Fetal Experimentation and Federal Regulation

Dennis J. Horan
FETAL EXPERIMENTATION AND FEDERAL REGULATION

DENNIS J. HORAN†

I. INTRODUCTION

The recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research¹ (Commission) were substantially incorporated by the Secretary of the Department of Health, Education and Welfare (HEW) into the rules and regulations² governing the grants and contracts made by HEW supporting research, development, and related activities involving the fetus, pregnant women, and human in vitro fertilization.³ Significantly, the HEW regulations concerning the fetus and in vitro fertilization are part of an overall scheme of research regulation involving the “Protection of Human Subjects,”⁴ although no regulations exist as yet concerning in vitro fertilization.⁵

Although the Commission’s recommendations were generally followed by the Secretary of HEW in the regulations, there were areas

† Lecturer in Law, University of Chicago Law School. Vice Chairman, American Bar Association Medicine and Law Committee. Member of the Illinois Bar. B.S., Loyola University, Chicago, 1957; J.D., Loyola University School of Law, Chicago, 1963.

¹. NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIO-MEDICAL AND BEHAVIORAL RESEARCH, REPORT AND RECOMMENDATIONS: RESEARCH ON THE FETUS (DHEW Publication No. (OS) 76-127, 1975), also printed in 40 Fed. Reg. 33,530 (1975) (partially codified in 45 C.F.R. §§ 46.101–301 (1976)) [hereinafter cited as COMMISSION’S REPORT]. For the reader’s convenience, chapters VIII and IX of the COMMISSION’S REPORT are reprinted in this symposium at pp. 300–24, and unless otherwise indicated, all citations to the COMMISSION’S REPORT refer to these pages.


³. Id. § 46.201–301 (emphasis added). The policy of the regulations is stated to be in part: “safeguarding the rights and welfare of subjects at risk in activities supported under grants and contracts from DHEW.” Id. § 46.102. The regulations provide protective procedures for DHEW grants similar to those required by the Food and Drug Administration. See 21 C.F.R. § 361.1(d)(s) (1976).

⁴. In vitro fertilization is defined in the regulations as “any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.” 45 C.F.R. § 46.203(g) (1976). According to the Secretary of DHEW, no regulations govern in vitro fertilization “because biomedical research is not yet near the point of being able to maintain for a substantial period the non-implanted product of in vitro fertilization . . . .

Given the state of research, we believe that regulation would be premature.” 40 Fed. Reg. 33,527 (1975).
of disagreement. Therefore, the regulations themselves rather than the recommendations of the Commission govern fetal experimentation under HEW contracts. Even though the prestige of the Commission adds great weight to its recommendations and, indeed, in public debate may be dispositive of fetal experimentation issues to many, it should be remembered that the Commission's regulations concern fetal experimentation only in the narrow area of contract grants under HEW. This observation is significant, since statutory and case law, although influenced by the regulations and the recommendations of the Commission, may develop in different and contrary directions. These developments could in turn cause substantial future changes in the regulations. Consequently, this article will confine itself primarily to a discussion of the regulations themselves, with special emphasis placed upon the deficiencies of the regulations.

In spite of such deficiencies, however, one cannot help but be impressed by the work of the Commission, given the present status of the fetus under the decision of the United States Supreme Court in Roe v. Wade. Maintaining an attitude of dignity and respect for the fetus in the face of that opinion is not only a difficult task but often schizophrenic and unrealistic. Yet the Commission has maintained such an attitude and, through its prestige, has transferred that attitude of dignity and respect to these regulations. This is an accomplishment worthy of our note. If the recommendations of the Commission or the regulations themselves fall short of what fetal protection should be under our Constitution, neither the Commission nor the Secretary of HEW are entirely to blame (with certain exceptions, such as the status of the fetus ex utero). They have done, if not the best that can be done, at least something that is not unworthy of our praise: they have raised the value of fetal life above that accorded it by the United States Supreme Court in Roe v. Wade. This accomplishment should not be forgotten as the balance of this article is read.

6. See, e.g., 40 Fed. Reg. 33,528 (1975) for the comments of the Assistant Secretary of Health concerning activities directed toward the fetus ex utero. Noting that the Commission recommended that no procedures be applied to a nonviable fetus ex utero which would alter its duration of life, the Assistant Secretary was persuaded that an exception was necessary in the public interest because experimentation on the nonviable fetus ex utero had contributed substantially to the ability of physicians to bring to viability increasingly small fetuses. Id. 7. 410 U.S. 113 (1973).

8. In his dissenting statement, Commissioner David Louisell pointed out with respect to the effect of Roe v. Wade on fetal experimentation: "Little wonder that intelligent people are asking: how can one [the fetus] who has no right to life itself have the lesser right of precluding experimentation on his or her person?" COMMISSION'S REPORT, supra note 1, at 316.

9. See text accompanying notes 71-78 infra.
II. DEFINITIONAL DIFFICULTIES

The regulations create several troublesome definitional problems. Some of the concepts contained in the definitional section of the regulations were adopted from the definitions used by the Commission, but with certain substantial differences. For example, the regulations define the term "pregnancy" as the period of time from confirmation of implantation until expulsion or extraction of the fetus. However, such a definition of pregnancy is scientifically incomplete at best; pregnancy presumably begins at the time of fertilization. For purposes of regulations concerning fetal experimentation, the fact that such a definition is incorrect or incomplete may be unimportant, since experimentation cannot take place prior to implantation. However, since these regulations are supposedly designed to include in vitro fertilization, that observation misses the point. Although the purpose for excluding the time between conception and implantation from the regulations is never made explicit, it appears obvious that the purpose is to ensure that nothing contained in the regulations interferes with current methods of contracepting even though certain current methods may also be abortifacient prior to implantation.

The Commission admitted that certain of its definitions differed from medical, legal, or common usage but argued that these changes were adopted in the interest of clarity or to conform to the language used in the legislative mandate. There is certainly nothing surprising


11. For example, the Commission defined "fetus" as the human from the time of implantation until a determination is made that the fetus is viable or possibly viable. COMMISSION'S REPORT, supra note 1, at 40 Fed. Reg. 33,531 (1975). The Commission then stated: "If it is viable or possibly viable, it is thereupon designated an infant." Id. (emphasis added). The regulations, on the other hand, use the term "product of conception" instead of "human" in defining the fetus and omit the reference to a possibly viable fetus being considered an infant. 45 C.F.R. § 46.203(e) (1976). A better understanding of the differences between the Commission and DHEW could be reached by minutely comparing the concepts and recommendations of the one with the other. However, that is a task beyond the purview of this article.


13. See R. Rugh & L. Sheftiles, FROM CONCEPTION TO BIRTH 17-26 (1971). After describing the creation of the new "individuals" id. at 20, and referring to this individual as an "embryo" even before implantation, id. at 26, the authors continue to depict the various stages of embryo development, concluding that "[a]ll of this occurs before a woman could possibly be certain that she is pregnant." Id. at 25. See generally M. Gilbert, BIOGRAPHY OF THE UNBORN (1963).

14. See note 5 supra.

15. See generally Hilgers, The Intrauterine Device, Contraceptive or Abortifacient?, 57 MINN. MED. 493 (1974); note 19 infra.

about an attempt to make analysis of ethical problems more accurate by making language more clear. However, one must ask how clear or accurate the ethical conclusions can be if the definitional beginnings of the study are scientifically inaccurate. Thus, if one defines the ethical problem to exclude the most difficult area of that problem, one prejudges at least a portion of the result. For example, by excluding from the definition of pregnancy the area between conception and implantation, has not the Commission and HEW legitimated in vitro fertilization by defining it as an area involving the nonhuman?

Ethical considerations were a primary concern of the Commission. However, ethical considerations must begin with scientific reality and should ignore the polarization of science which has occurred since the beginning of the abortion debate. Prior to that debate and the subsequent polarization it was clear that individual human life began at conception and that medical science defined pregnancy as

17. As part of its deliberations, the Commission considered the papers of nine ethicists. See Appendix, supra note 1, at 2-10 to 20-16. These papers are summarized in Commission's Report, supra note 1, at 10 Fed. Reg. 33,537-40 (1975).

18. One commentator has given the following example of the polarization of science in response to the abortion debate:

In January and February, 1962, Guttmacher was sent by the Population Council and the International Planned Parenthood Federation to study conception control around the world. When he returned to New York, he advised the Population Council that the "best chance for immediate success lay in work with intrauterine contraception," an astounding suggestion from the same man who only 3 years previously had soundly condemned such practice.

In [the Second International Conference on Intrauterine Contraception] discussion was begun on the abortifacient capability of IUD's. Candidly expressing that an abortifacient label would be detrimental to promoting the device in under-developed countries like Pakistan, where abortion is strongly opposed, the population planners began to redefine abortion and pregnancy.

In considering redefinition, the likelihood that IUD's destroy blastocysts prior to implantation led the planners to consider defining the blastocyst out of existence. Pregnancy, they said, should be redefined to begin at implantation. It seems that all subsequent scientific conferences on the "Preimplantation Stages of Pregnancy" were to be considered mere fiction.

Later, a scientific group of the World Health Organization (WHO) gave careful consideration to the proper name for these devices. After considering such names as "intrauterine foreign body" (IUF), "intrauterine contraceptive device" (IUCD), and "intrauterine device" (IUD), they unanimously accepted the name "intrauterine device" (IUD) with the recommendation that it be universally used in the medical literature. However, most articles in the literature, written primarily through grants from the Ford Foundation and the Population Council, have ignored this recommendation and continued to use intrauterine contraceptive device. This rhetorical ploy is in direct contradiction to the mounting scientific evidence that the principal mode of action of the IUD as a "contraceptive device" is not the prevention of conception but, rather, the destruction of the human blastocyst prior to implantation.

Hilgers, The Intrauterine Device: Contraceptive or Abortifacient?, 5 Mar. & Fam. Newsletter 3 (1974) (footnotes omitted) (can be obtained by writing P.O. Box 190, Midnapore, Alberta, Canada).
Avoiding debate and confrontation by defining pregnancy as beginning with implantation may be “prudent,” but it leads this reader of the Commission’s Report and the Secretary of HEW’s regulations to question not only the results but the wisdom of the entire proceedings.

Other definitional problems are equally troublesome. The definition of fetus excludes the viable fetus in the uterus. Consideration for such a fetus falls within those regulations governing research on pregnant women or fetuses in utero. These definitions imply that a viable fetus in utero does not have the same legal standing as the viable fetus ex utero. This line of reasoning appears to spring from the misconception, contrary to much authority, that the fetus has no standing in the law until it is born or expelled from the uterus.


20. “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.” 45 C.F.R. § 46.203(c) (1976).

21. Id. § 46.207.

22. Id. § 46.208.

23. The tort cases for wrongful death provide an excellent example of the debate surrounding this issue. At the time of the Roe v. Wade decision, a distinct majority of courts allowed an action for the wrongful death of the fetus. Annot., 15 A.L.R.3d 992 (1967). The Wade court paid scant attention to these authorities, dismissing them as representing the vindication only of the rights of the survivors (the parents) 410 U.S. at 162. However, Professor John Hart Ely has noted: “To the extent they are not entirely inconclusive, the bodies of doctrine to which the Court adverts respecting the protection of fetuses under general legal doctrine tend to undercut rather than support its conclusion.” Ely, The Wages of Crying Wolf: A Comment on Roe v. Wade, 82 YALE L.J. 920, 925 (1973) (footnote omitted). Four state supreme courts since Roe v. Wade have created a cause of action for the viable unborn child. Eich v. Town of Gulf Shores, 293 Ala. 95, 300 So. 2d 354 (1974); Chrisafogeorgis v. Brandenburg, 55 Ill. 2d 368, 304 N.E.2d 88 (1973); Mone v. Greyhound Lines, Inc., ___ Mass. ___, 331 N.E.2d 916 (1975); Libbee v. Permanene Clinic, 268 Ore. 258, 518 P.2d 636 (1974).

It is frequently argued that these cases do not represent a legal right in the child itself, but only vindication of the right of the parents or of the survivor. This argument is clearly erroneous since in order for the action to exist the unborn child must be found to be a “person” within the meaning of that word as used in the wrongful death statute. Once the court has so found, then the right which accrues to the unborn child is identical to the right which accrues to any adult for whom the same cause of action might exist. The conclusion is inescapable: the unborn viable child is a bearer in its own right of legal personhood for purposes of the wrongful death cause of action. This proposition, although clearly the majority point of view in America, is contrary to the constitutional interpretation of Justice Blackmun in Roe v. Wade.
Fortunately, the regulations give the maximum of protection to the fetus in utero, in that it may not be subject to any experimentation not directed at its particular health needs with one exception. The exception allows experimentation on the fetus in utero which is not for the health needs of the particular fetus if the risk is "minimal" and the purpose of the experiment is the development of important biomedical knowledge which cannot be obtained by other means.

The term "minimal risk" is not defined in the regulations. The chief proponent of proxy consent, Reverend Richard A. McCormick, S.J., urged the Commission, if it accepted proxy consent, to limit the experimentations where proxy consent was acceptable to those which hold "no discernible risk." There is probably a difference between the terms "no discernible risk" and "minimal risk"; however, neither the regulations nor the Commission Report makes any such distinction.

The most troublesome definition of all is that which creates the new category of subhuman: the nonviable fetus or fetus ex utero. This new creature will be discussed separately below.

III. In vitro Fertilization: A Separate Moral Problem

According to a statement made by the Secretary of HEW, in vitro fertilization is excluded from the scope of the regulations "because biomedical research is not yet near the point of being able to maintain for a substantial period the non-implanted product of such fertilization." Regulation 46.204(e) requires that proposals involving in vitro fertilization be first reviewed by the Ethical Advisory Board, which for it indicates that legal personhood (and, in my opinion, constitutional personhood) begins en ventre sa mere.

The Supreme Court's argument is additionally flawed since it would be unnecessary to consider viability at all if the action were merely to vindicate the parent. This is because viability is a concept which concerns the developmental qualities of the unborn child itself in terms of its capacity to sustain its own life outside the womb. Indeed, it would be contradictory to make use of the concept of viability if an action in wrongful death were only for the vindication of the parent, since the parent presumably wants the child, indeed loves the child, as much one week before viability as one week after. For further discussion of wrongful death actions involving fetuses, see 21 Vill. L. Rev. 994-1005 (1976).

25. Id. at § 46.208(a)(2).
26. See text accompanying notes 43-68 supra.
27. Appendix, supra note 1, at 5-9 through 5-10.
28. Commissioner Karen Lebacqz raised the minimal risk issue in her separate statement: "[T]he interpretation of risk and the designation of acceptable 'minimal risk' merit considerable attention by the scientific community and the lay public." COMMISSION'S REPORT, supra note 1, at 321.
29. 45 C.F.R. § 46.203(e) (1976).
30. See text accompanying notes 71-78 infra.
must render advice as to the acceptability of the proposal from "an ethical standpoint." 32 Since there are no other regulations governing in vitro fertilization, it is impossible to determine what the "ethical standpoint" might be.

The lack of clarity in the regulations becomes manifest when one considers that the use of the words "substantial period" by the Secretary of HEW implies the lack of any ethical standard. That is to say, the statement of the Secretary of HEW implies that, although biomedical research can fertilize the egg and sperm in vitro and create a new living organism, that new living organism can currently survive only for a short period of time; consequently, the problem is of insufficient consequence to warrant drafting regulations. The fact that the new living organism is human is apparently irrelevant.

For some, this approach creates significant moral problems. Can in vitro fertilization ever be moral when we know beforehand that the product of such conception must be destroyed? The answer is obviously no. Those who have accepted the theory of delayed hominization 33 could perhaps answer that question in the affirmative as long as the new being's lifespan was less than that which would involve infanticide. In a recent review of this question, Benedict Ashley concluded that "according to present biological knowledge, theories of delayed hominization lack any solid empirical evidence." 34 If this is so, in vitro fertilization without a reasonable prospect of maintaining the new life to maturity must be considered to be immoral experimentation. Experimentation with in vitro fertilization, which is implicitly allowed by the regulation — albeit subject to some ethical restraints — should be stopped.

IV. ANOTHER SEPARATE MORAL PROBLEM — ETHICAL ADVISORY BOARDS

The regulations create two separate Ethical Advisory Boards. 35 One is to advise the Public Health Service, while the other is to advise all other agencies and components within HEW. These boards

32. 45 C.F.R. § 46.204(e) (1976).
33. Donceel, Immediate Animation and Delayed Hominization, 31 THEOLOGICAL STUD. 76 (1970). The term "delayed hominization" as used by Donceel refers to the Thomistic principle that the human soul can only inform matter sufficiently prepared for it. Id. In order to be prepared, Donceel argues that the human matter must be sufficiently differentiated into organs, including the cerebral cortex, the site of the human animal's highest activity. Id.
35. See 45 C.F.R. § 46.204 (1976).
are to be staffed so that they are competent to deal with medical, legal, social, ethical and related issues. They may include research scientists, physicians, sociologists, educators, lawyers and ethicists as well as members of the general public.

These Ethical Advisory Boards “shall render advice consistent with the policies and requirements of this Part as to ethical issues . . . raised by individual applications or proposals.” Thus, the question arises as to whether someone can serve on an Ethical Advisory Board who might, even on occasion, render advice inconsistent with those policies and requirements. Do the regulations mean, for example, that persons who consider in vitro fertilization morally wrong may not sit on such an Ethical Advisory Board, since the regulations implicitly allow such experimentation? On the other hand, if it is true that the persons who sit on the Ethical Advisory Boards must agree with the ethical orientation of the regulations, then most right-to-life advocates have been effectively eliminated from such Ethical Advisory Boards, as have those persons who agree with the ethical positions of Joseph Fletcher.

Professor David Louisell has stated dissenting views to two of the recommendations made by the National Commission. His primary concern was with that part of the National Commission’s Report which allows experimentation on what is now called the nonviable fetus ex utero but which up to now has been known as a premature infant. The regulations allow experimentation on the nonviable fetus ex utero, even to the extent of altering duration of life. Are we to presume, then, that persons with convictions similar to those expressed by Professor Louisell are to be either automatically excluded from participating in the activities of the Ethical Advisory Boards or obligated to exclude themselves voluntarily, since their advice could not be consistent with the mandate stated in the regulations? If so, then I must withdraw my praise of the Commission and Secretary of HEW, since, despite arguments to the contrary with which I agree, it once again has become evident that the abortion issue cannot be entirely separated from the fetal experimentation issue. These dilemmas emphasize the ultimate necessity for a constitutional amendment vesting the constitutional

36. Id.
37. Id. § 46.204(c) (emphasis added). The reference to “this Part” means Part 46 of the Code of Federal Regulations (C.F.R.), “Protection of Human Subjects.”
38. For a discussion of the ethical views of Joseph Fletcher, see text accompanying notes 141–43 infra.
39. COMMISSION’S REPORT, supra note 1, at 315.
40. 45 C.F.R. § 46.209(b) (1976).
41. See text accompanying notes 7 & 8 supra.
right to life at the time of conception without such gaps as have been created by Roe v. Wade.

V. CONSENT AND INFORMED CONSENT

The federal regulations place the burden of monitoring the consent process with the Institutional Review Boards.43 The regulations refer to monitoring the "actual consent process."44 This choice of words could not be more apt. Consent, unless it is an informed consent, is meaningless in both the legal and the ethical sense. Of all aspects of clinical investigation, informed consent has been the most severely criticized;45 of all problems in the area of fetal research, the question of consent is said to be the "thorniest problem."46

Justice Cardozo said: concerning the necessity for obtaining consent for any treatment, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages."47 In an earlier case, relied upon by Justice Cardozo, an Illinois appellate court had been called upon to answer the same question.48 After noting that not a single case could be found in the English or American reports where a surgeon had been held liable for performing an operation without consent, the court nonetheless stated:

On the contrary, under free government at least, the free citizen's first and greatest right, which underlies all others — the right to the inviolability of his person, in other words, his right to himself — is the subject of universal acquiescence, and this right necessarily forbids a physician or surgeon, however skillful or eminent, who has been asked to examine, diagnose, advise and prescribe (which are at least necessary first steps in treatment and care), to violate without permission the bodily integrity of his patient by a major or capital operation, placing him under anaesthetics for that purpose, and operating on him without his consent or knowledge.49

43. 45 C.F.R. § 46.205(a)(2) (1976).
44. Id.
49. Id.
Not only must the consent be obtained, but it must also be a free and voluntary consent based upon a knowledge and understanding of the risks involved. That is to say, the consent must be an informed consent or it is no consent at all. Nondisclosure of a material risk can never be justified in experimental therapy unless an emergency exists.

No one disputes the application of these laudable principles to him or herself. They have been disputed, however, when applied to children or the unborn. Except in extreme emergencies, therapists or medical practitioners cannot act without the consent of the patient or legal guardian. Many state statutes indicate that the consent of only one parent is necessary. However, a parent may not withhold consent to medical treatment for a child where that treatment is necessary to preserve the child's life.

It must be clearly understood that the law does not allow a parent to give consent for medical intervention on behalf of a child unless such intervention is for the child's benefit. Consequently, a parent may not consent to nonbeneficial treatment such as clinical research or nontherapeutic experimentation, even when the risk is minimal. Indeed, this is so even if there is no discernible risk whatsoever. However, the law is not concerned with de minimus or merely technical wrongs which cause no injury. Therefore clinical research or experimentation in which there is no discernible risk is still a legal wrong because of the impropriety of the consent, but it is a wrong without practical redress since there is no harm.

If harm occurs during nontherapeutic research on the child, then the consent is vitiated. Parental consent, no matter how informed, will not protect an investigator from liability if a child is injured in the course of nontherapeutic research. This is because the injury is to the child, not the parents. Their consent will only mean that recovery to them personally may be barred. Thus, there is no such thing in the law as proxy consent for nontherapeutic experimentation involving children. The Commissioners and the Secretary of HEW are laboring

50. See Horan, Authority for Medical Treatment: Consent, in Illinois Institute of Continuing Legal Education: Medical Malpractice 7–1 through 7–31 (1975).
52. Fletcher, Fetal Research: An Ethical Appraisal, in Appendix, supra note 1, at 3–1.
55. See, e.g., Wallace v. Labrenze, 411 Ill. 618, 104 N.E.2d 769 (1952).
under a misconception of the state of the law if they think otherwise.\footnote{56} In short, "a child is not the property of its parents and may not be dealt with without regard for his best interests."\footnote{57} Professor Paul Freund has said that "[t]he law here is that parents may consent for the child if the invasion of the child's body is for the child's welfare or benefit."\footnote{58} Similarly the United States Supreme Court has stated that "[p]arents may be free to become martyrs themselves. But it does not follow that they are free, in identical circumstances, to make martyrs of their children. . . ."\footnote{59}

In the words of Chief Justice Warren E. Burger:

No adult has the legal power to consent to experiments on an infant unless the treatment is for the benefit of the infant. . . . It is the lamentable use in experiments of such subjects as infant children, incompetents in mental institutions, unconsenting soldiers subject to military discipline — as has been done — that is indefensible; and no rational social order will or should tolerate it.\footnote{60} Those few cases which have allowed parents to consent on behalf of children for donor transplants of kidneys or tissue to a brother or sister have rationalized the consent either on the basis of an insignificant invasion of the donor minor or the psychological benefit to the donor in saving a brother or sister's life.\footnote{61} Under no circumstances could

\footnote{56. In fact, of those few courts which have addressed the subject of experimental medical procedures done for the patient's own benefit, some have held that there is a cause of action in strict liability for any injury sustained during such experimentation. \textit{See} Carpenter v. Blake, 60 Barb. ch. 488 (Sup. Ct. N.Y. 1871); J. Waltz & F. Inbau, \textit{supra} note 53, at 183-84. \textit{But see} Brown v. Hughes, 30 P.2d 259 (Colo. 1934); Fortner v. Koch, 272 Mich. 273, 261 N.W. 762 (1935). It would follow, then, that if the purpose of the procedure is not to benefit the person upon whom it is performed, a cause of action in strict liability would exist.}

\footnote{57. Morse, \textit{Legal Implications of Clinical Investigations}, 20 \textit{Vand. L. Rev.} 747, 754 (1967).}


\footnote{59. Prince v. Massachusetts, 321 U.S. 158 (1944) (conviction of Jehovah's Witnesses for furnishing their minor children with materials to be sold in public places, in violation of state law forbidding such sale, held not violative of first or fourteenth amendments).


\footnote{61. Such consents are sometimes referred to as "substituted judgments." This doctrine has been used to substantiate the consent of a parent for the donation of an organ by an incompetent to an ill brother. Strunk v. Strunk, 445 S.W.2d 145 (Ky. 1969). In \textit{Strunk}, the court reasoned that giving consent for the removal of the kidney of the incompetent brother was for that brother's benefit since the brother's death due to inability to obtain a donor would have had a traumatizing effect on the incompetent. \textit{Id.} at 146. In addition, the risk to the donor was determined to be minimal, estimated at approximately 0.07 percent. \textit{Id.} at 149. The dissent vigorously disagreed. \textit{Id.} It is obviously wrong, however, to extend that doctrine to allow a parent to give consent for nontherapeutic experimentation upon a child. Legal authorities seem to agree. \textit{See}, e.g., Grad, \textit{Legislative Responses to the New Biology: Limits}
those cases be stretched to provide support for the proposition that parents have the right of consent to nontherapeutic medical procedures on their children.

If parents may not consent to nontherapeutic medical procedures on their children, neither may they give such consent on behalf of their unborn children regardless of whether a particular child is wanted or not. In support of this statement, Hans Tiefel has stated:

Consent for such research may not be given for children — whom fetuses most resemble — and should not be given for unborn children either . . .

An even stronger case can be made against harmful non-therapeutic research with abortion fetuses. Not only can such experiments not rely on maternal consent in cases of induced abortions, since the pregnant woman refuses to become a mother, but the assumption that the woman has the best interests of the fetus at heart is weakened, though not necessarily excluded, by her decision to end fetal life through abortion. More importantly, abortions usually lead to the death of the fetus, to an induced death in a case of induced abortion. That places abortion fetuses in the special class of dying human beings. Therefore, they deserve not only the protection from non-necessary or non-beneficial harm that we grant to children but also the additional respect that we offer to the dying.  

The federal regulations agree that the fetus falls within the scope of the protection accorded human subjects and even admonish those concerned “that no research be conducted or supported which fails to treat the fetus with proper care and dignity.”

Treating the fetus with proper care and dignity consistent with its human genetic heritage means applying the same legal principles to the developing child in the womb as are applied to the born child. The legality of abortion is irrelevant to our considerations here. The fact that a woman is able to decide to abort in consort with her physician does not mean that the human being she bears has any less right to


My greatest concern with the substituted judgment doctrine is its use in the case of defective children whose parents refuse consent to necessary medical treatment. For a discussion of various legal theories to support court action in such circumstances, see Baron, Botsford & Cole, Live Organ and Tissue Transplants from Minor Donors in Massachusetts, 55 B.U. L. Rev. 159 (1975).

62. Tiefel, supra note 45, at 87-88.

the dignity of his or her person, or that the unborn human being may be experimented upon merely because he or she is unwanted.

The working draft HEW report submitted for public comment on November 16, 1973, stated these principles very well: “Respect for the dignity of human life must not be compromised whatever the age, circumstance, or expectation of life of the individual. Therefore, all appropriate procedures providing protection for children as subjects in biomedical research must be applied with equal rigor and with additional safeguards to the fetus.”

However, the final federal regulations fall short of these standards. Informed consent is required, but parents are allowed to consent to experiments on the unborn which are not for the benefit of the particular fetus but rather benefit the class of fetuses of which he or she may be a member. Although the risk must be minimal, the term “minimal” is undefined and under certain circumstances is a comparative concept only. For example, section 46.207(a) says that the fetus can be placed at risk only to the minimum extent necessary to meet the health needs of the mother. Yet the lesson of *Roe v. Wade* is that the health needs of the mother are of such significance that no risk to the fetus could supersede those needs; thus, “minimal risk” apparently includes death. Furthermore, where the fetus has been aborted and thus is intended for death, it is obvious that permissive investigators will interpret “minimal risk” in the light of ultimate death. The term “minimal risk” should be more clearly defined or replaced entirely with Richard McCormick’s concept of “no discernible risk.”

Section 46.208(b) allows the mother to consent to nontherapeutic experimentation on the fetus for the sake of biomedical knowledge if 1) the father’s identity or whereabouts cannot be reasonably ascertained, 2) the father is not available, or 3) the mother is a rape victim. However, such research is permitted only if the risk is minimal.

All nontherapeutic research involving the unborn should be prohibited unless that research or experimentation is for the benefit of the particular fetus involved. The same standards used to determine the adequacy of parental consent for research on born children should be applied to the unborn. Thus, no parent should be allowed to give

---

66. Id. § 46.207.
67. For a discussion of permissive investigators, see text accompanying notes 130–37 infra.
68. For a discussion of the term “discernible risk,” see text accompanying notes.
69. 45 C.F.R. § 46.208(b).

---

Published by Villanova University Charles Widger School of Law Digital Repository, 1977
consent to nontherapeutic research involving the unborn unless there is no discernible risk involved. If the fetus is nevertheless injured, a cause of action in strict liability against the researchers would be appropriate notwithstanding the consent.\textsuperscript{70}

VI. A NEW CATEGORY OF HUMAN —

THE NONVIALBE FETUS \textit{Ex Utero}

Perhaps the greatest disservice to mankind caused by both the National Commission’s recommendations and HEW’s regulations is the creation of a new category of human being: the nonviable fetus \textit{ex utero}. One cannot be too hard on either body since the genesis of the problem is the decision of the Supreme Court in \textit{Roe v. Wade} which made the unborn a nonperson under the Federal Constitution. However, merely because the word “person” in the Federal Constitution does not include the unborn, it is not necessarily true that the unborn is not a legal person for other purposes. For example, in the case of wrongful death actions the viable fetus has been determined to have legal rights.\textsuperscript{71}

There has been an unwarranted assumption made that merely because a woman has a constitutional right to abort, she therefore has a mandate to kill the unborn. This does not follow.\textsuperscript{72} The constitutional rights of the mother under the Federal Constitution are supreme over all and any state created rights of the fetus, \textit{but only where those rights are in conflict}. Where there is no conflict, the legal rights of the unborn have equal weight with other legal rights. In the fetal experimentation area no conflict exists between the constitutional right of a mother to abort and the legal rights accorded a living, \textit{ex utero} fetus. Consequently, a fetus born alive by either spontaneous or induced abortion is a legal and constitutional person and is entitled to all the rights and respect accorded to any person. If a fetus is dying because of nonviability, this does not mean it should be accorded less respect.\textsuperscript{73}

\textsuperscript{70} The Model Statute printed in Appendix A follows these principles.

\textsuperscript{71} See note 20 supra. For a survey of the legal rights which have been granted the unborn, see Kindregan, \textit{Abortion, the Law, and Defective Children: A Legal-Medical Study}, 3 Suffolk L. Rev. (1969). In many states the unborn’s intestate rights of succession to property vest immediately upon the death of the decedent, subject to divestment if the child is not born alive. See, e.g., Tomlin v. Laws, 301 Ill. 616, 134 N.E. 24 (1922); Deal v. Septon, 144 N.C. 110, 56 S.E. 691 (1907).

\textsuperscript{72} We should remember that prior to the legalization of abortion by the U.S. Supreme Court, some state abortion statutes allowed abortion to save the child’s life. See, e.g., 40A Minn. Stat. Ann. §§ 617.18, 617.19 (1964) (repealed 1974).

\textsuperscript{73} State legislatures are enacting laws to clarify these questions. For example, in 1975 the state legislature of Illinois passed the 1975 Illinois Abortion Act, which clearly stated that in all areas of the law where the rights of the unborn and the rights
regulations, however, allow nontherapeutic experimentation on the nonviable fetus *ex utero*, requiring merely that the parent or parents give an informed consent.\(^{74}\)

In addition, the language of the regulations is dangerously ambiguous. For example, section 46.209 prohibits experimentation on the fetus *ex utero* prior to the determination of viability unless there is no "added risk" to the fetus.\(^{75}\) Although there is no definition of fetus *ex utero* in the regulations, the term "nonviable fetus" is defined in section 46.203(e) as a living, nonviable fetus *ex utero*.\(^{76}\) If the fetus is nonviable, the limit placed upon experimentation is illusory, since by definition the nonviable fetus is dying and no greater risk can be added than death itself.

A dying fetus should be accorded the same dignity and respect as a dying adult. It is odd indeed that at a time when there is such a hue and cry to accord dignity to the dying adult, there should be so little concern for the dying fetus.\(^{77}\) Professor Louisell in his dissent to the Commission's Report puts the proposition very succinctly: "Recommendation 6 concerns what is now called the 'nonviable fetus of the mother are not in conflict, the unborn child is a legal person from the time of conception. The statute reads:

Section 1. It is the intention of the General Assembly of the State of Illinois to reasonably regulate abortion in conformance with the decision of the United State Supreme Court of January 22, 1973. Without in any way restricting the right of privacy of a woman or the right of a woman to an abortion under those decisions, the General Assembly of the State of Illinois do solemnly declare and find in reaffirmation of the longstanding policy of this State, that the unborn child is a human being from the time of conception and is therefore, a legal person for purposes of the unborn child's right to life and is entitled to the right to life from conception under the laws and Constitution of this State. Further, the General Assembly finds and declares that long-standing policy of this State to protect the right to life of the unborn child from conception by prohibiting abortion unless necessary to preserve the life of the mother is impermissible only because of the decisions of the United States Supreme Court and that, therefore, if those decisions of the United States Supreme Court are ever reversed or modified or the United States Constitution is amended to allow protection of the unborn then the former policy of this State to prohibit abortions unless necessary for the preservation of the mother's life shall be reinstated.

ILL. REV. STAT. ch. 38, § 81-21 to 81-33 (1975).

Under this legislative finding, the nonviable fetus *ex utero* is a legal person entitled to all of the rights and protections of other legal persons. Consequently any experimentation involving the nonviable fetus *ex utero* in Illinois must be for the benefit of that particular fetus or at least have no discernible risk for that fetus. A three-judge federal court has granted a temporary injunction against enforcement of this entire act. Wynn v. Scott, No. 75C-3975 (N.D. Ill., filed Dec. 2, 1976); Long v. Scott, No. 75C-3981 (N.D. Ill. filed Dec. 2, 1976).

74. 45 C.F.R. § 46.209 (1976).

75. Id.

76. Id. § 46.203(e).

77. See P. RAMSEY, supra note 42, at 34.
ex utero,' but which up to now has been known by the law, and I think by society generally, as an infant, however premature."78

In his paper to the National Commission, Professor Capron stated:

As we have seen, nonviable fetuses ex utero have been regarded as persons under the common law of crimes, protected against murder and assault; under statutory law a still greater burden of care (than might be warranted by its "nonviability") may be imposed, as in some abortion laws, and restrictions may be placed on what can be done with it, as in the statutes governing what Louisiana vividly denominates "the crime of human experimentation." The common law of torts and property, and the rules of equity, also regard the nonviable fetus ex utero as a "person" to be accorded the full protection of the law. Although its small size and weight and general lack of development preclude such a fetus from having any true independent existence, the fact of its physical separation from its mother is sufficient to confer upon it the presumption of such independence.79

Thus, the nonviable fetus ex utero is a person under the law — is, indeed, a constitutional person80 — and should be included in experimental protocol only on the same basis as are other persons. Consequently those sections of the federal regulations involving children should be applicable to the nonviable fetus ex utero.

78. Commission's Report, supra note 1, at 317. A three-judge federal court interpreting a Minnesota statute recently discussed this question and declared that a fetus who is "born alive and is capable of living independently of its mother . . . becomes a person — protected by the usual constitutional rights." Hodgson v. Anderson, 378 F. Supp. 1008, 1017 (D. Minn. 1974), appeal dismissed on other grounds sub nom., Spannaus v. Hodgson, 420 U.S. 903 (1975), partially aff'd and partially rev'd on other grounds sub nom., Hodgson v. Lawson, 542 F.2d 1350 (8th Cir. 1976). The statute was nonetheless found unconstitutional because of its declaration that during the second half of the fetus' gestation period (18–20 weeks) a fetus was to be considered "potentially" viable. The District Court thought this created a presumption of viability at the 20th week which it felt was not in accord with the teaching of Roe v. Wade, 378 F. Supp. at 1016. However, Dr. Leon Kass recommended to the National Commission that "accurate evaluation of the viability of a fetus in utero between 20 and 28 weeks gestational age is not possible; such a fetus should be presumed viable if a heartbeat is audible using a stethoscope." Commission's Report, supra note 1, at 40 Fed. Reg. 33,544 (1975). The Peel Report recommended no research beyond the 20th week and defined viability for research purposes to begin at 20 weeks. See P. Ramsey, supra note 42, at 69. For a discussion of the concept of viability, see Horan, Viability, Values and the Vast Cosmos, 22 Cath. Law. 1 (1976).

79. Appendix, supra note 1, at 13–1 to 13–25 (footnote omitted). Professor Capron then raised the question of whether such protection to the nonviable fetus ex utero is wise, but he nonetheless cited and concurred with the authorities which support the clear legal proposition that the nonviable fetus ex utero is a person under the law.

80. Roe v. Wade is silent on the subject of fetal experimentation but by implication indicates that live birth confers personhood. See 410 U.S. at 156–62.
VII. The Fetus in Utero

A. The Fetus in Utero and Pain

One of the most intriguing aspects of the papers delivered to the National Commission concerns the fetus in utero and its ability or inability to perceive pain. Dean Wilson refers to this in his legal paper81 as do the ethicists Sisela Bok82 and Commissioner Karen Lebacqz83 in their individual statements. To all three, the perception or nonperception of pain was dispositive in some way of important ethical issues at stake in fetal experimentation. For example, Commissioner Lebacqz says that recommendation 6 regarding research on the fetus during the abortion procedure and on the nonviable fetus ex utero should be changed if the fetus is able to experience pain before the twentieth week of gestation.84

Consider the ramifications of such moral reasoning upon the treatment of the comatose patient. Since such a patient feels no pain, does it necessarily follow that he or she can be experimented upon? Surely no one would propose that we should be able to experiment as we choose as long as the subjects are sedated. It is unclear, then, what the fetus' receptivity to pain has to do with ethical principles. For Commissioner Lebacqz, if the fetus does feel pain then the pain of the dying subject may be minimized even if its lifespan is shortened.85 For Professor Wilson the receptivity of the fetus to pain is relevant because of the brutalizing effect nontherapeutic experimentation would have under such circumstances.86

The issue, however, is not pain but human rights. As the Supreme Court of West Germany has said, "Where human life exists, human dignity is present to it; it is not decisive that the bearer of this dignity himself be conscious of it and know personally how to preserve it."87 The question of pain resurrects the fundamental issue of fetal experimentation in utero: the status of the fetus in utero. Ex utero and alive, the fetus is a legal person. What is the fetus in utero either before or after viability? The answer to this question may depend upon the value our society places upon each individual human life and the time

81. Appendix, supra note 1, at 14-18.
82. Appendix, supra note 1, at 2-4, 2-7.
83. COMMISSION'S REPORT, supra note 1, at 321-22.
84. Id.
85. Id. at 85.
86. Appendix, supra note 1, at 14-18.
when that value commences. If that value is a constitutional right to life, then the legal question is when that constitutional right to life vests. If the fetus in utero is a human being, then that human is entitled to the same legal protection as any other. The rights created by the United States Supreme Court in *Roe v. Wade* take precedence, but when the maternal rights there defined are not involved and are not in conflict with any rights asserted on behalf of the unborn, as is the case when we are discussing fetal experimentation, then the teachings of *Roe v. Wade* should not cloud our ability to analyze other legal questions in a clear and concise manner.

B. The Development of the Fetus In Utero

Justice Blackmun wrote in *Roe v. Wade*: "We need not resolve the difficult question of when life begins. When those trained in the respective disciplines of medicine, philosophy, and theology are unable to arrive at any consensus, the judiciary, at this point in the development of man's knowledge, is not in a position to speculate as to the answer." However, he also stated that "we do not agree that, by adopting one theory of life, [that individual human life begins at conception] Texas may override the rights of the pregnant woman that are at stake." 

This contrasts vividly with the holding of the West German Supreme Court which found in its constitution an affirmative mandate to protect human life at all stages of its development. Indeed, even the dissent in the West German Court agreed that human life existed in utero and disagreed only with the way in which the affirmative constitutional mandate should be carried out.

In September, 1948, the World Medical Association (of which the United States is a founding member), after a lengthy discussion of war crimes, based upon information from the United Nations War Crimes Commission, adopted the Declaration of Geneva which says: "I will maintain the utmost respect for human life, from the time of conception; even under threat, I will not use my medical knowledge contrary to the laws of humanity." This was followed in October 1949 by the International Code of Medical Ethics, which states that "a doctor must always bear in mind the importance of preserving human life from the time of conception until death." This was reaffirmed

89. Id. at 162.
90. See Gorby & Jones, supra note 87.
91. 1 WORLD MED. A. BULL. 22 (1949).
92. Id.
93. 2 WORLD MED. A. BULL. 5–34 (1950).
by the World Medical Association in 1950 with the Declaration of Oslo: "[T]he first moral imposed upon the doctor is respect for human life as expressed in the clause of the Declaration of Geneva: 'I will maintain the utmost respect for human life from the time of conception.'" 94

Furthermore, on November 20, 1959, the General Assembly of the United Nations unanimously adopted the Declaration of the Rights of the Child. The Preamble to the declaration emphasized that children, by reason of their physical and mental immaturity, need particular safeguards and care, including appropriate legal protection, both before and after birth. 95

Individual human life begins at conception (the union of the mother's egg with the father's sperm) and is a progressive, ongoing continuum until natural death. This is not merely a theory, as so many have asserted. There is nothing theoretical about the beginning of each human life; the unborn is actual, not potential. 96

From conception the child is a complex, dynamic, rapidly growing individual. 97 By a natural and continuous process, the single fertilized ovum will, over a period of approximately nine months, develop into the trillions of cells of the newborn. The natural end of the individual sperm and ovum is death unless fertilization occurs. In other words, we are neither grown-up sperms nor are we grown-up eggs. At fertilization a new and unique individual is created which, although receiving one-half of its chromosomes from each parent, is really unlike either. 98

The events that follow fertilization are self-generated by the new individual under the guidance of his or her new and absolutely unique hereditary plan. The new combination of chromosomes sets in motion the individual's life, controlled by his or her own individual code (genes) with its enormous library of information projected from the

94. Id.
96. The leading textbooks on embryology all agree. See, e.g., texts cited in note 18 supra.
97. I gratefully acknowledge the work of Dr. Bart Heffernan and Dr. Thomas W. Hilgers in compiling the material and in preparing the amicus curiae brief on behalf of the unborn child in Roe v. Wade from which the following account of the development of the unborn is taken. This brief was reprinted in 75 LANDMARK BRIEFS AND ARGUMENTS OF THE SUPREME COURT OF THE UNITED STATES: CONSTITUTIONAL LAW 381–488 (P. Kurland & G. Casper eds. 1976). See also ABORTION AND SOCIAL JUSTICE (T. Hilgers & D. Horan eds. 1973).
98. See generally L.B. AREY, supra note 18; A. INGLEMAN-SUNDBERG & C. WIRSEN, supra note 18; B.M. PATTEN, supra note 18; R. RUGH & L.B. SHETTLES, supra note 13.
past on the helix of deoxyribonucleic acid (DNA). A single thread of DNA from a human cell contains information equivalent to 600,000 printed pages with 500 words on a page, or a library of 1,000 volumes. The stored knowledge at conception in the new individual's library of instructions is fifty times more than that contained in the Encyclopedia Britanica. These unique and individual instructions are operative throughout the individual's life and form a continuum of human existence even into succeeding generations.

The first month of life probably represents the most outstanding biological achievement which any individual human life experiences. The complexity of this early human life is so great that it is literally beyond our comprehension, and it therefore demands our respect. Sometimes, because we do not understand this process, we belittle it without giving any thought to the dynamics of what is actually happening.

With the development of sophisticated radio immunoassay techniques, the diagnosis of pregnancy can be made within nine days after fertilization and prior to implantation. Very shortly after conception the prospective sex of the child can be determined. Marcel and Exchaquet observed contractions of the human heart in embryos as early as two weeks after conception. By five weeks of age, tracings exhibiting the classical elements of the adult electrocardiogram can be obtained.

The primitive skeletal system is completely developed by the end of the sixth week and the electroencephalogram has detected brain waves as early as forty-three days. During the sixth and seventh weeks, the nerves and muscles begin working together for the first time, and the lips become sensitive to touch (the first area of the body to do so), and when gently stroked, the child responds predictably.

102. Marcel & Exchaquet, L'electrocardiogramme du Foetus Human avec un cas de Double Rythme Auriculaire Verifie, 13 ARCH. MAL. COEUR 504 (1938).
103. See, e.g., L.B. Arey, supra note 18, at 55; B.M. Patten, supra note 18, at 39.
105. Arey, supra note 18, at 55.
By the seventh week of life, the child's shape and form is unmistakably human. The child now has all the internal organs of the adult; the stomach produces digestive juices, the liver manufactures red blood cells, and the kidney eliminates uric acid from the blood. From this point in development, until age twenty-five to twenty-seven years, when full growth and development is complete, the only major changes will be in the size and sophistication of functioning parts.

Fingerprints begin to develop at eight weeks and will remain a unique feature of the individual for the duration of a lifetime. The eyelids and palms of the hands become sensitive to touch at about eight-and-one-half weeks. At this point, if the eyelids are touched, the child squints; if the palm is touched, the fingers close into a small fist. Sex hormones, especially estrogens and androgens, have been identified as early as nine weeks. At ten weeks, somatotrophic hormone (growth hormone) is detectable, and at ten-and-one-half weeks, the thyroid and adrenal glands have begun to function. At ten weeks it is possible to detect the child's heartbeat with the use of ultrasonic techniques which are used routinely by obstetricians.

By the end of the third month, the unborn child has become very active. The child can now kick its legs, turn its feet, curl and fan its toes, make a fist, move its thumb, bend its wrist, turn its head, squint, frown, open its mouth, and press its lips tightly together. The child is able to swallow and drink the surrounding amniotic fluid. Inhaling and exhaling respiratory movements begin to move fluid in and out

107. G.L. FLANAGAN, supra note 103; B.M. PATTEN, supra note 18, at 39.
109. G.L. FLANAGAN, supra note 103; B.M. PATTEN, supra note 18, at 39.
111. A. GESSELL, supra note 105; Miller, Dermal Ridge Patterns: Techniques for Their Study in Human Fetuses, 73 J. PEDiatrics 614 (1968).
112. See G.L. FLANAGAN, supra note 103; D. HOOKER, EARLY HUMAN FETAL BEHAVIOR, supra note 103; D. HOOKER, THE ORIGIN OF OVERT BEHAVIOR, supra note 103; D. HOOKER, THE PRENATAL ORIGIN OF BEHAVIOR, supra note 103.
114. Id.
115. Id.; Shephard, Onset of Function in the Human Fetal Thyroid: Biochemical and Radiotopographic Studies from Organ Culture, 27 J. CLINICAL ENDOCRINOLOGY & METABOLISM 945 (1967).
of its lungs. Thumbsucking is first noted at this age.\textsuperscript{118} The child has vocal chords and fingernails and is able to urinate.\textsuperscript{119}

During the fourth month of life the unborn child grows very rapidly. Weight increases six times over and the child grows eight to ten inches in length.\textsuperscript{120} In the fifth month (sixteen to twenty weeks), the unborn child will become one foot tall and weigh approximately one pound. Hair begins to grow on its head; eyebrows and a fringe of eyelashes appear. The child sleeps and wakes just as it will after birth\textsuperscript{121} and may even be aroused from sleep by external vibrations.\textsuperscript{122} The skeleton hardens and the muscles become stronger. Finally, the mother perceives the child’s activities.

Certainly the fetus is in control of its own environment during the course of its development in the womb.\textsuperscript{123} The fetus is not a passive, dependent, nerveless, fragile vegetable, as tradition has held, but a young human being, dynamic, plastic and resilient.

The fetus is aware of pain and discomfort and responds with violent movement to needle puncture and the intramuscular or intraperitoneal injection of cold or hypertonic solutions. Although we would accept that these stimuli are painful for adults, children, and, judging from its reaction, for the neonate, we are not entitled to assert that the fetus feels pain. Nevertheless, it is the purposeful avoidance of discomfort which determines fetal position \textit{in utero}.\textsuperscript{124}

The fetus is responsible for the regulation of the amniotic fluid volume. The fetus does not need kidneys to regulate body water and electrolytes, since the placenta handles this task; but the fetus does

\begin{footnotesize}
\begin{enumerate}
\item[118.] G.L. Flanagan, \textit{The First Nine Months of Life}, \textit{supra} note 103; D. Hooker, \textit{The Prenatal Origin of Behavior}, \textit{supra} note 103.
\item[119.] L.B. Arey, \textit{supra} note 18, at 55; G.L. Flanagan, \textit{supra} note 103; B.M. Patten, \textit{supra} note 18, at 39.
\item[122.] G.L. Flanagan, \textit{supra} note 103.
\item[124.] \textit{Id.}
\end{enumerate}
\end{footnotesize}
need kidneys for maintenance of amniotic fluid volume. A patent and functional gastro-intestinal tract is also required.\textsuperscript{125}

Fetal swallowing regulates amniotic fluid volume; it is not clear what regulates fetal swallowing. Whereas fetal urination does not contribute to fetal hydration, fetal swallowing does appear to contribute to fetal nutrition, for babies who cannot swallow amniotic fluid (e.g., those with esophageal or duodenal atresia) are smaller at maturity than normal babies.\textsuperscript{126} This evidence raises the possibility that fetal hunger in fact regulates fetal swallowing.

Another type of fetal control and perhaps its most dazzling achievement is the fetus' command of a parabiotic situation.\textsuperscript{127} In an out-bred population, mother and fetus are inevitably immunological foreigners; the baby is immunologically foreign to the mother just as the frequently rejected heart transplant is immunologically foreign to the recipient. Yet for successful pregnancy they must be made to accept each other as mutual homografts. Early explanation of this mutual acceptance attempted to give credit to the mother. However, the uterus is certainly not an immunologically privileged site, and the conceptus can grow in sites other than the uterus — for instance, the tube or peritoneum. Thus, it now appears that it is a component of the fetus which ensures the immunological success of pregnancy. This component is the trophoblast, which not only forms a continuous barrier between the circulations of mother and fetus but also fails to express any transplantation antigens itself. The trophoblast acts as an immunological barrier or buffer between mother and fetus so that each is completely indifferent not only to the transplantation antigen of the other but even to a specific sensitivity of the other against his own antigens.

It has been shown that flashing lights applied to the maternal abdominal wall produce fluctuations in the fetal heart rate.\textsuperscript{128} A sudden noise in a quiet room startles the fetus lined up under an image intensifier. The fetus drinks more amniotic fluid if it is sweetened and swallows very little if the amniotic fluid is made bitter. It even appears inescapable that the normal onset of labor is triggered by mechanisms controlled by the fetus.\textsuperscript{129}

Because the medicine of adults preceded the medicine of the infant, neonate and fetus, a tendency has developed in all fields from surgery to psychiatry to study adult life first and then work backwards. Since the standard of all that is normal in medicine has been the fit young

\textsuperscript{125} Id.
\textsuperscript{126} Id.
\textsuperscript{127} Id.
\textsuperscript{128} Id.
\textsuperscript{129} Id.
adult male, any function in the baby which differs from this standard has been considered as immaturity, and by inference, inferiority. The net effect has been to consider the fetus and neonate as a poorly functioning adult rather than as a splendidly functioning baby.

There is little question that a major thrust of medicine in the last fifteen years has been to treat the unborn child as an independent patient in its own right. We have now made great strides in the diagnosis and the treatment of diseases of the unborn. The first major development in this regard was accomplished by Doctor Sir William Liley, who first performed an intrauterine transfusion to treat an infant afflicted with Rh disease. This marked the beginning of the new science of fetology, the study of the unborn, and Doctor Liley is generally considered to be the “father of fetology.” Since that time a number of other advances have been made, the most dramatic of which has been the direct surgical operation on the unborn. A pioneer in this field, Doctor Stanley Aasensio, of the University of Puerto Rico School of Medicine, has actually taken the fetus out of the mother’s womb, performed the operation, and then placed him back into the womb only to be later delivered as a healthy, normal child.

A most appropriate comment regarding the fetus in utero was written by Doctor Sir William Liley:

Not all of us will live to be old, but we were each once a fetus. We had some engaging qualities which unfortunately we lost as we grew older. We were supple and physically active. We were not prone to disc lesions and were not obese. Our most depraved vice was thumbsucking, and the worst consequence of drinking liquor was hiccups. We ruled our mothers with a serene efficiency which our fathers could not hope to emulate. Our main handicap in a world of adults was that we were small, naked, nameless and voiceless. But surely if any of us count for anything now, we counted for something before we were born.

The study of the unborn is still a relatively new science and yet in its short existence it has put into perspective what the obstetrician has known for years; when working with a pregnant woman, there are two patients involved. Research over the past fifteen to twenty years has proven that the child within its mother is a distinct individual in need of the most diligent study and care. Both patients, mother and child, require and challenge the fullest expertise of our medical art. Consequently, no experimentation should be allowed in utero from the

130. See Rorvik, The Brave New World of the Unborn, Look, Nov. 4, 1969, at 76.
131. Id. at 74.
132. Liley, supra note 120.
time of conception onward unless such experimentation is for the health needs of mother and child.

VIII. THE REGULATORY SCHEME AND NORMATIVE ETHICS

Although the regulations of HEW are an important step in the control of fetal experimentation, they are not sufficient. They contain many pitfalls, as we have seen, and are limited in scope to research supported by grants from HEW. Thus, there is a continuing need for state statutory and regulatory schemes.

Regulation is especially critical due to the disregard for human safety and dignity manifested by many researchers. Beginning in 1966, the National Institutes of Health (NIH), the Food and Drug Administration (FDA) and HEW began issuing regulations governing experimentation with human subjects. Although investigators have complained about this “interference,” a recent study indicated, “[o]n the basis of our results I would argue that there is indeed inadequate ethical concern among biomedical investigators, that it is reflected in excessively risky procedures and that better internal and external controls are essential.”

Although no such records are specifically maintained, NIH says that about one-third of its approved projects involve human subjects. Concern that these human subjects exercise an informed consent has been heightened by the revelations in recent years of experiments conducted without adequate informed consent of the subject and, indeed, in some instances without any knowledge at all on the part of the human subjects involved. For example, “[i]n the 1960’s two respected cancer investigators who were studying the immune response to malignancies injected live cancer cells into a number of geriatric patients at the Jewish Hospital and Medical Center of Brooklyn without first obtaining the patients’ informed consent.”

In another famous case, a leading virologist exposed severely retarded children to hepatitis virus. One of the most well-known incidents involves the syphilis experiments in Tuskegee, Alabama. As late as 1945, when penicillin had become available as a safe and effective cure of syphilis, participants were maintained on observation without being given the penicillin, and presumably some men died of the disease who could have been cured.

---

134. Id.
135. Id. at 26.
136. Id.
137. Id.
A pediatric neurosurgeon recently told this author that he had
been requested by his teaching medical institution to undertake a con-
trolled study which, in his opinion, was unethical. This study consisted
of withholding certain kinds of treatment from defective newborns
whose long term health outlook would then be compared to the treated
group. He refused. Another example of experimentation conducted
without the participants' consent concerns the Army's disclosure
eighteen years after the fact that "volunteer" participants in a chemical
warfare program had unknowingly consumed LSD.138 One of the
participants in this experimental program had committed suicide, and
it was only the persistence of his family which brought this noncon-
sensual experimentation to light.

In their carefully controlled study of attitudes of researchers,
Barber and his group concluded that "whereas the majority of the
investigators were what we called 'strict' with regard to balancing
risks against benefits, a significant minority were 'permissive,' that is
they were much more willing to accept an unsatisfactory risk-benefit
ratio."139 If this finding is true with regard to experimentation on
adults and children, one can imagine what would be the corresponding
result of such a survey where the experimentation involved unborn
children destined for abortion or the nonviable fetus ex utero. Ob-
viously, the ethically permissive researcher as described by Barber
would find little in the way of ethical concerns to deter him in his
research protocols. How would such a permissive research type inter-
pret the very significant words "minimal risk" as used in the regula-
tions?

It becomes even clearer that regulatory control of research in-
volving the fetus is necessary when one considers this significant finding
from Barber's study:

How does it happen that the treatment of human subjects is some-
times less than ethical, even in some of the most respected uni-
versity-hospital centers? We think the abuses can be traced to
defects in the training of physicians and in the screening and
monitoring of research by review committees, and also to a funda-
mental tension between investigation and therapy. We have data
bearing on each of these causative factors.

It is in medical school that the profession's central and most
serious concerns are presumably given time and place and that
its basic knowledge and values are instilled. Yet the evidence from
our interviews shows that there is not much training in research
ethics in medical school. Of the more than 300 investigators who

139. Barber, supra note 130, at 27.
responded to questions in this area, only 13 percent reported they had been exposed in medical school to part of a course, a seminar or even a single lecture devoted to the ethical issues involved in experimentation with human subjects; only one respondent said he had taken an entire course dealing with the issues. Another 13 percent reported that the subject had come to their attention when, as students, they did practice procedures on one another; for 24 percent it was in the course of experiments with animals; 34 percent remembered discussion of ethical issues in specific research projects. One or more of these learning experiences were reported by 43 percent of the respondents — but the remaining 57 percent reported not a single such experience. The figures were about the same whether the investigators were graduates of elite U.S. medical schools, other U.S. schools or foreign schools. The figures were a little better, however, for those who had graduated since 1950 than for older investigators.\(^4\)

Such findings raise the question of what kind of normative ethics are being referred to in the HEW regulations which require the submission of protocols to Ethical Advisory Boards for ethical review. The regulations approach the subject of fetal experimentation as though ethical norms existed with which all agreed, or as though a broad consensus in the community still prevailed. That consensus may still exist with respect to most medical-ethical questions where nondefective born children, or adults not terminally ill are concerned; however, where the unborn are concerned and where abortion is involved, to speak of ethical norms is nonsense.

Joseph Fletcher stated the issue best: "The core question at stake in the ethics of fetal research is whether a fetus is a person."\(^1\) He concluded that the fetus is not a person and only has value when it is wanted. His ethical appraisal leads him to five conclusions:

1. It is justifiable, depending on the clinical situation and the design, to make any use of abortuses or dead fetuses — whole, tissues, or uterine materials — whether from voluntary or therapeutic abortions, and with or without maternal consent.

2. It is justifiable, depending on the clinical situation and the design, to make any use of live fetuses ex utero, previable or viable, if survival is not purposed or wanted, and if there is maternal consent.

3. It is justifiable, depending on the clinical situation and the design, to make any use of live fetuses in utero, if survival is not purposed or wanted, and if there is maternal consent.

\(^{140}\) Id. at 29.
\(^{141}\) Fletcher, Fetal Research: An Ethical Appraisal, in Appendix, supra note 1, at 3-3.
(4) It is justifiable, depending on the clinical situation and the design, to use live fetuses in utero even if survival is intended, if there is no substantial risk to the fetus, and if there is both maternal and spouse-paternal consent.

(5) As a fifth finding we may add the point already discussed, that regulations by the public authority are unethical if the reasons for them, the ethics they are rested upon, are not disclosed fully and frankly.\(^{142}\)

When the regulations refer to ethics and ethical norms, are the ethics of Fletcher those to which they refer? Presumably not, since the regulations have rejected such thinking. But who is to say whether individual members of the Ethical Advisory Boards or the review boards will not follow the ethical norms as set forth by Fletcher? This is not a farfetched concern; the ethical norms about which Fletcher speaks have had a profound effect upon the legalization of abortion and are leading to the legalization of infanticide and euthanasia.\(^{143}\)

The obvious purpose of Fletcher’s last conclusion, that public regulations are unethical if the ethics supporting them are not disclosed fully and frankly, is to give to investigators who want to avoid the regulations an ethical rationale for doing so. Similar reasoning supported the abortionists who flaunted the law when abortion was illegal. With Fletcher as their guide, researchers may well flaunt these governmental regulations, even when applicable, “for the good of mankind.”

Clearly, then, research on the unborn requires closer regulation. Appendix A sets forth a model state statutory scheme for the protection of human subjects, including the unborn.\(^{144}\) Obviously, such a proposed piece of legislation must be studied carefully before being proposed for adoption in a particular state. It is intended to be merely a starting point for states interested in legislation to regulate the conduct of clinical research with human subjects, including the unborn. Nevertheless, the statute does attempt to obviate most of the pitfalls of the federal regulations outlined in this article, including the problems involved in legislating only in the area of fetal experimentation. Adopting such a statutory scheme would go far toward resolving the difficult and troublesome issues presented by fetal experimentation. However, it is my belief that only a constitutional amendment which restores the constitutional right to life to the unborn will ultimately solve all of these problems.

\(^{142}\) Id. at 3–11.

\(^{143}\) J. Fletcher, Ethics and Euthanasia, in To Live and to Die: When, Why and How 113–22 (1973). See also Duff & Campbell, supra note 51.

\(^{144}\) I have used a model piece of legislation previously introduced into the Illinois Assembly but modified to fit my objections.
APPENDIX A

AN ACT to regulate the conduct of clinical research with human subjects, including the unborn.

Be it enacted by the People of the State of __________, represented in the General Assembly:

Section 1. This Act may be referred to and cited as the "__________ Clinical Research Act."

Section 2. The conduct of clinical research in the State of __________ is declared to affect the public health, safety, and welfare. It is further declared that the purpose of this Act is to safeguard the health and welfare of human subjects including the unborn and to assure the continued excellence of clinical research in __________. Further, it is the intent of the legislature of the State of __________ that no research be conducted or supported in __________ which fails to treat all humans, including the unborn, with proper care and dignity. This Act shall be liberally construed to carry out these purposes.

Section 3. This Act applies to all clinical research conducted in the State of __________ and to all persons conducting or participating in such research, but this Act does not apply to professional medical or dental practice by any one licensed under the laws of the State, in which disease in a particular, individual patient is investigated and treatment initiated solely with the view of preventing, arresting, or curing the disease in that patient.

Section 4. For the purposes of this Act, unless the context otherwise requires, the terms specified in Section 4.01 through 4.13 have the meanings ascribed to them in those Sections.

Section 4.01. "Clinical Research" means any biomedical or behavioral research involving human subjects, including the unborn, conducted according to a formal procedure. The term is to be construed liberally to embrace research concerning all physiological processes in man and includes research involving human in vitro fertilization.

Section 4.02. "Subject at risk" or "subject" means any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.

Section 4.03. "Informed consent" means the knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary to such consent include:

(1) A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;
(2) a description of any attendant discomforts and risks reasonably to be expected;
(3) a description of any benefits reasonably to be expected;
(4) a disclosure of any appropriate alternative procedures that might be advantageous for the subject;
(5) an offer to answer any inquiries concerning the procedures; and
(6) an instruction that the person is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the subject.

Section 4.04. "Research Review Committee" or "Committee" means an institutional review committee, board or similar body, the structure and function of which has been accepted by the Department as being consistent with generally established rules and regulations for conducting scientific research.

Section 4.05. "Pregnancy" encompasses the period of time from confirmation of conception until expulsion or extraction of the fetus.

Section 4.06. "Fetus" means the product of conception from the time of conception until a determination is made, following expulsion or extraction of the fetus, that it is viable.

Section 4.07. "Viable" as it pertains to the fetus means being able, after either spontaneous or induced delivery, including abortion, to survive, if given the benefit of
available medical therapy, to the point of independently maintaining heartbeat and respiration.

Section 4.08. "Nonviable fetus" means a fetus ex utero which, although living, is not viable.

Section 4.09. "Live fetus" means a fetus ex utero which exhibits either heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, or pulsation of the umbilical cord (if still attached).

Section 4.10. "In vitro fertilization" means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.

Section 4.11. "Person" means any individual, firm, partnership, association, State or local governmental agency, corporation, whether organized for profit or not, or any form of business, charitable, or education enterprise.

Section 4.12. "Department" means the Department of Public Health of the State of [blank].

Section 4.13. "Institution" means any public or private organization or agency, including State and local government agencies.

Section 4.14. "Non-therapeutic clinical research or experimentation" means any biomedical or behavioral research involving human subjects including the unborn conducted according to a formal procedure but not for the particular benefit of the subjects involved.

Section 5. Clinical Research may be conducted in the State of [blank] only if:

(a) a Committee of the institution has reviewed and approved such activity, and the institution has submitted to the Department a certification of such review and approval, in accordance with the requirements of this Section.

(b) this review shall determine whether the subjects will be placed at risk, and if risk is involved, whether:

(1) 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 a decision to allow the subject to accept those risks;

(2) the rights and welfare of any such subjects will be adequately protected;

(3) legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provisions of Section 6; and

(4) the conduct of the activity will be reviewed at timely intervals.

(c) approval of research involving human subjects at risk shall not be given to an individual unless he is affiliated with or sponsored by an institution which can and does assume responsibility for the subjects involved.

Section 6. The actual procedure utilized in obtaining legally effective informed consent and the basis for Committee determinations that the procedures are adequate and appropriate shall be fully documented. The documentation of consent will employ one of the following three forms:

(a) Provision of a written consent document embodying all of the basic elements of informed consent. This may be read to the subject or to his legally authorized representative, but in any event he or his legally authorized representative must be given adequate opportunity to read it. This document is to be signed by the subject or his legally authorized representative. Sample copies of the consent form as approved by the Committee are to be retained in its records.

(b) Provision of a "short form" written consent document indicating that the basic elements of informed consent have been presented orally to the subject or his legally authorized representative. Written summaries of what is to be said to the patient are to be approved by the Committee. The short form is to be signed by the subject or his legally authorized representative and by an auditor witness to the oral presentation and to the subject's signature. A copy of the approved summary, annotated to show any additions, is to be signed by its persons officially obtaining the consent and by the auditor witness. Sample copies of the consent form and of the summaries as approved by the Committee are to be retained in its records.

Section 7. Minors, or mentally incompetent persons may be used as subjects only if:

(a) the nature of the investigation is such that adults or mentally competent persons would not be suitable subjects, and
(b) consent, in writing, is given by both parents or legal guardian of the subject, under circumstances in which a prudent adult would reasonably be expected to volunteer himself as a subject, and there is no discernible risk to the minor child or incompetent.

(c) consent to research not conducted in the interest of a particular incompetent or minor child, may be granted only by a court in addition to the written consent of both parents. Such consent shall be granted only where there are no discernible risks to the incompetent or minor child.

Section 8. Any other provision of this act notwithstanding:

(a) No clinical research activity involving fetuses or pregnant women shall be conducted unless:

(1) Appropriate studies on animals and nonpregnant individuals have been completed;

(2) Except where the purpose of the activity is to meet the health needs of the particular fetus, there is no discernible risk to the fetus and, in all cases, is the least possible risk for achieving the objectives of the activity;

(3) Individuals engaged in the activity will have no part in: (i) Any decisions as to the timing, method, and procedures used to terminate the pregnancy, and (ii) determining the viability of the fetus at the termination of the pregnancy; and

(4) No procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.

(b) No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

(c) No consent to involve a pregnant woman or a fetus as a subject in clinical research activity shall be valid unless the persons giving consent have been fully informed as provided in Section 6.

Section 9. In addition to other provisions of this Act:

(a) No pregnant woman may be involved as a subject in any clinical research activity unless: (1) The purpose of the activity is to meet the health needs of the mother 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 is minimal.

(b) An activity permitted under paragraph (a) of this Section may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (1) The purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape.

Section 10. In addition to other provisions of this Act:

(a) No fetus in utero may be involved as a subject in any clinical research activity unless 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.

(b) An activity permitted under paragraph (a) of this Section 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.

Section 11. In addition to other provisions of this Act:

(a) No live fetus ex utero may be involved as a subject in any clinical research activity unless 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.

(b) In the event the live fetus ex utero is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of this Act pertaining to minors.

(c) An activity permitted under paragraph (a) or (b) of this Section 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 (2) the pregnancy resulted from rape.
Section 12. Clinical research activities involving a dead fetus, mascerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with rules and regulations of the Department except as otherwise directed by State or local laws.

Section 13. No clinical research activity involving human in vitro fertilization shall be conducted unless there is a reasonable degree of medical certainty that the products of such in vitro fertilization can survive to maturity without unreasonable risk of harm.

Section 14. Each Research Review Committee shall maintain full records of its proceedings and deliberations, and of all protocols, proposals, reports, consent forms, and other papers submitted to it concerning clinical research conducted in Illinois. Each Research Review Committee shall complete a form prescribed and furnished by the Department at the end of each calendar quarter. Such form shall include, but not be limited to the following information concerning any clinical research conducted in the State of Illinois:

(a) the name of the person conducting the research,
(b) the title and purpose of the research, and
(c) the location of the investigation; provided, however, that no filing shall be required hereunder for clinical research for which a separate filing is required under Section ______ of the _______________ Food, Drug and Cosmetic Act, as now or hereafter amended. Records of the Research Review Committee shall be open to inspection by qualified persons in the Department at all reasonable times. No person qualified to inspect these records shall communicate orally or in writing, to or for any other person, or make available for public inspection matters that are:

(a) specifically exempted from disclosure by statute;
(b) trade secrets and commercial or financial information obtained from a person and privileged or confidential; or
(c) personnel and medical files and similar files the disclosure of which would constitute an unwarranted invasion of personal privacy.

Section 15. The conduct by any person of clinical research not approved in accordance with this Act is declared a nuisance inimical to the public health. The Director of the Department, the Attorney General of the State of _______________, the State's Attorney of any county in the State, or any resident citizen may maintain an action in the name of the people of the State of ________________ for an injunction in any court of competent jurisdiction to enjoin the conduct of any such unapproved clinical research until compliance with the provisions of this Act has been obtained. In case of violation of any injunction issued under the provisions of this Section, the court or any judge thereof, may summarily try and punish the offender for contempt of court.

Section 16. Any other provision of this Act notwithstanding, any child, whether born or unborn, injured in non-therapeutic clinical research or experimentation, shall have a cause of action in strict tort liability for damages against those persons having charge of such non-therapeutic clinical research or experimentation or their employers, any consent to such non-therapeutic clinical research or experimentation by parents or guardians notwithstanding.