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FETAL RESEARCH: AN INVESTIGATOR'S VIEW

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"So among the experiments that may be tried on man, those that can only harm are forbidden, those that are innocent are permissible, and those that may do good are obligatory."¹ These clear precepts established in another century by the French physiologist, Claude Bernard, represent a distillate of most of the ethical principles of modern investigators. Indeed, Bernard's guidelines would be sufficient today were it not for the fact that they apply only to the decisions of the experimenting physician and not to the interaction between that investigator and his human subject. They would be complete had Bernard written: "So among the experiments that may be tried on *consenting* man"

Much of the debate concerning research on human subjects has been engendered by groups or individuals who perceive certain biomedical studies as profound violations of the principles of informed consent. Though many investigators would prefer to carry on this debate within the confines of the medical community, it is obvious that society has moved beyond the cozy period during which professionals could establish their own rules of conduct absent consultation with the broader community. Seventy years ago, Walter Reed was a national hero for illuminating the cause and prevention of yellow fever by deliberately exposing volunteers to that fatal disease. A great hospital is now named for him. Today, he might possibly be sentenced to prison by an outraged community, for it is increasingly apparent that our society is, in general, unwilling to acquire biomedical information, no matter the import, at the expense of the weak, the unprotected, or the zealous, ill-informed volunteer. Perhaps the growing national distrust of all technocrats, from nuclear experts to supersonic aircraft engineers, now includes biomedical investigators. A return to the eighteenth and nineteenth century body snatcher image of the medical scientist is in progress in certain circles.

Indeed, on rare occasions, biomedical scientists have earned their newly awarded opprobrium. Reports of dangerous experiments carried out without adequate informed consent have occasionally appeared

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1. C. BERNARD, INTRODUCTION TO THE STUDY OF EXPERIMENTAL MEDICINE 102 (1927).

during the past ten years. Such reports are infrequent, but the public must wonder whether they constitute the tip of an iceberg.

In response to public rumblings of suspicion, the National Institute of Health (NIH), the major funding source of biomedical research in the United States, has expended a large effort to determine the actual risk of research on human subjects, at least among its own grantees. In fact, that risk is not greater than the risks incurred in a control population; but more importantly, NIH has imposed increasingly complex controls over the independent decisions of the individual investigators who are its grantees. The authority of hospital review committees and their public members over the design of protocols involving human investigation is increasing.

Though this NIH action has been very useful and reassuring, one of the most vexing problems that has yet to be resolved is the value of informed consent in certain populations. For example, does the loyal patient of a devoted physician actually give "informed consent" when that physician asks the patient to consent to an investigative procedure? Even if a third party makes the request, the very knowledge that a particular physician is the investigator can be enough to influence the patient's judgment. Bernard must have recognized that problem. He puts the entire onus of responsibility for the "right" decision directly on the physician.² The quality of the patient's consent is ignored. A further example is the soldier or the prisoner. Both are in a chain of command, and the latter is desperate for approval, relief from tedium and, above all, freedom. Can either make informed, voluntary decisions?

The third major group to cause confusion and debate are children. Can parents consent to nontherapeutic research on their children? Will a parent consent to such procedures on "behalf" of one child to whom he or she relates poorly, while zealously protecting a favorite from any potentially unnecessary procedures? None of the above ethical questions are easy to resolve. In practice, they are approached on a case-by-case basis using institutional review committees and other techniques which, while cumbersome, represent at least a halting start toward clarification through experience. But all of the above problems appear absurdly simple when they are compared with the use of the pregnant woman and her fetus as subjects of medical research.

On the surface, research on the fetuses of pregnant women who plan to give birth would appear to raise more important and delicate concerns. But, curiously, this does not appear to be the case, because abortion is not involved, and because it is generally believed that the

2. *Id.* at 101-02.

mother will exercise caution and the obstetrician and pediatrician involved in such research will, above all, protect the health and welfare of the mother *and* the fetus. It is the use of the pregnant woman and her about-to-be-aborted fetus as subjects of research that seriously impacts upon the fundamental principle of protection of the weak and induces passionate theological responses. When medical research, no matter what its nature, is performed upon a fetus that is to be aborted, society may gain valuable information from that particular abortion. Many of those who violently oppose abortion on a theological or ethical basis wish to deny any societal gain from what they consider a heinous act. They insist that the research be prohibited. In fact, the more valuable the research results may be, the more some would condemn them, because widespread appreciation of the results might increase public acceptance of abortion.

Perhaps this controversy would have been limited to a few religious or secular professional groups, but the *Roe v. Wade*³ decision dispelled any hope for containment. Once the opponents of abortion lost political control over the abortion procedure, even in those states where they believed that they held a majority, only one avenue was left open to them — a constitutional amendment that would limit the practice. To accomplish such an amendment in the face of determined liberal opposition would necessarily require neutralization of any general societal gains from the procedure. Research on the about-to-be-aborted fetus became a prime target of abortion opponents. Prodded by angry constituents, local district attorneys began to prowl through hospital laboratories in search of potential villains. False horror stories involving decapitated fetuses and other ugly practices were infiltrated into hastily arranged hearings. The Boston "Antibiotic" case, in which reasonable physicians were actually indicted for grave robbing, the catastrophic trial of Doctor Kenneth Edelin in the same city,⁴ and a flurry of state laws regulating and even abolishing fetal research⁵ began to dominate the headlines. As local anti-abortionists and medical investigators began loudly to confront one another, the cacophony began to rise out of the state legislative assemblies and into the halls of the United States Congress.

3. 410 U.S. 113 (1973).

4. See *Commonwealth v. Edelin*, — Mass. —, 359 N.E.2d 4 (1976) (reversing the conviction of Dr. Edelin). See generally Culliton, *Edelin Trial: Jury Not Persuaded by Scientists for the Defense*, 187 Science 814-16 (1975); Culliton, *Manslaughter: The Charge Against Edelin of Boston City Hospital*, 186 Science 327-30 (1974).

5. See, e.g., MASS. GEN. LAWS ANN. ch. 112, § 12J (West Supp. 1976-77) (amended 1976).

As the pressure mounted, the strategy of the anti-abortionists became apparent. Many abortions are underwritten by Medicaid funds. If these funds could be restricted, as well as funds for fetal research, both abortion and its research benefits could be curtailed. A two-pronged legislative attack was designed: 1) Stop all federally funded fetal research; 2) Stop all Medicaid funding for abortions and link that bill to the *total* medical research budget. The latter move would, they thought, neutralize the investigators who might be willing to forego research on the fetus and would not protest discrimination against the poor if preservation of the total research budget was at stake.

In fact, neither stratagem was effective. Federal support for fetal research goes on, and federal courts have declared the second approach unconstitutional.⁶ The court decisions were expected by most thoughtful jurists and probably even by those who enacted the legislative restrictions in the first place. The first issue, however, research on the fetus, was far more complex. Its resolution required careful diplomacy, reasonable attention to opposing views, good will and, above all, hard work. In light of those demands, the thoughtful guidelines which were established by the report (Report) of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Commission)⁷ should be considered an outstanding achievement. It should be emphasized that the Commission was created in an advisory role to the Secretary of Health, Education and Welfare (HEW).⁸ Its deliberations were carried out during a moratorium on federally funded fetal research,⁹ but its conclusions were not binding on then Secretary Weinberger. In fact, the Report of the Commission prompted the Secretary to accept all but one of its recommendations and to lift the moratorium.¹⁰

Though the Commissioners performed their labors during a period of increasing national controversy when charges of political domination

6. See *McRae v. Mathews*, 421 F. Supp. 533 (E.D.N.Y. 1976); *Klein v. Nassau County Med. Center*, 409 F. Supp. 731 (E.D.N.Y. 1976); *Roe v. Norton*, 408 F. Supp. 660 (D. Conn. 1975).

7. NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, REPORT AND RECOMMENDATIONS: RESEARCH ON THE FETUS (DHEW Pub. No. (OS) 76-127, 1975), 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. For a careful review of the *Commission's Report*, see Ingelfinger, *Ethics of Human Experimentation Defined by a National Commission*, 296 NEW ENGLAND J. MED. 44 (1977).

8. National Research Act, Pub. L. No. 93-348, §§ 201-205, 88 Stat. 342 (1974).

9. *Id.* § 213.

10. 45 C.F.R. §§ 46.201-301 (1976).

by religious groups filled the air, the deliberations proved to be conducted at a very high level, and very valuable ethical concepts emerged. In addition, the Report offers, in lay language, a précis of the current state of the art of fetal physiology, the care of the premature, and the technology of prenatal diagnosis of inherited disease. It is a document well worth careful study.

Before analyzing the Report, a brief review of a certain form of research on the about-to-be-aborted fetus would help the lay reader to understand much of the investigator's dilemma. Sickle cell anemia and Cooley's anemia are two inherited disorders of the blood that cause disability and usually death at an early age. Cooley's anemia is more severe. This disease occurs predominantly in the countries bordering the Mediterranean Sea. It is sometimes called Mediterranean anemia or thalassemia (sea in the blood). It also occurs in the Middle East, India, the Far East and Africa. It is estimated that some 60,000 children are born each year with Cooley's anemia. A roughly equal number of children are born each year with sickle cell anemia, mainly in Africa or in countries such as the United States where large numbers of Americans of African descent reside. Cooley's anemia is less common in the United States than sickle cell anemia, because ethnic outbreeding is more common in Caucasians than Blacks. In any case, without particular regard for case incidence in the United States, these two serious inherited diseases of the blood are more common worldwide than is childhood acute leukemia.

When two carriers, or heterozygotes, of either sickle cell anemia or Cooley's anemia mate, there is one chance in four that the fetus of any pregnancy developed by the couple will inherit the abnormal gene from both parents and have so-called homozygous sickle cell anemia or homozygous Cooley's anemia. In many cases, the difficult and short life of the homozygote is enough to persuade heterozygous parents at risk to abort all pregnancies rather than take the one out of four chance that the fetus may be a homozygote. The purpose of prenatal diagnosis of such inherited diseases is to permit such parents to have children without fear. A perfect prenatal diagnostic test identifies homozygotes unequivocally and clearly separates them from normal or heterozygote fetuses. Only the homozygote is aborted. The other three pregnancies go to term. Thus, when a technique for prenatal diagnosis is operating optimally, three out of four about-to-be-aborted fetuses are salvaged. Without prenatal diagnosis, none of these fetuses would be salvaged. The entire effort of research in this area of prenatal diagnosis has, therefore, as its ultimate aim, the retention of fetal life in the vast proportion of cases.

The techniques necessary for a prenatal diagnostic test, however, must often be developed by studying fetuses that are about to be electively aborted. For example, in Cooley's anemia or sickle cell anemia, the prenatal diagnostic test currently demands that the investigator take a small sample of the circulating red cells of the fetus. This he can do by sampling the fetal blood supply to the placenta. This is a far more technically difficult and even potentially more hazardous technique than is the simple sampling of the amniotic fluid that surrounds the fetus (amniocentesis). The latter fluid contains certain fetal skin cells that can be used for many prenatal diagnoses. Unfortunately, these cells cannot be used for the diagnosis of Cooley's anemia or sickle cell anemia because they do not produce hemoglobin. Furthermore, a test for an inherited disease in the fetus can scarcely be created without detailed knowledge of the variations in normal fetuses.

When the laboratory and the obstetrical units associated with us began to approach the problem of the development of the technology for such prenatal diagnoses in fetal red cells, we were immediately confronted with two ethical problems in potential conflict. One ethical precept is derived from Bernard's statement that experiments that may do good are obligatory.¹¹ There is no question that the successful outcome of research to develop a good prenatal diagnostic test for the inherited disorders of hemoglobin would have a good outcome; therefore, under Bernard's precept, the research is obligatory. However, a second precept is that experiments that can only do harm are forbidden. At the time that the necessary obstetrical research needed to be done to derive a method for fetal blood sampling, it was not clear that such an approach might not do harm either by injury or inaccuracy. It certainly could be envisaged that an aspiration of blood from the placenta could itself endanger the pregnancy or that the inherent variations within normal fetuses could obfuscate diagnoses. Therefore, it was decided that initial experience with tiny samples must be gathered in the about-to-be-aborted fetus since the pregnancy would be terminated in any case and larger samples would be available post-abortion to test reliability. Once it could be shown that fetal blood could be acquired with reasonable safety at the time of the intended abortion and that the test was sufficiently accurate, the technology could then be applied to those pregnancies where there was a known risk of the inherited anemia. In other words, the investigators of the problem felt that the risk of the development of this technique should be shared among many different mothers and not be borne solely by the mothers whose pregnancies were threatened by the risk of inherited anemia.

11. See C. BERNARD, *supra* note 1, at 101.

This ethical judgment as to fetal research clashes with a cardinal principle of those who oppose the research on equally strong ethical grounds. The opponents believe that the fetus is a person who cannot give informed consent; that the fetus about to be aborted is completely defenseless; that it has been abandoned by its mother; and that, therefore, such research practices, no matter what their benefits might be, constitute an unethical attack on the dying by the researcher. Ethicists and theologians who take the latter position do so for two reasons. The first is the aversion to abortion itself and the unwillingness to see any benefit from the procedure. The second is the fear that somehow the research conducted on the fetus may actually be a very ugly affair characterized by potential pain or anguish in the fetus before it is summarily executed. The possibility that investigators might perform or tolerate ghastly intrauterine intrusions prior to abortion because they do not think of the fetus as a person, creates deep moral and ethical concerns. Indeed, a few of my colleagues occasionally lend some credence to that fear by referring to the fetus as just "a piece of tissue." Obviously the fetus is not just any piece of tissue. The fetus may not be a person in the *legal* sense, but *common* sense and common dignity elevate it above the status of a gallbladder. The potential of a gallbladder is to become an older gallbladder, whereas the fetus has the potential to become a person. Callous disregard of that special status of the fetus, no matter what its gestational age, brutalizes the investigator and violates an important ethic. Furthermore, it is arrogant and stupid to conclude that all those who share such concerns are members of a single religious denomination, are uneducated, are against prenatal diagnosis, or are even against all selective abortion. These stereotypes are misapplied. Given absolute assurances of respect for the totality of pregnancy, many concerned individuals (some of whom are as expert in their fields as researchers claim to be) can find ways to permit important research to flourish while preventing mindless acts of potential cruelty. In fact, although the obstetrical component of research in this area has been temporarily halted in Massachusetts, it will probably resume in the near future largely because of the efforts of those who previously led the original attack against unbridled fetal research.

Too often, a strident hostility towards the university based medical establishment where fetal research is performed and an overzealous use of political pressure complicate the discussion. It should be mentioned that the intrusion of anti-abortion groups into the political process, and even into the judicial process, as witnessed by the Edelin trial, has created a very serious backlash among the liberals and a wave of anti-orthodoxy that is unfortunate and often unfair. In fact, it appears

that certain members of the "Right to Life" groups have begun to be somewhat damaged by their own successes. Many politicians and increasing numbers of the general public are beginning to recognize that they have perhaps been led astray. It is one thing to take a firm stand against abortion. It is quite another matter to attack research that will prevent abortion or reduce birth defects. The attacks by "Pro-life" or "Right to Life" groups against the National Foundation March of Dimes were unwise. That organization has done as much for improvement of maternal and child health as any private organization in the country. Because the foundation supports research on the developing fetus, it became the object of utterly mindless calumny. This sort of blunderbuss attack tends to turn away more thoughtful individuals who also cannot tolerate abortion or cruelty to the defenseless, but who have the capacity to look at the entire issue broadly. In light of all of this conflict, the work of the Commission is all the more admirable. The membership was obviously chosen to ensure a broad range of opinions, a high level of intelligence, and a capacity to absorb a great deal of information.

There are two major features of the Report and the subsequent regulations (Regulations)¹² which must be studied in great detail. The first deals with activities directed toward fetuses *in utero* as subjects. The Regulations state:

No fetus *in utero* may be involved as a subject of any activity covered by this subpart unless:

- (1) The purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or
- (2) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by any other means.¹³

The Regulations would permit the necessary research for improved prenatal diagnostic methods but would require extremely careful review of procedure at a local and national level.¹⁴

With respect to nontherapeutic research directed toward the non-viable fetus *ex utero*, the Commission recommended that such research might be carried out under stringent limitations, particularly if the fetus is less than twenty weeks gestation, but made it clear that no such research be carried out which might alter the duration of life of the

12. 45 C.F.R. §§ 46.201-301 (1976).

13. *Id.* § 46.208(a).

14. *See id.* §§ 46.204-205.

nonviable fetus *ex utero*.¹⁵ This last recommendation was not accepted by the Secretary of HEW, and the final regulations stated:

No nonviable fetus may be involved as a subject in an activity covered by this subpart unless:

- (1) Vital functions of the fetus will not be artificially maintained except where the purpose of the activity is to develop new methods for enabling fetuses to survive to the point of viability,
- (2) experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and
- (3) the purpose of the activities is the development of important biomedical knowledge which cannot be obtained by other means.¹⁶

The Secretary of HEW evidently did not follow the recommendations of the Commission in this single area because he was persuaded that the ban on fetal research, which might lengthen the life of the fetus *ex utero*, would seriously impede the development of the technology necessary to maintain life in very premature infants. Here, two ethical concerns conflict once again. On one hand, many thoughtful ethicists find repugnant the idea of attaching hopelessly nonviable fetuses to life support machines, all in the name of science. They conjure up the image of rows of helpless humanoids boxed in isolettes, their tiny chests helplessly pumped up and down by mechanical respirators while doctors draw body fluids from every orifice. On the other hand, the legislature of the state of California has just passed a law making it a criminal offense for an obstetrician to fail to offer the ultimate in life support systems to aborted fetuses which might possibly be considered viable.¹⁷ Thus, a group of individuals operating from the same general concern for fetal life has become internally polarized. In fact, an obstetrician operating in good faith under the Regulations for the protection of fetuses would be at risk of losing all federal grant support if he obeyed the California law and applied full support technology to a fetus later determined to be nonviable. On the other hand, if he followed the Regulations and failed to provide such support, he would be in danger of imprisonment under the California legislation.¹⁸ Little

15. See COMMISSION'S REPORT, *supra* note 7, at 312.

16. 45 C.F.R. § 46.209(b) (1976).

17. CAL. HEALTH & SAFETY CODE § 25955.9 (West 1976) (misdemeanor).

18. *Id.* It should be noted that while the obstetrician is in a practical dilemma, he is not in a legal dilemma, because the Regulations make it clear that in such a situation, state law controls. See 45 C.F.R. § 46.201(b) (1976). Thus, the obstetrician is bound to follow state law.

wonder that the Secretary of HEW has considered a proposal to permit responsible investigators and hospitals to carry out important studies of the nonviable fetus *ex utero* under strict institutional controls and with the oversight of a national ethical review board if necessary.¹⁹

What is the future of fetal research in the United States now that the Commission has reported, the wave of inhibitory fetal research laws appears to have peaked, and limited research is being undertaken once again?

First of all, the scientific community has probably learned a great deal from the events of the last three or four years. It has relearned what has been drummed home repeatedly: the general public is concerned about the ethics of medical investigation. The public is unwilling to accept benefits at too high a risk — either to the community or to the individuals. Public leaders must be kept informed of research developments and needs if necessary support is to be gained and suspicion allayed. The biomedical community must remember that in the public mind it is associated with all other technocrats, and responsible inclusion of public representatives into future research planning is mandatory.

Public leaders, including those who represent the concerns of "Right to Life" organizations, must come to grips with another reality. While many biomedical investigators carry out their work for the benefit of patients, it is beyond argument that there is often self-interest involved. Almost all researchers have ego involvement in their work, but the motivating force behind clinical investigation is the welfare of particular patients now or in the future. No group representing ethical concerns can prevent for very long what the responsible clinical investigator honestly believes to be in the best interest of patients. Although work on the development of techniques for prenatal diagnosis of abnormal hemoglobins was stopped in Massachusetts after passage of a restrictive fetal research law,²⁰ the work continued at a reasonably rapid rate because the Massachusetts investigators allied themselves with colleagues in London and New Haven, Connecticut. Had roadblocks been erected in London and New Haven, another co-operative enterprise would have been generated, because the work had to go on for the benefit of the parents at risk. Furthermore, it was clear to almost all dispassionate observers that the work was highly ethical and

19. See 42 Fed. Reg. 2,792-93 (1977) (proposed amendment to 45 C.F.R. § 24.209). This amendment would permit activities directed toward the nonviable fetus *ex utero* where the purpose of such activity is to bring the subject fetus to the point of viability. *Id.*

20. See MASS. GEN. LAWS ANN. ch. 112, § 125 (West) (Supp. 1976-77) (amended 1976).

was carried out in a reasonable fashion. In fact, many individuals who opposed the work initially now see it as a valuable method by which more babies may be born, and for this reason these early opponents have successfully sought ways to modify the Massachusetts laws in order to permit the work to move forward in the Commonwealth. A very interesting addition to the Massachusetts law has reduced the risk of unexpected indictment²¹ and should encourage responsible investigators to return to their research after careful institutional review.

The negotiations necessary on the local scene have been substantially aided by the example of the powerfully constructive thinking generated by the Commission. There seems little question that productive and high quality fetal research will resume in the United States. There will be careful limits. There will be public discussion. But the work will move forward, and as a result, the health and welfare of pregnant women and their fetuses will be maintained and improved.²²

21. See 1976 Mass. Adv. Legis. Serv. 337-42 (to be codified at MASS. GEN. LAWS ANN. ch. 112, § 12J). The law itself permits diagnostic or remedial procedures if the purpose is to determine the life or health of the fetus or preserve the life or health of the fetus or mother. *Id.* at 337. Of paramount importance to the physician or researcher is the fact that the amendment provides for a complete defense from prosecution if (1) a court has not previously found the particular research protocol in question violative of the substantive requirements of the section and, (2) if the physician or researcher has obtained prior written approval of the procedure from an Institutional Review Board. *Id.* at 338. In addition, the amendment provides that

[a] copy of the written approval, together with any attached protocol or other writing, shall be filed with the office of the District Attorney for the county in which the hospital or other institution for which the board acts, is located. Such copy shall be available for public inspection at reasonable times.

Id.

22. For additional reading, *see generally* 40 Fed. Reg. 33,526-52 (1975) (Protection of Human Subjects, Part III: Fetuses, Pregnant Women, and In Vitro Fertilization); H. HARRIS, *PRENATAL DIAGNOSIS AND SELECTIVE ABORTION* (1975); P. RAMSEY, *THE ETHICS OF FETAL RESEARCH* (1975); *THE MORALITY OF ABORTION* (J. Noonan ed. 1970); The Advisory Group to Department of Health and Social Security, *The Use of Fetuses and Fetal Material for Research* (Her Majesty's Stationery Office, 1972), *reprinted in* NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, *Appendix to REPORT AND RECOMMENDATIONS: RESEARCH ON THE FETUS 19-1 to 19-17* (DHEW Pub. No. (OS) 76-128, 1976); Gaylin & Lappe, *Fetal Politics*, ATLANTIC MONTHLY, May, 1975, at 66; Scarf, *The Fetus as Guinea Pig*, N.Y. Times, Oct. 19, 1975, § 6 (Magazine), at 13.