experimental purposes. Or, if her maternal interest in the fetus is a fundamental right included within the notion of privacy, it would seem to follow that paternal rights should be on an equal footing.\textsuperscript{227}

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\textsuperscript{225} The Court in \textit{Roe} said:

The privacy right involved, therefore, cannot be said to be absolute. In fact, it is not clear to us that the claim asserted by some \textit{amici} that one has an unlimited right to do with one's body as one pleases bears a close relationship to the right of privacy previously articulated in the Court's decisions . . . .

We, therefore, conclude that the right of personal privacy includes the abortion decision, but that this right is not unqualified and must be considered against important state interests in regulation.


\textsuperscript{224} \textit{See In re Smith}, 16 Md. App. 209, 295 A.2d 238 (1972), which upheld a minor's right to refuse an abortion her mother bought for her.

\textsuperscript{227} In Planned Parenthood v. Danforth, 96 S. Ct. 2831 (1976), Justice Blackmun, writing for the majority, concluded

that the State cannot "delegate to a spouse a veto power which the state itself is absolutely and totally prohibited from exercising during the first trimester of pregnancy."

\textit{Id.} at 2841. By speaking in terms of delegation, the Court appeared to deny the existence of a natural or fundamental right of fatherhood, although it stated that

[since it is the woman who physically bears the child and who is the more directly and immediately affected by the pregnancy, as between the two, the balance weighs in her favor. Cf. \textit{Roe v. Wade}, 410 U.S., at 153 . . . .

\textit{Id.} at 2842. Mr. Justice Stewart, in a concurring opinion in which Mr. Justice Powell joined, went somewhat farther, saying "that a man's right to father children and enjoy the association of his offspring is a constitutionally protected freedom"; however, in choosing between these competing rights, he concurred that the balance weighs in the woman's favor. \textit{Id.} at 2850-51. Mr. Justice White, concurring in part and dissenting in part, disagreed:

[T]he State is not . . . . delegating to the husband the power to vindicate the State's interest in the future life of the fetus. It is instead recognizing that the husband has an interest of his own in the life of the fetus which should not be extinguished by the unilateral decision of the wife. It by no means follows, from the fact that the mother's interest in deciding 'whether or not to terminate her pregnancy' outweighs the State's interest in the potential life of the fetus, that the husband's interest is also outweighed and
Certainly a prospective father has a substantial interest in the fate of his unborn child, an interest ranging from possible emotional attachment to a state-compelled duty of maintenance and support. A father may wish to shield the fetus in utero from unnecessary potential harm or pain; and there is no logical reason why his wishes in this regard should be outweighed by those of the pregnant woman, as they are in the case of abortion. The mother’s freedom to decide whether or not to terminate a pregnancy is not impaired if she is prevented from authorizing research. Since experimentation is not designed to benefit her physically, no predominant health interest can be claimed. The father is simply asserting a legitimate interest in protecting the fetus. Since he is a copartner in the conception, it cannot be said that the woman alone should speak in this protective capacity. And if there are sound reasons to support maternal and paternal consent to experimentation on a fetus in utero, these reasons should be even more persuasive once a fetus has been expelled from the womb.

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may not be protected by the State. A father’s interest in having a child—perhaps his only child—may be unmatched by any other interest in his life. See Stanley v. Illinois, 405 U.S. 645, 651 . . . . Id. at 2852 (footnote omitted). As the Chief Justice and Mr. Justice Rehnquist joined in the dissent, a total of five of the justices joined in either the concurring or dissenting opinion; it thus seems that a majority of the Court recognizes the fundamental nature of paternal rights.

Where a pregnant woman’s health may be endangered and experimental procedures are indicated, the regulations permit medical intervention with her consent alone. See 45 C.F.R. § 46.207(b)(1) (1976).

To the extent that a decision to withhold therapeutic research might impinge on the woman’s abortion decision, it would probably be unconstitutional under the reasoning of Roe v. Wade, 410 U.S. 113 (1973), and Planned Parenthood v. Danforth, 96 S. Ct. 2831 (1976).

Support for this position may be inferred from Stanley v. Illinois, 405 U.S. 645 (1972), although the case can be distinguished as it did not address the issue of informed consent. Stanley involved an Illinois statute which presumptively held a father unfit, because of his unwed status, to be the guardian of his children following their mother’s death; yet custody by natural or adoptive married parents or by an unwed mother could only be terminated through a neglect proceeding. Finding a denial of Stanley’s due process and equal protection rights guaranteed by the fourteenth amendment, the Court stated: “The private interest here, that of a man in the children he has sired and raised, undeniably warrants deference and, absent a powerful countervailing interest, protection.” Id. at 651. This language evidences an expanding recognition of paternal rights and a desire to eliminate sexual stereotypes; it strongly suggests that, in the context of consent to fetal research, the father should stand on a co-equal footing with the mother.
2. Review Procedures

In order to expose hidden biases and unanticipated perils, many commentators have suggested review by a committee prior to commencing research activities on human subjects. A review committee is probably a useful safeguard, if for no other reason than that it forces researchers to openly articulate their procedures and objectives. This experience alone may induce the experimenters to alter research design or to halt unethical research altogether. The extra delay and bureaucratic formality imposed by committee review is a relatively trivial burden to ensure meticulous care in protecting incompetent subjects.

The federal regulations require committee review, in some cases by two committees, for research proposals involving human subjects. The process is complex. In the case of experimentation on a fetus, every proposed research activity must be reviewed and approved in the first instance by an Institutional Review Board. No proposal may be funded unless Board approval is certified to the Department. The Institutional Review Board's scope of re-

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231 Comment, Non-therapeutic Medical Research Involving Human Subjects, 24 Syracuse L. Rev. 1067, 1093 (1973). See also Robertson, supra note 186, at 264, 268. It has been suggested that these review committees not be associated in any way with institutions sponsoring research. Note, Experimentation on Human Beings, 20 Stan. L. Rev. 99, 109 (1967). Also recommended is inclusion on the committees of physicians who are not involved in research as well as those who are. Lewis, McCollum, Schwartz, & Grunt, Informed Consent in Pediatric Research, 16 Children 148 (1969). One commentator has recommended a panel, fifty percent of whose members would be drawn from the community. See Comment, Non-therapeutic Medical Research Involving Human Subjects, supra at 1093. Community representation is suggested because the decision to proceed with research often involves normative judgments; but it has also been questioned on the ground that outside “experts” and laymen may be no more capable than parents or physicians at resolving complex social and ethical questions posed by a particular project. Robertson, supra note 186, at 265. Even though normative, non-technical judgments are often required, these judgments frequently must be meshed with a thorough understanding of the technical aspects of a project. Lay members of review committees tend to rely on those with greater technical expertise. Not surprisingly, the success of these committees has been cited as less than spectacular. Id.

232 45 C.F.R. § 46.102(a) (1976). The Department’s regulations concerning fetal experimentation do not preempt state law: “Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws. . . .” Id. § 46.201(b). A number of state fetal experimentation statutes (see supra note 32) impose greater restraints than the federal regulation; and researchers must conform with these local standards even after they obtain HEW approval.

233 45 C.F.R. §§ 46.102, 46.205(3)(b) (1976).
view is broad: It determines not only whether a proposed activity conforms to the general standards for research on human sub-
jects, but also whether the activity is permissible under the applicable standards governing research on the fetus. While it is still too early to assess the precise functioning of these boards, in all likelihood they will: (1) monitor the informed consent pro-
cess; (2) periodically (at least once a year) monitor research activities already approved to insure that there are no unexpected problems or risks for research subjects; (3) determine that prior animal testing has been performed; (4) insure that there is only “minimal risk” to the fetus; and (5) insure that researchers take no part in decisions as to timing, methods, and procedures used to terminate pregnancies and are excluded from evaluating the viability of fetuses used in research.

Upon receiving certification of approval by an Institutional Review Board, the Secretary of HEW has three options: He may grant final approval, reject the proposal, or request further advice from an Ethical Advisory Board. The Secretary will exercise this latter option when, in his opinion, a research activity raises complex medical, legal, social, and ethical problems which require close scrutiny and review. The regulations prescribe that two Eth-

A Board may establish, with the approval of the Secretary, classes of applications or proposals which: (1) Must be submitted to the Board, or (2) need not be submitted to the Board. Where the Board so establishes a class of applications or proposals which must be submitted, no application or proposal within the class may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Board and the Board has rendered advice as to its acceptability from an ethical stand-

\[\text{\textsuperscript{214}}\text{ Id. } \S 46.101, -102.\]
\[\text{\textsuperscript{215}}\text{ Id. } \S 46.205(a)(1).\]
\[\text{\textsuperscript{216}}\text{ Id. } \S 46.109, -110.\]
\[\text{\textsuperscript{217}}\text{ Id. } \S 46.107(f), (g).\]
\[\text{\textsuperscript{218}}\text{ Id. } \S 46.206(1).\]
\[\text{\textsuperscript{219}}\text{ Id. } \S 46.206(2).\]
\[\text{\textsuperscript{220}}\text{ Id. } \S 46.206(3).\]
\[\text{\textsuperscript{221}}\text{ Id. } \S 46.204(a).\]
\[\text{\textsuperscript{222}}\text{ Id. } \S 46.204(d).\]
This provision enables an Ethical Advisory Board, with the approval of the Secretary, to review every research proposal in a given class. For example, since the fetus scheduled for abortion and the nonviable *ex utero* fetus are particularly vulnerable, an Ethical Advisory Board could require that all research proposals involving such fetuses be submitted to it for careful review. This procedure would constitute a desirable supplemental mechanism, in addition to parental consent, for protection of fetal rights. While the Secretary is not bound by a Board's recommendation, a finding that a proposal fails to conform to acceptable ethical standards will carry great weight.

B. *Mechanisms Not Prescribed by Federal Regulations*

1. Physician Advocates

Another possible protective device is a requirement that a physician who is not one of the researchers be present in any research situation to be responsible for the research subject as a patient. This physician would communicate the progress of research faithfully to the parents or guardian, make sure that their consent is truly informed, insure that every precaution is taken, and withdraw the fetus from the research if the risk of harm is unnecessary or too great.

Although this protective device has merit, it duplicates many of the duties of the Institutional Review Boards. Having both a review committee and a physician advocate would probably be an unnecessary additional restriction on researchers in most situa-

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14 See text accompanying notes 216-17 supra.

144 In particular, the Boards should closely scrutinize any research in which the purpose "is to develop new methods for enabling fetuses to survive to the point of viability." 45 C.F.R. § 46.209(b)(1) (1976). I recommend that the following standards be applied by the Ethical Advisory Boards for this class of research:

(1) The general rule should be that researchers may not alter the duration of fetal life; and the development of an artificial placenta should be a specific, narrowly limited exception to the general rule.

(2) There should be no reasonable alternative to the use of nonviable fetuses as research subjects (e.g., could a possibly viable fetus who might benefit from this research be used instead of a nonviable fetus?).

(3) The degree of bodily invasion of the proposed experiment should be considered a relevant factor in determining its ethical propriety.

(4) There should be a showing that the proposed experiment will result in the development of important biomedical knowledge which cannot be obtained by other means.

tions. Moreover, the presence of an additional, independent physician would constitute an unwarranted interference with the researcher's professional responsibility, especially in the context of therapeutic experimentation.

2. Litigation

Another significant method of quality control—indeed, within the medical profession currently, perhaps the most efficacious method—is after-the-fact litigation, usually in the form of suits for malpractice. Applied to fetal experimentation, litigation would permit the gradual development and testing of legal doctrine in this very perplexing area. A common law approach would avoid sweeping generalizations enunciated in regulations in favor of an adjudication of liability and assessment of damages in specific cases. Over a period of time it would probably provide the best guide to the behavior of physician-researchers. Unfortunately, the rate of development in medical research frustrates an unhurried case-by-case analysis of concomitant legal problems. In addition, although rules pieced out in judicial opinions may ultimately be of critical importance in regulating the scope of research activities, it will be necessary first to modify the legal doctrines which can be used as a basis for assessing liability. The present body of judicial opinions relating to research in general is of limited quantity and usefulness; and most of these cases embody criteria which apply imperfectly or not at all to the facts of fetal experimentation.

a. Contract

Suit based on a contract theory, for example, presupposes an express or implied contract that the physician will perform professional services in return for reasonable compensation from the patient. An initial problem presented by an action in contract is identification of the parties other than the doctor. In the context of therapeutic experimentation, presumably the parents or guardian of an in utero fetus would constitute a party, the fetus not being a "person" under the fourteenth amendment. If ex utero, however, the fetus may be regarded as an incompetent

147 See note 117 and accompanying text supra.
minor child capable of bringing suit in its own name as a third party beneficiary of the contract. On the other hand, when non-therapeutic research is performed on an ex utero fetus, questions are raised respecting the third party beneficiary status of the fetus—no benefit to the fetus being contemplated—and the adequacy of consideration from the researcher. Moreover, measurement of damages may be extremely difficult, depending on the fetus' stage of development (nonviable or viable) and status (in utero or ex utero).

b. Tort

Difficulties similarly arise in the application of tort theories to fetal research. For example, a physician has a duty to inform the patient or the patient's representative of "all of the material facts of the treatment proposed, including risks of death or serious bodily harm, the probability of success, the alternatives to the treatment (including nontreatment), and their risks and probabilities of success." Where the patient or his representative consents but foreseeable collateral risks are not disclosed, a negligence issue—failure to obtain informed consent—is presented.

If, in light of the patient's condition, the probability of success, and the severity and likelihood of harm, good medical practice requires therapeutic research, the physician is only obligated to disclose those risks which he knows or reasonably should know. Where nontherapeutic research is involved, however, the result is much less clear: Can nontherapeutic research ever con-

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24 Nontherapeutic research on a fetus ex utero also raises the issue of whether the contract agreement to perform nonbeneficial procedures on a "child" is void as against public policy.
26 An action for battery might also be instituted:
   [T]heories of assault and battery are to be employed only where the defendant doctor has operated on a part of the body as to which no consent was obtained or where the doctor has simply acted viciously and committed a true battery.
J. Waltz & F. Inbau, supra note 246, at 156.
27 If therapeutic research is not dictated by good medical practice, obtaining informed consent to the risks will not protect the physician from liability. Id. at 200-01.
28 See generally id. at 191.
29 As yet, decisional law in the United States with respect to this type of research is virtually nonexistent. Comment, Non-therapeutic Medical Research Involving Human
stitute good medical practice, given that the research subject is not expected to receive any benefit? Must every conceivable risk be mentioned? It could be maintained that the standard of care is not good medical practice but good research practice, and that, in the latter context, the major risk to be disclosed is the very fact that not all risks may be foreseen in advance.  

A natural corollary of this dilemma is posed by the common law rule that "a physician has the obligation to his patient to possess and employ such reasonable skill and care as are commonly had and exercised by reputable, average physicians in the same general system or school of practice in the same or similar localities." Physicians are required to adhere to generally accepted tenets of medicine, although majority and minority views regarding certain therapeutic practices are tolerated when there is no evidence that one school is clearly the most efficacious. By definition, however, an experimental procedure is not generally accepted practice; and a physician may be acting at his peril when he utilizes an innovative therapy. In a 1935 decision which enunciated a more liberal view, the Supreme Court of Michigan recognized society's need for experimentation to further medical progress; nevertheless, it held that therapeutic research procedures were permissible only if they did "not vary too radically from the accepted method of procedure." In a few cases since that time, however, courts have permitted relatively extreme departures from accepted practice when the patient has consented and the physician has acted prudently under the circumstances.

Subjects, 24 Syracuse L. Rev. 1067, 1071 (1943). See also J. Waltz & F. Inbau, supra note 246, at 181 n.11.

See G. Annas, supra note 249.

J. Waltz & F. Inbau, supra note 246, at 42.

Carpenter v. Blake, 60 Barb. 488 (N.Y. Sup. Ct. 1871), rev'd on other grounds, 50 N.Y. 696 (1872). The court stated:

[W]hen the case is one as to which a system of treatment has been followed for a long time, there should be no departure from it, unless the surgeon who does it is prepared to take the risk of establishing, by his success, the propriety and safety of his experiment.

Id. at 524 (emphasis added).


Id. at 282, 261 N.W. at 765.

Quality control by way of malpractice actions presents other, equally troublesome problems in the context of fetal research. To bring a successful suit, plaintiffs must prove a causal relationship between the researcher's conduct and the injury which occurs. For the fetus in utero, this task may be formidable: Twenty percent of all pregnancies terminate in spontaneous abortions, usually the result of gross fetal abnormalities, and many children are born with greater or lesser degrees of impairment. In view of these facts, it may be nearly impossible to link a relatively innocuous experiment with a defect or to establish that an experiment enhanced an existing defect. It may also be an arduous proposition to establish damages, even if liability can be proved.

c. Strict liability

These multifarious difficulties suggest resort to the doctrine of strict liability, particularly with respect to nontherapeutic research. There is appeal in the notion that an experimenter should proceed at his peril, that he has exclusive control of the experimental situation and should be held liable without fault if an injury occurs. Through resort to insurance, the costs—as well as the advantages—of medical research would be distributed among all recipients of medical services.

Despite its appeal, however, this approach presents difficult, perhaps insurmountable, policy choices. The specter of strict liability might seriously chill the initiation of valuable research. Where other controls are present, such as consent and committee review, immunity from liability for nonnegligent injury may be a necessary price to pay for the substantial benefits to medical knowledge which fetal research may yield. This consideration has particular weight where the research is therapeutic and where doctor and patient, or, in the case of fetal experimentation, doctor and parents, are both in search of the best therapy. In this situa-

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170, 179-80 (1957). In Karp, the Fifth Circuit upheld a directed verdict for a physician where the plaintiff failed to present expert testimony that use of a previously untried mechanical heart was negligent. Apparently, the court felt that an experimental, but therapeutic, procedure is proper where the patient consents and conventional modes of treatment offer little hope of survival.


tion, parents and fetus are in a sense joint venturers with the physician. It seems harsh to hold a doctor solely responsible under the circumstances, at least when a nonnegligent injury occurs.\textsuperscript{262}

3. Compensation Fund

If strict liability is an unacceptable approach in a society dedicated to the advancement of knowledge through research, some other mechanism for providing compensation, independent of traditional notions of contract or tort, is desirable. When an injury occurs to a fetus or its mother which involves expenses over a lifetime, staggering sums may be involved. Compensation through a suit for malpractice may be insufficient or unobtainable, \textit{e.g.}, if proof of causation is insufficient; yet parents should not be required to shoulder the entire risk alone. Take, for example, the case of a fetus \textit{ex utero} with no apparent chance of survival. The parents are told that a new experimental technique may save the fetus, but that no one can predict the harm which may occur through its use. Faced with this cruel choice, some parents will consent in desperation to use of the technique. Others will understandably hesitate or refuse, in part fearing the economic hardship which may result if they cannot obtain compensation for nonnegligent injury. In addition, a doctor confronted with the possibility of strict liability despite his exercise of due care may equally be tempted to forego life-saving efforts in marginal cases.\textsuperscript{263}

The present system offers essentially two choices if an injury occurs: If the injury results from negligence which can be proved, the negligent party must pay damages to the extent he is able; if the injury results from causes unrelated to negligence, the victim (or those responsible for the victim) must shoulder the entire cost. This system is rigid and inequitable. It is important, on the one hand, to make researchers or their sponsoring institutions bear the costs of their mistakes as a way of insuring quality control;


\textsuperscript{263} Note, however, that at least 18 state fetal experimentation statutes require physicians to take measures to preserve the life of a viable fetus following an abortion. 4 Family Planning Population Reporter at 111-12 (1975).
but the fear of personal liability may dry up some kinds of useful research; and the actual recovery of money damages by a victim may be insufficient. On the other hand, if a subject is participating in research for the benefit of medical science, his ability to recover for injuries should not be limited to cases where fault can be demonstrated. Injuries constitute a research cost which should ultimately be borne by the research industry and society rather than by the unfortunate subject.

Society should underwrite a portion of this cost through establishment of a compensation fund. Victims should be reimbursed from the fund upon proof of injury and a showing that a substantial purpose of the research was nontherapeutic, designed to benefit society rather than the subject. Compensation should be allowed for both negligent and nonnegligent causes of injury. In both situations, payment of the total amount of compensation should be allocated among the researcher, the research institution, and a national fund, a scheme similar in nature to workmen's compensation. The amount paid by each party might constitute a percentage of the whole; however, the preferable scheme would make the researcher and the research institution jointly liable for damages up to a fixed amount, with the national fund obligated to pay the remainder. The liability of the researcher and research institution would be lower in the case of nonnegligent injuries, e.g., $200,000, and higher where negligence could be proved, e.g., $500,000.

The higher amount of recovery for negligence is intended to apply pressure on a researcher and research institution to exercise due care. Also, by imposing strict liability for nonnegligent injuries, this scheme discourages researchers from conducting experimentation until all risks are minimized. It provides a strong incentive for Institutional Review Boards to recommend against

\[2^{24} \text{ The National Commission intends to consider the establishment of a compensation fund. See Fetal Research Report, supra note 19, at 33,547. See also Nathan v. Farinelli, Eq. No. 74-87 (Mass. July 3, 1974), reprinted in 1974 Ins. L.J. 411.}\]

\[2^{25} \text{ Until the efficacy and cost of the fund is determined, compensation should be limited to injuries arising from nontherapeutic research. Serious consideration should also be given, however, to compensating injuries arising from therapeutic research. Does not society benefit from therapeutic as well as nontherapeutic research?}\]

\[2^{26} \text{ Adams & Shea-Stonum, supra note 262, at 637-48. See also, Havinghurst, Compensating Persons Injured in Human Experimentation, 169 Science 153 (1970).}\]
undertaking research projects until every precaution has been taken to avoid injury. As stated by Professor Calabresi:

[Approval by a review committee of a particular experiment will require conscious consideration not only of the possible payoff (either in market or scientific terms), but also of the risks, converted to money, that the project entails. This may not deter many experiments, but it may cause those involved in the most risky or least useful ones to consider carefully whether or not the experiment is worth it, whether or not it is best done by those who propose to do it, and whether there is an alternative, and safer, way of obtaining approximately the same results.]

Establishing the federal compensation fund described above would serve at least two important objectives. By relieving researchers and research institutions of liability for very substantial awards of damages, it would not inhibit worthwhile research. At the same time, by furnishing compensation only if damages exceed certain amounts, it would encourage a maximum amount of care. Such a fund, established through appropriations from general tax revenues, would adequately represent society's stake in medical research.

**Conclusion**

For research on the fetus, two obvious issues are presented. The first is a matter of definition: Is the fetus a person entitled to protection? The answer to that question shapes the second issue: What protections should be afforded a fetal research subject during the various stages of its development?

At least for the foreseeable future, *Roe v. Wade* has conclusively settled that a fetus *in utero* is not a person entitled to constitutional protection under the fourteenth amendment. But a mother's fundamental right to abortion does not imply a corresponding right to experimentation; as a potential human being, the fetus *in utero* is entitled to substantial protection. If this potentiality is lost (as in the case of a fetus to be aborted or a nonviable fetus), other factors, including the "dignity" of the fetus, require significant safeguards before research is undertaken. Although a nonviable, *ex utero* fetus is arguably in a differ-

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18 A court, probably sitting without a jury unless there is an allegation of negligence, would determine the total award; or a special tribunal could be set up for this purpose.
ent, and less protected, status for research purposes than other human beings, its "personhood" should be assumed if the necessary indices of life are present. A definition of humanness should not depend solely on the present state of technological development; rather, defining the nonviable fetus as a person will spur research efforts to expand the period of viability.

The regulations of the Department, by requiring consent by both parents and by establishing a hierarchy of review committees, comprise significant safeguards. As a prospective control, however, the role of the review committees is insufficiently defined with respect to both the in utero fetus to be aborted and the nonviable fetus. Lastly, a compensation fund is not mandated by the regulations; such a fund should be established as a means of insuring maximum care in research efforts and as a device to allocate more fairly the costs of research which benefits us all.