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National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research: Research on the Fetus

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NATIONAL COMMISSION FOR THE PROTECTION OF
HUMAN SUBJECTS OF BIOMEDICAL AND
BEHAVIORAL RESEARCH: RESEARCH
ON THE FETUS

STATEMENT OF COMMISSIONER KAREN LEBACQZ[†] WITH THE
CONCURRENCE OF COMMISSIONER ALBERT R. JONSEN[‡]
ON THE FIRST ITEM

The following comments include some points of dissent from the Recommendations of the Commission. For the most part, however, these comments are intended as elaborations on the Report rather than dissent from it.

1. At several points, the Commission established as a criterion for permissible research an acceptable level of risk — e.g., “no risk” or “minimal risk.” I support the Commission’s Recommendations regarding such criteria, but I wish to make several interpretative comments.

First, I think it should be stressed that in the first trials on human subjects or on a new class of human subjects, the risks are almost always unknown. The Commission heard compelling evidence that differences in physiology and pharmacology between human and other mammalian fetuses are such that even with substantial trials in animal models it is often not possible to assess the risks for the first trials with human fetuses. For example, evidence from animal trials in the testing of thalidomide provided grounds for an estimation of low risk to human subjects; the initial trials in the human fetus resulted in massive teratogenic effects.

I would therefore urge review boards to exercise caution in the interpretation of “risk” and to avoid the temptation to consider the risks “minimal” when in fact they cannot be fully assessed.

Second, I think it important to emphasize the evaluative nature of judgments of risk. The term “risk” means *chance of harm*. Interpretation of risk involves both an assessment of statistical *chance* of injury and an assessment of the *nature* of the injury. Value judgments about what constitutes a “harm” and what percentage chance of harm is acceptable are both involved in the determination of acceptable risk. A small chance of great harm may be considered unacceptable where a greater chance of a smaller harm would be acceptable. For example, it is com-

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monly accepted that a 1-2 percent chance of having a child with Down's syndrome is a "high" risk, where the same chance of minor infection from amniocentesis would be considered a "low" risk. Opinions will differ both about what constitutes "harm" or injury and also about what chance of a particular harm is acceptable.

For all these reasons, the interpretation of risk and the designation of acceptable "minimal risk" merit considerable attention by the scientific community and the lay public. The provision of national review in problematic instances should engender serious deliberation on these critical issues.

Third, the establishment of criteria for "no risk" or "minimal risk" is obviously related to the interpretation of "harm." In general, the Commission has discussed "harm" in terms of two indices: (1) injury or diminished faculty, and (2) pain. A third commonly accepted definition of "harm" is "offense against right or morality"; this meaning of harm has been subsumed under the rubric of violation of dignity or integrity of the fetus, and thus is separated out of the Commission's deliberations on acceptable levels of risk. In establishing acceptable levels of risk, therefore, the Commission has been concerned with injury and pain to the fetus.

Several ethicists argued cogently before the Commission that the ability to experience pain is morally relevant to decisions regarding research. Indeed, the argument was advanced that the ability to experience pain is a more appropriate consideration than is viability for purposes of establishing the limits of intervention into fetal life.

However, scientific opinion is divided on the question of whether the fetus can experience pain — and on the appropriate indices on which to measure the experience of pain. Several experts argue that the fetus does not feel pain.

I believe that the Commission has implicitly accepted this view in making Recommendation (6) regarding research on the fetus during the abortion procedure and on the nonviable fetus *ex utero*. Should this view not be correct, and should the fetus indeed be able to experience pain before the twentieth week of gestation, I would modify Recommendation (6) in two ways:

First, the Recommendation as it now stands does not specify an acceptable level of risk. The reason for this omission is essentially as follows: in a dying subject prior to viability, "diminution of faculties" does not appear to be a meaningful index of harm since this index refers largely to future life expectations. Therefore, the critical meaning of "harm" for such a subject lies in the possibility of experiencing pain. If the fetus does not feel pain it cannot be "harmed" in this sense, and

thus there is no risk of harm for such a fetus. It is for this reason that the Commission has not specified an acceptable level of “risk” for fetuses in this category, although it has been careful to protect the dignity of the fetus.

Clearly, however, if the fetus does indeed feel pain, then it can be “harmed” by the above definition of harm. If so, then I would argue that an acceptable level of risk should be established at the same level as that considered acceptable for fetuses *in utero* — namely, “no risk” or “minimal risk.”

Second, the Commission has concluded that out of respect for the dying subject, no interventions are permissible which would alter the duration of life of the subject — i.e., by shortening or lengthening the dying process (item h). I find the prohibition against shortening the life of the dying fetus to be acceptable provided the fetus does not feel pain. If the fetus does feel pain, however, then its dying may be painful and respect for the dying subject may require that its pain be minimized even if its life-span is shortened in so doing.

2. The Commission has stated that its provisions regarding therapeutic and nontherapeutic research directed toward the pregnant woman are not intended to limit research on improving abortion techniques. I support this stand and wish to clarify the reasons for my support.

In supporting this statement, I neither condone nor encourage widespread abortion. However, I do believe that some abortions are both legally and morally justifiable. It is therefore consonant with the principle of minimizing harm to develop techniques of abortion that are least harmful. Indeed, under the present climate of legal freedom to abort and widespread practice of abortion, adherence to the principle of not-harming may impose an obligation on us to research abortion technology in order to minimize harm. This obligation arises not only out of consideration of the health and well-being of the woman but also from a concern for possible pain or discomfort of the fetus during the abortion procedure.

3. Evidence presented to the Commission indicates that there is a strong emphasis in the law on avoiding possible injury to a child to be born. This evidence, coupled with the uncertainty of risks in a new class of human subjects, suggests that considerable importance ought to be attached to the question of compensation for injury incurred during research.

The Commission will study this question in depth at a later time, and therefore has not made any recommendations on compensation at this time. As a matter of personal opinion, I would like to note that I

am reluctant to allow any research on the living human fetus unless provision has been made for adequate compensation of subjects injured during research.

4. The Commission's Recommendation on research during the abortion procedure and on the nonviable fetus *ex utero* prevents prolongation of the dying process for purposes of research. This prohibition may appear to have the effect of preventing research on the development of an artificial placenta.

It is my understanding that such an effect does not necessarily follow. Steps toward the development of an artificial placenta are prohibited only through *nontherapeutic* research; innovative therapy or therapeutic research on the possibly viable infant is not only condoned but encouraged. Thus the development of an artificial placenta may proceed, but under more restricted circumstances in which it is limited to therapeutic research or to nontherapeutic research which does not alter the duration of life. I do not believe that it was the intention of the Commission to curtail all research toward the development of an artificial placenta, nor do I believe that such will be the effect of the Commission's Recommendations.

Were the Recommendations to have such an effect, however, I would dissent. Indeed, I would argue that a prematurely delivered fetus that is unable to survive, given the support of available medical technology, would have an interest in the development of an artificial placenta that would allow others like it to survive. Thus it would not be contrary to the interests of that fetus for it to be subjected to nontherapeutic research in the development of an artificial placenta.

In making such an argument, I invoke a principle that I call the "principle of proximity": namely, that research is ethically more acceptable the more closely it approximates what the considered interests of the subject would reasonably be. For example, Hans Jones has argued that dying subjects should not be used in nontherapeutic research, even when they have consented, unless the research deals directly with the cause from which they are dying; that is, it is presumed that a dying subject has an interest in his/her own disease which legitimates research on that disease where research in general would not be legitimate.

Such a principle is, of course, open to wide interpretation. But I think it not unreasonable to suggest that the dying fetus would have an interest in the cause of its dying or in the development of technology which would allow others like it to survive. On such a principle, one might argue that it is more ethically acceptable to use dying fetuses with Tay-Sachs disease as subjects in nontherapeutic research on Tay-

Sachs disease than in nontherapeutic research on general fetal pharmacology. Similarly, one might argue that it is ethically acceptable to use nonviable fetuses *ex utero* as subjects in nontherapeutic research on the development of an artificial placenta. The development of a full rationale for such a position would require an analysis along the lines suggested by McCormick and Toulmin, and I cannot attempt that here. At this point I simply wish to suggest that I believe it is possible to argue for both therapeutic and nontherapeutic research directed toward the development of artificial placenta.

5. Finally, members of the Commission disagreed about changes in the timing or method of abortion in relation to research. Recommendation (10) states clearly that the recommendations of a physician regarding timing and method of abortion should not be determined by the design or conduct of nontherapeutic research. I am in full agreement with this Recommendation.

The provision in Recommendation (6) (item g), however, is more ambiguous. I would argue that changes in timing or method of abortion are ethically acceptable provided that they are freely chosen by the woman and that she has been fully informed of all possible risks from such changes. I base this argument on the right of any patient to be informed about alternative courses of treatment and to choose between them. It seems to me that the pregnant woman, as a patient, may choose the timing and method of abortion, provided that she has been fully informed of the following: 1) the relation of alternative methods of abortion to possible research on the fetus; 2) risks to herself and to possible future children of alternative possible methods of abortion; and 3) procedures which would be introduced into the abortion as part of the research design which would not be medically indicated.

Some members of the Commission have argued that a woman might choose such changes provided that they entail no additional risk. While I appreciate the concern to protect the woman's health and well-being, such a restriction seems to me a violation of her right to freedom of choice as a patient. Thus I would allow a woman to choose to delay her abortion until the second trimester for purposes of research, *provided that* she has been fully informed of all risks in so doing. One restriction seems imperative to me, however: in no case, would she be allowed to delay the abortion beyond the twentieth week of gestation *for research purposes*. This position is reflected in the Deliberations and Conclusions of the Commission's Report.