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Kevin O'Rourke

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An Ethical Evaluation of Federal Norms for Fetal Experimentation

Kevin O'Rourke, O.P.

Father O'Rourke is Director of the Medical-Moral Department of the Catholic Hospital Association in St. Louis. In this article, he raises some questions regarding the work which was done by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

In July, 1974, Congress passed the National Research Act which imposed a temporary moratorium on research on human fetuses, either before or after induced abortion, if carried out or financed by the Department of Health, Education, and Welfare (DHEW). The act also created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to study the legal, ethical, and medical aspects of scientific research upon human subjects.¹ The first task assigned by Congress to the commission was extremely difficult. The commission was asked to explore fetal experimentation, an extremely controversial topic, and to submit recommendations concerning such experimentation to the secretary, DHEW. This study required that the demands and necessities of a pluralistic society, as well as the dignity of human subjects and the

needs of scientific progress, be considered. On May 21, 1975, the commission submitted its recommendations to Secretary Caspar W. Weinberger. In August, Weinberger lifted the year-long ban on fetal research and issued federal regulations for fetal experimentation which, for the most part, are consistent with the commission's recommendations. The regulations, along with the full report of the commission, were published in the *Federal Register*, August 8, 1975.²

Given the difficulty of the task, the brief time frame allowed for formulating norms, and the novelty of the assignment, the commission should be commended for its sincere and open-minded effort. Moreover, it deserves praise for the method followed, i.e., first stating principles that it intended to follow and then applying these principles to the various types of fetuses that might be used for experimentation or research. However, the work of the commission has one serious drawback: the recommendations fail to apply the principles consistently and accurately. As a consequence, the federal regulations, consistent with the recommendations, call into question centuries of humane tradition whereby the human

rights of the weak and infirm have been protected.

Because the matter of human research and experimentation is so important, not only for the future of medical research but for the future quality of human relationships in our society, it will be worthwhile to present the principles for research upon human subjects formulated by the commission and how some of the recommendations fail to meet the standards set by these principles.

I. The Principles of Medical Research

The commission lists the following four principles "among the general principles for research on human subjects judged to be valid and binding:

1. To avoid harm whenever possible, or at least to minimize harm;
2. To provide for fair treatment by avoiding discrimination between classes or among members of the same class (referred to later as the principle of equality);
3. To respect the integrity of human subjects by requiring informed consent;
4. To respect the human character of the fetus." (VIII. B).

Later, when discussing the matter of risk and consent, the commission lists a fifth principle:

"The commission affirms as a general principle that manifest risks imposed on nonconsenting subjects cannot be tolerated. Therefore, the commission concludes that only minimal risk can be accepted as permissible for nonconsenting subjects in nontherapeutic research." (VIII, C, 3).

In addition to these five principles, the commission states that certain general requirements are necessary for ethical research upon fetuses. These would be ascertained in the review process which must precede approval of any research project. These general requirements are:

1. "Appropriate prior investigations using animal models and non-pregnant humans must have been completed.
2. The knowledge to be gained must be important and obtainable by no reasonable alternative means.
3. Risks and benefits to both the mother and the fetus must have been fully evaluated and described.
4. Informed consent must be sought and granted under proper conditions.
5. Subjects must be selected so that risks and benefits will not fall inequitably among economic, racial, ethnic, and social classes." (VIII, C, 3).

Each of these principles and requirements is valid, and each protects and/or fosters the dignity of human subjects of research and experimentation. If they had been applied consistently in accord with the express intention of the commission to treat the fetus as "a human subject," then a humane and acceptable set of recommendations could have been formulated. But the principles were not applied consistently. One reason for the lack of consistency and accuracy in applying these principles may have been insufficient time. The commission admitted that it was "placed un-

der severe limitation of time by its Congressional mandate. As a result, these considerations on research involving fetuses have necessarily been developed prior to the commission's larger task of studying the nature of research, the basic ethical principles which should guide it, the problem of informed consent and the review process." (VIII). Hence, the commission admitted that it "has not yet studied the issues surrounding informed consent for nontherapeutic research." (VIII, C). Yet it proceeded to approve recommendations, which in order to be just and humane, require a clear notion of the principle of informed consent as well as the import of its corollary: manifest risks imposed upon nonconsenting subjects cannot be tolerated.

Clearly, the commission should have finished the consideration concerning consent before formulating recommendations. This would have been more important than meeting the Congressional deadline. Consent is, after all, the heart of the matter for human research. The ramifications of contradicting the principle of informed consent for harmful experimentation are far-reaching. Our civilization is based upon respect for individual dignity and equality; one of its highest ideals is to protect the weak and infirm from harm; it professes that the individual does not exist for the state and cannot be sacrificed unwillingly for public welfare. All these values might be endangered if the principles of informed con-

sent are not followed faithfully. By proceeding as it did, the commission opted for an interpretation of this principle that is so broad it is meaningless.

II. The Specific Recommendations

In order to show the specific instances where the conclusions of the commission are not in accord with the principles it avows, let us study the recommendations in greater detail.

The first two recommendations concern therapeutic research, the first considering research upon the fetus and the second concerned with research upon pregnant women. The first is adequate, but the second gives cause for concern. The reason for concern is that research directed primarily toward the pregnant woman in many cases will affect the fetus as well, and it is important that the rights of the fetus be protected. Recognizing that "the therapeutic research directed toward the pregnant woman may expose the fetus to risk for the benefit of another subject," the commission makes some effort to protect the fetus by stating that the research upon pregnant women may be supported provided that such research will "put the fetus at minimum risk consistent with the provision of health care for the woman." (VIII, C, 2). But the actual protection afforded the fetus is extremely tenuous because the commission also recognizes "the woman's priority regarding her own health care." This latter phrase would allow

research that would injure or even destroy the fetus if it were "consistent with the health needs of the mother." If the term "health of the mother" is interpreted as it was in the Supreme Court decision regarding abortion (and there is no reason to think it will not be), then any research which treats a pregnant woman for emotional or psychological difficulty, as well as for physiological maladies, could justify research endangering the fetus. In such cases, the fetus would not be treated as a "human subject in scientific research" as the commission avowed it should. Rather, in spite of some palliative language, the fetus is treated as a thing, to be disposed of if the "health needs of the pregnant woman" warrant it.

Acknowledging the Supreme Court's decisions which subordinated the fetus' right to life and the right to due process of the woman's right to privacy (*Roe vs. Wade*, *Doe vs. Bolton*), the commission might have felt unable to give greater recognition to the fetus' right to be considered a human subject. But if the Supreme Court's decision is to be used as the guiding standard for formulating fetal experimentation norms, then the effort to formulate humane norms is worthless from the beginning. Why spend time debating when and how fetal experimentation can take place if the fetus has no right to be treated as a human subject, no right to life, and no right to human dignity? Rightful consideration would be given to the fetus if the

clause "consistent with meeting the health needs of the pregnant woman" were eliminated, and the woman's health did not receive priority. In this way, the rights of the fetus and those of the woman would be balanced one against the other and protected equally. Even though the Supreme Court has denied the human fetus equal protection under law under the guise of the right to privacy, the commission should not have made the same mistake under the guise of therapeutic research.

Non-Therapeutic Research

In recommendation 3, the commission considers nontherapeutic research directed toward the pregnant woman. Once again, the key question is: will the fetus be respected as a human subject? The commission seems to recognize the right of the fetus to be protected for it concludes in recommendation 3 that nontherapeutic research directed toward a pregnant woman should be funded only if the research "a) has been evaluated for possible impact upon the well-being of the fetus; and b) will impose minimal or no risk to the well-being of the fetus." However, the commission also admits that "the term minimal involves a value judgment and acknowledges that medical opinion will differ regarding what constitutes minimal risk." (VIII, C. 3). The main factor causing differences of opinion about minimal risk is whether or not the fetus will be aborted. Minimal risk for a fetus going to term is different, according to some commis-

sion members, from one that will be aborted. The thought seems to be: if the fetus is going to be destroyed, then less care need be devoted to it.

The commission states that in any research procedure, the "determination of acceptable minimal risk is a function of the review process." But the door is clearly open for those who conduct the review process to use more lenient norms for minimal risk in the case of fetuses to be aborted than for those who will be carried to term. According to the report, "there is a basic agreement among commission members as to the validity of the equality principle. There is disagreement as to its application to individual fetuses and classes of fetuses." (VIII, C, 3). It seems, however, that the absence of more definite protection from harmful experimentation for the fetus to be aborted amounts to a disavowal and contradiction of the equality principle, not merely a disagreement in regard to its application. Indeed, to allow human subjects to be used for medical research experimentation simply because they will soon die, especially if the research might be harmful, endangers the humane tradition of western civilization. If the commission wished to grant the fetus its rights as a human subject, it would have refused to consider the possibility of any research which would allow the fetus to be treated differently simply because it would later be aborted. This would put "minimal risk" into

proper context. The commission considered this possibility and rejected it. (VIII, C, 3).

The fourth recommendation concerns nontherapeutic research directed toward the fetus *in utero* when abortion is not anticipated. This recommendation affords ample protection to the fetus, and were it applied to fetuses that will be aborted, the commission would have been acting in accord with its principles. Instead, the commission treated fetuses *in utero* that would be aborted in a separate section, recommendation 5. Recommendation 5 has two serious shortcomings: first of all, it allows for the same ambiguous interpretation of minimal risk in the case of fetuses to be aborted that was mentioned in regard to recommendation 3. Secondly, it contains an "escape clause" which states:

"research presenting special problems related to the interpretation or application of these guidelines may be conducted or supported by the DHEW secretary, provided that such research has been approved by a national ethical review body."

What "special problems" might be used to justify different treatment for fetuses to be aborted, the commission does not declare, but judging from some of the experiments that have been performed on aborted fetuses throughout the world, this clause could open a Pandora's box. Moreover, it violates the principle of equality as well as the principle that only minimal risk can be accepted as permissible for subjects

in nontherapeutic research. As David Louisell, a committee member who felt obliged to write a minority report, declared, "this clause should be omitted and in its place there should be a declaration that no research should be permitted on a fetus to be aborted that would not be permitted on one to go to term." The decision that a woman makes to have an abortion should not make it possible for a human fetus to be misused, no matter what national interest or medical knowledge might be involved.

Dying Fetuses

Recommendation 6, concerning nontherapeutic research upon fetuses that are dying, that is, research directed toward the fetus during the abortion process and the nonviable fetus *ex utero*. The commission seemingly makes an effort to protect these fetuses by requiring that "no significant procedural changes are introduced into the abortion procedure in the interest of research alone; and no intrusion into the fetus is made which alters the duration of life." But there is no requirement which would protect the dying fetus from harmful experimentation which did not shorten or lengthen its life. The mere fact that a fetus is dying, no matter from what cause, is not sufficient grounds for allowing experimentation upon it, especially harmful experimentation, or for withdrawing the protection afforded other human subjects. Would we experiment with dying adults if we did not have their consent? Would we

carry out harmful experimentations upon dying children, even if their parents gave proxy consent? It seems that the commission is following the thought of the Supreme Court, and depriving the fetus to be aborted of all human consideration. If the commission wishes to treat the dying fetus as a "human subject in scientific research," and if it wishes to apply consistently the principle of equality, then it must consider how other dying members of so-called shortened by proposed research. and experimentation are under consideration.

The harmful "escape clause" appended to recommendation 5 is also contained in recommendation 6. Given this opening, the DHEW secretary, Caspar Weinberger, made the federal regulation concerning dying fetuses even more permissive than the recommendation of the commission. The commission had stated that the dying fetus's life could not be extended or shortened by proposed research. However, the Federal Regulations reverses this position, explaining:

"the secretary is persuaded by the weight of scientific evidence that research performed on the nonviable fetus *ex utero* has contributed substantially to the ability of physicians to bring to viability increasingly small fetuses. The secretary perceives that it is in the public interest to continue this successful research and accordingly an exemption is made to the recommendation of the commission to permit research to develop new methods for enabling fetuses to survive to the point of viability."

Advancing the state of medical knowledge that more immature fetuses can survive is indeed a worthy goal, but the means approved by the Federal Regulations are highly unethical. The Regulations would allow for harmful experimentation upon dying fetuses, would allow its life to be shortened or lengthened, would allow fetuses to be harvested and maintained for the sole purpose of research. By means of this regulation the fetus can be treated as a thing, with no dignity or rights of its own. Even those who would not give full human rights to the fetus, must think long and hard about this regulation and its implications for the future. It represents a breakdown, a denial, of the total medical, ethical and social standards of our society. If fetuses can be treated as things in the interest of "society or medical progress," then so can anyone else.

Possibly Viable Infants and Dead Fetuses

The seventh recommendation concerns research directed toward the possibly viable infant. Here the requirements are sound and well stated, being based upon the conviction "that there is a moral legal obligation to attempt to save the life of a possibly viable infant." (VIII, C, 4). Recommendation 9 stipulates the conditions for research on dead fetuses and fetal tissue. Hence, the commission recommends that such "research be permitted if consistent with local law, the Uniform Anatomical Gift Act and commonly

held convictions about respect for the dead." What these "commonly held convictions about respect for the dead" are, the commission does not state. Certainly, disputes will arise concerning the practical implementation of this recommendation, but accepted protocol for research upon dead adults could serve as a guide for conducting the review process on research on dead fetuses. For example, some thought should be given to the matter of consent. Who will give the consent needed to release dead fetuses for research? Would the mother of an aborted fetus have relinquished this right by reason of her decision to have the fetus destroyed? Would the court be empowered to grant this permission? Or would it be presumed that dead fetuses, unlike dead children or dead adults, are public property and can be disposed of indiscriminately? In many countries where abortion is commonplace, scandalous practices, such as buying and selling dying and dead fetuses, have occurred. Firm steps should be taken to avoid the possibility of this happening in the United States. While the dead fetus cannot be harmed by such practices, one of the principles of the commission is that the human character of the fetus should be respected. This demands some control over the way fetuses are provided for experimentation, even if they are no longer living. Moreover, concern for the dead and the way their remains are treated is also a measure of the humanity

of the living.

The other recommendations, 8 and 10 through 16, concern the review process, rights of conscience which allow one to refuse to participate in a research activity if contrary to his moral convictions or religious beliefs, and certain requirements for the procedures of research. While all these recommendations have ethical implications, they are not directly connected with the principles enunciated by the commission.

Conclusion

Because the federal regulations for fetal experimentation, based upon the recommendations of the commission, have now been promulgated by the Secretary of DHEW, it would seem that the issue of their merit is closed. But this is not the case. In the first place, views and arguments relating to the recommendations of the commission may be sent to the DHEW secretary, and on the basis of such considerations, the DHEW secretary "may proceed to further proposed rule making and possible amendments to the regulations as issued."

In the second place, let us realize that the matter of fetal experimentation was brought into the public forum because of public concern. The concern of "ordinary people" not only led to the actions taken by Congress in regard to fetal experimentation, it

also caused 15 states to ban completely fetal experimentation. Hence, if these federal regulations do not seem to express a consensus acceptable to the people, perhaps the matter will be in the hands of Congress once again. As one writer observed, "At a minimum, American researchers should understand that they face a legislative ban on experimentation unless a compromise solution is adopted."⁴ Could these recommendations which form the substance of the federal regulations be called a compromise? Do they express a general consensus for a pluralistic society if they violate the principles of equality and informed consent and allow human subjects to be treated as things in the interest of research? While appreciating all the beneficial work that the commission produced, concerned persons should offer to their elected representatives a polite but firm objection to the Federal Regulations as they now stand.

REFERENCES

1. For a brief explanation of how this commission came into being, see Ramsey, Paul, *The Ethics of Fetal Research* (New Haven, Conn.: Yale University Press, 1975).
2. *Federal Register*, Vol. 40, No. 154, Friday, August 8, 1975, pp. 33526-33551.
3. *Op. cit.*, p. 33548.
4. Rebeck, Gary, "Fetal Experimentation, Moral, Legal, and Medical Implications," *Stanford Law Review* (May, 1974), pp. 1191-1207, n. 135.