National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research : [transcript of the third meeting], February 14-15, 1975 ... Bethesda, Maryland.

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

February 14-15, 1975
Building 31
Conference Room 6
9000 Rockville Pike
Bethesda, Maryland
(Entire Meeting Open to the Public)

Members Present

Joseph V. Brady, Ph.D.
Professor of Behavioral Biology
School of Medicine
Johns Hopkins University
Baltimore, Maryland 21205

Robert E. Cooke, M.D.
Vice Chancellor for Health Services
University of Wisconsin
Madison, Wisconsin 53705

Dorothy I. Height
President, National Council
of Negro Women, Inc.
815 Second Avenue
New York, New York 10017

Albert R. Jonsen, S.J., Ph.D.
Adjunct Associate Professor of Bioethics
School of Medicine
University of California
San Fmacisco, California 94122

Patricia King, J.D.
Professor of Law
Georgetown University Law Center
600 New Jersey Avenue
Washington, D.C. 20001

Karen A. Lebacqz, Ph.D.
Assistant Professor of Christian
Ethics
Pacific School of Religion
1798 Scenic Avenue
Berkeley, California 94709

David W. Louisell, J.D.
Professor of Law
School of Law
University of California
Berkeley, California 94720

Kenneth J. Ryan, M.D.
Chief of Staff
Boston Hospital for Women
221 Longwood Avenue
Boston, Massachusetts 02115

Donald W. Seldin, M.D. *
Professor and Chairman
Department of Internal Medicine
University of Texas
Southwestern Medical School
5323 Harry Hines Boulevard
Dallas, Texas 75235

Eliot Stellar, Ph.D.
Provost of the University
& Professor of Physiological
Psychology
University of Pennsylvania
Philadelphia, Pennsylvania 19174

Robert H. Turtle, LL.B.
Attorney-at-Law
1700 K Street, N.W.
Washington, D.C. 20006

*(Did not attend full session)

Staff Present

Charles U. Lowe, M.D., Executive Director

Michael S. Yesley, J.D., Staff Director

Duane Alexander, M.D.

Edward Dixon, J.D.

Bradford Gray, Ph.D.

Miriam Kelty, Ph.D.

Robert Levine, M.D.

Barbara Mishkin, M.A.

R. Anne Ballard, Information Officer

Bonnie M. Lee, Administrative Assistant

S P E A K E R S

Testifying at the meeting of February 14, 1975

1. C.D. Christian, M.D. Ph.D.
   American College of Obstetricians
   and Gynecologists

2. Robert Marshall,
   U.S. Coalition for Life

3. Thomas Oliver, M.D.
   Association of American Medical
   Colleges

4. Judith Mears,
   Project on Reproductive Freedom
   ACLU

5. David G. Nathan, M.D.
   Harvard Medical School and
   Children's Hospital Medical Center

6. Audrey McMahon,
   Private Citizen

7. Robert Greenberg, M.D.
   Society for Pediatric Research
   and American Pediatric Society, Inc.

8. Sumner J. Yaffe, M.D.
   American Academy of Pediatrics

9. Lois Schiffer
   Center for Law and Social Policy

10. Kay Katz,
    National Tay-Sachs Foundation

11. Arthur Silverstein, Ph.D.
    American Society for Experimental
    Pathology

12. Rev. James McHugh
    U.S. Catholic Conference

13. Jo Anne Brasel, M.D.
    Endocrine Society

14. Nancy Raymond
    Maryland Action for Human Life

S P E A K E R S (Continued)

15. Sean O'Reilly, M.D.
George Washington University
Medical Center
(Read by Nancy Raymond)

16. Chris Mooney
Pregnancy Aid Centers

17. Walter L. Herrmann, M.D.
University of Washington, Seattle

18. Mary O'Donnell
National Pro Life Coalition and
Maryland Right to Life

19. LeRoy Jackson, M.D.
Washington, D.C.

20. Karen Mulhauser
National Abortion Rights Action
League

21. Ernest Hopkins, M.D.
Howard University College of
Medicine

22. J. V. Klavins, M.D.
Long Island Jewish-Hillside
Medical Center

23. Myron Winick, M.D. Ph.D.
American Institute of Nutrition

Friday, February 14, 1975

P R O C E E D I N G S

DR. RYAN: I wonder if we could come to order, please.

This is the third meeting of the National Commission for the Portection of Human Subjects, and all day we will be hearing public testimony.

We have a large number of participants and we are going to try to adhere to a relatively tight schedule, allowing no more than ten minutes for presentation and ten minutes for questioning for each individual.

I would like to call to the attention of the Commission members, on page 2 of your book is a list of the speakers and the order in which they will be heard.

If we may, I would like to start with the first speaker, representing the American College of Obstetricians and Gynecologists, Dr. C. D. Christian.

Would you have a seat at the end of the table?

DR. CHRISTIAN: Dr. Ryan, and Members of the Commission and Staff, I am representing today the American College of Obstetricians and Gynecologists, an organization some 24 years of age, and has as its members 16,000 plus practicing obstetricians and gynecologists.

The statement herein read has been generated by our Ethics Committee of the College which was instituted late in 1973, and has had some four meetings since early '

I think a summary statement is in order in telling you how we attempted to arrive at this.

To limit and direct the efforts of the Committee, it was decided to attempt to separate areas of substantial agreement within the profession from questions which are likely to prove more difficult. It was also necessary to separate the consideraiton of the ethical problems related to the elective interruption of prenancy to those related to research.

It was generally agreed, that the desirable goal of research should not affect the clinical decision for abortion, or substantially affect its timing. Research on the pregnant woman that would cause harm to the fetus and thus make the decision to abort irrevocable would be avoided.

With the above factors eliminated, the products of conception could be considered for research as if resulting from spontaneous abortion in every case.

Therefore, no objection beyond proper consent should be raised regarding the use of the placenta or to the research on the fetus or abortus which is already dead. A fetus that is viable at delivery is recognized as a premature infant and will be treated in a manner consistent with the best hope for unimpaired life.

You have a list of the people on the Committee. We could expand on that, as you might wish.

The statement which takes in my lonely room about seven minutes to read, is as follows:

Biomedical research during the perinatal period is essential to continued reduction in material and perinatal morbidity and mortality, which is among the goals to which the American College of Obstetricians and Gynecologists is dedicated. Such research frequently represents new methodologies and avenues of approach, and is of incalculable value to children now alive and to generations as yet unborn. The list of positive accomplishments in this field resulting from perinatal research is long and distinguished.

Perinatal research is directed to the investigation of normal and abnormal maternal-fetal physiology at various stages of fetal development from fertilization through the neonatal period. Medical science has historically engaged in voluntary efforts to assure that every patient -- whether mother, fetus, or infant -- is accorded full protection of rights as a patient. To this end, technical and ethical guidelines designed to safeguard the subjects of such research should be clearly defined.

The perinatal period has traditionally been an area of major concern to the obstetrician-gynecologist and in daily practice he has been cognizant of the importance of the several lives entrusted to his care even beyond the requirements of law. Although such concern has always

extended as well to basic and clinical investigation in which conflicts of interest may arise. The obstetrician-gynecologist has consistently affirmed this overriding responsibility and concern for the welfare of both mother and fetus. The College also recognizes the growing public concern for the ethical aspects of biomedical research, and in these ethical considerations of perinatal research reaffirms the traditional and continuing concern of its Fellows.

The College believes it is necessary to separate areas of substantial agreement from questions which are likely to prove very difficult. It is particularly important to distinguish ethical problems of patient care from those of research. In this context, the ethical problems of abortion should be separate from those involved in fetal research. Conscientious physicians, and certainly ethicians and many other thoughtful citizens, have always recognized that differing and sometimes conflicting values are involved in any practical problems, including those of medical care. It is particularly necessary to identify these differing elements in the area of fetal research.

In an attempt to arrive at general considerations, the following has been generated. These guidelines for research are intended as a statement of reasonable principles rather than as absolute and restrictive regulations.

Guidelines should be concerned with existing problems and those that might reasonably be anticipated to arise in the future.

Human experimentation is a necessary part of medical research because certain information can be obtained in no other way. Such experimentation may be attended by a certain element of risk; therefore, in research design, all available means must be employed to ensure safety and to narrow the risk. This includes full exploration of appropriate animal models before such protocols are applied to humans.

Personnel shall not be required to participate in perinatal research which is opposed to their ethical attitudes.

It is recognized that the welfare of the patients are always the primary concern. Clinical management should not be affected by research objectives, regardless of the persons -- whether clinician, researcher, or both -- who make decisions and recommendations to the patients. A physician's involvement in a research protocol in no way diminishes his responsibility to or sensitivity for the most appropriate clinical management of the patient. For example, the desirable goal of research should not affect the clinical decision for abortion or affect its timing, such as delay abortion to obtain a later gestational age which might be more suitable for the research project.

All perinatal research requires the usual informed parental consent. All research should be considered on its merits which will be subjected to appropriate institutional and agency review.

Research consisting only of observation and recording is of ethical concern only insofar as it involves informed consent and the preservation of privacy and otherwise does not alter clinical management.

Research utilizing placenta, amniotic fluid and membranes or other tissue samples ordinarily obtained for patient care without adverse effect on mother or fetus does not present a separate ethical problem.

Research involving the dead fetus or infant is of ethical concern only insofar as it relates to the preservation of respect for human remains or tissue. Local regulations on autopsy should be followed. Such research requires the usual informed consent.

Research involving the pregnant woman or the in-utero fetus must always take into account the possibility of harm to the fetus. Research which would knowingly produce such harm is not appropriate even when the eventual termination of the previable pregnancy is intended.

Research on the previable infant who shows signs of life is permitted only when it is assured that the infant is truly previable as measured by gestational age, birth

weight, and other available indicators. Prolonging or shortening the life of the previable infant for the purposes of investigation only is inappropriate. This should not preclude research directed at improving infant survival. When doubt exists as to viability, the infant should be treated as a viable infant.

Research on the viable infant should be governed by the same principles governing all human experimentation, particularly those that relate to infants and children.

Informed consent is not only as necessary as in any medical procedure, but also is of special significance in research. The appropriate persons to give consent may vary with the circumstance.

In the case of the dead fetus or other products of conception, consent would be obtained in the same manner as for disposal of human remains or tissue.

In obtaining consent for research on the previable infant resulting from spontaneous abortion, the mother may usually be presumed to act in its interests as well as her own. There is an unresolved question regarding the appropriateness of the mother electing abortion to give consent for the in-utero fetus or previable infant. This is, however, a problem inherent in elective abortion rather than research.

Throughout the development of this policy

statement, the Committee has attempted to strike a reasonable balance between the public, medical, scientific and legal concerns regarding research that involves the fetus and fetal material and the benefits society will derive from advances in medicine, especially as they relate to reducing perinatal mortality and improving the quality of life.

Thank you.

DR. RYAN: Does Staff have any questions they want to direct?

Alexander.

DR. ALEXANDER: Doctor Christian, on page 3 of your statement you deal with the issue of the involvement of the physician and researcher with the same patients. It has been suggested that the researcher should not -- and the physician -- should not necessarily be the same person. There would be a possible conflict of interest. Would you clarify the College's position on this?

DR. CHRISTIAN: The College's position is, and the perceived implication is, that if someone were involved in research, that somehow diminishes their sensitivity to their patient has been received with considerable concern in all of medicine across the country. I think the reasonable position is that if a person is involved in the research protocol it does not change him, or her, into someone who is less sensitive or acts inappropriately in regard to the

patient.

I would say there is no reason to divide the two.

DR. ALEXANDER: One further question.

In research involving a fetus in-utero, the question of possible harm to the fetus, you state that nothing should be done which would intentionally or knowingly harm the fetus.

How would you propose that review of proposed research be carried out where there is an uncertainty as to the possibility of harm to the fetus? Do you feel the present proposals or procedures are adequate, or do you feel additional safeguards should be employed?

DR. CHRISTIAN: I think it is impossible, as reasonable people agree, to write regulations regarding judgment. You have to do what reasonably might or might not be done. There comes some final common denominator where judgment has to be involved in any protocol. I don't think a regulation can be written regarding that. I am not being evasive.

DR. ALEXANDER: No further questions.

DR. RYAN: Do any of the Commission Members have any questions?

Dr. Lebacqz.

DR. LEBAZQZ: The statement was that research should not affect the clinical decision for abortion or

substantially affect its timing. That was the original statement.

In our statement this morning, the statement is research should not affect its timing. Is the word "substantially" significant, and if so, what does it pertain to?

DR. CHRISTIAN: We elected because it is a judgmental word and "substantially", of course, could mean different things, that your position would be fairer to say "should not affect the timing."

DR. RYAN: Doctor Lebacqz, the transcript which you have in front of you now is the official one which has been submitted to us.

Doctor Cook.

DOCTOR COOK: On page 6 of the statement you use the term "competence of the mother in giving consent." I am not a lawyer, but I wonder if the usual use of the word "competence" would apply here? The mother in the legal sense is competent to understand and so forth. The question of whether or not it is appropriate for her to be giving consent is the issue I would like to raise and find out what you see is possible?

DR. CHRISTIAN: I think we did not mean it in a legalistic sense of competence, but rather the sense of appropriateness. I cannot take it on myself to change that

statement this morning.

DR. RYAN: Thank you, Doctor.

MS. MISHKIN: On page 4, in response to an earlier question about knowingly producing some harm --

DR. RYAN: Could you speak louder?

MS. MISHKIN: I am looking for futher clarification to his answer to Doctor Alexander on his statement on the bottom of page 4 where it says, knowingly produce such harm to the fetus in-utero was not appropriate. Do I understand, then, that if you do not know, in other words, if the fact is that there is no way of knowing whether or not something may produce harm, how would the College stand on that?

DR. CHRISTIAN: Well, again, it is a matter of reasonable acts by reasonable people. If there were known or a high percentage chance of that sort of risk, it would not be appropriate. If it were a sheer inadvertence, obviously, there is no way it can be precluded or not done.

MS. MISHKIN: In your best judgment if you did not know and had no scientific way of knowing what the result would be on the field whatever the purpose of the research was?

DR. CHRISTIAN: Presumably this would have gone by appropriate agency review, they would know that they are reasonable people, well informed with the leading edge of

of information and technology, so they presumably would be the best people to do the projected research. Does that answer your question?

MS. MISHKIN: My problem is even if all those people are reasonable, they may not have the judgment.

DR. CHRISTIAN: I think we are saying the same thing. It is impossible to write.

DR. RYAN: I think you are on the risk versus benefit dilemma which we will have to consider one other time.

There is one last question from Dr. Louisell.

MR. LOUISELL: In connection with your point that there is no inconsistency between the treating physician functioning as the researcher, are you acquainted in the transplant operations a sharp distinction is made between the donor's treating physician and the prospective transplanter's?

DR. CHRISTIAN: That may be for other reasons. Most people involved with the trauma that leads to that sort of early cadaver transport are not the people who do the transplants. So there may be additional technical reasons that haven't anything to do with ethical reasons. I would not want the wrong conclusion drawn from the separation of duties in the transplant. That is not entirely the reason, but it is certainly part of the reason. The perceived

implication by physicians in the country that in fact to be involved or even if your name, even in an administrative position, on a research protocol, that that would strip you of appropriate clinical management and your appropriate sensitivity to a patient has been received poorly across the country.

My point is you can do one and the same and be both.

DR. LOUISELL: But isn't there the same potential as far as motivation is concerned for a conflict of interest when you have the relation of researcher and treating physician?

DR. CHRISTIAN: This is a situation I think we can stop. All of us stting around the room would know each of us would act in a patient's best interest. It is everyone else we are worried about.

DR. RYAN: Doctor Christian, thank you very much.

If we may go on now to Mr. Robert Marshall, representing the U.S. Coalition for Life.

You have your presentation.

MR. LOUISELL: Was his presentation included in the original group?

DR. RYAN: They have been distributed this morning, David. They should be in your pile.

There are no numbered pages 15, 16, and 17.

Text is complete.

Mr. Marshall.

MR. MARSHALL: My name is Robert G. Marshall, Special Assistant for Congressional Affairs to the U.S. Coalition for Live - a clearinghouse and research center for pro-life activities.

My past experience includes: (1) Legislative Assistant during 1970-1971 to John A. Blatnik, Chairman of the House Committee on Public Works, (2) GS-11 Grant Reviewer at the Office of Economic Opportunity during 1973 in the Office of Program Review, (3) Medical Technician in 1972.

I thank the panel here today for the opportunity to testify on the subject of fetal research.

Part One of my presentation will deal with the proposed regulations as published in the Federal Register for November 16, 1973. Part Two will deal with topics not covered by proposed regulations.

Section 46:24

1. DHEW ACTIVITY:

Support of bio-medical or behavioral research involving human beings can be direct or indirect. Indirect support consists of providing money or staff to (A) individuals or organizations who have contracting ability and who delegate to others the responsibility for performing such research, (B) individuals or organizations part of whose activities consist of such research.

RECOMMENDATIONS:

Any conditions promulgated by DHEW surrounding the use of such tax originated monies used to support bio-medical or behavioral research involving human beings apply to both direct and indirect use of such money.

2. NEEDS OF SUBJECT:

As a subject in any DHEW activity which goes beyond the application of those established and accepted methods necessary to meet his need.

Persons take drugs in the absence of a diseased condition, i.e. birth control pills, morning after pills, marijuana.

RECOMMENDATIONS:

Researchers should (A) indicate the parameters of "normalcy". (B) Define the level of "need" being fulfilled in the experiment.

3. CHILD:

"Child" means an individual who has not attained the legal age of consent to participate in research.

Many states permit persons otherwise considered as "minors" to consent to and receive prescriptive birth control and abortifacient devices -- IUD's -- as well as abortions.

RECOMMENDATIONS:

The U.S. Coalition for Life opposed the

interpretation of such statutes so as to place in such "minors" and not their parents, the power of consent in such experimentation.

DR. RYAN: The hearings today are on live human fetal research. Could you direct your comments to that subject, please.

MR. MARSHALL: These are the conditions surrounding the holding of such research. I am directing my comments to that area based upon these regulations. That is why I developed my presentation this way.

DR. RYAN: The Commission has nothing to do with the regulations.

MR. MARSHALL: Nothing at all?

DR. RYAN: No.

MR. MARSHALL: Then I have been misinformed. How do you suggest I proceed?

DR. LOWE: regulations have been published by the Department to encourage public discussion and is a function of the Department. The Commission is independent of the Department and operates in a totally different manner. I think it is important to make that distinction so that your comments should be properly directed to the Secretary, not at many members of this Commission. Certainly, you are entitled to submit comments in writing to the Commission.

DR. STELLAR: May we accept the comments in

lieu of the testimony today? Would that be agreeable?

MR. MARSHALL: Could I just read the comments, because they do pertain to --

DR. RYAN: If you could scan through and cover those that would be pertinent to the subject at hand, pelase proceed.

MR. MARSHALL: You have nothing to do with making recommendations concerning the ethical review board at all?

DR. RYAN: We will be making recommendations. The request for information today was concerned with live human fetal research. That was the order of business today. If we make requests in the future, the requests will be made so.

MR. MARSHALL: I understand the requests were made around conditions concerning that.

DR. RYAN: I don't want to spend everyone's time here in trying to work out an accomodation at this point. Would you please, Mr. Marshall, if you have comments with respect to live human research or comments in here which would be pertinent, please state them. We will give you additional time.

MR. MARSHALL: Thank you.

Concerning the subject matter of live human research, we have some questions here.

Lest it be unlear, the Coalition for Life is

opposed to any procedure called medical which does not have the effect of or is not directed at preserving the life or restoring the health of the immediate patient or patients. Unarticulated, but nevertheless assumed in the proposed regulations are notions concerning both the nature of man medicine that are in actual or potential conflict with the Juedo-Christian moral ethic. Namely, that man -- being the animal with the capacity to reason -- is made in the image of God and is the only terrestial creature that has the spiritual aspect of personhood. The teaching of man's special creation -- that the origin of both the individual and the race cannot be accounted for by the operation of the purely natural causes which operate in the biological process of reproduction. Only man is immortal -- that the human soul is capable of subsisting apart from the body, even though its perfection requires it to be reunited with the body. Only man has free will and moral responsibility -- that each person will be judged for his acts by the Creator of us all.

The Coalition holds that any attempt to place considerations of knowledge above the beforementioned understanding of man is misguided from the start and results in man being treated as a means only and not an end. With that understanding the U.S. Coalition also recommends the following safeguards and sincerely hopes that this

study commission will both consider and adopt them:

Concerning Experiments:

Adoption of the Golden Rule as a criteria of who shall be a participant in any experiment. If an experimenter will not submit either himself or one he loves to such a procedure neither should anyone else be submitted.

Adoption of an absolute prohibition on the medically needy as participants in experiments except in the circumstance of immediate danger to life. To offer free medical treatment or monetary compensation to the poor as an inducement to participation in an experiment is to take unfair advantage of a person's situation. If anyone wants to help the poor via legislation then we should lobby for a just tax structure.

Valid consent entails that participants be told in language intelligible to the prospective participant, what the experiment involves both on themselves and the unborn. Participants should be required to write out in full, as opposed to merely filling in spaces with their name, the purpose of the experiment.

The experimentor should reveal his or her competence and not merely statistical projections of the morbidity and complication rate of other experimentors.

Additional material is included and ask permission to submit future material, if necessary. Thank you.

Mr. Marshall's prepared statement follows:

My name is Robert G. Marshall, Special Assistant for Congressional Affairs to the U. S. Coalition for Life - a clearinghouse and research center for pro-life activities.

My past experience includes: (1) Legislative Assistant during 1970-1971 to John A. Blatnik, Chairman of the House Committee on Public Works, (2) GS-11 Grant Reviewer at the Office of Economic Opportunity during 1973 in the Office of Program Review, (3) Medical Technician in 1972.

I thank the panel here today for the oppotunity to testify on the subject of fetal research. Part One of my presentation will deal with the proposed regulations as published in the Federal Register for November 16, 1973. Part Two will deal with topics not covered by proposed regulations.

PART ONE:

Discussion: Proposed Policy Regulations for the Protection Of Human Subjects:

Section 46:24
1. DHEW ACTIVITY:

PROPOSED REGULATION:

The conduct or support (through grants, contracts, or other awards) of bio-medical or behavioral research involving human subjects.

COMMENT:

Support of bio-medical or behavioral research involving human beings can be direct or indirect. Indirect support consists of prov ing

money or staff to (A) individuals or organizations who have contracting ability and who delegate to tohers the responsibility for performing such research, (B) individuals or organizations part of whose activities consist of such research.

RECOMMENDATIONS:

Any conditions promulgated by DHEW surrounding the use of such tax originated monies used to support biomedical or behavioral research involving human beings apply to both direct and indirect use of such money.

2. NEEDS OF SUBJECT:

PROPOSED REGULATION:

as a subject in any DHEW activity which goes beyond the application of those established and accepted methods necessary to meet his needs.

COMMENT:

Persons take drugs in the absence of a diseased condition, i.e. birth control pills, morning after pills,, marijuana.

RECOMMENDATIONS:

Researchers should (A) indicate the parameters of "normalcy" (B) Define the level of "need" being fulfilled in the experiment.

3. CHILD:

PROPSED REGULATION:

"Child" means an individual who has not attained the legal age of consent to participate in research..

COMMENT:

Many states permit persons otherwise considered as "minors" to consent to and receive prescriptive birth control and abortifacient devices (IUD's) as well as abortions.

RECOMMENDATIONS:

The U. S. Coalition for Life opposes the interpretation of such statutes so as to place in such "minors" and not their parents, the power of consent.

Section 46:25
4. AGENCY ETHICAL REVIEW BOARD:ESTABLISHMENT:

PROPOSED REGULATION:

The head of each agency shall establish an Ethical Review Board.

COMMENT:

Will an Ethical Review Board be established for each regional office of the Agency or only one Ethical Review Board here in Washington?

RECOMMENDATIONS:

Regional Boards should be set up if regional grants and contracts are made.

5. COMPOSITION:

PROPOSED REGULATION:

The Board shall be composed of research scientists (biomedical, behavioral, and/or social), physicians, lawyers, clergy, ethicists, and representatives of the public. It shall consist of 15 members appointed by the agency head from outside the Federal Governemnt.

COMMENT:

Government by appointment minimizes direct citizens' imput, the very group which is supposed to benefit from the experiment.

RECOMMENDATIONS:

To be eligible as a public representative on the ERB, a person should be (1) nominated by direct petition of the people (a minimum of 1,000 registered voters), (2) collect at least half of the legal requirement (500) by him or himself, (3) the petition should describe

the function of the ERB and any compensation for service on the board.

6. BOARD FUNCTION:

PROPOSED REGULATION:

"..review each proposed activity to which this subpart applies.."

COMMENT:

Good grant review involves much reading, questioning, and thought. QUESTIONS: Is the ERB paid to engage in such activity? What material will they review? Can they question the experimentors? How many grants will they review and in what period of time? Or, will the ERB merely use material prepared during the internal grant review process of the Agency? Will persons experienced in grant review be on the board? How long will people spend on the board? Who may dismiss board members and for what cause? How will the board know that all proposed experiments concerning humans are being presented to it for review?

RECOMMENDATIONS:

Based upon my experience in reviewing millions of dollars in federal grants, unless the ERB is to be a paid staff (no where indicated) the "review" will either be severely deficient in quality or become a kind of rubber stamp window dressing for decisions made elsewhere. Therefore, compensation shall be provided over a sufficient time period to allow a full review by the board.

7. BOARD'S STANDARD OF JUDGEMENT:

PROPOSED REGULATION:

"..from the standpoint of societal need and ethical · siderations, taking into account,,the potential benefit of the pr sed activity.."

the function of the ERB and any compensation for service on the board.

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RECOMMENDATIONS:

Based upon my experience in reviewing millions of dollars in federal grants, unless the ERB is to be a paid staff (no where indicated) the "review" will either be severely deficient in quality or become a kind of rubber stamp window dressing for decisions made elsewhere. Therefore, compensation shall be provided over a sufficient time period to allow a full review by the board.

7. BOARD'S STANDARD OF JUDGEMENT:

PROPOSED REGULATION:

"..from the standpoint of societal need and ethical considerations, taking into account,,the potential benefit of the proposed activity.."

COMMENT:

Does "potential benefit" mean societal need or patient need?

RECOMMENDATIONS:

The ERB should specify which weighs more and why.

Section 42:46
8. PROTECTION COMMITTEE - COMPOSITION:

PROPOSED REGULATION:

"..no activity covered by th subpart will be approved unless it provides for the establishment by the applicant of a Protection Committee..None of the members shall have any association with the proposed activity, and at least one-half shall have np association with any organization or individual conducting or supporting the activity."

COMMENT:

SAME AS FOR #1

REGULATIONS:

SAME AS FOR #1

Section 46:27
9. PROHIBITION OF CERTAIN CHILDREN IN EXPERIMENTS:

PROPOSED REGULATION:

"..the child has only one known living parent who is available..Both the child's parents are available.."

COMMENT:

What does "available" mean? Does it include attempts to make contact by phone, registered mail, personal visits?

RECOMMENDATIONS:

Please specify.

Section 46:28
10. ACTIVITIES OUTSIDE OF U.S.:

PROPOSED REGULATION:

"..must include written documentation satisfactory to DHEW that the proposed activity is acceptable under the legal, social, and ethical standards of the locale in which it is to be performed."

COMMENT:

Some of the most objectionable experiments in the area of fetal research have taken place in foreign countries with American tax dollars. (See enclosures)

RECOMMENDATIONS:

Keep U.S. dollars in the United States.

Section 46:33
11. PREGNANCY:

PROPOSED REGULATION:

"..means the period of time from implantation of a fertilized ovum until delivery.."

COMMENT:

What ever happened to the conception that took place 7 to 9 days prior? This, combined with an up to two week margin of error on the late side in pinpointing the actual date of conception or fertilization could result in experiments being performed on unborn children who are beyond the date of viability by as much as 3 weeks. How many Edelin cases is NIH prepared to fight?

RECOMMENDATIONS:

Upon proof that any individual or organization uses a little one (latin - fetus) in an experiment beyond the second trimester be subject to (1) immediate suspension of any remaining grant or contract money (2) such indivuals or organizations be prohibited from receiving

like grants from the said agency for not less than 3 years from the date of the grant or contract termination.

Section 46:35
12. MATERNAL CONSENT INVOLVING EXPERIMENTATION ON THE UNBORN:

PROPOSED REGULATION:

"..vital functions if the abortus will not be maintained artificially for purposes of research.."

COMMENT:

This does not exclude the abortionists from keeping the vital functions of the little one operative for purposes other than research since under prior regulations he is barred from the research.

RECOMMENDATIONS:

Please clarify.

Section 46:37
13. PROHIBITION OF CERTAIN EXPERIMENTS:

PROPOSED REGULATION:

"No activity to which this subpart is applicable may involve a pregnant woman if the Primary Review Committee finds that the fetus might be adversely affected, unless the primary purpose of the activity is to benefit that fetus."

COMMENT:

What is the Primary Review Committee? Is this section meant to apply to as a prohibition on certain kinds of fetal experimentation where the woman desires to carry the baby to term?

RECOMMENDATIONS:

Please Clarify.

Section 46:38
14. OTHER CONSENT NECESSARY:

PROPOSED REGULATION:

"..unless maternal consent has been obtained, as well as the consent of the father if he is available.."

COMMENT:

What is "available?"

RECOMMENDATIONS:

Please specify.

15. Section 46.62
Records-Additional Recommendations;

1-Files should be open to the public where names have been omitted from the narration of the experiment.

2-Where a person consents for themself or another any subsequent medical history developed should, as a matter of course, be sent to their own doctor.

Part Two

Lest it be unclear, the Coalition for Life is opposed to any procedure called medical which does not have the effect of or is not directed at preserving the life or restoring the health of the immediate patient or patients. Unarticulated, but nevertheless assumed in the proposed regulations are notions concerning both the nature of man and medecine that are in actual or potential conflict with the Judeo-Christian moral ethic. Namely, that man-being the animal with the capacity to reason-is made in the image of God and is the only terrestial creature that has the spiritual aspect of personhood. (2)The teaching of man's special creation-that the origin of both the individual and the race cannot be accounted for by the operation of the purely natural causes

which operate in the biological process of reproduction. (3) Only man is immortal-that the human soul is capable of subsisting apart from the body, even though its perfection requires it to be re-united with the body. (4) Only man has free will and moral responsibility-that each person will be judged for his acts by tbe Creator of us all.

The Coalition holds that any attempt to place considerations of knowledge above the before-mentioned understanding of man is mis-guided from the start adn results in man being treated as a means only and not an end. With that understanding the U.S.Coalition also recommends the following safeguards and sincerely hopes that this study commission will both consider and adopt them.

1-Adoption of the "Golden Rule" as a criteria of who shall be a participant in any experiment. If an experimenter will not submit either himself or one he loves to such procedures neither should anyone else be submitted.

2-Adoption of an absolute prohibition on the medically needy as participants in experiments except in the circumstance of immediate danger to life. To offer 'free medical treatment' or monetary compensation to the poor as an inducement to participation in an experiment is to take unfair advantage of a person's situation. If anyone wants to help the poor via legislation them we should lobby for a just tax structure.

3-Valid consent entails that participants be told, in language intelligible to the prospective participant, what the experiment involves both on themselves and the unborn. Participants should be required to write out in full-as opposed to merely filling in spaces with their name-the purpose of the experiment.

4-The experimentor should reveal his or her competence and not merely stastical projections of the morbidity and complication rate of other experimentors.

Additional material is included and ask permission to submit future material if necessary. Thank you.

DR. RYAN: Thank you very much.

I think the problem is the material which was submitted and which we based our invitation to you on is different from that which you submitted today. We appreciate what you just stated.

Are there any questions?

MS. MISHKIN: Following up on your Golden Rule principle, could you elaborate to the extent that you can tell us whether or not you would oppose non invasive observational research?

MR. MARSHALL: In other words, you mean just like the use of fetus scopes?

MS. MISHKIN: That's correct.

MR. MARSHALL: No. That is not in a sense a harm, or not intended as a harm. I worked for a medical doctor, quite a brilliant man, who developed a devise to help physically rehabilitate people who had muscular ailments. He, before he submitted anyone else to his device, himself submitted himself to the device. In other words, this is kind of an ethical safeguard to be sure that he wouldn't have anybody -- looking with a jaundiced view on the subject as a subject instead of an experiment.

MS. MISHKIN: You would broaden your restrictions, preserving the life or the health of the immediate patient, you would also include observational items that have nothing

to do with the immediate patient, but neither would it harm the patient?

MR. MARSHALL: We see nothing wrong with that.

MS. MISHKIN: Thank you.

DR. RYAN: Mr. Marshall, Thank you very much.

MR. LOUISELL: I have a question. I wanted to ask about the notion of research on minors, that is, children, as contrasted with the normal assumedly free adult. Do you draw a distinction there with respect to their being a further requirement for a minor being the subject of research, as distinguished from an adult?

MR. MARSHALL: Again, I am not sure that even a parent has the capacity to consent to research that would cause a harm to the child or a foreseeable harm. In other words, there outght to be a strict bar even on the powers of parents to consent to certain kinds of items. You are going to ask a question as to what kind of research, and that would be a factual consideration based upon the risk.

MR. LOUISELL: You can foresee of situations where an adult would be justified from every legal and moral viewpoints to submitting himself to the risk of research, and yet where it would still be improper for him to submit his own minor child?

MR. MARSHALL: Yes. There is the circumstance of the head of a department who wants to perform certain

experiments soliciting assistance from the children of subordinates in his department. And because of the potential conflict there, the person in the subordinate position refusing a superior to submit the child to what the superior says is a harmless experiment, you might develop categories which are an absolute prohibition to this. Is my job in heopardy if I don't submit my child to this experiment? I think these kinds of situations should be drawn out so you can prohibit the occasion from coming out.

DR. COOKE: In your statement you essentially indicate -- along the same lines -- that the mother may give proxy concent for the fetus, is that correct?

MR. MARSHALL: Yes, to certain procedures. Again, if they are designed to aid the health or preserve the life of the unborn.

MR. LOUISELL: You are not arguing the mother could give such consent for a harmful procedure on the unborn?

MR. MARSHALL: I don't think she has any right to do it. She has the power to do it.

DR. RYAN: Any other Commission Members have questions?

DR. COOKE: This is Ms. Mishkin's statement again, if the harm could not be judged because there have been

no track records, in a sense, how would your association react in regard to the fetus with regard to the minor basis?

MR. MARSHALL: In other words, the administration of drugs?

DR. COOKE: There was no known harm, but no strong documentation that harm cannot result. That is a problem with many experiments?

MR. MARSHALL: We first request or hope that all prior methods have been used to try to help this unborn, all the established methods. If and when they fail, that is when you are morally justified in turning to a circumstance where you don't know the consequence, but your intent is to help. If it turn out the other way, that is unfortunate.

DR. COOKE: So intent becomes a very important issue?

MR. MARSHALL: Motive and intent, as ascertained by the nature of the treatment you are going to give.

DR. RYAN: Do other Commission Members have questions?

(No response.)

DR. RYAN: Thank you very much, Mr. Marshall.

The next speaker represents the Association of American Medical Colleges, Doctor Thomas Oliver. You should have his testimony before you.

Dr. Oliver, may I caution you as the last witness

to please address yourself to the question of research on the live human fetus?

DR. OLIVER: Thank you.

I am Thomas K. Oliver, Jr., Professor of Pediatrics and Chairman of the Department of Pediatrics at the University of Pittsburgh School of Medicine. I am pleased to appear before you today on behalf of the Association of American Medical Colleges and particularly on behalf of the 58 academic societies affiliated with the Association.

In the interest of time, I will not go into the position of the Association. It represents medical schools and teaching hospitals.

During the past ten years there has been a remarkable reduction in the death rate of premature infants. At the same time these survivors of premature birth have become dramatically healthier and more vigorous. For example, in 1960 an infant weighing less than three and one-half pounds had a 50 percent chance of dying; but today that infant has better than an 80 percent chance of living. Two-thirds of those premature infants who did survive in 1960 had serious neurologic damage including blindness, mental retardation, or cerebral palsy. Today not only do four out of five prematures survive but they do so with about the same low rate of neurologic damage as full-term babies. These dramatic successes can be attributed directly to fetal

research and the consequent improvement in care of the fetus and newborn. Although these advances have lowered the mortality rate of the newborn infant the rate of illness and death in newborns is still high and further research is urgently needed.

In discussions of fetal research the ethical issues raised by this research are mistakenly connected with emotionally charged issues relating to induced abortion or the use of fetal materials resulting from spontaneous abortion.

The Association believes that a careful separation of issues concerning fetal research from issues concerning the ethical and moral concerns of abortion must be maintained. Several subsequent speakers will address themselves to fetal research during that part of pregnancy during which abortion can be a concern. We would like to address ourselves at this time to issues relating to fetal research in the later stages of pregnancy, particularly in the third trimester. In this way we will provide a clear example of the need for continuing research on the fetal-maternal unit in order to promote the well-being of the motion and child and to assure that every child has the healthiest possible beginning of life with the least possible risk.

Following are two examples of life-saving

techniques developed by research which would have been impossible under the proposed regulations.

Past experience overwhelmingly demonstrates that it is essential to collectinformation on the normal mother and the normal fetus during pregnancy, particularly during the last trimester of pregnancy. Advances which have been made through fetal research have profoundly altered the care of the premature and full-term infant. Through the collection and study of amniotic fluid by amniocentesis, we can identify before birth the fetus with Rh incompatibility. This disease results when the fetus' blood cells are a different type than the mothers'. The fetal red cells stimulate Rh antibodies which will destroy the fetal cells and cause brain damage or death before or after birth. To detect this problem before birth a needle is directed into the amniotic sac and amniotic fluid is withdrawn. This method was developed and proven by research.

Through the study of amniotic fluid from normal pregnancies we established normal values which permits us to identify the abnormal fetus. This knowledge of normal pregnancies has not only improved diagnosis of Rh disease but has also led to striking improvement in treatment. This research provided the first example in which the fetus could be directly treated in utero by transfusion of blood into the fetus, a life-saving procedure since otherwise these babies

would have been stillborn. Thus, many women who cannot safely bear children are able to do so as a direct result of fetal research.

Another example of research that shows great promise for reducing infant mortality involves the collection and study of amniotic fluid by amniocentesis to determine the ability of infants to breathe successfully after birth. There exist in amniotic fluid materials that indicate potential lung readiness for air breathing. The greatest cause of infant death, particularly in premature infants, is hyaline membrane disease. In the United States each year 40,000 babies are stricken and approximately 25,000 die. Four years ago it became possible to analyze amniotic fluid surrounding infants who may be born prematurely in order to determine whether the lungs are ready for air breathing. Furthermore, two years ago it became possible to treat infants whose lungs are not yet ready for birth by hormone injection of the motions. The hormone injection assures that the fetal lung will develop this essential function.

All this saving of lives and prevention of disease was made possible by research which would be impossible under the proposed regulations governing research on pregnant women and the fetus. There are other examples that I could cite but these appear to be particularly important for two reasons: first, there are no animal models of Rh

incompatibility or of hyaline membrane disease. Second, these diseases do not occur in adults, and therefore it is impossible to study these diseases in adults. Only by human fetal research were these advances possible.

The Association of American Medical Colleges firmly supports the promulgation of regulations to protect the maternal and the fetal subjects of research. We believe the regulations currently proposed represent a firm foundation for the protection of human subjects in general and of maternal and fetal subjects in particular. These regulations have been widely discussed by conscientious and thoughtful persons in government and in the lay and biomedical community. The Association believes, however, that the regulations still require modification in several important areas.

We respectfully direct the attention of the Commission to the appended comments of the American Federation of Clinical Research which the Association endorses in general. These comments are thought-provoking and have been carefully framed to allow productive and responsible research to continue on problems similar to those which have been described.

It is doubtful whether any of us is farsighted enough to preduct which diseases will similarly succumb to careful fetal research in mothers and fetuses in the

distant future. This leads us to consider the means by which human endeavors are regulated. There is no doubt that this Commission will give its best attention to the protection of human subjects and will publish guidelines carefully drawn to meet the problems of 1975. How effective these guidelines will be ten years from now, none of us can predict. Medical science will undoubtedly advance and opportunities now unforeseen will occur, therefore would it not be wise to establish a mechanism by which we can respond to these advances and opportunities? We believe the most responsive mechanism which might be relatively unresponsive to change but to create an Ethical Advisory Board. We strongly support the creation of such a Board. We would hope that the function of such a Board would not be only the review of grant applications involving human subjects. We suggest it would be better to require the Board to review only applications in which ethical questions have been rained by organizational or agency review, to hear appeals by investigators or subjects -- or their representatives -- and to continue to improve the guidelines for the safe, ethical and effective condut of research. The Board should be required to publish its findings and opinions. The Association hopes you will recommend creation of such a Board with clear authority to supervise the ethical and moral issues of clinical research.

In concluding, I would like to stress again the

importance of studies in the normal mother and fetus. Most diseases of the newborn begin during fetal development. If we have not studied normal fetuses how can we know what is abnormal or pathological? Studies on the normal mother and fetus are, therefore, absolutely essential in assuring for each child the right to be well born. We consider this point so important that we strongly suggest that guidelines be drawn so that research will be permitted in normal pregnancies where the benefit to mothers and fetuses as a class out-weighs the risks. Research should not be limited to benefits to the particular mother or fetus for the reasons given in the examples above.

The Association of American Medical Colleges hopes you will recommend clear guidelines which will permit necessary research leading to future successes in the fight against maternal and fetal death and disease. We will be pleased to assist you in any way possible in discharging your heavy responsibilities.

Thank you.

DR. RYAN: Thank you, Doctor Oliver.

MS. KING: With respect to your suggestion of the Ethical Advisory Board, could you tell me what composition did you have in mind for such a Board; and, two, in terms of membership, where you anticipate locating such a Board, at what level, State and regional level?

DR. OLIVER: The regulations which have been circularized and to which there was earlier referral, has suggested the Ethical Advisory Board be located at a national level. There is also a suggestion as to what its composition should be. We would support those general recommendations.

DR. LEBACQZ: Could you tell me, please, on what class of fetuses was the original research done in transfusion of blood into the fetus? Was it done on norma fetuses, in-utero, prior to abortion and so on?

DR. OLIVER: Once the technique of amniocentesis and the recognition of the fetus was appreciated and improved treatment resolved, it still was apparently that approximately ten percent died as stillborns. They became so anemic before they could sustain life, that they died. In the 28th, 30th, 32nd week. Because one could identify the risk infant by this technique, it was decided that he or she should be studied by the transfusion process. There was no other modeal available. The outcome was known in this case about the baby and it was research and treatment directed to the affected fetus.

DR. RYAN: Dr. Louisell.

DR. LOUISELL: In connection with your references to amniotic fluid research, it is a fact, isn't it, that that kind of research with respect to extraction of the fluid,

that could be carried on without any significant danger to the fetus?

DR. OLIVER: Absolutely. I think at the present time there is concern in terms of the proposed regulations whether this would be allowed or not. In terms of strict interpretation of them. I don't know whether other techniques may be developed in succeeding years beyond amniotic fluid analysis. We are comfortable with that. We know the risk-benefit ratio. We need, I think, to be able to continue studies for the very reasons that amniocentesis has been done.

DR. LOUISELL: Isn't it the Commission's real job, if it can be done, to draw distinctions between types of research that are sound from a basic research viewpoint and don't run undue risk of injury to the subject, and types of risks, on the other hand, that are inherently too dangerous to be tolerated on human persons? Isn't that our real job?

DR. OLIVER: Yes, by all means, that is your real job. I use amniocentesis as an example because I am not sure ten years ago what the Commission's position would be. I personally can recall that I was terrified at this. Because the fetus was considered inviolable, could not be studied in any way.

DR. LOUISELL: But there isn't anything in your

position that essentially would justify subjecting the fetus to a greater risk than any born person in the performance of research?

DR. OLIVER: Yes, you are right. And to study normal babies, fetuses, mothers, to study better the abnormal fetus.

DR. RYAN: Doctor Cooke.

DR. COOKE: Tom, what you have given is two examples of fetal research, at least as you presented them, and as I understand it, it did not involve the fetus at all and would not be considered fetal research.

DR. OLIVER: I guess, Bob, you will have to decide who amniotic fluid belongs to. I have always considered it the fetus's.

DR. COOKE: It is a fluid surrounding the fetus. It isn't the intact fetus. The cells that are shed in the amniotic fluid, I would have to take the position they are not part of the intact fetus. Most people would not say that is an invasion of the fetus anymore than an analysis of some urine in a specimen container was an invasion of the adult who passed that specimen. Now, that, I think, that type of interpretation might make it possible to learn a good deal about fetal studies. But the direct invasion of the fetus is, I think, one of the considerations. I take it that was not part of these two research problems?

DR. OLIVER: Clearly, the outcomes that one hopes for in terms of ultimate treatment of the fetus is his invasion. By drugs, by needles in the case of transfusion. And, indeed, that may well be a consequence.

DR. COOKE: Your statement about transfusion, though, in answer to a previous question, transfusion was done on the fetus requiring treatment for its survival. So the intent was quite clear.

DR. OLIVER: That's correct.

DR. COOKE: It was the survival of the individual and not essentially a normal subject that was being transfused for investigational purposes. You do make a statement which I think is somewhat difficult to interpret. I think it is subject to misinterpretation. I wonder if you want to clarify it. Where the benefit to the mothers and fetuses as a class outweighs the risk, then research is justified. That implies that if the risk is still rather considerable for the individual, even though as a class the benefits might be considerable and outweigh the risk, that research might be justified. I doubt if you mean that?

DR. OLIVER: We are at the risk-benefit gray zone that roubles us all, and which I hope through an Ethical Advisory Board and other agencies, one could establish what are the risk-benefits. I would simply state that amniotic fluid analysis now is known to be a low risk-high yield for

certain conditions. It may well be that other such procedures will be developed.

DR. RYAN: There are other members of the Committee who want to question. Do you want to pursue that?

DR. COOKE: It is a very important issue as to whether or not you consider that the risk to the class and the benefits of the class might take precedence over the risk to the individual. This isn't just restricted, obviously, to the fetus. But children in general might benefit substantially by such research of a particular type. And yet the individual who is the subject might be at some risk.

How would you handle that particular ethical problem?

DR. OLIVER: If, obviously, the risk to the individual is high, the procedure should not be undertaken.

DR. COOKE: Even though there might be substantial benefit to the class?

DR. OLIVER: The theoretical situation you raised, that's right.

DR. RYAN: Dr. Jonsen.

DR. JONSEN: The statement submitted by the College of Obstetricians and Gynecologists says research that would knowingly produce harm to the in-utero fetus is not appropriate even when the eventual termination of a previable pregnancy is intended. That appears to bring up the

point of research that would be relatively high risk being done when there is an elective abortion intended. And this would appear to prohibit such research.

Does the Association have a position on this matter, in which, for example, the mother who entertains such experimentation on her fetus would change her mind?

DR. OLIVER: We in general support the position as outlined in the position paper of the American Federation of Clinical Research, in which such studies with the informed consent might lead to our advanced knowledge.

DR. RYAN: Dr. Oliver, thank you very much.

I am sorry, Dr. Lebacqz, but we have to keep to some sort of a schedule to accommodate all of the individuals.

* * * * *

Dr. Oliver's prepared statement follows:

TESTIMONY OF THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES

I am Thomas K. Oliver, Jr., Professor of Pediatrics and Chairman of the Department of Pediatrics at the University of Pittsburgh School of Medicine. I am pleased to appear before you today on behalf of the Association of American Medical Colleges and particularly on behalf of the 58 academic societies affiliated with the Association.

Now in its 98th year, the Association represents the whole complex of persons and institutions charged with the undergraduate and graduate education of physicians. It serves as a national spokesman for all of the 115 operational U.S. medical schools and their students, 400 of the major teaching hospitals, and 58 learned academic societies whose members are engaged in medical education and research.

The Association is anxious to comment on the issue of fetal research because of the important role of the nation's medical schools in biomedical research training and the equally important role of such training in the quality of American medicine and medical education and, also, because of the deep involvement of the schools in assuring the highest ethical, moral and social concerns in all scientific inquiry, particularly when it involves human subjects.

During the past ten years there has been a remarkable reduction in the death rate of premature infants. At the same time these survivors of premature birth have become dramatically

healthier and more vigorous. For example, in 1960 an infant weighing less than 3 1/2 lbs. had a 50% chance of dying; but today that infant has better than an 80% chance of living. Two-thirds of those premature infants who did survive in 1960 had serious neurologic damage including blindness, mental retardation, or cerebral palsy. Today not only do 4 out of 5 prematures survive but they do so with about the same low rate of neurologic damage as full-term babies. These dramatic successes can be attributed directly to fetal research and the consequent improvement in care of the fetus and newborn. Although these advances have lowered the mortality rate of the newborn infant the rate of illness and death in newborns is still high and further research is urgently needed.

In discussions of fetal research the ethical issues raised by this research are immediately mistakenly connected with emotionally charged issues relating to induced abortion or the use of fetal materials resulting from spontaneous abortion. The Association believes that a careful separation of issues concerning fetal research from issues concerning the ethical and moral concerns of abortion must be maintained. Several subsequent speakers will address themselves to fetal research during that part of pregnancy during which abortion can be a concern. We would like to address ourselves at this time to issues relating to fetal research in the later stages of pregnancy particularly in the third trimester. In this way we will provide a clear example of the need for continuing research on the fetal-maternal unit in order to promote the well-

being of the mother and child and to assure that every child has the healthiest possible beginning of life with the least possible risk.

Following are two examples of life-saving techniques developed by research which would have been impossible under the proposed regulations.

Past experience overwhelmingly demonstrates that it is essential to collect information on the normal mother and the normal fetus during pregnancy, particularly during the last trimester of pregnancy. Advances which have been made through fetal research have profoundly altered the care of the premature and full-term infant. Through the collection and study of amniotic fluid by amniocentesis, we can identify before birth the fetus with Rh incompatibility. This disease results when the fetus' blood cells are a different type than the mothers'. The fetal red cells stimulate Rh antibodies which will destroy the fetal cells and cause brain damage or death before or after birth. To detect this problem before birth a needle is directed into the amniotic sac and amniotic fluid is withdrawn. This method was developed and proven by research. Through the study of amniotic fluid from normal pregnancies we established normal values which permits us to identify the abnormal fetus. This knowledge of normal pregnancies has not only improved diagnosis of Rh disease but has also led to striking improvement in treatment. This research provided the first example in which the fetus could be

directly treated in utero by transfusion of blood into the fetus, a life-saving procedure since otherwise these babies would have been stillborn. Thus, many women who cannot safely bear children are able to do so as a direct result of fetal research.

Another example of research that shows great promise for reducing infant mortality involves the collection and study of amniotic fluid by amniocentesis to determine the ability of infants to breathe successfully after birth. There exist in amniotic fluid materials that indicate potential lung readiness for air breathing. The greatest cause of infant death, particularly in premature infants, is hyaline membrane disease. In the United States each year 40,000 babies are stricken and approximately 25,000 die. Four years ago it became possible to analyze amniotic fluid surrounding infants who may be born prematurely in order to determine whether the lungs are ready for air breathing. Furthermore, two years ago it became possible to treat infants whose lungs are not yet ready for birth by hormone injection of the mothers. The hormone injection assures that the fetal lung will develop this essential function.

All this saving of lives and prevention of disease was made possible by research which would be impossible under the proposed regulations governing research on pregnant women and the fetus. There are other examples that I could cite but these appear to be particularly important for two reasons: first, there are no animal models of Rh incompatibility or of hyaline membrane disease.

Second, these diseases do not occur in adults, and therefore it is impossible to study these diseases in adults. Only by human fetal research were these advances possible.

The Association of American Medical Colleges firmly supports the promulgation of regulations to protect the maternal and the fetal subjects of research. We believe the regulations currently proposed represent a firm foundation for the protection of human subjects in general and of maternal and fetal subjects in particular. These regulations have been widely discussed by conscientious and thoughtful persons in government and in the lay and biomedical community. The Association believes, however, that the regulations still require modification in several important areas. We respectfully direct the attention of the Commission to the appended comments of the American Federation of Clinical Research which the Association endorses in general. These comments are thought-provoking and have been carefully framed to allow productive and responsible research to continue on problems similar to those which have been described. It is doubtful whether any of us is farsighted enough to predict which diseases will similarly succomb to careful fetal research in mothers and fetuses in the distant future. This leads us to consider the means by which human endeavors are regulated. There is no doubt that this Commission will give its best attention to the protection of human subjects and will publish guidelines carefully drawn to meet the problems of 1975. How effective these guidelines will be ten years from now, none of us can predict. Medical science will undoubtedly advance and

opportunities now unforeseen will occur, therefore would it not be wise to establish a mechanism by which we can respond to these advances and opportunities? We believe the most responsive mechanism which might be relatively unresponsive to change but to create an Ethical Advisory Board. We strongly support the creation of such a Board. We would hope that the function of such a Board would not be only the review of grant applications involving human subjects. We suggest it would be better to require the Board to review only applications in which ethical questions have been raised by organizational or agency review, to hear appeals by investigators or subjects (or their representatives) and to continue to improve the guidelines for the safe, ethical and effective conduct of research. The Board should be required to publish its findings and opinions. The Association hopes you will recommend creation of such a Board with clear authority to supervise the ethical and moral issues of clinical research.

In concluding I would like to stress again the importance of studies in the normal mother and fetus. Most diseases of the newborn begin during fetal development. If we have not studied normal fetuses how can we know what is abnormal or pathological? Studies on the normal mother and fetus are, therefore, absolutely essential in assuring for each child the right to be well born. We consider this point so important that we strongly suggest that guidelines be drawn so that research will be permitted in normal pregnancies where the benefit to mothers and fetuses <u>as a class</u> out-weighs the risks. Research should <u>not</u> be limited to benefits

to the particular mother or fetus for the reasons given in the examples above.

The Association of American Medical Colleges hopes you will recommend clear guidelines which will permit necessary research leading to future successes in the fight against maternal and fetal death and disease. We will be pleased to assist you in any way possible in discharging your heavy responsibilities.

Reprinted from Clinical Research: vol. 23, no. 2, February, 1975.

Position Statement of the American Federation for Clinical Research on the DHEW Proposed Rules on Protection of Human Subjects*†

The American Federation for Clinical Research (AFCR) has forwarded position statements on previous DHEW proposed rules and policies for protection of human subjects. For reference, copies of the AFCR position statements dated November 6, 1973, (Appendix 1),[1] and December 27, 1973, (Appendix 2),[2] are attached. Among other things these statements will introduce the organization, its mechanism for developing position statements, and the underlying premises from which the present comments are derived.

Subpart C

46.304: We have reservations about the proposed Ethical Advisory Board (EAB) similar to those we expressed earlier (Appendix 2) on the proposal to establish Ethical Review Boards. We feel that the interests of all concerned will be best served if the EAB devotes most of its energies to the continuing development of policy. It is likely to prove to be a needless and expensive duplication of effort for it to review each proposed activity, particularly since this will have already been accomplished by the Organizational Review Committee (ORC) (previously designated Primary Review Committee). Other useful functions of the EAB might include review of procedures proposed by ORCs to see if they are adequate. Further, the EAB could serve as a court of appeals in cases in which irreconcilable differences of opinion develop between investigators and ORCs.

However, if it is determined not to change the present proposed policy—that is, if the EAB is charged with the responsibility of reviewing "all applications or proposals for support of activities"—we should like to offer one further suggestion for procedural modification: In the event the EAB raises a question about the ethics of a proposed activity—one which is sufficiently serious that the agency might consider it grounds for rejection of a proposal which would be approved on its scientific merits—contact should be made with the ORC of the institution from which the proposal originated. This communication between the agency and the ORC should be accomplished before final action is taken. The reasons for this suggestion are as follows:

Members of ORCs often find that ethical questions can be raised in the course of their consideration of the written descriptions of proposed activities. Most commonly, these ethical issues can be resolved through direct communication with the investigators. Some apparent problems are due to inadequate descriptions of the procedures the investigators actually intend to follow—but fail to describe—to safeguard the rights and welfare of the subjects. Other problems are due to either a failure on the part of an investigator to anticipate some of the risks inherent in his proposed activity or a lack of familiarity with some of the procedures available to safeguard the rights and welfare of the subjects. Following discussions between investigators and ORC members new understandings are often reached which permit investigators to develop acceptable proposals from what at first appeared unacceptable. For example, there may be improved technical measures for protection of confidentiality. There may be improvement in the wording of the consent form. In some cases there may even be a redesign of the proposed experimental method so as to provide a more favorable risk-benefit ratio.

We feel that similar modifications could be achieved through negotiations between the ORC and either the funding agency or its EAB.

Although EAB activity is not now required by law we are aware that those involved in review activities at DHEW are sensitive to ethical issues. We are further aware that some proposals which passed review by ORCs were subsequently rejected by DHEW on grounds that there was inadequate protection of the subjects. In some cases the grounds seem to be of the sort that could easily have been negotiated so as to make them acceptable to DHEW. Yet what happens in actual fact is that after a rather long delay the investigator re-

*Drafted by the AFCR Public Policy Committee and presented by Dr. Robert J. Levine to the Chief, Institutional Relations Branch, Division of Research Grants, National Institutes of Health, on November 12, 1974.

†Federal Register 39:No. 165, 30648-30657, August 23, 1974.

ceives word from DHEW that his proposal has been rejected on the basis of what was assumed to be an ethical impropriety. This, of course, is most discouraging to the investigator. There is also the possibility that such procedures will prove to be demoralizing to ORC members. If ORCs operate with the understanding that what they approve may be disapproved at a higher level and with the further understanding that what they disapprove will never even be reviewed at a federal level it seems reasonable to predict that they will become increasingly lax in their functions.

46.305: We are pleased with the conceptual development expressed on page 30650, section D, resulting in the shift from the previous proposal of Protection Committees to the present proposal for Consent Committees (CC). However, we continue to believe that the best way to understand the proper methods through which to design CCs and to understand their functions would be to establish on an experimental basis various sorts of CCs in a small number of institutions. Protocols could then be developed to get precise information on what the impact is of the existence of CCs of differing compositions and with differing responsibilities on the actual protection–as opposed to the documentation of apparent protection–of subjects.

Further, we continue to believe that it would be important to get information on the costs of these activities which would afford the possibility to develop cost-benefit assessments. It is quite clear that the operation of these committees will be expensive in terms of time and energy investment as well as financially. We do not challenge the necessity for meticulous protection of subjects–particularly subjects with limited capacities to consent as defined in these proposed rules; however, we think it would be unwise to make major investments in committees charged with this purpose, meeting separately with their own rules of procedure, etc, when, perhaps, some less cumbersome and less expensive mechanism might bring about the same benefit.

Thus, we request that the requirement for formally constructed consent committees be postponed until the above proposed research could be accomplished and evaluated.

Further questions raised in our previous position statement (Appendix 2) that remain to be answered include the following: How can we finance the activities of members of CCs who have no association with any organization or individual involved in either conducting or supporting the research activity? That is, if neither the research institution nor DHEW reimburses CC members for their efforts, who will? As soon as one agency or the other assumes this responsibility what sorts of conflicts of interest might develop?

Having stated our preference with regard to the development of CCs we understand that the final rule-making may still require their development as proposed. The following statements are addressed to how we feel CCs might best be developed and administered in the absence of the information we wish were available.

We propose that the statements of general assurance described under section 46.4 of Subtitle A of the CFR be required to state only that in the event an activity is proposed that is covered by Subparts C, D, or E, a CC will be developed meeting the specifications of the relevant subpart. That is to say, no organization will be required to have standing CCs just in case it wishes to propose an activity that would require one. Part of the basis for this request as well as the requests contained in subsequent paragraphs is that the CCs necessary to properly execute the functions for each of the subparts will differ substantially. For example, a CC charged with responsibilities under paragraph *46.305* is likely to include a pediatrician while the membership of a CC designed to meet the requirements of paragraph *46.405* is more likely to include a clinical pharmacologist.

We understand that the need for a CC as well as its composition and responsibilities will, for each proposed activity, be determined by the ORC. While this is not stated explicitly in *46.305 (a)*, it is suggested in *46.305 (c)*. The concept that the development of a CC is a local option residing with the ORC is further suggested on page 30650, paragraph D. In another context, another type of CC–that described in *46.506*–it states explicitly that the CC must be "...approved by the ORC and the Secretary)...."

We feel that in the case of each proposed activity the determination as to whether a CC will be required should be made by the ORC. The proposal forwarded to DHEW should contain a description in general terms of the composition of the CC; that is, it should state what sorts of individuals should be appointed to the committee. It should also define in specific terms their responsi-

bilities and which of the activities described under *46.305 (a)* and *(b)* will be expected of them. Appointment of specific individuals to membership on the CC should be postponed until word has been received that the proposed activity will be funded. This will, among other things, obviate the necessity for the existence of several CCs with precise rules of procedure, etc, which have nothing to do. It will also afford maximal possibility for valuable communication between DHEW and the ORC which should result in the development of CCs designed specifically to meet the needs of specific activities.

The purpose of the CC is, among other things, "...to oversee the actual process by which individual consents...are secured, to monitor the progress of the activity...," etc. Thus there is no need for the CC to exist until shortly before the actual activity is initiated, a sufficient amount of time to develop and understand its procedures before it must begin to implement them.

We wish to assure you that evidence exists of the awareness of investigators and ORCs of the need for special protections for subjects with limited capacities to consent. For example, we are aware of cases antedating these proposed rules in which investigators have suggested to ORCs the need for "third party" involvement in the consent process meeting many of the functions described in paragraph *46.305*. We are also aware of other cases in which ORCs have imposed on investigators the requirement for "third parties" having such functions. In some cases the requirement for such third parties has been imposed for activities involving subjects who in the view of the ORC have limited capacities to consent but who are neither children nor the types of individuals described in subparts C,D, or E. However, we are not aware of any precedent antedating these proposed rules where these "third parties" have been structured as committees conducting their business at convened meetings with one of the members designated as chairperson.

46.306: Several aspects of this section seem dangerously and unnecessarily restrictive. In some other cases some of the potential problems may be based upon semantics; that is, it is possible we do not understand the real intent of the proposal.

(a) It may be an oversight but the way this paragraph is now written it precludes all research in pregnant women which entails no conceivable risk to the fetus. For example, a strict interpretation of this paragraph would forbid all social research, drawing of small amounts of blood, collection of urine specimens and other trivial maneuvers and manipulations done with research intent.

(a)(1): The problem with this phrase may be a semantic one. All research must be based on the *a priori* assumption that you do not know in advance the outcome of the research. Therefore, it is impossible to conduct a research activity the purpose of which is "to benefit the particular fetus or to respond to the health needs of the mother." At best, one can perform a research intervention with the intent or wish to bring direct benefit to these individuals; obviously, the likelihood of achieving this intent or wish should be supported by appropriate past experience such as laboratory, preclinical, or clinical investigations.

For example, consider the possibility of administration to a pregnant woman of an antibiotic which had not previously been administered to pregnant women. In this case we shall assume that she has been shown to have an infection with an organism that is sensitive to that antibiotic but to no other agent approved for use in pregnant women. It might be appropriate to administer this antibiotic with the wish or intent to bring direct benefit to both the mother and the fetus. However, since this antibiotic had not previously been tested in pregnant women there could be no assurance that it would be effective and, further, no assurance that it would be safe for either the mother or the fetus. Various measurements might be performed during and after administration of the antibiotic and after the birth of the infant which would enlarge our knowledge of the safety and efficacy of this agent. In most cases before permitting such experimentation one would, of course, wish to have completed appropriate preclinical investigations including tests for teratogenicity and mutagenicity. Further, in most cases one would wish a prior demonstration of the safety and efficacy of this agent in persons who were not pregnant. Yet, in an emergency situation—a life-threatening infection in a pregnant woman—one might conceive of circumstances in which one might be willing to waive the requirements specified in the preceding two sentences.

(a)(2): There are two ways in which this statement is excessively restrictive without necessarily enhancing the protection of subjects. The first is

the requirement that the activity be "...conducted as part of (but not prior to the commencement of) a procedure to terminate the pregnancy...." The second is the remainder of the phrase which attempts to define all of the acceptable purposes for such research.

Addressing the second objection first: It is probably dangerous to attempt to anticipate in a regulation all of the purposes of research to be done in this class of subjects that we would be able to find acceptable. This wording, for example, would preclude the development of methods for treatment of diseases which are neither genetic nor congenital. It would further preclude studies designed to test whether drugs administered to the mother concentrate in the fetus or in any particular part of the human fetus. It may be possible to accomplish some of these types of research under the proposed rules as now worded. However, because this is unclear, we shall subsequently propose alternative wording which we believe will satisfy the intent of this phrase.

The issue mentioned as our first reservation about *(a)(2)* is a matter of great concern. This requirement for timing of the activity to be concurrent with the procedure to terminate the pregnancy is probably based on the concept contained on page 31742 of the earlier draft of these proposed rules: "This obligation, along with the right of every woman to change her decision regarding abortion, requires that no experimental procedures entailing risk to the fetus be undertaken in anticipation of abortion." We expressed our reservations on this point at length in our previous position statement (Appendix 2) and feel that we must do so again.

Many advances in our understanding of fetal physiology, pharmacology, diagnosis, and therapy, have come about because it was possible to initiate research in anticipation of an abortion. To cite one example, in order to develop the procedure of amniocentesis it was first necessary to show that it was effective in making diagnoses. Demonstration that this particular procedure was effective could be accomplished under the new proposal. However, demonstration of its safety could not. In order to demonstrate that it was safe it was necessary to perform amniocenteses prior to the commencement of procedures designed to terminate pregnancies—wait a day or two—and then conduct observations as to whether any damage had been done to the fetus or other intrauterine contents. This demonstration would have been impossible within the framework of the currently proposed rules. Similarly, the current development of fetoscopy requires for demonstration of its safety a delay between its performance on an experimental basis and the commencement of the procedure to terminate pregnancy. As mentioned earlier the currently proposed rules would terminate all research designed to explore the pharmacodynamics in the fetus of drugs administered to its mother. This, of course, would lead to a perpetuation of our ignorance of the safety of drugs in pregnant women. This ignorance, in turn, will tend to perpetuate the necessity for the FDA to require that the labelling of virtually all new drugs state: "The safe use of (this drug) in pregnancy has not been established" or other similar caveats.

Several other examples could be cited but we hope that we have made clear, in general, the sorts of information that society would be sacrificing under this proposal. It might be worth sacrificing the potential development of such information if it were possible through doing so to afford any meaningful additional protection to human subjects—in this case fetuses who are destined to become abortuses.

While we agree that every individual has the right to change his mind we are aware of no data indicating that women who agree to participate in research which is justified by the fact that they are anticipating abortions often change their minds. Further information should be obtained to determine how frequently this issue might actually be raised in the research environment. We must find out if there is a significant number of women who feel that they have been deprived of their options to refuse abortion because they have agreed to become subjects of studies which might have damaged the fetus.

Until such information is available it seems inappropriate to develop a rigid rule which might afford some additional protection to what we anticipate will prove to be a small class of individuals while depriving a much larger class of individuals of their rights and benefits. The small class of individuals who might be benefited by this rigid proscription would be the fetuses conceived by parents who are uncertain about their wishes for abortion even within days or hours of the time for which it is scheduled. It must be further em-

phasized that this scheduling invariably will have been accomplished because the parents (or in some cases the mother) have initiated contact with a physician for purposes of requesting the abortion. The larger class of individuals who will be deprived of their rights under this proposal would be those parents who are determined to proceed with the abortion procedures and who wish—for a variety of complex reasons—to contribute meaningfully to society through permitting research to be done in association with the abortion procedure. The even larger class of individuals that would be deprived of its benefits would be pregnant women and fetuses (and the infants that they will become) in general. Thus, it seems important at this point to develop some compromise procedure which will limit to the extent we can the risks to the small group while protecting the rights of the larger group. The compromise we suggest is as follows: During the consent negotiation it should be clearly stated to the pregnant woman (and, if appropriate, the father of the fetus which she is carrying) that consent to participation in a research activity which might damage the fetus is tantamount to initiating the procedure to terminate pregnancy at the time the research activity is begun. It should be made clear to them that agreement to participate in the research entails a sacrifice of the option to withdraw once the research activity has been commenced. We would further suggest that the parents be approached for consent to research only after agreements have been reached about the procedure to terminate the pregnancy which involve a specific scheduling of the procedure and a selection of the method to be employed. We further suggest that the consent should be discussed in detail with the parents and they should be allowed a sufficient period of time to consider all of their options before they are asked to formally give consent (*eg*, sign the consent form).

In this way we expect that the invitation to participate in a research project would be conducted under circumstances that are relatively devoid of coercive potential. This is particularly true in light of the other protections afforded by the proposed rules in subpart C. We further expect that under these circumstances those who are uncertain about whether to proceed with the abortion will be alerted to refuse to participate as subjects in order to hold their options open. We suspect that most of these women will proceed with the abortions in any event. However, we believe that in light of our current state of understanding of this issue, this provides a suitable compromise which not only will protect the legitimate interests of investigators and the public, but also will protect the interests of prospective research subjects; *viz*, parents (of the fetus) who, in most cases, will have made the decision to change the status of that fetus to that of abortus.

In summary, we propose that section *46.306 (a)* be revised as follows:

It should first make clear that no special protections are required in the case of proposed activities which present negligible risk to the fetus. Following this we suggest:

"No activity to which this subpart is applicable, involving known or potential risk to fetuses in utero may be undertaken unless: (1) the intent of the activity—based upon suitable laboratory, preclinical, or clinical experiments or experience which indicate a likelihood that the intent will be achieved—is to benefit the particular fetus or to respond to the health needs of the mother, or (2) the activity is conducted ~~in association with a procedure to terminate the pregnancy~~ * and designed to develop information that is expected to be of benefit to pregnant women or fetuses as a class.

46.306 (c): The issues we wish to raise in our discussion of this section are relatively minor. Our main concern here is that—given all the other special protections afforded by this subpart—these provisions may needlessly increase the numbers of individuals with whom the parents must interact.

(1) We suggest that it might be perfectly appropriate to have the investigator involved in decisions as to timing, method, or procedures if these decisions are made prior to the initiation of the consent discussion. Thus, at the start of the consent negotiation the physician—investigator might be able to say: Now that we have agreed to perform the procedure to terminate your pregnancy at 9:00 Wednesday morning I should like to invite you to participate in a research procedure. Your participation in this procedure is entirely voluntary. That is, if you prefer not to participate in the research procedure you will still have the procedure to terminate pregnancy performed exactly as we arranged previously. Also, if you choose not to participate your relationships with this institution and all of its personnel will in no

* The AAMC agrees with the AFCR position with the deletion shown. This modification will permit research to be conducted in situations in which no termination of pregnancy is anticipated. For further discussion see AAMC testimony.

way be adversely prejudiced. All of this, of course, would be presented in language that the prospective subject would understand.

The present wording of *(1)* would be appropriate under two circumstances. First, is the case in which the research itself is designed to explore new methods or procedures to terminate pregnancy. The second is the situation in which agreement to participate in the research would necessarily entail a change in the timing or location of the procedure designed to terminate the pregnancy.

(c)(2): The purpose of this phrase is unclear. First, it seems to imply that there are no objective criteria available through which one can make a determination as to whether or not the fetus is viable. If there are objective criteria it seems rather inconsequential as to who will apply them. Further, assuming that there are no objective criteria—that decisions could be made either way depending upon the judgment or biases of the decision maker—it is unclear whom this phrase is designed to protect. Is an investigator more likely to make a determination in a questionable case that a fetus is viable or non-viable? In what way are such decisions made by investigators likely to differ from those made by physicians who are not conducting research? Perhaps it would be more appropriate to require that in those cases in which viability (as defined in *46.303 (e)*), is questionable, consultation should be obtained with a physician who is not associated with the research.

46.307 (c) Our comments on this paragraph are the same as those for section *46.306 (c)*.

(d) (e): We have addressed these provisions (Appendix 2) in the previous draft of these proposed rules in detail. At this point we shall only briefly reiterate.

This proposal defines viability (*46.303 (e)*) and the abortus (*46.303 (f)*). Having taken great pains to define the abortus as something which is not alive it seems inappropriate to express concern with its rights. *46.307 (d) (e)* would interfere with the conduct of various types of important research while affording protection only to something that you have already defined as dead. We suggest that both of these paragraphs be removed.

The only conceivable purpose for these paragraphs might be based on the assumption that the abortus, though legally dead, is capable of experiencing sensation, presumably of discomfort, at a conscious level. Even if this is the motivation, these proposals seem inappropriate. Thus, proposal *(d)* would prohibit unnecessary prolongation of presumed unpleasant experiences while proposal *(e)* would achieve the opposite—it would forbid their termination.

Subpart D

46.401 (b) We assume that this general statement does not mean that requirements described under Subparts C and E designed specifically for protection of subjects described in those subparts are not what is intended. For example, we assume that the Ethical Advisory Board described in *46.304* with specific functions related to subpart C is not expected to review activities pertaining to prisoners. Similarly, the general statement in subpart E, *46.501 (c)* is not, as we understand it, meant to imply that the EAB will review activities involving the institutionalized mentally disabled.

46.404 (1): If this requirement is interpreted incorrectly or rigidly it may without intending to do so put an end to some important types of research. Considerable flexibility must be permitted the ORC to determine what constitutes undue inducement. For example, if an experiment requires repeated physical examinations this might be construed as offering the subjects of the proposed activity better medical care than that generally available to prisoners. Similarly, the quality of food is likely to differ materially if the experiment calls for a controlled diet.

46.404 (2) (ii): This statement may be more restrictive in its present wording than is intended. The specific problem is presented by the term "negligible risk." This might preclude, for example, the conduct of some sociologic studies because there might be the potential for violation of the confidentiality of the subjects. A variety of other types of research that one might agree are appropriate could be cited. Accordingly, we suggest that this be reworded as follows: "*(ii)* the activity is for the purpose of studying the effects of incarceration on such subjects and the potential risk is outweighed either by the potential benefits to prisoners as a group or by the importance (in the judgment of the ORC and CC) of the knowledge to be gained." This suggestion is made only in the context of understanding that each prisoner will be free to refuse to participate and that all of the other provisions proscribing undue coercion contained in this subpart will be applied.

46.405: In general, our comments on *46.305* apply here. However, we must acknowledge that, in general, formal third party scrutiny of the consent process is more necessary here than it is in either subparts C or E.

Subpart E

Our comments on *46.505 (2)* are the same as those made on *46.404 (a) (1)*.

Our comments on *46.506* are the same as those made on *46.305*.

Subpart F

46.603 (a): In this paragraph we are concerned with the mechanism of keeping records of the subject's consent. It is our wish that this requirement be restated to impose the requirements for keeping records of individual subject's consent on the specific investigator who proposes and conducts the activity. The ORC should be required only to keep records on the general procedures that the investigators intend to use. If the ORC is required to keep the consent forms signed by individual subjects it will become very much more difficult to preserve confidentiality. This problem is elaborated further in our comments on *46.603 (b)*.

46.603 (b): We endorse wholeheartedly the intent of this requirement to prevent excessive dissemination of information obtained through research which can be identified with a particular subject. However, we must express a serious concern that some of the requirements in these proposed rules may be detrimental to this objective.

In our efforts to maintain confidentiality we continually strive to see to it that the names of individuals involved in specific research projects are known to as few people as possible. The mere knowledge that an individual has agreed to participate in a specific project may imply something about him that he would wish not be generally known. For example, if a subject agrees to participate in a study designed to explore the pathogenesis of cirrhosis, knowledge that he has signed a consent form agreeing to participate in this will imply to one who obtains that knowledge that he has cirrhosis. This is why we request that the specific consent forms signed by individuals be kept by the investigators and not by other agents of the proposing institution.

Research institutions which are committed to protection of the confidentiality of research subjects are capable through various formal and informal mechanisms of having their employees and faculty members comply with procedures to protect confidentiality. Universities, for example, can develop policies designed to protect the confidentiality of information when appropriate. If a faculty member violates such policies considerable social sanctions can be brought to bear on him. If these fail even more coercive sanctions can be employed; *eg*, he may have his appointment at the university terminated. Thus, if a faculty member through membership on the ORC were to learn the names of specific subjects of a research activity he would not be likely to pass this information to others. However, now that there are requirements for membership on the ORC for individuals who are not employed by the university and for representatives of the community it becomes much more difficult to hold the university accountable for their actions. We do not see what social or other pressures the university could bring to bear on ORC members who are not employed by the university and who, in some cases, are deliberately selected so as not to share in the values and assumptions of the university community. For these reasons we request that the ORC not be charged with responsibility for retaining consent forms signed by individual research subjects. Rather, the signed consent forms should be obtained by the principal investigators and filed in a way that reduces to a minimum the possibility of violation of confidentiality. The ORC may be held responsible for keeping on file copies of the general consent forms that will be used.

The concerns expressed in the preceding paragraph become an even greater threat when one considers the functions and membership of the consent committees which might be established by these proposed rules. Under the current proposals—unless they are appropriately modified—there seems to be no way to avoid increasing the numbers of persons who will be aware of the names of individuals who are participating as subjects in specific research projects. Further, the individuals who will become aware of these names will, with increasing frequency, be those who are not employed by the university (or other sponsoring institution). The dangers inherent in these proposed rules to protection of confidentiality thus seem self-evident.

46.607: Both parts of this paragraph raise some

questions. *(a)* does not seem to be an exception in that *46.301* gives the same specifications.

(b): This raises the question as to why there should be a double standard. That is, why can each DHEW agency head adopt procedural modifications as may be appropriate from an administrative standpoint unless the same option is offered to institutions outside DHEW?

Thus, we suggest that in the interest of avoiding the impression that there is a double standard—that is, that research conducted within DHEW might be governed by different rules than that conducted outside DHEW—section *46.607* should be deleted.

We are pleased to have had this opportunity to respond to your invitation to comment on the proposed rules. If you wish any additional input from the AFCR, please contact either of the two following members of the Public Policy Committee:

ROBERT J. LEVINE, M.D., Editor, *Clinical Research*
ROBERT A. KREISBERG, M.D., President, AFCR.

References

1. Position statement of the AFCR on the proposed amendments to Subtitle A of the DHEW Regulations. Clin Res 22:52-54, 1974.
2. Position statement of the AFCR on the proposed policies and procedures for protection of human subjects. Clin Res 22:135-138, 1974.

DR. RYAN: The next speaker will be the Reproductive Freedom project of the ACLU, represented by Miss Judith Mears. Welcome. May I advise you that we want testimony with respect to the fetal research issue.

MS. MEARS: Dr. Ryan and Members of the Commission, my name is Judith Mears. I am the Director of the American Civil Liberties Union's Reproductive Freedom Project. I appreciate the opportunity to come before you today and you do have copies of my statement. I intend not to read the whole thing but read excerpts.

The Commission is charged with making

recommendations to the Secretary of the Department of Health, Education and Welfare on the issue of fetal research. Pending the completion of your report, and any action taken in response to it, there is in effect a moratorium on DHEW-funded research activities involving live fetuses. Strictly speaking, the moratorium extends only to research activities involving live fetuses before or after an induced abortion, but the medical community has, with an understandable abundance of caution, terminated all HEW-funded research on live fetuses.

This moratorium represents a judgment that the propriety -- whether legal, medical or ethical -- of the type of research activities involving live fetuses carried on in the past is so unclear and the prima facie claim of live fetuses to "protection" at least for the period while the issue is being debated is so strong that immediate action must be taken.

In the law we would liken it to the issuance of a preliminary injunction while the main issues in the lawsuit have yet to be tried. A preliminary injunction is not granted unless the court finds the threat of irreparable injury in the status quo and a substantial likelihood of future success on the merits. I suggest to you that these two factors have already been found by the authors of the moratorium, and that we, consequently, are forced to defend the status quo -- i.e.,

the traditional conduct of fetal research. I note also that there exists no comparable moratorium on research conducted on living prisoners or living metnally disabled persons, yet the reason for this disparate treatment is unclear.

I come before you as the Director of the American Civil Liberties Union's Reproductive Freedom Project. The Project has two general goals: to enforce compliance with the Supreme Court's decision on abortion, Roe v. Wade, 410 U.S. 113 and Doe v. Bolton, 410 U.S. 179, and to ensure that abortions and voluntary sterilizations are available to all who want them. I hope that this Commission and later, the Department of HEW, will not make any pronouncements about the "protectable" nature of the fetus or place any restrictions on fetal research which would have the effect of undermining the ruling in Doe and Roe that the pre-viable fetus is not a person whom the law may protect vis a vis the women's fundamental right to an abortion.

It is not the presence or absence of ongoing fetal research at a hospital or clinic which should determine whether -- or how many -- abortions will be performed there. To argue otherwise is to presume that the abortion patients are merely convenient fodder for the research objectives of the hospital staff. Section 46.306(c) of the proposed HEW regulations is directed at just that possibility by requiring that researchers have no control over the nature or timing of the abortion procedures performed upon patients whom they

hope to study. Indeed, we want to avoid placing medical personnel in positions where a conflict of interest between clinical objectives and research objectives is unavoidable. At the same time, however, we should try to facilitate research in situations where pregnant women have already decided to abort and would freely and willingly agree to give the researchers control over the timing and method of abortion.

It should be possible to discuss and resolve issues concerning fetal research without mentioning abortion at all, but for the fact that opponents of abortion have diligently and continuously linked the two together. It is hardly clear whether they believe that less fetal research will mean fewer abortions, or whether they believe that a government agency's acknowledgement of the "personhood" of the fetus implicit in any effort to exempt it from biomedical research will reap subsequent semantic and legal victories in the struggle to pass a constitutional amendment banning elective abortion.

The public dialogue concerning such an amendment has already been cast in terms of whether or not the fetus is a person and entitled as such to all the constitutional rights of other persons. The Supreme Court, of course, has already held that a pre-viable fetus is not a person within the meaning of the 14th amendment. The texts of three constitutional amendments introduced in the Senate last month

very clearly would bestow personhood upon the fetus.

On page 5 of my statement the text of those constitutional amendments are laid out. I will read just one to you. They are pretty much alike.

Senate Judiciary Resolution 6 reads:

> "With respect to the right to life guaranteed in this Constitution, every human being, subject to the jurisdiction of the United States, or of any State, shall be deemed, from the moment of fertilization, to be a person and entitled to the right to life."

And in response to amendments such as these have come warnings that fetal personhood, once bestowed, may have wide-ranging repercussions which our legal system is ill-equipped to assimilate. See, for example, the article by Harriet Pilpel attached to the end of this statement.

The inescapable truth is that whatever recommendations on fetal research this Commission makes will be the stuff from which political arguments about abortion will be fashioned. I urge, therefore, that you aim for specific guidelines whose restrictions, if any, are based upon the necessity to continue fetal research, to keep abortions safe and legal for the women who would seek them even if they were not, and, finally, to keep the legal concept of fetal "personhood" from eliminating both. Thank you.

DR. RYAN: Thank you, Miss Mears.

MR. LOUISELL: Do I understand your position correctly when I put it this way, Miss mears, that once a woman has determined upon an elective abortion, then the decision of the United States Supreme Court in the abortion cases prevents any protection of the fetus in respect of research, if it is a pre-viable fetus?

MS. MEARS: That question was unclear in my previous summary and is something we should make clear today. The Supreme Court decision only considered the rights of the mother and the pre-viable fetus in regard to abortion. The Supreme Court's decision says nothing about the woman's desire or interest in participating in any other medical procedures that might harm the fetus. So that I must concede to you that you have little guidance about the protection of the state as to the fetus in matters other than abortion.

MR. LOUISELL: But your position does deduce from those decisions the net conclusion that once the abortion decision had been decided upon by the mother, that there is no power in the state or any other agency to attempt to give any protections to the fetus?

MS. MEARS: In the abortion, yes.

DR. LOUISELL: Or in respect to experimentation?

MS. MEARS: The Supreme Court did not touch upon the issue of experimentation.

DR. LOUISELL: Your position is there should be no recognition of any right in the fetus in respect of experimentation once the mother has decided upon an elective abortion, regardless of what the Court's logical deductions may be in that regard. That is the position of the American Civil Liberties people?

MS. MEARS: I think the position of the ACLU is that any recognition that there are rights of a person attaching to a fetus in regard to biomedical research inevitably redounds upon the rights of the fetus in an abortion and undermines the Supreme Court's decision.

DR. LOUISELL: Do you think the position of the ACLU takes into account the potential reversal of the decision by the mother that although she has once decided upon an abortion, thereby removing all protection from experimentation that she might later change her decision?

MS. MEARS: It is quite clear, after she has undergone the abortion, leaving out the issue of fetal research, she may change her mind. The Supreme Court does not talk to that either. You can regulate the timeframe within which she can change her mind...

DR. TURTLE: Miss Mears, aren't you really trying to tell us not to attach some labels in order to reach the result that we might desire to reach? If those labels might affect other areas in which we are interested?

It is necessarily inevitable that if we afford some protection to the fetus, that will impact upon the range of the decision.

MS. MEARS: Certainly, the semantic factors are very important. And certainly I would agree with you, whatever you do is going to have some impact.

DR. TURTLE: Suppose we didn't attach, suppose we came up with a position which was not based upon labels of a person, but is based upon some other consideration, would that then present the problem for your organization?

MS. MEARS: It would present a problem in that it would still give a very strong argument to those who would ban elective abortions, but not as strong an arguing point as if the Commission had bestowed "personhood" upon the fetus.

DR. TURTLE: In your order of priorities, your greatest interest is in having us be aware of the fact that any labeling we may do in this area may reflect upon other areas?

MS. MEARS: Yes.

DR. TURTLE: And secondarily, you really have a position upon any of the legal or ethical things involved, beyond the question of the impact this may have upon the abortion?

MS. MEARS: I think the traditional ACLU concern

with consent freely and intelligently given is long-standing. Other people are going to address themselves to that.

DR. TURTLE: On the question of consent, and from that point of view, if there were to be such a thing as consent from a pre-viable fetus, a situation in which the mother had elected an abortion, would you presume that she ought to be able to give consent before any procedure be undertaken with regard to the fetus?

MS. MEARS: Only in terms of the mother's consent.

DR. TURTLE: For research to be carried out on her?

MS. MEARS: On her.

DR. TURTLE: You would not attach her consent to the fetus at any stage after she had elected to detach herself, is that correct?

MS. MEARS: It is difficult for me to understand exactly what you mean. I assume she has the power to consent to have medical procedures performed upon her, whether they impact upon the fetus or not.

DR. TURTLE: The situation I am thinking of is the situation in which she first decides she wants an abortion, and let's say, the results of an abortion then are available possibly for some further research. The question then becomes should we look to the mother in that instance

for consent to do the research?

MS. MEARS: Did you have anyone else in mind to look to?

DR. TURTLE: Do I? Personally? No.

MS. MEARS: I think, yes, she is the proper person to look to for consent.

DR. COOKE: Would you explain why, please?

MS. MEARS: Well, because I believe that there is no other person who has any property rights, so to speak, in that fetus. If you wanted to get down to the level of property rights. In the case of cadavers, the next of kin always has the right to give consent.

DR. COOKE: This pre-viable fetus still has a beating heart and some experiments are undertaken with life support measures, you consider her to be the appropriate person to give permission because she is acting in the best interests of the fetus? Or is it a piece of property? It is still alive.

MS. MEARS: There are state laws which require that all possible means of support be given to pre-viable fetuses that are aborted alive. Certainly, in that case her consent is irrelevant, if the state requires that the measures be taken for that fetus, for that premature infant at that time.

DR. COOKE: In the absence of such state

regulations what should be done?

MS. MEARS: If there is a pre-viable live aborted fetus and the question is whether or not she may consent to have that fetus used for research which may go on?

DR. COOKE: Yes.

MS. MEARS: I consider that if there is a medical judgment that that fetus has no chance for meaningful existence, even with all the tools of medical science, yes, she should have that power.

DR. RYAN: Excuse me. Doctor Lebacqz.

DR. LEBACQZ: In a sense I want to press the question Dr. Turtle is raising.

On page 4 of your statement you say it should be possible to discuss and resolve issues concerning fetal research without mentioning abortion at all, but for the fact that opponents of abortion have diligently and continuously linked the two together. I am getting the sense here it is not only opponents of abortion that link the two, but also the proponents, or, more accurately, the proponents of a woman's elective right to have an abortion, in that I don't feel you are making a statement about a position on fetal research per se, but once again as Dr. Turtle suggests, really raising a question of concern about the impact on abortion decisions of any statement made on fetal research.

Is that accurate?

MS. MEARS: Yes, I think so. You are all aware of the fact there was extensive fetal research way before there was elective abortion. And before there was elective abortion, the subject of a fetal research as a public issue about which there was debate hardly surfaced. It has been since this that the concern over fetal research has really grown tremendously. In that sense any statement is a response to the drawing together of those two subjects.

DR. LEBACQZ: So how are we to interpret the statement "it should be possible to discuss and resolve these issues without mentioning abortion at all"?

MS. MEARS: It should be possible to resolve the question of fetal research, within the permissible limits, the parameters of state regulation to it, without discussion of abortion because there had been and there will be fetal research even without easily accessible free, cheap abortion. I am saying since it has been staged to you that the two are linked, I am saying to you, yes, you must unlink them in this regard.

DR. RYAN: I am sorry that our time is up.

DR. JONSEN: Could I ask one question about the ACLU's position about experimentation in general? Would it draw any distinction between experimentation on children as compared to adults? Are there any considerations requiring

more reservation about human experimentation on children than there are in connection with adults?

MS. MEARS: It would be unfair for me to tell you there is a statement about that, becuase I don't believe we have reached and considered that narrow issue.

DR. RYAN: Thank you.

I am sorry to such a tough taskmaster, but we do have an agenda. Many people have travelled. We want to have them all heard.

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Ms. Mears' prepared statement follows:

This Commission is charged with making recommendations to the Secretary of the Department of Health, Education and Welfare on the issue of fetal research. Pending the completion of your report, and any action taken in response to it, there is in effect a moratorium on DHEW-funded research activities involving live fetuses. (Strictly speaking, the moratorium extends only to research activities involving live fetuses before or after an induced abortion, but the medical community has, with an understandable abundance of caution, terminated all HEW-funded research on live fetuses.[1])

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[1] This moratorium represents a judgment that the propriety (whether legal, medical or ethical) of the type of research activities involving live fetuses carried on in the past is so unclear and the prima facie claim of live fetuses to "protection" at least for the period while the issue is being debated is so strong that immediate action must be taken. In the law we would liken it to the issuance of a preliminary injunction while the main issues in the lawsuit have yet to be tried. A preliminary injunction is not granted unless the court finds the threat of irreparable injury in the status quo and a substantial likelihood of future success on the merits. I suggest to you that these two factors have already been found by the authors of the moratorium, and that we, consequently, are forced to defend the status quo--i.e., the traditional conduct of fetal research. I note also that there exists no comparable moratorium on research conducted on living prisoners or living mentally disabled persons, yet the reason for this disparate treatment is unclear.

. Research carried out only on fetal tissue has not been affected by this moratorium, even though such research accounts for a much greater proportion of all the activities supported by grants from the National Institutes of Health. The Commission must be aware, however, that there are individuals and groups who advocate a total ban on all fetal research, regardless of whether the tissue is live or dead at the time it is studied. I need hardly remind you that there is a long medical tradition in this country of working with and learning from cadavers of all ages. And to my knowledge, there has never been responsible opinion that such medical usage nurtures a disrespect for the sanctity of human life. At least as polemic an argument can be made that the medical advances made possible by cadaver research help advance human life against disease and sickness. Since any disagreement that remains on the particular question of whether a dead body should remain inviolate from the ravages of science is largely between the medical and religious professions, I will leave that debate and instead append a statement from the American Academy of Pediatrics which has implications for research carried out both on live fetuses and fetal tissue. It is a list of some of the new methods of diagnosis and treatment made possible only through fetal research. I urge you to give it your most careful attention, because it represents the best achievements of the status quo (see footnote 1).

I leave the medical aspects of the issue to those who are more qualified to debate them, and instead turn to some of the

legal questions. I come before you as the Director of the American Civil Liberties Union's Reproductive Freedom Project. The Project has two general goals: to enforce compliance with the Supreme Court's decision(s) on abortion, Roe v. Wade, 410 U.S. 113 and Doe v. Bolton, 410 U.S. 179, and to ensure that abortions and voluntary sterilizations are available to all who want them. I hope that this Commission and later, the Department of HEW, will not make any pronouncements about the "protectable" nature of the fetus or place any restrictions on fetal research which would have the effect of undermining the ruling in Doe and Roe that the pre-viable fetus is not a person whom the law may protect vis a vis the woman's fundamental right to an abortion.

It is not the presence or absence of ongoing fetal research at a hospital or clinic which should determine whether (or how many) abortions will be performed there. To argue otherwise is to presume that the abortion patients are merely convenient fodder for the research objectives of the hospital staff. Section 46.306(c) of the proposed HEW regulations is directed at just that possibility by requiring that researchers have no control over the nature or timing of the abortion procedures performed upon patients whom they hope to study. Indeed, we want to avoid placing medical personnel in positions where a conflict of interest between clinical objectives and research objectives is unavoidable. At the same time, however, we should try to facilitate research when pregnant women who have decided to abort and who would freely and willingly agree to give the

researchers control over the timing and method of abortion.[2]

It should be possible to discuss and resolve issues concerning fetal research without mentioning abortion at all, but for the fact that opponents of abortion have diligently and continuously linked the two together. It is hardly clear whether they believe that less fetal research will mean fewer abortions, or whether they believe that a government agency's acknowledgement of the "personhood" of the fetus implicit in any effort to exempt it from biomedical research will reap subsequent semantic and legal victories in the struggle to pass a constitutional amendment banning elective abortion.

The public dialogue concerning such an amendment has already been cast in terms of whether or not the fetus is a person and entitled as such to all the constitutional rights of other persons. The Supreme Court, of course, has already held that a pre-viable fetus is not a person within the meaning of the 14th amendment. The texts of three constitutional amendments introduced in the

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[2]On this point I would like to retreat somewhat from that section of my Summary to this Commission, in which I labelled clearly unconstitutional any law or policy which restricts a woman's desired access to medical procedures (other than abortion) whose impact upon the fetus is less certain but which may either result in, precede, succeed, or occur simultaneously with, an abortion. Roe and Doe certainly held that a woman could not be denied an abortion by a state trying to protect her fetus' potential for life. Her right to privacy outbalanced, if you like, its right to life. It does not inexorably follow, however, that any medical procedure the woman might wish to undergo or participate in (especially when the procedure is not as important to her life and future as an abortion is) always similarly outbalances the fetus' interests. This question is one the Supreme Court was not called upon to decide and did not decide. And on this narrow issue, therefore, Roe and Doe provide little guidance to the Members of this Commission.

Senate last month very clearly would bestow personhood upon the fetus, viz:

> Section 1. With respect to the right to life guaranteed in this Constitution, every human being, subject to the jurisdiction of the United States, or of any State, shall be deemed, from the moment of fertilization, to be a person and entitled to the right to life.
>
> S.J. Res. 6

> Section 1. With respect to the right to life, the word "person" as used in this article and in the fifth and fourteenth articles of amendment to the Constitution of the United States, applies to all human beings, including their unborn offspring at every stage of their biological development, irrespective of age, health, function or condition of dependency.
>
> S.J. Res. 10

> Section 1. With respect to the right to life, the word 'person,' as used in this article and in the fifth and fourteenth articles of amendment to the Constitution of the United States, applies to all human beings, irrespective of age, health, function, or condition of dependency, including their unborn offspring at every stage of their biological development.
>
> S.J. Res. 11.

And in response to amendments such as these have come warnings that fetal personhood, once bestowed, may have wide-ranging repercussions which our legal system is ill-equipped to assimilate. (See, for example, the article by Harriet Pilpel attached at the end of this statement.)

The inescapable truth is that whatever recommendations on fetal research this Commission makes will be the stuff from which political arguments about abortion will be fashioned. I urge you, therefore, to aim for specific guidelines whose

restrictions, if any, are based upon the necessity to continue fetal research, to keep abortions safe and legal for the women who would seek them even if they were not, and, finally, to keep the legal concept of fetal "personhood" from eliminating both.

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DR. RYAN: The next speaker is Doctor David G. Nathan, from Harvard Medical School.

I know you have a very thick testimony. We would be happy to accept this in that form. Please address yourself to fetal research and perhaps summarize your statement.

DR. NATHAN: I intend to do that, Mr. Chairman. I will simply use the document before you as a guide as I summarize.

I would like to state that I would like to discuss only a very narrow part of the problem of fetal research.

DR. RYAN: Mr. Louisell, the names and so on of all the witnesses will be on page 2 of your black book.

Is everyone in order now?

Okay. Doctor Nathan, please.

DR. NATHAN: I intend to discuss with the Commission, as I mentioned, a very narrow area of fetal research, and that is the diagnosis of the major inherited disorders, Cooley's anemia, Sickle Cell Anemia, this kind of research, I think illustrates the present problem we have in developing guidelines. In the interest of time I am not going to go through the first several pages of this document, which describes these two major abnormalities. I would like you to accept they are serious disorders that create in most cases a lifetime of quite severe disability.

In any pregnancy there is a 25 percent chance of producing a so=called homozygotes infant with Sickle Cell or Cooley's Anemia, and 75 percent of having the child be healthy. They will be carriers, however. Since the carrier state is innocuous, it is rather sad that affected couples often choose to prevent or abort all pregnancies rather than accept 25 percent risk of a severely ill child.

The goal of antenatal diagnosis is to salvage those three fetuses that would otherwise be aborted. I am sure you have heard or will hear a great deal about how amniocentesis has in fact provided that kind of decrease of abortion, rather than increase. Unfortunately, amniocentesis is not effective for hemoglobin disorders. Hemoglobin system is not currently expressible in fetal skin cells, so, the individual such as myself interested in the problems of

developing a system for the diagnosis of these disorders faces four research requirements.

First, we must prove that the normal physiology of hemoglobin is expressible in the first half of pregnancy. Secondly, we must prove that the diseases themselves are detectable in the first half of pregnancy. Thirdly, we must develop methods by which we may sample the fetal red cell, since that is the only cell which might possibly express the disorders. Finally, we must deal with the technique.

I would like to go through with you briefly how we have gone at that problem. First, by examining a large number of blood samples of fetuses that were delivered at hysterotomy for various reasons, it was possible to determine that in fact the hemoglobin -- by the say, I am citing a lot of work done in a number of excellent laboratories around the world. Secondly, it was possibly a sample of a large number of human pregnancies terminated to define the presence of these diseases in these cells.

The next problem was the sampling itself. How to safely deliver a red cell to the diagnostician. And here there were two approaches. First, one could try to use a suggestion made by Dr. Frederic Frigoletto. During amniocentesis the placenta is invaded by the needle. Would it be possible that this sample needle could be done deliberately with a production of a small number of red

cells. Indeed, Frigoletto's suggestion proved to be correct. In 50 percent of such attempts, using almost the same technology as possible, to collect such cells it was possible. However, that yield is low. Fifty percent is not very satisfactory. And other workers, particularly Dr. John Hobins at Yale, have been developing an amnioscope, a fetus scope, on which a needle is attached and by which a sample of red cells can be directly taken after divisualization of a fetal vein on the surface of the placenta.

Now, it was vital this work be done, obviously, prior to a planned abortion. Although, some screening work could be done to develop such techniques, the simian pregnancy has two problems. First, it doesn't have any of the human diseases. Second, In the ordinary simian system, a third trimester pregnancy is the only one large enough to cope with such instrumentation. And as has been shown, the third trimester simian pregnancy is remarkably resistant to any invasive procedure.

We were faced with the following quandary: how will we develop an instrument which would have the capability of sampling from a placenta a vein and be certain it is acutely safe, that it doesn't immediately damage the pregnancy. So, here we are in the area you have been discussing all morning, research prior to planned abortion.

We felt the most important single issue was not

to force the woman at risk to bear the entire risk of the procedure. We feel that it was reasonable and ethical to ask a woman at the moment of planned abortion to accept the amnioscope, to allow us to try to sample a placental vein, and then to inject whatever materials might go through into the pregnancy for the abortion. This would allow us to know whether the instrument was one, efficacious and gave a sample; and two, controllable within the woman's womb, and does not immediately disrupt the pregnancy.

I might say with some of the success of this work there have been worldwide five such diagnoses performed. Three have been successful and accurage diagnoses were made. One such baby has been delivered and is normal. Two more are about to be delivered. In these five cases none were aborted. All of these women came for abortions, none of them were, and we are proving the point with this kind of technology, we will reduce rather than enhance abortion.

But how about the ethical problems you are discussing? I want to point out as I conclude, that in Massachusetts we have been struggling with this problem: how can we put together all of the mingled feelings in this room in some sort of a coherent structure? We have not got an answer to that yet, but I think most of us agree with a couple of principles: it is necessary to push forward diagnostic and therapeutic research beyond question.

I frankly feel it is also very important to push forward all kinds of fetal research that will help the fetus in the long run. But the timing of the research, to me, is becoming increasingly important. The change of mind problem I have become persuaded is critical. Therefore, we must design studies such that they can be started and completed at the time -- at the moment of interruption. That if we do an invasive procedure of a drug, say, several drugs, before a planned abortion in order to test it, and we love to do that, but we would love to know it is really safe for several days, we are getting into a serious problem. Because we are really saying to the woman that if she changes her mind, we have potentially damaged her fetus. I think that is what you have to work with.

The other areas I really think have become somewhat in a sense woman's personal reaction to the problems. But this is usually I think something that should be resolved, and that is where I think we are going in Massachusetts with this, although I don't want to present myself as any kind of a philosopher and certainly not a lawyer.

I think we are getting there, to that point. I would like to stop there.

DR. RYAN: Dr. Jonsen.

DR. JONSEN: A clarification. You said that the

first trials of the fetascope were done on women who came intending abortion and none of those abortions were carried out. Do you mean that they came intending an abortion because of the possibility that the child they were carrying was affected by one of these disorders and you determined they were not?

DR. NATHAN: Well, I brought a slide of it, but I can explain it. These women came with the fear they were carrying another -- they had homozygotes deliveries before, had lost children. They didn't want another such disaster. We used both techniques. We used placenta antenatal first, and it worked in two cases. The others did not. In one of the cases in whom this failed we went to the amnioscope and got a successful sample. In three there have been good samples, but I don't want to push this because only one baby has been delivered. That was done in San Francisco. The baby was normal. Now, we have done two, one in London and one in Boston. One is normal and one has the trait, but we are waiting nervously.

DR. JONSEN: This was done as intended therapy, they were not done on normals?

DR. NATHAN: But let me make clear all of the development of getting there was done on normals. Just to see if it works at all. I want to make it clear we cannot, in my opinion, go to an indexed woman and say, "We have got

a brand new method here that hasn't been tried. We don't know if it is safe, but you take the risk." I don't think that is right.

DR. ALEXANDER: Doctor Nathan, your work represents the frontier that this Commission is really primarily interested in. Could you describe for our benefit some of the review procedures for approval of your project it went through?

DR. NATHAN: They are rather rigid at the Boston Hospital for Women and the Children's Hospital where this work is going on. We have rather tough, and I think, well organized hospital review committees. And that work, all of the plans of this work, were submitted to that committee, to both committees for both hospitals, and separately approved. The Harvard regulations were approved by the Harvard Committee. So these go through three committees.

As I understand it, the applications which have supported this through NIH were subjected to very intensive review inside NIH, even though the machinery wasn't set up at the time.

So I think it has been very carefully looked at. I must say it has been scrutinized by the entire Commonwealth of Massachusetts. I think it has had enough inquiry. We tried to be very careful about that.

DR. ALEXANDER: What about consent from the

patient?

DR. NATHAN: We hold in this work that it is very important, that the mother can give informed consent to this procedure. And she was -- there are risks to the mother. We would exclude Rh incompatibility from this work. A mother set up for Rh stimulation should not have this work done. We have to explain all those possibilities, and we do. It is an elaborate consent form, in what I would call English.

We then rely on her consent for this, because we think that is perfectly reasonable to accept her consent. But what we are concerned about more and more is timing, to be certain that we do not inhibit her capacity to change her mind.

DR. COOKE: I am obviously very sympathetic to this kind of approach, since a substantial amount of the early work was done at my department in my institution. There are a few questions I think would be useful for public clarification.

One, you made the statement that the early work, a substantial part of the fetal material was obtained by hysterotomy. Would you clarify as to whether those hysterotomies were done because of research or because of medical indications?

DR. NATHAN: We had nothing to do with the

hysterotomies at all. I would certainly subscribe to that, absolutely.

DR. COOKE: The other question is a much more difficult one. Could you try to make some guesses as to whether you could visualize any of this work being done except for the last kind of final therapeutic approaches that might be done if there was much more extensive opportunity for research in animals, many different species we don't work with because of limitations in dollars and so forth? That is an issue we have to address ourselves to in this Commission.

DR. NATHAN: First of all, I would like to recognize that there is no question that the first -- not the first work, but certainly the best work that started off the whole business -- was the work in Baltimore. And the question of animals I have given a lot of thought to.

This is my own view on it. Perhaps others don't share it. I think that the animal can be used to train the hands of an investigator to get used to equipment. That is, I have made it sound as though this can be done easily. The problem is it is not immediately applicable in those parts of the world where these disorders are tremendously common. Worldwide, they are menaces. We don't think about them in this country because they are relatively rare, fortunately.

This technology is very difficult to do because of the problems involved. I think you could, perhaps, get a

doctor to at least know what the instrument looks like at hysterectomy or in the uterus of a small monkey But to go from that point and say it is safe because an operator has examined sheep, cows and even gorillas, would be incorrect. If I were a hospital research committee, I would never accept that evidence. I know that animal and human pregnancies are totally different. I would want to see that instrument go through several planned abortions to be certain there is not acute damage. Then I would be very concerned about it, because you don't know the long-term risks of putting a scope in and bleeding a placenta. We are not going to know that. I believe it is fair for the indexed case to bear that risk.

I think we will collect enough information about long-term risk by asking the women to bear the risks. I don't think they should bear the short-term risk because this is a new technology. It should not be tried on a woman who would save her pregnancy.

MR. LOUISELL: In your research following these hyterectomies, was there any concern at all about the procurement of the consent of anybody?

DR. NATHAN: No. Well, I can't answer that.

I am not the obstetrician. I receive red cells. I am certain there must be women who don't want any research done on them. If you are referring to the patient's studied, there was no problem. Prior to planned

abortion, there must be plenty of women who don't want research done, and many that do.

DR. RYAN: Thank you very much.

* * * * *

Dr. Nathan's prepared statement follows:

1. Introduction

This presentation to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research concerns antenatal diagnosis of the human hemoglobinopathies, a very narrow area of fetal research. However, the investigation itself, its purpose and the technology necessary for success of the research does impact very broadly on the general problem of fetal research now under so much discussion in this country.

As a witness before the Commission, I come with few credentials in fetal research as a broad discipline. I am a pediatric hematologist and oncologist most of whose research has been in the area of inherited diseases of the red cell with particular reference to the inherited hemolytic anemias; those associated with abnormalities of red cell enzymes and the red cell membrane and those due to mutations of the hemoglobin molecule.

The hemoglobin mutants have dominated much of my investigative career in pediatric hematology, and I have been particularly involved in research in Cooley's anemia and sickle cell anemia. My work has led me to the inescapable conclusion that prevention is a very practical and worthwhile contribution that we can make to parents who carry the genes for the important mutant hemoglobins. This is particularly true for the Cooley's

anemia or thalassemia genes for which specific therapy is presently lacking and for which future specific therapy seems to be very distant.

In this presentation, I shall briefly review the characteristics and frequency of Cooley's anemia and sickle cell anemia. I shall also discuss the genetic rationale for and the present status of antenatal diagnosis for these conditions. I will describe future needs for refinement and extension of this technology and will touch upon an entirely new technology which may render present approaches quite obsolete. Finally, I would like to show how we in Massachusetts have attempted to deal with the problem of antenatal diagnosis of the hemoglobinopathies with reference to the Massachusetts fetal research law. In the latter discussion, it will be necessary for me to present my own ethical view of the research in which I am involved. However, in no way do I wish to present myself as an ethicist or philosopher of any consequence. Hopefully, all of us who do research think about the ethical consequences of our acts. Fortunately we are also aided by hospital research committees that think for us if we are about to allow ethical lapses. Finally, we have NIH review committees as yet another ethical safety check. In the end, however, each of us must live with the consequences of our acts. I hope to be able to point out to the Commission why I am at peace with myself in this delicate area, while at the same time acknowledging that I am more than willing to meet any reasonable individual's ethics halfway if he or she will meet me openly and honestly.

2. Cooley's Anemia (Thalassemia) and Sickle Cell Anemia

A. Cooley's Anemia

The term Cooley's Anemia or beta thalassemia refers to a mutation of hemoglobin synthesis in man in which one half of the hemoglobin molecule, the beta chain, is produced at a very slow rate if at all. The hemoglobin molecule is comprised of two alpha chains and two beta chains. Each individual

inherits at least one alpha gene from each parent and one beta gene from each parent. Thus each normal individual has at least two alpha genes and two beta genes. Mutations of the alpha genes do occur but the consequences of such mutation are either fatal in utero or relatively mild. They are not therefore appropriate subjects for inquiry in the area of antenatal diagnosis. Cooley's anemia is due to homozygous reduction of the output of the beta genes. It results from the inheritance of an abnormal beta gene from both parents, a gene incapable of producing beta globin for the hemoglobin molecule. Individuals who are affected only by a single abnormal beta gene have Cooley's trait or beta thalassemia trait, an innocuous illness characterized by very mild changes in the red cell and associated with a perfectly normal lifespan. It is only in the homozygous state when both genes are involved that the disorder is extremely severe. The consequences of homozygous beta thalassemia include failure to produce a normal amount of hemoglobin in the cell. Hence the cell is referred to as a hypochromic red cell lacking hemoglobin. This would not be quite so serious a lesion were it not for the fact that alpha chains are produced normally by the intact alpha genes in beta thalassemia. The alpha hemoglobin chains accumulate in the cell, are unmatched with beta chains and precipitate like rocks in the red cell. This leads to rapid destruction of the red cell within the bone marrow where the red cell is produced as well as in the spleen and liver and throughout the body. The result of this double disability of the cell is a massive attempt by the marrow to make new cells to replace those that are rapidly lost. The bone marrow, liver and spleen expands greatly to attempt to fulfill this requirement for red cells, but it is all ineffective or in vain. In fact, the expansion of marrow, liver and spleen with what amounts to a proliferating mass of useless red cells acts almost like a tumor expanding the hollow marrow of the bones to the fracture point causing interference with liver function and interference with

intestinal function by a huge spleen. Tragically the children with this disorder appear perfectly normal at birth, but three or four months later become pale and listless. They then must embark on a lifetime of blood transfusions in order to supply them with sufficient red cells. Unfortunately, however, the iron in red cells transfused to an individual cannot be eliminated from the body; the iron accumulation is highly toxic and currently there are no highly useful agents available which will rid the body of this excessive iron. The iron accumulates in the vital organs, particularly the heart, and causes severe cardiac damage. Death usually occurs in the second or early in the third decade of life. In less well developed countries than the United States, the age of death is considerably earlier. The afflicted children cannot be far from medical care.' They require red cell transfusions every three to six weeks. They fail to grow, their faces are abnormal due to bony overgrowth, their social adjustments can be very difficult and, the pressures on their parents overwhelming.

B. Sickle Cell Anemia.

Sickle cell anemia has been so highly publicized in recent years that an extensive description of the disorder is probably unnecessary here. This disease is also due to an abnormality of the beta chain, but instead of a beta chain that is underproduced, the sickle mutation leads to a normal amount of an abnormal beta chain. As is probably known to members of the Commission, the problem with the sickle mutation is that hemoglobin that contains the beta S chain rather than the normal beta chain transmogrifies to a sickle shape when it is deoxygenated. The sickled shape of the hemoglobin changes the form of the red cells which contain it into a sickle shaped cell and the sickled cell blocks the small blood vessels throughout the body. These patients are therefore subjected to obstructed blood flow or crises in multiple organs, particularly in bones, but also in liver, spleen, lungs,

skin, brain, etc. As a result of these multiple blockades of blood vessels, the organs gradually fail and after a lifetime that is punctuated by numerous painful and destructive episodes the patients succumb usually in the fourth decade. Some patients with sickle cell anemia are, however, quite mildly affected and may live relatively long and productive lives. On the other hand, most are closely tied to medical facilities, have extremely difficult social adjustments and unhappy personal relationships, because of their dependency and frequent disabilities. Again it must be emphasized that the heterozygous state for the sickle cell gene, meaning the situation in which only one beta S gene is present, is almost entirely innocuous and compatible with a completely normal lifespan.

C. Genetics.

The above description suggests that a couple, each of whom is affected by either Cooley's trait or sickle trait, have a 75% chance of producing a perfectly healthy child. Admittedly two thirds of such healthy children will be carriers of either Cooley's trait or sickle trait, but the carrier state as emphasized above is almost completely innocuous. 25% of the children of such a marriage will be so called homozygotes, meaning that both beta genes are affected. The purpose of antenatal diagnosis is to detect unambiguously the homozygous state in the first half of pregnancy. The frequency of Cooley's anemia and sickle cell anemia in the United States is not well determined, but both disorders are relatively rare compared to the major public health hazards such as lung disease, heart disease, cancer and accidents. As is undoubtedly known to the Commission, sickle cell anemia is observed almost entirely in Blacks though it is known in other races as well. We estimate that there are perhaps 60,000 Black Americans with sickle cell anemia. The incidence of sickle trait is approximately 8% in the American Black population, hence, 1 in 400 births among the

Black American population would produce an infant with sickle cell anemia. This relatively low incidence is to be contrasted with the massive incidence of the sickle trait gene in a country such as Nigeria. There the gene incidence is closer to 30%. At the Lagos Island Hospital in Nigeria there are approximately 36,000 births a year; 45 new patients with sickle cell anemia per month are born at that hospital, a staggering burden on an already encumbered medical and social system, but more important an immense problem for the patient and his or her family. Similarly Cooley's anemia ranks with sickle cell anemia as one of the major scourges on a worldwide basis, though the disease, observed mainly in Greeks and Italians is uncommon in the United States. Worldwide, both illnesses rank with malaria, schistosomiasis and tuberculosis as extraordinarily common and serious diseases. The Cooley's anemia gene is seen throughout the Mediterranean world, in Africa and in the Far East as well, whereas the sickle gene is concentrated largely in Africa. Apparently both genes are present in high frequency in those parts of the world because the mutations must have conferred some sort of immunity to lethal cerebral malaria. Thus we see an enormous concentration of the gene wherever malaria was rampant in the Old World.

In any case though antenatal diagnosis of both of these disorders would be most desirable to many parents in the United States, the great need for this technology is in parts of the world that are less developed medically. This is unfortunate because as you will see the technology involved in such antenatal diagnosis requires extremely sophisticated medical care.

3. The Current State of Antenatal Diagnosis of Sickle Cell Anemia and Cooley's Anemia

There are four major requirements for successful antenatal diagnosis of

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footnote: For reference material supporting the above review, please see Nathan, D.G. and Oski, F.A. Hematology of Infancy and Childhood. Saunders, 1974. Chapters 14 and 15.

the beta chain hemoglobinopathies. (a) The normal beta chain must be produced in the first half of pregnancy. (b) It must be possible to sample the fetal red cell in the first half of pregnancy without damage to the pregnancy. (c) The diseases themselves must be expressed in the first half of pregnancy. (d) The technology by which the presence of the diseases are detected must be adapted to extraordinarily small samples.

a. Gene expression of normal beta chains during early fetal life

My colleagues and I have previously published a review of the evidence that has recently been acquired which proves conclusively that the beta chain of normal human hemoglobin is in fact produced very early in fetal life. Several workers in this country and abroad have confirmed that fact and I shall therefore not belabor it further in this report.*

b. Sampling of fetal red cells in human and simian systems

Although many inherited disorders which cause severe disability and even mental retardation may be diagnosed by means of simple amniocentesis, disorders of hemoglobin cannot. Amniocentesis is a process by which the amniotic fluid is merely aspirated through a needle of small diameter and the fetal skin cells present in the amniotic fluid examined chemically for the presence of certain key enzymes. Tay-Sachs disease, an illness of lipid metabolism which leads to severe mental retardation and death can be diagnosed by this approach. Many other inherited diseases can also be diagnosed in fetal life in this fashion. But the hemoglobin genes are not ordinarily expressed in the fetal skin cell. Hence it is vital to obtain a small sample of fetal red cells in order to determine the nature of the production of the fetal cell hemoglobin chains. Two approaches have been used to sample fetal cells and

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*Many of the approaches described in the remainder of this review may be found in detail in Alter et al., Clinics in Haematology, Vol. 3, No. 2, D.J. Weatherall, Ed., W.B. Saunders Co., Ltd., London, pp. 509-526, 1974.

both involve aspiration of the placenta where the fetal and maternal circulations mix. By means of ultrasound it is possible to localize the placenta with great accuracy. Using a needle of the size used in amniocentesis, Dr. Fredric Frigoletto of the Boston Hospital for Women suggested that it is possible for the operator to guide the needle directly into the placenta and then aspirate a very small volume. In approximately 50% of the cases or somewhat less, it is possible to aspirate sufficient fetal cells to determine fetal cell beta chain synthesis. This is probably an extremely safe maneuver because amniocentesis itself is often associated with transfixion of the placenta by the aspirating needle. There is little evidence that placement of a small needle of #20-22 caliber would be likely to damage a pregnancy. The yield is, however, a problem. As I mentioned, only 50% of the samples are productive of sufficient fetal cells. To improve the yield a second approach has been employed in recent years. This involves the use of direct visualization of the placenta, so-called amnioscopy or fetoscopy. A needle of approximately #14 caliber is inserted into the amniotic space. The obturator or plug of this needle is removed and a tiny optical device equipped with lenses and a light source is inserted through the needle. The needle is also equipped with a shield through which an extremely small second needle may be passed. The widest diameter of the total piece of equipment is 1.7 mm. The operator can now visualize the placenta directly and then find a fetal vein on its surface. He can then advance the small needle within the shield and aspirate fetal cells directly from the placental vein. In our experience, working with Dr. John Hobbins at Yale, this has been a highly productive procedure. But the needle is larger and the degree of safety is unknown. Obstetricians differ on the question of safety of such an instrument. Unfortunately at this time such an instrument is quite limited in its capacity to deliver a sample because it is not possible to use the present stiff and rigid instrumentation to acquire a sample from an anterior placenta. This is

because the placenta would be transfixed on the way into the amniotic cavity and the operator could not visualize it. It is therefore highly desirable to develop a flexible amnioscope equipped with a needle so that the placenta can be identified and a fetal vein sampled irrespective of placental localization. We believe that it is mandatory to develop such new instrumentation in human pregnancies prior to planned abortions for the following reasons. First, the simian pregnancy, though somewhat useful for developing obstetrical skills, is in no way appropriate for the determination of efficacy or safety of such instrumentation. A late third trimester simian pregnancy has fetal cells which contain hemoglobin chains similar to those in man and is large enough to permit the introduction of such instruments and the sampling of placental veins. However, as Jackson and his colleagues have shown the third trimester simian uterus both during anesthesia and beyond is remarkably resistant to trauma. The sorts of experiments accomplished by Jackson* in the simian system involving exteriorization of the fetus without precipitating delivery could never be accomplished in the first or midtrimester human pregnancy which would certainly be expelled as a consequence of such maneuvers. Certainly the late simian pregnancy together with the rare human pregnant hysterectomy can and should be used by the obstetrician to develop a certain degree of familiarity with instrumentation. However, it would be irresponsible to recommend such a procedure for a circumstance in which retention of a healthy fetus is desired by the mother unless the instrumentation itself was first shown to be effective and not immediately destructive of human pregnancy. Thus fetoscopy at the time of planned abortion is certainly the only way to develop the instrumentation. Fortunately such determinations can be made at the very moment of planned abortions since the only difference between amnioscopy and placental

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*Novy, M.J., Piasecki, G.J., Hill, J.D. and Jackson, B.T.: J. Appl. Physiology 31:788, 1971.

blood sampling and the insertion of either saline or prostaglandin for an abortion is (1) the use of a somewhat larger needle and (2) a somewhat longer period of time for the procedure. Since preparations for the use of the amnioscope do not require any preoperative maneuvers other than ultrasonics, the procedure cannot impede a change of mind concerning the abortion by the mother until the very moment of the abortion procedure itself. This type of fetal investigation does not in any way contribute to a climate which might increase abortion or to the acceptability of an abortion within an institution.

c. Expression of the abnormalities of the beta chains of hemoglobin in first and midtrimester: The biological basis of an ethical rationale

Having decided to develop this technology in human pregnancy prior to planned abortion, we and others have unequivocally demonstrated the detectability of the sickle and Cooley's anemia genes in the first trimester. This discovery would have been manifestly impossible if the simian system had been investigated. Kazazian and his coworkers in Baltimore and our group in Boston have detected the sickle gene in the blood of fetuses that had been removed at hysterotomy for various reasons submitted to us for analysis by our special biochemical techniques. I shall not burden the Commission with the biochemical methodology.

It has taken a major enterprise to determine whether the beta thalassemia gene is so expressed. After all the beta chain of human hemoglobin is produced at a very low rate normally in the first and midtrimester human fetus. Can the further reduction in beta-thalassemia be recognized? Recent studies carried out by our group in Boston in collaboration with Dr. Bernadette Modell and Ernest Huehns of the University College Hospital in London provided an answer to this question. The vacuum extraction abortions of Cypriot women who have a very high incidence of the thalassemia gene were studied, and indeed the thalassemia gene is expressed in these samples both in its heterozygous (trait)

and homozygous (Cooley's anemia) state. These results will be published shortly. The important point is that we were able to distinguish, albeit in a small number of fetal samples, the difference between normal, thalassemia trait and homozygous thalassemia or Cooley's anemia. This is, of course, the crucial issue. After all mothers who have sickle or Cooley's anemia trait and are married to men with these traits have one question in mind when they are pregnant. Do they carry a homozygous infant? If they do, they often wish to abort the pregnancy, but if the fetus is normal or merely has the trait, they most assuredly do not wish to abort the pregnancy. We must refine our techniques so that we can give an unequivocal answer that distinguishes between a trait condition and the homozygous state. The ethical rationale for our work in many ways rests upon this technical capacity. This is because such women are now in many cases aborting all of their pregnancies rather than take the risk of a homozygous birth. Yet when they do so, they are aborting perfectly healthy fetuses three times out of four. Obviously effective antenatal diagnosis, which unambiguously identifies the homozygotes would salvage three out of four such pregnancies. Hence, the antenatal diagnostician would in fact be salvaging three pregnancies for every one for which interruption might be recommended and accepted. On the other hand, if the trait for either condition is confused with the homozygous state, only one pregnancy would be salvaged and three aborted. Hence, no matter where one stands on the issue of abortion, technique and its development is intertwined with the ethical issues.

d. Small sample size

Very small fetal cell samples are produced by placentocentesis or by needle amnioscopy and these are often contaminated by maternal cells. We are currently working on methods by which we can concentrate fetal cells from such mixtures using a human fetal cell specific antigen - the so-called i antigen and an antibody which agglutinates these cells - the anti-i antibody. A new

laser-activated cell sorter may be extremely useful in this regard

4. Clinical Experience

With the discovery that both the sickle gene and the Cooley's anemia gene could be diagnosed in the first to midtrimester and with the availability of relatively safe albeit somewhat crude instrumentation for fetal blood sampling, five antenatal diagnoses for the hemoglobinopathies have been attempted. The first was in Boston in a woman with sickle trait who had previously lost a young child with sickle cell anemia. An aspiration of the placenta was attempted, but a very poor sample of fetal red cells was acquired. The study was unreliable, but did not show unequivocal evidence of sickle cell anemia in the fetus. The mother elected to continue the pregnancy and a normal baby was born. The second study was performed in San Francisco. The mother had previously borne a child with homozygous Cooley's anemia and was again pregnant. She wished to abort the pregnancy, but was persuaded to undergo an antenatal test instead. The test indicated that the fetus was normal. The pregnancy went to term, the baby was just born and indeed was normal. The third study was performed in Boston. The mother had previously borne two children with homozygous Cooley's anemia. Several attempts to aspirate red cells from the placenta were unusccessful. The mother finally underwent amnioscopy and a small sample of fetal cells was obtained. We determined that the fetus is normal; the pregnancy is going to term, and delivery is planned for the end of March. A Cypriot mother in London had previously delivered a baby with Cooley's anemia. Aspiration of the placenta on two occasions failed to produce fetal cells. She has decided not to abort. A second Cypriot mother in London was also studied. This time sampling was successful and revealed fetal thalassemia trait. The mother has elected to carry the pregnancy to term. Though these represent an extremely small number of cases, they are important to us. First, we have salvaged five pregnancies that would have otherwise been aborted. Secondly, we

have not injured the pregnancies with our technology even though we know the technology needs improvement. Third, we believe we have successfully diagnosed thalassemia trait prenatally in a pregnancy which was to be retained; and fourth, we believe that our original hypothesis that it would be possible to provide such a service to parents is going to be realized. We admit that we have years of work to do to develop this technique in a much simpler fashion and we also know that we do not really know the long-range safety. Far more experience is required; we need better amnioscopes and improved technology for sampling and detection of the hemoglobin chains in the cells, but we have made much more progress than we had dared to hope when we began a scant three years ago. I should add that all of this technology may become obsolete in a few years. In our laboratory and here in the National Institutes of Health, intensive efforts are being made to learn how to awaken the hemoglobin genes in the fetal skin cell so that one day we can return to amniocentesis for these procedures, abandoning amnioscopes and their cumbersome and complex methodologies. This would open up antenatal diagnosis to underdeveloped nations where busy obstetricians might not be able to find the time to master the techniques that we are developing here. In no way do I wish to state here that such work has been accomplished or is even on the horizon, but it is coming and a great deal of priority should be given to it. For once it is pleasurable to discuss one's own obsolescence.

Finally, I believe that it is my duty to inform this Commission as to how we have tried to resolve the data that I have given you as well as many other issues concerning abortion and fetal research in Massachusetts. As some of you may have read, we have been under a great deal of political and medical stress from these subjects in the past year. The same concerns which have led to the development of this Commission have been felt intensively in the Commonwealth

of Massachusetts. In fact last year a bill which would have outlawed all fetal research was nearly passed in the Massachusetts Legislature. Fortunately, some of us involved in the hemoglobin work and in other fetal research as well were able to communicate with the proponents of such a bill and to analyze the areas that divided us. Though as medical scientists we tend to consider ourselves the sole repositories of brilliance in this area, the authors of the Massachusetts bill are also rather able citizens. One is a leading physician in a fine hospital in the Boston area. Another is a professor of law in one of our excellent law schools and the author of a manual for judicial procedures in the Commonwealth of Massachusetts. A third is a very promising young Representative to the Massachusetts Legislature. As a result of the urging of another fine Representative, the editor of the New England Journal of Medicine, and the good offices of the Speaker of the House, we were all brought together to start a series of discussions which have certainly not ended. We are thoroughly exploring our different feelings on this subject. In fact we have a Commission of our own.

It is impossible to discuss fetal research without examining one's attitudes about abortion. Unless there is planned abortion, there is no fetal research of the type that I have described here. There is a wide spectrum of opinion about abortion among those who favor fetal investigation. Some of us believe that abortion before viability is a totally acceptable procedure, not only legally, but morally and ethically. Others have definite reservations about the casual use of abortion as a form of birth control. On the other hand, those who would stringently regulate fetal research, though in general opposed to abortion, have varying beliefs regarding the rights of women to determine the condition of the fetus that they bear and to control or influence the number of children with severe inherited disease that they produce. All of us, I think, share a common concern about the climate surrounding abortion

in an institution, and the possible role of research in that climate. We hold that abortion if performed at all should be an entirely private matter. Any process which subtly coerces a mother to abort her pregnancy is to be avoided. A research program which directly or indirectly coerces a woman to have an abortion by instituting a procedure which would make a planned abortion irreversible well before the abortion is performed should not be accepted. For example, an invasive research procedure with a drug, vaccine or instrument which potentially contaminates or otherwise damages the fetus or placenta performed several days prior to planned abortion should not be permitted no matter how valuable the research might be. For if the mother were to change her mind about the abortion, the procedure would have endangered her fetus. Hence, as we attempt to compromise our differences about fetal research (and compromise we must), we seem to be heading toward a solution in which certain kinds of research may be carried out at the very moment of abortion but not before. Others take the additional position that the gestational age of the fetus is extremely important with respect to research. I have less concern about precise fetal age as a guideline though certainly viability would usually be a contraindication.

At the moment the various proponents of positions have found a way to communicate. We are holding new hearings, attempting to gather more points of view and will I believe write a very enlightened law about fetal research in Massachusetts. We hope it will be a law that will stand as a model for this country and that this Commission will be very interested in its status. For if we in Massachusetts, which at least superficially would appear to have a very polarized community, can find a way to deal with this problem, then perhaps the federal government and even this Commission can learn from our experience. In no way do I wish to indicate that this has been an easy problem to resolve. It has not been easy and furthermore it is not yet resolved. But I think most of us in Massachusetts agree that diagnostic technology must go

forward in human pregnancy. It will hopefully be followed by therapeutic technology. Furthermore, most of us agree that such diagnostic or therapeutic technology should best be developed at the time of a planned interruption of pregnancy, rather than be tested for the first time in a pregnancy which would be retained if the test or therapy were to be successful. This is just common sense, and I believe that research committees in almost any institution would virtually demand that the investigator provide strong evidence that his so-called diagnostic procedure is itself at least acutely safe in pregnancy before it is applied in what we might call an index case, a case in which the woman would retain a pregnancy should the fetus be shown to be normal.

This then is a brief summary of the biological, technical and ethical considerations which have confronted us during this past three years of development. We have come a long way in a relatively short period of time, but far more investigation is required before this technology will become available to the couples who need it. I hope that this Commission will endorse our efforts.

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DR. RYAN: Out next speaker, Mrs. Audrey McMahon, private citizen.

MRS. McMAHON: I speak as an unlettered housewife. As the mother of two developmentally disabled children, I may represent more citizens than commonly appreciated.

In considering our own ethical obligations to posterity, please let us take a clue from a survivor from the prehistoric ages -- the tortoise; he moves carefully, but in order to proceed at all, he must stick his neck out.

In Britain the Advisory Group on the Use of Fetuses and Fetal Material for Research reported that the contribution to the health and welfare of the entire population is of such importance that the development of research using fetuses should continue subject to safeguards and controls. I consider their recommendations, as reported in Lancet, altogether sensible. The contributions they regard as so significant are well known to the public, but better defined in this context by the professionals present here.

I think it is a conservative estimate to state that 20 percent of all our children suffer from some form of developmental disabilities; etiology unknown. Special education for pupils who cannot process information

according to expectancy cost this country 300,000,000 Federal dollars in 1974. This does not include the cost of anguish evolving from these misfits in society.

The phenomenal growth of Parent Power -- volunteer organizations -- is an indicator of public concern. Prevention of developmental disabilities is a matter of prime importance. the annual convention of the Association for Children with Learning Disabilities alone draws up to 6,000 people.

In our own family neurological and perceptual deficits appear from generation to generation; etiology unknown -- genetic counselling impossible, yet. We care that future citizens shall not be denied their own civil liberty and their birth right to be born as wholly functioning human beings through reactionary rulings for which this Commission would be responsible.

The Director of the National Institute for Neurological Diseases and Stroke predicted on January 17, 1975 that this would be the decade of the Central Nervous System. Eccles regards brain research as the ultimate problem confronting man. Reports relating to the vulnerable stages of the fetal brain; Valk's five-year study with new scanning methods defining demonstrable damage in 80 percent of the Strauss syndrome children are only two from hundreds of examples why research must continue.

We need not force anyone disinclined to participate in the face of calculated risks, but just as Armstrong was not denied the privilege of that first risky step on to the moon, future brave parents, possibly my own daughter among them, and dedicated responsible researchers should not be shackled by law from pioneering on behalf of their own children and posterity.

Thank you so much.

DR. RYAN: Dr. Lebacqz.

DR. LEBACQZ: Just one question. You indicated that the abortus should be treated under codes applicable to autopsy. Did you mean by that to include living abortuses? Abortuses with signs of life, as well as those that are obviously dead? I am not clear whether the Code of Autopsy were meant to apply to abortuses across the board.

MRS. McMAHON: I am not a scientist and will leave that question of viability to you. I think the British Code mentioned 20 weeks, but I am not an expert in the field.

DR. RYAN: Are there other questions from the staff or Commission Members?

If not, thank you, Mrs. McMahon.

We will go to our next witness, Society for Pediatric Research and American Pediatric Society, Inc., represented by Dr. Robert Greenberg.

Dr. Greenberg.

DR. GREENBERG: I am Robert Greenberg, Professor and Chairman, Department of Pediatrics, Charles R. Drew Post-graduate Medical School and Pediatrician-in-Chief, Martin Luther King, Jr. General Hospital, Los Angeles. In addition, I am President of the Society for Pediatric Research and a member of the American Pediatric Society, and am representing the membership of both societies in this presentation of views regarding research on the fetus. These two societies are professional organizations of educators and investigators, whose primary goals and functions are to promote optimal child health through effective and incisive education and research. Both societies are committed to full utilization of their collective and individual skills to further the potential of the developing fetus and child to achieve normal growth and development.

I would like initially to briefly take a look at the health status of the fetus. From my point of view and from that of the societies, this is one of the major areas of concern. If we look at the health status of the fetus, and we do it on the basis of comparing what happens to conceptions, some very interesting data has been derived by a variety of individual.

Let's take, then, one hundred conceptions and ask the question what happens to them according to current

information. Approximately twelve of one hundred or twelve percent by current statistics, perhaps it is more now, will end unsuccessfully, if you will, through induced abortion. Twice that number will end through spontaneous abortion. It is indeed true that of spontaneous abortions, perhaps fifty percent of demonstrable abnormalities or chromosomal abnormalities indicate marked abnormalities of the fetus itself. It is true that fifty percent do not, indicating that perhaps fifty percent may well be preventable.

To continue, two percent or two and a half percent of conceptions will die currently during the last half of gestation. Of those a considerable percentage may well be preventable. And further, over one percent of conceptions succumb either natally or during the first year of life.

Thus, approximately four hundred out of very one thousand conceptions end in death by one year of postnatal age, and if you remove induced abortions, that leaves two hundred seventy out of one thousand.

The latest figures regarding infant mortality indicate in our country in 1973, 17.6 infants out of 1,000 live births succumb. If you want to make any comparisons between infant mortality and fetal mortality rate, it is obvious the fetal losses are a staggering proportion.

Infant mortality is an end result of a variety

of associated factors, both medical and social. Of principal importance is the recognition of the impact of retardation of fetal growth. The infant mortality rate in low birth weight infants is seventeen times that of normal birth weight infants. Further, more than 70 percent of the neonatal deaths due to asphyxia occur in low birth weight infants. It has been estimated, thus, that over half of the infant deaths in our country are associated with low birth weight. Clearly, increased understanding of factors that lead to premature delivery and that regulate intrauterine growth is mandatory if improvement in the infant mortality rate is to occur.

The United States is recurrently and justifiably criticized for its relatively high infant mortality rate. Improvement in this rate cannot occur, it seems evident, without continued research on those factors that influence and determine fetal development.

Impact of previous research.

Significant advances have been made in improving the status of fetal health. The horrible effect of rubella on the fetus has been largely eliminated. The deleterious effects of Rh incompatibility on late fetal development have also largely been negated. The impact of respiratory distress syndrome on neonatal mortality is appreciable; however, studies of the past few years and those in progress promise

to result in striking improvements in the prevention of neonatal respiratory distress. All of these advances required investigative efforts involving the human fetus. None of the advances that have occurred could have happened in the absence of fetal research.

The problem of deleterious effects on subsequent development.

The spectrum of human disease resulting from aberrant events occurring during fetal and perinatal life is still far from being delineated. The pervasive effects of retarded intrauterine growth were previously alluded to. The disastrous effects of perinatal viral infections are becoming increasingly apparent. It has been shown, for example, that elevations of a particular class of immunoglobulins, IgM, in cord blood may serve as an indicator of fetal infection. Approximately three percent of children at birth have elevated IgM levels. In approximately 20 percent of these children, infection with known agents can be documented, leaving 80 percent unexplained. The potential deleterious impact of asymptomatic infections is suggested by a recent study in which inapparent congenital syto-megalovirus infection was associated with significant impairment in hearing and probably redution in intelligence. Other studies suggest the deleterious impact of clinically inapparent viral infections on brain development.

The incidence of fetal infection remains undetermined. On the basis of available data, clinically important mental and auditory impairment may occur in one out of every 1000 live births as a result of fetal infection with one agent alone -- i.e., cytomegalovirus infections. It is clear that the total spectrum of fetal infection is a much larger and more significant one than previously recognized. The capacity for the fetus to withstand infection is clearly different and less effective than during subsequent developmental periods. There needs to be much attention urgently paid to developmental periods. There needs to be much attention urgently paid to answering the many questions that exist concerning the incidence and nature of infectious processes that affect the mother and fetus.

Effect of Socioeconomic factors.

In the previous discussion the deleterious impacts of retarded fetal growth and intrauterine infection on subsequent development of the child have been emphasized. The incidence of low birth weight infants is marketly increased in the low-income and minority population. Further, the risk of recognized intrauterine infection is also appreciably increased in lower socioeconomic groups.

Thus, the fetus of the mother who lives in a socioeconomically deprived environment is at increased jeopardy, for not only succumbing at an increased rate

during infancy, but also for experiencing persisten deleterious effects on central nervous system function as a consequence of adverse intrauterine events.

Unanswered questions regarding fetal development.

On the basis of these and other data characterizing health problems currently existent during fetal life and early infancy, it is possible to define, in general, the nature of biologic questions which must be solved by research if improvement in the health status of the fetus and infant is to be achieved. Such questions include, but are not restricted to, the following:

Delineation of factors regulating intrauterine growth, including placental transport of nutrients.

Defining the mechanisms whereby socioeconomic deprivation impedes optimal fetal growth.

Definition of mechanisms productive of congenital malformations.

Elucidation of the significance of intrauterine infections on both intra and extra-uterine growth and development, and defining means of both identifying and treating such infections.

Developing methods of protecting the fetus from the consequences of maternal disease.

Utilization of advanced techniques for the diagnosis of fetal abnormalities, and development of

methods of medical and surgical therapy.

These areas of requisite research mandate certain investigative approaches which necessitate preservation of the right of the mother to provide informed consent. We have indicated that the current health status of the fetus is shocking, in terms of both mortality and morbidity rates. The long-range effects of aberrations in fetal development may extract a huge toll of human suffering. Improvements in the health status require continuation of responsible, incisive research.

We urge the Commission to consider the fact that genuine concern for the fetus requires marked improvements in health care available to the developing human during intrauterine life. Such improvements in health care, both preventive and therapeutic in nature, require acquisition of increased understanding through research.

Thank you.

DR. RYAN: Any questions from the Staff?

Do the Commission members have any questions?

DR. JONSEN: Dr. Greenberg, could you tell us what sort of interventions in the fetus would be of use for the clarification of the nature of interuteral viral infections?

DR. GREENBERG: In thinking through that question, the issue that Dr. Cooke raised formerly, I think,

is quite clear. It becomes quite evident, for example, that significant advances in detection of infection may require sampling of fetal blood. We are then perhaps in a similar situation where we were ten years ago. Namely, we were looking for sampling of amniotic fluid at that time, with the same fears and concerns. It may be now necessary to sample fetal blood. Fetal blood is different because there is no question that that is a component of the fetus.

I would submit to you that is quite a great likelihood, that it will require a sampling of fetal blood in order to significantly advance detection and treatment of infection. Perhaps that is a significant example.

DR. JONSEN: This might possibly involve procedures which would have to be used some time before an induced or planned abortion. If one were attempting to do studies in immunization, one might want to intervene some time before the time of an abortion.

DR. GREENBERG: The issue I am referring to has nothing to do with abortion.

DR. JONSEN: Would it not be valuable to attempt to do studies of this sort before elective abortion?

DR. GREENBERG: I think the issues that Dr. Nathan raised are germane. The problems of development of technology previously discussed. I would agree with everything he said. Extending that, the application of that has

nothing to do with abortion.

DR. JONSEN: I am thinking here of the change of mind problem, again, that Dr. Nathan mentioned.

DR. GREENBERG: I think you are talking about the development of the methodology for fetal flood sampling, correct?

DR. JONSEN: That is one possibility.

DR. GREENBERG: If we extend your question, then, to the index case, if you will, that individual who would be suspected or asked to bear long-range implications, would be an individual who would be designated by further research as being likely to have an infected fetus. By criteria, that has been approved.

DR. RYAN: Dr. Cooke.

DR. COOKE: Bob, I will not dispute the fact that there might be some circumstances with regard to fetal infection where fetal blood sampling might be necessary. But that certainly would be unusual at the present time in our knowledge of viral infections or other infections, since the mother's blood seems to be a far better indicator or, at lease, some specific response to viruses or other infections.

If one were to set up a program of detection of fetal infection, it would be possible, it seems to me, to do this by maternal screening, at least with our present state of the art.

DR. GREENBERG: That is not the interpretation of my reading of the more recent studies with respect to herbies.

DR. COOKE: Those are the toughest ones.

DR. GREENBERG: But they are the more common.

DR. COOKE: Let's assume that that is a possibility. Would you make some comments as to the order of magnitude of increase, and what one would call comparative obstetrics? It puts us in a position where much more work would be done on the animal than on the human. What order of magnitude are we talking about to have such an expansion?

DR. GREENBERG: As I understand, and I feel reasonably comfortable about this, when you speak of the use of primate methodology, technologically in terms of the development of techniques capable of fetal blood sampling, then, I think everyone in this room would be in complete support. When it comes to the issue of, for example, the infectious agents that invade the fetus, the primate simply is completely different. We would enter a study of the infectious diseases of the primate, but that would have nothing to do with the infectious diseases of the human. The infectious agents are completely different. That raises an unstoppable problem. The human fetus remains the only viable substrain in order to investigate those illnesses that invade the human fetus.

MR. LOUISELL: In your concluding statement, as I understand it, you said that genuine concern for the fetus requires a continuation of many of these types of research. You were there using the, the word "fetus" in a general sense. That is, improvement of the condition of an on-coming fetus. You were not attempting to direct that remark specifically to the necessity of research in regard to a particular fetus?

DR. GREENBERG: I have. Actually, in preparing this testimony, I was myself impressed with the "health data" that currently is available about the human fetus. I think they are shocking. I think, also, the data that begins to suggest the incidence of relatively minor illnesses that have deleterious subsequent impact is of very critical importance. Therefore, I can't answer your question directly because I think in an increasing number of incidences, as our capacity for recognizing and diagnosing fetal growth is increased, it will be directed to reatment, diagnosis, et cetera.

MR. LOUISELL: But the interest or the rights of a particular fetus under the logic that you conclude with may have to be subordinated to the general interest of fetal research much, much, more than you would be willing to subject the particular interests or rights of a given born individual to research?

DR. GREENBERG: No, I don't believe that is true.

I believe when the Commission, for example, responds to the issue as it will, of research in minors, the same issues will be extant and the same position would be appropriate. That that research needs to conform to the type of safeguards, concerns, guidelines, procedures that have been developed and will be continued to be implemented regarding the safeguards for human research. I don't believe there is any difference.

DR. COOKE: I don't think I framed my question properly, I guess.

At the present time we can learn relevantly little about viral infections in a human from the study of animals. I think we could have said four years ago we might learn very little about the trizome from the study of animals. Now we know there are animals in which it exists.

What I am saying is, I think, maybe it is a rhetorical question, if we had much greater support for animal research, could we not have a very substantial part of research that has been done in the past, at least, on humans performed in animals? I am not saying all.

Would you want to comment on that?

DR. GREENBERG: I would answer it in this way: I think that if there were support, facilities, and the capacity for much more effective primate research, then I think it would be safe to say that part of the procedure

should be the development as far as is possible of research questions in primate models. My own feeling is no matter how well developed funding is, accessibility, the primate models will in no way lead to much resolution of those questions that I posed in the latter part of the testimony. Thas it my own feeling.

DR. RYAN: Do any other Commission members or Staff have questions?

* * * * *

Dr. Greenberg's prepared statement follows:

Introduction: Members of the National Commission, my name is Robert Greenberg, M.D. I am Professor and Chairman, Department of Pediatrics, Charles R. Drew Postgraduate Medical School and Pediatrician-in-Chief, Martin Luther King, Jr. General Hospital, Los Angeles. In addition, I am President of the Society for Pediatric Research and a member of the American Pediatric Society, and am representing the membership of both societies in this presentation of views regarding research on the fetus. These two societies are professional organizations of educators and investigators, whose primary goals and functions are to promote optimal child health through effective and incisive education and research. Both societies are committed to full utilization of their collective and individual skills to further the potential of the developing fetus and child to achieve normal growth and development.

Summary:

1) Appraisal of current statistics regarding the health status of the fetus indicates extremely high fetal mortality and morbidity rates, when compared to post-natal data.

2) A significant percentage of fetal and perinatal deaths are preventable.

3) There is increasing evidence suggesting that processes occurring during fetal life (i.e. intrauterine infection, retarded fetal growth) may have a deleterious impact on post-natal growth and development.

4) In the poverty-stricken and minority populations, the incidence of adverse fetal development is further increased, as is the presumed incidence of aberrant post-natal development caused by intrauterine events.

5) The above considerations indicate that a number of biologic questions must be solved if improvement in the health status of the fetus is to be achieved. Such questions include, but are not restricted to the following:

- Delineation of factors regulating intrauterine growth, including placental transport of nutrients .
- Definition of mechanisms productive of congenital malformations.
- Elucidation of the significance of intrauterine infections on both intra- and extra-uterine growth and development, and defining means of both identifying and treating such infections.
- Developing methods of protecting the fetus from the consequences of maternal disease.
- Utilization of advanced techniques to diagnosis and treat fetal abnormalities.

6) In order to solve these basic questions, it is necessary for research in the fetus to continue and the right of the mother to provide informed consent for investigation must be preserved. We are in complete agreement with and fully support all efforts to protect the rights and interests of the mother

and her fetus. Full protection of the fetus, however, mandates that further research be carried out in order that optimal intrauterine and post-natal development can be achieved for each individual.

Position Statement in Greater Detail:

The membership of the Society for Pediatric Research and American Pediatric Society are deeply concerned about and supportive of the safeguards that must continue to be implemented and developed in order to protect the fetus and mother. It is our firm opinion, however, that full protection of the fetus and mother requires comprehension of those factors that lead to the high rates of morbidity and mortality that characterize fetal life. Prevention of the untoward effects on subsequent development produced by intrauterine events is a task of critical importance. In order to accomplish these major advances in child health, human fetal research must be continued.

1. Analysis of the health status of the fetus.

Based on the current level of live births and consideration of reproductive loss, it has been estimated that approximately 5,168,000 conceptions occurred in our country last year (1,2). Many of these conceptions did not survive the full period of gestation; others who were born alive died soon after birth; still others were significantly impaired by events occurring during early fetal development.

Based on available information, approximately 630,000 pregnancies were terminated by parental decision. Although these losses are considerable, the incidence of spontaneous abortion is even higher. Approximately 1,220,000 spontaneous abortions were estimated to occur during 1973. There is an increased incidence of congenital malformations or chromosomal abnormalities in fetuses who are spontaneously aborted. However, there remains a large percentage in which no discernible fetal abnormality can be detected; these must be considered, then, as potentially preventable deaths.

During the last half of gestation, about 118,000 babies die annually. Causes of late fetal deaths have been evaluated in other countries as follows:

(PERCENTAGE)

	DEFECTS OF PLACENTA/CORD	DEFECTS OF FETUS	TOXEMIA MATERNAL DISEASE	AT DELIVERY	RH	OTHER
CANADA	47.7	17.3	10.2	9.3	9.2	6.3
NETHERLANDS	34.2	14.1	21.0	12.9	5.7	12.1
ENGLAND & WALES	33.4	22.7	20.8	12.5	5.4	5.2
NEW ZEALAND	40.7	16.9	20.9	7.5	7.1	6.9

At least one out of five of these deaths are preventable, based on current knowledge.

After birth, approximately 40,000 babies died in the first four postnatal weeks. 12% of these deaths occur in the first hour, 59% of the first day, 91% the first week. An additional 19,000 died between four weeks and one year of age.

To summarize these data, the following table depicts the percentage of conceptions that ended in death at various developmental periods:

	NUMBER PER YEAR	% TOTAL CONCEPTIONS
INDUCED ABORTION	630,000	12.2
SPONTANEOUS ABORTION	1,221,000	23.6
FETAL DEATHS (last half of gestation)	118,000	2.3
NEONATAL DEATHS	40,000	0.8
POSTNEONATAL DEATHS	19,000	0.4
	TOTAL	39.3

Thus, approximately 400 out of every 1000 conceptions end in death by one year of postnatal age. If induced abortions are excluded, approximately 270 out of every 1000 conceptions end unsuccessfully. The latest figures regarding infant mortality indicate that the rate in the United States in 1973 was 17.6 deaths per 1000 live births. (4) The fetal losses, when expressed in terms of conceptions, are of staggering proportions.

2. Deleterious impact of intrauterine events on subsequent development

a) Appraisal of causes of infant deaths.

In 1968, the causes of infant deaths in the U.S. were identified as follows:

Congenital anomalies	14.5%
Asphyxia of newborn	13.4
Immaturity	12.3
Influenza and pneumonia	10.4
Complications of labor and delivery	9.5
Hyaline membrane disease	6.0
Respiratory distress syndrome	4.9
Other causes	29.0

Infant mortality is an end result of a variety of associated factors, both medical and social. Of principal importance is the recognition of the impact of retardation of fetal growth. The infant mortality rate in low birth weight infants is 17 times that of normal birth weight infants. Further, more than 70% of the neonatal deaths due to asphyxia occur in low birth weight infants. It has been estimated, thus, that over half of the infant deaths in our country are associated with low birth weight. Clearly, increased understanding of factors that lead to premature delivery and that regulate intrauterine growth is mandatory if improvement in the infant mortality rate is to occur. The United States is recurrently and justifiably criticized for its relatively high infant mortality rate. Improvement in this rate cannot occur, it seems evident, without continued research on those factors that influence and determine fetal development.

b) Impact of previous research.

Significant advances have been made in improving the status of fetal health. The horrible effect of rubella on the fetus has been largely eliminated. The deleterious effects of rH incompatibility on late fetal development have also largely been negated. The impact of respiratory distress syndrome on neonatal mortality is appreciable; however, studies of the past few years and those in progress promise to result in striking improvements in the prevention of neonatal respiratory distress. All of these advances required investigative efforts involving the human fetus. None of the advances that have occurred could have happened in the absence of fetal research.

c) The problem of deleterious effects on subsequent development.

The spectrum of human disease resulting from aberrant events occurring during fetal and perinatal life is still far from being delineated. The pervasive effects of retarded intrauterine growth were previously alluded to. The disastrous effects of perinatal viral infections are becoming increasingly apparent. It has been shown, for example, that elevations of a particular class of immunoglobulins, IgM, in cord blood may serve as an indicator of fetal infection. Approximately 3 per cent of children at birth have elevated IgM levels. In approximately 20% of these children, infection with known agents can be documented, leaving 80% unexplained. The potential deleterious impact of asymptomatic infections is suggested by a recent study in which inapparent congenital cytomegalovirus infection was associated with significant impairment in hearing and probable reduction in intelligence (6). Other studies suggest the deleterious impact of clinically inapparent viral infections on brain development (7).

The incidence of fetal infection remains undetermined. On the basis of available data, clinically important mental and auditory impairment may occur in one out of every 1000 live births as a result of fetal infection with one agent alone (i.e. cytomegalovirus infections). It is clear that the total spectrum of fetal infection is a much larger and more significant one than previously recognized. The capacity for the fetus to withstand infection is clearly different and less effective than during subsequent developmental periods. There needs to be much attention urgently paid to answering the many questions that exist concerning the incidence and nature of infectious processes that affect the mother and fetus.

d) Effect of socioeconomic factors.

In the previous discussion, the deleterious impacts of retarded fetal growth and intrauterine infection on subsequent development of the child have been emphasized. The incidence of low birth weight infants is markedly increased in the low-income and minority population (8). Further, the risk of recognized intrauterine infection is also appreciably increased in lower socio-economic groups.

Thus, the fetus of the mother who lives in a socio-economically deprived environment is at increased jeopardy, for not only succumbing at an increased rate during infancy, but also for experiencing persistent deleterious effects on central nervous system function as a consequence of adverse intrauterine events.

3. Unanswered questions regarding fetal development.

On the basis of these and other data characterizing health problems currently existent during fetal life and early infancy, it is possible to define, in general, the nature of biologic questions which must be solved by research if improvement in the health status of the fetus and infant is to be achieved. Such questions include, but are not restricted to, the following:

- Delineation of factors regulating intrauterine growth, including placental transport of nutrients.
- Defining the mechanism(s) whereby socioeconomic deprivation impedes optimal fetal growth.
- Definition of mechanisms productive of congenital malformations.
- Elucidation of the significance of intrauterine infections on both intra- and extra-uterine growth and development, and defining means of both identifying and treating such infections.
- Developing methods of protecting the fetus from the consequences of maternal disease.
- Utilization of advanced techniques for the diagnosis of fetal abnormalities, and development of methods of medical and surgical therapy.

These areas of requisite research mandate certain investigative approaches which necessitate preservation of the right of the mother to provide informed consent. We have indicated that the current health status of the fetus is shocking, in terms of both mortality and morbidity rates. The long-range effects of aberrations in fetal development may extract a huge toll of human suffering. Improvements in the health status require continuation of responsible, incisive research.

We urge the Commission to consider the fact that genuine concern for the fetus requires marked improvements in health care available to the developing human during intrauterine life. Such improvements in health care, both preventive and therapeutic in nature, require acquisition of increased understanding through research.

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DR. RYAN: The next speaker, we do not have a submitted statement for. I wonder if he is in attendance? Mr. McKenna. He has not signed in as yet. We will move on to the next speaker. I believe the presentation has been destributed. The American Academy of Pediatrics.

Dr. Yaffe, I know you have a long presentation. Our time is limited, so are you going to read it?

DR. YAFFE: No. I am going to read part of it, because you do have the entire statement, although, if I were to read this I would come within the ten minutes limitation.

I am Sumner J. Yaffe, M.D., Professor and acting chairman of the Department of Pediatrics at the State University of New York

at Buffalo and the Children's Hospital of Buffalo. I am pleased to appear before the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research on behalf of the American Academy of Pediatrics.

The Academy is the national organization of more than 16,000 board certified physicians specializing in the care of infants, children and adolescents. The Academy was organized in 1930 for the primary purpose of ensuring "the attainment by all children of the Americas of their full potential for physical, emotional and social health." From its inception, the Academy has been striving to foster excellence in pediatric education and practice.

The Academy correlates all aspects of work involved in caring for children and its members are engaged in teaching, research, and the provision of medical care to infants, children and adolescents. Essentially, we are a group of physicians working actively to improve the quality of life for children by establishing standards.

In keeping with this tradition, we have recently developed a code of ethics for the conduct of research involving fetuses. The code is attached to my written presenation which has been distributed to you.

Research on the fetus and newborn is of the greatest importance in contributing to the health and welfare of the entire population and should be continued and fostered,

subject to adequate and clearly defined safeguards.

The American Academy of Pediatrics is aware of the benefits which have accrued from fetal research and recognizes the need for continuing studies to sustain and enhance these benefits. Therefore, the Academy supports fetal research. Examples of the proven benefits and also of future research needs are cited in the following paragraphs. Since my research and clinical experience was concentrated on drugs, this will be emphasized.

The past several decades have witnesses a significant decline in maternal mortality and morbidity. During the same time period, the decline in perinatal mortality and morbidity has been less dramatic because diseases that effect the fetus and newborn infant have been relative refractory to both prophylaxis and therapeutics. As our understanding has been furthered by research in this age group, efforts directed at therapy of the fetus have increased. A new concept of fetal therapeutics has arisen because of our ability to diagnose and treat the fetus in utero.

In addition to these sophisticated approaches, fetal therapeutics is also the care or lack of care that the mother receives during pregnancy and even before conception. We are just now beginning to learn the effects on the fetus of such variables as the external environment, maternal medication, diet, activities, emotions, physical and

behavioral illness. Much more research is needed to optimize fetal development so that infants are born free from disease.

The future of any society rests with its children; this truism is the foundation of our nation and deserves the highest priority of attention. Fetal research, which benefits future generations of children, will considerably enhance this objective.

In pregnancies complicated by maternal or fetal disease the initial goal of treatment is the delivery of a viable fetus at a gestational age compatible with extra-uterine survival. In the management of these pregnancies, frequently the physician must consider induction of labor and delivery of a premature infant. This question is answered by determination of the benefit/risk ratio from remaining in the uterus versus functional immaturity in the nursery.

The marked advances which have occurred in the care of the newborn and premature infant have permitted infants to be delivered earlier in gestation and thus removed from the risks of continued existence in utero. The next several paragraphs are intended to demonstrate how fetal research has permitted major therapeutic advances with subsequent production of healthier babies.

The Rh-positive fetus of an Rh=negative sensitized mother is at risk from an acquired hemolytic anemia which

may be severe enough to cause death. The management of this anemia, as with most anemias, is via blood transfusion, but since this could only be performed at birth the most severely affected infants died in utero. The introduction of amniocentesis and the subsequent demonstration of a correlation between the amniotic fluid concentration and extent of fetal hemolysis permitted a new form of therapy, intrauterine transfusion, with marked improvement in intrauterine mortality. While these clinical approaches to the already sensitized Rh-negative pregnant patient were being developed, concurrent investigations were directed at prevention of the initial formation of Rh-positive antibodies in the Rh-negative woman at risk.

The fundamental approach was based on the concept of antibody-mediated immune suppression. It was proven that passive immunization of high anti-D antibody-specific immunoglobulin G fraction prevented isoimmunization to the Rh-antigen. The method is presently recommended for use in the immediate post-abortal or postpartum Rh-negative unsensitized patient. The conscientious application of this prophylaxis will result eventually in the infrequent occurrence of erythroblastosis fetalis secondary to Rh sensitization. It is obvious that none of this progress would have been possible without research in the human fetus.

Pregnancy complicated by diabetes meillitus is

a consequence of modern medicine. The administration of insulin to diabetic girls and adolescents has resulted in their survival up to and through childbearing. Unfortunately, for the 2-5 percent of the population which is diabetic or prediabetic, pregnancy is not without risk particularly to the fetus and newborn infant. The mortality rate itself is 0 percent and 9 percent of the offspring of diabetic women have major congenital malformations. It is not entirely apparent why such high mortality/morbidity exists. Recent research in glucose metabolism during pregnancy and in the fetus has provided some answers, but much more research is needed to enable diabetics to produce normal offspring. In order to practice optimal fetal therapeutics, it is essential to understand the special problems and the delicate balance in the metabolism of the diatetic who is pregnant.

In spite of intensive therapeutic efforts, the fatality rate in respiratory distress syndrome of the newborn infant remains high. It now appears that prediction and possibly prevention of this disease is imminent. By examining the concentration of phospholipids in amniotic fluid, it is possible to predict the potential for respiratory difficulty in the newborn infant.

Relative lung maturity can now be diagnosed by amniocentesis and the physician can employ this in managing pregnancy. Very recently the administration of corticosteroids

to the mother prior to delivery has been shown to accelerate fetal lung maturation and thus significantly reduce the occurrence of respiratory distress syndrome in treated infants. Much more research in this phenomenon needs to be done both concerning the mechanism as well as regarding the short and long term side effects of hormone therapy.

The advances in fetal therapeutics described in the preceeding paragraphs are examples of the successful application of knowledge which was derived from basic clinical experimentation. Continued advancement is limited by the relative lack of information about the normal and pathological processes of fetal and infant development. This information gap is most acutely felt in pediatric drug therapy.

In the past several decades a series of extraordinary mishaps attributable to commonly used therapeutic agents has focused attention upon the unique responses of developing organisms to many pharmacologically active compounds. The Thalidomide disaster with which you are familiar, led to the 1962 amendments to the Food, Drug and Cosmetic Act which authorized the FDA to ensure that drugs be effective as well as safe under the conditions in which they will be used. It has been estimated that 75 percent of all therapeutic agents are not approved for use in infants, children and pregnant women because conclusive evidence of their safety and efficacy in this population is not available.

Many of the therapeutic agents used during pregnancy are administered in an aura of ignorance with potential hazard to the fetus as well as the mother. As we enter the era of sophisticated fetal therapeutics, it is most important to resolve this problem through increased clinical pharmacologic investigation.

A recent report from the National Academy of Sciences details some of these research needs. A copy of this report has been submitted for the Commission's perusal. I have also transmitted a report which the Committee on Grust of the American Academy of Pediatrics has submitted to the Food and Drug Administration concerning the evaluation of drugs which are to be used during pregnancy and for the treatment of infants and children. This report is an expression of the Committee on Drugs' concern regarding the evaluation of drugs to be used during pregnancy. Thus, we clearly appreciate the need for an increase in clinical investigation as this is the only means to provide more rational and safe therapy for the fetus.

Legal compliance with the Food, Drug and Cosmetic Act requires research on the human fetus and pregnant woman if the use of phrmacologic agents in this special population is to be based on valid scientific data instead of emiricism.

I might say one word before I conclude about the

species or the value of other species, the question having been raised by Commissioners in the past several testimonies. I think with drugs there is a unique situation in which no species that I know of, except perhaps the subhuman primate, and we are jsut entering this area, can furnish any information regarding drug metabolism. I other words, below the primate there is absolutely no information permissible from species research.

As far as the law is concerned, the law requires that research be performed in the human fetus in pregnant women.

Thank you.

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Dr. Yaffe's prepared statement follows:

PRESENTATION OF THE AMERICAN ACADEMY OF PEDIATRICS
TO THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS
CONCERNING RESEARCH ON THE FETUS - FEBRUARY 14, 1975

I am Sumner J. Yaffe, M.D., Professor and Acting Chairman of the Department of Pediatrics at the State University of New York at Buffalo and the Children's Hospital of Buffalo. I am pleased to appear before the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research on behalf of the American Academy of Pediatrics. The Academy is the national organization of more than 16,000 board certified physicians specializing in the care of infants, children and adolescents. The Academy was organized in 1930 for the primary purpose of ensuring "the attainment by all children of the Americas of their full potential for physical, emotional and social health". From its inception, the Academy has been striving to foster excellence in pediatric education and practice. The Academy correlates all aspects of work involved in caring for children and its members are engaged in teaching, research and the provision of medical care to infants, children and adolescents. Essentially, we are a group of physicians working actively to improve the quality of life for children by establishing standards. In keeping with this tradition, we have recently developed a code of ethics for the conduct of research involving fetuses. The code is

attached to my written presentation which has been distributed to you.

Research on the fetus and newborn is of the greatest importance in contributing to the health and welfare of the entire population and should be continued and fostered subject to adequate and clearly defined safeguards. The American Academy of Pediatrics is aware of the benefits which have accrued from fetal research and recognizes the need for continuing studies to sustain and enhance these benefits. Therefore, the Academy supports fetal research. Examples of the proven benefits and also of future research needs are cited in the following paragraphs. Since my research and clinical experience has concentrated on drugs, this will be emphasized.

The past several decades have witnessed a significant decline in maternal mortality and morbidity. During the same time period, the decline in perinatal mortality and morbidity has been less dramatic because diseases that effect the fetus and newborn infant have been relatively refractory to both prophylaxis and therapeutics. As our understanding has been furthered by research in this age group, efforts directed at therapy of the fetus have increased. A new concept of fetal therapeutics has arisen because of our ability to diagnose and treat the fetus in utero. In addition to these sophisticated approaches, fetal therapeutics is also the care or lack of care that the mother receives during pregnancy and even before conception. We are just now beginning to learn the effects on the fetus of such variables as the external environment, maternal medication, diet, activities, emotions, physical and behavioral illness. Much more research is needed to

optimize fetal development so that infants are born free from disease. The future of any society rests with its children; this truism is the foundation of our nation and deserves the highest priority of attention.. Fetal research, which benefits future generations of children, will considerably enhance this objective.

In pregnancies complicated by maternal or fetal disease the initial goal of treatment is the delivery of a viable fetus at a gestational age compatible with extra-uterine survival. In the management of these pregnancies, frequently the physician must consider induction of labor and delivery of a premature infant. This question is answered by determination of the benefit/risk ratio from remaining in the uterus versus functional immaturity in the nursery. The marked advances which have occurred in the care of the newborn and premature infant have permitted infants to be delivered earlier in gestation and thus removed from the risks of continued existence in utero. The next several paragraphs are intended to demonstrate how fetal research has permitted major therapeutic advances with subsequent production of healthier babies.

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a new form of therapy, intrauterine transfusion, with marked improvement in intrauterine mortality. While these clinical approaches to the already sensitized Rh-negative pregnant patient were being developed, concurrent investigations were directed at prevention of the initial formation of Rh-positive antibodies in the Rh-negative woman at risk. The fundamental approach was based on the concept of antibody-mediated immune supression. It was proven that passive immunization with high anti-D antibody-specific immunoglobulin G fraction prevented isoimmunization to the Rh-antigen. The method is presently recommended for use in the immediate postabortal or postpartum Rh-negative unsensitized patient. The conscientious application of this prophylaxis will result eventually in the infrequent occurrence of erythroblastosis fetalis secondary to Rh sensitization. It is obvious that none of this progress would have been possible without research in the human fetus.

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normal offspring. In order to practice optimal fetal therapeutics, it is essential to understand the special problems and the delicate balance in the metabolism of the diabetic who is pregnant.

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The advances in fetal therapeutics described in the preceeding paragraphs are examples of the successful application of knowledge which was derived from basic clinical experimentation. Continued advancement is limited by the relative lack of information about the normal and pathological processes of fetal and infant development. This information gap is most acutely felt in pediatric drug therapy. In the past several decades a series of extraordinary mishaps attributable to commonly used therapeutic agents has focused attention upon the unique responses of developing organisms to many pharmacologically active compounds. The thalidomide disaster with which you are familiar

led to the 1962 amendments to the Food, Drug and Cosmetic Act which authorized the FDA to ensure that drugs be effective as well as safe under the conditions in which they will be used. It has been estimated that 75% of all therapeutic agents are not approved for use in infants, children and pregnant women because conclusive evidence of their safety and efficacy in this population is not available. Many of the therapeutic agents used during pregnancy are administered in an aura of ignorance with potential hazard to the fetus as well as the mother. As we enter the era of sophisticated fetal therapeutics, it is most important to resolve this problem through increased clinical pharmacologic investigation. A recent report from the National Academy of Sciences details some of these research needs. A copy of this report has been submitted for the Commission's perusal. I have also transmitted a report which the Committee on Drugs of the American Academy of Pediatrics has submitted to the Food and Drug Administration concerning the evaluation of drugs which are to be used during pregnancy and for the treatment of infants and children. This report is an expression of the Committee on Drugs concern regarding the evaluation of drugs to be used during pregnancy. Thus, we clearly appreciate the need for an increase in clinical investigation as this is the only means to provide more rational and safe therapy for the fetus. Legal compliance with the Food, Drug and Cosmetic Act requires research on the human fetus and pregnant woman if the use of pharmacologic agents in this special population is to be based on valid scientific data instead of empiricism.

The AAP code of ethics for the use of fetuses and fetal material for research that was referred to by Dr. Yaffe in his testimony is as follows:

AAP CODE OF ETHICS FOR THE USE OF
FETUSES AND FETAL MATERIAL FOR RESEARCH

Introduction

Research on the fetus and newborn is of the greatest importance in contributing to the health and welfare of the entire population. Such research, motivated by humane concern, should be continued and fostered, subject to adequate and clearly defined safeguards.

The American Academy of Pediatrics recognizes that through research involving previable fetuses, new knowledge may be gained which would ultimately benefit viable infants. The American Academy of Pediatrics also recognizes that some of these areas of research, while not jeopardizing the health and welfare of the fetus, are not of direct benefit to that particular fetus. In such cases express consent should be obtained from the parent. "The whole previable fetus has offered an important opportunity that cannot be obtained in any other way for making observations of great value on the transfer of substances across the human placenta, the reaction of the immature fetus to drugs, and on the endocrinological development of the fetus and the development of the placenta."[1]

Research activities involving the fetus in utero, or pregnant women may be undertaken[1] for the purpose of benefiting that particular fetus or to respond to the health needs of the mother,[2] as part of the procedure to terminate the pregnancy and for the purpose of evaluating or improving methods of prenatal diagnosis, methods of prevention of premature birth, or methods of intervention to offset the effects of genetic abnormality or congenital injury or to ascertain the safety and efficacy to the fetus of drugs which might be needed by pregnant

women. [2]

For the purposes of this code of recommendations, the following definitions have been accepted:

> Viability of the Fetus means the ability of the fetus, after either spontaneous or induced delivery, to survive (given the benefit of medical therapy) to the point of independently maintaining heart beat and respiration. If the fetus has this ability, it is viable and therefore a premature infant.
>
> Abortus means a fetus when it is expelled whole, prior to viability, whether spontaneously or as a result of medical or surgical intervention. The term does not apply to the placental fetal material which is macerated at the time of expulsion; or cells, tissue, or organs excised from a dead fetus. [3]

Because of the rapid changes taking place in medical knowledge, the definition of viability should be reviewed regularly in order that it be consistent with these rapid changes.

Determination of viability entails a subjective and objective judgment by the physician attending labor or examining the product of conception, and must be made by a physician other than the investigator wishing to use fetal tissue in research. In general, and all other circumstances notwithstanding, a beating heart alone is not sufficient evidence of viability. At least one additional necessary condition is the possibility that the lungs can be inflated. Without this precondition, no currently available mechanisms to initiate or maintain respiration can sustain life; and in this case, though the heart is beating, the fetus or abortus is in fact non-viable. [4]

CODE

1. Research on the Fetus in Utero (where delivery of a previable fetus is not contemplated)

Investigations and tests may be carried out with the intention of benefiting the mother, her expected child, or both. For these investigations and tests, informed consent should be obtained.

2. Research on the Viable Fetus

When the fetus is viable after delivery, the ethical obligation is to sustain its life so far as possible. It is both unethical and illegal to carry out any experiments which are inconsistent with treatment necessary to promote the life of the fetus. It is recognized that in many instances the techniques used to aid a distressed fetus may be so new that in some degree they may be considered experimental.

3. Research on the Previable Fetus in Utero (where abortion is planned) or Abortus

This research is permissible providing:

(a) animal studies, if appropriate, have been completed;

(b) the mother and father are legally competent and have given their consent, except that the father's consent need not be secured if his identity or whereabouts cannot reasonably be ascertained;

(c) individuals engaged in the research will have no part in:

1) any decisions as to the timing, method or procedures used to terminate the pregnancy, and

2) evaluating the viability of the fetus at the termination of the pregnancy;

(d) such research is only carried out in departments directly related to a medical institution and with the express sanction of its committee on human experimentation;

(e) before permitting such research the committee on human experimentation satisfy itself: 1) on the validity of the research; 2) that the required information cannot be obtained in any other way, and 3) that the investigators have the necessary facilities, skill and integrity;

(f) dissection of the dead fetus or experiments on the fetus or fetal material do not occur in the operating theatre or place of delivery;

(g) there is no monetary exchange for fetuses or fetal material, and

(h) full records are kept by the relevant institution.

4. Research on the Dead Fetus or Abortus

This research is permissible provided the conditions in paragraph 3 (b)-(h) above are observed and the research conducted in accordance with any applicable State or local laws governing autopsy.

If the abortus is an organ or tissue donor, the research shall be conducted in accordance with any applicable State or local laws governing transplantation or anatomical gifts. Thank you.

DR. ALEXANDER: With respect to the perinatal research to which you referred, in trying to consider this in the light of what Dr. Nathan indicated, and as far as the problem of a mother changing her mind is concerned, can the pharmacological research be conducted if it is limited to a period of time right around the induction of an abortion, or is it the time of research you prefer have initiated earlier?

DR. YAFFE: I don't have the answer to the question, I must say. I think I personally would be happy with the research regarding, let's say, a transmission of drugs from the mother to the fetus, where this procedure began after the abortion procedure was instituted. I think you

could derive enough information. I am not sure, of course, there will be circumstances for longer acting compounds in which one might have to introduce these into the mother, which is the usual means, but as techniques develop, we will have drugs which will be introduced directly into the fetus.

DR. RYAN: Dr. Cooke.

DR. COOKE: One of the two approaches to the study of transmission of drugs in humans, it seems to me, in regard to the fetus, one might be characterized as an opportunistic approach, where you have a woman who has a serious illness and requires the drugs, and by coincidence she is going to need an abortion and so forth, or one could carry it out more systematic investigation, which is what you are essentially suggesting.

Would you care to hazard a guess as to the success of the first approack, the difficulties and so forth? This has been suggested as one way we could get this kind of information.

DR. YAFFE: The difficulties have to do with organization and the logistics of knowing where that woman was and when she was going to undergo a procedure terminating pregnancy. She has, by your definition, been on this drug for purposes which are her own. She is ill and requires the drug. It seems to me that woman should, of course, take advantage of that situation. But logistically it is not as

readily done as if one were to introduce in a prospective way drugs into the mother whose pregnancy has been -- who decided to terminate her pregnancy. Therefore, one could get at some of the data which are required regarding the transmission across the placenta. You can alter the time at which the drug can be given to the mother prior to the delivery of the fetus.

DR. COOKE: The delays would be several years in accumulating the information to have statistical information?

DR. YAFFE: Yes, I would think that one could systematically approach this and shorten the time interval whereby this information is provided by several years, at least.

I wanted to go on for a minute, because I didn't want to leave the impression that the only concern we have is for placental transport. We do have a great deal of concern for what the fetus itself is doing to the drug. In other words, metabolism on the drug only occurs in the human fetus. It doesn't occur in any other subhuman species that I know of. It has been speculated and there is now data accumulated that perhaps the mechanism for the production of congenital malformations result from the metabolism of a drug which the mother has been given by the fetus into the production of a very highly reactive metabolism.

DR. RYAN: I just wanted to point out, I am sure

you are aware of the collaborative drug surveillance program that goes on. In the name of therapy, if you will, the research that goes on, is to screen large populations. In that sense they can turn up things which would not turn up, as you have said, in the opportunistic situation on a one on one basis. The best example is the increased incidence of congenital anomolies on a statistical basis in women who have epilepsy. Then, the added problem is we don't know whether the disease itself is also contributed. These are the things that cannot be easily sorted out, but they are providing information in the name of therapy, research being the observation of patients under therapy. It does pose a problem in the use of any drug in the pregnant women, and how to get about determing safety, when the drug is being used for her benefit or for the benefit of the unborn child.

DR. LEBACQZ: Your comments this morning were directed to the fetus in the hope of providing therapy for the fetus. Are there kinds of research you would not consider to be feasible? Research to design abortion technology, or whether it is possible to make such distinctions?

DR. YAFFE: I am not an obstetrician, so I would rather not answer that question. But if you would allow a pediatrician to comment on it --

(Laughter.)

DR. LEBACQZ: I think that is what I am asking for.

DR. YAFFE: Well, I don't see, personally, any great impediment to this type of research, provided, of course, it has gone through the traditional preclinical evaluation in animals. And here I am not knowledgeable about species, differences do exist with respect to the response in the uterus to different drugs.

DR. RYAN: Dr. Lebacqz, did you throw in the issue of research on the abortion process itself?

DR. LEBACQZ: Yes.

DR. LOUISELL: I was wondering if you feel able to generalize, as I understood the preceeding witness to do, that the balancing of risks for fetal research are essentially the same or should be the same as they afe for balancing of risks of children?

DR. YAFFE: Yes, I support Dr. Greenberg's statement.

DR. JONSEN: I assume that certain of the studies to which you would be interested might be carried out efficiently in fetuses whose life is purposely stabilized, pre-viable fetuses, whose life is purposfully sustained in order to do the studies, that studies might be efficiently done in such fetuses. If that were the case, would you approve of sustaining life of a fetus for the purpose of

research?

DR. YAFFE: If I understood your question, you are discussing research during that, let's say, stage of pregnacy in which the fetus has been agreed upon to be previable, and instituting that research for the sake of research?

DR. JONSEN: I am directing this to the abortus. That we have an abortus which is not viable, but which can be sustained alive for a certain period of time to do metabolic studies and so forth.

DR. YAFFE: After it has been delivered?

DR. JONSEN: Yes, after delivery.

DR. YAFFE: You are asking whether or not I support that type of research?

DR. JONSEN: Yes. First of all, I will split my question and say, do you think that certain of the studies, certain studies could be done more efficiently in this way, and secondly, whether you would consider such studies ethical?

DR. YAFFE: I don't know. But the answer to the first portion of your question -- this is not what I meant before. I don't think when I was discussing this with Dr. Cooke the efficiency of risk of undertaking fetal drug research, I don't see that this enhances our efficiency for many of the kinds of pharmacological investigation one can conduct. You can conduct this without keeping the abortus

alive by artificial means. So that this is not necessary for drug research.

Now, as far as my personal ethics are concerned about this, I have never participated in this research and I don't believe I would.

DR. RYAN: Our time is up. Thank you very much, Dr. Yaffe.

The next speaker will be Lois Schiffer from the Center for Law and Social Policy.

If you will give us an opportunity to -- do we have the statement?

Will you please proceed?

Ms. Schiffer read her prepared statement which follows:

INTRODUCTION

We submit these Comments on behalf of three organizations concerned with the rights of women.

Women's Equity Action League (WEAL) is a nationwide membership organization established in 1968 to promote non-discriminatory treatment of American women; it has recognized the crucial importance of health issues, which affect all aspects of women's lives.

Women's Legal Defense Fund (WLDF) is an organization which provides legal and paralegal services for the protection of the rights and interests of women. WLDF has had a continuing concern with the effect on the pregnant woman of procedures for protecting the subjects of fetal research promulgated by the Department of Health, Education and Welfare.[1/]

Human Rights for Women (HRW) is an organization devoted to the achievement of equality between men and women. It has had a continuing interest in the rights of women to good health care, and has participated as amicus curiae in several Supreme Court cases involving the rights of women to contraception and abortion.

1/ Protection of Human Subjects - Proposed Policy", 38 Fed. Reg. 27882 (Oct. 9, 1973) (Comments filed January 22, 1974); "Protection of Human Subjects - Proposed Policy", 39 Fed. Reg. 30618, et seq. (August 23, 1974) (Comments filed November 22, 1974).

As lawyers with the Women's Rights Project of the Center for Law and Social Policy, we have had a continuing interest in and involvement with issues concerning women, especially in the area of health.

By this Comment we wish to stress to the Commission the importance of considering the interests of women, and in particular the pregnant woman, as well as the fetus, in drafting and promulgating procedures concerning fetal research pursuant to §202(b) of the National Research Act, P.L. 93-347. Most considerations of the appropriateness of fetal research and the conditions under which it may be undertaken focus on giving protection to the fetus. Often, the serious interest of the pregnant woman, including the effect which procedures for fetal research may have on her physical health and psychological well-being, are overlooked. WEAL, WLDF and HRW limit their comments to the area of their primary concern and expertise, matters which affect the rights and interests of pregnant or potentially pregnant women, and do not address other aspects of fetal research.

In implementing fetal research, not only is consideration of the pregnant woman's interest desirable, it is mandated. For these rights and interests in physical and psychological health and well-being are extremely important and are protected by the United States Constitution, as the Supreme Court has recognized in its decisions in Roe v. Wade, 410 U.S. 113 (1973) and Doe v. Bolton, 410 U.S. 179 (1973). Failure of the Commission to recognize these rights in its recommendations

may lead to laws which abrogate these constitutionally-protected interests. Generally, the rights of the pregnant women must be regarded as paramount -- ethically as well as constitutionally.

SUMMARY

We make the following recommendations to this Commission regarding its report on fetal research:

1. biomedical research which may affect the fetus in utero must be permitted in order to assure that proper and effective medical care and treatment are available to the pregnant woman;

2. any recommendations regarding fetal research must not limit the right of a pregnant women to relief from experimental therapy to save her own life or health;

3. a policy regarding fetal research must expressly provide for the pregnant woman's rights to be fully informed of the effect on her own health and well-being of research practices on the fetus in utero, and should provide for appropriate follow-up care for the pregnant woman;

4. a policy on fetal research cannot require the consent of the father or the pregnant woman's husband before the pregnant woman can submit to research involving the fetus as part of a procedure to terminate the pregnancy without limiting rights and interests of the mother recognized by Supreme Court decisions;

5. a policy on fetal research should permit a pregnant woman to participate in research to improve abortion procedures; and

6. any ethical review committees or other bodies recommended by the Commission to administer a fetal research policy at the national or local level should expressly include women members.

I. Biomedical And Behavioral Research Which May Affect The Fetus In Utero Must Be Permitted In Order to Assure That Proper And Effective Medical Care And Treatment Are Available To The Pregnant Woman.

Curtailment of biomedical research affecting the fetus in utero seriously limits the possibility for developing sound scientific data on the effects of medicines, drugs, nutrition, and environmental stress on the developing fetus. Without such information, because of the special interrelationship between the pregnant woman and the fetus, the pregnant woman is forced to rely on guessing and rumor in determining what medicine and food to use for her own health and comfort during her pregnancy. The result is that she may often forego the use of medicine and foods essential to improve her own health and comfort for fear that they may adversely affect the fetus. Similarly, without such research she may eat foods which can adversely affect her own health in the undocumented belief that they assist fetal development. Without scientific biomedical and behavioral research on these matters, the health of the pregnant woman can be seriously and adversely affected.

The policies of the Supreme Court expressed in Roe, supra, and Doe, supra, are that the interest of the woman and the state in the health of the pregnant woman must be given precedence over the fetus throughout the entire term of the

pregnancy.[2/] That policy supports the need for biomedical and behavioral research affecting fetuses which affect the health of the pregnant woman.

Therefore, biomedical and behavioral research on the effect of drugs, nutrition, and environmental stresses on the fetus in utero must be permitted in order to protect the health of the pregnant woman. The moratorium on such research imposed by §213 of the National Research Act should be lifted immediately in order to realize this goal.

II. Any Recommendations Regarding Fetal Research Must Not Limit The Right Of A Pregnant Woman To Relief From Experimental Therapy To Save Her Own Life Or Health.

Any policy regarding fetal research (even a policy prohibiting it) must necessarily entail a decision about permitting a pregnant woman to submit to federally-sponsored therapy affecting her own life or health. In addition, any policy permitting fetal research will necessarily entail establishment of procedures for determining when fetal research is appropriate and conditions under which it can be carried out. Such

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2/ In Roe v. Wade, supra, 410 U.S. at 164-5, the Supreme Court holds that during the first trimester of pregnancy, the interest of the pregnant woman in consultation with her doctor is the only interest to be weighed; during the second trimester, some weight may be given by the state to its interest in the health of the mother; during the third trimester, the state may protect the potentiality of life except when abortion is necessary to preserve the life or health of the mother, Roe, supra at 410 U.S. 164-5. Throughout the pregnancy, the interest of the pregnant woman and the state in the life and health of the pregnant woman takes precedence over any interest of the state in protecting the potentiality of life of the fetus.

policy and procedures must permit a woman to participate in life and health-saving treatments. For example, a woman who finds in the second month of a pregnancy that she has a cancer which can be treated only by an experimental chemical which may affect the fetus must be permitted to undertake such treatment to save her own life and health.

The Supreme Court has held that during the first three months of a pregnancy, the decision about an abortion, which obviously affects the fetus, must be left to the pregnant woman and her attending physician; that decision must override any concern for the fetus. During the second trimester of pregnancy, the state may regulate the abortion procedure only in ways that are reasonably related to maternal health; again, protection of the fetus must be subordinate to the interest of the pregnant woman. Finally, during the last trimester, a state may balance the interest in protecting the potentiality of life (the fetus) with the pregnant women's interest; but even at this stage, the state cannot elevate its interest in protecting the unborn fetus above a medical judgment that the abortion is required to preserve the life or health of the mother. Roe, supra, 410 U.S. at 164-5.

Any policy which treated the protection of the fetus throughout the pregnancy as a more important interest than the desire of the mother to terminate the pregnancy for whatever reason, or the interest of the pregnant woman and the state in the woman's health, would abrogate the constitutional rights of the mother to make her own determinations about continuation of the pregnancy in the first six months, and to

have her life and health protected in the last three months.[3/] That any other policy may be motivated by "ethical" concerns for the protection of the fetus does not change its unconstitutional effect on the mother's rights. In addition, a policy failing to protect the pregnant woman's interest in her own health may force a woman who wishes to participate in a particular research program for life-saving, health-saving, or any other reason, to undergo an abortion she might not otherwise choose in order to be free from restraints on participation.

A sensible and constitutional policy requires that the pregnant woman be as fully informed as possible of the potential risk of the research to the fetus and then be permitted freely to choose whether to participate. At the least, a policy regarding fetal research should incorporate the principle that the interests of the pregnant woman in continuing the pregnancy, or in her own health, may be exercised throughout her pregnancy in accordance with the constitutional principles set forth by the Supreme Court.

III. A Policy Regarding Fetal Research Must Expressly Provide For The Pregnant Women's Rights To Be Fully Informed Of The Effect On Her Own Health And Well-Being Of Research Practices On The Fetus In Utero And Should Provide For Appropriate Follow-Up Care For The Pregnant Woman.

Any policy regarding fetal research should require that

3/ The Supreme Court in Roe v. Wade leaves open the possibility that a state may choose to permit a mother to make an unfettered choice about abortion throughout her pregnancy; the decision simply sets forth the most restrictive statute a state may enact. Therefore, in some jurisdictions, the state may determine not to protect the potentiality of human life at any time.

maternal consent be obtained, and that it be informed consent.[4/] The policy should specify that maternal consent (or informed consent) can be given for research on the fetus in utero only when the mother has full and adequate information about the effect of the research on her own health and body, as well as on the health of the fetus. Certainly, in each instance in which research is undertaken on a fetus in utero, because of the special interrelationship between the pregnant woman and the fetus, full information about the effect of the research on the pregnant woman's health -- the risks and benefits to her -- is an essential prerequisite to meaningful consideration or consent by the pregnant woman. Encouragement of investigation of effects on the mother so that sufficient information can be communicated to provide the pregnant woman with a basis for decision would be a desirable side-effect of this policy.

In addition to providing (and developing) information on the risks and benefits to maternal health of the research undertaken, this Commission should require that research protocols make adequate provision for follow-up care for the

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4/ One of the tasks of this Commission is to review the procedures for informed consent used in federally-funded research. Because that inquiry will be extensive, we do not anticipate it here, but note that generally-adopted procedures for securing informed consent, including a notion of "transmitting adequate information", should be explicitly incorporated into fetal research policies and regulations. In the interim, the definitions of informed consent set forth in the HEW Regulations on Protection of Human Subjects, 39 Fed. Reg. 18917 (May 30, 1974) at §46.3, should be explicitly incorporated into any statement of policy on fetal research. In addition, in both cases the policy should provide mechanisms for adequately insuring that procedures for such informed consent from pregnant women involved in fetal research studies will be enforced.

pregnant woman who is the subject of research involving the fetus in utero. Since the health of the pregnant woman as well as the fetus may be affected by these studies, care for that health should be routinely provided.

IV. A Policy On Fetal Research Cannot Require The Consent Of The Father or Pregnant Woman's Husband Before The Pregnant Woman Can Submit To Research Involving The Fetus As Part Of A Procedure To Terminate The Pregnancy Without Limiting Rights And Interest Of The Mother Recognized By Supreme Court Decisions.

A policy regarding fetal research cannot lawfully require paternal or spousal consent for research activities undertaken to save the life or health of the pregnant woman or undertaken at the time of a procedure to terminate pregnancy. For the Supreme Court has recognized in Roe, supra, and Doe, supra, the right of the pregnant woman to make decisions about pregnancy termination, including method of pregnancy termination, in consultation with only her doctor. Therefore, a policy which limits that right by imposing a constraint of paternal or spousal consent when a pregnancy termination will result contravenes the Constitution.[5/]

5/ Although the Supreme Court reserved decision on the question of paternal rights in Roe, supra, 410 U.S. at 165 n. 67, it would seem that the right of the father to protect the fetus cannot be any greater than the right of the fetus -- an unprotectible interest during the first two trimesters. Lower courts have consistently held that the putative father and the husband have no right to restrain a pregnant woman from having an abortion. See, e.g., Doe v. Bellin Memorial Hospital, 479 F.2d 756, 759 (7th Cir., 1973) (putative father); Coe v. Gerstein, 376 F.Supp. 695, 697-8 (S.D. Fla., 1974) (3-judge court), cert. denied 94 S.Ct. 2246 (1974) (husband); Doe v. Rampton, 366 F.Supp. 189, 193 (D. Utah, 1973) (3-judge court) (husband and father); Doe v. Doe, 43 U.S.L.W. 2029 (Supreme Court of Massachusetts, July 3, 1974) (husband).

In addition, any paternal or spousal consent required before pregnancy termination in conjunction with fetal research serves no legitimate interest of the father or husband. Certainly, the father has a substantial and protectible interest in the health and well-being of any child which may be born, in part because the father may be obligated to support the child; that interest may support a requirement that the father consent to research activity on a fetus in utero which anticipates that the fetus will be carried to term.[6/] When, however, the research is undertaken at the time of the termination of the pregnancy, the father's interest in a potential child is not present. Therefore, a requirement for his consent or that of the husband in such circumstances has no basis, and a policy on fetal research should not provide for it.[7/]

Further, any policy which does not give primacy to the strong life-and-health interest of the mother by recognizing that paternal consent cannot be required before the mother can participate even in research to save her own life would violate constitutional principles set forth in Doe v. Bolton and Roe v. Wade. Although the interest of the father in the health and well-being of his child is an important one, balancing of that interest with the mother's interest in preserving her own life or health requires a determination that the mother's

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6/ Such interest inheres only in the putative father, not in the husband of the pregnant woman.

7/ This exclusion of a father's consent provision would cover, inter alia, research for the purpose of evaluating or improving methods of abortion. See pp. 11-12, infra.

interest in this narrow area of therapeutic research is paramount.[8/]

At the least, therefore, a policy regarding fetal research should permit a pregnant woman to participate in research which could save her life or health, even if such research may adversely affect the fetus. Nor should the consent of the father or husband be required if the research will end in termination of the pregnancy. Also, out of concern for the independence and self-determination of the pregnant woman, paternal consent should in no event be required if the father cannot be identified or found.

V. A Policy On Fetal Research Should Permit A Pregnant Woman To Participate In Research To Improve Abortion Procedures

In Roe v. Wade, 410 U.S. 113, 164-5 (1973), the Supreme Court held that for the first trimester of pregnancy, the abortion decision and its effectuation must be left to the medical judgment of the pregnant woman's attending physician; in the second trimester, the state may additionally regulate the abortion procedure in ways reasonably related to maternal health; in the third trimester, the state may limit abortions to those cases in which they are required to preserve the life or health of the mother. Throughout the pregnancy, method of pregnancy termination is a matter for choice between a woman and her doctor, limited only by standards for protecting the

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8/ That the pregnant woman's interest in her own health is sufficiently great to overcome any requirement of paternal consent in research to save her own life of health has been recognized by the Department of Health, Education and Welfare in its most recent draft of regulations regarding Protection of Human Subjects in fetal research. 39 Fed. Reg. 30618 et seq. at §46.306.

woman's health. A policy on fetal research must recognize that right by providing the opportunity for a woman who seeks to terminate her pregnancy to participate in research conducted for the purpose of evaluating or improving methods of abortion -- research which affects only the method of pregnancy termination. Moreover, a policy which permits research in the area of abortion affects the interests not only of the pregnant woman who may want to participate, but of all women who may wish at some time to have an abortion by safe, effective means.

VI. Any Ethical Review Committees Or Other Bodies Recommended By The Commission To Administer A Fetal Research Policy Should Expressly Include Women Members.

Any general policy on fetal research will have to be implemented through an administrative body or bodies which apply the policy to a series of decisions on particular research projects. Because pregnancy and the fetus in utero are matters which particularly affect women, and affect them in a manner which male decision-makers cannot always adequately reflect, the views which women would bring to decision-making bodies are unique and important. Therefore, we suggest that any policy on fetal research provide in the section on implementation that affirmative efforts be made to include women among the members of bodies which administer the policy, and that a general provision explicitly barring discrimination on the basis of sex in selection of members of such bodies be made part of the implementation policy.

CONCLUSION

This Commission should adopt a report which permits research

on the fetus in utero to be carried out so that information on medicine, drugs, nutrition and environmental stress may affect the life and health of the pregnant woman as well as the fetus may be developed. The report should expressly provide that such research be conceived and conducted to protect the health and other interests of the pregnant woman as well as the fetus in the manner which we have specified herein.

Thank you.

DR. RYAN: Could you respond to one question, and that is, in your conclusion you talk only about the fetus in-utero. Do you have an opinion about research in the living fetus after abortion?

MS. SCHIFFER: My clients have taken no particular position about it. I think the arguments made by the ACLU that the mother is the obvious next of kin to give consent to such procedures is appropriate.

MR. DIXON: I have two questions I would like to ask.

First, in your opinion, would any law which limits research on the fetus, which could have preserved the woman's access to medical care, could you find that unconstitutional.

MS. SCHIFFER: It would also have to keep clear her access to abortion, or the law would be unconstitutional.

MR. DIXON: Secondly, in your discussion of the Supreme Court's decisions in Roe and Doe, since both of those decisions apply, where you are assuming that women as a class have a right to abortion without regard to fetus --

MS. SCHIFFER: I am sorry?

MR. DIXON: Do you think that the Supreme Court's decisions, Roe and Doe, imply, on the other hand, that women as a class have a right to abortion?

MS. SCHIFFER: In other words, can the woman be a subject of experimentation? I think the Roe and Doe decisions don't speak to this.

MR. LOUISELL: In connection with your statement on page 3, under your second principal point, "Therefore, even if an experimental drug or therapy may adversely affect the fetus in utero, if it is necessary to save the life or health of the pregnant woman any policy on fetal research must permit her to use that experimental drug or therapy throughout the pregnancy." How do you define "health" for purposes of that?

MS. SCHIFFER: Those are the words the Supreme Court used. I don't purport to construe that here. I think there are some general understandings in the medical community what the health of the mother means. I think the life and health standard has been part of the law of many states long before the Roe and Doe decision, and that term has been applied by many doctors and the courts for some time.

MR. LOUISELL: Then, as I get the implication of that statement, your position really boils down to the fact that the fetus isn't entitled to any consideration in the balancing of the risks of experimentation?

MS. SCHIFFER: I have not said that. I think that certainly, if the research is undertaken in conjunction with a pregnancy termination during the first two trimesters,

it is true pursuant to the Supreme Court's decisions that the interests of the fetus are not to be taken into account. During the third trimester, the interests of the state in protecting the life and health of the mother are clearly paramount to the interests of the fetus. I think, however, that within those constraints that the fetal insterest is certainly one which is recognized by the Supreme Court and can be recognized by this Commission.

MR. LOUISELL: You don't see any way during the first two trimesters of being consistent with the Court's holding in the Roe and Doe cases and stillgiving any account -- taking into account in any way the relative risk to the fetus?

MS. SCHIFFER: Not in connection with research which involves a pregnancy termination. In connection with research which involves a continuation of the pregnancy, that is not covered by my statement and I think some interest could be given to the fetus there. We would urge you not to use language of giving personhood to the fetus which would cut back on the Doe and Roe decisions.

MR. LOUISELL: Does your stand take into account a changed decision on the part of a woman who agreed to an induced abortion?

MS. SCHIFFER: My clients, as I said in my statement, have limited themselves to research involved at the time of the pregnancy termination, so the changed decision

would not come into play. For myself, it seems to me this is possibly an issue which we don't know very much about and a possible solution might be to permit a woman to make a decision, undergo research in connection with a proposed pregnancy termination, for some limited period of time before, and just see if this change of mind occurs empirically. And this Commission could make at that time a reassessment on the basis of whether these changes in mind occurred.

DR. RYAN: Of course, there is one problem that is troubling us up here. You are asking questions about potential risks to the fetus. The risk to the fetus is to have the abortion done. There may be other perceived activities with respect to the fetus which is of concern to people. But that is a risk that is written within the law so that --

MR. LOUISELL: The ultimate risk is that of the abortion. But even within that ambit, it seems there are other risks. For example, risks of unnecessary infliction of suffering. And the relative risk of the -- what is done to the fetus as the number of witnesses have put it -- as I understand it -- on this basic premise that the problem is the same for children, any born children essentially as it is for the fetus. We have got to take into account all the types of situations that may develop, including that of a changed decision.

DR. RYAN: Mr. Mangel wants to ask a question, but you should bring out that distinction, the risk of having an abortion itself, and then the risk of the other areas that are of concern to you.

MR. LOUISELL: It is extremely important, because for one thing, I am unable at this point to draw this sharp dichotomy between the problem of fetal experimentation and the problem of abortion. It seems to be subsumed in so much of the discussion of the problem.

DR. RYAN: There is one aspect, of course, and that is the research while the fetus in-utero, which you are trying to maintain as a right for a woman?

MS. SCHIFFER: Completely apart from the abortion proceeding?

DR. RYAN: No.

MS. SCHIFFER: No, not unless it was involved in saving the life or health of the woman.

MR. MANGEL: I would like to explore just how binding you feel the decisions in Roe and Doe are, with respect to the considerations of the Commission with regard to quite distinct and different considerations. The implications are clear. But I wonder if it is not possible to read Roe and Doe as not requiring the preclusion that I feel it does. Is it not possible to read Roe and Doe as saying that where a state attempts to regulate a

constitutionally protected right, it must have a compelling interest in doing so, and that in looking at the pre-viable fetus, the Court determined that the state had no such compelling interest in the pre-viable fetus. And if you go along with me so far, that when you turn it around, do you have such an attempt, for instance, by the Government in regulating the kind of research that can be done on a pre-viable fetus, inasmuch as you are not attempting in all cases to regulate the constitutionally protected right that the woman has to an abortion? So that the focus is different, you need such a compelling difference to regulate research on a pre-viable fetus.

MS. SCHIFFER: I understand. I think that certainly the focus is different. I think, however, that insofar as regulation of research cuts back on what the Supreme Court has recognized as constitutionally protectable rights, there must be shown a compelling interest to do it. The Supreme Court has specifically said any interest in the life of a pre-viable fetus is not such a compelling interest. I think that that really is dispositive of the issue on research which is involved at the time before a pregnancy is terminated, or involved with the life or health of the mother. If you are talking about research which will not result in a pregnancy--undertaken in a context which will not result in a pregnancy termination, leaving aside the life and

health of the mother, then I think it is right. The context in which the Supreme Court decision is phrased does not go to that issue.

MR. MANGEL: Suppose the state decided it was bad, it didn't want to support the research?

MS. SCHIFFER: If the state said that, they would not need the same kind of compelling justification required in regulating a woman's right to an abortion? Roe and Doe don't say there must be field research.

DR. RYAN: Dr. Cooke has one compelling question.

DR. COOKE: Dr. Lebacqz referred earlier to the issue of experimentation with the abortion procedure. And you addressed yourself specifically to that on page 5 of your statement. I would like to ask this question: In the study of the abortion procedure techniques, et cetera, one of the possible outcomes of such experimentation is what I would call infective abortion, namely, the non-death of the fetus with subsequent birth with defect. Should there be opportunity for claims against the mother, claims against the doctor, claims by the father against the mother, and should there be damages provided in coverage for damages for such experimentation in light of that possibility?

MS. SCHIFFER: To my knowledge insofar as those cases have arisen and have been considered by the courts, there has not been success in suits against the doctor.

MS. SCHIFFER: I think that careful medical procedure should be used, that the normal practice kinds of considerations--

DR. COOKE: These are experimental techniques. I am taking issue with you on the question of new procedures for inducing abortions. Experiments.

MS. SCHIFFER: I think that the way that human experimentation has been conducted in the past is to use appropriate informed consent procedures, and to rely on those procedures. People know they are being subjected to experiments. They should know, if the informed consent is being administered properly, that there is some risk involved. That is then assumed by the person who undergoes the procedure.

DR. COOKE: The fetus is the one having the risk in this instance.

MS. SCHIFFER: Not if there is a pregnancy termination within the limitations of the Supreme Court decision of Doe and Roe, then that is not a valid or constitutional consideration to be taken into account.

DR. RYAN: If I can address that, because it is an area involved in obstetrics, one of the prime examples are the so-called interreceptives, the medication taken within the first five days of possible conception. And the interest there is to protect the fetus and the patient and

the state, depending on whose interests one is looking at, that should abortion not -- should pregnancy eventuate, even though an attempt was made to prevent it, other means of abortion would be used. All of this in the pre-viable period. So many of the questions that you ask could be addressed with respect to timing of the abortion and appropriate back-up safeguards. That is what is done with all abortion research now. Research into the abortion procedure.

DR. LEBACQZ: I don't believe that was speaking to the way I understood Dr. Cooke's question.

I did notice also in your testimony on page 4, under you. fourth point, that you speak about paternal or spousal consent as serving no legitimate interest of a father or husband in the health and well being of the child since there will be no child. I think the question that is being asked now is, suppose a woman consents to an experimental pregnancy termination procedure which in fact results in a living child, rather than resulting in the death of an aborted fetus?

MS. SCHIFFER: I don't think the situation is any different than if the woman were being subjected to what would be regarded as a non-experimental abortion procedure. It would be the same consideration s that were applied. It is my understanding under the laws -- it is clear under

the laws at present that neither spousal or paternal consent can be legally required in a non experimental context. When one is talking about experimental methods of abortion, I think that it is true that efficacy, whether it will produce an abortion or not, is one factor of the experimental method. But as has been pointed out, there are back-up methods. If the woman has made a determination to go forward under an experimental method, she can then terminate the pregnancy by another means.

DR. LEBACQZ: The question is not whether the attempt to terminate pregnancy fails, but whether the attempt results in a dead or a living viable fetus. Once a fetus has been delivered from the mother's body if it is in fact viable and living, then it doesn't do any good to talk about back-up abortion procedures. The abortion has been successful in that it has expelled the fetus.

MS. SCHIFFER: The same considerations would apply as are presently applicable under non-experimental methods. Presently the consent of the father or the spouse is not a legitimate consideration.

DR. RYAN: I perhaps can help you. The only safeguard is with the timing with respect to experimental procedures. And that timing would clearly be countervened in many existing or soon to exist state laws with respect to viability.

MR. LOUISELL: Have we gotten to the heart of the problem? Suppose the child is born with a serious defect, like a missing arm as a result of the earlier attempted abortion procedure and he continues to live with this disability?

DR. RYAN: Right. This has happened.

MR. LOUISELL: Who, if anybody, is responsible for that abnormal state of physical disability?

DR. RYAN: Yes. I am not sure that this Commission sitting around this table talking to our witnesses today are going to be able to resolve that question.

DR. COOKE: That is one of the questions we have to address ourselves to, whether or not the subjects of experimental research should be protected and whether there should be compensation and so forth. I am raising the question with regard to the fetus.

DR. LOWE: That is a departmental concern, but not a charge.

DR. RYAN: Thank you very much.

MS. SCHIFFER: Thank you.

DR. RYAN: Unfortunately, Dr. Aubrey Milunsky, who was to present at this time has suffered an injury and will not be here. The person who was supposed to speak in his behalf was in an auto accident this morning and will not be here this morning either.

So we will go on to the next speaker, Kay Katz, from the National Tay-Sachs Foundation. If you will give us a minute to identify your testimony.

Please proceed.

MRS. KATZ: Doctor Ryan and Members of the Commission, I would like to introduce myself and thank you for the opportunity to testify in opposition to proposals intended to outlaw fetal research in the United States.

My name is Kay Jacobs Katz, and I reside in Silver Spring, Maryland. I am the mother of a child who has died of Tay-Sachs disease. I appear heretoday to express my personal beliefs and to represent the National Capital Tay-Sachs Foundation, an organization committed to public education, cure research, health care, and prevention of Tay-Sachs disease and its allied disorders.

These genetic diseases, known as sphigolipidoses or lipid storage diseases, are characterized by inborn errors of lipid metabolism. In each disease an enzyme necessary for normal human function is either deficient or inactive. In Tay-Sachs disease the crucial enzyme is hexosaminidase-A, the lack of which results in neurological deterioration and early death.

It is estimated that one in every 30 American Jews of Eastern European ancestry is a carrier of this trait. A carrier is totally unaffected by the disease, but a blood

test can determine that the amount of activity of "hex-A" is somewhat less than that of most individuals. Statistically, one in every 900 Jewish marriages is between two carriers who are, therefore, capable of producing a child with Tay-Sachs disease. One in every 3600 births to Jewish couples will be afflicted with Tay-Sachs disease, and every child born with this disease will die by the age of five.

I am here to help develop an understanding of the need to preserve the right to amniocentesis when a fetus is at risk for having Tay-Sachs disease or a comparable disorder. There are a great many people who wish to deny potential parents of infants with fatal genetic disorders the option to diagnose in utero affected pregnancies. However, once a doomed baby is born, these same people who insist on his birth disappear, leaving total responsibility to his parents. Besides the heartbreak, mental anguish, and, quite frankly, physical burden that the parents must endure, there is the problem of finding willing or qualified people to help in caring for such a child.

In most cases the families seek out institutionalization at some point because of increasing medical problems or simply overwhelming demands on the parents' time. Most retardation centers are inappropriate, and hospital care costs are prohibitive. Most insurance companies refuse to cover prolonged hospital care on the basis that it is

custodial care -- even though the medical profession disagrees. Even those insurance companies that do cover a prolonged hospital stay will not cover the cost of a nurse at home, which for many families would be a much more acceptable form of help. For those afflicted families fortunate enough to live in a five county area in Maryland, there is a very progressive state-operated retardation center whose hospital is very satisfactory and whose nursing staff is loving and caring. But to place one's child in even such a fine center is a terribly sad event as it is an admission that one more aspect of normalcy is being stolen from the child's life. I strongly urge every member of this Commission to visit the patients in the Great Oaks Center Hospital Building in Silver Spring, Maryland, and see for yourself exactly whom you will be deciding about.

It all started for us about five years ago when we had our first baby. She was beautiful and, we were assured, healthy and normal. She grew and developed very normally for several months -- or so we were told. There were a few little problems such as a pronounced startle response which she never outgrew, but the doctor reassured us that she was normal. By ten months of age she had begun to grow weak and to lose some of the skills she had learned, and once again I pleaded with the pediatrician to tell me what was wrong. Again, as before, I was put off.

Finally, a couple of weeks prior to her first birthday, he admitted that her development was not progressing normally, and we were referred to a specialist at Children's Hospital here in Washington. We brought Joann home the day before her first birthday with the knowledge that she had Tay-Sachs disease, that the birthday cake placed in front of her the next day would be the only one she would ever see, and that she would no doubt be dead before her fourth birthday.

We made every effort possible for Joann's sake to continue to provide a normal environment for her. As she continued to lose skills and awareness, we adapted our lifestyle and care of her to her needs. I took her for physical therapy and learned the exercise program myself so I could prevent stiffness from taking over her body as she moved about in her crib less and less.

Although we made a valiant attempt to believe that a cure would come along in time to save her life and restore some of her intelligence, each passing week took more and more away from her. So as not to dwell on her deterioration, I will summarize by stating that by the time she died on May 20, 1973,she was a blind invalid, seizuring and drowning in her own secretions, requiring daily enemas, naso-gastric feeding (fed a liquid diet via a tube plunged down the nose into the stomach) and

spending more time in oxygen and on antibiotics than not. These were the very real events we had to stand by and helplessly witness, and when you love someone the way we loved Joann, you would do anything to reverse the insidious process that was taking her away from you, and short of that, anything to prevent its recurrence.

When Joann was diagnosed, we learned that Tay-Sachs disease is an incurable degenerative disease of the nervous system, uniformly fatal by the fifth year of life; beyond all that it is hereditary. Not only was it going to kill my daughter, it would mean that if I were to conceive again there would be a 25 percent chance of any fetus being affected with the disorder.

We also learned that in the case of this particular genetic disease, and a growing number of others, prenatal diagnosis was now possible, and that if the fetus in question were affected, safe, legal termination of the pregnancy was also possible. We had a big decision to make because we desperately wanted more children of our own. After several months of soul-searching, we decided to go ahead and plan a second pregnancy, as I came to the decision that even abortion was better than bringing another Tay-Sachs baby into the world. We had, after all, established a love relationship with Joann before her illness had become apparent. With a subsequent baby we would know from the day

of his birth of his impending death and could never give him the same loving kind of care we gave Joann and feel we owe our children. At some point the instinct of self-preservation forces one to protect himself from pain.

All this information is really background material to help you understand why we feel so strongly that by depriving couples like us of the option of having children unaffected by such serious and hopeless disorders, you are really depriving us of having children at all. Most of us would simply not be foolhardy enough to knowingly risk a pregnancy without this alternative. We now have a healthy, normal three year old son, and six month old daughter. If fetal research is permanently banned, I will be one of the lucky few who had the freedom to have such a family in the few short years while the medical and scientific capability was available and legal.

As soon as we learned of its existence, we joined the National Capital Tay-Sachs Foundation which was composed of parents whose children were dying or had died of Tay-Sachs disease. Until shortly before our entry into the group, its main purpose had been one of mutual moral support for the parents, but it had just become involved in planning, supporting, and executing the first community screening for a genetic disease, which took place on May 2, 1971, in Bethesda, Maryland. For the first time it was theoretically possible for a carrier couple of a genetic disease to

selectively have a normal family of its own without first suffering the heartbreak of having a baby afflicted with the disorder. If you think this idea was not popular, you are mistaken. Over 1300 people came to roll up their sleeves and have a sample of their blood drawn in order to avoid personal tragedy.

These voluntary testings have continued under the auspices of Johns Hopkins Hospital, and they are held about twice a year in the D.C. area. Each couple needs an appointment for the test, and they are given preliminary information over the phone. We try to make certain that everyone who comes to be tested understands what the test is for, and what the results will mean. At the testing center, genetic counselling is available. This plan has been copied in major metropolitan areas all over the United States, and in other countries as well.

Tay-Sachs is only one of a number of related disorders; it is also the most common. For parents of children suffering with some of the allied diseases, there is as yet no prenatal diagnosis, and these couples are hopeful that medical research will find the means to make it available so they too may have children with a fair chance of survival. It is these families that a ban on fetal research will be punishing more than anyone else, as it will force them to give up hope of having more children.

The suggestion has been made that two known carriers simply not marry each other. This idea rings of the same simplistic reasoning that I have heard again and agin in anti-abortion thinking. This is not the beginning of time; marriages between carriers already exist. My husband and I are an example of this. Would it suit society's needs better if we dissolve our marriage to avoid having children together? Not only is the argument simplistic, it is fallacious. A couple who decides against marriage because they share one of 2,000 currently identifiable lethal genes might separately marry someone else with whom they share the potential for some other genetic disease in their offspring as it is a well-established medical fact that each of us carries between five and ten such traits. This idea is unreasonable as well because the law would then be denying individuals a very basic human right in our society -- the right to marry the person of one's choice. Once again we confront the conflict of exactly whose rights are to be protected, those of the fetus or those of the couple who conceived it.

Were prenatal diagnosis and safe, legal abortions unavilable, we would once again be caught in a vacuum offering few alternatives. We do not believe that amniocentesis and abortion are the final answer; we would prefer it if the odds were better, if therapy were available, or

best yet if our sick children could be made well. Because of this, my husband and I with the help and support of family and friends, have established the Joann Katz Foundation for Neuroscientific Research and Education to keep cure research alive, however successful therapy may never be possible without continued fetal research.

It would seem also that calling a halt to fetal research would force us to undergo sterilization because no means of contraception is totally effective for everyone, and we wish to avoid having doomed children. If we are faithfully practicing birth control, and our method fails us, we are then forced to bring a child into the world whose life and death will break our hearts, or forced, as in earlier days, to terminate all pregnancies, not just the affected ones, as there would be no way to differentiate between them. As Dr. John Fletcher, Associate Editor of the Encyclopedia of Bioethics, has stated, "Those who are in favor of banning fetal research will cause more abortions than would otherwise occur."

The decision to attempt a second pregnancy and utilize amniocentesis was a difficult one for me. Please understand that what we wanted was not an abortion, but a viable baby. Difficult though the decision may be I demand the right to make that decision for myself, and I want that right preserved for others. I refuse to sit idly by and

watch pressure groups exert their influence on my government to erode my rights as an American citizen, and I implore you and your colleagues to reject these efforts in favor of the individual freedom upon which our society is based.

I would like to read you a letter written to the editor of the Washington Post by a mother of a child with Down's Syndrome. The author's name is Marilyn Trainer.

"Amidst the often strident voices of the anti-abortionists there are other quieter voices which must be heard. These are the voices of those who speak for the genetically afflicted for whom medical research -- including fetal research -- offers the only hope for the future. If certain fringe elements of the anti-abortion groups have their way, there will be no more fetal research, no more hope.

"It is incredible to us that there are those who are actually making a concerted effort to take this hope away. In attempting to limit fetal research these zealots are jeopardizing chances of finding possible ameliorative treatment for many victims of genetic disorders.

"We believe that study of the fetus/embryo and fetal/embryonic material is absolutely essential if the ultimate cause of genetic afflictions such as Down's Syndrome or Tay-Sachs Disease, for example, is ever to be found. To

prohibit such study seems to us an attack on every family who has had or will ever have a defective child born to them. While it may be too late for our own children, research may help thousands like them yet unborn -- provided such research is not thwarted.

"Among those anti-abortionists on Capital Hill recently were many parochial school children bused in as part of the body count. Seeing those nice, normal-looking kids, we couldn't help but wonder how many of them had been immunized against polio, measles, and German measles? Immunization against these diseases is the result of original studies with human embryonic tissues. (New England Journal of Medicine, May 23, 1974.)

"But there was no one marching that day to stop the immunizations those kids were benefitting from.

"Amniocentesis now makes it possible for those of us who have had a defective child to know whether ensuing pregnancies will result in another such child, or a longed-for normal child. We who live with the problems of raising an afflicted child feel that it is our inalienable right to choose whether or not we will take on a second or third, et cetera, responsibility. No groups nor individuals -- none -- have the right to impose their convictions on us in this matter, for we are the ones who must live with it day by day.

"If those in Congress should vote to limit fetal

research, including amniocentesis as some are urging, they will then be dealing a triple blow to families like ours. First, they will be reducing the chances to improve the lives of our genetically afflicted children already born.

Second, they will be limiting chances for finding the cause of these afflictions.

Third, they will be forcing families to risk bringing more such children into the world, or rather than edure that risk, forego the joy of having a normal child.

"It is our earnest plea that Congress will not be misguided by those who surely know not what they do, not only to the research they would destroy but to those families for whom such research is a lifeline of hope."

The fact that my oldest child had Tay-Sachs disease is important, but this was something over which we had no control. What is equally important, however, is that my two subsequent children are not so afflicted. The fact that they are not ill is also a matter over which we had no control, But the fact that they are alive at all is due to fetal research done in the recent past. Because, without prenatal diagnosis made possible by fetal research, we would never have had the courage to attempt another child.

This testimony has been endorsed by the National Tay-Sachs and Allied Diseases Association.

Thank you.

DR. RYAN: Any questions?

MRS. KATZ: If there are no questions, I might just mention something that has happened in the last couple of days while I was busy preparing this. My husband took a phone call that came from a couple to our home. They are strangers to us, but they received our name from one of the doctors we worked with. They have a three year old son with cystic fibrosis. They have subsequently aborted a pregnancy, not knowing whether or not that fetus would be afflicted. And I know that certain people are on the verge and are saying that it is quite possible to diagnose cystic fibrosis in utero However, this is not an established procedure right now. And it can't be done because of the ban. This family is in fact being deprived of having children because of this ban.

DR. RYAN: Thank you very much.

The next presentation is the American Society for Experimental Pathology, Dr. Arthur Silverstein.

Will you allow us a minute while we be sure we have your testimony?

Please address yourself to the question of fetal research.

Dr. Silverstein read his prepared statement which follows:

Mr. Chairman and Members of the Commission:

I am Dr. Arthur M. Silverstein, Professor of Ophthalmic Immunology at The Johns Hopkins University School of Medicine. I am an immunologist and experimental pathologist, and have been engaged for the past fifteen years in experimental animal studies on normal and abnormal fetal development and its implications for human congenital infectious disease processes. I speak today on behalf of the American Society for Experimental Pathology, an organization of some 1300 pathologists and other biomedical scientists. I am grateful for the opportunity to appear before this Commission to speak for the importance and continuing need for a rational program of fetal research, and of the contributions that such a program can make to the present and future health needs of this country.

The fetus is unique in many biological respects. During the period of its rapid intrauterine growth, it is susceptible to the deleterious effects of many drugs and infectious agents that do not harm the adult. It manifests almost uniquely in its rapidly differentiating tissues a number of genetic and metabolic patterns, the elucidation of which will be critically important to our understanding not only of the nature of certain diseases, but indeed of the nature of health itself. Finally, fetal tissues--and only fetal tissues--can be used for certain experimental purposes. For example, rapidly growing fetal tissues provide a better model for cancer growth than does any other normal tissue, and permit a wide variety of studies on growth rate and growth regulation so important in understanding what distinguishes a tumor cell from a normal cell.

One may validly ask why all fetal research cannot be performed upon experimental animals. The answer to this is quite simple: much useful information

can be obtained from animal models, and the expansion of support in this area should be encouraged. However, the human fetus is not exactly like any other animal fetus. Its placental relationship to its mother and many of its physiologic and endocrinologic processes are different from those of most other animals, and it suffers from a number of diseases peculiar to the human. Thus, animal data can only take us so far before their applicability to the human situation must be tested. A good example of the importance of the availability of human fetal tissue lies in the growth of poliomyelitis virus for vaccine purposes. This virus grows best in fetal tissues. Initially, fetal monkey tissues were employed for this purpose, until it was learned that most of these tissues were contaminated with the ubiquitous Simian Virus 40, which is known to transform human cells to tumors, and should certainly not be introduced into humans. It was important, therefore, to switch production of the vaccine virus to human fetal tissue cultures which were not contaminated with this viral impurity.

In discussing experimental work using tissues from the dead fetus, we may consider together the specimens derived from spontaneous abortions and those from elective abortions. (We must rigidly separate here the question of the moral decision on abortion from the diagnostic or research uses to which the resultant tissues are put; society will presumably define the legal and ethical questions involved, and biomedical science will assuredly operate within these rules.)

It is important that biomedical science not be deprived of the opportunity to study the tissues of dead abortuses. Just as society accepts the use of cornea, kidney, or heart transplants derived from a human cadaver, or the use of cadaver tissues for pathological diagnosis or for other purposes, so it should not be

unwilling to permit analogous fetal cadaver tissue to be used for similar purposes. Let me give you several examples of how these tissues are used, and of the importance of continuing their availability. Most spontaneous abortuses, because of the varying states of deterioration of the tissues, are useful only for chromosomal studies. It is estimated that 10% of all pregnancies end in spontaneous abortion, mostly during the first trimester. Of these, some 40% prove to be chromosomally abnormal and could not survive. This is nature's way of getting rid of chance reproductive errors. But think how important it is to permit study of these fetuses, since the detection of some of these sporadic chromosomal abnormalities can serve to reassure the parents that the abortion was accidental and "not their fault", so that they may feel free to have other children. These and other important statistics on chromosomal abnormalities would not have been known without fetal research.

It is even more important to maintain the availability (again under reasonable legal safeguards) of the fresher fetal materials obtainable at elective abortion. Such tissues can be used in culture to study the special susceptibilities of fetal tissues to the harmful effects of certain drugs, to study normal cell regulatory mechanisms such as growth and differentiation, the mode of enzyme action, hemoglobin formation, etc., whose understanding will have future importance in disease therapy. Further, certain fetal tissues such as the thymus are uniquely suitable for transplantation, as a replacement therapy for certain human diseases. An example of this is the recent success experienced in the reconstitution with fetal thymus of immunologic activity in several children suffering from the immunologic impairment due to defects in the development of

I mentioned above that drug research might be carried out on the living fetus, and this may sound somewhat sinister. But my other comment should be remembered also: that certain drugs which are harmless or beneficial to the adult may be extremely toxic to the fetus. I can best illustrate this with the example of a research project carried on some fifteen years ago. Where there is premature rupture of the fetal membranes, there is always the danger of fetal infection. It had always been a matter of faith that the antibiotic chloramphenicol, so useful in adult infections, was equally useful in combating fetal infection following premature rupture. A controlled study was performed, in which one group of newborns got chloramphenicol, and another group was not given this antibiotic. The results of the study demonstrated a far greater mortality in those getting chloramphenicol than in those not getting the drug. This research showed conclusively that while chloramphenicol might be valuable in the treatment of adult infections, it was extremely toxic to the developing infant and should not be used. Only by studies of this type will it be possible to find out what is safe to use in the fetus, and only this type of research will prevent our making tragic errors in applying to the fetus inapplicable data derived from the adult, or from animal studies.

It is for the reasons cited above among many others, Mr. Chairman, that I appeal to this Commission to recognize the continuing importance of fetal research, and the fact that not only biomedical science but society in general owes to the developing human fetus a recognition of the special problems arising from its biological uniqueness. Only through the type of research described above will we be able to solve these problems and do justice to the special medical problems of the fetus.

Thank you.

DR. RYAN: Thank you, Dr. Silverstein.

Are there any questions from the Staff? Commission Members?

DR. JONSEN: Dr. Silverstein, on page 3 of your testimony you indicate that a study is being done in fetal materials, being done by elective abortion. What is your opinion about the use of abortuses whose life is artificially sustained for such studies as these? The necessity or the utility of studies of that sort?

DR. SILVERSTEIN: I have not addressed that question in my testimony. I would say the following: that there are, from the scientific point of view, certain studies that could be done more effectively, where much more compelling evidence could be obtained in answer to whatever the questions are that are asked.

However, I personally would not be in favor of that. If one is talking about the delivered, still beating fetus.

DR. JONSEN: Thank you, Doctor.

MR. LOUISELL: Doctor, on page 2 you make the statement parenthetically, "We must rigidly separate here the question of the moral decision on abortion from the diagnostic or research uses to which the resultant tissues are put;" I think I uncerstance the sense in which you may mean that, but it seems to me there is some ambiguity there.

You would not argue, as a scientist, that society should encourage completely permissive abortion because thereby you obtain more material for scientific reseatch? You would not argue that?

DR. SILVERSTEIN: Absolutely not.

MR. LOUISELL: That would be like arguing we should favor capital punishment because it increases the cadavers available for inspection. You would not mean that.

DR. SILVERSTEIN: No.

MR. LOUISELL: What exactly do you mean by that statement? Do you mean we perform our judgment, society does, on the legitimacy of induced abortion, and then as a consequence of that decision we have some additional tissue available for scientific purposes?

DR. SILVERSTEIN: I don't think the decision on abortion entered the question of fetal research. Not exactly and directly. I think the decision on abortion is one for which the society will set up the legal and ethical rules, and is in fact in the process of doing this,

And I argue that those decisions, the moral and ethical and legal decisions on whether or not there should be abortion, what the timing shall be, and when life begins or ends, is not the issue here. That those are decision that will be made apart. The issue here is that given a society which

permits abortion, for whatever reason, , will the research scientist be permitted access to the tissue, and under what rules? I am suggesting society will make whatever rules required,

And then biomedical science will operate from there.

MR. LOUISELL: Isn't it possible that after increasing obtainability of abortuses, induced abortuses, that the research community will get a vested interest in this that may then have sort of an overstill into the societal judgment on legitimacy of induced abortions?

DR. SILVERSTEIN: I can only answer the question this way, sir: I don't know the number of people working in the field, but I can assure you right now, given that I understand to be the number of abortions going on in this country, the number of workers operating in the field of fetal research that might avail themselves of these tissues, that there is more than enough to go around. And I couldn't conceive the vested interests would call for more abortions. I can point out because of the moratorium today and the problems imposed or belived rightly or wrongly to exist, good medical scientists who are doing important work are not able to get the tissues they need to do that work.

MR. LOUISELL: Isn't there enough material from spontaneou abortions?

MR. SILVERSTEIN: Spontaneous abortions in general are not suitable for this because they come out with varying degrees of reservation. It is impossible often even to get a chromosomal analysis. It is rare that the tissues will be suitable.

MR. LOUISELL: So in this sense it can hardly be disputed, can it, that there is a vested research interest in the procurement of induced abortions?

DR. RYAN: Doctor Louisell, what did you ask him?

MR. LOUISELL: Isn't it really to be conceded that under this approach there is a vested research interest in the availability of induced abortions?

DR. RYAN: Are you stating that as an opinion or asking a question?

MR. LOUISELL: I am asking.

DR. SILVERSTEIN: There are vested interests in this world. Dentists could be accused of having vested interests in eating candy. I don't think this is a fair approach to take up with the researchers.

MR. LOUISELL: Prior to the day of your modern almost current complete freedom of abortion decision, were spontaneous abortuses used for research purposes?

DR. SILVERSTEIN: No, sir. Well, they are occasionally under certain very special conditions, but prior

to the time when abortions were permitted in this country, most of the signigicant fetal research was done in Sweden and elsewhere.

MR. LOUISELL: So it is the fact of induced abortion that has made available these additional research projects?

DR. RYAN: Dr. Silverstein, would you respond to that?

DR. SILVERSTEIN: I think that is fair.

DR. STELLAR: I would like to make a historical appeal to Dr. Louisell, I think we have learned how to live with the use of cadavers in the education of medical students without resorting to murder to produce them. Although this was done at an earlier point in history, before we learned to live with this. Grave robbins and other unsavory means of producing cadavers is something that the human being is capable of. Fortunately our society has succeeded in regulating it very well.

I think basically in my estimation you are discussing the same issue in asking the question of whether we will be tempted to produce abortions in order to do research that requires the live abortus. I think that we have the capability of managing that issue just as we did in the case of cadavers.

DR. RYAN: It should also be recorded as a matter of history that the thrust for freer abortions didn't come

out of the research establishment. It came out of women who were obtaining abortions illegally with a high death rate to the women having the abortions. Those fetuses were not undergoing any research. If that is of any consolation.

DR. LOUISELL: I don't think it is of any relevance.

DR. LEBACQZ: I appreciate your careful exposition, particularly for those of us without medical backgrounds. I find myself feeling a bit frustrated because it seems to me you, like several others, have spoken largely to the question of goals or end of fetal research. That research will be helpful in providing therapy. Many of us might well adopt those same goals, but might want to make some question about alternative means available to achieve those goals.

I wonder if you have any guidance for us with regard to different means, different kinds of research, whether you set limits on certain kinds of research, and so on?

DR. SILVERSTEIN: Well, I think I must answer that I lack the competence to speak to other than the question of the research goals and what one would like to accomplish if one is permitted to have access to fetal materials and fetuses under certain carefully prescibed conditions.

I would say, as I said in my testimony, that I think that the Government ought to further support and encourage fetal research in experimental animals. Certainly many of the ideas, many of the preliminary approaches, can best be obtained in them. But, as I point out also, there are certain questions that can only be asked and answered in the human fetus. I think there are certain restrictions that ought to be put on fetal research. But I am not sure that they are other than the restrictions that a moral and ethical and I hate to use the term, proper kind of society would want to see put on any form of research, any human research, even what is put on the animal research.

What I am trying to say is there is nothing special about the fetus, except its biological problems. It is these we are concerned with.

DR. RYAN: I would like to close up the morning session in a few minutes. But we have two other Commissioners that would like to address questions to you. If you could try to keep your exchanges brief. First Mr. Turtle and then Dr. Cooke.

DR. TURTLE: Going back to the point you make, there are certain researches that can only be carried out on human fetuses is a very compelling point. They you continue with an example that says rapidly growing fetal tissues provide a better model for cancer growth than any other

normal tissue. We expect it is better in terms of degree, or are you telling us it is absolutely impossible to carry out the same type of research without using the fetal tissues?

Another example of that, on the second page, you tell us animal data can only take us so far and we have to use human fetal tissue in connection with the growth of polio virus. You say this virus grows best in fetal tissues. Is it a matter of best, or is it really impossible?

DR. SILVERSTEIN: One has to ask a specific question. This is a general question which has many answers. It would be possible to grow polio viruses in monkey tissues if they are developed in a very elaborate condition to make sure they were pure. It would be possible to grow SV virus, which may have tremendous importance in the understanding of a number of human diseases. It may be possible one will ultimately find another tissue in which to grow the virus. But thus far it can only be grown in primary liver cultures from a human fetus. The only way to know about the virus is to study it. For that, one needs a human fetus.

There are other instances in which I think a substitute for the human fetus could be found. But it is a spectrum at the one end which you don't need a human fetus, and at the other end you must have a human fetus.

DR. TURTLE: The cancer growth example you gave

us, would that fall at one end or the other? You seem to indicate you could grow that in other tissues, other than fetal tissues. I am concerned about -- I hear the statement over and over again that there are certain research items that can only be accomplished with fetus tissues. The very examples you give seem to be examples where you concede it is merely a better approach at the present time. How do you make that distinction?

DR. SILVERSTEIN: We don't even know enough yet to be able to answer your question about making a distinction. The only way we will find out is to find out. That is the way science works, unfortunately.

DR. RYAN: Dr. Cooke, please.

DR. COOKE: I would like to return to Dr. Louisell's problem. That is, the problem of vested interest in the researcher. Would it be helpful from your point of view, if there was a distinct separation of the researcher from the decisionmaker regarding the abortion?

DR. SILVERSTEIN: Sure.

DR. COOKE: You feel this would protect the public interest?

DR. SILVERSTEIN: Yes. I must say I don't knof of any researcher that is not divorced from that.

DR. COOKE: I believe that came up in an earlier discussion and there was a different point of view presented

at that time.

DR. RYAN: I think you are referring to Dr. Christian's testimony in which he talked about perhaps the researcher, if I could editorialize, I think we may have been concerned occasionally with the individual who is providing obstetrical care in a clinical research situation concerned perhaps with the health of the mother, in which the investigator might very well also be providing clinical care. Most institutions are concerned about conflict of interest with respect to this.

With respect to the products of abortion, almost everyone would agree that those two events ought to be completely separated. I think Dr. Christian was really talking about the individual caring for the mother and perhaps doing research which might affect the utero but was not espousing the cause of having the clinician and researcher be one and the same in all instances.

I guess he was also sensitive, as I perceived it, that just because someone does occasionally do research, he would be sensitive not to feel that in other circumstances he might be perceived as unfeeling in a situation in which he was conducting research. But there is potential conflict.

I didn't understand the exchange between Dr. Louisell and myself to be a conflict of interest, about the individual case, but whether or not the pressures of fetal

research were creating a number of demands for abortions.

DR. LOUISELL: Apparently all of the witnesses, why are they so reluctant to keep an abortus alive for purposes of further experimentation if, by definition, it is not entitled to any protected rights? Why are they so concerned?

DR. RYAN: You didn't ask them that. Most of them had responded they would not. I wanted to ask the rhetorical question, perhaps of the questioners, we didn't have enough time to ask the witnesses, but how absolute is that conviction? How far could you press that issue? If by doing that form of research, is there anything conceivable that would benefit mankind, for example, which would justify it? Under any circumstances?

I think when you start pushing that extreme and you say in maintaining the pre-viable fetus alive for five days and then stopping experiment you could provide a cure for cancer for all of mankind, would it be worth it? Would it be ethical? I think it is unfair to ask just the rhetorical question, because under the guise of public pressure your people are going to say no.

I was surprised that the unanimity of all the people who testified, that no one would back off and say I hate to make an absolute statement, and that there may be some times, some ways, that this would be justifiable and

would be of such overwhelming benefit to all of mankind that this would serve its need. I don't know that that would ever come to pass.

DR. COOKE: We know that such studies have been done.

DR. RYAN: That have provided that benefit, that you would consider justified?

DR. COOKE: Research of this type.

DR. RYAN: And most people don't like it. What I am trying to point out --

DR. COOKE: Some do.

DR. RYAN: We have not heard testimony to that effect today. But we have not pushed the question to its extreme position, and that is -- and perhaps that will form some of the basis of our deliberation.

I want to thank all of the witnesses for bearing with us and the Commissioners and Staff and say we will reconvene at 2:00 o'clock and continue with our testimony.

(Whereupon, at 12:45 p.m., the meeting was recessed, to reconvene at 2:00 p.m.)

AFTERNOON SESSION

2:05 p.m.

DR. RYAN: I wonder if we could convene the afternoon meeting.

For the Commission Members, the testimony for this afternoon is arranged in order, under your name tag.

If we can come to order, I would like to ask that the Reverend James McHugh from the United States Catholic Conference, please proceed.

* * * * *

Monseigneur McHugh read his prepared statement which follows:

Appearing here today on behalf of the United States Catholic Conference, I welcome this opportunity to add to the continuing discussion concerning research and experimentation on human fetuses and infants.

Research and experimentation on the human fetus must be seen in the context of the U.S. Supreme Court decisions in Roe v. Wade and Doe v. Bolton, in which the Court held that the fetus is not considered a person, and is not entitled to any legal protection during the first six or seven months of pregnancy. The majority opinion of the Court offered no justification for its conclusion--which is essentially a moral judgment--that the fetus is not a person in the whole sense, and "at most, represents only the potentiality of life."

All else aside for the moment, the Court's majority opinion has denigrated the human fetus and reduces it to the status of little more than an experimental animal for the first six or seven months of life in the mother's womb. Although the major concern of these hearings is the establishment of ethical norms governing fetal experimentation, it remains true that attitudes toward abortion overshadow and becloud the discussion of experiments on the fetus. Nonetheless, the fetus is a human being in the earliest stages of human growth and development, and the ethical norms governing experiments on the fetus derive from the basic ethical principles governing experimentation

on all human subjects, especially infants and children.

A second point I wish to make at the outset is that the work of this Commission in regard to fetal experimentation must occasion a fresh reexamination ofand independence from the ongoing efforts of DHEW to establish regulations governing fetal experimentation. Less than two years ago a major official at NIH declared that there was no foreseeable reason why NIH would fund research on live aborted fetuses. But the process of writing, revising and rewriting regulations seems almost calculated to reverse that purported NIH policy. The regulations that have been published thus far have moved toward vagueness rather than precision, virtually assuring that they will have little or no legal effectiveness. For instance, the fetus is defined as "the product of conception from the time of implantation to the time of delivery." But pregnancy is defined as the "time from confirmation of implantation until delivery." Within the same regulations there are two designations as to when fetal life begins.

Thirdly, it seems that this Commission must clarify the existing public misunderstanding as to the nature and purposes of fetal experimentation, and the reasons for some guidelines in this area. In preparation for this hearing, I reviewed some of the press reports on fetal experimentation, particularly those concerning four Boston doctors who are being prosecuted for violating a state law in Massachusetts. The New York Times reported (April 21, 1974) that the doctors were indicted by a grand jury "for illegally dissecting legally

aborted fetuses." The Times' writer described this as "using standard medical techniques . However, the doctors are reported to have given chemicals to the mothers prior to abortion and then dissected the fetuses to measure concentration of the chemicals in the fetus.

There are two questions involved here. First, is such pre-abortion chemical experimentation consistent with human dignity? I contend that it is not, since it involves giving a potentially harmful drug to a living fetus, not for the good of the fetus, but for the experimentation purposes allied to scientific investigations. In most cases, the drug is given while the fetus is living a normal fetal life, which, if uninterrupted, will culminate in the birth of a healthy human infant. Consent by the mother is a mockery, since the mother has presumably already decided to extinguish the life of the fetus. However, such experiments also practically eliminate any possible last-minute change of mind for the mother.

The second question raised by such experiments has to do with the responsibilities that our society has in regard to unborn human life. Does a doctor ever have a responsibility to the unborn fetus? If so, what are the requirements of that responsibility, and when do they cease? Shall we allow the pursuit of scientific information to outweigh the value that society places on unborn human life? Finally, should not experiments on live aborted fetuses be subject to the same ethical and/or legal restrictions applicable to other human cadavers? If not, why not?

The Washington Post reports (January 11, 1975) that Congress has placed a moratorium on fetal research until May 1, 1975. "What members of Congress had in mind," says the Post, "were experiments on living fetuses in mothers about to have abortions, or in the small number of middle pregnancy fetuses that are aborted intact and live for a few moments." But the Post also quotes scientists as interpreting the Congressional ban as prohibiting "amnioscopy" and "fetoscopy." Although these procedures may be utilized experimentally on women scheduled for abortion, there is no consensus that such procedures are purely experimental. Though somewhat risky, they can be justified--and perhaps medically indicated--procedures to protect fetal and maternal health and assure a safe delivery. Clearly, the ethical propriety of these procedures would depend on the reason for which they are used.

At any rate, charges have been made that "the Boston cases" will lead to controls on fetal experimentation and that "curtailing such experimentation now will seriously retard medical progress in many other areas." We contend that there is no proof for this assertion. Moreover, no serious person has called for an absolute ban on all fetal research, but some distinctions must be made and some regulation is necessary and possible.

These cases are instructive because they clearly raise the question of the humanness of the fetus, and the judiciousness of ethical and/or legal restraint on experiments on the fetus.

First of all, the humanness of the fetus is assumed by all concerned about fetal research, and the basic reasons given for any experiments on fetuses and infants are: (1) to gain knowledge about the development of the fetus during pregnancy so as to insure a safe birth and healthy childhood, and (2) to broaden our informational base concerning human genetics so as to discover the causes and possible cures for genetic diseases. No doubt the objectives of most researchers are good, i.e., the elimination or treatment of disease. However, the good intention does not resolve the problem, and thus the need for discussion of the methods used, i.e., the specific experiments. A simple utilitarian calculus is not sufficient.

The second issue is the judiciousness of ethical or legal restraint on fetal experiments. Here we are in the area of public policy decision-making. Up until the last few years, there were virtually no laws regulating fetal experiments. With the escalation of the abortion debate and the increased scientific and technological competence in dealing with the unborn, a need for some type of regulation became apparent. One of the best examples of this was the effort in Massachusetts to write a law regulating fetal research. This effort, described in Science magazine (24 January 1975 and 7 February 1975) showed that legislators and scientists could work out a law that respected fetal life and legitimate scientific investigation. However, fetal experimentation has been taking place, and there has been no effort to pry into the research of or police the efforts of scientists. Even

the Boston case affecting the four doctors resulted from an article they published in a scientific journal.

It is entirely appropriate that governmental agencies examine the ethical implications of the use of public funds. The debate within HEW has centered not on the ethical propriety of fetal research, but on the criteria under which NIH would fund such research. The government is responsible for protecting human rights as well as maintaining a social system that respects individual liberties. When there is a conflict, the minimal role of law is to protect human rights, even if some personal liberties are restrained. Moreover, the government serves the people by safeguarding society from the possible harm that may be inflicted by an individual or group of individuals. Again, law is a teacher, and it has the capacity to direct the energies of society in socially constructive efforts. On the other hand, silence or inaction on the part of government can readily be regarded as tacit consent, endorsement or approval of what an individual or group may feel is appropriate in a particular case.

Thus, government funding of experiments on aborted fetuses and infants constitutes something of approval and encouragement of experiments which place the fetus or infant in the category of experimental specimen. The issue is not simply the right or wrong of fetal experimentation--an ethical problem that exists regardless of federal funding--but rather the

responsibility of government to encourage respect for human life, even when the unborn child or aborted infant has been rejected by its parents. The government must not accede to those who say that since a woman has decided on having an abortion, the fetus is of no value but to be experimented on, or the life of the aborted child is of diminished value and need not be sustained. Granting that some information may be gained by such experiments, the far-reaching implications are too great for government to abandon its responsibility to impose some restrictions.

Therefore, the first responsibility of government is to act as the guardian of every fetus from conception on. This is the basis for good maternal and child health care. It is the basis for developing alternatives to abortion. Thus, when the mother decides on an abortion, the government, through appropriate structures of guardianship, shall insure that no experiments take place on the fetus prior to the abortion, unless such experiments are to insure the survival of the fetus. Moreover, such a guardianship system would also provide consent for the use of therapeutic procedures--even those which are deemed experimental--to assist the living aborted infant to maintain life and health with a view to survival.

There are also other supportive reasons for a government policy of restriction rather than of encouragement or permissiveness. First of all, there is a tendency to overestimate the projected results of fetal experiments. Yet, much of the knowledge that is to be gained by experiments on

the fetus or infant can also be gained by animal research. It may be more expensive and more demanding, but where the choice exists, animals should be used instead of fetuses or infants. There do not seem to be any genetic diseases where experimentation on live fetuses is required in order to continue present research efforts. Before proceeding then, we need much more specific scientific information as to what is possible and what are the attendant risks and dangers.

Secondly, much of the information needed to overcome genetic diseases is gained by sampling the amniotic fluid, not from fetal research. The basic research data in the efforts to overcome sickle-cell anemia and Tay-Sachs disease was accumulated prior to the recent use of the live fetus as a research specimen. Moreover, the presence of Tay-Sachs disease can be detected by sampling the amniotic fluid.

There is a serious question among specialists as to whether any serious gains can be achieved by widespread experimentation on aborted fetuses. Dr. James Miller, professor of pediatrics at the University of British Columbia, maintains that very little can be gained from general experimentation on therapeutically aborted fetuses. Dr. Kurt Hirshhorn of Mt. Sinai Hospital in New York agrees that therapeutic abortions do not yield much valid information. In April, 1973, Dr. Robert Berliner, NIH Deputy Director for Science, stated that "NIH does not now support research on live aborted human fetuses and does not contemplate approving the support of such

research. We know of no circumstances at present or in the foreseeable future which would justify NIH support of research on live aborted human fetuses."

Fourthly, a basic requisite for any experiment is the informed consent of the patient. That is impossible in cases of experiments on the aborted fetus or infant, because the fetus cannot consent and the mother has already decided on the death of the fetus. Thus, some system of guardianship, along the lines outlined above, is necessary to satisfy the requirement of informed consent for the fetus.

There is certainly a need for considerably more dispassionate discussion then has taken place up till now. We are told that fetal experimentation is necessary to save children's lives, to gain scientific knowledge, to overcome genetic disease. These generalizations must be tested and proven before any effective dialogue can take place. Moreover, even when the individual assertion can be proven to some degree, it is often basically a utilitarian argument. If experimentation on the fetus is justified to gain knowledge or overcome genetic disease for others, then the same principle can be applied to experiments on other human beings, sick or well, old or young, dying or growing better, abandoned or rejected by others.

Granting that much more attention must be given to what is meant by fetal experimentation, what can reasonably be expected in terms of results and dangers, how some consent system can be fairly arrived at, and what

are the long-range implications of federal funding of fetal experiments, we submit the following as basic principles to guide the ongoing discussion.

1. Experimentation on the unborn fetus in the womb of its mother is to be prohibited unless such experimentation is necessary to insure the survival of the fetus or insure its health and well being after birth.

2. All experiments and procedures on the fetus that survives an abortion are to be prohibited unless such actions are directed toward preserving the life of the fetus. This allows the use of techniques to save the fetus even though the chances of success are slim.

3. All experiments on the fetus, prior to or in the process of abortion are also to be prohibited. The rules of informed consent for human experimentation apply here, and the fetus cannot give consent. Moreover, the consent of the mother, who has already decided to end the life of her yet unborn offspring, cannot be accepted as a fair or just decision on behalf of the unborn.

4. Experiments on the fetus prior to abortion that are to be completed after the abortion and death of the fetus are also to be prohibited. Once again, the unborn child cannot consent, nor can anyone else presumptively consent in his or her behalf.

5. There should be a general predisposition against experiments on dead fetuses after abortion. However, some distinctions must be made:

a) Experiments on the stillborn child or spontaneously aborted fetus are permitted to determine the cause of death or spontaneous abortion and to insure survival of other infants. The norms apply here as would apply to an autopsy of an adult.

b) Experiments on dead fetuses that are purely speculative and are performed simply to describe the human organs to scientists or medical students should be prohibited. The type of experiment considered here would be surgical exploration of organs, measured reactions to drugs, etc. The knowledge gained in this type of experiment can be gained from animal studies or from other cadavers. The reason for a more severe limitation of such experiments on dead fetuses is that in light of the value judgment reached by the U.S. Supreme Court in Wade and Bolton, the human fetus can too easily be reduced to the status of an experimental animal. Government should not allow this to happen.

c) Specific experiments directed toward the elimination of a particular disease, may be permitted on the dead fetus, e.g., tissue culture. In such a case, the intended purpose of the experiment should be carefully spelled out, there should be

reasonable hope that specific scientific information that is otherwise unavailable will be obtained, and no other experiments may be carried out. Consent of the parents should be obtained. Once the scientific hypothesis is verified satisfactorily, such experiments should no longer be permitted.

d) The physician who performs the abortion should never be allowed to perform or participate in the experiments on a dead fetus.

In conclusion, the preponderant scientific evidence establishes that the fetus is a living human being in its mother's womb, and often continues to live for at least a short time after certain abortion techniques such as hysterotomy. This procedure is the one usually employed when preservation of the fetus for experimentation is anticipated. However, we cannot allow a dedication to scientific inquiry to blind us to the reality of existing human life, nor can we justify denying the unborn child the rights and dignified treatment accorded other human beings simply for utilitarian reasons. The observation of the NAS group of molecular biologists calling for self-restraint by scientists engaged in specific genetic experiments can be helpful in this area also. The group acknowledged that their concern was based on judgments of potential rather than demonstrated risk, and that adherence to their recommendations might entail postponement or possible abandonment of certain types of scientifically worthwhile experiments. Nevertheless, the group concluded that their concern for the possible unfortunate consequences

of indiscriminate application of certain techniques prompted them to urge fellow scientists to withhold specific experiments "until attempts have been made to evaluate the hazards and some resolution of the outstanding questions has been achieved." Many outstanding questions pertinent to the value of human life at every stage of its existence and the responsibilities of society to protect that life demand consideration before we embark on a permissive course in regard to fetal experimentation. I trust that this Commission will provide some direction in this area.

* * * * *

DR. RYAN: Thank you.

MS. MISHKIN: On page 10, in your item -- most of the items there, I notice that you use the word "experimentation" rather than research. Is it fair to conclude from that or not that you would not oppose necessarily research which is not an experiment in the sense of being evasive, but is simply observational?

REV. McHUGH: It seems to me most of the research involves experimentation, we know so little.

MS. MISHKIN: I am thinking of weights,

measuring, data collection, monitoring certain functions which might result in information but is not an experiment in the sense of doing something to the fetus, other than observational data processing?

DR. COOKE: Would you, for example, include the recording of the electrocardiogram?

REV. McHUGH: I don't think those types of observations should be prohibited. We are talking of direct activity on the fetus itself. Science trying to find out something they don't already know or verify some type of hypotheses. If they are observing what is going on, there is no ethical reaction to that, providing it will not harm the fetus or mother.

MS. MISHKIN: You use the term from time to time of preserving the life of a fetus. Would you also be opposed to experimentation, to use your term, the purpose of which was to safeguard the health?

REV. McHUGH: I think I used the words "safeguarding the life " or "preserving of health".

MS. MISHKIN: There was one instance in which you did.

REV. McHUGH: That is the general thrust. Whatever is done to save life or preserve health is not considered "experimentation."

DR. RYAN: Are there questions by any of the Commission Members?

DR. TURTLE: I believe that you asked the question

shall we allow the pursuit of scientific investigation to outweight the weight society places on the human life. You later state that government should act as the guardian for the fetus in the case of an elected abortion. Would you allow the government to undertake that balance, and if so, under what circumtance?

REV. McHUGH: I presume that was the reason for the hearings and for the charge, the mandate given to this Commission, that there is a question of what the government is going to do. Right now the government has placed a temporary ban, presumably and the end of the time limit the ban ceases. It seems to me there is going to be some kind of regulation, restriction, or legislation, and those who are going to draw the legislation are going to have to balance some interests. It is my concern in the balancing process that the legislator or the person who draws the regulations goes through, attention will be paid to ethical, philosophical and theological matters, as well as the sciences.

DR. TURTLE: The balancing you are talking about would take place in the legislation. Is there a possibility that the government as guardian of the unwanted fetus, the balance might take place in an ad hoc situation? The review of a particular case, or research project? If that were sufficiently aired and all sides had an opportunity to express their interests, which side seemed to be more important?

REV. McHUGH: You are talking about something like a due process situation in practically every case?

DR. TURTLE: Perhaps with regard to each research protocol.

REV. McHUGH: Presumptively that is going to happen because most of this is located within the context of the existing HEW or NIH regulations. I would be happy to have a due process situation for each and every experiment, but I also think the law does two things: it tries to work out the balancing by reason of due process but it also sets a general tone. And it is the setting of the general tone that I thought was a more prominent interest right now. That is why the government or its agencies should be taking the positive role of protecting and enhancing the unborn human life rather than disregarding it and simply putting on restrictions that will evade the more gross results or the more gross examples we are sometimes exposed to.

DR. JONSEN: I didn't hear you mention, and I don't see on a cursory reading of your testimony, any mention of experimental procedures which may be of extremely low risk. Do you consider that an irrelevant issue in fetal experimentation?

REV. McHUGH: No, I have to distinguish it. I would be generally negative even on that type of procedure in regard to a living fetus. I think permissiveness in that

regard sets a tone. That is, that a fetus can be experimented on, provided it is proportionately unlikely the experimental procedure will do any harm. I think that all of our discussion of the fetus is set in the context of the attitudes set in the Supreme Court's decision in the abortion cases, which I think are generally negative with regard to the fetus.

Now, within the guidelines that I specified here, I did recognize that in terms of the dead fetus, certain experiments, such as tissue culture, might be allowed, under appropriate circumstances. So that type of non-harmful and, also, I would consider non-threatening in terms of the dignity of the human cadaver, should be able to be allowed.

DR. RYAN: Can I pursue that? I was thinking of the studies which you referred to that took place in Boston, which I don't want to talk about specifically because they have not come to trial yet, but perhaps the hypothetical question, which Doctor Johnsen raised, the question of, in which the risk to the fetus is relatively small, would you ever weigh that against the potentiality of substantial benefit to mankind in general or to all fetuses of the future?

REV. McHUGH: Yes, I would weigh those things. But, at the present time I would still be very conservative or cautious on it, because I think we are dealing in a society which has, by reason of the Supreme Court's opinion, deprived

the human fetus of any sense of humanity. That can be redressed and I think that appropriate regulations will do it.

DR. RYAN: You would not exclude that consideration?

REV. McHUGH: I would not exclude it.

DR. LEBACQZ: That was to be my first question.

I would like to tack on to that one other point for clarification.

Would you consider puncture of the amniotic sac to constitute experimentation on the fetus, or are we to separate out the fetus from experimenting with the amniotic fluid and its contents?

REV. McHUGH: I would not consider tapping the sac an experiment on the fetus. In the testimony I made the observation that fetusscopy should not be considered experiments on the fetus. Once again --

DR. LEBACQZ: Then I have one other more substantive matter.

In your recommendations you have indicated at several points that where a woman plans an abortion, experimentation may not be done, in part because the unborn child cannot consent nor can anyone presumptively consent on behalf of the unborn child.

I am wondering whether you would allow presumptive consent on the part of the mother or the parents for the

child which is still in the womb and for which no abortion is scheduled? We do allow parents presumptive consent for doing all kinds of things while the woman is pregnant. I am wondering whether you would set more restrictions on scientific research than on other kinds of activities that parents might like to engage in during the time the woman is pregnant?

REV. McHUGH: That is a long question, but as I understand it what you are saying is let's set the question of fetal experimentation on a possible abortus aside, and talk about the experimentation on fetuses or unborn children generally.

DR. LEBACQZ: Yes.

REV. McHUGH: I see no reason why the mother cannot give consent and presuming that consent by her physician, on the basis he has some reason to presume she would be in agreement with, I would not see any problems in those kinds of experiments. However, I might also make a point that I think too much experimentation goes on without parents being properly informed about what the experiment is about. I would be opposed to that.

DR. LEBACQZ: May I just clarify this now?

On your point 1, on page 10, you indicate experimentation is to be prohibited unless necessary to assure the survival of the fetus in the womb. I am asking

whether experimentation on the unborn fetus in the womb may be permitted on the assumption that parents may give presumptive consent for the fetus? In other words, experimentation that is not necessarily for the survival and well-being of the individual fetus, but is for the purpose of gathering scientific data of some kind?

REV. McHUGH: If the fetus is not to be aborted, it seems to me no experimentation is permissible unless the parents give consent, which seems logically possible to do in most instances. I don't see how an experimental design can be drawn for a research project where we can't get permission from the parents. That is difficult to imagine.

Secondly, if the fetus is to be aborted, and that is what we are talking about, then I do not think that presumptive consent or even the mother's consent really matters very much since the decision has already been made to kill the child.

DR. LEBACQZ: I am still not clear. My question must not be very clear.

Let me see if I can give you an example that will clarify what I am asking here.

Let us assume that I am pregnant and have no intention of aborting my fetus. I am aware of the fact that some research is going on at the moment to develop means for removing samples of tissue from the fetus in the womb. May

I give presumptive consent for my unborn child to participate in such an experiment which will put my child at a certain amount of risk but has potentially great benefit for the class of all children?

REV. McHUGH: You may give consent, and I would not want to restrict you from giving the consent or the scientist from doing it. Presumptive consent means they don't ask you. They presume you would be agreeable. I see no reason why they have to presume that. They can ask you.

DR. LEBACQZ: I should have said proxy consent.

REV. McHUGH: All right.

DR. RYAN: Dr. Louisell, very briefly, please.

DR. LOUISELL: I just have one question.

Sometimes we hear reports that the very methods selected to do an abortion, that that method is selected because of considerations of enhancing the use of the abortus for experimental purposes, as, for example, in the hysterotomies allegedly performed in Sweden. Have you seen any evidence to confirm those reports? We neglected to go into that with the physicians this morning. I was just wondering if those reports can really be verifiable? Have you hear of any such evidence?

REV. McHUGH: I would think that they would be difficult to verify in the United States because there has been a general ban on fetal research in this country.

However, I have spoken to scientists engaged in this type of research, they have told me they would like to see a clarification in the law and regulations permitting them to use that type of abortion so as to perform research on the fetus. So I think from speaking to scientists I would feel they would be positively inclined that there is a body of opinion out there sustaining that kind of an opinion. But I think you could not say that we have any hard data right now because generally there has not been that much fetal exerimentation going on in the United States.

DR. JONSEN: I get the impression that the major thrust of your testimony has to do with experimentation on aborted or about to be aborted fetuses. And your position with regard to experimentation on fetuses in other situations is not the main thrust.

REV. McHUGH: Yes, I would say you are right. The main thrust is the fetus that has been aborted or is soon to be aborted. That is what the regulations were all about. And that was why the charge, I believe, was placed upon this Commission to take this up as the first item of business. I also think that generally, from the scientists I have spoken to, they have an ethical reason to use fetuses not to be aborted.

DR. RYAN: Thank you very much.

If we may now proceed, Dr. Jo Anne Brasel,

from the Encocrine Society.

Dr. Brasel read her prepared statement which follows;

Mr. Chairman and Commission Members:

Thank you for the opportunity to present the views of the Endocrine Society on the importance of fetal research. The Endocrine Society consists of approximately 3000 persons interested in the role of hormones in health and disease. Membership consists of physicians-internists, pediatricians, obstetricians and gynecologists, of physiologists, biochemists, pharmacologists and others who have made significant contributions to the welfare of the fetus in the past and who have the interest and expertise to make further advances in unsolved problem areas in the future. This testimony will focus on past research which has led to important improvements in fetal care and on future needed research which could be affected by the deliberations of this Commission. I am personally qualified to speak on behalf of the Endocrine Society in this matter on the basis of my past training and present position. I am an Associate Professor of Pediatrics at the Columbia University College of Physicians and Surgeons and Director of the Division of Growth and Development in the Department of Pediatrics and the Institute of Human Nutrition. I have had three years of formal postdoctoral fellowship training in Pediatric Endocrinology at Johns Hopkins University School of Medicine and have held full time faculty positions at Cornell University Medical College and Johns Hopkins prior to coming to Columbia. My time is divided between patient care, teaching and research activities.

The contributions of endocrinologic research to fetal welfare and survival are many, but time restrictions limit us to only a few examples. Past research on normal and abnormal pregnancies, i.e. pregnancies where threatened or actual fetal death occurred, demonstrated that certain hormones made by the placenta and/or the fetus were reduced in the at risk pregnancies. The measurement of levels of these hormones, that is estrogens, progesterone compounds and the placental growth hormone, called placental lactogen, is now a part of standard obstetric practice in following the course of a pregnancy where there is concern over fetal welfare. Low levels alert the physician that the mother and fetal pair deserve special attention and often specific treatment if further complications and fetal loss are to be prevented. The initial studies required the study of levels in normal pregnant women, as well as in women at risk, and might have been prevented depending upon the interpretation of the present regulations. Future studies of a similar nature to provide even more sensitive indicators of complications of pregnancy in their earliest stages are needed and should not be prevented if improved fetal welfare is the ultimate aim.

Based on the earlier studies that low hormone levels occurred in at risk pregnancies, physicians began to treat women with threatened fetal loss with the hormones which were at low levels. This perfectly reasonable step has now been shown by subsequent research to be unproductive since the low levels were the result of the threatened loss and not the cause. Furthermore, in some instances, such treatment has been shown to have serious, deleterious effects on the fetus. Twenty years later certain female children of women who received estrogens to prevent a threatened abortion are now developing vaginal cancer, a very unusual cancer and an obvious unintended side effect. Other women were given compounds of a progesterone nature for similar reasons; certain of their infant daughters

were masculinized by the medication so that at birth a question of the infant's sex arose. In some the wrong sex assignment was made initially and in many corrective plastic surgery was required to correct the abnormal genitalia. You can imagine the concern and anxiety such a problem creates in the parents' minds. You have already heard or will hear from others today about the importance of understanding the handling and effects of drugs given to the mother upon the fetus. The same is true for hormones, even those given in every expectation of benefit for the fetus. Thus there is continued need for careful evaluation of any forms of hormone treatment given to pregnant women whether for their benefit or for the benefit of the fetus. Future attempts to prevent a threatened abortion, to correct fetal deficiencies, to treat fetal diseases or to treat the mother should only be carried out in association with or after careful studies done to assess the effects of the agents on the unborn. Only in this manner can we prevent tragedies like those following estrogen and progesterone from occurring in the future. It is extremely important that such research not be prohibited if we are to make progress in these areas.

There are many areas where further hormonal research is needed to improve fetal welfare. Time allows mention of only a few of them. Premature labor and birth is still one of the commonest causes of fetal loss; the factors which control the onset of labor are poorly understood at best They are, in large part, hormonal in nature and deserve much more extensive study. There are certain hormonal deficiencies which begin before birth and have long term consequences on fetal development; it is conceivable that the future will bring the possibility of treatment before birth if research provides the right answers. For example, thyroid hormone deficiency at birth is probably more common than phenylketonuria; if untreated, it leads to permanent mental retardation. If treated early

enough, complete recovery is possible. We are now aware that some cases require treatment even before birth if we are to reverse the abnormalities. New sensitive techniques are available for diagnosis at birth and should be applicable prenatally as well; however further research as to normal thyroid hormone levels in the fetus are required before any progress in this area can be made. A final example of particular poignancy is the diabetic pregnancy. Diabetic women have greater difficulties becoming pregnant in the first place; they have a higher rate of spontaneous abortions and congenital defects; when born, their babies have a high incidence of complications in the first few days of life which cause death or serious long term complications including mental retardation. This is an area of intense interest and research aimed at improving the pregnancy outcome of these mothers. Past evidence has led us to believe that the severity of the symptoms immediately after birth relate to the severity of the maternal diabetes, especially to the control of the blood sugar, so that high maternal blood sugar levels lead to a particularly rocky course for the infant characterized by abnormally low blood sugar levels and seizures. Very recent data suggest that the pancreas of these infants may not be responding to blood glucose levels after all and that other signals may be responsible for the excessive insulin release of the infant after birth. If this is the case, we must rethink our whole approach to these infants and much more research on the nature of the factors which affect the fetal pancreas must be performed if we are to make significant inroads into the fetal losses in this condition.

The Endocrine Society shares the concerns of many research workers, society as a whole and the Congress which mandated your study of this issue. We wholly support your efforts to see that ethical considerations are met in the conduct of human research. We feel equally strongly,

however, that the welfare of future mothers and infants will not be met by interdicting research wholesale. We hope this brief testimony has served to make the point that endocrine research of the fetus is directed at saving fetal life and not taking it. The goal is improvement in both the quantity and the quality of life. We look forward to meeting some of the unmet needs in this area and trust that your thoughtful deliberations will result in a climate for investigation which will allow us to meet this goal.

Thank you.

DR. RYAN: Thank you.

Questions from the Staff?

DR. COOKE: Jo Anne, on page 3, you cite two examples of serious consequences of administering chemical agents on the child born as a consequence of the administration of those agents. You further indicated there was need for research on the fetus to avoid this in the future and so forth.

In those two examples, would you say that much more extensive animal research should have been done, and if it had been done, would have given some clues as to the possibility of these compliactions?

The second question relative to that is how would you decide in your own mind whose fetuses were to be volunteered to carry out such studies on the effects of estrogen?

DR. BRASEL: To attempt to answer your first question, I think in these particular instances, perhaps additional primate work might have provided some information. But, perhaps, these particular instances, in light of this particular question, might not have been the best examples for me to choose to bring before the Commission in regard to the applicability of animal research. These are good examples

to show how careful we should be in administering medicines to pregnant women There are other instances in endocrinology where, as in other examples cited to the Commission today, when animal studies would not provide the answers. Only certain amounts of limited information can be obtained, and if what we are interested in is human physiology, with respect to certain problems, humans will have to be studied.

With regard to your second question, again, you know, perhaps we are dealing with examples that don't serve the point you want to make with your question. Obviously, I don't think there is anybody in their right mind would want anybody to volunteer a fetus for experiments or research that might answer this question I don't think that is a germane question. That has not come up in terms of the type of research that I am talking about. This was a situation where later in retrospect we found there were very serious side effects in a place where we were trying to do good. It makes those of us who use medications to treat a pregnant episodes or are involved in the care of pregnancies very hesitant about using medication. Each time one of these things occur, we get more and more hesitant and concerned that everything must be done to find out what possible deleterious effects may happen.

To wait for reports to appear in a registry would provide information years later, or waiting for reports to

appear in The New York Times, I don't find that satisfactory. There are more direct methods of getting at this information in situations where we can do so before hand.

DR. RYAN: May I interject? The two situations you described were results that occurred in connection with therapy given to patients. Not really the outgrowth, necessarily, of research-evaluation?

DR. BRASEL: They were done to prevent an abortion.

DR. COOKE: The point made was that research on the fetus might have predicted such consequences and I would challenge that at the present time , that those particular examples, I don't know what fetal research that people are doing would have predicted those outcomes.

DR. BRASEL: Prior to the termination of a pregnancy, administration of some of these compounds might have revealed the masculinization of the female fetus.

DR. COOKE: Animal work could have done that.

DR. BRASEL: In part, but not for all of these agents. The fact they are not virilizing for the mother, but are for the fetus, points out how vulnerable the fetus is. I am not sure I would accept that negative animal work means we are safe as far as the human fetus is concerned. Particularly with hormones, which can be seen differently

in the fetal organism ____ than in the mother.

DR. LEBACQZ: This issue of long-term risk is one we have not brought out until now. We have heard a great deal about the possible long-term benefits of continuing fetal research. But I am now hearing there will be things we might do with the fetus which may have long-term consequences we wouldn't know about for possibly 20 years.

I am wondering whether the Endocrine Society takes a position on the issue of balancing long-term risks and benefits? I would gather from your statement that you would nonetheless feel that the long-term benefits are such as to outweight the long-term risks, but I would like to have some clarification on how you approach this question of balancing long term consequences, both sides of the issue?

DR. BRASEL: The point that I attempted to make in this testimony is that there are a number of questions that remain to be answered, some of which have, as you have seen in the past, led to deleterious effects. The plea is for the research be done now so we know what is going to happen when the agents are given to a mother. Some effects which relate to relatively acute short-term risks, can and should be studied.

Quite frankly, I am not sure, based on current medical knowledge in the state of the art, that we are going to, based on a few even very carefully well conducted short-

term experiments, prevent the estrogen carcinoma business from occurring again at a later date. It takes 20 years. But there are things we certainly can do, that should be done, with any agent before it is given to a pregnant woman to make sure they are going to have no acute deleterious side effects we are missing. We must forever and ever watch subsequently in terms of other treatments to make sure the risk is not greater than the benefit.

DR. LOUISELL: In your concluding statement on page 5, where it is said that endocrine research in the fetus is directed at saving fetal life and not taking it, as a general pronouncement I certainly understand that. But can we interpret that to mean that there are no instances of this kind of research that run a severe risk of terminating the life of the fetus?

DR. BRASEL: I am not sure I really understand what you are saying, but the Endocrine Society as a whole has done research to benefit fetal welfare in circumstances where fetal life is no longer a consideration. That is, we are not talking about dealing with viable fetuses. That is, a premature infant. And research on the premature infant should fall under the same sorts of regulations that meet research in the young child, adult or prisoner. We are talking about research in previable fetuses.

DR. LOUISELL: Which in many cases proceeds on

the basis of an election having been made to have the abortion.

DR. BRASEL: That would be the situation. There are other circumstances which have been alluded to elsewhere today in testimony where there is a case to be made by the Endocrine Society and pediatricians that certain types of research which carry no significant risk to the fetus will provide additional information, information beyond the point of previability, into the area of viability. We think this should be allowed, assuming that the risk is negligible and informed consent has been obtained. We are not talking about fetal research whose purpose is to stop fetal life.

DR. RYAN: Dr. Turtle, briefly?

DR. TURTLE: You indicated that some of these projects that are shown on page 2 could have been done on primate research, but some fetal research would be necessary.

DR. BRASEL: Human.

DR. TURTLE: Human as opposed to fetal. What experiments would you have done or set up, possibly, involving humans?

DR. BRASEL: There are specific aspects of the hormonal system, which is what endocrinology is all about. In the human population, it is unique. It does not exist in the primate. Therefore, one has to sift the questions about aspects about fetal endocrinology. One cannot ask

them in the primate system.

DR. TURTLE: You are not restricting it to fetal research?

DR. BRASEL: If it is human fetal endocrinology, yes. You can't look at a two year old child.

DR. RYAN: Can I take one crack at that?

It is quite possible that had appropriate fetal endocrinology research been done, those forms of treatment would never have been given.

DR. TURTLE: My question is, what would appropriate fetal research consist of in that situation?

DR. RYAN: In many of these instances drawing of small amounts of blood, or urine from the mother, to determine appropriate levels and dynamics of the steroids as they normally secreted a normal pregnancy without any manipulation to the fetus and minimal risk.

DR. COOKE: Isn't it fair to say that you could say exactly the same thing about appropriate animal research? What I think is the scientific community --

DR. RYAN: Not with respect to the endocrinology of human pregnancy.

DR. COOKE: The two examples given here. We are not accustomed in human biomedical research to consider that the human being is an animal in biologic terms, and that there are animals out there somewhere that must have endocrine

systems partly different, but also partly similar, that have enzymatic systems that are similar. And if you search hard enough, you will find animal systems that are very, very close to humans. We know, for example certain aspects of rat kidney functions are identical to those of humans, some aspects aren't. But we have not searched very much because it costs a lot of money.

DR. RYAN: We are not arguing about that point. I want to illustrate one aspect of it, and that is the genesis of giving the agent which caused masculinization in the female fetus was based on animal work in which it worked. It caused harm without have efficacy in the human. Had appropriate research been done, it would not have been used in therapy. In that example no one would quarrel with you about the need for very extensive animal research before going on to the human, when appropriate.

But there are some instances in which you have to make that gap, that short gap before it is put into therapy for the human. I don't think we have crossed for these purposes.

MS. KING: Did I understand you to say that you are advocating research on the previable fetus?

DR. BRASEL: I think the pre-viable fetus should be made available for research, given the fact we meet current ethical standards as society defines them. We attempt

to obtain consent from the mother. I speak in this way as an individual and not as a representative of the Endocrine Society.

MS. KING: A further question would be, are you talking about research in pre-viable fetuses, with the idea of preserving life, or with the idea of benefitting manking, womankind, benefitting fetuses, in general?

DR. BRASEL: Benefitting fetuses as a class, which requires not only the study of precise disease processes which we know may affect fetal development, but also obtaining baseline information. One cannot determine what is abnormal if one does not know what the normal is. Therefore, much of what people in medicine are doing in certain projects is obtaining what the normal is so they can say this lies outside the mormal and means that something is wrong and let's see if we can understand what is wrong and go about correcting it.

In that broad context, I recommend that the previable fetus be available for study.

MS. KING: Would that include using a previable fetus whose "life signs" are being artificially maintained in order to perform the research?

DR. BRASEL: No, I am out of time, but I think

the whole problem in the definition of viability is a difficult one that has been tackled in part by the regulations in the Register, in which the point was made that most of us would completely agree with that the state of the art changes. What is previable today may be viable later on. It is important that strict number requirements with regard to viability not be listed and that one looks at the state of the art and what is possible in terms of maintaining fetal susrvival.

What I am speaking about is assuming that based on those definitions, whatever they are and how often or how extensively they change, if the previable, meaning there is nothing in the current state of the art we can do to maintain survival, that those tissues should be used.

DR. RYAN: Thank you.

We are running behind time and I want to be fair to those who have yet to be heard.

The next speaker is Nancy Raymond, representing Maryland Action for Human Life.

MS. RAYMOND: I am also going to be reading the testimony of Dr. Sean O'Reilly, who is, I understand from his wife, not very well. So I will read his, but not comment on it. I wanted to give an introduction to his.

I received my BS from Cornell in Nursing in 1963. I have been doing public speaking for the last five

years. My husband is a physician in the Navy, and I am the mother of four adopted children, one of whom has cystic fibrosis.

Daniel Callahan, Director of the Institute of Society, Ethics and the Life Sciences, recently said: "There is nothing harder than distinguishing 'right' from 'wrong', 'good' from 'bad'. 'better' from 'worse', but nothing is so imperative as to make the attempt, just as all other generations have had to do."

Maryland Action for Human Life, whose goal is the protection and respect for human life at all stages of its development, feels in agreement with Daniel Callahan that the new ethical issues in medicine and biology must be treated in a sober systematic and professional way.

Our basic belief is that the unborn young in the womb be treated with fairness and dignity irrespective of whether he or she is a desired child or one scheduled for abortion. We feel that the living, premature infant or fetus, delivered spontaneously or through a planned abortion, be accorded the same measure of respect, no matter his mode of entry into the world. We feel the method -- normal delivery or abortion -- of the child's presentation should in no way affect his candidacy for experimental research.

We believe that a doctor should not knowingly harm his patient or the subject of his research. We feel

that it would be damaging to society in general if the human fetus be treated as a creature with no intrinsic value and relegated for use without controls as a convenient and highly specialized laboratory animal.

Even if the decision to abort has been made, we feel the fetus is entitled to full protection from potentially harmful or painful research and look to this Commission to set up guidelines for its protection.

We ask consideration of the following guidelines:

1. That laws pertaining to human fetal research be considered part of the civil courts rather than the criminal courts.

2. That research conducted on dead human fetuses be allowed with the mother's consent, as long as the researcher is not the same person who performs the abortion with the promise of the use of the dead human fetus for research.

3. That research on living human fetuses, whether within or without the womb, be prohibited -- with the following exceptions:

(a) This prohibition would not apply to diagnostic tests, such as amniocentesis, to determine the state of health of the human fetus.

(b) This prohibition would not apply to remedial

procedures intended to preserve the life or health of the fetus or mother.

(c) This prohibition would not apply to non-diagnostic procedures incident to the study of the human fetus within the womb if such procedures do not substantially jeopardize the life or health of the fetus, and if the fetus is not a candidate for a planned abortion.

(d) This prohibition would not apply, even if the fetus is the subject of a planned abortion, to normal diagnostic tests to be made on him, if they did not substantially jeopardize his life or health.

(e) This prohibition would not apply to necessary experimental diagnostic tests -- amnioscopy -- if they are judged to be in the best interest of the particular human fetus and provide the mother with specific information about her particular fetus even though an abortion may be contemplated.

4. That a permanent board of medical and legal persons be created to advise scientists in the area of human fetal research.

Thank you.

DR. RYAN: Thank you.

Does Staff have any questions?

MS. MISHKIN: One minor question: I am a mother,

as you are. Neither one of us have anything to do with lawyers, but you specify only medical and legal persons be on the board.

MS. RAYMOND: Yes.

MS. MISHKIN: Why is that?

MS. RAYMOND: That was an oversight. If I had gone through your roster here, I would have included everything. I was typing at three in the morning which is the only quiet time in my house. I meant really for it not to be just in the arena of medicine. I think today medicine has to share the arena of ethical issues with many other philosophies. You could name 12 or 13 areas. I didn't mean to limit it.

DR. COOKE: I think it interesting and thoughtful, your statement. Could you amplify a little bit on the limitations on normal diagnostic tests?

MS. RAYMOND: Limitations on --

DR. COOKE: What do you mean by that? What would be the scope of normal diagnostic tests?

MS. RAYMOND: Maybe I could clarify your question, because I also talk about non-diagnostic procedures. Is that what you are talking about?

DR. COOKE: I would like to know what you encompass by those. There is a lot riding on that.

MS. RAYMOND: Diagnostic tests would be, even if

you separated them from experimental tests, if they deal with a particular fetus concerned, would be used to diagnose conditions that a particular fetus have. If they don't jeopardize his life or health, we find that to be allowable. Sampling through the blood, that is all right.

DR. COOKE: Sampling of fetal blood you would consider normal diagnostic tests?

MS. RAYMOND: Yes.

DR. COOKE: I see.

MS. RAYMOND : I mentioned the only illustration I gave for a diagnostic test was the amniocentesis. If it benefits that particular human fetus whose condition is to be known from that test, then it would be allowable. I think that the main thrust of my question 3, that research on the living human fetus be prohibited, the one prohibition I think I mentioned is if the fetus is not a candidate for a planned abortion we feel nothing should be done. This is the easiest way for society to control research of this nature, if the mother intends to have this child viable and live born. If she allows the research, you look to her judgment and the researcher's judgment to create a climate where there would be controlled research. And the reason we say this is because a mother who is definitely planning on an abortion would sometimes have the sky be the limit.

We think the easiest way to control an ethical

issue is to have experimental research done on a mother whose child is to be live born, that would be the easiest way to control it,

MR. YESLEY: Would you elaborate briefly on your first recommendation that laws pertaining to fetal research be considered as a part of the civil court system rather than in the criminal court system?

MS. RAYMOND: I think in terms of ethical issues, this should all be in the civil court system. We are treading in a gray area where a lot of people, doctors and scientists, are afraid they are going to be breaking the law without knowing future guidelines. I think for quite a long time, not ten years, THAT this should be the domain of the civil courts. I think it is an issue that is such a gray area, it should definitely not be considered in the criminal courts.

DR. LEBACQZ: I am a little puzzled about the situation of fetuses that are scheduled to be aborted. You have used the phrase here "substantially jeopardizing life or health." I am assuming you would allow a fetus that is not going to be aborted to be put at some risk, perhaps minimal risk, but at some risk, so long as it isn't substantial jeopardy. If then a fetus which is to be brought to term may be put at some risk, especially in a non diagnostic procedure, then why not also a fetus that is to be aborted?

This seems strange to say the ones who may have to live with whatever harm there is may be subjected to it, whereas those that will die anyway would not be subjected to it.

MS. RAYMOND: I think this gets back to my term of internal controls or specific controls. We have to realize of course you would have to get consent from the mother, and hopefully,it would be advised consent, so you would not be subjecting her fetus to unusual things. I merely put the control in because we assume that bizarre or harmful or painful research would not be done on the unborn if the mother had full intentions of having the child be live born. It is a inner control type mechanism. But for future controls this might be the safest route. I did mention that necessary experimental diagnostic tests can be performed on a fetus scheduled for abortion. But I think when you get in the realm of a child, you know you will not have to come to a hearing such as this, and say I am sorry I did that to him. Look how awful he looks now. If you know that child is not going to make it, I am afraid it then gives science researchers a little too much leeway, because the mother, as was said before, has already abrogated her rights to the child's future wellbeing. So we are concerned with protecting the child's wellbeing and feel the best way to do that is to have fetal research limited to mothers who are expecting a live birth. We feel that is a

form of inner control. Not that the two children would be physiologically different or fetuses would share any differences. That is a very subjective decision by the mother.

DR. RYAN: I wonder if perhaps you might bo on to Dr. O'Reilly's testimony now.

MS. RAYMOND: All right. Fine.

DR. RYAN: This will be read for us as a courtesy to Dr. O'Reilly. His wife drove a long way to present this testimony.

(Testimony of Dr. Sean O'Reilly, George Washington University Medical Center, Read by Ms. Nancy Raymond.)

MS. RAYMOND: I don't know Dr. O'Reilly, but I will read it well.

I am Dr. Sean O'Reilly, Professor of Neurology and Director of a Neurobiology Research Training Program at the George Washington University. I am also a member of the standing Committee on Human Experimentation of the George Washington University Medical Center.

This introduction is simply for the purpose of identifying my interest and competence in requesting the opportunity of testifying before the Commission.

In this testimony I do not represent the University, the Committee on Human Experimentation of the

Medical Center nor the members of our Neurobiology Research Training Program. I am here on my own recognizances, so to speak. I wish to put before you a summary of what I consider to be the essential scientific 'Facts of Life', followed by my views on the application of ethical principles to the question of fetal experimentation in the light of the implications of these facts.

A. Here are the scientific 'Facts of Life':

1. One of the unique and distinguishing characteristics of living matter is its ability to reproduce its own kind. The biological details of this reporductive process have been fairly well-established in the past century and a half in the case of mammalian and human reproduction.

2. It is now known that a new and unique individual comes into existence when a spermatozoan and a mature oocyte intermingle their chromosomes at metaphase of the first mitotic division of the zygote.

3. This new entity is an unique individual, specifically human. This statement is not in dispute among reputable biologiests, geneticists and medical scientists.

4. This new individual, although receiving one half of his or her chromosomes from each parent, is really unlike either of them, in a fundamentally

biological sense, and is distict from either parent. It is, I repeat, an unique individual.

5. The events that follow fertilization are self-generated by the new individual under the guidance of a new and absolutely unique hereditary plan which determines the pattern of that individual's constitutional development and his capacity to respond to exogenous influences.

6. The presence of this new individual can be established within a few days of fertilization, and probably before implantation, by demonstrating the presence of a hormone, human chorionic gonadotrophin, in the maternal blood serum. This hormone is manufactured, not by the mother, but by the rapidly growing new individual.

7. This new individual is also an autonomous individual in many fundamental respects.

8. From its beginning at fertilization this new individual's life is a continuum, without any fundamental change from the scientific point of view.

9. If this individual is not by itself a full human being it could never become such, because something would have to be added to it, and we know that does not happen.

B. The Ethics of Human Experimentation.

In our work on the Committee on Human Experimentation at the George Washington University Medical Center, I attempt to apply the following principles in the scrutiny of each research proposal that involves human subjects. These principles are:

1. No one shall have experimental procedures of any kind performed on him or her without explicit consent.

2. This consent must be fully informed. The subject must be capable of understanding at least in a recognizably adequate way the nature, the risks, and the possible benefits, either to himself or to other patients, of the proposed procedure, and must freely consent to allow it. By 'freely' is meant freedom from undue pressure.

3. In the case of subjects unable to be fully informed or to give free consent, that is, unconscious patients, the next-of-kin may give consent on his or her behalf only in the circumstance that the proposed experimental procedure is expected to benefit the patient, and the risk-benefit ratio favors the patient. The consent from the next-of-kin in this circumstance must be as fully informed and free as in the case of the patient himself. It is presumed that the next-of-kin have the interest of the patient at heart.

These principles essentially express a right to be protected from experimentation without informed consent,

a right derived from the fundamental right to life that inheres in the human person because of his intrinsic nature, conceded to him by civilized thought and guaranteed by the Constitution of the United States. The phrase 'a full human being', used in the presentation of the known scientific facts, implies personhood, a term with definitive and inescapable implications.

I maintain that the scientific facts warrant the conclusion that the unborn child is a human person endowed with all the rights of a human person. There is no doubt that an unborn child cannot give consent, informed or otherwise.

The parents can give informed consent on behalf of their unborn child only for procedures expected to benefit that child, as in the case of post-natal children. It is true that the Supreme Court of the United States in effect declared the unborn person a non-person, by virtue of what one of its members called an exercise of "raw judicial power." But so did the Supreme Court in its Dred Scott decision declare the Negro a non-person. And so did the Third Reich deprive Jews and other unwanted groups in Germany of their legal personhood, and withdrew from them the protection of the law.

The Nazis drew the logical conclusion that since these non-persons were going to be killed, it was legitimate,

may laudable, to use them as guinea-pigs." The verdict of civilized society on such logic is enshrined in the judgment and sentences handed down by the Nuremberg Tribunal.

We cannot concede to any Court, anywhere, the right to declare any one a non-person on grounds of age, physical dependence, or the presumed 'quality' of his life, or on the grounds that he has been condemned to death.

Experimentation on the unborn human, who cannot give informed consent, on the grounds that he is doomed to die anyhow by abortion, may be given legal sanction. It cannot be given ethical approval by those standards and principles enshrined in the Nuremberg Code and in the HEW Guidelines governing the issue of experimentation on human subjects.

Nor may parental informed consent be held to allow such experimentation since the parents have already disqualified themselves: they cannot be said to have the interests of their unborn child at heart since they have already decided he is to be deprived of his right to life."

DR. RYAN: Thank you very much, Mrs. Raymond.

There will be no discussion of Dr. O'Reilly's testimony since he is not here.

DR. COOKE: Could we ask questions of the Commission with regard to some points?

DR. RYAN: I wonder if it would be all right to do that, Tom, which will be an open session. I would be

happy to do it after we have all of the speakers through. Would that be acceptable?

Thank you.

Chris Mooney, representing the Pregnancy Aid Centers, Inc.

MS. MOONEY: Chris Mooney.

DR. RYAN: Right.

MS. MOONEY: Thank you. It is a privilege to be here and I am happy to submit my name, since I am the only one testifying from the point of view of the pregnant woman who is distressfully pregnant.

My name is Chris Mooney and I am speaking to you as President of Pregnancy Aid Centers, Inc., a non-profit, service organization which provides support on all levels to women experiencing untimely pregnancies and to their pre-born children.

My everyday dealings are with women carrying within themselves the possible subjects of future experimentation, and it is with concern for the welfare of these women and their children that I find myself here today.

It seems the day is about to dawn when experimentation which may be harmful or lethal may be legally perpetrated against live, human beings in the earliest stage of their development. As I am sure you are aware, this type of research on a massive scale has become possible largely

because of legalized abortion. If the subjects of these experiments were not readily available, the research could not be conducted.

Because I am vitally concerned with trying to find solutions to problems which all too often result in problem pregnancies, I am also very disturbed with these procedures, attitudes, laws, et cetera, which continue to mask the true problems of our society and which provide only temporary relief from the very complex problems which result in unwanted pregnancies and hardship for women. Legalization of experimentation on the live, pre-born human being will have the indirect effect of further entrenching our dependence pseudo solutions such as abortion, and thus further retarding progress toward tackling the real problems in our society which bring about distressful pregnancies. Because experimentation on the pre-natal human depends largely on continued legalized abortion, I would like to present the following for your consideration:

Abortion is as effective in preventing problems related to pregnancy, as shaving your legs is to stopping the growth of hair. Abortion is not a solution to pregnancy problems, but no solution will be found as long as easy, profit-making pseudo-solutions continued to be condoned. I have yet to meet a person genuinely concerned with women's problems who believes that abortion can provide lasting

solutions to the difficulties faced by women. It is no secret that abortion does not cure the problems which force unwanted pregnancies to occur. Even those who counsel for abortion with whom I have spoken unanimously agree that abortion is only an expedient, and that they would welcome the day when abortion is no longer necessary -- when our society will supply adequate aid and services before the distressful pregnancy occurs. But our present society continues to avoid giving a troubled woman viable alternatives to abortion and makes the choice extremely one-sided in favor of abortion.

For instance: the vast majority of health insurance policies cover abortion for unmarried women, but not delivery or pre-natal care; the profit-making nature of abortion makes it readily available, while services to the woman who is continuing her pregnancy are grossly inadequate because they are by their very nature, non-profit making; the Federal Government provides enormous sums of money on projects and institutions which promote narraw, chauvinistic ideals rather than enlightened humanitarianism, but comparatively little to stop the gross inadequacies and inequalities in our society which make abortion seem a desirable out for many economically underprivileged, sexually uneduated or emotionally troubled women; and we, as a society, continue to allow stimatization on many levels of

the unmarried, pregnant woman.

On top of all this, I foresee the further possibility of having yet another inducement toward abortion -- that is the argument that the woman will be contributing to the betterment of mankind by donating her developing child, alive or dead, to the cause of science.

Those who work in certain medical and biological fields who might benefit from such experimentation may be biased toward further encouraging abortion. This possibility contains all the ingredients for an inevitable double-standard in medical ethics, a grave conflict of interest situation for many physicians and medical counselors, and a futther threat to the freedom and dignity of the human female in choosing to deal with her distressful pregnancy. If we legalize experimentation on the live, pre-born human being, it will have the indirect effect of further entrenching abortion, thus further delaying action to alleviate the true problems of our society which bring about the need for abortion in the first place. How can the medical profession encourage legal experimentation on the pre-born human, and yet be concerned and active in ending the need for abortion?

Further, in my oonstant interraction with counsellors for such difficulties as drug abuse, suicide and emotional disturbance, an marked increase in the number of female clients suffering from post-abortion guild underlying

their disturbance has been related to me. Very often the self-persecution or self-doubt will not manifest itself until several years following an abortion and, according to many counselors, a majority of these women were given standard counseling on abortion and alternatives before the procedure was performed.

With the above in mind, I must implore you to consider the possibility that the full psychological consequences of the surrender of her unborn child through abortion by a troubled, pregnant woman may not yet be known. I sincerely request that no monetary or altruistic inducement be proposed to women aborting who consider submitting their unborn children for experimentation.

Thank you.

DR. RYAN: Thank you.

MS. MISHKIN: In your experience in working with these women, can you tell us the extent to which you find that experimentation and the possibility of having women's fetuses available is a factor in abortion for a woman?

MS. MOONEY: You mean if the woman is presented with the opporunity --

MS. MISHKIN: I gather that you say that the possibility of having this be an inducement is going to increase the number of abortions. I wonder to what extent you have seen this?

MS. MOONEY: It is more my own conjecture. I have not seen a large number of women who have had this experience of being prompted to abort for these reasons.

MS. MISHKIN: It has not happened to your personal knowledge. Do you think if one were to say that a woman could not be approached about experimentation until after the decision to abort has been reached, would that solve the problem?

MS. MOONEY: Perhaps it would. My main concern in giving this speech is as long as a woman is given -- all right, let me sort out my thoughts.

What I am saying is that in order for these experiments to take place, a large number of fetuses must be available for experimentation. And if there is no inducement by the doctors to do this, the fact -- it is kind of a double effect thing. You have in the one sense a large number of fetuses available which makes it possible to do the research. On the other hand, you have women having successful pregnancies who could be induced to abort by the promise of contributing to mankind.

MS. MISHKIN: I was just wondering if this inducement could be precluded by saying you could not talk to her about it until after the decision was made?

MS. MOONEY: Certainly, I think that would be advisable.

DR. KING: On page 2 of your testimony you allude to the profit making nature of the abortion makes it readily available. Would you explain what you mean by the profit making nature?

MS. MOONEY: There was front page headline articles on the Wall Street Journal in early '74 which the headline read "Abortion is Billion Dollar Business." It was because over $1 billion in abortions was reported being earned by private individuals.

DR. KING: You do not mean in any way you are talking about profit making -- the sale or use of inducements?

MS. MOONEY: No, that is not what I was talking about.

DR. RYAN: If there are no other questions, I would like to thank you very much.

We will be on next to the testimony of Dr. Walter L. Herrmann of the University of Washington, Seattle.

DR. RYAN: You have a very thick presentation.

DR. HERRMANN: You must have somebody else's. I only have three pages.

DR. RYAN: Okay.

DR. HERRMANN: I was instructed to attach my CV.

DR. RYAN: Please proceed.

DR. HERRMANN: I am speaking as a representative

for the Society for Gynecologic Investigations, representing individuals engaged in investigation in the reproduction and prenatal field. I am primarily speaking as an obstetrician who has dedicted his career for the last 25 years to the care of women. During these years I have witnessed much progress in our ability to understand the natural process of growth and development of the unborn baby and the intricate processes of the interaction between the material and fetal organism. In fact, I would like to state at this time that the recognition of the interrelationship between the mother and fetus constitutes one of the scientific milestones in our past and in our ongoing quest for knowledge. It thus must be borne in mind that the anatomical and biochemical, physiological or psychological interdependence is so great that no investigation of the fetus in utero is possible without involving the mother. Neither is there a possibility of maternal investigation without considering the fetus, with few exceptions of minor significance.

The recent and ever growing fund of knowledge must not be considered as having served primarily the enjoyment and satisfaction of the scientific community. On the contrary, there has been much immediate benefit to the patient; and, through association with such disciplines as pharmacology, the sciences dealing with infections, with defense mechanisms of the organisms, epidemiology, demography,

engineering, just to name a few, it has become possible for us to change our role from one of technical facilitator of the birth process to one of far greater challenge and responsibility: to work towards an improved environment, for the health and comfort of the mother and her child before conception, throughout pregnancy and the birth process.

A few examples of progress through research which would not be possible under the present rules, to substantiate this claim may be in order.

1. First and foremost, the evaluation of agents to stimulate labor. These agents prevent the long labors that formerly led to maternal morbidity and mortality. These agents usually induce or control unteral contractions. If evaluated improperly, they can lead to suffocation of the baby and rupture of the uterus and loss of the baby.

2. The evaluation of new anesthesia techniques for vaginal delivery and cesarean section, making these procedures safer for mother as well as child.

3. The evaluation of madalities for the therapy of preeclampsia, a toxic reaction to pregnancy associated with high blood pressure, convulsions, and kidney damage, which have decreased the rate of eclampsia and resultant maternal death.

4. The evaluation of different regimens which have so greatly reduced the danger to the woman with heart disease

or metabolic disease in pregnancy.

5. The evaluation of timing of delivery and antibiotic use for premature rupture of the membranes which have kept the infection rate to a minimum.

It is indeed gratifying to compare the amount of knowledge required of the young physician striving for certification of specialist in obstetrics with the information available to me 20 years ago.

Nonetheless, most gratifying is the decline of death and disease during pregnancy and childbirth, although not equal for all women in this country. Gratifying also is the attitude and confidence of the modern woman contemplating pregnancy.

If we must pause today to avoid the temptation of self-righteousness, we must ask for the developments which have led to undisputable progress. Among these are foremost the scientific achievements and the social awareness and recognition of the right of women to expect an equal share of the benefits of our health care system.

Is this fact really so? Does the national research effort in health care bring justice to the women and mothers in this country? Is maximal effort being supplied to support an ongoing determined process of scientific and social development to give all women the rightful opportunity to a healthy body before, during and after

pregnancy, and a healthy child?

I am afraid that the answer is not an unqualified "yes". In fact, there is a general lack of awareness of the importance of the unanswered questions that decide the future of generations of women and their offspring. The proposed policy for protection of human subjects now before us provides some evidence for this argument. I am aware that the Commission is not responsible for its current content. Time is of the essence, however, and I must emphasize the need for revision in order to provide not only the scientist but also the public with a set of rules conceived to direct science to its only function: to serve manking and in this instance the mother and child.

There is in these rules and regulations a misplaced emphasis in the order of priority as suggested in the title, "Subpart C -- Additional Protections Pertaining to Biomedical Research, Development, and Related Activities Involving Fetuses, Abortuses, Pregnant Women, and In Vitro Fertilization."

This peculiar sense of relevance is demonstrated again under, "Definitions", where pregnancy merely appears as a concept of a period in time from confirmation of implantation until delivery. There is no scientific method to confirm the moment of implantation; and, if pregnancy is conceived only as the passing of days, there is no way to

distinguish the tumorous and sometimes malignant degeneration of the placenta -- without an identifiable fetus -- or the blighted ovum -- the empty egg consisting of membranes, placenta, but no fetus -- from a normal early pregnancy. Yet this definition and concept of pregnancy is used when guidelines in prohibition for research are established.

My most serious objections, however, deal with Paragraph 46306 entitled, "Activities involving fetuses in utero or pregnant women." It is an impediment to the acquisition of additional biomedical information pertaining to human gestation. Wording of this section seems to be directed at regulation of research at the time of abortion. It does not take into account that the vast majority of new knowledge of pregnant women is being and has been acquired without involving the need for abortion or women seeking abortions.

It speaks of termination of pregnancy without consideration of the induction of labor at term or near term for the purpose of preventing intrauterine damage or death. This is practiced in patients with diabetes, Rh disease, placental insufficiency, et cetera. Specifically, there is no distinction of medical or scientific activity in the third trimester where abortion is never a question under legal circumstances.

This section also forbids the participation of

an obstetrician in a research project investigating, for example, carbohydrates metabolism in pregnancy, if he is the one to deliver the patient before term, a procedure often necessary in diabetic women to ensure survival of the baby.

I doubt that the authors of this article had this situation in mind. Considering the wording, however, one must ask why a true interpretation of the full meaning of pregnancy was not taken into account.

Worst of all, however, seems the confusion existing between empirical treatment and scientific procedure. This limitation excludes the accumulation of normative data. Thus, for instance, if we are to use a new technique, ultrasound, to establish growth retardation in utero, we must have information on normal growth with the same technique for comparison.

Considering the diversity and multi-disciplinary complexity of current ongoing research to benefit pregnant women without even a remote connection with an abortion procedure, this paragraph clearly suggests a rather careless approach to regulation for safety and progress.

There is no question inour minds that proper rules and regulations to safeguard individual rights and irreproachable standards of ethics are most welcome to our scientific community. We would like to urge, however, that:

A. The abortion issue be kept separate so as to not prejudice or influence the general rules and regulations governing investigations in human pregnancy.

B. That consideration be given to the complexity of multidisciplinary research in pregnant women so as to avoid summary prohibition without the benefit of careful analysis of relative risk factors and scientific gain.

C. That in the appropriate sections of these regulations, full emphasis be placed on the pregnant women as the subject to be protected so as to not infringe upon her rights nor deprive her from gain of scientific discovery.

DR. RYAN: Thank you, Dr. Herrmann.

DR. ALEXANDER: One question: you deal directly with this in your testimony, impliedly. We have heard it suggested several times today that in order to have available fetuses for research, physicians might encourage the use of abortion. Do you have figures from your institution or elsewhere suggesting the numbers of abortions that occur or available fetuses and the actual percentage or number of fetuses that might be used in fetal research?

DR. HERRMANN: You want to know the number of abortuses which are being used in my institution for research?

DR. ALEXANDER: Percentage of number of actual fetuses available?

DR. HERRMANN: I think very few. Because for one

we are doing relatively few abortions. Furthermore, all of our abortions for all practical purposes are really abortions using the suction method, which yields very little material for anybody's scientific use. Whatever is being used in Seattle is usually coming from other hospitals.

DR. ALEXANDER: Any idea as to the percentage of the available fetuses that might be used for research? In other words, would the percentage be large enough that it would suggest that there is an inducement on the part of physicians to encourage abortions to obtain material for research?

DR. HERRMANN: I would not see how the percentage -- the percentage really is an expression of how early an abortion is done. All early abortions are done by suction and, therefore, there is very little material. And if you have a larger number of older fetuses for research, this means there is something wrong somewhere else in terms of either education of the public or whatnot.

As far as any inducement for physicians, to the best of my knowledge, and I can vouch for this in my own institution, the people that are doing fetal research, they are not involved in doing the abortions. That would eliminate that factor. I am not saying if they were involved in doing the abortion that this would constitute an inducement. This is a point I just can't agree with. If we

assume this sort of thing, we must also assume the physician would let a patient sit with pneumonia because he is studying without giving treatment to serve the scientific interest. I think the question is very basic in ethics.

DR. RYAN: Dr. Cooke.

DR. COOKE: Would you -- I gather you would support the notion that the people who are involved in the decisionmaking regarding the abortion should be distinct and uninfluenced by the individuals that might be carrying out research on that fetus or fetus material?

DR. HERRMANN: There should be differences? Not necessarily.

DR. COOKE: May I ask, then, would you feel that there has been, not necessarily in this country but elsewhere, influence in the kind and possible timing of an abortion to suit the particular needs of investigators studying the fetus?

DR. HERRMANN: Yes, I think there are a few well publicized examples which most likely constitute the reason for your question. I don't think these isolated instances really represent the standard of practice.

DR. COOKE: What percentage? How many?

DR. HERRMANN: There were a few papers. The enormous amount of abortions going on, this has been taken out of context.

DR. COOKE: There is a limited amount of field research, let's face it. But of the amount of fetal research that has been done, how much as the need for a particular type of fetal material influenced the kind of abortion? That is different from the number of abortions being done in the world.

DR. HERRMANN: The kind of abortions, you are talking techniques?

DR. COOKE: Yes.

DR. HERRMANN: Well --

DR. COOKE: Let me say a few years ago, before I was sensitive to some of these problems, we were involved in the planning of a rather extensive research project involving the study of the trisomic (phonetic) fetus. The experimental design required the intact fetal brain. In the planning of that work, which was not implemented, but in the planning of that work consideration of the kind of abortion that was performed was very important. If it had and were performed -- and we had nothing but essentially liquid material to work with, the research would have been impos-isble. And so the investigators planning the research on the fetus were concerned about the type of abortion to be performed.

DR. HERRMANN: In broad terms I think any manipulation of the patient or any handling of the patient which

for the sake of research would subject her to a greater risk, and is not proper medicine. I don't think that is correct. And as far as I am concerned, I would not approve or permit that.

DR. RYAN: Dr. Cooke, are you aware of such things taking place?

DR. COOKE: They have occurred. Certainly. You can find a good deal of material in the Swedish studies.

DR. RYAN: Let's talk about the United States.

DR. COOKE: I don't know.

DR. RYAN: With respect to the Swedish studies, part of theproblem in delay in getting abortions in Sweden were associated with the formalities with respect to consent which were quite strict. And inevitably they delayed the doing of the abortion until later period of time. This is part of the Code they had to get through the legal process to get an abortion. Are you telling me you are aware of many instances in which --

DR. COOKE: Some instances.

DR. RYAN: One?

DR. COOKE: More than one.

DR. RYAN: I would like --

DR. COOKE: Studies done where the hysterotomy was done to have an intact fetus.

DR. RYAN: I grant you that almost anything you

can think of quite possibly could have happened, but that is a non issue, is it not? Or is it an issue? Is that so much of a problem that anyone has asked for that? I think that Dr. Herrmann's response -- I am trying to clarify the probing in that direction.

DR. COOKE: I think we could say the same thing about all biomedical research. I believe that the biomedical research community has been extraordinarily responsible. It doesn't mean there haven't been a few violations. And the Commission was set up for exactly that purpose. I am exploring whether or not there may be some safeguards to violations, even though extraordinarily rare, that may seem somewhat monstrous to people sitting around this table, but they have occurred. One might be an interrelation to the influence on the kind of abortion procedure performed to determine the product. As I say, the research group I was involve in actually gave some consideration to the kind of procedure that might be done to have a fetal material that was more satisfactory. Consideration was given to that. It was not executed. But I want to point out that consideration was given to that. I believe that has come up before.

DR. HERRMANN: Can I respond to one comment?

DR. RYAN: Let's get a quick and easy to and fro.

DR. HERRMANN: I think a request for research of

this sort would not make it past my department. My office certainly would not let it pass the hospital ethics commission. It would not make it past the study section of HEW at the present time.

DR. LOUISELL: If you are right, Doctor, as you put it on page 3, paragraph A, that the abortion issue should be kept separate, doesn't it logically follow that the criteria for the experimentation on a fetus when a planned abortion is in contemplation, or has been arranged, those criteria should be the same as they are on a fetus for which no induced abortion is planned? Shouldn't the criteria be the same?

DR. HERRMANN: The criteria to be used for fetus that is obtained through an abortion should be the same as the criteria used for a baby at term? Is that what you are asking, or for fetus from a spontaneous abortion?

DR. LOUISELL: Shouldn't the criteria as to experimentation on a fetus for which no abortion is planned --

DR. HERRMANN: A fetus in-utero.

DR. LOUISELL: Shouldn't they be the same criteria as for a fetus for whom an induced abortion is planned? Or do you think the criteria for experimentation should be more liberal in respect to the fetus for whom an abortion is planned?

DR. HERRMANN: You are asking my personal opinion,

now?

DR. LOUISELL: In your capacity as an expert.

DR. HERRMANN: I have not addressed myself to the issue, but it has come up before today several times. You are asking me, then, would it be permissible to conduct research on a fetus in utero with the idea that this fetus will be aborted, a reseach you would not conduct on a fetus who is not going to be aborted.

I think it would be permissible, in view of the need of society and of our current law, I think it could be permitted, yes.

DR. LOUISELL: Once the decision has been made to have an induced abortion, there is something about that particular fetus that is different for experimental purposes --

DR. HERRMANN: That's correct.

DR. RYAN: Doctor Jonsen.

DR. JONSEN: Just a comment on your question about the choice of technique of abortion, whether it is or is not an issue. I just suggest if the choice of technique is dictated by a research protocol, there are two possibilities that might make an issue. One is that the attempt to deliver an intact fetus might deliver a living fetus which gives us that problem. Secondly, that the choice may dictate a procedure which would be, as Dr. Herrman pointed out, poor medical procedure, subjecting a patient to something more

drastic than may otherwise be done.

DR. LEBACQZ: A footnote to that issue would be, also, whether in fact the woman is asked to give consent to the particular method for procuring an abortion, whether she understands that there are alternatives and so on. I have not heard that issue specifically addressed, either.

DR. RYAN: Are there other comments?

If not, I want to thank you, Dr. Herrmann.

Dr. Herrmann's prepared statement follows:

I am speaking as an obstetrician who has dedicated his career for the last 25 years to the care of women. During these years I have witnessed much progress in our ability to understand the natural process of growth and development of the unborn baby and the intricate processes of the interaction between the maternal and fetal organism. In fact, I would like to state at this time that the recognition of the interrelationship between the mother and fetus constitutes one of the scientific milestones in our past and in our ongoing quest for knowledge. It thus must be born in mind that the anatomical and biochemical, physiological or psychological interdependence is so great that no investigation of the fetus in utero is possible without involving the mother. Neither is there a possibility of maternal investigation without considering the fetus, with few exceptions of minor significance.

The recent and ever growing fund of knowledge must not be considered as having served primarily the enjoyment and satisfaction of the scientific community. On the contrary, there has been much immediate benefit to the patient; and, through association with such disciplines as pharmacology, the sciences dealing with infections, with defense mechanisms of the organisms, epidemiology, demography, engineering, just to name a few, it has become possible for us to change our role from one of technical facilitator of the birth process to one of far greater challenge and responsibility: to work towards an improved environment, for the health and comfort of the mother and her child before conception, throughout pregnancy and the birth process.

A few examples of progress through research (which would not be possible under the present rules) to substantiate this claim may be in order.

1. First and foremost, the evaluation of agents to stimulate labor. These agents prevent the long labors that formerly led to maternal morbidity and mortality.

2. The evaluation of new anesthesia techniques for vaginal delivery and cesarean section, making these procedures safer for mother as well as child.

3. The evaluation of modalities for the therapy of preeclampsia, a toxic reaction to pregnancy associated with high blood pressure, convulsions, and kidney damage, which have decreased the rate of eclampsia and resultant maternal deaths.

4. The evaluation of different regimens which have so greatly reduced the danger to the woman with heart disease or metabolic disease in pregnancy.

5. The evaluation of timing of delivery and antibiotic use for premature rupture of the membranes which have kept the infection rate to a minimum.

It is indeed gratifying to compare the amount of knowledge required of the young physician striving for certification of specialist in obstetrics with the information available to me 20 years ago. A note of humility, however, is unavoidable because all that is known is not mastered and much that needs to be studied has defied our probing.

Nonetheless, most gratifying is the decline of death and disease during pregnancy and childbirth, although not equal for all women in this country. Gratifying also is the attitude and confidence of the modern woman contemplating pregnancy.

If we must pause today to avoid the temptation of self-righteousness, we must ask for the developments which have led to undisputable progress. Among these are foremost the scientific achievements and the social awareness and recognition of the right of women to expect an equal share of the benefits of our health care system.

Is this fact really so? Does the national research effort in health care bring justice to the women and mothers in this country? Is maximal effort being supplied to support an ongoing determined process of scientific and social development to give all women the rightful opportunity to a healthy body before, during and after pregnancy, and a healthy child?

I am afraid that the answer is not an unqualified, "yes". In fact, there is a general lack of awareness of the importance of the unanswered questions that decide the future of generations of women and their offspring. The proposed policy for protection of human subjects now before us provides some evidence for this argument. I am aware that the Commission is not responsible for its current content. Time is of the essence, however, and I must emphasize the need for revision in order to provide not only the scientist but also the public with a set of rules conceived to direct science to its only function: to serve mankind and in this instance the mother and child.

There is in these rules and regulations a misplaced emphasis in the order of priority as suggested in the title, "Subpart C--Additional Protections Pertaining to Biomedical Research, Development, and Related Activities Involving Fetuses, Abortuses, Pregnant Women, and In Vitro Fertilization."

This peculiar sense of relevance is demonstrated again under, "Definitions", where pregnancy merely appears as a concept of a period in time from confirmation of implantation until delivery. There is no scientific method to confirm the moment of implantation; and, if pregnancy is conceived only as the passing of days, there is no way to distinguish the tumorous and sometimes malignant degeneration of the placenta (without an identifiable fetus) or the blighted ovum (the empty egg consisting of membranes, placenta, but no fetus) from a normal early pregnancy. Yet this definition and concept of pregnancy is used when guidelines in prohibition for research are established.

My most serious objections, however, deal with Paragraph 46306 entitled, "Activities involving fetuses in utero or pregnant women." It is an impediment to the acquisition of additional biomedical information pertaining to human gestation. Wording of this section seems to be directed at regulation of research at the time of abortion. It does not take into account that the vast majority of new knowledge of pregnant women is being and has been acquired without involving the need for abortion or women seeking abortions.

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B. That consideration be given to the complexity of multi-disciplinary research in pregnant women so as to avoid summary prohibition without the benefit of careful analysis of relative risk factors and scientific gain.

C. That in the appropriate sections of these regulations, full emphasis be placed on the pregnant woman as the subject to be protected so as to not infringe upon her rights nor deprive her from gain of scientific discovery.

We will go on. The next speaker is Mary O'Donnell, National Pro Life Coalition and Maryland Right to Life. I presume that is different from the Maryland Action for Human Life?

My name is Mary O'Donnell. I live at 9504 Edgeley Road, Bethesda, Maryland. I am a nursing student at the Catholic University of America. I appreciate this opportunity to testify on the subject of fetal research. I am here today as an interested individual and while I believe that my views are probably representative of the National Youth Pro-Life Coalition, an organization founded on the principle that all human life merits our respect, and to which I belong, I am not testifying formally on behalf of NYPLC.

I realize that the term fetal research is very broad and often misunderstood, and I hope that this hearing

will, among other things, clarify the meaning of that term and help to assess the ethical implications of the public funding of fetal experimentation.

A proper and scientific assessment of fetal experimentation and, indeed, of fetal life itself, has been made difficult by the Supreme Court's decision on abortion. The Court has said in effect that life before birth has no substantial, legally recognized value. It would not be too difficult to conclude from this that there are no legal restrictions on fetal experimentation -- and to take that a step further it would not be a purely Huxlian dream to think that fetuses may indeed replace the cats, frogs, and mice now commonly used in our laboratories.

The scientific mind, it seems, is more discerning of human life in its embryonic stage and, we can be glad, still keenly aware of the obligation to respect and preserve that life. In this respect, I am reminded especially of the recent change of heart and attitude of Dr. Bernard N. Nathanson, who described himself as having been "outspokenly militant" in favor of abortion. After resigning from the Center for Reproductive and Sexual Health, the largest abortion clinic in the Western world, Dr. Nathanson said he was "deeply troubled by my own increasing certainty that I had in fact presided over 60,000 deaths." In his article in The New England Journal of Medicine, November 28, 1974,

Dr. Nathanson wrote:

"Life is an interdependent phenomenon for us all. It is a continuous spectrum that begins in utero and ends at death -- the bands of the spectrum are designated by words such as fetus, infant, child, adolescent, and adult."

I mention this simply to show that fetal life is human life deserving of our respect and protection, and, consequently, fetal experimentation or research must be carefully restricted and monitored. To be more specific, these are the kinds of experimentation procedures that I think would be acceptable:

1. Diagnostic procedures on unborn children such as sampling of fetal blood and/or amniotic fluid when these are undertaken to insure survival, health, and the well being of the child before and after birth.

2. All life-preserving procedures and experiments performed on a fetus surviving an abortion, regardless of whether the abortion was spontaneous or induced.

3. Autopsies on stillborn children or spontaneously aborted fetuses to discover the cause of death.

4. Tissue cultures taken from a dead fetus for the purpose of combating a specific disease and/or obtaining certain knowledge that would otherwise be unobtainable.

I would support these forms of fetal experimentation because they represent legitimate scientific inquiry aimed at the conquest of disease while at the same time carefully regarding the humanity and dignity of the fetus.

There are experimentations, however, that fail to recognize the fetus for the developing human being he or she is or was. Among these is the experimental injection of drugs and chemical substances into the fetus directly or through the mother in order to observe fetal reaction both in the womb and after an abortion. Experiments of this type are unacceptable for a number of reasons:

1. They deprive the woman assenting to such experimentation the opportunity to change her mind before the abortion is performed.

2. They violate the Geneva Protocol of 1925 which barred the use of bacteriological and chemical substances as instruments of war. Also, President Ford said last week that the United States would not use any form of chemical warfare. If enemies of the state have been so protected, should not the unborn child -- who has been cast in the role of "enemy of the Bureau of the Budget" -- be accorded the same protection?

3. They violate our most basic moral values. The United States Senate voted last summer by a margin of 76 to 12 to protect beagle puppies for humane reasons from chemical research and experimentation. We make a mockery of

human life if we are more concerned with our pets than we are with our own offspring.

We need, and soon, a code of ethics for fetal experimentation, a code that will protect the fetus just as it would any other human being. For living fetuses only those experiments that preserve, protect, and enhance the life of the individual should be permitted; for dead fetuses, only specific techniques with limited and clearly defined objectives should be allowed.

Indiscriminate experimentation on fetuses should be opposed for the same reason we oppose such experimentation on condemned criminals and terminal cancer patients: respect for human life. The "he's going to die anyway" justification for such experiments may be logical but it is hardly ethical. Those in Government and in medicine have a fundamental commitment to the preservation and protection of human life. We have seen a bewildering lapse in this commitment by our Supreme Court in their abortion decision; we must hope and pray and do all we can in a practical way to redress the harm done by this decision and prevent further dire and unethical inroads that may be made in the name of fetal experimentation.

Thank you very much.

DR. RYAN: May I ask you one question to sort of check your attitudes on one or two areas?

You feel that diagnostic procedures such as sampling blood or fluid are all right. You feel that the injection of chemical substances are always harmful or create ill effects. I didn't mention it with Monsignor McHugh, but many times the agents being used are an antibiotic which are life sustaining, and the determination is made as to whether it will get to the baby in a large enough concentration to help it, so that in the future, if one wanted to treat a pregnant women with child, one would risk that sort of thing. What about that kind of research, where the only difference is taking a blood sample? Would you throw that in the same category with chemical warfare?

MS. O'DONNELL: I think, if I understand you correctly, if they are administering chemicals that would help that particular child, then I go along with it.

DR. RYAN: It might not help that particular child, but help children in a class. I am wondering whether you object to the procedure, or if there is some degree of latitude in terms of the intent, the objective, and the nature of the research procedure?

MS. O'DONNELL: Well, I am thinking, if the substance that is going to be injected already is very well categorized as something that is not harmful, that would not harm that particular child even though that child would not need it, I can see it for that purpose. But if it is a

chemical being tried out, I would object.

DR. RYAN: Are there other questions?

Parenthetically, I want to set the record straight. The Senate law on beagle dogs was related to chemical welfare, and not biomedical research. They are used to screen for breast cancer. So I think that perhaps that should be kept in some perspective.

Dr. Cooke.

DR. COOKE: I would like to follow up on Dr. Ryan's question a little more.

Aspirin is fairly common. We are interested in finding out whether or not aspirin accumulated in the fetus. Certain fetuses might possibly have defects in which some accumulation of aspirin might lead to the death of the fetus or produce injury.

How would you look at the study of that particular problem?

MS. O'DONNELL: Is there a substantial number of children, unborn children, that would be harmed by this type of thing?

DR. COOKE: We are not sure how much harm. We know aspirin is a widely used agent. Yet we don't know whether aspirin produces some difficulties to the fetus, or to particular types of fetuses. But we are worried about that. There is some suggested information that maybe aspirin

might do something.

MS. O'DONNELL: I think if it is not necessary for that child to have it, since there is that possibility. I think that that should be very limited. I would not favor administering aspirin to see if it would harm the child, to find out if it was harmful.

DR. RYAN: Thank you very much.

May we proceed now to Dr. LeRoy Jackson, a physician from Washington, D.C.

DR. JACKSON: Thank you, Dr. Ryan.

I thank you for the opportunity to meet with the Commission today to discuss certain aspects of fetal research. I come both as an instructor of medical students and Obstetrical and Gynecological residents, as well as a private practitioner of Obstetrics and Gynecology in the Washington, D.C. area. From the academic aspect, I have participated in research involving the pregnant patient and certain abnormal conditions such as exlampsia and infertility. As a private practitioner I have used established procedures resulting from basic fetal research, i.e., amniocentesis and fetal monitoring.

There are four areas of fetal research acceptable at this time. (1) The dead fetus and products of conception; (2) The non-viable fetus in utero; (3) The viable delivered fetus; (4) The viable fetus in utero.

Use of the dead fetus and products of conceptions is a well established practice. Fetal products, i.e., fetal membranes, are a basic part of viral research and have been used in establishing the diagnosis of viruses pathogenic to man. In addition, the use of tissue culture is essential in cancer research. It is with this tissue culture that changes in the anatomic and metabolic states of human cells may be studied and the effects of drugs on these cells which simulate the malignant changes evolving from cancer can be evaluated. It is with this type of research that cures from some forms of malignancy have been effected and death from some viruses has been prevented.

Use of the non-viable fetus in utero offers the opportunity to study the developing human in its natural state. This kind of research has been limited until recent years because of the lack of availability of research material, i.e., the non-viable fetus. However, with changes in the abortion laws and the resulting increased availability of legal abortions, often done by Obstetricians and Gynecologiests in University Hospitals and Outpatient Clinics. This kind of valuable research is increasing.

A new field of medicine, Fetology, was developed using the viable delivered fetus as its primary research vehicle. The prevention of blindness in the premature infant by altering incubator oxygen concentration and the

prevention of death in the premature infant by increasing one's knowledge of pH and acid base balance are examples of the benefits from this kind of research.

The viable fetus in utero offers the best opportunity to study drug effects, disease processes and antomic and physiologic growth in the human. During these 240 days new and vulnerable cells are formed, new systems are developed, all leading toward the formation of new human life. Along with this great research potential should come the great desire to do no harm. Certainly, amniocentesis and its benefits in preventing death from Rh disease and predicting fetal maturity prior to delivery have increased fetal salvage. Fetal monitoring has decreased brain damage secondary to fetal anoxia by detecting early fetal distress and dictating cessation of labor and early delivery. However, it is in this area of fetal research that the question of informed consent and controlled research become extremely important.

There seems to be little problem involving the utilization of products of conception in tissue culture since these tissues are usually destroyed when not used as research vehicles. In the instance of the non-viable fetus in utero, once it has been established that the pregnancy is no longer desired the parents rarely care what happens to the products of conception so long as the mother in unharmed during the

termination procedure. However, a discussion of termination of pregnancy should include a discussion of disposition of the products of conception.

The last two categories represent areas in which the need for guidelines and controls are greatest. The "no harm" doctrine is essential in research in both categories. Only a few congenital malformations are known to be incompatible with life, notably anencephaly, therefore, researchers must constantly be aware of the harmful effects of research and the parent who has the responsibility of giving consent must indeed be informed. This places a tremendous responsibility on the part of the researcher to overcome ethnic, language and intellectual barriers to be sure that the person giving consent knows exactly what is to be done and all ramifications of the procedures.

Unfortunately, the intellectual capabilities of researchers are not always paralleled by patient concern. The patient or the fetus in this instance becomes a number and that number as history has written is often a black number or an Indian number or a Mexican number. It is impossible to determine how high the number goes, but we can try to prevent this number from increasing. How can this be effected?

1. Government agencies must become as zealous in their review of research as they are in establishing

criteria for approval of grants, not only reviewing the number of cases involved but, also, the integrity of the researcher.

2. Making sure Review Committees contain members that are:

(a) Trained in the area of the research being done;

(b) Capable of communicating with the individuals on which research is done, i.e., pregnant mothers;

(c) Conduct detailed reviews of Research Projects, including the wording of consent forms and consent procedures, i.e., interviews with patients;

(d) Racially representative of the individuals on whom research is being done.

3. Appeal to non-government supported research facilities to follow national guidelines which protect the rights of individuals.

4. Establish guidelines to prevent research which will result in the separation of the viable fetus from its mother with resulting death of the fetus.

4. Make illegal any research which includes withholding established therapeutic principles to establish the life history of disease processes.

It is a poor commentary that the legal profession has had to make the country suit conscious to control the

activities of an overzealous few and to awaken the ethical conscience of those of us with the potential to do so much good.

Thank you.

DR. RYAN: Thank you very much, Dr. Jackson.

Any questions?

MS. KING: On page 3 -- I want to thank you for raising for the first time today the problem of obtaining informed consent.

In terms of who should give consent to experimentation on the fetus, you say the parent. And for the record, are you suggesting that it can be the mother, father, both, or what do you mean?

DR. JACKSON: That area of consent involving both parties is a very good one. Often times we can only obtain the mother's.

MS. KING: If the father is available for consent, are you suggesting that consent has to be obtained from both parents?

DR. JACKSON: If both --

MS. KING: Or would it be sufficient to have the consent of the mother?

DR. JACKSON: If both are available, both should be consulted.

MS. KING: You said consulted.

DR. JACKSON: The final decision is that of the mother.

DR. LEBACQZ: I have some confusion. At the bottom of page 1, you talk about the non-viable fetus in-utero, suggesting that this kind of research was limited until recent years because of the lack of availability of such non-viable fetuses in-utero. Then you mention the change itself in the abortion laws. Do I understand, then, that when you talk about permissible research being research on a non-viable fetus in-utero, you, in fact, mean research that begins with the non-viable fetus in-utero, but eventually it is in the abortion of that fetus?

DR. JACKSON: I think that that that classification of fetus generally involves the fetus that is to be aborted.

DR. LEBACQZ: Is there any category of fetus you are excluding from research? You did not specifically mention the non-viable fetus ex-utero.

DR. JACKSON: That classification is included in dead fetuses and products of conception.

DR. LEBACQZ: There may be a difference between a living viable fetus ex-utero and a dead fetus ex-utero. Would there not be a period of time when one could have a non-viable fetus outside the uterus that has signs of life? I am sorry to press you so hard, but I need to get the

distinction.

DR. JACKSON: This is cutting the line close as to the question of viability. If that fetus shows signs of life, that that is a viable fetus.

DR. COOKE: What would you give as signs of life?

DR. JACKSON: Heartbeat, brain waves.

DR. COOKE: Beating heart and brain waves? Just beating heart?

DR. JACKSON: And brain waves.

DR. LEBACQZ: So a fetus ex-utero with a beating heart would be, by your definition --

DR. COOKE: And brain waves.

DR. LEBACQZ: -- would be a viable fetus, What about a fetus with a beating heart but without evidence of brain waves?

DR. JACKSON: That is very close. I would have to say one or the other. If both criteria -- in my mind, and this is my definition as I define viability, my definition is that both must be present.

DR. COOKE: Let's say there is no lung development. There is beating heart, brain wave, and no lung development, so that independent survival is impossible. Would that be a viable or non-viable fetus?

DR. JACKSON: To use the example of the low figures meaning -- if that ratio is low, that fetus cannot

survive or has a very, very poor chance. In that particular instance we are talking about a fetus we are going to do everything possible to help survive. The only distinction I make is the fetus with absolutely no chance of survival. We are talking about a fetus less than 500 grams, or 300 grams, historically to have no chance of survival. One or two instances perhaps. We are talking about a fetus of 1500 grams, 2000 grams, with only one or two of the criteria, but with improved medical care that would get an increase in this rate.

To go back to where I mentioned earlier in the testimony, the basic point in research is once the definition of viability has been established as a criteria, then the research should be designed not to harm the fetus. If you are doing a research product on a four week old pregnancy, conception, that has been decided by the parents to be terminated, if that baby is delivered at four weeks, if it could be, that baby would not survive. So that we know whatever research is done on that infant by a predetermined policy of the parents is different from the fetus born prematurely at 16 or 20 weeks that has at least a better chance of survival. Not as much as 28 weeks or 32 weeks, but increasing chance of survival with the term of gestation.

MR. MANGEL: May I follow up on Mrs. King's question? What is your experience with respect to what

consent is required, if any, with respect to the use of fetal material?

DR. JACKSON: None. Placental material, no consent.

MR. MANGEL: Similarly, with respect to a dead fetus?

DR. JACKSON: Religiously there becomes a question involving the dead fetus. Some of the religions in the Washington area, the intent of the parent is to have a funeral for that fetus. That parent must be asked about this infant prior to any research being done.

MR. MANGEL: Now, which parent? Either? Both?

DR. JACKSON: The one that is available. The mother is available. If both are available, then both are asked.

MR. MANGEL: I guess the point is, with respect to a dead fetus, you would not defer to the decision of the mother, as you would say with a fetus in utero? You are saying either parent might suffice with respect to a dead fetus?

DR. JACKSON: Psychologically with a dead fetus, it is difficult to discuss the disposition with the mother. The father is often times the one who gives the consent, even for an autopsy. If there is no father, the mother is the only one from whom consent can be obtained.

MR. MANGEL: I have two more questions. I am trying to have these answers expressed so your answers would be non-incriminating.

With respect to a delivered but non-viable fetus, what is your experience, and perhaps what thoughts would you have with consent? From whom?

DR. JACKSON: Non-viable delivered?

MR. MANGEL: But alive, if I may use that sense. In other words, not a dead fetus.

DR. JACKSON: My experience with consent for research on that kind of fetus is limited. In the private practice of medicine this is something you rarely have, in this area.

MR. MANGEL: You mean research with a non-viable?

DR. JACKSON: Yes.

MR. MANGEL: And similarly, a viable abortus, would your answer be the same?

DR. JACKSON: The question goes back to really the age of abortion. You are getting into hysterotomy versus suction. The procedure for producing a non-viable live fetus involves primarily very, very early spontaneous delivery of hysterotomy as part of the legal abortion. The hysterotomy procedure is becoming decreasingly sifnificant in the Washington area.

MR. MANGEL: Is your answer, then, there are not

enough viable abortuses really to form an answer?

DR. JACKSON: I would say,yes, there are not.

DR. LEBACQZ: I am sorry, it is getting late in the day and I think I am getting more obtuse as time goes by. I am still not clear as to whether the four areas of acceptable fetal research that you list on page 1 are in fact intended to cover research on the pre-viable aborted fetus? So that, for example, could a researcher take an aborted fetus that is pre-viable but not dead, that has at least one of those signs of life you mentioned, and perform an experiment on that? It is not listed here explicitly, and I wanted to know whether you meant to exclude that?

DR. JACKSON: I did not. The probability would be minus 3. I think the important thing would be the consent portion be intact before any research is done.

DR. RYAN: Thank you very much, Dr. Jackson.

We should next hear from National Abortion Rights Action League, Karen Mulhauser.

MS. MULHAUSER: Dr. Ryan, Commissioners and Staff, I work as co-director of the National Abortion Rights Action League in the Washington office. I have had previous experience as a trainer for people doing pregnancy alternative counselling and have had myself considerable experience, probably with counselling several hundred women who were

searching with the decision as to whether or not to abort a fetus. But my professional training was in biochemistry and have had some limited experience with research, although I don't think I could respond to any scientific questions.

The National Abortion Rights Action League -- NARAL -- is the only national membership organization dedicated to the single purpose of preserving the Supreme Court decisions which legalized abortions. In preparing these comments I was concerned with the possible effect of an agency supporting abortion responding to the questions surrounding fetal research. But it becomes clear to me today, considering the testimony you have heard, especially from the anti-choice groups speaking to the fetal research issue, that it is indeed appropriate that you hear from a pro-choice group.

The Supreme Court decisions of January 1973 -- have made it possible for all women -- not just the rich -- to choose abortion for whatever reason. We do not advocate abortion. We recognize that 1,000,000 women a year in this country during the 1960's chose abortion rather than continuing an unwanted pregnancy. Most of these abortions were illegal or self-induced and were done at the risk of the woman's life. Most illegal procedures have now been replaced by medically safe legal abortions. I want to draw your attention to the attached article from the Center for Disease Control's Morbidity and Mortality Weekly Report of January

18, 1975, which clearly demonstrates that deaths from abortion dropped dramatically once illegal abortions were replaced with legal procedures.

The National Abortion Rights Action League has been drawn into the debate over the question of fetal research. We wish to point out that abortion rights and the ethics of fetal research are two distinct issues.

It is apparent that our opponents in the abortion rights struggle have become involved in the controversy for different reasons. Some appear to have a genuine concern for the "right to life" of fetal tissue, while others are equally concerned with the use of contraception and fertility control in general. There are some leaders opposed to abortion who publically express their true concerns, such as Representative John Zwach at the Senate hearings on abortion, March 6, 1974, when he stated that there is a sickness in this country that we seem to need to have intercourse.

Consider also the remarks of Dr. K. F. Gunning, an international leader against abortion, at the World Population Conference in Bucharest: "It is a pity there is no mention of moderating sexual behavior anywhere in the World Plan of Action." Many others may share their fear that by removing the threat of pregnancy by the use of birth control methods, including abortion, we will change the moral

climate of our country.

Women have always used abortion as a backup method so that they can plan when to have children they want. For example, an International Planned Parenthood Federation study of abortion tells us that in 1971 55 million women in the world had abortions, and 38.5 million were not legal.

National Abortion Rights Action League does not believe abortion should be used as a primary method of family planning. However, while contraceptive failures continue to occur and birth control information remains unavailable to many individuals of childbearing age, we maintain that abortion must be viewed as a backup method of family planning to prevent an unwanted pregnancy.

It is important to realize that most abortions are now performed in the first trimester. As education about abortion and the availability of the procedure increases, we will find that 95 percent or more are performed in the first ten weeks, as is the case in Washington State. The women who seek second trimester abortions fall into two main groups:

1) Teenagers who deny the fact that they are pregnant -- even to themselves -- for two or three months, and women for whom abortion services are not readily available either because of the lack of nearby facilities or bureaucratic red tape.

2) Women who must wait until the 14th week of pregnancy to undergo amniocentesis to determine if the fetus carries a genetic disorder. If a disorder is detected and the woman chooses to abort the fetus, it is of necessity a second trimester abortion.

It is rare, indeed, now to find third trimester abortions, except in cases where a woman's health is concerned. The center for Disease Control reports only 2% of abortions occur after 21 weeks. These are usually considered to be premature deliveries.

I would like to stress that the issues involved in the choice to have an abortion differ from those in the area of fetal research. Abortion is a human and civil right that was confirmed two years ago by the Supreme Court. The Court ruled that the right to privacy guaranteed by the 14th Amendment is broad enough to include the decision of abortion. The Court noted that the word "person" as used in the 14th Amendment "does not include the unborn." Thus, a woman makes a personal decision concerning her present and future life and responsibilities in consultation with her physician.

While abortion is inherently a personal decision, the complex medical considerations of fetal research fall in the public realm. The far reaching health benefits derived from research on the human fetus makes the disposition of fetal tissue a concern not only of the woman involved but of the scientists performing experiments and of the public that

will profit from the research.

The so-called Right to Life groups have focused their attention to overturning the Supreme Court decisions legalizing abortion. As mentioned above, the health benefits of legal versus illegal abortion are obvious. The same groups now are directing their attention to banning fetal research when the real medical advances from this essential research are advantageous to infants, children and adults. Attached to this testimony is a letter from L. Stanley James, M.D. to Representative Rogers, Chairman of the Health Subcommittee in the House of Representatives, including a policy statement of the American Academy of Pediatrics and highlighting necessary fetal experimentation.

Study of the previable fetus provides information to improve the care, growth and development of premature infants, develop vaccines for well children, increase the understanding of fetal organ development and function, to improve the early detection of genetic disorders, and to learn more about drug metabolism and effects in pregnant women and fetuses. Obviously, some of this research must be initiated prior to termination of pregnancy and we hope the Commission suggests that there be no limitations on such in utero research when adequate informed consent is received from women who choose abortion.

Further, NARAL opposes any limitation of research

on abortion procedures at the time of pregnancy as this inhibits development of improved and safer abortion techniques.

It is interesting to note that those groups which purport to have a concern for the "right to life" expressed at their June 1974 annual meeting that they are opposed to the March of Dimes, an organization dedicated to preventing disabling children's diseases.

The Supreme Court recognizes that until viability the fetus does not have the rights of "persons". It is extremely unlikely that medical science will develop techniques in the near future to keep a pre-viable fetus artificially alive long enough to insure its independent existence. National Abortion Rights Action League hopes, therefore, that the Commission will recommend that experimentation be permitted on human fetal tissues with no more restrictive limitations than exist for other research practices.

Thank you.

DR. RYAN: You meant research practices concerning other forms of human beings?

MS. MULHAUSER: Yes.

MS. MISHKIN: You alluded to it, but didn't really specify, can you clarify in your report, by women who intended to have abortions, to what extent, if any,

are you concerned with the woman's possibility of changing her mind? Or have you found in your experience this does not arise?

MS. Mulhauser: I am concerned with that question. It is obviously an important concern. It is not going to be easy for this Commission to write guidelines, but I do know from my experience in councelling women that it is very easy to determine which women with 99.99 probability, will not change their minds. Women who show signs of some ambivalence obviously should not be asked to participate. I don't know how we can guarantee protections against a change of mind. As Dr. Ryan mentioned earlier, we may find in the future that the balance of health benefits from this kind of research outweigh the possible problems resulting from a change of mind. We should not close the door nor should we write legislation that will make it impossible to carry on this kind of research.

As others have suggested, I would agree that there should be an ongoing ethical advisory committee to allow for changes in the future.

DR. LOUISELL: Do you have any source to cite for your statement on page 1 that during the 1960's there were one million abortions a year in this country?

MS. MULHAUSER: I don't have the article with me. There are several medical articles by reputable medical

groups and physicians that say -- many of them say this is a conservative estimate.

DR. LOUISELL: Do you know of any such organizations by name?

DR. RYAN: The Population Council in New York has all of the data, obviously, with the illegal abortions, some of them are estimates. But there was a time not too long ago when the leading cause of maternal death in the City of New York was that having to do with the abortive process.

DR. COOKE: There is a panel of medical sciences that is studying the consequences of illegal abortion. That study you refer to should be ready.

DR. LOUISELL: We should obtain that.

MS. MULHAUSER: It is not ready yet, but should be very soon if you are referring to the study by the National Academy of Sciences.

DR. COOKE: I think that portion, to answer your question, is available.

DR. LOUISELL: My recollection is that Dr. Tetse took serious dispute with the claims being torn out of the air about the number of deaths.

DR. RYAN: He is the most conservative one in estimating these and would refer you, the Commission, to him, if that number is of importance.

May I ask a question, because it has been asked of researchers whether or not they thought the research was used as an inducement for abortion. What do you think is the motivating force for abortion by women, and do you think research is an important issue?

MS. MULHAUSER: I think that would be the very last line on a woman's consideration as to whether or not to have an abortion. Women seek abortions for a variety of reasons.

Some of them are women who thought they were beyond their reproductive life and ceased using contraceptives. These are women whose children are grown and they find themselves pregnant.

I think the statistics show that most of the women seeking abortions are not married, and their lives would be disrupted by having a child. They would not be able to continue a career or an education.

There are an increasing number of teenagers that are receiving abortions, and the argument we often hear against abortion is that legal abortion causes promiscuity. It is suggested that we are causing teenagers to get involved in sexual activities that they would not otherwise be involved in. I think the evidence goes against this, because the teenagers who find their ways to an abortion clinic have been involved in sexual activity for

other reasons, not because of the availability of abortion, or the ready availability of contraceptives. There are other factors in our society that have nothing to do with abortion.

DR. RYAN: I don't want us to get too far off the track.

MS. MULHAUSER: To answer your question, no I don't think women are motivated to choose abortion because of fetal research.

DR. STELLAR: Does anybody have any more information on the position of the woman changing her mind? If a woman changes her mind and has lost that chance, is that a common matter, in your experience, or perhaps anybody else's experience?

DR. RYAN: I can give you a certain amount of anecdotal and real experience in large institutions. I think it is becoming much less of a problem because the interval between the time that the woman makes the decision and the time that the abortion is offered to her has been shortened. Now, some people might say it has been made too short, as they have with the sterilization procedure in which they require now for people on welfare to have a 72 hour interval between the time they make the decision and the time the procedure is done, so that they have the right to change their mind and are better informed.

In days previously, when the request for the

abortion had to go through an abortion committee, and the interval was prolonged, the opportunity for this was increased. Occasionally women would in fact change their minds.

DR. STELLAR: Is this something that happens one percent of the time, ten percent, a quarter of one percent?

DR. RYAN: My feeling with reference to this is it is a very small percentage at the present time. But I think it is hazardous to give a figure on this. I think the whole environment in which the abortion is being requested and done has changed over the last five or ten years, and experiences that were perhaps pertinent or valid ten years ago are no longer valid.

MS. MULHAUSER: In addition to this, one of the reasons that women may have changed their minds earlier, when it was against the law, or she had to get consultation with two physicians or three psychiatrists, she was under the pressure of thinking she was doing something wrong. Now she does not have the second thoughts.

DR. STELLAR: I am thinking of how we make up our minds as to what kinds of regulations are needed for the special cases that we are concerned about, where there is an abortion decided upon and then some form of experimentation which may provide some risk to the fetus, and then a change

in mind. That is a rare combination, it would seem. If it is rare, we ought to think of it one way. If it is the kind of thing that would happen a lot, we ought to think of it another way in trying to arrive at a wise guideline.

DR. RYAN: Do you have anything to add substantively to that?

DR. KELTY: Just a reference as to where to get the information, the Trans National Family Research Institute, AIR, in Silver Spring. They have an abortion information clearing house. Dr. David is quite well informed on the abortion literature.

DR. STELLAR: I would like to know.

DR. KELTY: There are studies on attitudes toward abortion after the fact. I don't know if this answers your question.

DR. RYAN: Mr. Turtle, please.

DR. TURTLE: I came in the middle of the question addressed to you. It seems to me you are saying these same people making abortion decisions now, previously could not make valid decisions on other matters. The unwanted pregnancy was fouling them up. A large percentage of the same group of people is concerned, and why do we now seem to think that we should let them make decisions with regard to this unwanted fetus, when before we relied on the fact that they were in such poor emotional state that they could

not do it?

MS. MULHAUSER: That was due to the nature of the law before. Most of the articles just referred to-- which we could find at the Trans-National Family Research Institute -- show that when the law required a woman go through five different steps before she could have what the Supreme Court says she can have by talking to a physician, it added several layers of trauma to the decision now made very easily. The woman may discuss it with the father, or others significant in her life. It is a simple decision. The studies of the post-abortion emotional situation of women now are interesting. The Commission should have access to the articles. Psychiatrists found 10 years ago women did have emotional problems with their decision to abort. Now, the problems are not there.

DR. TURTLE: Suppose we accept one of the recommendations we heard here today to the effect there should not be any fetal research done in a situation where there is an induced abortion, because use of the internal check or control of having the researcher being potentially responsible for the abortion, would that concern your organization?

MS. MULHAUSER: I can't really understand that.

DR. TURTLE: The line of language is that perhaps you can even view it in terms of informed consent. Perhaps

the parent or guardian of the child would be able to make a decision for the benefit of that child, might be able to make some decisions for the health or benefit of children as a class. Now, we are talking about allowing somebody who is not interested in assuming that responsibility ultimately to make the decision, or give informed consent, so to speak, as to what can be done with the aborted fetus. Do they really have an interest, and would they have in the judicial sense standing to make a decision on that matter?

MS. MULHAUSER: Correct me if I am wrong, but for other medical research on human subjects, an arm is severed or something, the patient has to sign some kind of waiver or consent or something for the disposition of the tissue. If the woman who went through the abortion did not sign such a waiver or be involved in the decision of the disposition I don't know who would. I would think that fetal research, the necessary type we have been hearing about all day, should be allowed. But most of the fetuses now are from abortions, not from miscarriages, and where would you be getting the tissue to do the research if not from an aborted fetus?

DR. COOKE: On page 5 you say that you oppose any limitation of research on abortion procedures. Does your organization support the awarding of financial damages to the infant through the mother or through some funds that

are established by the granting agencies in case the abortion techniques that are experimental produce damage to an infant that survives?

MS. MULHAUSER: I think this was discussed earlier, that if a woman participated in an experimental procedure for a new abortion technique and it did not work, she would still have available the other abortion techniques we know work, and we would not have a viable fetus.

You are referring to if the abortion --

DR. COOKE: I am talking about a viable product of this procedure. We do it, let's say, fairly late. May I set up a situation?

We are interested in a safe procedure -- safer procedure -- for a mid trimester, maybe late mid-trimester abortion. We set up another method. And it takes a little while to make sure the procedure works in terms of killing the fetus, but the fetus comes out alive.

MS. MULHAUSER: This is still at the pre-viable stage.

DR. COOKE: It comes out alive and viable. We know that we are having abortions on live, viable babies now. So out comes one damaged by this experimental procedure. Should there be damages against the mother for agreement? Should the father be involved in the decision? Should there be a fund to protect the infant that is damaged?

MS. MULHAUSER: I don't feel competent to answer. I am not completely clear of the kind of situation you are referring to. I can envision a damaged premature infant.

MR. MANGEL: A case like this occurred in New Jersey, where the question was what damages do you get by virtue of the fact you are accidentally allowed to live. The Court said it so boggled the mind to try to calculate damages for someone who would have been killed otherwise.

DR. COOKE: It is easy to accept damages for premature induction labor, because there have been such suits with very large settlements. So we have a situation here where there might be some kind of damages involved.

I think the question I am leading to is that when a woman recommends, let's say, no limitations of research on abortion procedures, that is undertaking a very substantial statement that has some consequenses and I would think that before that is made, the consequences would be worked out.

MS. MULHAUSER: My problem with this conversation is that in my mind a third trimester procedure is not -- I do not think of that as an abortion.

DR. COOKE: Late second.

MS. MULHAUSER: Then it is non-viable.

DR. COOKE: Let me ask my second question, then. Would you be in favor of research on the artificial uterus,

which makes it possible for the non-viable fetus to suddenly assume personhood and become a viable fetus?

MS. MULHAUSER: I am curious --

DR. COOKE: With all the consequent damages possible?

MS. MULHAUSER: Damages from living in an artificial uterus?

DR. COOKE: Being prematurely induced.

MS. MULHAUSER: It is the next step from the incubator.

MS. MULHAUSER: This kind of work is being done, or was.

DR. RYAN: I was going to ask you --

DR. COOKE: Has been.

DR. RYAN: It was in Life Magazine, I assume it is not being done in the United States now.

DR. COOKE: It is in the world being done.

DR. RYAN: Doctor Mahoney should inform us of that.

I want to thank you for having been with us. Our time is up and I want to allow some time for our three other speakers.

Ms. Mulhauser's prepared statement follows:

The National Abortion Rights Action League-NARAL-is the only national membership organization dedicated to the single purpose of preserving the Supreme Court decisions which legalized abortions. These Court rulings of January 1973 have made it possible for all women-not just the rich-to choose abortion for whatever reason. We do not advocate abortion. We recognize that 1,000,000 women a year in this country during the 1960's chose abortion rather than continuing an unwanted pregnancy. Most of these abortions were illegal or self-induced and were done at the risk of the woman's life. Most illegal procedures have now been replaced by medically safe legal abortions. I want to draw your attention to the attached article from the Center for Disease Control's Morbidity and Mortality Weekly Report of January 18, 1975, which clearly demonstrates that pregnancy related deaths dropped dramatically once illegal abortions were replaced with legal procedures.

NARAL has been drawn into the debate over the question of fetal research by those anti-abortion individuals who link abortion and fetal research. We wish to point out that abortion rights and the ethics of fetal research are two distinct issues.

It is apparent that our opponents in the abortion rights struggle have become involved in the controversy for different reasons. Some appear to have a genuine concern for the "right to life" of fetal

tissue, while others are equally concerned with the use of contraception and fertility control in general. There are some leaders opposed to abortion who publically express their true concerns, such as Rep. John Zwach at the Senate hearings on abortion, March 6, 1974 when he stated that there is a sickness in this country that we seem to need to have intercourse.

Consider also the remarks of Dr. K.F. Gunning, an international leader against abortion, at the World Population Conference in Bucharest: "It is a pity there is no mention of moderating sexual behavior anywhere in the World Plan of Action." Many others may share their fear that by removing the threat of pregnancy by the use of birth control methods including abortion we will change the moral climate of our country.

Women have always used abortion as a backup method so that they can plan when to have children they want. For example, an International Planned Parenthood Federation study of abortion tells us that in 1971 55 million women had abortions and 38.5 million were not legal.

NARAL does not believe abortion should be used as a primary method of family planning. However, while contraceptive failures continue to occur and birth control information remains unavailable to many individuals of childbearing age, we maintain that abortion must be viewed as a backup method of family planning to prevent an unwanted pregnancy.

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It is important to realize that most abortions are now performed in the first trimester. As education about abortion and the availability of the procedure increase, we will find that 95% or more are performed in the first ten weeks, as is the case in Washington State. The women who seek second trimester abortions fall into two main groups:

--teenagers who deny the fact that they are pregnant-even to themselves themselves-for two or three months and women for whom abortion services are not readily available either because of the lack of nearby facilities or bureaucratic red tape.

--women who must wait until the 14th week of pregnancy to undergo amniocentesis to determine if the fetus carries a genetic disorder. If a disorder is detected and the woman chooses to abort the fetus, it is of necessity a second trimester abortion.

It is rare indeed now to find third trimester abortions except in cases where a woman's health is concerned. These are usually considered premature deliveries.

I would like to stress that the issues involved in the choice to have an abortion differ from those in the area of fetal research. Abortion is a human and civil right that was confirmed two years ago by the Supreme Court. The Court ruled that the right to privacy guaranteed by the 14th Amendment is broad enough to include the decision of abortion. The Court noted that the word "person" as used in the 14th Amendment "does not include the unborn". Thus, a woman makes a personal decision concerning her present and future life and responsibilities in consultation with her physician.

While abortion is inherently a personal decision, the complex medical considerations of fetal research fall in the public realm. The far reaching health benefits derived from research on the human fetus makes the disposition of fetal tissue a concern not only of the woman involved but of the scientists performing experiments and of the public that will profit from the research.

The so called Right to Life groups have focused their attention to overturning the Supreme Court decisions legalizing abortion. As mentioned above, the health benefits of legal verses illegal abortion are obvious. The same groups now are directing their attention to banning fetal research when the real medical advances from this essential research are advantageous to infants, children and adults. Attached to this testimony is a letter from L.Stanley James, M.D. to Rep. Rogers Chairman of the Health Subcommittee in the House of Representatives including a policy statement of the American Academy of Pediatrics and highlighting necessary fetal experimentation.

Study of the previable fetus provides information to improve the care, growth and development of premature infants, develop vaccines for well children, increase the understanding of fetal organ development and function, to improve the early detection of genetic disorders, and to learn more about drug metabolism and effects in pregnant women and fetuses. Obviously some of this research must

be initiated prior to termination of pregnancy and we hope the Commission suggests that there be no limitations on such in utero research when adequate informed concent is received from women who choose abortion.

Further, NARAL opposes any limitation of research on abortion procedures at the time of pregnancy as this inhibits development or improved and safer abortion techniques.

It is interesting to note that those groups which purport to have a concern for the"right to life" expressed at their June 1974 annual meeting that they are opposed to the March of Dimes, an organization dedicated to preventing disabling children's diseases.

The Supreme Court recognizes that until viability the fetus does not have the rights of "persons". It is extremely unlikely that medical science will develop techniques in the near future to keep a previable fetus artificially alive long enough to insure its independent existence. NARAL hopes therefore that the Commission will recommend that experimentation be permitted on human fetal tissue with no more restrictive limitations than exist for other research practices.

DR. RYAN: Dr. Hopkins, please? Howard University College of Medicine.

Dr. HOPKINS: Mr. Chairman, I am Dr. Ernest

Loyd Hopkins, Professor of Obstetrics and Gynecology at Howard University. I am interested in this problem of the protection of the fetus from several standpoints. I have been called a "hospital bum" in that I have been trained in Internal Medicine, and particularly I have been trained in the Post-Ob-Gyn residency in human reproduction.

For the past ten years I have been working at Howard with a mostly black population of poor people. And we have all of the problems that are attendant with poor prenatal and near natal statistics, as I have tried to dramatically indicate in the first paragraph of my summary testimony.

The black mother dies three to four times more frequently than the white mother during the childbirth period. The black newborn dies twotimes more frequently than his white counterpart. During the first day of life, the black baby dies at a rate which is 28 times greater than his caucasian mate. Perinatal factors carry much responsibility for these disparities.

There are geographical discrepancies and economic differences which are also apparent. A baby born in Mississippi dies at a rate which is 50 percent higher than the counterpart born in Utah. A baby born to a poor family is destined to be premature and/or a perinatal mortality

statistics in 50 percent of the cases.

The answers to these problems may be obtained from well designed research models which probe into the normal physiology of pregnancy and study the altered physiology which exists during late pregnancy, labor and delivery. Emphasis must be placed upon the relationship between maternal and fetal adjustment during late pregnancy, labor and delivery.

Too often the goal of knowledge is considered to be of such importance as to override the fundamental rights of patients. Historically patients of all classes have shown a willingness to undergo risks in order to provide models for experimental design to answer specific questions. The information provided by the research is essential. The protection of the rights of the patient subjects is mandatory.

The provision of information must be surrounded by safeguards which will provide the following:

1. Information to the patient about the nature of the research to be performed, the risks involved, and the potential information to be derived from the study.

2. Data to the patient on the status of such research in the medical care spectrum and where possible the estimated likelihood that useful information will be

obtained to help the patient subject and others of similar health status.

3. Total information to patient should be provided in a language and format that the patient uderstands. Proof of patient understanding as provided by return explanation given by the patient and documentation in the patient's own language to insure full understanding.

4. Clearly stated policy and implementation which permits non-resistant withdrawal of patient at any time from any project to which she may have previously consented.

5. Collaborative exchange of positive results with the entire medical community. This is essential to provide entry into the health care delivery process especially as it relates to indigent and poor patients.

6. The association of an established clinical unit in collaboration with every facility in which intricate experimental designs in human reproduction are carried out.

Complex and intricate design would not be the goal, but only a means whereby data is obtained, which becomes a part of the ongoing health delivery process.

The non-viable fetus is a part of the mother, inseparably tied to her survival. The mother has the right

and responsibility to decide what types of procedures may be performed upon her. She further has the right and the responsibility to determine the fate of fluid or tissues which may be removed for research purposes. The greatest safeguard for the mother and fetus is to be found in the integrity, judgment and technical skill of her physician. These are reinforced by a peer review process which requires review of experimental procedures to be performed upon the pregnant woman. There should be direct access of the patient to the peer review body for consultation.

I have been very much impressed with the hearing today and I have heard some things which I would like to dispell as a summary statement.

Number 1, I have sat for many hours and cried with women who were in the process of deliberating over whether ot have an abortion. These were women who were locked into a societal situation where they could not afford to have babies. Many of them were married and they were honorable people who were looking at their lifestyle and looking at the possibility for future survival of themselves and in a very realistic way. They knew they did not have the wherewithall to survive themselves, and to bring a baby into the world under these circumstances would have been catos-trophic. These women, on the other hand, are intelligent and in fact many of them had no formal education, but they

had the kind of wisdom which was extremely satisfying.

Now, if one relies on the principal of informed consent to sit before such a woman and discuss with her a very concerned and a very, very emotionally involved woman with the pregnancy that she had, if one sits down and has to explain to her the kind of experimental design he has in mind to perform on the fetus that she has within her, she is not going to accept any outlandish or bizarre treatment of that baby that she has to get rid of. And I think that one of the very important aspects of this deliveration has to consider the fact that many women get rid of pregnancies or terminate pregnancies because they have no other alternative. And this is true of most of the poor people that I have had contact with. In many instances there is no way for these people to change their mind. They have no other choice.

DR. RYAN: Thank you very much, Dr. Hopkins. I am intrigued by your last statement. It has been mentioned many times in the testimony today that women seeking the abortion are somehow disqualified from the human race with respect to making judgments about what might be harmful or might be an extreme type of research. And the import is that one cannot have an abortion with love, if you will. That it is an act of hate or destruction. Certainly the society has to come to grips with this sort of conflict about whether, because the woman says she wants an abortion she

now loses the right to make any decisions about the well being, if you will, of the fetus during that process. And you have rejected that. I think you are the only one who has so far. I am intrigued by that comment.

DR. ALEXANDER: In view of the statistics that you cite on your first page in your testimony, and based on your experience and your practice, could you indicate for the Commission how a ban on fetal research might be viewed by the population you serve?

DR. HOPKINS: I think that for the population that I serve it would be a catastrophic situation. The efforts that most of us are pushing for now, particularly in terms of interuterine diagnosis, would be certainly beneficial for the most part to the poor and the indigent people of this country. And I think that where the thrust has to be is in the area of total and informed consent. These people have to given the opportunity of making the decision to participate. Because of the fact the patient has the right and the responsibility, we feel, to make a responsible judgment in this area, they very often do.

DR. RYAN: Dr. Cooke.

DR. COOKE: The statistic on the first page astounds me. The black newborn who survives has a 50/50 chance of being alive at the first year. Is that in the United States?

DR. HOPKINS: Yes.

DR. COOKE: After 30 days?

DR. HOPKINS: He has a 50/50 chance after being alive in one year.

DR. COOKE: I take it that means a baby who has gone through the newborn period?

DR. HOPKINS. I should have said the black infant that survives birth.

DR. COOKE: That is a fantastic mortality figure.

DR. HOPKINS: That's right. It is true for the poor population. I would be glad to furnish the data to the Commission.

DR. RYAN: Dr. Hopkins. I think you should.

MS. HEIGHT: I was going to say there has been released just recently a study on the black population in the United States, and the figures on mortality, infant mortality and the early years were absolutely astounding. These are based on Bureau of the Census.

I want to ask Dr. Hopkins today earlier we heard of a Code which is -- this Code was presented and dealt with this whole quesiton of informed consent. I noticed the kind of things that you have suggested. I would be interested in knowing whether you find that dealing with people in the lower socio-economic groupings with limited education and other opportunities, whether there have b-en any real studies

made or efforts made in the direction of seeing how the words "informed consent" are made to have real meaning?

DR. HOPKINS: At Howard we have been looking into the matter for the last three of four years with some vigor. We found that among our own people conducting research in human reproduction that we had been somewhat remiss with respect to our responsibilities in terms of informed consent, in that we went through the motions with respect to informing a patient, but then when we had some studies which had to do with patient explanation of what they understood from what they were told, we found that in many instances an earnest effort was made to inform the patient, but the patient had no idea exactly what was going on with respect to what she had been told.

So we have instituted a procedure now which involves the patients, to be told before the procedure is done exactly what she understands from the explanation that has been given her. We think that is very important when we are dealing with people who have limited academic backgrounds.

DR. COOKE: Could we get the exact figures on this? I think it would give the public utterly the wrong impression. It is impossible that half the babies who survive the newborn period die in the first year of life in the United States. It just is not possible.

DR. RYAN: I have asked Dr. Hopkins to get the figures. That seems relatively steep to me. We should verify that.

DR. JONSEN: Your presentation, Doctor, presents something of a dilemma that faces the Commission. I would like to comment on this.

The statistics relative to the status of newborns and children in the black community, regardless of this one point, are obviously overwhelming. The compromised birth weight, nutritional basis, all of that. That community, because they suffer those problems, very likely have to bear the burden of the research. A great deal of it will have to be done there. And taking advantage not only of the presence of those problems, but also sometimes of the "availability" of such populations for research purposes. So on the one hand we are faced with the need to advance research in these problems, and on the other hand faced with the problem of if our regulations are lax, adding still greater burdens to such a population.

DR. HOPKINS: Yes. And that is, I believe, where we feel the heart of informed consent lies. That recognizing that there is a problem in a particular population, very often that population becomes a target for zealous research. And not infrequently the zeal of the researcher becomes so great he overrides the rights of the individual. This is what we

are saying. In spite of the fact that much good would come from the research, that the individual patient ought to have and must have the right to determine if that particular research model will be utilized on her.

DR. JONSEN: Thank you.

DR. LEBACQZ: I appreciate very much the stress that you have put on obtaining full informed consent, particularly for women who may exist in what I consider to be specially vulnerable population.

I want to know whether, in addition to the requirement of informed consent, you would set other kinds of restrictions on fetal research, and if so, what those would be?

DR. HOPKINS: I think the basic restriction, as indicated, has to be in the integrity and judgment and skill of the physician. I don't think that you can get away from that. I believe that the physicians in the community, they are by and large a responsible group.

Beyond the particular physician, I would certainly look at the peer review groups that comprise the research committees in the established institutions which usually have very rigid guidelines for human reproduction experimentation, and from the standpoint of the broad look at it, I would certainly look toward groups such as this with broad expertise who would set general guidelines

and review protocols from time to time and hold hearings of this kind from time to time to keep a sensitivity level at such a peak that we all would benefit.

DR. RYAN: Thank you very much.

May we now hear from Dr. J. M. Klavins

DR. KLAVINS: Mr. Chairman, Members of the Commission, ladies and gentlemen. My name is J. V. Klavins and I thank you for giving me the opportunity to present my views on research on the fetus. I will present my views in ten parts.

The first part will be introduction of myself, but I think it is relevant to my views, which I will be presenting later.

DR. RYAN: You may give it in ten parts, if you give it in ten minutes.

DR. KLAVINS: Yes.

1) I have studied to obtain M.D. and Ph.D. degrees and a diploma in music. In addition, I am diplomate of American Boards of Anatomic Pathology, Clinical Pathology, and Nutrition.

Presently I am Director of Laboratories at Queens Hospital Center, Long Island Jewish-Hillside Medical Center Affiliation, and I hold the following academic appointments: Professor of Pathology, Health Science Center, State University of New York at Stony Brook; Professorial

Lecturer in Pathology at the Downstate Medical Center; and Lecturer of Pathology at Columbia University, College of Physicians and Surgeons.

Over a 20 year period I have made 111 printed contributions to the biomedical field with my present efforts concentrated on cancer research.

Because of my philosophical interests in the future of mankind, for the annual meeting of the American Institute of Biological Sciences in 1973 at the University of Massachusetts I organized and chaired a symposium on "Perspectives of Biological Evolution." Scholars from biological sciences, arts, political sciences, and religion participated at this symposium.

2. According to the present practice research on human subject is carried out with the consent of adults, and consent of parents when minors are involved. I suggest that research on the fetus can be performed with the consent of the mother, and father when available. It is the right and obligation of the parents to determine the development of their offspring. Research on children is performed to develop technologies so that the parents can most effectively exercise their right to determine the best interest of the children. The only logical consequence is to perform research on the fetus as well.

3. Since the Supreme Court in 1973 ruled that a woman

has the right to procure an abortion of her fetus in the first two trimesters for any purpose, there is no reason why, within the confines of this legality, research on the fetus could not be conducted. When the Department of Health, Education and Welfare declared a moratorium on research on the fetus, in my opinion it exceeded the concern for the rights of children and adults. I do not believe that the majority of our society can tolerate the paradox whereby the destruction of the fetus is permitted but research which causes no harm or suffering is prohibited.

4. The merits of research on the fetus are immense for the benefit of the individual involved. Correcting of genetic disorders of a fetus in the distant future will indeed save traumatic experiences of abortion for those parents who are presently much concerned about it. Continued research on fetuses planned for abortion in the very near future will result in such benefits as, for example, development of an amnioscope and ability to diagnose sickle cell anemia or thalassemia -- Cooley's anemia -- prenatally. The studies with rubella vaccine can be carried out only on human subjects. All such studies are urgent on the basis of a morality that every child has a right to be born healthy in all respects.

5. The benefits of research on the fetus for future generations will be even greater than for the

fetus involved. Any additional knowledge on human fetal development will supplement our present information on both beneficial and adverse conditions which during gestational period predetermine the entire post-uterine life of an individual.

6. In the biological evolution the emergence of man has signified the end of the Darwinian period and the beginning of an evolutionary consciousness. This period of increasing evolutionary consciousness invariably will bring into the existence technologies according to a rational species to evolve in chosen directions. Before, from our present view, the future dramatic changes will have taken place in terms of human desires, we all bear a deep primordial instinct of the survival of species. Therefore, not out of concern about our own destiny, but of concern about the future of mankind, in some distant future humanity will have to resort to technologies for a rational adaptation to environmental pressures. This argument adds an additional justification of research on the human fetus.

7. It has been argued that some prospective technologies particularly as they relate to embryonic research may dehumanize our lives. Let us look, for example, at the artificial insemination or artificial fertilization in connection with the presently available technologies for relieving childlessness. Clearly, this procedure deletes

the union of two people physically and spiritually in the act of procreation. But there is no reason to assume that by carrying out the rational laboratory procedure of reproduction in isolated instances we will condition mankind to become dehumanized.

8. What moral or religious objections could there be on research on the fetus if we follow the ancient principle of "primum non nocere" -- first of all, do not hurt. It is this moral principle that has guided mankind over centuries and will guide it in the future.

9. The question can be raised, who oversees that the research meets the moral and legal standards? We all know that the most common practice to satisfy this requirement has been local institutional research committees or local peer review. Such practice has functioned well in the past and can continue as well in the future.

10. In my views, society should not have the right to intervene in an individual's self-determined destiny; also not in the parents' right to their procreative behavior and their decisions concerning the best interests of their offspring.

I believe in the sanctity of life, however, a quote from Jean Rostand's book "A Biologist's Notes on the Future of Mankind" -- Saturday Review Press, New York, 1973 -- is worthy of remembrance, "in some cases a total, inalterable

respect for human life can lead to an impasse or a contradiction, and that in certain circumstances it can even result in advocating conduct that would be contrary to the true interests of human life.

Thank you.

DR. LOUISELL: Do you, Doctor, see anything wrong when a fetus is expelled still living? Do you see anything wrong in maintaining the life of that fetus for experimental purposes?

DR. KLAVINS: I do not believe in such a situation as you present, Doctor, where I will find a viable fetus. Anybody would design an experiment and would do that?

DR. LOUISELL: You are aware that such circumstances have been fulfilled in the past? That the fetus was alive when expelled and has been maintained living in order to conduct experiments?

DR. KLAVINS: I do not believe so.

. well, the first question is, what is life? I think there may have been instances in planned abortions where the fetus may have shown certain physiological functions which are considered part of life.

But ultimately this particular fetus was not capable of living or the researcher was not capable to maintain the life. In situations where in the opinion of the investigator there is even minimal probability of viability, I think this question has been brought up earlier, I would have great qualms of doing research. However, it must be weighed against the merits of such research.

DR. LOUISELL: Why would you have qualms about that type of research?

DR. KLAVINS: I would , because of my personal ethical convictions. On the other hand, we have seen hundreds, thousands of people destroyed, adults, for some certain reason. If there were justifiable reasons, I would do it.

DR. LOUISELL: By justifiable --

DR. KLAVINS: Reasons that would be of great importance. Immense merit.

DR. RYAN: Mr. Turtle.

DR. TURTLE: Would you have made that decision as to whether the research ends might justify the actions?

DR. KLAVINS: As I pointed out, the first judgment has to be made by the researcher and by the mother, and father if available. One must obtain the consent. Then we have a peer review, which considers all research.

DR. TURTLE: We are talking about a situation where you deposit this semi-viable fetus which was the

result of the planned abortion -- the mother had made the decision to abort the fetus. You have some sort of viable fetus. You still say at that point in time the consent for that semi-viable fetus should come from the mother, is that correct?

DR. KLAVINS: Yes.

DR. STELLAR: I am on the same point. I think Dr. Louisell and Dr. Turtle have brought up the questions in my mind. There are two sorts of "living". One is where the living tissue is not viable and won't at some time in the future. Then there is the viable. You try to find a gray area in between there. Those words are all emotionally loaded. One of the troubles when they testify is when we asked them if they will work on a living fetus, it is not entirely clear as a listener they are answering the question about a living non-viable fetus, or a living viable fetus. We should be careful.

Dr. KLAVINS: Let me attempt to clarify this subject with my personal views. I believe that some research procedures which would not be considered normally acceptable by a researcher, would be permissible in planned abortion situations.

The other question is, is it permissible to do such research after the fetus has been removed from the mother. I think we are dealing with this question, and

several times we have expressed some hesitation to this.

Analyzing the situation, the fact that the fetus has been predestined, and let us assume the fetus is by no means, with the present technology we are not able to sustain the life of this fetus which is taken out of the mother's uterus, the question is can we do now the same kind of research, or not?

I think we can do it, because if we can do that kind of research while the fetus is in the uterus why can we not do it when it is out? In order morally and ethically , should we put the fetus back in the uterus and then continue the research?

DR. STELLAR: Let me turn the question around. I ask you now again whether the informed consent of the mother means anything? Why should it? It is now a detachment of the mother, whatever value or relevance it has it seems not to relate to the mother at all. It might be of interest to the researcher or the government or Washington. Why has the mother to make the choice?

DR. KLAVINS: Our present practice in medicine is such that for example to perform autopsies we need consent from the next of kin. I proposed earlier that the consent of the mother and father if available should be obtained. I would consider this in the same context as for example in the performance of autopsies.

DR. LOUISELL: Once the fetus is expelled and we are no longer concerned with her bodily protection, why should the consent of the mother be any more significant than that of the father?

DR. KLAVINS: In my written presentation I have indicated mother alone, but in my talk I included father. There may be situations, for example, that the gestation is carried out in a foster mother. The foster mother is simply providing nourishment to develop. I think in this, which is not developed, we are close to it, in such a situation the father's decision would be extremely important and would be equally important as the mother's.

DR. RYAN: Mr. Mangel.

MR. MANGEL: You suggest in your presentation, as a number of people have today, that the issue of research in the fetus be likened to the issue of research in children. Is that based on your assumption that parents may consent to research on children? Parents alone?

DR. KLAVINS: Yes, that is my assumption.

MR. MANGEL: You would then extrapolate and say parents should be able to consent?

DR. KLAVINS: Yes.

MR. MANGEL: If the law in this country were to develop so that the courts recognize some right in children, so that parents could not consent to research in children

that was not for their own best interests, which I suggest is not exactly unlikely, would you still say that the non-viable fetus in utero should also be subject to -- let's suggest the court says you have to get court approval of research in a child, if it is not in the child's best interest, would you similarly extrapolate and say that would be true of research in the fetus?

DR. KLAVINS: Mr. Mangel, that becomes a different situation. If courts and not the parents will determine the behavior of their offspring then I would assume, this would be extrapolated also to fetuses.

MR. MANGEL: It is not altogether clear. Many people assume, but it is not clear, that the law today in this country is that a parent can consent to research on a child. There is much research on children that is going forward on that assumption. There is no basis to conclude that will be the case. So I am wondering when you and others suggest that the consent procedures ought to be the same with respect to children and fetuses, whether you are taking into account that the law might develop in the area of children so that parents cannot consent without some kind of additional safeguard?

DR. KLAVINS: Mr. Mangel, as a law abiding citizen I would have to follow the law. But morally I

think no government has the right to infringe on these personal individual decisions. The consequences of government infringement on individual's rights are well known to us.

DR. LOUISELL: You mean to say no government has the right to take special precautionary means to protect children?

DR. KLAVINS: I am not saying that. The government should not have the right to determine the destiny of a child. That is the prerogative of the parent.

DR. LOUISELL: Do you think since a parent could consent to an experiment on himself he is thereby qualified to consent to an experiment on a minor child?

DR. KLAVINS: If yes, it is in the best interest of the child. That is a qualification.

MR. MANGEL: My question is with respect to clinical research that would be for the best interests of mankind and only some small benefit accruing to the child. We know that an adult can consent for themselves to participate in a clinical research project for the interest of mankind. I am saying there is some question as to whether a parent can consent to a risk procedure not for the benefit of the child. I am just wondering, when you say that fetuses at all stages and children should be treated the same, whether you would be willing or also would include that kind of a

protection?

DR. KLAVINS: No, parents should not consent to a procedure which is a risk for the child. But there should be no restrictions of research in cases of planned abortion.

DR. RYAN: Thank you very much.

We have one more speaker, if he is still here. Dr. Myron Winick, representing the American Institute of Nutrition.

DR. WINICK: The American Institute of Nutrition and the American Society for Clinical Nutrition are two organizations comprised of a membership of 1700 physicians and Ph.D's in Nutrition. These two organizations represent the major clinical and research arm of the nutrition community and are therefore vitally interested in learning more about the relationship of nutrition to good health in all age groups, including the fetus.

I am presently R. R. Williams Professor of Nutrition, Professor of Pediatrics, and Director of the Institute of Human Nutrition and the Center for Nutrition, Genetics and Human Development at Columbia University, College of Physicians & Surgeons. My major scientific interest has been, and still is, the effect of malnutrition during prenatal and early postnatal life on development of the brain.

Animal and human data have demonstrated that

during early development, severe malnutrition will result in a permanent reduction in the number of brain cells. In addition, the nerve sheaths and connections are reduced and substances necessary for the conduction of nerve impulses are produced in smaller quantities. What is of more concern, however, is that the brain does not function properly. Infants who have been malnourished very early in life are destined to become children who are unable to learn properly in school and adults who will not have acquired the skills to break the poverty cycle.

Thuse we have learned, partly by studying animals and partly by studying children, that there is a critical time during development when the brain is extremely vulnerable to undernutrition. During this period permanent damage may be induced. When does this critical period occur? Animal studies have suggested that it begins before birth. Malnourishing pregnant rats or dogs will result in the birth of pups with a reduced number of brain cells, with microscopically visable brain damage, and with behavioral abnormalities which persist throughout life. In addition, the dogs born of such mothers are extremely prone to convulsions and show an epileptic pattern in their elctroencephalograms.

What happens to the human fetus subjected to maternal undernutrition? We know from epidemiologic studies

that he grows more slowly and will be smaller at birth. This in itself is alarming. The smaller the infant at birth, the higher the mortality rate. In fact, the difference in infant mortality between poor and rich, between black and white, can be entirely explained by the fact that poor babies and black babies have a lower birth weight than rich babies or white babies. Pound for pound, the poor baby does as well as the rich baby, the black baby as well as the white baby. We know from food supplementation studies in poor populations that we can significantly increase birth weight by improving the mother's diet. We have learned this from studies which would be categorized as fetal research.

The key issue is whether or not research involving human fetuses or fetal tissues is necessary to understand the consequences of nutrient deficiencies or excesses during pregnancy. And if so, can this understanding be translated to therapeutic programs aimed at better fetal nutrition, thereby increasing not only the quantity but the quality of life. I believe the answer to both questions is yes. For example, we do not know whether malnutrition of the human fetus will result in a reduced cell number and other biochemical brain abnormalities. Such information is crucial to our setting therapeutic priorities. The availability of tissue specimens coupled with an assessment of the mother's nutritional condition is the only direct way of

answering the question.

If, indeed, the data demonstrate that brain growth and maturation is affected by maternal malnutrition, several important lines of investigation should be pursued. Can we diagnose fetal malnutrition early enough in pregnancy so that intervention programs can be useful in speeding up fetal growth? What kind of feeding program is necessary to allow normal fetal brain development?

The study of amniotic fluid in addition to fetal tissues may help answer these questions. This fluid contains fetal urine and cells and other material. Its composition could give us a clue to the state of fetal nutrition. Hopefully we could develop simple tests by which the malnourished fetus could be detected early and rational feeding or other therapeutic programs could be introduced which would increase fetal growth and decrease neonatal death and brain damage.

The area of how the placenta transports nutrients is virtually uncharted. We do not know how essential substances such as vitamins read the fetus. We do know what constitutes a "fetal vitamin deficiency", or what high doses of vitamins, a current American craze, may do to the developing fetus. For example, recently two infants have been reported to have developed scurvy, severe vitamin C deficiency, within the first six weeks of life. Scurvy at

this age is almost unheard of since normal fetal reserves of vitamin C take longer to be exhausted. Why then did these infants develop the disease? History revealed that their mothers had taken large doses of vitamin C during pregnancy. Could there be a relationship? Studies were undertaken in the pregnant guinea pig. Mothers on high doses had pups who developed lethal scurvy more easily. Why? The pups metabolized vitamin C more rapidly. In essence, exposure to high doses of vitamin C in utero had "tuned up" in some way the machinery normally involved in vitamin C breadkown.

Is this true in the human? This is no theoretical problem. How many Americans are taking high doses of C? How many are pregnant? Our dilemma is a real one. If we continue vitamin C, the newborn may have this abnormality. If we stop it in a woman who has already been taking it, will we induce deficiency in the fetus? We cannot answer these questions without fetal research.

The human handles vitamin C differently than almost all other animals. We know almost nothing about how the human fetus handles this vitamin and equally little about how the human placenta transports the vitamin. We know that high doses are perfectly safe for the mother. Thus, the means are at hand to study the placenta and fetal tissues of women taking high doses of vitamin C - a direct

way to solve a problem which by indirect means might never yield the necessary information and even if it could might take years.

What I have just said about vitamin C is equally true about many other nutrients. We have no knowledge of how the human fetus gets and uses many essential nutrients. Should we wait until two or ten or hundreds of newborns get the equivalent of scurvy? The means of studying the nutrient requirements of the human fetus are now available. If we are truly interested in promoting optimal fetal development, we must find a way with maximum protection for all concerned, to utilize this opportunity.

Finally, it should be stressed that nutritional research in fetuses is aimed at increasing fetal growth, reducing infant mortality and improving the quality of life. The aim in identifying a malnourished fetus is to introduce rational nutritional interventions, <u>not</u> to terminate the pregnancy.

Thank you.

DR. RYAN: Thank you.

DR. JONSEN: Doctor Winick, the studies you described, perhaps more than others that have been mentioned today, are ones that in theory would seem to be susceptible to various sorts of control experiments, randomization, for example. And yet this brings up certain problems,

deprivation of one population and so forth.

Do you have any thoughts about controlled experimentation in the area in which you work?

DR. WINICK: Yes, I do. I think firstly, it is very, very important to not deprive any population of anything that we feel is necessary for that population. So that the experiment must be superimposed on what we think is the best medical or feeding situation that is available.

Now, once that is established, then if one does not know whether one form of intervention might be better than another form of intervention to make the situation even better, then it becomes reasonable to go ahead and set up a controlled program. To me it is not reasonable to deprive any population of any nutrient that we know is necessary.

We know that vitamin C, or think that vitamin C certainly in high doses is safe for adults. It would be logical then in a woman who is to undergo a therapeutic abortion, to give her, with her consent, a high dose of vitamin C, and then look and see how the fetal tissues metabolized the vitamin C. This would tell us a tremendous amount of information I don't see any other way of getting.

DR. TURTLE: From what I have heard here today, there could not have been much research going on before we had all these therapeutic abortions, is that correct?

DR. WINICK: The unavailability of fetal tissues

precluded a certain kind of research on fetuses. The kinds of research that were done were by people that went to Sweden and Finland and did work there or the people in those countries. Certain fetal tissues, as was pointed out earlier, are really not useful for this kind of research if the abortus is spontaneous. Because by the time you get the tissue it doesn't work out.

The second thing is, if I can just make another point, in the nutrition area particularly, there are a number of fads, call them, I guess, which occur and which have no great medical experimentation, to say the least, to back them up. But literaly hundreds of thousands of people are doing this. And large numbers of them may very well be pregnant. And some means of finding out how the fetus handles nutrients is now becoming available. I would hate to see those means lost. That is the one individual we don't know about. We don't know what the amino acid requirements of the fetus are. We know it for the child and the adult, but not the fetus.

DR. COOKE: I am a little troubled by your vitamin C example, because it concerns me we are about to embark on a large amount of research because the effectiveness of the large doses of vitamin C were never established in any scientific study, they never should have been given in large amounts to anyone, adult or otherwise, as far as I

can determine, in terms of effectiveness. Here we are studying in fetuses the effects of excessive doses of vitamin C that never should have been given.

I am troubled by the example of why we need fetal research.

DR. WINICK: We are dealing with this, this is a fact of life. This is not only in vitamin C, but everything else. We must address ourselves to what is happening to these fetuses. In the case of vitamin C, not very good things may be happening.

DR. COOKE: On the other hand, we can predict pretty well when you give something that shouldn't be given, you are liable to run into trouble. And I think that emphasis ought to be placed on controlling or properly studying potential consequences of the use of agents that have not been properly evaluted. One of them would be large doses of vitamin C. It was exploited by the drug companies and so forth and possibly may have serious consequences.

Now, I am not denying there are many problems nutritionally that have to be studied. I would like to ask how you would approach this particular problem which cuts across a number of lines. We know that the off-spring of homozygotes PKU's, female, will have 100 percent chance of defective infants. Good data for that. We have as effective

measures for dealing with this permanent or temporary materialization of these women, or abortions, or their giving birth to defective babies regardless of whom they marry.

The other alternative is the appropriate study of the metabolism in the fetus born, conceived in a PKU mother. Can you see how that problem can be studied in the absence of fetal experimentation?

DR. WINICK: Well, probably if I say I can't you are going to give me the way it can be done.

DR. COOKE: No, I am not.

DR. WINICK: I don't think, first of all, that we want to -- I don't want to get involved in what course this family should take. That is another issue.

DR. COOKE: But they have no option of having normal children unless we solve this problem.

DR. WINICK: That has to be made clear to her, that at this particular point there is no option of her having a normal child. If she were to elect to terminate her pregnancy because of that, the next question is should we study the metabolism in this homozygotes infant?

DR. COOKE: I am saying medicine has that responsibility.

DR. WINICK: I would think the answer would be that such a fetus, if it could be available, we should study. You ask me if there is another way we can get the same

answer, I can't think of one offhand.

DR. COOKE: I am just asking if you can visualize any other way.

DR. WINICK: I can't. The fetus is very specific to a human. I don't know of a satisfactory model animal.

MS. HEIGHT: What I was hearing, too, in what you were saying is that this whole question within particular minority groups and the poor, the low birth weight and the impact of hunger and malnutrition, somehow we still -- as I hear what you are saying, that needs to be understood before birth. I think this is what I was hearing. It seems to me that it raises a question about -- takes you back to the question Dr. Hopkins raised about the uneveness of people that was established long before. That seems to me to be important. I can't speak on the vitamin C, but it seems to me there is something you are speaking to there that is a problem that really is critical, especially in a world with the food problems we have. But also with the fact that there are these dilemmas about the high rates of infant mortality, and then the relationship between the food and malnutrition and growth.

DR. RYAN: Dr. Stellar.

DR. STELLAR: Dorothy made my point. I wanted to broaden the base of your remarks to include the economically disadvantaged, not only in this country but around

the world, and partly because of special dietary aversions or practices which lead to a self-imposed malnutrition which may not be necessary.

DR. WINICK: If I can introduce a statistic, there are 300 million people by conservative estimates today that have suffered a serious bout with malnutrition within the first year in life.

DR. STELLAR: If we had a clearer idea of the consequences of such malnutrition or other dietary regimen for a pregnant woman, on the fetus, I think we might view the problem even more differently and with more alarm and more concern than we do today.

DR. RYAN: Unless there are other questions, Dr. Winick, thank you very much.

DR. LOUISELL: Before we adjourn, I would like to suggest to legal counsel that more thought be given, perhaps more research, to the proposition that we seem to have gotten on a tack here that is not so tenable, that a parent has the right to consent to experimentation on his minor child. To me the best expression on that is still that of Mr. Justice Douglas in Prince v. Massachusetts, that the parent may have a right to make a martyr of himself, but not of the child. I am afraid we have gotten off on some serious misconceptions today in that area. We should be straightened out on that.

DR. RYAN: Mr. Yesley tells me that is an area that will be gone into.

I would like to adjourn us until 9:00 o'clock tomorrow morning.

(Whereupon, at 5:55 p.m., the hearing was adjourned, to reconvene at 9:00 o'clock, Saturday, February 15, 1975.)

Dr. Milunsky was unable to present his testimony at the February 14, 1975 meeting of the National Commission for the Protection of Human Subjects. His prepared statement, which was submitted in advance, follows.

Position Statement and the Philosophy of Prenatal Genetic Diagnosis

Dr. Aubrey Milunsky

The fundamental philosophy, aim and essential thrust of prenatal genetic diagnosis should be underscored. It is the assurance to prospective parents of selectively having unaffected offspring when the procreative risk for having defective children becomes unacceptably high. The emphasis then is not on the removal of defective offspring, but on the provision of life for children who may never even have been born. Indeed, about 95% of all prenatal diagnostic studies conclude at present with the demonstration of fetal normalcy. Studies in our laboratory of well over 1,000 cases (the largest single experience in the USA), repeatedly demonstrate that parents who otherwise would not have children do so following the selective reassurance provided by prenatal diagnosis. Indeed in our experience, very many more pregnancies would have been terminated than continued, but for the availability of the reassuring answers so often provided by prenatal genetic studies.

Recent technologic advances through fetal research now allow for the prenatal diagnosis of an increasing number of serious/fatal genetic diseases. Enormous efforts over a relatively short period have lead to these advances in diagnosis. Unfortunately, the only option to those parents found to have an affected fetus is therapeutic abortion. This clearly is far from an optimal approach. In the classic tradition of medicine, a primary option would rather be to treat the affected fetus where possible. Such opportunities are currently exceedingly rare. The pregnant phenylketonuric woman (with a risk of almost 100% for having retarded or malformed offspring) and those prospective mothers with galactosemia, can be managed by dietary techniques which ultimately may allow for the birth of undamaged offsp . Just last year and for the

first time, it became possible to treat the fetus via injection therapy of the mother (in methylmalonic aciduria). This first breakthrough in the treatment of the fetus has given rise to much hope for continued progress in therapy. In the promulgation of laws to regulate fetal research, the greatest care should be exercised not to interdict the critical research aimed at ultimate fetal treatments. Preventing such research would represent a grave disservice to those patients affected by genetic disease, all prospective parents and to society.

The Burden of Genetic Disease:

Almost 2,000 genetic diseases have been categorized affecting some 15 million Americans. Over half the US population have first-hand family contact with an affected individual. Over 20,000 live births each year are infants with chromosomal abnormalities. In 1973 less than 75 such cases are estimated to have been diagnosed prenatally. Some 2-3% of all live births are found to be infants with major birth defects. Some 25-30% of all admissions to major teaching hospitals in the US and Canada are for genetic disease or genetically related disorders. The prevalence of moderate to severe mental retardation (IQ $\angle$50) is roughly 5.4 per 1,000 of the population. Genetic disease or malformations rank as one of the most important causes of perinatal death and death in early infancy today.

What Fetal Research Has Accomplished for Prenatal Diagnosis of Genetic Disorders:

It was only 15 years ago that the first known chromosomal abnormality (mongolism) was described. No one guessed then that it would be possible within some years thereafter to virtually diagnose all chromosomal abnormalities in utero - as is the case today (others will testify about the pioneering work on amniotic fluid which led to the intrauterine

transfusions for Rh incompatibility disease and the subsequent prevention by administration of Rh immunoglobulin).

(a) Current Status of Prenatal Diagnosis

Sex-Linked Disease

About 20 years ago following the crucial observations by Barr and Bertram of morphologic sex differences in the nerve cell nuclei of cats, the feasibility of fetal sex determination from amniotic fluid cells became apparent. While efforts were made to utilize this approach to prevent X-linked disease, only after successful amniotic fluid cell culture had been achieved did it really become possible to reliably and consistently demonstrate not only the fetal sex but the fetal chromosomes. The ability to consistently and successfully culture amniotic fluid cells and thereby determine the fetal sex, karyotype and other biochemical parameters is not yet a decade old. Indeed there are some states in the union where such studies are still not available. The achievement of fetal sex determination alone now allows for prenatal genetic diagnostic studies of the about 150 different sex-linked disorders. Only 3 of these disorders however, can be specifically diagnosed in utero (Hunter's syndrome, Fabry's disease, Lesch-Nyhan syndrome). For all other sex-linked disorders, it remains possible only to determine fetal sex - and if it is a male, then a 50% risk still obtains that that fetus may be free of the disease. A great deal more of research is required to change the unsophisticated approaches we must make do with today in this group of disorders.

Chromosomal Abnormalities

It is now possible to make the prenatal diagnosis of virtually all known chromosomal abnormalities today. The specific indications for

chromosomal studies today are largely those for

1. translocation carriers
2. advanced maternal age - for mothers 35 years and over (about 10% of all births are to mothers who are 35 years and over representing roughly about 400,000 women)
3. those parents who have previously had a child with Down's syndrome (mongolism)

Biochemical Disorders of Metabolism

Barely five years have elapsed since the first prospective prenatal diagnosis of a biochemical disorder of metabolism. It is positively remarkable that within the space of five years some 65 biochemical disorders of metabolism are now diagnosable in utero. It should be noted that the vast majority of these disorders are, in life, characterized by irreparable mental retardation and/or serious or fatal genetic disease. While individually rare these inborn errors of metabolism represent generally a 25% risk to those parents who are known carriers of the disease in question. Many disorders however are not diagnosable prenatally in this category and include cystic fibrosis - the commonest genetic killer in childhood. Fetal research will ultimately be necessary for the prenatal diagnosis and intrauterine treatment of cystic fibrosis.

Miscellaneous Disorders

Just over two years ago during fetal research studies, it was noticed that a particular protein (alpha-fetoprotein) was elevated in the amniotic fluid belonging to fetuses affected by neural tube defects (anencephaly, myelomeningocele, spina bifida.). Just over one year after such observations were made we began offering diagnostic studies to parents who had previously had offspring with these defects. Today using the alpha-fetoprotein test, it is possible to make the prenatal diagnosis of 90% of such defects, a yield which can be increased some 5% by the additional

use of ultrasound and amniography. Hence for a group of disorders not diagnosable prior to two years ago, it is now possible to make the prenatal diagnosis of some 95% of cases. It should be noted that roughly 8,000 affected offspring are born each year in the US. The serious limitation of the alpha-fetoprotein test however, is that presently it is applied only to those families where a prior tragedy has occurred. Very recently, research studies have indicated that testing the mother's blood may prove to be a valuable screening approach as part of routine obstetric care. Research studies now underway should be able to confirm preliminary observations suggesting that anencephaly and spina bifida could be suspected (or predicted) in 80% and 50% respectively of affected fetuses by testing maternal blood early in pregnancy. More research studies are urgently needed.

(b) Critical Problems - Present and Future

Investigation of the Causes

In patients with moderate-severe mental retardation, no clue to the etiology is apparent in excess of 40% of such cases. The need to know about the control mechanisms of labor and delivery as well as the physiological and pathophysiological aspects of pregnancies at risk require continued attention if any inroad is to be made into the still high figures for perinatal morbidity and mortality.

The causes of congenital malformations (other than chromosomal) for the most part remain unknown. While the effects of common drugs in the experimental situation on the animal fetus have been recognized (and include teratogenic effects of aspirin, tranquilizers, antibiotics, etc.), the effects of such medications on the human fetus are much more difficult to discover. Recently attention has been drawn to the effects of the

commonly used drugs (Librium, Meprobamate) which it appears may have associations with a higher frequency of malformations in the human fetus. Without pharmacologic fetal research, we will remain ignorant of the dangers of fetal exposure to many drugs needed in the care of the mother that may inadvertently or coincidently be administered during pregnancy.

The effects of atmospheric pollution are not really understood in regard to fetal wellbeing. Pause for reflection is provided by observations made from cord blood samples with elevated lead concentrations in one study. We have recently found both nicotine and cotinine (the metabolic products of smoking) in the amniotic fluid of smoking mothers in early pregnancy. We already know that smoking mothers may give birth to low birth weight infants, but we have been given cause to worry that there could be more and other sinister effects.

The effects of maternal diseases on the fetus provide an area of continuing concern, because so often the fetus is at high risk in such cases. In the maternal diabetes for example, where the fetus has a clearly poorer prognosis for survival there is also a five times increased frequency of congenital heart disease (transposition of the great vessels) as well as indications that the syndrome of sacral agenesis occurs also more commonly. There is data to show that women with thyroid disease bear offspring with an increased frequency of chromosome abnormalities. These lone two examples simply indicate the need again to be fully knowledgeable of the physiological and pathophysiological aspects of fetalmetabolism in order to provide parents with the opportunity of having quality offspring.

Prenatal Genetic Diagnosis

Major efforts are in progress to recognize genetic diseases and to

attempt to characterize their defects in red blood cells, white blood cells, tissues in culture, etc. Once characterized in a particular tissue system, such advances can be applied to the fetus in utero, thereby insuring increasing progress towards greater abilities for prevention through carrier detection and prenatal diagnosis and ultimately treatment of genetic disease.

The development of fetoscopy (presently more potential than development) will have remarkable benefits for those at risk for having offspring with genetic disease. By using a tiny caliber instrument introduced into the uterus via the abdominal wall, it should be possible consistently, reliably and safely to obtain fetal blood. In this way it will be possible to determine the chromosomes of the fetus in 3-5 days (instead of 2-4 weeks) and to determine the presence of enzymatic deficiencies within a few hours instead of as long as six weeks. Indeed the occasional instances of obtaining no result at all through inability of the cells to grow or the occurrence of culture contamination could be removed. Obtaining fetal blood safely will also allow for the first time the prenatal diagnosis of sickle cell anemia (the commonest genetic killer of Blacks) and other hemoglobinopathies (most commonly affecting individuals of Mediterranean descent). Fetal research has thus far brought the prenatal diagnosis of these disorders to the point of reality. By directly visualizing the fetus (after more research studies at instrument development) it should be possible to make the prenatal diagnosis of over 60 malformation syndromes <u>not</u> now diagnosable in utero. Ultimately, muscle biopsy (for muscular dystrophy) or indeed of other organs may be possible where there is risk of serious or fatal genetic disease. The fetuscope would indeed open up a variety of avenues to diagnose genetic disorders not

approachable in utero at this time.

Treatment

The vast majority of genetic disorders are irreversible and irremediable. For most of these disorders, genetic disease has become established very early in fetal life and indeed microscopic or macroscopic evidence of disease can be detected early in gestation in the fetal brain. Only a handful of genetic disorders are presently treatable, e.g. phenylketonuria, Wilson's disease, galactosemia, vitamin dependent disorders.

We are still mainly in an era of morphologic recognition and only now beginning to move to questions of treatment for genetic disorders affecting the fetus. I have referred to treatment of the fetus via the mother. Real possibilities exist for treating the fetus directly, for example by administering enzymes (gene therapy) entrapped in gels or in liposomes. (Liposomes are minute biodegradeable spheres that consist of one or more concentric phospholipid bilayers alternating with aqueous compartments within which water soluable substances (such as enzymes) can be accommodated.). Following the perfection of a fetoscopic technique, it is conceivable that liposomes can be administered directly into the fetal circulation thereby opening up possibilities of enzyme therapy for the fetus. Major problems however require resolution first. For example will these liposomes with their contained enzymes really reach the diseased area (e.g. the brain) where the disease is manifesting. Enormous efforts in fetal research are still required to move from hypothesis to reality for fetal enzyme therapy. The use of tissue transplantation as another therapeutic approach will require much greater understanding of normal immune mechanisms and techniques for their modification. We

must first however, study and know the normal, for how else can we recognize and treat those affected?

Dr. Aubrey Milunsky was born in South Africa and had his medical education there and in England. He is a Board Certified Internist and Board Certified Pediatrician, a Fellow of the Royal Society of Medicine, a member of the Royal College of Physicians (England), and a member of the Society for Pediatric Research. His laboraotory is the single state facility for prenatal genetic diagnosis in Massachusetts, and is located at the Walter E. Fernald State School in Waltham, He is the author of the monograph entitled "The Prenatal Diagnosis of Hereditary Disorders," published by Charles C. Thomas, Springfield, Illinois. In 1974 he edited the second volume of "Clinics in Perinatology" published by W.B. Saunders Company. His latest book due to be published March 1975 by W.B. Saunders Company is entitled "The Prevention of Genetic Disease and Mental Retardation." In addition he has published scientific papers extensively on genetic disease and fetal research.

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In vitrofertilization, for example, we embark on a program of vitrofertilization with a certain number of program dollars. Should the possible long-term consequences be looked at and that be essentially mandated before one embarks on such a program? I think that is the issue I am raising here.

MR. RYAN: How do you propose that the Commission deal with that concept, Bob?

DR. COOKE: It would seem to me this is the kind of sticky problem that one probably again ought to take some historical perspective, if possible, or attempt to take a few selected areas and ask individuals expert in those areas and others possibly expert in the social consequences and so forth, look at a few of these to see whether or not indeed it is practicable.

But it would seem to me that out of that might come a kind of conceptualization of the importance of long-term consequences of present research and impress someone enough with the fact that this may be a necessary ingredient in research funding.

MR. RYAN: I think perhaps the best way to deal with that again is to make staff note of it and see if this is not covered in any of the areas which have been mandated by the Congress and already implemented in some of the contracts.

It may not be starred and may not have as much attention as Dr. Cooke is focusing on it, but I think we should

take cognizance of it and see where it fits in our total activity.

MR. STELLAR: I am thinking of the general problem you are raising. There will be a whole host where we want information and we would like a chance to talk to each other to arrive at a consensus and possibly changing our opinions radically after such a discussion.

I wonder how we will cope with the issue of which one do we embark on first. If we do this now we will not be able to do another thing later because of the lack of time and resources.

I am hoping we might have some time today, Ken, as you and I have talked informally in planning out this aspect of our future work and having a way of laying it out. I am a little hazy.

I think I see the whole fetal research issue and what lies after us and what we have to do, but in these other areas I have no feeling for how big they are or how long they will take.

This is a very good and important area, but it seems to me there are a whole lot of others on the docket. We really have not lined up in terms of how we get to them or whether we use a contract or simply ask the staff to provide us with some basic information and so on.

I would like to see that part of our planning.

MR. LOUISELL: In some ways as I get to Dr. Cooke's thesis here it is really a problem that inures in our overall approach from the ethical viewpoint to all the charge we have, except you add to it the very significant thing of tying itto each research project as a part of the project, which might be the most satisfactory way that it is not neglected.

But which number of them we would pick, like fertilization as an example, might become a crutial point, the selection of which specific topics to pick.

So, maybe we should again, as you suggested, Dr. Ryan, note this as a subject matter for final disposition as a basic plan at the next meeting.

MR. RYAN: Dr. Kelty.

DR. KELTY: I wanted to ask Dr. Cooke if you feel that the special study geta at some of the kinds of issues that you are dealing with? The special study says an analysis and evaluation for both individuals and society. Implications could conceivably be interpreted in terms of consequences, utility and whatever. I saw it as being in that part of the legislation.

MR. RYAN: Dr. Kelty, I felt the same thing when I referred to other parts of our activity. I think, however, unless the intent that Dr. Cooke has put on this particular area is put into the contract and worked on specifically, it may not satisfy them.

DR. COOKE: That is possible.

MR. RYAN: It may not.

MR. JONSEN: If staff wants to do a little early research on this problem, they might look to the effort carried out by the National Heart and Lung Institute on the assessment of the implications of the totally implantable artificial heart which was done last year.

I think it is the only example of an explicit attempt to do that in connection with a biomedical development. Dr. Ringler, who is still head of that Institute,was very much involved in the design of that assessment program.

DR. COOKE: Is that now published?

MR. JONSEN: Yes, it was published last year.

MR. LONG: I think such a critical one for the kind of problem we are dealing with would be of tremendous help to me to have copies. Can the staff get ahold of those without difficulty?

MR. JONSEN: They should.

MR. RYAN: I would like to talk about a few administrative matters just to begin with. We will conduct our meetings as long today as is necessary to get our work done. Luncheon may be a problem for us. We will deal with that as an issue when it arrives because there are no food services within the building on Saturday. That is number one.

Number two, we will have three preliminary reports

today from Drs. Mahoney, Behrman and Burkhart.

Dr. Mahoney is here and I would like to get to their reports fairly soon. Before we start on that Mr. Yesley can review the contents of our black book with you and refer you to things which you may want to look at as various materials are presented.

MR. YESLEY: Under item 1, entitled, "Ethical and Legal Issues of Contracts," we have included the work scopes and the curriculum vitae of the different contractors or consultants whom we contacted in response to requests made at the last meeting of the Commission.

MR. RYAN: Don't go into detail.

MR. YESLEY: I would just note that the work scope for Dr. Wasserstrom is not there because he has the identical assignment as the otherethicists.

The next item, "The Historical Contract," is the one which we have entered into in response to the request for a study of the possibility of reasonable alternatives of the use of human fetuses in connection with certain advances that have resulted from such research. That contract was entered into with the Batelle-Columbus Laboratory.

The third item is composed of two requests which went out, one to the General Council and one to the Pharmaceutical Manufacturers Association. The request to the General Council was to clear up the conditions which should be imposed for the

Food and Drug Administration to transmit information to this Commission which might be comprised of trade secrets or other confidential material.

We have not yet received responses to either of these requests.

The fourth item is a list of 80 groups roughly evenly divided between commercial organizations and institutions of higher learning who have responded to the announcements of the special study seeking statements of interest and capability.

We have a voluminous response to those announcements which were published during most of January in part because of reprints due to typographical errors and in part due to going back with a slightly different announcement suggesting people might want to indicate their interest in conducting only part of the study.

I would propose toward the end of our agenda we discuss the possibility of contracting for the special study based on the memorandum which we mailed out unfortunately only at the beginning of this week.

The fifth item is composed of the preliminary drafts of either three or four ethicists who will be presenting their final drafts hopefully in time to be mailed in advance of the March meeting.

In addition to those drafts we received after the agenda book had already gone to press,and those were distributed

and should have been at your places this morning.

MR. STELLAR: Can you tell us what they are?

MR. YESLEY: Siegel, McCormick and Dr. Ramsey's final draft.

DR. COOKE: Those were distributed last night?

MR. YESLEY: Yes, those were distributed last night.

The sixth item is comprised of the correspondence which has been received in one form or another by the Commission or by certain commissioners who forwarded it to the Commission staff for wider distribution.

This generally comprises all substantive correspondence that we have received. There is a brief index which identifies the items preceding it.

DR. COOKE: May I make one comment about that index, please. In fairness to the Genetic Society and the American Society of Human Genetics, what is listed as number 22, materials sent to Dr. Cooke, it says, "Statement on Fetal Reaearch." That tends to give the impression that this may not have the weight of any organization.

I would like to call your attention to the fact that the statement on fetal research is from the Genetic Society of America, the American Society of Human Genetics, and is one on which they spent a great deal of time and effort.

I think it should be properly noted so the Commission members would not possibly miss it.

MR. YESLEY: I am sorry that was not identified. We will try not to in the future.

The seventh and eighth items were developed by the commissioners to be kept abreast of ongoing trials and ongoing reportage that might be of interest to the Commission.

Neither the newsclips nor the case register are intended to be comprehensive. We will be glad to add any cases to the case register that you are aware of and about which we can get information.

The clips are intended to be perhaps a subjective selection of those that are more significant. We will continue both items seven and eight for each Commission meeting.

MR. RYAN: Mr. Yesley, with respect to item 6, "Correspondence," is that all of the correspondence that the staff has received?

MR. YESLEY: I believe that is correct.

MR. LEE: There are other letters requesting a copy of letters from members or requesting a copy of the Act.

MR. RYAN: Was there a list of correspondence in our last book

MR. LEE: This starts from the beginning of our first meeting.

MR. RYAN: I think some correspondence is not included in here and, as you recall, the commissioners did vote last time to review all such correspondence and then act

on any they felt appropriate so that the general public felt the Commission was paying attention to the input it received.

MS. HEIGHT: I did not realize we were leaving the hearings. I would like to go back to them for a moment.

I had the feeling within the context of our work, it may be difficult to acquire,but I had the feeling yesterday that getting the scientific data was presenting one kind of thing. For example, we heard several people who referred to the deleterious effects and impact of socio-economic factors.

For example, even Dr. Hopkins' figure I think communicates differently to different people. When President Kennedy said a black child has half the chance of a white child to survive, people understood what he was saying.

I don't think it is a statistic. I think it is a factor drawn out of the culture and the life of our society. This Commission is apparently the result of public concern and reaction in relation to people with a particular concern for a history that shows that those in the lower socio-economic groups and those with minority backgrounds have pretty clearly played a great part in the selection of human subjects.

Therefore, I made some effort, but I was not successful, but I feel somehow or other we will need to make sure that we get what began to come through yesterday in some of Dr. Greenberg's testimony.

I think Dr. Hopkins and others referred to it.

I listened very carefully when I heard someone say, if we have the kinds of professionals that we can trust we can be sure that things will move.

Having spent all my life in the society, I know that, for example, black women feel that they are often treated, even in the hands of some of the best institutions, in ways that increase their risk over other risks.

I just want to register that I felt that there are elements here that I don't know how we will get at, but unless we do the work, this Commission will have a very strong scientific base but its socio-economic, the reflection of the problem in our culture, this would not be true.

If we were not living in a racist society I think it would be much easier to discuss this. I don't know how we get it out but I think a new thing that would be attributed to the American society would be to have a group of this composition come through with something that is sound enough to get a hearing and strong enough to make some impact on how people are viewed, and how their understanding and consent becomes more than a routine.

I just felt I had to register that because I was greatly pleased with the hearing. I was glad to have as many women's voices as we heard. I think some of them were soft but they were saying some of the things women are saying.

I also feel the whole problem of those we call the

minority groups in this country somehow has to get before us. I don't know how we will do it now that our hearings are over.

MR. RYAN: Ms. Height, I believe we felt these would not be the end of hearings but they would be the only public hearing you would have with respect to the fetal research issue where we are required to prepare a report by May 1.

I think this issue was raised at our first meeting. We asked Dr. Chalkley about it and we do have a record in our transcripts that this is an area that must be looked at, who is selected for research and the whole question of informed consent.

The whole question of prisoners, mentally retarded and others in the deliberations of the proceedings, there should be ample opportunity for this. I think you ought to keep after the Commission to be sure that you are satisfied that we are paying enough attention to it as we go along.

MS. LEBACQZ: I want to second that concern very strongly and say it too seems to me it really comes out in the two ways we have discussed but one we will need to keep redirecting our attention to.

One of those is the issue Dr. Jonsen raised yesterday in suggesting that the very groups which are most vulnerable to abuses in research may also be the roots for whom research is needed so as to tackle special kinds of problems.

I think also with regard to the abuse of women who

have language or cultural differences, I think we will need also to keep those two things before us. Even with this issue, with the fetal research issue, we have a tendency to talk about fetuses as though they had no color.

Fetuses do have color and they exist in women who have color. We will need to be very careful to talk about the women's consent, how careful we are. I find myself wondering if we can get at the kind of data base that will help us get a handle on this issue in terms of knowing who becomes a research subject, and also in terms of knowing how consent is obtained and whether there are differences in comprehension of people geographically, by race, by whatever kind of criteria. I don't know how we go about that.

MR. RYAN: We have an expert down at the end of the table who is itching to talk. First, I would like to ask Dr. Cooke to comment.

DR. COOKE: I think Miss Height's statement brought something which I should ask in the form of a question. A number of interesting issues were raised yesterday by various people in various contexts.

How does the staff or the chair propose to handle these, to highlight them to allow additional discussion. I have jotted down some notes as I went along. What will happen to what issues were raised yesterday?

MR. RYAN: May I tackle that as a formal agenda item?

I would like to ask Dr. Gray if he has any comments in response to what Dr.Lebacqz or Dr. Cooke mentioned.

DR. GRAY: I guess I can be forgiven for mentioning a book which was just published which addresses some empirical information derived from research subjects, two of the questions raised thus far.

It addresses the question of what is the nature of informed consent and what are the difficulties that take place with informed consent. By chance, the subjects that were interviewed were participating in one instance in a labor induction drug study and in the other instance, the research that was involved was fetal research.

Neither study was selected for study for that reason. It just happens that come issues have become relevant subsequently.

Another thing addressed in that study that is relevant here is the differences between the selection and the process by which ward patients or clinic patients become involved in research as opposed to private patients of one institution.

It seems to me with the study, it is my own book, so it is called, "Human Subjects in Medical Experimentation," and perhaps ---

MR. RYAN: The author is who?

DR. GRAY: Bradford Gray.

MR. STELLAR: Will we get copies?

MR. RYAN: Yes. I was just talking to Mr. Yesley. If you desire, Dr. Gray is on the staff because he has done this work and because he is interested and he has expertise that this Commission wants.

MS. LEBACQZ: We want it.

MR. RYAN: If you desire a copy of this, then please request it from Mr. Yesley.

DR. GRAY: Perhaps the limitation of the study which is based on one institution and on subjects in two research projects -- the Commission may be interested in extending the same kind of information-gathering effort to other contexts as well.

MS. KING: That brings up a procedural problem about how we proceed. It seems to me we all agree that one of the problems will be with informed consent and what it means and how we want to approach it. That has been left for work after the May report.

It might be helpful if we were to read at least some materials we have available because I for one do have some difficulty. I don't know how to get around about having anything more than a statement that informed consent with respect to the fetal research subject, will be subject later to the decisions of the Commission.

Maybe if some of us would just do some preliminary reading perhaps Dr. Gray's books or other sections on

human experimentation, it would be a better way of approaching it. I suggest it is a real issue we can't resolve before April but it would be helpful to have some additional information.

MR. RYAN: Dr. Louisell is an expert on informed consent. I think what we should do is to identify those areas that you feel are deficient as we proceed. I would like to address the question that Dr. Cooke raised, if I may, with respect to the carrying out of the Commission's duties, especially as we approach the May 1 deadline.

DR. SELDIN: I have the same reluctance as Dr. Gray in this regard.

MR. RYAN: We will get the information out as we identify the appropriate source material. If I can just speak in generalities for a moment, what I would like to propose to the commissioners is that starting in March and thereafter there will be desks in the Commission offices for the commissioners to stay beyond the regular meeting, probably for one day, perhaps longer. At that time they can do their homework collate the material which is being accumulated in ever-increasing quantities, interact with the staff and help in any appropriate way in drafting materials which we can then consider in a formal way in our meetings.

These extra days will not be formal meetings. No meetings will be held but there will be an opportunity to work

on some of the materials which Dr. Cooke has raised. We have had, I believe, excellent public testimony yesterday and an opportunity to talk to a wide segment of society on this issue.

I would imagine that the staff will be able to collate this material, but I am sure all of us have not had an opportunity to read all of the testimony as yet, to raise the questions and issues which we ought to bring up for public discussion.

I think that that would be the homework that we have between today and the end of the March meeting. We will have the ethics papers, the preliminary drafts that you will have in March. You will have the public testimony and in a few minutes you will have the preliminary reports of three other large studies.

I would suggest to the Commission that those who have the time and want to work that there will be desks available so that we can become a more active, working Commission as well. I don't know of any way, Dr. Cooke, of formalizing our interaction any more than that except to say we will have to read this public testimony, digest it, ask the staff to highlight those areas.

If we agree with the highlighting of those areas they ought to be brought up for public discussion and resolution. It would seem to me after the March meeting we will have to start with the drafting process for the first Commission report.

MR. STELLAR: I wonder if we might do one more thing, that is, those of us who felt moved to do so, perhaps write something after we leave this meeting about the hearings and our viewpoints and conclusions and perhaps send them in. If enough people do that perhaps it would be worthy to get them circulated.

I was making alist as you did, Bob, and I chose to make a list of general issues that came up again. I would like to try to list them and list them while they are fresh in my mind.

In addition to everything else you have suggested I wonder if anybody feels filled up enough with what we heard yesterday and what we have been thinking about to feel this is the time to try to set something down? Maybe it is premature for some people.

MR. RYAN: I don't think so, Dr. Stellar. If you would share the issues you and Dr. Cooke jotted down with the staff then the staff can have as much input for identifying current issues that have to be tackled as possible and it can become part of our report. That is the process we will have.

We have all been concerned about how we will conduct this remendous amount of business the Commission has to do. I think the only way we will be able to do it is do a lot of reading between the meetings and have workdays after each meeting where there will be an opportunity to have the staff

resources and a desk for you to work on the Commission business.

MR. STELLAR: Where would that be physically? Is it in this building?

MR. YESLEY: Our offices are in the westward building about five miles from here, Massachusetts Avenue, extended out from Westmoreland Center.

DR. COOKE: The day after each meeting is a Sunday. Would the staff be there?

MR. RYAN: Some of them would be.

DR. COOKE: It seems to me fairly shortly it would be helpful to have basically a kind of laundry list of issues as the staff has perceived them. We add to that laundry list and then some of the parts of the laundry list may require, I am afraid, some additional studies possibly, even though it is a very short time. A brief position paper might have to be put together by some knowledgeable people. I don't see how else we are going to be able to properly address ourselves to the enormous range of things that came up yesterday.

MR. RYAN: I think the writing of the subsequent reports and subsequent studies, Dr. Cooke, is going to reside with the staff and the Commission from this point on unless anyone can bring up specific matters that we have not addressed ourselves to yet.

Is there any comment or response to the question of

the work periods after our Commission meeting?

MS. LEBACQZ: Would it also be possible for us to come in a day early and work the day prior? I realize that would probably be a little bit more difficult for staff since they will be at that point getting ready for the meeting a day earlier.

MR. RYAN: A desk would be available to you if you wanted to come in a day earlier. I thought also a day after would be available for Commission members. If you want to stay a longer period of time I am sure they will make office facilities available to you.

MR. STELLAR: Another aspect of this work that strikes me as extremely important that we have not had time to do, perhaps in a large open meeting like this that the staff can bat around some of these issues among themselves, that is with the Commission and the staff.

There are ideas that have occurred to me that I would like to bounce off colleagues on the Commission and staff members and perhaps send them off as Bob Cooke implied, to write a position on something on which we cannot resolve the issues.

I know we had to go through the hearings and do the other things we have had to do and I have no complaint about that, but I feel there is a point in time coming up very soon where we will have to devote perhaps a morning or a whole day

to this kind of discussion that we are all full of now and try to identify issues that the staff can write position papers on, get us position papers on and so on.

I think the staff participation would be very important.

DR. COOKE: I would think we could do it this afternoon. It is a long way from the west coast and Wisconsin to come back for such a thing.

MR. RYAN: There is a possibility if we have time this afternoon we can start this. We can certainly reserve time in the March meeting.

DR. SELDIN: I feel that is among our primary needs -- an opportunity for deliberative discussion based upon what we think tentatively has been shown. If we let that kind of deliberation go into March -- well, the longer we let it go, the less opportunity there is for a reconciliation of apparent conflicts in views.

MR. RYAN: Agreed, and in order to get on with our business, what I would like to do now is have the reports from the investigators that we have invited here and then whatever time is left in the meeting can be used for that purpose, if that is agreeable.

MR. TURTLE: Are there any administrative matters on which you want us to take action?

MR. RYAN: I would prefer to allow our invited

speakers to speak first, go on to administrative action matters and then throw it open for the kinds of discussion that Drs. Stellar, Cooke and Louisell were recommending.

MS. LEBACQZ: I have a short administrative matter.

MR. RYAN: As a courtesy I think we should allow the invited guests who have traveled some distance to be here to be heard now.

We have a report from Morris J. Mahoney, dated February 15, 1975. Do all of you have it in front of you? You are seeing this for the first time. Dr. Mahoney, why don't you tell us what your group has been doing, where you are, what you have accomplished and the like.

MR. MAHONEY: Yes. This is a preliminary report. Its body is a recapitulation of what we have derived from a literature review.

I am not satisfied with it as yet and it is very much preliminary. A final report will be with you four weeks from now.

I would ask though as you look at this, there will be considerable work of my own and people I am working with in the next two weeks in terms of making this final. I have found in working with the materials so far that perhaps some direction from the commissioners as to how this material would be most useful to you could give me guidance in writing the final report.

GASDOR/eh

P R O C E E D I N G S

9:00 a.m.

DR. RYAN: The meeting is formally begun. Dr. Cooke, would you state the issues?

DR. COOKE: Yes. I think the question I raised yesterday was, we should consider under protection the issue of financial protection in the case of damages sustained by the fetus or abortion procedure research.

I was concerned this might not be discussed by the Commission.

DR. RYAN: Dr. Cooke, for purposes, is it necessary to consider this separately for recompense and this as a subset of that.

DR. COOKE: I think as long as we recognize that the fetus becomes a child, sustains the injury and the compensation would be considered for him or her, is the issue I would like to make sure exists. There is one statement in here that talks about compensation for the mother, for example.

MR. LOWE: I think there is a while question of how you compensate an individual injured in research. I merely suggest for your consideration that it is apparently so complex it goes way beyond the information that is now inputting to the Commission. You may or may not wish to discuss it. I won't enter into this.

DR. COOKE: The trouble is we have to give some

report in regard to fetal research. It would seem to me we would probably not be doing out job completely if we did not make reference to the fact that there may be a point where compensation is an important issue.

MR. STELLAR: Can we take recognition of the fact that it is a problem and indicate we will go into it more thoroughly and really postpone any recommendation in regard to the fetus per se until we have had an opportunity to go into this thoroughly, if we should decide to do that generally.

MR. LOUISELL: Of course, Mr. Chairman, this problem has had its counterpart in the general problem of human experimentation, and the discussion of human experimentation and the risks thereof -- some consideration was given to the basic thesis that maybe the time had come to abandon mere common law liability for negligence and create and insurance system of compensation as you all know.

Therefore in this area of fetal experimentation I agree it becomes a very important phase of the problem. It is an area quite discreet in its area of competence. At least we require the acturial expertise also and with the great pressure we are under perhaps the best we can do is to make a reservation of the problem and point out that this is something for subsequent study, because how we could do this in addition to all else we have to do before May 1 presents a very difficult obstacle.

DR. RYAN: Is there other discussion about this? Does someone want to make a formal motion so we have in the record how we are going to act on this and so that it is not left uncovered.

Dr. Louisell, could you restate your recommendation relatively succinctly?

MR. LOUISELL: I just wonder, Mr. Chairman, would it be wiser not to try to formalize this at the moment until others have had a chance to think it through.

MR. RYAN: Mr. Yesley, will you make special note of the fact that there has been reference to compensation for damages in the fetal issue and the staff has elected to take cognizance of it but not render a decision on that issue until it has more information. Is that a fair statement?

MR. LOUISELL: Excellent.

MR. RYAN: I am afraid if we don't star something it would get lost.

MR. RYAN: Could we discuss any aspect of the public hearings which we had yesterday which you desire to discuss, while they are fresh in your mind, any aspect of them?

DR. COOKE: There was a point which I think I did not adequately speak to. This came up a number of times somewhat indirectly and relates to the matter of consequences, a study of the potential consequences before embarking on a research program or the support of research and a statement

from the National Insurance Institute of General Medical Sciences probably sums it up as succinctly as possible.

For every dollar spent on development, in that case new genetic technolog, how much should be spent in assessing its ultimate utility and harm or by whom.

As a general principle it would seem to me we ought to give that consideration. That is no more applicable in fetal research then any other but it certainly has not been a general policy, it seems to me, of the granting agencies that a certain part of the program monies look at or are used to looking at the possible application and the utility or harm that may accrue from the production of such research.

I think it is very applicable in this particular situation.

MR. RYAN: In the total thrust of our activity that finally the Congress has mandated and set aside a review body to look at it in general and have a successor body look at the question you are raising, not only the question of doing research but now the utility and the consequences of research. That is part of our social study.

DR. COOKE: I think I am saying as a principle this should be cranked in at the beginning of our research and not wait and let some other group monitor what has happened.

What I am saying is that some part of the research dollar might address itself to possible consequences.

There are opportunities to lighlight issues in ethical terms, opportunities to pull out cases of research which have raised ethical issues which we have not done.

I am wondering whether the Commission wants us to organize our information in this way. The information so far has been organized mainly in a scientific-medical way -- what kind of advances have come from field research; what their impact has been on the practice of medicine; on the well-being of the fetus as a patient.

So, I would very definitely appreciate within the next weeks personal contact from anybody if you feel a direction different from this would be useful to you in making this report final.

MR. RYAN: I would recommend such direction go through the staff office, Mr. Mahoney, so it can be coordinated in case several people have the same request. Otherwise, you may get just one point of view rather than the Commission request.

MR. MAHONEY: The report is organized as follows: The first page has a short introduction to recap for you the basis of this literature review. Also, there are the definitions which we have as a group which we have agreed upon to use. Certainly these definitions might not be the ones you prefer to use in the handling of the fetal research issue, but they are the ones we have used.

For example, fetus has been used to apply to

everything, every stage of human life from conception until parturition or the point of viability where we start calling the organism a premature infant.

Classical people have divided these into embryonic and fetal stages. We have used the word fetal to cover all of these. We have used fetus to talk about the human organism outside of the uterus. Others would not accept this.

We have not felt it usual to split our use of terms that way. So the definitions are as stated. They are based on the ones the English Commission under John Peale used.

The organization of the literature search data is summarized at the bottom of page 1 and the top of page 2. We divided the area of living fetal research, research on living fetusus in these four broad areas. There is overlap and in the handling of each area you will find that there are some aspects that are either repeated or treated in one section which might have been treated in another section.

Those comments at the end of page 2 relate to areas we excluded from our literature review and those were excluded after the discussions that I had with you here. That is, we have not addressed the problem of the first days of human life, that is from conceptual until the time the embryo is implanted into the uterus and we have not investigated the implantation process, the research which goes on about that period.

Of course, there are very important research issues there, one of the most important ones being interruption of pregnancy at this point. So, the very earliest embryos and the invitrofertilization are not part of this literature review.

Likewise, research using the purely dead fetus, and in talking about the purely dead fetuses we really considered the fetus to be dead only when what we felt were reasonable criteria of heart, brain, muscle and lung action were no longer evident.

A fetus whose tissues could still grow cells, where not every cell was dead, we still define it as dead if there is no major activity of those major body systems.

But, we did not try to split hairs there where a fetus was alive or dead depending on whether it could take a breath or not or whether it had electrical brain activity. So we used a definition of death which I think almost everyone would be willing to accept.

We excluded from out literature search essentially on autopsy, the research which goes on with a clearly dead fetus.

The fourth item there, "Research with a Viable Fetus," which we define as a premature infant, was excluded. We felt the issues there, and I think you were in agreement, are the issues of research on newborns, where they are born somewhat

prematurely or not. Again, we were very liberal with our definition of viability so that the areas which we reviewed really were dealing with a lot of infants which were viable and did live.

But, some would not be viable and there is a very hazy distinction of viability which changes both with progress in research and with the area in which the sophistication of medical technology, where the infant is.

I was not satisfied with our work in the first area, that is the area of normal and abnormal growth of the implanted fetus. I thought it was too disorganized to me to be useful to you so I did not include it in this preliminary report.

That is why on page 3 it starts with area 2 instead of 1. The bibliography which we have battered is one which I thought would be useful for the people working in these areas, would be useful to the commissioners if they wanted to go to sources.

It is heavily laden with review articles, some case reports of research which are meant to highlight a research technology or a research approach which may have ethical implications. By no means was the bibliography meant to be an exhaustive search of research.

The bibliography as far as we gleaned it from the National Library of Medicine is available to you. It is on

the staff here. Dr. Alexander has a copy. So, that is available. I think probably it would be of very limited use to you.

The body of the report then, in the three areas, on page 2 and 3, I think it would not be of any major use for me to try to summarize it for you.

Let me also direct your attention to the last page of this report. These are the activities which my group will be interested in in the next four weeks.

The first item which has highest priority in terms of completing it and completing it earliest, is to make this literature review final. That is why I say if there are directions that would be useful that I take in writing this up finally, please try to flow this to me through the staff.

In addition to making this literature review final, those other three items will be addressed as well.

DR. COOKE: What page?

MR. MAHONEY: Page 28, the last page of the report. That five, by the way, should have been erased better than it was. There are only four items there.

We surveyed current fetal research in in academic institutions by letter, by a lot of phone conversations with investigators and by our own knowledge of the field. We will make comments about what the investigators are doing right now and what they wish to do in the near future, and the directions we think research would go if not constrained.

We also specifically at the request of the Commission will file our own viewpoints on an ethical base as to why we do fetal research and what we feel about it.

The fourth item will also address what we feel will be the impact on not only advances in fetal medicine but general scientific bio-medical advances should there be such restraints placed on fetal research.

We will address it as outlined there until the Commission would direct us to some other outline. That is, we will consider the consequences of not being permitted to do research on a dead fetus or not being ablt to do research on a dead fetus which was available, as the consequence of an induced abortion versus available by some other process.

We will address ourselves to the fetus in utero, addressing those four alternatives as well, that is the fetus which could not be viable outside the uterus versus the fetus which could be.

The terms theraputic research and nontheraputic research are very controversial ones and many scientists feel it is a false distinction. We thought we would try to use them in an operational way as we outlined in that last sentence, that is, that theraputic research is research where the investigator has the intent to implement the viability of the fetus or to help the fetus attain or maintain viability. Nontheraputic research does not have that intent, even though

it may not be detrimental to the viability of the fetus being researched.

We realize there are definite limitations and one does find theraputic and nontheraputic does confuse in places.

The fetus that is to be aborted and the fetus that is meant to continue to live will be considered as two different categories and for the fetus that is to be aborted we will address the issue of should research be done, or what would happen if research was restrained only for the period of abortion or where the research procedure could be started.

Then we will address ourselves to the fetus outside the uterus, the fetus viability outside,the fetus as a premature infant, and have the same kind of analysis, I believe, as any other premature infant would.

But again, the issue of spontaneous abortion versus induced abortion and the process at which the fetus becomes viable to the investigator is one variable which we will address in the theraputic and nontheraputic research issue.

MR. RYAN: Perhaps it would be worthwhile to see if the commissioners have any questions of you at this juncture. You have just brought your report which has just been finished. None of us has had an opportunity to read it.

I was leafing through it while you were talking. I think it is going to highlight for the nonbio-medical members of the Commission specific examples of fetal research that you

can refer to so that you have something more concrete to deal with than the generalities which have gone across the table up until now.

I commend to you reading areas three and four as descriptions of what pharmacological research is all about and what the research of the previable fetus outside the uterus is all about.

Without offending the sensitivities of people, Dr. Mahoney has described the types of specific research that have been in the newspapers and have been read by people, that is, profusion of the head.

Going from that, I am on page 20 now to something that might be considered innocuous, that of measuring blood from the cord which is done routinely to measure the health of the infant. It could also be considered research.

You are beginning to provide the Commission with specifics that will be helpful to the Commission in dealing with the issues before it and highlighting the specific research projects that people will be concerned about.

Dr. Cooke?

DR. COOKE: Jerry, your exclusion number 4, if we took this literally, I think you would be excluding a very important area. I doubt that you have, and that is the viable fetus in utero, all the research done in the latter part of pregnancy would seem important.

I don't think you meant to exclude it. I would guess you were referring to research with a viable fetus outside the uterus.

MR. MAHONEY: That last sentence is what we have done.

MR. RYAN: So, your concern, Bob, he has covered?

DR. COOKE: Yes, the last trimester in utero.

MS. LEBACQZ: One of the things this Commission will have to be very careful about as we do our work is defining what we are talking about -- and I really appreciate the care and attention you have given to some definitions here.

I would like to ask you to clarify for me if you can another distinction that is not clear in my own mind and that is whether it is appropriate to use the word "experimentation" or the word "research." What is the difference between those two?

I notice you have carefully used the word "research" here and I wonder if there was a particular reason for that, and if you can clarify that distinction for me.

MR. MAHONEY: Dr. Lebacqz, I don't recognize a distinction in the use of the two words as it applies to the areas we have looked at.

MR. RYAN: There are obviously semantic differences that I am sure you are not interested in.

MS. LEBACQZ: No.

MR. STELLAR: I offer one suggestion that might be helpful to you if others agree --that experimentation involves the manipulation of the variable, to introduce some kind of a change with a suitable control.

Research may include observation in which you don't do anything to the situation and it is the broader term. Experimentation is actually the manipulation of an independent variable to see the effects on a dependent variable, the thing you are measuring.

I think that is the basic distinction in my mind between the two. I know we use the two interchangeably but if you bear that in mind. When they are noninterchangeable you are talking about a manipulation in the use of the word "experiment" and possibly experimentation. But I know it is not strictly adhered to.

MR. RYAN: Are there other comments or questions that individuals would like to address to Dr. Mahoney?

MR. LOUISELL: I realize this comes perhaps to the ultimate difficulty and not particularly for Dr. Mahoney but for the Commission itself, but it seems to me -- and I can't even guess preliminarily to what extent your format is already planned to produce this -- but your results will be most relatable to the results of the ethics studies and vice versa if, despite your preliminary need, of course, of adhereing to accurate methodology from a medical viewpoint, it would be

apparent from your studies to us particularly the lay persons medically speaking, how much of the techniques that you deal with themselves cause the termination of life or serious risk to life.

Secondly, if it would be clear to us how much of these techniques presuppose or assume the necessity of data, underlying data by way of preabortion.

In other words, to what extent an inhibition on an abortion would be preclusive of the necessary data for your study?

To the extent that we could perceive these things I think there would be great contribution to the inter-relationship of your work.

MR. RYAN: I did not understand your last question. I don't know if other people did. Perhaps you could paraphrase it or help me.

MR. LOUISELL: I mean, to what extent, even when the technique of research or experimentaion does not in any way directly cause the termination of life or serious risk to the life, to what extent does it, nevertheless, presuppose the availability of adequate sources of data for the experimentation by way of free abortion?

I mean, proceeding on the assumption of free abortion in society.

MR. RYAN: By free, you don't mean in an economic

sense?

MR. LOUISELL: Permissive induced abortion.

MR. RYAN: What you are really talking about is a large number of abortions regardless of the mechanism by which it is achieved. You are talking about numbers?

MR. LOUISELL: Numbers is one thing but mechanism by which it is achieved. For example, we had some discussion yesterday on the possibility at least of techniques of abortion being selective in performing the abortion by reason of guaranteeing them more suitable as research and experimental materials.

MR. RYAN: Would the question you are raising be satisfied by an analysis of research that is dependent upon abortive material and one that is independent of it?

MR. LOUISELL: That would be one factor.

MR. RYAN: I think that is achievable, is it not, Dr. Mahoney? That is certainly readily apparent.

MR. MAHONEY: We can certainly approach it from that viewpoint and give comment to it. Certainly the activity in fetal research, Dr. Louisell, is a consequence of the availability of abortuses. I think everyone working in the area fully recognizes it.

It is opportunistic research that could not have been done if abortion were further restricted.

DR. SELDIN: Is it possible to define between

abortions that are from any viewpoint including the most traditional, regarded as acceptable as contradistinguished from those that are induced by decision?

MS. MISHKIN: On the final definition between theraputic and nontheraputic, the people we heard yesterday, there were a number of people they had to limit not simply to life-saving techniques but did not oppose techniques that went with clear purpose and intent to benefiting that fetus in utero or ex utero.

I am wondering if the definition of either viability or nonviability is the most useful. What would you do with research involving clear category? He has defined theraputic as going to viability.

My question is whether theraputic ought to be understood to include other things than going to viability, referring to his page 28.

MR. RYAN: I know what you are referring to and I understand your qeustion.

MS. MISHKIN: I thought it was something you could draw your attention to.

MR. RYAN: I think quite possibly it would be too restrictive. Is that the thrust of your comment, that it would be too restrictive, that research ought to be evaluated in a different sense, or therapy should be interpreted in a broader sense and the beneficial effects of direct therapy,

or that which would be of use in a different context, but that which was neither beneficial or advantageous.

MR. ALEXANDER: Perhaps it could be altered.

MR. RYAN: I think specific therapy has to be kept in mind because research with the objective of sustaining life or providing therapy apparently is not an issue in the broad context. We ought to know when someone is doing research clearly in the interest of that fetus to sustain its life to viable or beyond.

So, I think theraputic, beneficial, nonbeneficial are the kinds of categories that have been most helpful in the past.

MR. MAHONEY: Is there anything beneficial to a fetus except bringing it to viability? Certainly relief of pain and prolonging life and so forth have definite benefits where the fetus will be asked to address that? Are those same concepts applicable to fetal life?

So whatever terms we use we will have difficulty with them and we will try to address them.

MR. RYAN: Several other commissioners want to address question to you. I want to point out that no matter what we say around this table we will not significantly expand your work scope unless we tell you as a Commission action that we are expanding the Commission work scope.

Insofar as we can there is general agreement that we will try to comply with dealing with data you have that would

be most beneficial to the Commission if you can do it within the time frames we are talking about, to address yourselves to the question that Professor Louisell raised.

We will come back to that but I think there is more discussion. First, Dr. Cooke.

DR. COOKE: Jerry, is it within your scope, do you plan to do and so forth, the matter of the prolongation of life of the previable by some support measures and HEW regs in this regard? What does this do in the area of research?

MR. MAHONEY: We want to point out that research efforts can be done to provide viable life. One can refrain from actively restraining whatever time it takes for the fetus to die naturally. We recognize that and will try to make comment on it. We will not try to answer.

DR. COOKE: Do you have examples of such activities and the consequences of a policy which would prevent that?

MR. MAHONEY: Yes, we will have examples that used to mean to keep the fetus alive while information was being gained and the assumption being if those means were not used, such information could not be obtained.

Of course, that last assumption can be questioned. But procedures, for example, where the baby's circulation to the placenta during the period the uterus was open and studies started, at that time over an hour's period -- but here the process is ongoing.

The fetus is profused with blood in order to maintain certain life functions of that fetus while other data were being examined. Some examples of that are here and if more are needed we will provide more.

DR. COOKE: Have you had the opportunity to see Dr. Ramsey's statement. He spent a lot of time on this particular point. It will be one of the stickier issues.

MR. RYAN: It might be important for the commissioners to do so also?

DR. COOKE: Yes. But, I think it would be very important for the study group to look at it, too. Dr. Jonsen had a question.

MR. JONSEN: Your test, when we talked about the work scope, does not explicitly include a discussion of the ethical issues. But, we did ask that you be attentive to them and we have given the specific task to others for the emphasis.

Just glancing at it, you have produced what looks like an excellent review paper. I note on page 5 under your discussion of RH incompatability that you have a paragraph explaining the research design to the extent that this research was originally done, only when the fetus was severely jeopardized by homologic incompatability.

Through the rest of your paper, if you address yourself from time to time to what might be the kinds of things that an ethical review committee would be attempting to find

in looking at a protocol, to the extent that is viable in the literature ---

For example, issues of risk benefit, the informed consent problem, the selection of research subjects, the design of the experiment in terms of randomization, use of various kinds of controls, prolongation of surgical procedures, and all that king of thing that an experimental committee would look to.

I think it would be helpful to try to do that for us when you can. It seems to me that that is the kind of information that is most frequently ommitted from a scientific report. It is very rare that anybody gives you that.

I would hope that as our Commission goes to review the state of experimentation in generaly that we would advise that formal reports of scientific work include that kind of information.

So, I am suggesting to the extent that you can, provide a model of that sort in this type of paper. It might be valuable.

MR. MAHONEY: As you suggest,in large part it will have to come from us. The literature has very little in it.

MR. RYAN: Dr. Jonsen, were you suggesting instead of having information methods, results and conclusions that each paper have a section called ethical review?

MR. JONSEN: Yes, I am.

MR. RYAN: I find that very intriguing. Dr. Seldin was next.

DR. SELDIN: One of the point on which distinction was drawn, your orientation section has to do with theraputic and nontheraputic research. Theraputic research is defined as that kind benefiting the fetus for prolonging life. Clearly, the term intent is a loaded one.

Nevertheless, it seems to me we can recognize intent on one end of the scale and it become blurred as you come toward the middle with polar extremes and unambiguous theraputic and unambiguous nontheraputic research.

Nontheraputic research when it is identified in some publicly acceptable manner, nontheraputic research which can presumably be done of a type which benefits not necessarily that fetus but that class of fetus -- Say you study sickle cell disease and the observations of sickle cell disease might not benefit that sickle cell fetus but might benefit sickle cell fetuses in general or in the future, this can be contrasted with some more losely defined search for truth such as central blood flow.

This might benefit the sickle cell fetuses also but the pathway is somewhat ambiguous. What I would like you to do, and we discussed this at the time you made your original presentation, is to flag those things which you regard as theraputic in the sense that the intent is to concur viability or

at least the benefit; those things which are not theraputic which can confer benefit to that class of fetus, recognizing the definitional problems inherent in intent of classes of fetus, and so forth; and those which explore basic truth.

Dr. Jonsen pointed out the problem of risk benefit analysis as one parameter by which research should be evaluated. Another parameter would be this very complex issue of intent which goes to some of the things, highlighting what you raised earlier.

It is evident, for example, in some of the sections you had in your report and several other reports that I glanced at that the issue of intent is very critical. It would be very worthwhile to try to do something about it since you are scouring this material anyway, and see how these can be classified.

I want to call particular attention, however, to the issue of nontheraputic research where a distinction might legitimately be drawn between nontheraputic research which is nevertheless very critically pertinent to a class of disturbances of which that particular fetus is a part, versus nontheraputic research which is a little bit more disinterested, even though we recognize this is only a distinction that lies on a calculus of probability.

I think it would be helpful at least to me, that this issue of intent, theraputic and nontheraputic benefits

to the fetus were flagged to some extent. This is very, very pertinent in my opinion and in the discussions of people in research connected with such diseases, sickle cell diseases and the like.

It is also very pertinent to the empirical assessment of what it means to do research on disadvantaged groups.

MR. TURTLE: Dr. Mahoney, yesterday we had public hearing testimony from many people engaged in various kinds of research and we heard comments that fetal research was absolutely necessary and we received a series of examples.

I would appreciate it if it is not too difficult, if your group could look at the papers and the examples provided and perhaps give us some comments whether in your opinion those are good examples which could be undertaken without the availability of fetal research.

MR. RYAN: I think, Bob, the problem is that your question was addressing itself to whether or not there was an alternate means of doing the research.

MR. TURTLE: No, I did not mean it to be that broad. I was saying particularly this group which has done a literature search. They are aware of all the research that has gone on. There were examples cited yesterday.

I am interested in knowing if those examples are opinions of scientific developments that could not have been accomplished without fetal material. That is the sole

limitation. I recognize the other studies going on.

MR. RYAN: Can we kind of recap the kinds of questions that have been addressed to Dr. Mahoney to see whether or not they are do-able within the time frame and if we can identify them. I suppose the first one was Dr. Louisell's question, which was, could you identify the research which you described with respect to whether or not it depended on the free availability of abortuses. That is one of the questions Dr. Louisell asked.

MR. LOUISELL: That is correct with respect to induced abortions as distinguished from spontaneous abortions. It is also correct also to the extent that it is possible the reason for the abortion, whether purely elective in the sense of no reason for it other than the choice of the woman involved as distinguished from abortions where there would be a consensus of perhaps a unanimity of opinion respecting the legitimacy of the abortion.

MR. RYAN: That information would not be available in the literature search, David.

MR. LOUISELL: My concern is this: I read the preliminary report of Dr. Ramsey last night. I can foresee a direct confrontation between the ethical assumptions and perhaps that would be an almost if not a completely unanimous approach to the problem, the ethical presuppositions and the medical data. There will be no way of really relating the

two unless we can have real specificity from the medical viewpoint.

MR. RYAN: I think we will have to get it from the Commission. I do not think you will get it from the review unless they document the abortion was done for medical reasons associated with specific medical problems.

I would think in most instances that is not available.

MR. MAHONEY: What you are asking would be very much opinions of ours and not things that we could document?

MR. LOUISELL: Would there be any way of making an opinion or reaching an opinion that would be an arguably-sound basis for having the opinion?

DR. COOKE: I am not sure that problem is as difficult prior to legalized abortions, taking certain areas, which would have been for reasons that most people would say represented medical necessity, et cetera, versus research after permissive abortion where one would say we don't know whether that particular material was or was not.

The terms of numbers would be probably, that it was permissive. What would be one comparative.

MR. MAHONEY. The quantative analyses were proper. I think all of us can understand ---

MR. LOUISELL: At least from an historical viewpoint, that could be understood.

MR. MAHONEY: It is easy to document that research

in fetal work jumps when there is a lot of material available in fetus research.

MR. LOUISELL: I think that would be relatable to the ethical approach.

MR. MAHONEY: Still,there will be opinionated statements from us that we will be dealing with.

DR. COOKE: But you try to document your last statement because that is a big statement. I take it your intent would be to document with as much evidence as possible, the quantum jump that had acquired as a consequence.

MR. MAHONEY. Document it in terms of published papers or groups of investigators working, the quality of knowledge coming from it again, will be a judgment we can make comment to, but it will be difficult to justify it.

DR. COOKE: I would think a group of scientists sitting around could identify several areas that we could agree on which represented "quantum groups," at least the major accomplishments. One could ask whether or not those great jumps in the basic information was required, et cetera, and was antedated or postdated for the permissive abortion period.

The process leaves me kind of cold quite honestly. It says if you have a lot of material you will have a lot of investigators. That does not necessarily say the accomplishments would be that much greater.

MR. RYAN: Bob, we could not hear you, would you

repeat what you said?

MR. TURTLE: It was an add-on to Dr. Cooke's suggestion, that the accomplishments could not be achieved in some other way.

MS. KING: I am a little troubled about the discussion of what we are asking Dr. Mahoney to do. I am troubled because I think it is within the purvue of this Commission: Since we have commissioned all of these studies, legal, ethical, medical,et cetera, to start making the connections and interrelationships between the studies.

I understand, I think, Dr. Louisell's point about wanting some information from the medical study, but I thought that we at least began to take a little care of that by requesting your ethical comments, which was an opportunity to express your ethical opinions of individuals and how you approach doing what you did,to give us a better idea of your assumptions.

I for one am very unwilling to ask you to do more in the way of ethical consideration because, quite frankly, I think you are doing what we asked you to do.

I think what we are now asking you to do is what the Commission should be doing. As a lay person on the Commission with less knowledge than other people, I think I would be willing to try to tackle what we are suggesting that you do.

I am not sure I want Dr. Mahoney to do it. I for one am opposed to the suggestions, I think, I am hearing aboutthe

additional requests of Dr. Mahoney.

MR. LOUISELL: I think Miss King's comments misconstrued really what we are after. Dr. Jonsen added the proposal about the ethical conclusions, which I think is also supplementally at least helpful.

But my primary concern is to get from the scientist, data that will be relative to the underlying ethical problems because we want more than a generalized confrontation between science and ethical approaches, if such is the inevitable confrontation. We want the data from each discipline.

All I am asking for is this data to the extent it is feasible, to the extent it is possible. I understand the problems of medical research in a general way and it may not always be possible.

I think already we have had agreement on previous occasions with Dr. Mahoney that there is some plausibility to getting the induced abortion data differentiated from the spontaneous abortion data.

MR. RYAN: For the record, I want to respond to that. I don't see us sledding toward a conflict between ethics and science.

I think there is a spectrum of ethics, of opinion, and we will have to reconcile differences with the ethics of the spectrum. Not only should they read Ramsey's report but they should read all of the ethicists' reports in trying to

address the issues involved.

I agree with you that we should try to get as much factual data as we possibly can. What I am trying to do now before we break for coffee is to identify those things which are reasonable to ask Dr. Mahoney to do with respect to the attaining of infomration within his work scope and within the time frame we have.

Everyone will get a chance to speak but I want to try to restate them.

One, you want to know from a historical point of view and factual point of view when you can identify the type of abortion which was done in relationship to the research? For examples, you select, you probably will be able to do that, Dr. Mahoney, I think.

I don't think you can do it for all of your literature search but for the examples you selected in the preliminary report. I know you can do that.

I don't think you will be able to make distinctions within these abortions as to what the motivation of the woman requesting the abortion was in all instances, whether it was medically motivated. That is possible. That is one issue you want to know about.

The other was, Mr. Turtle wanted you to address the question, or your association, whether ketone production in the head of the human fetuses could have been obtainable by

another mechanism. I think that summarizes the requests that have been addressed to you.

The third item was, and you provoked that one yourself when you stated that you thought that the volume of research in this area was related to the availability of human material for this purpose, and Dr. Cooke said, prove it, those are the three areas that I have identified.

I want to now ask other people to comment but I don't want us to lose sight of the fact that we have to send Dr. Mahoney out of here with something specific to do.

Those three are the items and if there are no others, we are fine. Take them in order now.

MISS KING: I will pass.

MR. RYAN: Dr. Stellar?

MR. STELLAR: In regard to the first point, one thing bothers me as a logical matter. That is,reliance on the comparison of research done before legal abortion and afterwards.

The change in availability of material through abortion is not the only variable that would contribute to the goodness or quality of, or results of the research, or the results obtained.

While the analysis might be performed, I think we have to be very cautious in interpreting it.

The second is as Charles McKay points out to me. There is an emphasis on some of this and it might be easier for

the report to contain some of the ethical aspects, is that correct? Is he apt to be able to do this?

MR. MAHONEY: Yes, I think he has been directing us all along as we have been directing the research and as we wanted to analize impacts and restraints. So it is directed somewhat that way already.

MR. RYAN: Please keep you comments brief. We have been sitting for a long time and I want us to stand up and have a little coffee. If we can resolve Dr. Mahoney's charge before we stand up, I would like to.

DR. SELDIN: The point I tried to make is a rather important one. I wonder if the Commission is interested in seeing this kind of data. I feel myself it has to do with the distinction between theraputic research as research which will benefit that particular fetus, and nontheraputic research as ---

MR. RYAN: We agree with you. You don't have to elaborate. That was in his original charge. The way you have defined it, I will add it to the three I already have.

I would agree with that and we can take a vote on the four items now.

Dr. Lebacqz, do we have five?

MS. LEBACQZ: I hope this is possible to do. One of the representatives from the scientific community who testified here yesterday made the comment that material from

spontaneous abortions is very nonuseful for research purposes.

I would appreciate some kind of guidance from you. I think that that is included in one of the items that you are planning to do anyway, listed on your list of pages here as to whether spontaneous abortion does in fact result in useful research material.

MR. MAHONEY: We will certainly comment about those.

MR. RYAN: Those are the five items. Is there any additional?

MR. LOUISELL: In your good summary of the problem, I am not sure whether it includes induced versus spontaneous?

MR. RYAN: Yes, Karen just referred to that. I did not mean to short-change any of the aspects. I was trying to identify the major areas. Please make a note of that.

MR. MAHONEY: The one thing I also heard from Mr. Turtle was could we comment upon all of the public testimony of yesterday as to the examples of research, whether he thought they were real or important ones.

MR. RYAN: I did not think he asked you to do that, did you?

MR. TURTLE: There were several statements among the statements given yesterday which attempted to make the point that fetal research is absolutely essential to the wellbeing of this country. In each instance in those statements several examples of important research were given.

I just want to know whether basically, first of all, whether that literature search was accomplished with fetuses and secondly, does it appear to your group that it could have been accomplished any other way?

MR. RYAN: Bob, I think that is going to be part of the Batelle study.

MR. TURTLE: The Batelle study deals with four specific aspects.

MR. RYAN: One of them was RH, so there is overlap. I am just afraid -- we can pull out the examples and compare them between Batelle and others. We could ask the staff to discuss this with Dr. Mahoney.

I am just sort of trying to be an arbiter to get everything we need before we sit down to do the work and the ability of Dr. Mahoney to comply.

MR. TURTLE: I would ask the staff to pull out what they feel has not been pulled out.

MR. STELLAR: Sometimes it is helpful to the author and the reader if the author forces himself to draw not only some summary statements but some conclusions or recommendations.

I am wondering if this is possible. I notice in this report there is no overall by far set of conclusions. Could we have one page worth? Does that make sense around the table? Then we could argue or agree or disagree.

MR. RYAN: Eliot, I think it would be very difficult

for him to make a general summary statement covering growth and development, the previable fetus, ex utero, the fetus in utero, et cetera. Where possible you can make judgmental comments. Where you are researching fact we want to know that is research fact; that is where you have been requested to give an opinion that would be helpful to the Commission, that it be identified as an opinion of the people providing the information.

I think that if we lose sight of the fact that we have asked Dr. Mahoney not just to give us opinion but go to the world literature and research it, that is what is taking the time and effort.

I want that effort documented in a way that we can recognize it and insofar as he can give us conclusions about it, well, this type of research in general has led to this and we think it is worthwhile or we think it could have been obtained in another way, that would be appropriate.

But, it should be so identified. I think we ought to take a 15-minute break, reconvene at 11:15, unless anyone wants Dr. Mahoney for other things. I would like to start with Dr. Behrman right at 11:15, if we may.

(A brief recess was taken.)

MR. RYAN: Could we reconvene, please?

Before we start, there are one or two items of business before we start with Behrman. I want to indicate to

Dr. Mahoney that I think we have a sense of the Commission. I think I enumerated them. I would ask that he consult with staff for interpretation.

We will review that so that if it falls within our work scope and time frame, if you have questions you can address them to staff. We may have more time in our discussion if you are able to be with us later in the day to consider any questions you have or if the Commission wants to interact more.

I think in courtesy to the two other gentlemen following you I would like to have them make their formal presentation and then we will base our time as we see fit.

MR. STELLAR: I would like to make a request of the staff with respect to Dr. Louisell's book, to Xerox the chapter on informed consent so we may have that circulated to the Commission members.

MR. RYAN: Would you make that in the form of a motion?

MR. STELLAR: I so move.

MS. LEBACQZ: Second.

MR. RYAN: All in favor say,aye; opposed, no. The motion is carried.

Dr. Behrman, it is my understanding you are going to present only an oral report?

MR. BEHRMAN: We are one stage behind Dr. Mahoney

in the sequence of things, our contract having been started later by a month or so.

I will recapitulate what we have done and where we are going now, and then I would appreciate you comments on this way of proceeding.

Specifically, we were first asked to survey the changes that have occurred in the last 10 years in survival rates between mature infants and the factors responsible for the changes.

We surveyed the latter on this issue extracting approximately 42 detailed reports that have adequate views. We have surveyed 31 Senators, obtaining from them to various degrees this kind of information.

Unfortunately, in many instances even the best Senators in the country, the information does not go back 10 years so it is going to be spotty, although in certain instances we may have the whole 10 years, and in other instances, only a few years.

There is really no national information that is really relevant on this or the world health because almost all of that information cuts off at 1000 grams or at 2500 grams.

In other words, they will lump all of the data collected on an international level. This has required really requesting the directors of those centers to go back and dig

out the information for us which is a laborious task and clearly one that is worthwhile. We have had a fairly enthustiastic response but it is a different kind of task than doing a literature search.

MR. RYAN: May I ask is it possible to get good data in the institutions that you have asked when you to go back. Is there record keeping such ---

MR. BEHRMAN: In some. We will try to make a comment or evaluation on that data. We have asked the people to give us a sense of where this data is coming from and what their opinion is of it. We also do that ourselves.

In some instances it is outstanding. For example, New York City, all of the designated premature centers have had a constant layer of reporting 250-gram weight reporting for over 10 years, so that data we have been able to extract.

MR. RYAN: At what weight do they start?

MR. BEHRMAN: No one starts under 500 of the city, State or national data. To get weight classifications below 250 gram intervals or to get them below a thousand we have to go to individual centers.

We have four centers so far that have such data that seems to be of good quality and particularly the most useful data is the data we have from the Province of Quebec.

They are going through their data for us. Their data is computerized, semi-manually computerized from all

provinces and all hospitals. Some of this has been put together and are they are working with it already. They have gone back after a meeting in which we had representatives from about 13 of the centers and we did a preliminary look at the data.

They have gone back and are pulling out our data for us. For example, there is poor data on gestational age. They do the very last menstrual period on their cards in Quebec.

With all of the kinds of limitation on that data, they have not pulled it out. They are going back and getting it for us.

So, I think we will be able to put together a pattern, probably not a national pattern or world pattern, but patterns at different centers that will reflect the weight specific age groups.

Some data from Colorado, some data from Arizona and some data from California, four centers, have it by 50-gram weight groups. They are pulling it out. They have had it but they have not analyzed it. They are pulling that all together for us.

We do have the Quebec and San Francisco data. This essentially then will give us a probability table, if you will, of the chance of survival at different weight groups, hopefully broken down with as small weight increments as possible, 50 would be the best, 250 is a poor likely and 500 is what most of the world does.

I can give you an example of that, not a final example, but the Quebec data we took, the 500 to 1000 grams survivers by weight, and essentially we plot the weights at increments against the number of survivors. Then we can get some sense of where the survival rate goes to zero.

We will present it as separate pieces of information from separate centers and then try to put those bits of information together that seemed reasonable to put together in terms of either the weight classifications or the quality of the data.

MR. RYAN: Mr. Yesley just asked a very important question, and that is why classification for survival are you using? There is the AMA 1 and 2 perinatal figures depending on seven days of life and 28 days survival. What are you talking about?

MR. BEHRMAN: The Quebec data 28 days and 7 days, WHO data. That is now under revision by the World Health Organization but we have to accept that.

MR. RYAN: You will be talking about survival for seven days and 28 days?

MR. BEHRMAN: Yes, and where we have it differently we will express it differently because the different centers have it differently, so we will have to indicate that.

That is why it will not be possible to lump the data to come out with some data that really makes sense.

MR. STELLAR: Can you clarify the seven days and 28 days? I am not sure what that means.

MR. RYAN: The figures are given from 1000 grams either lifeborn or stillborn or neonatal death from seven days up to 28 days of life . The AMA class 2 is 500 grams, 28 days post-delivery survival or death within that period.

All perinatal figures are given in those terms. WHO has some slightly different classifications than that but I think that is what you are talking about, is it not?

MR. BEHRMAN: Yes. For recording purposes worldwide the quality of the information you get is significantly poor when you try to make any kind of counting of death between seven days and 28 days postnatal life just by the nature of life and society and the hospitals reporting.

The first seven days of life is considered a whole quantum jump better information and that is what the World Health Organization wanted. This may differ in New York or California. They may have very good data on 28 days just because of the society into which those babies go, so they can track the data.

That we are working on and we will be able to give the Committee that. We are going to express all of that information in terms of percents survival. The information is expressed in many different ways in the different states, local and nationally.

We are trying to convert it to one form that we felt would be the most useful. The next thing was the changes in survey in medical technology during the last 10 years which has contributed to the survival of premature infants. This is a much more qualitative request and essentially we have asked the same groups and representatives to give their impression. It is an impression because often there is no documentation of exactly when something was started.

There is no historical record in most hospitals as to the day a particular kind of ventilator was used. Some places may have that but most places don't have that. It is just not recorded, so many of the changes, even the change, for example, the use of rogoen in the RH problem is not recorded.

You cannot find at a given center a date so you have to rely on the rememberance of the obstetrical people involved as to when they started to do that.

It also means there is a big spread of time as to when something was started and when something was generally used. Even in a given center, someone may have been using a particular new technique in treating a premature infant but that may represent only one of 50 men in that center making decisions about treating premature infants.

So, we had to get judgmental information as to when they thought in that center it was pretty widespread, a given advance. That is important,to understand that process because

that makes it very difficult to relate any changes in survival rates with specifics that are seen to relate to specific events.

We have approached this in the judgment of the people whom we consulted who are running this center by picking out index events that seem more important in everyone's judgment and clusters of changes in technology.

We will then look at the clusters of technology changes at each center where we have the appropriate data to which we can correlate. That is going to be very crude and subject to erros in a year or two depending on when different technologies were applied.

It is not possible to say that it will be useful on a given mortality rate as compared to a given event because the original data is not good enough to do that and also because we can't get a good handle on qualitative technology changes.

For a given center we may be able to get a little more precise look. For example, using indexed pressure, when respirators came in at a given time, we can capitulate that time for a given time and look at particular centers and be pretty sure within that span of time that it was used on all babies it was appropriate to use it on.

Then we can look at their mortality changes for that time. This is going to be spotty data in that we will have maybe a handful of centers with different diseases where

we can relate to technical changes.

More important as of this particular point in time, we can say because this is being looked at closely by a number of centers, the existing cluster of technology that is used now in the most advanced centers, and compare that in time with when they were not using most of this cluster of technology.

That is not controlled observations but it is the best we can do -- historically a look and a given stand on things then and now in terms of the technology being used.

That will involve also the third point of the contract -- an assessment of the current state of technology. We will try ot describe this technology in as nontechnical terms as we can to give you an impression of what it is that is being done to the infant.

DR. LOWE: Particularly in New York City, it seems to me there has been a rather radical change in the source of low-birthrate infants because of the general availability of abortions.

A different kind of woman is producing low-birthrate infants. Are you making any attempt to relate the weight specific mortalities to this other variable which I am sure is going to concern the Commission, the appearance of fairly freely available abortions?

MR. BEHRMAN; Yes, we will. We are looking closely at the Harlem data. There are differences between centers.

Places may all be called high-risk or premature centers but they can vary on a scale from one to 10, so they require some analysis of the intensity of therapy at those centers. From the New York data, we have a marked change in the number of babies below 1000 grams.

There is amarked decrease in the number of these babies below 1000 grams in the ghetto areas. Whether it is related to abortion or not is something a committee will have to decide.

Many medical commentators on this feel that it has been related to abortion. It is not a provable thing other than making an interim report from an association. That seems to be a real change.

That is important because the mortality in that rate is the highest, so the mortality rate then changes for that group and the mortality rate improves or the survival rate improves in that group.

DR. LOWE: The other question which does relate directly to this change is the maternal age of the low-birthrate infants. This has a remendous impact on viability. Is there any opportunity to relate that even to New York City.

MR. BEHRMAN: I am not sure. I would have to go through the yearly figures. It may be possible. I can check into that.

MR. RYAN: Please go on, Dr. Berman.

MR. BEHRMAN: The last point is perhaps the hardest and unquestionably the hardest. To refresh your minds you asked us based on these surveys, in the present medical technology, with the limitations I just described, and taking into account the varying State and local laws, to draft guidelines used by physicians in determining whether a fetus delivered by induced abortion is viable or nonviable at death.

We have focused on getting a working idea of what, from a biological point of view, those terms mean to the physicians making the decision. This has nothing to do with research at the moment. It has to do with what all of the decisions made by the physicians in the premature infants, what their biological working definitions are with all the restraints, because it is influenced by their own ethical considerations and a whole host of considerations.

I can give you a kind of tentative comment on that which I would like to in part read and I am loath -- it is not being submitted as a written report -- but the actual expression of this is important, I think, to have accurately.

We will try to work with some. It is derived from the meeting of the 13 or so representatives of the 31 centers and the literature.

A fetus, or a premature delivered infant, and again we have a definition problem because we are assuming technically it is not a fetus any longer if it is not connected with the

placenta, but most of the fetuses or babies are at this point separated from the placenta.

For purposes of this, I am saying either use fetus or simultaneously delivered fetus for purposes of this discussion. A fetus or prematurely delivered infant is biologically viable when a minimum number of independently sustained basic physiological functions are present.

In order to be viable the sum of these functions is considered together but must support the inference, and this is an inference that the fetus or prematurely delivered infant is able to increase in tissue mass and increase in the number and importance of physiological functions upon receiving generally accepted methods.

At this time the following functions taken together were considered as a matter of judgment, not as a matter of fact to constitute the minimum number of basic integrated physiologic functions.

This function consists of these components; inflation of lungs with oxygen, transfer of oxygen, across a membrane and the elimination of the carbon dioxide into the expired gas, so the function was considered normal.

The foregoing minimum basic integrated physiological functions cannot at present be separately assessed in the fetus or prematurely delivered infant in a consistent, reliable and exact manner in the opinions of various people whom we

consulted.

The absence of some of these functions however can be assessed indirectly in what was considered to be a reasonable and reliable manner by a measurement of weight and/or estimation of gestation age and gestational survival.

So clearly the physicians making the judgment make two things. They use their understanding which may vary considerably, of physiological processes and they use their knowledge of survival rates in making their judgment of viability in the delivery room in the premature nursery.

They may use other things which the Committee will have access to from other people but on a biological base, those are the two things used.

MR. RYAN: I am sort of amused because of all of the controversial issues in the press in that a viable infant may not survive and a nonviable infant may survive.

I appreciate the remendous amount of effort that went into the drafting of that statement.

MR. BEHRMAN: It sounds simple when you get down to it. From a biologic point of view, you have to make decisions on the basis of probabilities plus decisions on the basis of understanding physiopathologic processes. The latter are judgmental types of decisions.

The important thing is at this point in time it was really the unanimous opinion that there was not objective

information that could help you assess those functions in a reliable and consistent manner.

DR. COOKE: Orin, there would be some fetuses that unequivocally always would be beyond and so forth.

MR. RYAN: Let him elaborate.

MR. BEHRMAN: I think as I go through different parts of this I will hit obvious questions.

MS. LEBACQZ: This is not a question but just a request, if you wouldn't mind rereading the definition of viability again. I would find that helpful.

MR. BEHRMAN: The foregoing minimum basic integrated physiologic functions cannot presently be separately assessed in a consistent, reliable and exact manner.

MS. LEBACQZ: Back to the beginning.

MR. BEHRMAN: The fetus or prematurely delivered infant is biologically viable when a minimum number of independently sustained basic integrated physiologic functions are present. In order to be viable the sum of these functions considered together must support the inference that the fetus or prematurely delivered infant is able to increase in tissue mass and increase in number, complexity and coordination, a number of physiologic functions upon receiving the generally accepted medical treatment available in the community.

If some of these functions are not there the fetus or prematurely born infant is biologically nonviable. The

question them comes, how do we determine if these functions are present or not.

MR. RYAN: This will be in the transcript, I might add. I wondered why you put down the proviso about generally available in the community because we are teally talking about a relatively availability and an absolute one.

If that maybe was in New York City it would survive and I won't use the name of some other small community that does not have the resources, it might not survive.

DR. COOKE: Boston.

MR. BEHRMAN: This is preliminary to the preliminary report and I would not want to be held at this point.

MR. RYAN: I am jsut bringing it up for your consideration. If the Commission is trying to deal with absolute definitions, I can assure you your definition will be a matter of public record and quoted.

The one things that sticks out is that there are two aspects of that, and I know you are going to go on and I don't want to preempt your further discussion. One is whether or not you should restrict it in that way or take some cognizance of the fact that that may vary.

The other is the relationship to artificial sustaining, that is, potential for viability which is sort of like Dr. Mahoney's comment, to reach a stage at which it is able to function as a self-sustaining life or made able to reach that

stage. So that is a question of taking a previable into a viable by artificial support mechanisms.

I don't know whether we can deal with that.

MR. BEHRMAN: I don't know either.

MR. RYAN: I would like you to consider it because it has widespread implications with respect to the experiments you are talking about, in that the thrust might be one can take an infant and sustain it artificially by what some may call heroic extreme measures.

Please go on.

MR. BEHRMAN: On the basis of the incomplete data that I presently have, with the limitations which I described, particularly in terms of the lack of reporting at small-enough intervals of weight and the lack of recording of weights below 1000 grams by most places, fetuses or prematurely delivered infants of less than 600 grams or less than 23 weeks of gestation in a biologic sense are nonviable.

Now, that may be subject to modification because we are tracing down individual case reports, and the facts are no place in the compiled data.

That Canadian data is particularly important. Can we find any documentation beyond that other than the isolated case reports. They have to be carefully evaluated such as the one in a Polish report that was translated.

All those cases,for example, in that particular

instance, there are gross gestational age, the weight and length, the heart, and the report is reasonably good, from the people connected with the Polish center. We are trying to evaluate those but we have no reported instances in Canada or in this country of documented data from public health officials on the survival.

That may modify but at this point that is the information we have and that is what it indicates. These weights, gestational ages, signs of life, such as breathing heart, respiratory movement, cessation of umbilical cord and movement of voluntary muscles are a matter of our judgment.

In the judgment of these people, not adequate in themselves to be used to determine the basic, minimal integrated functions. The heart may continue to beat for half an hour.

In addition, regardless of weight and gestational age, the minimum number of basic integrated physiologic functions to sustain extra uterine development or survival are judged not to be present in fetuses or prematurely delivered infants with the following:

This is obviously based principally on survival outcome information. These categories are severe malformations of the nervous system.

All I am describing now is what is in fact the biologic factors that influence the judgment of the physician in the delivery room in saying a product of conception is viable

or nonviable.

In contrast, a weight of 600 grams or more and gestational age of 24 weeks or more do indicate that the minimal number of basic integrative physiologic functions necessary for independent growth and development are present when any of the following physical signs of life are also observed: a heart beat, spontaneous respiratory movements, spontaneous movement of voluntary muscles and pulsation of the umbilical cord. Such a fetus or prematurely delivered infant is viable.

Bob, those weights are judged to viable biologically. Again, I would like to repeat, you can make all sorts of legal and ethical decisions about it, but these are in fact what people are using as their biologic diagnosis.

MR. RYAN: Is the word "are" appropriate or should it be "may" in relationship to the fact that with those there may be other biological functions that are not perceived which would ultimately make such an infant; when all of the information is available, known to be nonviable, and you find that out only if it does not survive?

MR. BEHRMAN: Let me deal with that. It should be noted that an infant may be viable after premature delivery by these criteria which, by in utero estimation of gestational age and/or weight, using the most advanced current technology, were determined prenatally to be nonviable.

At present the ultrasonic measurement of the

biparietal diameter is the most accurate method for prenatal estimation of gestational age.

MR. RYAN: Did you want to restrict that to certain times during gestation? I think you will have to, the ultrasound, the times during gestation when it is, in fact.

MR. BEHRMAN: A discrepancy between prenatal and postnatal assessment of viability may occur notwithstanding a pregnant woman's intent to have an abortion, a legally authorized abortion, the best qualified independent physician's judgment of the fetal weight, estimate of gestational age by ultrasound, and an investigator's intent only to study a nonviable fetus or prematurely delivered infant.

There is an area of error that is related to current technology that cannot be resolved by technology or medical practice at this moment in time. It is entirely possible for someone exercising the best judgment to make the decision that a given fetus in utero is nonviable by anybody's opinion, and the afterwards be surprised because by the weight classification and by the other signs I have mentioned, the fetus turned out to be, at that point, independently judged as viable.

That is,how to deal with that fact, something that you have to decide. Fetal death or the death of a prematurely delivered infant, who has been determined to be viable, is judged to have occurred when there is a cessation of the minimal basic, independent integrative physiologic functions which,

considered together, result in sustained extrauterine growth and development. The absence of all of the following indicate the cessation of minimal basic independent integrative physiologic functions: a heart beat, spontaneous respiratory movements, spontaneous movement of voluntary muscles and pulsation of the umbilical cord.

When a prematurely delivered infant is being artificially ventilated ---

MR. RYAN: Would you speak a little slower?

MR. BEHRMAN: These are the criteria of the World Health Organization and they are used because they are physical observations that can be made by anybody who is there, essentially there, although it might require some experience in making them.

MR. LOUISELL: The absence of brain wave is the lack of feasibility?

MR. BEHRMAN: That is right. I will come to that in a moment.

When a prematurely delivered infant is being artificially ventilated, the absence of all of the above physical signs may no longer be reliable as an index of the cessation of the minimal basic integrative physiologic functions.

For example, if the heart beat and the lungs can be sustained by pace makers and by the ventilator, in which case using any of those functions would not be very useful once the infant is on the equipment.

Under these circumstances the presence of two flat electroencephalograms obtained 24 hours apart when the infant is not receiving central nervous system depressants should, in addition, be used to indicate a cessation of the minimal number of basic integrative physiologic functions necessary for independent growth and development which characterize biologic life for the fetus and prematurely delivered infant.

The first step really on four was to see if we could separate out with all of the limitations of trying to separate out by logic, material because the judgments are influenced by ethical, religious or the social orientation of the individual people.

There is no way around that but at least we get as clear as we can, tease those out. We have not gone on to the rest of the task in four which you are trying to analyze, that is in regard to the ethical and legal things mentioned in four.

MR. RYAN: They will be coming, Dr. Behrman?

MR. BEHRMAN: Yes. But I think most frankly that synthesis has to be done by the Commission for the same reasons that were mentioned earlier.

We could maybe develop possible options depending on whether you accept this kind of criteria or that kind of criteria, and it is certainly possible legally and ethically to reject some portion of the biologic facts known today because they are so undertain and there are certain uncertainties.

MR. RYAN: I want to express my admiration for what you have done thus far and hope that you will have a report for us in written form the next time we see you.

I would like to ask the Commission members or the staff if they have any questions they would like to address to you.

MR. LOUISELL: I was particularly interested in your exchange, Dr. Ryan, with Dr. Behrman about his use of the particular medical environment as a factor of viability.

MR. RYAN: Do you want to know why I brought it up?

MR. LOUISELL: Yes. To me it is almost impossible to set up the concept of viability independent of the environment.

MR. RYAN: I brought it up because the fact is we have what we call high-risk or resource or reference nurseries for infants that are outside a given community.

If we are talking about viability or survivorship in a general sense about what is possible at a given level of technology, then you have to relate that to the best technology you have.

Then, the survivorship or the viability is dependent upon that technology and not upon socio-economic factors which might deprive an infant from access to that technology.

I think those two points have to be made clear. In medical practice in the past it was always acceptable, for instance, to just practice at a level which was common for your

community. That community is becoming larger and larger. I think that the world community, if you will, is becoming smaller and smaller, and we will want to establish survivorship or viability on the best that we can offer patients rather than on what we would hope the socio-economic viability of the services.

A document purporting to provide these, between the viability of service and the level of scientific technology, have to be clear.

MR. LOUISELL: So the data will be on the ideal medical potential and on the practical level of what is feasible to give at that particular place?

MR. RYAN: Yes. I think for, for instance, there are many infants that would survive and be viable in a premature nursery. If a premature nursery is not viable that infant quite possibly would not survive.

DR. COOKE: Dick, the statement of the almost impossibility of judging viability at a given instance is a very critical issue. I would hope that your group might look at the preliminary draft by Miss Lebacqz that was submitted to the Commission because the very nature of that approach, which I think might find considerable acceptance in a number of circles, that there is greater protection given by society to the fetus.

There is a quantum jump in the protection at the point of viability and the whole argument rests on the ability

to discern viability with considerable accuracy at some stage. She basically argues at some stage it must be possible that essentially all, because the essentially all comes up in regard to this probability question.

I can't find the particular reference in the great mass of material I went through last night, but the issue of a judgment in the courts when the probability of a particular diagnosis was one in 25,000, as I recall and the physician did not carry out some procedure because the probability was only one in 25,000 that this might be the situation.

The courts ruled that is too great a probability to have omitted it, so they judged that the physician had basically committed malpractice by not considering something with a risk as high as one in 25,000.

That means we are talking here about probabilities that might be acceptable as regards the viability-nonviability issue which would really be way out, maybe 100,000. I don't know what it should be.

So, this issue of viability and her approach I think might be well worth trying to see whether you can reconcile this particular problem.

MR. BEHRMAN: I will certainly make that available.

MR. RYAN: Mr. Yesley can have a copy available for you for that specific purpose.

MR. BEHRMAN: I would just like to make a distinction.

We have not said it is impossible to judge viability. We have said it is impossible to judge separately these integrated functions as the present state of medical technology exists. That may mean several things for the Commission.

One, whatever process is decided on to deal with this problem has to be one which is reviewed periodically because changes in technology certainly do occur with an unexpected rapidity in some instances.

So, it may be possible to evaluate some of those critical functions a year from now but it is not now. From the social point of view, it may be important to have a mechanism by which such a review could be made with dispatch.

We have said at this time we can't separately assess those functions with any kind of agreement. We went into it at length trying to use various laboratory measures and to see whether there was an area of agreement, whether a given PH and given PO 2 and given blood sugar -- it is not possible to get consensus for any kind of agreement.

In fact, the uninimity was we couldn't do it even as much as would like to. Therefore, however, the fact is that those functions do influence your judgment in evaluating the probabilities. The probability statistics is where I started off.

That clearly is a big part of what we will try to give

the Commission, on the basis, for example, of the Canadian data that I referred to for Quebec. You can say that between 750 and 1000 in a high-risk -- let me use this as an example.

If I remember right, when you compare an intensive care unit at Royal Victory Hospital with a baby born in a non-regional center in Quebec you can say between 750 and 1000 grams. There is one chance in close to a million that a child in that weight group will survive in a community but there are two or three chances he will survive at the Royal Victory Hospital.

We will try to provide you with that kind of information. I am clearly not saying how you use that information. The inferences may be influenced by the ethical, legal and all sorts of other things. The physician does use that information. When faced with the probabilities that are very low, that influences his judgment about the presence of those integrated functions by which he characterizes the existence of life. That is when you wantresearch, irrespective of anything said about it.

MR. RYAN: Dr. Jonsen?

MR. JONSEN: I want to refer back to the interchange between yourself and Dr. Louisell just to point out I think it is immensely important for the view that we take on the special study as we begin to see definitions of biologic phenomena relative to technology as a predominant way of

defining such things as viability. I think that is immensely important for our future consideration.

MR. RYAN: Dr. Stellar?

MR. STELLAR: Perhaps more in line with what you are bringing up, Dr. Jonsen, could we have some information to think about in regard to the criteria of the flat EEG especially in a situation where there may be drugs used as you indicated, necessitated by the artificial ventilation procedure, or perhaps the literature is clear enough now. Perhaps the criteria is enough that you can just draw conclusions for us that represent solid opinion and views.

If it is not, it might be helpful to give us a brief statement of the status of this criteria from a physiologic point of view.

MR. BEHRMAN: Unfortunately, we have some reports in the human, usually above 750 grams, of descriptions of what the EEGs are like. They are usually flat most of the time with occasional spikes of electrical activity. They are often taken on a mix of patients.

There are very few reports and they are very scattered. The bulk of this report is based on the people doing the EEGs and arriving at conclusions.

Much of the electrical activity at this age is not cordical, so since EEGs can pick accurately only the cordical, it is a very crude tool. So, this was a judgment that in those

situations the only other technologic thing that was available to the physician in order to try to perceive those physiologic functions as this tool, but it has major limitations.

It was known that the activity could be depressed with depressant drugs so that qualification was put in so that it would indicate to the physician faced with that example, with autorespirator, no signs present, probably his next step would be to discontinue all drugs that had that effect and wait some period of time before doing the EEG. But, it is clearly not a provable fact.

MR. STELLAR: It would be helpful to have that kind of criteria to remind us.

MS. LEBACQZ: In talking about whether there would be certain factors such as weight or gestational age which could be used to assess the absence of some of the functions that make for viability.

You proposed 600 grams in 24 weeks. I noted that in particular because the field report suggests 400 to 500 grams. Did I understand you to say correctly at this time you have not been able to document the survival of a delivered infant of less than 24 weeks or less than 600 grams?

MR. BEHRMAN: With the qualifications I indicated initially that we have some of the material in. At the moment from material we have in and particularly the material that breaks it down into weight group classifications although

1000 with any kind of reliability.

We have not found a survivor. There may be one. This is very tentative. In addition there are some case reports that we are in the process of trying to evaluate, so I would not take this as firm in any sense.

There are other problems actually due to gestational aging which is subject to enormous error. For example, 15 to 30 percent used in the last mentrual period for gestational age, in 15 percent of those instances it is probably wrong in terms of the statistical analysis of that data.

There is very little available in terms of the ultrasound in large groups of infants, so that is a very selected kind of tool.

So, gestational age has enormous problems with it. In fact, that is based on at the moment only one piece of data from the Quebec data. We are getting from Colorado their data but it is not yet in on the gestational age. That is going to be the weakest basis.

The weight will be really the only thing one can with any real assurance hang one's hat on for survival. At the moment on weight, we do not have anything further but we may well have. We just don'g have in yet most of the data. Most of it is not available.

Certainly in a literature survey except for isolated case reports and two or three we are tracking down, we don't

have any, but the individual centers may come up with this.

MR. RYAN: Are you using Tennessee at all?

MR. BEHRMAN: We have asked them.

MR. RYAN: I think I have some references under 24 weeks. I will pull them out.

MR. BEHRMAN: I would appreciate that.

DR. COOKE: What is the smallest weight you have for survival now and how far back have you gone in the search? A long time before your time it used to be a common thing to report in sort of a contest as to who could come up with the smallest premature.

There were some remarkably small prematures before any of us were in the business.

MR. BEHRMAN: On the San Francisco data they have no weight, no survival over a 10-year period until -- and that is year by year in San Francisco, University of California Center-- they have no survival until they get to the 750 to 800 group.

I am not saying there are not other survivors. At the moment, we just don't have the data in. The Canadians had in the group of 601 to 650 they had one child. This is out of a total birth population of something approaching 250,000 deliveries.

Now, we will probably turn up some others. At the moment we just don't have all of the data. We don't have the breakdown from Colorado at thie moment. They are pulling that

out. They did not have it in weight classification.

In many cases a weight classification of 250 is not good enough. You would not know whether a survivor was at 751 or 1000, so this really presents the problem.

In this particular case report, for example, the one I referred to, the Polish report, the infant in that report is a 25 gestation, 25 centimeters and weight is 24 grams. That may be one that is qualified for this.

We have not put these in. I am trying to separate the sources of the data. We will then describe that as a source of data and you can make your own conclusions whether that is legitimate or not.

We were not able to determine what kind of scale was used although it looked accurate from the diagram given. It was in a rural hospital in Poland. The mother in this instance, interestingly enough, and this may be useful, the grandmother of the baby was a 900 gram premature. Her brother, the uncle, was a 1100 gram premature.

The point of that article is there may be some familial tendency in that family to give premature births to infants that is radically different from something in that family. We did not get that just from the weight.

For example, the presence of such a family history might be quite critical.

DR. COOKE: The reason for bringing this out, I am

sure is you are aware that a lot of arguments are riding on this matter of determination of viability. I apologize for not making my statement clear about prediction. I meant prediction in utero of the viability. A lot is riding on that.

Indeed, even the abortion issue and Edelin's trial and all the rest are held up on this question of viability. If one looks at the primate data that you and others have done a check and others for nongestational age there is tremendous weight differences. Also for the date of pregnancy threefold or more.

MR. RYAN: I want to mention two aspects of what you discussed. One, the point you raise is very important with respect to anecdotal information with respect to small weight survivalship, and what we can get out of our centers and premature nurseries.

I think it is extremely important for us to get some facts down and stop playing the game about some baby in the Guiness Book of World Records unless we can document it.

I went through the business myself of personally trying to go back to the literature. I saw the Canadian case, I forget the weight, 27 weeks gestation, Nova Scotia, weight on the second day of life on a gross scale and fed brandy and so on and so forth.

We can scarcely, with a medicine dropper -- we can scarcely as a product of -- this is an opportunity for us to

try to search out all the information we can and put it before the American people facts in the most explicit way we can. I think that that is an important issue. I think with the question of viability in utero with respect to the abortion issue, you are probably off-base because of all of the babies in which the abortion is done were potentially viable unless the infant has a congenital edict which is incompatible with viability or life.

In the Edelin case it is whether the infant was born, not whether or not the abortion was legal. The viability in utero I think is a different issue than the question of whether after it is born it is in fact viable.

DR. COOKE: It is a question of doing research on a baby that may be viable or nonviable in regard to the protection of that individual if abortion is to be done. That is the issue, and that viability-nonviability become very important in the graded context and when that abortion is to be performed.

MR. RYAN: I agree with that point.

MR. BEHRMAN: I would like to make two comments. One, gestational period in utero in the critical period is 21 to 22 weeks. There is considerable difference of opinion. I am sure the Committee is aware of the enthusiasm of the investigators and they distort things.

In the group in Colorado and elsewhere where they

are using ultrasound they enthusiastically feel they can detect it with an error that is much smaller than everyone else is prepared to accept. So, there is a real problem, for example, in just evaluation. We have taken the position when there is that much difference among people whom we have no reason to think are that diverse in terms of their abilities, then we have to accept that as a limitation of technology.

The other thing is the Commission will have to decide what to do about these isolated instances on the basis of probability, say, so-many millions of births in the world documented.

It may turn out there is one in 40 million chances of a baby -- I am pulling that out of the air -- I don't have the probability -- a baby of 450 grams surviving. That is something you will have to decide whether you deal with that probability the same way you deal with the probability one in 25,000 or with the probability that zero in so-many millions, and how you should deal with that not just this year but next year as the probability changes.

MR. RYAN: We are coming down the line toward lunch. I will continue the discussion. Dr. Capron, we will not be able to get to you before lunch. I don't think it would be profitable to subject you and the commissioners to a long discussion on an empty stomach. I think people need rest.

I will entertain a couple of questions for Dr. Behrman.

MR. STELLAR: Dr. Cooke put up a point on the variation of data on known gestational age. I hope this will be included as a reference, or if it is not too much to ask, some statement of what this information is because it will help us in interpreting the human data.

MR. RYAN: Dr. Behrman, I want to thank you very much for having been with us and for your preliminary report. We will look forward to the final one in one month.

I would like for us to reconvene at 1:30.

(Whereupon, at 12:30 p.m. the meeting was adjourned to reconvene at 1:30. p.m.)

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A F T E R N O O N S E S S I O N 1:45 p.m.

MR. RYAN: Could we commence the afternoon session. Some Commission members will be leaving at 4:00 p.m. and I would like to get through the remainder of our agenda if we possibly can.

Mr. Capron, I understand you do not have anything written for the Commission at this time so you will be giving an oral report. May we receive that now, please.

MR. CAPRON: In fact, Mr. Yesley, with whom I have spoken suggested that this might be an opportunity for me as a consultant to consult with you and to define more fully the scope of what I am to be doing so that I respond in the most helpful way to what the Commission wants on the legal aspects of human fetal experimentation.

The primary questions I see are, first, which interests of the fetus are protected,at what point in its development, and against what other countervailing interests of the public or others.

The focus here obviously is on fetus interest in life and health rather than on its interests in property rights and so forth. It would also extend to include its interests in its postmortal treatment. By that I don't mean to belie the question whether there is in fact death if there is not in fact life as we will be talking about it.

What is done with fetal remains remains a question

to be decided. The question is, since the fetus is clearly unable to exercise whatever rights or interests it has for itself, who is to speak for it? I think these could be summarized as the issue of personhood or as some people have been saying, to viability. And secondly, the issue of consent.

To go to the first issue, I don't propose today to address primarily questions raised by fetal experimentation statutes either.

It may be odd doing a report on new statutes not to go to them first but they may be fairly familiar to you. First, I want to talk about the general rules established about the fetus.

There are five sources of law I would identify, constitutional law, civil laws, contracts, torts and the like, administrative law, and what the PEEL Commission report called disciplinary relating to licensure and the like, about which I have nothing to comment.

I think it would be apparent if the medical profession were to reach a very strong or unanimous judgment on something to the extent to which those people who sit on disciplinary boards would revoke a physician's license because of what he was doing in the way of fetal experimentation, that may serve as a relative definition of the rights, but it would be an ad hoc judgment in all likelihood and would not derive from the kinds of conceptual concerns I want to address.

Going to the first category, constitutional law, I suppose here you are all familiar with the holding of the court in Roe versus Wade the 1973 abortion decision of the Supreme Court in which the court did a couple of things of interest to us. It balanced what it saw as the primary right of the pregnant woman to privacy which was taken to include her right to terminate her pregnancy against the rights of the fetus.

In so doing it determined the unborn had never been held under our law to be persons in the constitutional sense. The constitutional law obviously has been painted with a broad brush. It does not cover all issues or Federal questions in our terminology and it draws heavily on the common law as Justice Blackmun did in Roe versus Wade.

So, I am not sure how much the Roe opinion tells us other than there is a recognition of two sets of interests and there is the State's interest in protecting both of those. Indeed, the triparty, three sets of trimester distinctions which the court drew up which I think are similar to some of the things you have already seen emerging on fetal interests maturing over time, over stages.

Roe was drawn very largely from common law ideas. I would like to turn to those. First the criminal law and then the civil. There are a couple of reasons to look at the criminal law, the one I will talk about today and one I will cover in a more detailed record for you.

First as a guide to what society speaking through the courts and the legislatures have found to be acceptable over the years. The second reason for looking at the common law is it is a means of implementing whatever choices you arrive at. By you, I don't mean just this Commission but the secretarian recommendations to the Congress or State legislators as to the needs for criminal statutes.

It is more as the guide than as the means that I speak about it today. The kinds of prohibitions which the criminal law has had that you know of, of course, are prohibitions on murdering, and the like which would relate to the protection of the fetal life or health.

The major means has been legislation on abortion which in this country is still very much influx because many of the States have not yet fully responded to the Supreme Court's opinon, Some States' response in new legislation has been challenged and in some Federal courts it has been found to be unconstitutional and in some conflict with the Roe opinion.

I will not say much about the common law because much of it comes out in homicide. Just in brief, the traditional common law regarded abortion of a fetus that was not yet quick as not a crime at all and a quick fetus was regarded by the common law prior to the abortion statutes of the 19th century as a misdemeanor but not even manslaughter.

In the United States there was very little common law prior to the statutes, most of which have been stricken down by the Roe opinion. The major concern then is with how does the law of homicide, murder and manslaughter affect fetal interests?

The general view has been that the fetus is a person who would be protected under a law that said homicide is the killing of one person by another person only after live birth. There have been some cases that have taken an exception to this.

There is a famous California case, the Chavez case, but that was subsequently disapproved by a California appellate court. That involved a viable child that was killed and the court said that that would stand -- that was during the process of birth, viable but not yet born.

The court said that would stand as a grounds for an indictment for murder. The other situation that can occur is injuries that occur to the fetus still in utero. The fetus is then born live and we have to get to the question of what is live. Born comes through the birth process, disconnected from the placenta, the kind of definition Dr. Behrman was using before, and then dies of the injuries received in utero.

The test here has been primarily one of whether or not the child was viable at the time the injuries were received. It is difficult to know if you go beyond that point how you would reconcile the law of homicide of a fetus in this case

with the development in the area of abortion.

If it is permissible for a woman to have an abortion by directing some medical intervention which interferes with the development of her fetus, the fetus is then expelled and unexpectedly lives for a short period of time and dies of the very things the doctor used to cause the abortion or the fact the child was so premature it could not survive, although it could continue in utero and it could survive, that could be the basis for a charge of homicide.

There are different interests as the court recognized in the Roe opinion that we have a conflict in itself, and the woman's interests may predominate. This becomes some kind of justifiable homicide for the woman to save her own life.

It would be like a policeman who shoots someone to protect himself and/or any person who protects their own life by the use of deadly force.

The other limitation, of course, would be if the fetus is previable. That would not be inconsistent with the Roe opinion. The same kinds of distinctions have arisen in civil law. To focus this a little for you in terms of research, I imagine this question came up particularly vis-a-vis children who were injured by thalidomide. We could substitute for thalidomide any other drug given to a woman during pregnancy which would be for research purposes and causes some injuries to the fetus.

It seems to me this could eventuate in two ways that would be the most interest to you. One would be where there is injury and the fetus is later born. The traditional view that existed up to the middle of this century is there can be no recovery by the child but the woman could recover if there was a miscarriage.

As Lord Cooke said, it had no separate personality and there was no injury to a nonperson. One concern the law had was the difficulty of proving that the thing that happened during pregnancy was the thing that caused this injury. That is a concern to prevent fraud or deceit.

Justice Holmes, when he was on the Massachusetts Supreme Court, had the famous Dietrick case upholding this line of opinion. The modern view goes back to Justice Boggs of Illinois in the Allaire case and an early California and Louisiana cases in the 20s and 30s, It was not established as a rule of law until 1946 until the Federal court here in the District of Columbia articulated the rule that an infant could recover if viable when injured were it later born.

That case involved a professional malpractice question where the child had suffered an injury due to the intervention of the physician and then emerged early in the gestation process and survived long enough to bring the suit.

Some of the courts have now pushed this on further and allowed recovery for a child who dies because of an injury

that was received in utero if the fetus was either quick, as some courts say, or viable.

Now, the law I find in reading through the cases has different definitions of what is meant by quick and different articulations at the point at which this occurs. Some courts talk about quickening in the abortion process in six to eight weeks.

common law did not talk about quickening until about 16 or 18 weeks. That is the point at which the Supreme Court talked, in other words, four to five months were the first moments when the fetus would usually be felt, the first indication there was something alive, in the sense, shall we say, the pre-modern scientific view of what was going on. There was something coming alive, the soul, and the courts picked this up and talked about it.

Whether it is that point or viability, most of the courts now allow recovery if the fetus is born for some time and then dies of injuries that occurred after that point of viability.

A more difficult question is raised if the injury, say, this drug was given experimentally to the mother, produces a stillborn child. I point out this could also arise in a situation I have not heard discussed today. I assume it is

covered in Jerry's paper. That is, what about methods of research on abortion which is undertaken with the very purpose of ending fetal life. There are various opinion but there is no research on this. Clearly abortion is for the purpose of ending life and an experimental abortion technique would be research.

MR. RYAN: Research on whom?

MR. CAPRON: I assume it would be research on the woman and the fetus if the purpose is to get rid of the fetus. Whether the fetus is a subject or person is a question on which there is now division.

MR. RYAN: Or whether the research is on the mother. You talke about that. We are going to have to balance out in the legal considerations those points.

MR. CAPRON: I think you were more or less faced with the same set of concerns the Supreme Court was faced with. Certainly anything done here has to comport with those concerns. I don't think we can limit ourselves to constitutional limitations because the Supreme Court recognized while the law has never regarded the fetus of an unborn as theraputic as a person in the whole sense of the term, they did recognize there were certain protections.

For instance, I was not going to talk about it but I will mention the fetal property rights. A trust can be set up for an unborn child, a posthumous creature can be involved

and even though a child has not been born at the time the testator died.

MR. RYAN: Mr. Capron, how do you want to continue this?

MR. CAPRON: I think I would state what I see as the conflict in the law and then tell you what I have briefed you on.

DR. COOKE: I did not get the gist of the Washington technique for surgery.

MR. CAPRON: We are talking about an action in most States called wrongful death. There are two kinds of recovery that exist as a matter of statutory law for a person who has died and there is an attempt to recover from the person involved.

Recoveries are called either survivor actions, the rights a person has, assuming they begun it and survived their death. That is a right, a suit for that purpose. Say I was run over by a car. There would be a suit under survival action for me, the suffering I had gone through and settle my estate, et cetera.

Most States have followed the model of the wrongful death statute, some States have both. The named statutory beneficiaries who are primarily close relatives, parents and children who would take under test, are permitted for the loss to themselves to sue the wrongdoer for the debt.

Let us talk about the relatives of the fetuses. Could they assume someone? Would it include the mother or only the doctor? The cases that have all come up involved an outside wrongdoer, where the mother and father of the lawful child went in on a lawsuit.

Say you ran into this individual with your automobile and injured an unborn infant. The question is what happens to the children who are born and then die from those injuries. That is something that you can recover for because that child, when it is born, becomes a person.

Then the question comes up, what about the infant that is expelled dead, stillborn. Can there be recovery? We now have about 15 States and only within the last 15 years, that have said, yes. This is interesting because it is in the face of the movement going in the other direction on abortion. Those have been injuries by third parties.

Then the question would arrive, was the person viable. So far as I know the courts have all said, yes. I am still looking into this. It is a matter of doing some 50 jurisdictions to get this.

They ask, must the child be viable at the time? At the point you have viability you have in effect two persons, and either one could die without affecting the other. Thence it begins to go back to the live child who is not only injured but born before viability.

There have been a couple cases and I know from the figures Dr. Behrman gave today, 22 or 23 weeks.

Take a child that was born and lived for two hours. It is then considered born and then there can be, according to the Massachusetts courts, if it is a preinjured person, it comes out of the birth canal, moves around for a moment -- the details of that case don't tell us what happened. They merely said the person was alive.

We have complications here which I thought when I got into this area I would be able to lay out bright, clean lines on but those lines are not there. We have contradictions between criminal and the civil law.

MR. RYAN: What gestation period?

MR. CAPRON: In Massachusetts ---

MR. RYAN: In Massachusetts it depends on whether the birth certificate was surrendered. I wonder if they took someone where the birth certificate was not rendered.

MR. CAPRON: In Massachusetts 20 weeks and a birth certificate could be registered.

MR. RYAN: Most State statutes have a cut-off point with respect to whether it is a birth.

MR. CAPRON: I am considering putting together the information I gave you about the law. Earlier you heard Dr. Behrman's statement to not define as viable any child of less than 24 weeks or 600 grams, survival being seen as just more

than a few hours as it was in this case.

If that were the line, this child would be defined under the definition as previable although the Massachusetts' statute as to what kind of certificate is issued ---

MR. RYAN: Unless I am mistaken practically every State jurisdiction requires 20 weeks for a liveborn certificate or a stillborn certificate. We know because we deal with this on a day-to-day basis. It is not considered a birth until ---

MR. CAPRON: If I could add one point, most of the laws say 20 weeks or 500 grams. The best data is when the infant weighs about 400 grams.

If you go by gestational age, it is about 22 weeks and a 20-weeker is about 24 weeks, so there is a real discrepancy between weight and gestation.

MR. RYAN: But a birth certificate has to be rendered before it can be called liveborn. I wondered if anyone had an action against whom a birth certificate was not rendered.

MR. CAPRON: If it died very quickly in that nursery, it would not be viable.

The fourth area is the administrative laws which are these laws on the certification of birth and the certification of death. In many States the use of a special certificate for a stillborn child is used.

This is an area where I have not really finished my research work. I have started in just 10 States. Most of them

do draw a line for the issuance of a fetal death certificate at 20 weeks. This is the thing I think you are referring to, the Massachusetts' line, as well as a birth certificate after a couple of weeks.

In a number of States, however, it is not made material how long gestation is for the issuance of a fetal birth certificate. Some municipalities, New York, for instance, have added to this additional requirements as far as abortion reporting provisions are concerned.

I would plan in what I submit to you next month to include a statement what the law is there. I don't think this would yield as much of what the common law and civil law does because the administrative provisions have many reasons.

That concludes what I have to say about the interests of the fetus. On the second question of consent, the assumption behind the abortion provision is the woman can consent to certain manipulations on her own body but the fetus does not have consideration by the law.

In dead issue, all the States make clear that the parents can consent to the use of the dead tissue if that is what is expelled. So we are really narrowed down to this question of the living fetus and what life means here. I gather it is somewhat problematical.

In this group we have something that approaches research with an infant, any ordinary child, and this is one

of the most debated question in the research field, as you all know. There are conflicting reports from the commentators; there is no definitive focus or no definitive legislature on this.

The Human Experimentation Committee at the University of California has now been sued by Professor Nielson who is seeking to have the first declaratory judgment rendered on the status of parental consent, and so on, if you regard the fetus potentially viable you ought to be confronted with that you think should be the research on infants.

So, you have more than fetal interest before you, before you decide your recommendations on April 30 to the Secretary. Anything you say here you ought to have an eye on, and we would say the thing about children.

If you can draw a line and suggest something that will never be a child, but at the point that that becomes problematic I would think you would want that to be congruent.

MR. RYAN: The Commission gives you very little of what was mentioned in the Senate debates and they are not covered in court opinion. There is no indication of this.

One afternoon I am going to explore the question of how best interest judgments and instituted judgments in probate matters are handled. I hope we have some guidance there, but the courts have benerally limited that to the best interest criteria. It would be hard to say anything theraputic or

viable would be involved.

That concludes my outline and I welcome your suggestions.

I am going to ask the various Commission members and the staff members to interact with you. We want to be relatively specific so you or the Commission is not ambiguous on what your scope of work would be.

Those of you who make specific recommendations keep it in mind so we keep a record of it. Mr. Mangel wants to ask me a question.

MR. MANGEL: Alex, are you going to take into account in your considerations on the issue of the interests of the fetus and the issue of consent, the distinction between that research which is intended to be beneficial and that research which is not intended to be beneficial to the fetus.

MR. CAPRON: In the case of beneficial research I don't see the law raising that as a critical issue. I can include that statement in my report as a critical issue.

MR. RYAN: The counterpart of that might be something of benefit. When we talk about the patient or fetus being a newborn child having a consent formed by a parent it can go one of several ways.

We have also assumed the parent's interests would be with the best interests of the child.in mind. That question has been raised many times before with respect to therapy.

MR. MANGEL: This comes back to the question of intent which I believe Dr. Seldin was raising before

The articulated intent is to benefit the fetus either by giving or withholding the intervention. I don't know any cases that say parents are not the ones to exercise a choice just as with a child and I think this is true in any pregnancy.

MR. RYAN: The only question is when you act contrary. Let me say, a Jehovah witness who wants to deny their child a transfusion which in ordinary medical practice would be life saving, in which case someone become an advocate for the child and asks the court to intervene.

MR. CAPRON: I am referring mainly to the refusal which will affect the fetus without question, but they are not making a statement. They are making an interest judgment for that fetus. They are making a judgment for the woman and herself and will have consequences for the fetus.

In that case it may be possible and in the District of Columbia there are two or three ways in which the courts have intervened. They have done it most recently passing it as best they could, so that the intervention affects the mother's interests as much as possible.

He said we can get the baby out fast, maybe give it a transfusion after it is born. There is not a statement of the parents, we know the best interests of the child and you disagree with us. We say we know the best interests of ourselves

and at that point they get a distinction.

MR. MANGEL: In one case you see a problem and in the other case you do not see a problem, is that correct?

MR. CAPRON: That is right.

MR. MANGEL: There may be a distinction between that beneficial research which is administered perhaps while there is some other acceptable procedure but perhaps not as effective or not the hoped-for effect. So, there are those kinds of issues but that is not really what I was getting at.

The second question which is specific and short is this, you mentioned that you are going to evaluate the criminal law and the impact of criminal law in light of the Roe and Doe cases.

Can I assume you will also do that with your analysis of civil law?

MR. CAPRON: Yes, there is a wide divergence now between what the courts say and most of the commentators said Justice Blackmun left the door open.

MR. RYAN: Dr. Lowe:

MR. LOWE: Are you aware of the case before the Supreme Court now in which a decision is promised in the next month or so involving the perceived status by the State with the fetus in utero. There are a series of decisions in administrative law which permit the Federal government to participate in the payment of aid for families with dependent

children even when there are no children except one in utero.

Will you bring this to bear on the discussion?

MR. CAPRON: In effect the mother is asking to receive money for the fetus.

MR. RYAN: Dr. Levine?

DR. LEVINE: One real distraction is whether beneficial research is valid. It seems to me that beneficial research is a contradiction in terms and in fact there is another project going on by the staff where the categorical statements made that research is not beneficial based on the assumption you dont know the outcome in advance.

MR. CAPRON: This is Dr. Seldin's point.

DR. LEVINE: You can have goos intentions but to the extent they can be met or predictable, it involves research.

MR. RYAN: I will start over on this side of the room with Dr. Lebacqz. Just keep an eye on the clock.

MS. LEBACQZ: Alex, I may have missed this in your presentation but it would be very helpful to me if we could get some feeling or statute or case law on presumptive consent as well as the issue of proxy consent.

I am thinking about such things as American law where it is assumed someone would want to be saved if they were found lying beside a highway.

MR. RYAN: Specifically what did you want included?

MR. CAPRON: I understood that. Do you want me to

elaborate on it?

MR. RYAN: I don't think so now. Mr. Turtle?

MR. TURTLE: Mr. Mangel said you had no problem with the particular situation and it is beneficial if research is being done on a fetus, but the form of consent might very well come from a parent who tries to give you a problem. Suppose the fetus is the unplanned result of a requested abortion.

The question then,are the same parents interested in getting rid of the child really in consonant with their making a decision which may affect the continued viability of the fetus. Would you not almost have a conflict of interest?

MR. CAPRON: I don't know how under the law to answer that other than to suggest it would be possible to establish a procedure by which you would reach a case-by-case determination.

MR. TURTLE: Isn't there a body of law to determine what is done in a situation where there is a substantial conflict of interest by the presumed decision makers?

MR. CAPRON: The cases that do that in this area are the cases on minor donors. It is my view that the cases have been very unsatisfactory. The courts have at first in a rather strained and perhaps even spurious fashion found an affect on the donor and they approved the donation.

In later cases they no longer have a grounds for saying they have a grounds for saving the life of the recipient.

MR. TURTLE: Using your example, suppose an organ is to be donated.

MR. CAPRON: We are talking about siblings and parents making the decision to want to clearly save the ailing child therefore not be in a position to have foremost in their mind the donor.

I think that is the way it was framed. It made no difference that it was another child rather than a parent itself. I guess most parents would sooner die than expose their children to something but if one child could be saved they may approve of it for another child.

MR. TURTLE: What about judges stepping down themselves when they have an outcome in the decision process?

MR. RYAN: Excuse me. I just want to make a public announcement that Dr. Edelin has been found guilty in the Massachusetts case.

The reason I bring that up before the Commission, it may or may not be in the minds of the Commission relevant to its activities, but by virtue of the Commission's activities people may try to draw opinions from Commission members or from the Commission itself with respect to this case.

I should remind you the case had nothing to do with research but was on the abortion issue only, and I would imagine that our old ground rules would pertain and that is the individual Commission members would follow their own convictions

with respect to comments they make as personal individuals.

MR. LOUISELL: Like jurors we might be well advised not to discuss the facts of a particular case under litigation.

MR. RYAN: It may come up for appeal. I am sorry, but I just felt since people have been scurrying around telling us that the news media may approach the Commission while it is in session. I just wanted the Commission members to be aware of this prior to the time,and please excuse me.

This may interrupt the flow of thinking and thought but it has been preoccupying me up here at the chair.

MR. CAPRON: That is clearly relevant to what I am trying to research but you can't find anything from a jury's verdict.

MR. LOUISELL: There may be some instructions from the court.

MR. CAPRON: There were enough factual disputes in the case ---

MR. RYAN: This is a public meeting. If the press comes in to interrupt the meeting, we will adjourn it immediately but now we can proceed. It is a question of whether or not the meeting is interrupted.

MS. KING: It was my understanding although I sympathize with the chair in view of that possibility, but it was my understanding from the last Commission meeting that we have a procedure for treatment of press at Commission meetings.

I would urge that they have no right to interrupt our meetings. We decided they have a right to be present but we would continue our deliberations. Is that what you really meant or did you mean we would adjourn?

MR. RYAN: No, I meant if subject to a situation beyond our control we could not continue our meeting in an orderly fashion, I wanted you to be aware of that. I am sorry.

Mr. Turtle, resume your line of questioning. We have all been informed. We have a lot of work to do and it is hard to function with something like that going on.

MR. CAPRON: You suggest there are various analogies in the law and conflicts of interest disqualifying a decision maker. I would suggest it depends upon an actual finding, a self-declared finding in the case of a judge who accuses himself of, or one who has to be on motion of one of the parties, relieved of his duties, or an administrator of an estate or anyone else, some finding that that actually exists.

I would suggest that the time period in the connotations we are talking about is it would require a presumption that there was such a conflict or there was not.

MR. TURTLE: Such a presumption exists in the administrative law.

MR. CAPRON: That is matter of judgment, not a metter of law, whether you think it is more probably or not.

MR. TURTLE: I did not want your research or report

be based upon an assumption which I think Mr. Mangel stated there was no problem in that area.

MR. MANGEL: I did not mean to say there was no problem either.

MR. TURTLE: The only other question I have is in terms of defining the interests of a fetus. Have you found or would you expect to find that the interest attached to the fetus might differ depending upon the characterization of the opposing interests?

For instance, in the Roe case, we have the interests of the mother versus the interests of the fetus. In another case we had the interests of the fetus versus the interests of an insurance company.

In this case we may have the interests of a fetus versus the interests of medical technology to benefit all mankind or class of fetus, children generally.

Have you seen any distinctions in that where you would at least be on the lookout for the characterization, the fetal interests as opposed to what is being balanced off.

MR. RYAN: Ms. King, please?

MS. KING: First, did I understand you to say in discussion that you intended to exclude some aspects of property rights?

MR. CAPRON: I meant today. I think that is in fact an example of what we were talking about.

MS. KING: I didn't know if you meant to say anything about experimentation laws.

MR. CAPRON: No, I thought I would ask about the preexisting definition because these laws in the past few years have been aimed at a particular objective and they will face challenges if they are not proper constitutional changes on the right of people to do this type of research.

I would guess the law would have to go back and say what are these fundamental interests or rights. My report will include a discussion of those.

MS. KING: You brought up the fact of the status of the law of informed consent with respect to infants. One of the things that the Commission might want to consider or keep in mind was the relationship of consent to infants and the relationship to the infants.

Do you intend to raise that as an issue here or did you intend to discuss that in your paper, too? That could get fairly extensive.

MR. CAPRON: I think the cases I will draw on relate to choice of parents made about infants in research or in nonbeneficial procedures, the resolution of that. The reason I bring it up for your attention is I do think you have to have in mind how you want to resolve that issue and at least some kinds of fields of experimentation.

At other times you are dealing with a child not

quick or viable or wherever you draw the line we could have different rules. The interests that we have in protecting the patient, and the children from choices made by children, maybe children should not put their parents through the suffering if it is not going to do any good.

I don't know if you have a neurological report on that. That may be the more important line than any of these others.

MR. RYAN: May we move on?

DR. SELDIN: It seems to me that a great many of the critical problems about which the Committee will evolve certain views were the Holmes' reference and he says the fetus in this particular case was not a person and therefore to confer the Bill of Rights on the fetus was illegitimate and in continuance the mother had all the rights and it was her right that was at stake.

Implicit in this first is the notion of viability at least as this subsequently evolved and it would be important to get some insights into the legal merits of the fetus prior to a viability thing.

We know the issue of viability is a plastic one that has a change for technology and even a certain blurring as Dr. Behrman pointed out, but the intent of the law is clear, that there ought to be some sort of distinction between the viable and the nonviable fetus or at least a lot has gone through this.

I would appreciate having some reflection on the rights of the fetus versus the rights of the mother in a previable state but also the rights of the State and society in general. We say people can commit suicide and in some societies this is illegal. One can understand this and the behavior of one's self is not always countenanced by all societies.

I think it would be helpful if we had some reflection where the rights are scrutinized vis-a-vis the mother, the mother's rights and finally, society's right, what society wishes to stipulate to.

The same thing would be true at the point of viability. Here, as you pointed out, issues become more complex because the question of the status of the viable fetus as a person and consequently the imposition of the protections of the Bill of Rights begin to become formidable.

It would be of some interest to have some view of the fetus's, the mother's and the State's rights, if there is a status of person conferred upon a viable fetus it is not the same as adult's personhood.

We say not everybody can go to war even thought the age is becoming appallingly early. Not everybody can vote. Presumably there are constraints imposed on the rights of even a person where that person is construed not responsible in some sense.

So, just to answer the question posed by the chair, it would be very helpful to me to have three categories of distinction elaborated. One is be there any rights, the fetus, the mother and the States and the previable state.

It might be well to contrast that with the full adult rights, the full personal rights that are protected by the Bill of Rights.

Finally, all those three would be very helpful if you commented on the legal merits of the case in those categories.

MR. BRADY: Is it your impression there is guidance in the law on those issues, Mr. Capron?

MR. CAPRON: I have tried to suggest generally how those rights are regarded. It is not a uniform picture. The message you get today you will get in my final report to you.

DR. SELDIN: I am not sure you are the person who is consigned this responsibility but I think it would be well to have some reflections on the legal character of an experiment as defined by intent in some sense of the term.

In other words, the question Dr. Levine raised is one that there can be no beneficial research. This is semantic. It might be beneficial, but the intent he would say is blank.

If you want to do an experiment and define it as having a certain probability of helping the mother of the fetus, clearly that might be beneficial. It might be beneficial that it discloses new knowledge or it might have some benefit.

DR. LEVINE: I would say the contradiction is in terms when it is of benefit to the indiviudal who is the subject of that concern.

DR. SELDIN: It might be and one might be able to say something about probability. I don't want to make this a linguistic maneuver. I share your skepticism that research should be paramount to a class or society in general.

But at any rate I think it would be helpful in considering the issue to reevaluate the concept of intent as legitimitized one kind of investigation vis-a-vis another.

I think this is a complicated issue and it might be better posed in terms of risk but people tend to pose it in terms of benefit and I wonder if we might have some reflections on this?

MR. CAPRON: Unlike all the other points I have been writing down I don't see that within the gambit. I have an opinoin pretty much in agreement with what you say. I do think it is a pretty difficult issue.

Perhaps Mr. Mangel and the other legal advisors to the staff will give you an opinion on that instead of me.

MR. TURTLE: I think what you are talking about is not intent but really motive.

DR. SELDIN: All the philosophers talk about intention. I raise your arm. Is it raised for me or do I intend to raise it? Do I do an experiment toward helping the subject in some

complicated sense of the term or do I do it for truth in general.

I don't want to belabor this.

MR. TURTLE: We would be dealing with motivation rather than intention.

MR. RYAN: I sense there are other people who want to be heard.

Dr. Cooke?

DR. COOKE: Yesterday I asked some questions about research on the techniques of abortion. I posed what I think is a very real problem, and that is an experimental technique and for that matter, it would not have to be an experimental technique. Let's assume the experimental technique results in the birth of a premature infant. This is done rather late, the infant survives. The damage is possibly having been born very prematurely and postnatal anoxia, and all the rest.

What is the law as regards the law in suits for damages for premature induction of labor? We know there have been such cases where very large settlements have been made for premature induction of labor.

Would you have an opportunity to explore this?

MR. CAPRON: The most difficult area there is obviously one of any fetal rights against the mother if any. I am still searching to try to find something on that.

MR. RYAN: Dr. Louisell?

MR. LOUISELL: In the necessary generality of our reference to criminal law, you greatly emphasized the homicide aspect of it but I hope you won't overlook other types, such as the statutes. Up to the year of permissible abortion, I think every State had a criminal sanction against the performance of an abortion. Secondly, don't overlook the equity cases.

I don't know if you want to have a separate category here of equity. It really is a subdivision of civil law, but the equity cases that would approve the appointment of a guardian or trustee for the fetus to insure protection, that type of case.

In reference to the property type cases, I think maybe there is a bit of an overgeneralization that all property rights in a fetus depended upon the fetus being born live. I don't think all the cases can be cited with that proposition.

Only a few years ago in the UCLA Law Review, I think it revealed some of the property cases and the rights of the fetus regardless of the fetus survival. Lastly, I am wondering and this is only a question of my own really, how you can most profitably deal with the dissenting opinion in the Roe and Doe cases.

We all know that the Supreme Court, what it says is not necessarily the final word. Sometimes it is reversed by

war as indeed by dread. Scott was reversed by the Civil War. Sometimes it is reversed by constitutional amendment like the 16th Amendment, and sometimes in its own more mature wisdom it reverses itself.

We all know the extent to which the amendments on due process and so on are now superceded now. So, I would hope there would be some room for discussion of the largely derivative consenting opinions in these cases and not just relegate them to the background of immateriality.

MR. RYAN: I would like to point out that in about an hour some of the Commission members will have to leave. I will call on everyone if we can be reasonably time conscious as we go around. There are one or two items of business I do want the Commission to act on prior to the leaving of some of the Commission members.

MR. JONSEN: Something speculative, Alex. We have been spending a good deal of time discovering law. Might you not illuminate a little bit even if it is beyond your work scope about the question of model statute, whether there might be such and what form it might take?

MR. CAPRON: For fetal experiment?

MR. JONSEN: Yes.

MR. CAPRON: In my original conception of what the Commission wanted, it is a little different from what I gave you today. In reading over the scope of the work and the

discussion at the last meeting, from reading the transcript, I have the impresson you wanted pretty much what the law says more than anything speculative or synthetic rather than something in the way of a statute.

MR. TURTLE: At this point, but Al is saying you may be getting ready to go further.

MR. JONSEN: We would not want to waste all of this and have it go into the sand.

MS. HEIGHT: In the case of damage to the fetus, does the law differentiate on intent or motive or whether it was theraputic or whether it happened in the process of therapy, or what?

MR. CAPRON: Most of the kinds of cases that we have talked about that have come up in the law have arisen from an injury that was not intentional, in most instances where there was negligence,so that differentiation has not come up.

The intentional sorts of injuries on the civil side, talking about injuries, which the fetus would then recover after birth would be aggravated and the law provides more remedies for the person injured by someone intentionally.

MS. HEIGHT: I think the thing I was thinking about if in the course of therapy there is injury ---

MR. CAPRON: That is what I am thinking about, negligence in spite of theraputic intent or whatever, and recovery is just as a patient is injured by his or her doctor.

MR. RYAN: Miss King?

MS. KING: I think I understand what Dr. Jonsen was talking about. I am troubled because I want an analysis of the existing legislation. I think it would be very helpful. The reason I asked for a model law, asking for isolation, is it seems to me that may be one alternative for a State to over-fetal experimentation and to that degree, we ask for a discussion of other possible alternatives in the report. I think it is a little lopsided.

If I wanted the model law or give us an opinion about the model law, I think I would be inclined to go further and ask how does he see that as opposed to a State advisory commission or some other possible alternative.

Because of that I am not sure. I would like to see an attempt at a model law.

MR. JONSEN: I will clarify that. I didn't want to suggest it should be a part of the scope of work suggested to us. Since Alex had experience in this before, I thought he might be thinking about that for us should we select that as the route we want to go.

MR. LOUISELL: There is precedent for this particular research. He came up with a definition of death that prophesized a lot of confused thinking.

DR. SELDIN: There is a book published recently that takes a view it would be very bad to have a model law.

It advances very strong reasons and very interesting reasons why there are other institutional devices to handle this, too, I have no reason not to come to some formulation of a model law but, if so, I would certainly like some thoughts about whether this is a good way to go, a bad way to go and what alternative institutional devices there might be.

Not everybody thinks a model law is the best way to handle such issues.

MS. KING: I am disturbed and that is why I was waiting for clarification.

MR. RYAN: Your transcript is going to be fouled up. With all due respect, I don't want to stiffle interchange but look back here. I will announce your name and the transcript will reflect what you hope it does.

MR. STELLAR: I want to raise a different question. When Alex referred to the fetal experience, in my own estimation it is a very difficult issue to decide. I think the kind of information we have is not terribly helpful. But I am wondering if we ought to try to get Dr. Behrman or Dr. Mahoney to reflect on this at all or anyone else.

We are not going to leave it to Alex in his field, and I would be interested. Joe, do you have any thoughts?

MR. BRADY: It seems to me that this is a problem with neurological development, a development problem and there ought to be some reasonable data on sensory systems.

It is obviously a critical issue around which the necessity for research revolves to a considerable extent. To the best of my knowledge, I don't think that data exists, is what it amounts to.

MR. RYAN: We will make a note with respect to interest in that and perhaps work with staff to see if something can be developed.

MR. BRADY: I think staff approach is the first one we whould take.

MS. MISHKIN: What is the extent to which Alex considers it is or is not germaine to consider an issue which appears to be raised in a case against the New York Presbyterian Hospital, the Delcelio case in which parents are claiming disruption of property by reason of disruption of fertilization.

Do the parents have any property right which might or might not go to the question of consent. Is it germaine or not?

MR. CAPRON: I don't see that that would be within the scope of what I will do but clearly something coming out of that court might include language or relative thought. But, I would prefer not to get to the question of invitro fertilization.

MS. MISHKIN: Before the fetus had any rights, are there any parental rights?

MR. ALEXANDER: That has been recognized not in terms of interference of property but the injury in the miscarriage,

I suppose one of the difficulties in the wrongful death cases is the statutes provide for only pecuniary loss. One of the reasons some courts nave not allowed recovery for a stillborn fetus is they say, what is pecuniary loss, how can you possibly estimate that for the parents. If you have a 10 or 15 year old child it is hard enough to figure out their pecuniary loss.

They may be a Nobel prize winner or a derelict on skid row -- was there the suggestion there was no difference?

MR. DIXON: My question is very similar to Barbara's but I was wondering if you would look at some of the common law rules that have been developed over the years that may have actually started and still have implication of using property rights as the principle from which other rules have come?

MR. CAPRON: I will follow Professor Louisell's suggestion of going on to the protection of the courts of equity as given here, too, and not limit the law to the recovery of damages in torts or contracts. So, I will take that up.

MR. RYAN: I think we have perhaps worked you hard enough this afternoon. You have, I think, significant input from the Commission. As I understand it, you will give us data, facts on existing law, and you will try to identify for us the way in which that law might impact, if you will, and the kinds of Commission decisions we will make, the specific areas that you were asked to look at by the various Commission members that appear to be do-able within the work scope.

MR. CAPRON: With one or two exceptions which I expressed as I went along. Might I ask one question because this relates to an issue I might have to approach. I wonder if you have data on this forthcoming to you so it would be useful.

The question arises what happens when the method of abortion is altered for research purposes. That came up today. I think it was a question Professor Louisell was raising. I got somewhat lost in the discussion with Professor Mahoney.

I wonder is it assumed by the Commission that that has an effect on more than the risk to the mother herself? That is to say, do you have data or will you have data which suggests that that changes the risk of injury to the fetus and that there will be greater probability of a liveborn fetus?

MR. RYAN: Yes, there is well-established data.

MR. CAPRON: So you would like me to respond to the legal parameters?

MR. RYAN: Insofar as you can do so, I think it is appropriate. Thank you very much. You have been very patient and you have worked very hard.

I wonder if we could not go on to other Commission business. If we could turn to our black books, please, there are three items in the table of contents which I would like to take up, not necessarily in the order of their presentation, but perhaps we could turn to the special study responses, item 4 first.

I think you are all aware of the special study of the discussion that occurred in the Commission to make sure that individuals submitting interest in this could, for instance, indicate they might not want to do all of it but only a portion of it.

This was sent out by staff so that the requests to do the special study have come in, to do a portion of the study or the whole study. We have to do this now.

We have requests from 44 commissions and about 35 universities or institutions of higher learning. Staff has a suggestion and a plan for proceeding at this point. Will Dr. Kelty be telling us about this? Would you be brief, please, so the Commission can act on staff recommendations.

DR. KELTY: You should have all gotten a brief staff paper on the study which looks like this.

MR. YESLEY: It went out air mail special on Monday morning.

DR. KELTY: It is headed, "Special Study,"

MR. LOUISELL: Yes, I did get that in the last mail I got before I left Berkeley.

DR. KELTY: Let me quickly review from the beginning very briefly. I think you are all familiar with the fact that the Commission is required to undertake an extensive study which includes five particular pieces -- study of ethical, social and legal implications, advanced by medical behavioral research technology. We are required to do an evaluation of

scientific and technological advances, past, present and projected by medical research, analysis and evaluation of the advances for the individual and society, an analysis and evaluation of laws and principles governing the use of technology and medical practice, analysis and evaluation of public understanding of the attitudes of the laws and principles, and analysis and evaluation of the implications for public policy of the findings and recommendations made by the Commission with respect to the advances.

The special study was derived from a bill introduced by Senator Mondale by resolution in the Senate. Looking back over the legislative history it quite clearly stems directly from the National Research Act itself. There are some various changes from the original Mondale resolution which we point out to you in this paper.

The Mondale resolution makes it very clear that the intent was not to focus on things far into the future but rather on the kinds of crises that I would interpret as being right down the road, or already upon us.

There is history in the Mondale legislation. There are lists of some not so subtle and some relatively subtle advances to indicate what they are talking about. They mean specifically things like organ transplants, invitrofertilization, behavior modification.

Then, I think Edwards in his testimony about the kinds

of things that were a little more subtle, like sex determination, but they are all problems within the realm of current-day thinking and probability.

As a general approach to the special study mandate, it is likely that the study will be conducted in two stages. I am reading on page 4 now, if you want to follow. The first involving multiple contracting to provide the Commission with resource material for its deliberations.

The second stage involving the Commission's own activity including perhaps hearings, deliberations and the drafting of whatever the policy recommendations are going to be. This discussion and the recommendations that followed related only to the first of these stages including a special study.

The question of dividing the special study for contracting studies requires your attention now. The alternatives are to contract with institutions for each to conduct an extensive study or to contract for such extensive studies supplemented by partial studies.

In the latter case the division of the special study could be by subject, topic or it could be some aspect of Section 203. In other words, it could follow one and advance for all five required parts.

The advantage that might accrue from the special study would lie in making it possible for institutions with special but limited capacities to enter the competition in

the contracting process.

It should be noted, however, that the Commission received about 80 responses to its announcements regarding the special study, the specially sought announcement. Nearly all of these expressed interest in the entire study.

In addition, the division by subtopic might introduce a sequencing problem since all but the first subtopic section 203 build on the preceding subtopics that require completion of previous subtopics.

Under work scope, the alternative designs for work scope to conduct a special study are one, a statement in general terms using basically the language of section 203 with methods to be developed by meeting contract requirements such as multidisciplinary capabilities, resources, justification methodology, adequate utilization of existing data, and so forth.

Two, a specific statement detailing for the proposer the methodology to be employed, the area to be studied and the utilization to be made of existing studies, for example.

The general work scope would give potential contractors considerable latitude to develop creative approaches to the issues and might result in more complimentary proposalt from the multiple contractors than would be achieved if each carried out the same specific work scope.

It would allow the staff to engage in other activities

during this facing-up period of the Commission's existence. More time and attention would be required however for review of proposals and for the subsequent monitoring of contract progress since contracted work scopes will differ from each other as a result of using the general work scope in the RFP.

The second approach would require the staff in consultation with outside experts however and the Commission to arrive at conclusions regarding the methodology, the areas of concern, past and present on-going studies, disciplines to be realized, et ceters. This presumably would make the review of proposals and monitoring of contracts easier.

There is no guarantee that the results would be more useful to the Commission than those generated under carefully chosen contracts developed by the contractors themselves.

The final factor creates an additional problem if a second alternative is chosen, in view of a 60-day period now required for RFPs to be outstanding and for contract negotiations, contracting of the special study to be done late summer at the earliest.

Therefore, the staff proposes, one, the publication of an RFP soliciting proposal to conduct an extensive study encompassing the entire range of topics.

Two, a general statement of work scope in the RFP, using the language of section 203 which would allow potential

contractors considerable latitude in designing their proposals to the Commission.

MR. RYAN: So we have before us a recommendation from staff to get on with the special study.

DR. KELTY: There are two more point to it. The third is that the proposals be evaluated against the common set of evaluation criteria which would be specified in the RFP.

DR. LOWE: That is a requirement, you can't recommend it. The law says you do it that way.

DR. KELTY: Four, the award of multicontracts at the level of each contract for three or four professional years plus support in order to elicit different perspectives on common problems.

In other words, the recommendation is to go ahead and issue a general RFP.

MR. RYAN: Mr. Turtle?

MR. TURTLE: If we start with the proposition, I would favor the general approach, that is, taking the names of two or three and putting it out, not for the same reasons that the staff set forth but in reality, a large list of contractors.

MR. RYAN: Would you give us a motion when you are done discussing it if that is your wish?

MR. TURTLE: I have several points I want to make on this because I think it is a very important study and it will be a long-term study.

If we don't get it set right we might end up in the end with something we are unhappy with. Let's look at the time constraints. If you take more time in preparing a detailed RFP the response time by the contractor will be shorter in responding to a detailed work statement than just putting in various items.

In reality the time of contract between a general work statement and a detailed work statement would probably be about the same. The work done by the staff will not have to be redone by the contractor.

However, the most important thing in my mind at least is you will not have any basis for discrimination. You won't be able to chose between 40 contractors if you put out a detailed scope of work calling for four man-years of effort.

Everybody will respond to you in accordance with your work statement. You have told them how much work so you won't be able to decide. For that reason I think it is very important to go out to the contractors and that the basic evaluation factor be their understanding of the work as demonstrated in the particular methodology and program which they propose.

I don't know whether Dr. Ryan and I disagree on this. Evaluation factors have to be considered in advance but the evaluation criteria have to be considered very carefully. Perhaps it will have to be considered even by the Commission in

this instance to set them out. These are general evaluation criteria and they are really not bad. They come basically from the general source selection document.

Although I doubt if the words merit of the resources is in the general source selection procedure. I think we will have to undertake an effort to specifically spell out evaluation criteria and that is going to be crutial.

Whether the work is really sequestion or not may cut both ways. If it really is sequestion we probably ought to receive reports in a sequestion fashion and perhaps use a phased contracting approach.

We get in the first part, we think we want to continue, we continue to the second part with that contractor and again and again. I am not sure that the work is really sequestion. This is the point I made several weeks ago. Some of it seems to be being done in parallel and perhaps might be done even more efficiently in parallel.

I think we have to make a basic decision on that. There are also some parts of this report which it seems to me are a waste of public funds to be done in a redundant manner, that is the attitudinal study.

As Dr. Jonsen pointed out, in reality it is probably better to have a larger sample and study than three smaller ones. So, if we are going to put funds into attitude and opinion research, it seems to me we ought to put that into one

basket and get the best attitudinal study.

So, I would suggest perhaps even that be broken off for separate competition. I think that concludes my comments. I don't think I really want to make a motion at this point in time. I would just like to put it out for discussion.

MR. RYAN: I was trying to follow a parliamentary rule. Ultimately we will have to make some decision either to put forward a motion to act today. I would like to start you thinking about it, not to inhibit discussion.

Dr. Brady?

DR. BRADY: I am a little puzzled by the last paragraph where it says the aware of multiple contracts. I was under the impression that the RFP and the solicitation of proposals was essentially a competition in which there was one winner.

DR. KELTY: There is more than one precedent for more than one contract being let.

MR. RYAN: Especially if each of the contractors is coming back with their interpretation of how they would satisfy the need of the requirement. They might take a different tack.

I think Dr. Kelty gave examples of the different approached. Ultimately the Commission is to respond to Mr. Turtle's comment. We would hope that the staff would help us develop the criteria for the selection,and perhaps you have even talked about having a separate selection committee making

a recommendation to staff. The staff and/or the Commission, that is, and the staff making a recommendation to the Commission. But, the Commission itself is going to have to look at the criteria and the recommendations in terms of awarding these contracts which would be quite large.

DR. KELTY: I think in regard to the issue of multiple contracts which both of you talked about, Dr. Brady and you mentioned something about this, I think, that there are a number of options.

As I said before there is a precedent for multiple contracts being awarded in response to the same RFP. However, it is quite clear, although redundancy may be an interesting concept, it obviously is kind of expensive.

Another option that is available is to oblige the contractor to incorporate alternate viewpoints into his report. That is another way that it has been handled sometimes. Then it is up to the staff and the Commission, I guess, to see that the alternate viewpoints are there and that the contractor either then would offer or be required, or somehow reconcile the differences, if that is possible.

I think one of the problems we might have with redundancy is that we then end up with trying to figure out what to do with any design for emerging recommendations. We have to decide how we want to handle that problem, or do we want to get rid of it.

We could end up with six separate sets of recommendations.

DR. BRADY: I would be prepared to offer a motion if it seems appropriate at this point.

MR. RYAN: Yes, then we will entertain any other ciscussion.

DR. BRADY: My motion would be to accept the recommendation of the staff for the publication of an RFP soliciting proposal to conduct an extensive study incompassing the entire range of section 203 topics.

MR. LOUISELL: Second.

MR. GRAY: I was just going to comment on one thing Mr. Turtle mentioned. I think it is likely or it is very possible that not all contractors or all proposals would approach item number 4, the public attitudes part.

I believe that is number four as an empirical question requiring new research. There could be integration of past efforts in this regard so that that will not necessarily require a new study.

MR. TURTLE: That confuses me because again, staff tells me we have to do one, two and three before we do four because what we are asking them about in four is what we come up with in one, two and three.

If that has been done, maybe we don't have to do one, two and three either.

MR. GRAY: That may be treated as something in the research. There may be a great deal of variation from proposal to proposal.

MR. RYAN: We won't know until we sent ou the RFP and get in some of the proposals. The important thing is to find out all of the action the Commission wishes to take with respect to this at this time. That is, an RFP according to the recommendation of the staff to have the contractors develop how they would comply with the contract language.

MR. STELLAR: Is there some point in time where we are going to try to make a value judgment of how much should be expended for this? Is this a large expenditure? I realize we have not seen the proposal yet, but does anyone around the table or staff have a concept of what this is going to entail?

DR. COOKE: You have four or person years which is the way it is described, so we could make a guess that it is around $100,000.

MR. YESLEY: It would be closer to $150,000.

MR. STELLAR: Would you do two or three?

MR. YESLEY: Yes.

MR. STELLAR: You are talking about maybe half a million?

MR. RYAN: Dr. Lebacqz?

MS. LEBACQZ: I don't have any opposition to the

motion but I am concerned about the point that Mr. Turtle raised dealing with laying out very carefully what the value to criteria will be. So you asked the question is there anything else we need to do. I would want to put that before us again after we deal with this motion if we are going to deal with this motion.

MR. RYAN: The motion is simple to get the RFP out asking for potential contractors to send back recommendations.

DR. LEVINE: Is it implicit in the motin that the motion is to get the general broad RFP out with an expectation of approximately three such studies committing three-person years, is that all part of the motion?

MR. TURTLE: How many studies do we want?

MR. RYAN: The motion as it was stated, and I don't have the document before me that you are reading from, but the motion as I understood it was merely that we send out an RFP asking for recommendations.

The motion does not include approval of any that come in or its evaluative process, or how much or how many.

MR. TURTLE: You have to announce in the RFP how much contract you intend to award.

MR. STELLAR: Do we have to stick with it?

MR. TURTLE: No.

MR. RYAN: Let's just have one at a time.

MR. TURTLE: Going into the contracting area, we have

There is no transcription on numbered page 2-144.

to do this very carefully. Any proposed contract can and is very likely to be protested if it is not very well thought out in advance. Protests can delay awards of those contracts anywhere from six months to a year.

So, I think we want to be as explicit and as precise as possible to try to cover all of the possibilities in advance. To do that, I think we really have to determine how many contractors we are thinking about, how many dollars we are thinking about, the specific valuation criteria before we actually go out with an RFP.

I guess what I think I am saying is the motion is incomplete as it now stands. If it is merely that we get moving on this and we send out an RFP on the general rather than specific work statement, if that is the understanding, fine.

But, if we then have to continue then to understand some of the other issues ---

MR. RYAN: I was hoping we could get it moving, but those of you who have expertise, feed in the requirements. But if it is satisfactory to say one or more contracts, the Commission is not voting at this time for a specific number or for a specific dollar amount to cover these.

MS. KING: A point of clarification and I don't want Dr. Lowe to leave yet.

DR. LOWE: I am consulting with the individual who is advising the Commission and I think these points have to

be clarified with people having responsibility.

I was trying to clarify the use of the term, "a general RFP." I am not sure it means the same thing to everybody.

This is Mr. Waugamon.

MR. RYAN: Raise the question you have and then we will ask the expert.

MS. KING: I am particularly concerned with this study in a point raised by Miss Height at the December meeting and today that any such study and special expertise, and I call it that of special groups in our society -- I will not limit it to just the minority groups -- the implications of biomedical and behavioral research impact heavily in certain groups of society.

Therefore, I think it is essential that the perspective represented by those groups of society be represented in the studies.

My only experience in trying to do this, which is very hazy if I recall my government experience, has been in some way to get subcontracts under the main contracts, some AA contracts for example when there was a specific need to get either any forms of minority representation or viewpoint into the contracting process.

I can only in good conscience cast a vote in favor of the motion if I can be assured that there is going to be

nothing in the motion to preclude the inclusion of whatever special procedures we are allowed to take under the contracting law to get that perspective into this special study.

I am asking a question about whether the initial scope of work has to indicate in terms of the way we would evaluate proposals coming back in what contractors are capable in-house of giving or providing ---

DR. KELTY: Excuse me, or it could be by subcontract.

MS. KING: Or however you want to do it. It seems to me I have to have an indication from the initial response what expertise they have in these areas. I am asking the contract people if this needs to be done in the initial proposal. I assume it has to if that is to become an evaluation problem. I think Mr. Turtle understands.

MR. RYAN: Why don't we ask for a specific response to Miss King now with respect to what must be included so we can be certain those areas will be covered. Then if we can resolve that we go on to the next question of whether or not the motion is in order and is do-able and will not preclude other actions that the Commission may want to take.

MR. WAUGAMON: I think what you are suggesting is putting a proper emphasis in the work scope and the evaluation criteria on that kind of input to the substance of the special study, and a question that is totally possible.

I think that is probably worth discussion at the point this afternoon that we are ready to talk about the evaluation criteria.

MS. KING: There are two things involved here. One is to be able to go out. The easiest is attitudinal, and that is the easiest kind.

The other kind of input is a requirement that certain people working on the studies -- I know I am on thin ice -- but that a representation of viewpoints is included in the contractor's work staff.

I understand how much thin ice I am on but I also want to make myself perfectly clear that in a special study of this type both in my own opinion are necessary. My lawyer to the right---

MR. TURTLE: I am not saying anything.

MS. KING: What I want to know is are there ways of doing it legally and am I precluded by any action I take.

MR. WAUGAMON: You notice I am not Joe Mangel, so I cannot comment on ways for doing it legally.

MR. RYAN: Are we under a time restriction with respect to this because I am not sure we are going to get evaluation criteria this afternoon. What we are really raising is the issue of whether or not the Commission wants the staff to go ahead and develop this and the guidelines to go back to the staff and then the question of when it is released and

what time frames we have to work under. This has to be spelled out right now.

I don't want us to start into something like this and find out we are moving too rapidly or if we have to move rapidly, that we don't overlook something.

MR. YESLEY: It was our view this was a preliminary phase that could be gotten out of the way relatively easily and then we could turn our attention to other areas knowing this was proceeding.

However, if there are problems raised in connection with the design of the RFP, then I would say there is no advantage to jumping this ahead to the present time. We could go back and develop evaluation criteria and come in again to the Commission.

MS. KING: I therefore move to table the previous motion.

MR. STELLAR: I am not sure I understand the consequences of tableing that. How long a postponement does that mean?

MR. RYAN: I don't think we ought to dwell on parlimentary procedure if Miss King will excuse this. The thrust of my question was to find out from staff if we were trying to move too fast without enough input from Commission members to staff.

What I am suggesting here, and I think this is what

Miss King's suggestion was, is that with the input from Commission now and with the opportunity for input over the next month that in March, they can come back to us with the suggestions for an RFP covering the items which you want covered and also the evaluation process at that time.

If that is acceptable to the Commission members, I would prefer to do that than to have us move too rapidly now and leave something very important out. The special study is a big study, Mr. Turtle is right. If we get going we could be in enough difficulty if we don't plan the thing wisely.

MR. STELLAR: I understood there was a March 1 deadline for getting the RFP out?

MR. WAUGAMON: The only deadline that we would be confronted with is in terms of the fiscal year. Indeed if we would like to have the contract awarded by the first of July, and assuming a 12-month project of results back to the Commission by the first of July next year, we would have to have the RFP prepared to be issued by the first of March.

MR. RYAN: Barring that, what happens?

MR. WAUGAMON: Barring that, give yourself a month for each month you slip. If the RFPs are approved at two Commission meetings next month, then we would anticipate a start-up date around the first of August.

DR. COOKE: So we would have it in the fall if we let it slip?

MR. WAUGAMON: Yes.

MR. GRAY: There was some concern raised that academic institutions might have more difficult times responding in terms of making time available to faculty members and not having course commitments, and that sort of thing, if they knew that they had received a contract for the special study sometime before August or September.

I am not sure how we should evaluate that consideration.

MR. RYAN: I am sorry my fellow commissioners but I see no way of getting something this important done this afternoon. Please tell me if you think I am wrong, but if the only problem is delaying for one month to be sure we have things adequately covered and those are the facts that we are delaying, just the one month, then I would ask the staff to spend a little time in this area so we are ready to move on it next month.

I would also ask staff to interact so that the Commission can authorize that interaction, and I would suggest it does with Miss King and any other Commission members who feel they want special input into the special project. Does that seem reasonable?

DR. LOWE: Mr. Chairman, is it the sense of the Commission without a formal vote in the month of preparation that we will concentrate on the general RFP without limiting yourselves in any way to change it next time? I think some

direction is necessary.

MR. TURTLE: I think you will be working less with the statement of work and more detailed in the suggested evaluation criteria.

MR. RYAN: We have a motion and a second on the floor.

MS. KING: I moved to table the previous motion.

MR. STELLAR: Second.

MR. RYAN: All in favor say, aye; opposed, no. The motion is tabled.

I don't know that the Commission wants to take a formal action but I think the Commission and the staff should know we are interested in the point that Miss King and Miss Height made with respect to this, and this will have to be included in the RFP.

MR. WAUGAMON: There are ways.

MR. RYAN: So it will be taken care of.

Again, I am trying to get things done this afternoon under the gun.

Item 22, the historical contract. The historical contractas you understand, is the assessment of the role of research involving living fetuses. It is necessary to respond to questions raised by Commission members briefly to see if there could be alternative methods.

Some of the highlights are conduct reviews of the literature in the scientific fields, identify the critical

figures, gather information, conduct interviews with the principal figures needed to accomplish the analysis, utilizing methodology similar but not necessarily so to those utilized for the National Science Foundation, et cetera.

Batelle is the contractor who actually participated in that work. We are hoping for a preliminary and oral staff report on March 7, 25 copies of a final and oral report on March 14 and revised final report. This is at your request.

I think you were the one who sort of sponsored our general approach to this, Dr. Cooke. If we are going to get this done, and before that one, we will have to act on this proposal right now.

DR. LOWE: May I point out we have had under the pressure of time, we have had to act with a letter contract, which means in effect this is going, and we have to bring it to you after the fact.

There was no way to meet the requirements within the time constraints and though we would welcome comments and improvements, basically this is now what is under way.

MR. RYAN: This was authorized.

DR. COOKE: Could you tell us about the contractor, has this been awarded?

MR. RYAN: This was apparently authorized by the Commission last time. They are the ones that did the NSF study, the copies of which were sent to you.

I don't want a lot of presentation but Duane can respond to any questions.

MS. KING: I move the Commission ratify the contract,

DR. COOKE: Second.

MR. RYAN: All in favor say, aye; opposed, no. The motion is carried.

MR. TURTLE: You start without an independent statement and you end up saying he will incorporate any changes recommended into his work product. Do we really want to do that?

MR. YESLEY: I think the changes contemplated there are just changes that may be necessary for the contractor to comport with the work description. They are not changes as to his conclusions.

It is just to make sure he carries out his assignment.

MR. TURTLE: If he does not carry out his assignment he has to correct his report anyway. The problem is one of who is responsible for that report. When you start to direct any changes in his report, the responsibility then becomes the Commission's and the Commission is responsible for the entire report.

He is responsible for performing a statement of work and he is responsible for correcting his report as many times as he has to in order to conform to the statement of work.

I don't think that we want to be in the position of making corrections to his report.

DR. LOWE: They requested this additional 15 days so at the last meeting they could in fact listen to what the Commission had to say and, if necessary, have their final, final report in 15 days later.

I think this is in response to their request rather than our own.

MR. TURTLE: Then I have no problem with the timing if we could just take out the changes.

MR. BRADY: You could say changes to bring it in compliance with the work scope.

MS. KING: I will accept that as an amendment to my motion.

MR. RYAN: I don't think that if you have a contract now that one can do that.

MR. TURTLE: You have a letter contract which has not been priced out. Actually this should reduce the price on the contract because you are taking out the possibility of our asking them to do additional work.

MR. RYAN: What are you wishes, please?

MR. TURTLE: I would move to amend the motion to ratify to include a deletion of language that talks about changes directed by the Commission, to allow the contractor an opportunity to change his report up to 15 days after the

Commission meeting if he so desires.

MR. STELLAR: Can we simply take out directed by the Commission and that will give him an opportunity to make changes and could that be part of Pat's motion?

MS.KING: I will accept the amendment if the seconder accepts the amendment.

DR. COOKE: Yes, even though I don't understand all of this.

MR. RYAN: The point Mr. Turtle was making is that the contractor must in fact comply anyway and that the suggestion by you is the way it is worded, it sounds like the Commission is going to direct him to change the report.

MR. TURTLE: This is for the protection of the Commission. When you get into an area such as this one and you direct one or two changes in his report, you become responsible really for his entire report, and that is all I am saying.

DR. BRADY: Delete seven words and it sounds fine.

MR. RYAN: Just directed by the Commission is all you have to delete.

DR. BRADY: If required by the Commission.

MR. RYAN: "Directed by the Commission" should be deleted if it can be.

DR. LOWE: It points out that if we change the word Commission to project officer it is then in accord with normal

practice. The project officer can, in fact, direct the contractor officer. The project officer is a member of our staff.

MR. RYAN: Is everyone satisfied?

MR. TURTLE: I would rather have an amendment as stated.

MR. RYAN: Incorporating any changed on March 31, 1975 -- that is the motion before us. It has been amended and seconded. Can we have the amendment first?

All in favor say, aye; opposed, no. The motion is carried.

Next we have the regular motion to ratify this contract with the amendment we just approved. All in favor say, aye; opposed, no. The motion is carried. We have a contract now.

MS. LEBACQZ: Mr. Chairman, I have just received a document entitled, "Preliminary Survey of State Legislation on Fetal Research," put out by the Center on Bioethics.

I would like to request staff obtain copies for all Commission members. It might be helpful to us as we begin to work on the legislative aspects.

MR. YESLEY: Dr. Walters has already provided that to the staff and we can in turn provide it to others.

MS. KING: Are you going to take up other administrative matters?

MR. RYAN: Yes.

MS. KING: I would like to make a request and that is because we have so much to read and digest before the next Commission meeting that the staff send out the drafts as they come in rather than maybe waiting one week prior to the meeting to try to send us everything.

DR. JONSEN: Second.

MR. RYAN: All in favor say, aye; opposed, no. The staff surrounding me were shaking their heads, yes, so it seems it would be something they would be happy to comply with.

DR. LOWE: Would you like everything repeated in the notebook? That is not an insignificant point. You will have your own copy at home but everything will be assembled in a notebook.

MS. KING: You understood me absolutely.

MR. RYAN: I would like to go to the table of contents one, if I am not taking this too fast. There are three work scopes and a CV. These are work scopes for small contracts mandated to the Commission by the staff.

The first one is on professional case, and that is an SA which is survey. I didn't think the philosophical approach to defining the fetal life and death.

DR. COOKE: I so move.

MR. JONSEN: Second.

MR. RYAN: The next one is a scope on Professor Stevens -- Wasserstrom. We should consider this because we selected him

out as someone with a legal background as well as being an ethicist, philosopher and he has been given the identical work scope of the other ethicists.

DR. COOKE: I so move.

MR. JONSEN: Yes.

MR. RYAN: This is the same as went to Lebacqz and others.

DR. COOKE: He has his essay in there. It is a past contract.

MR. TURTLE: We have not paid him though.

MR. RYAN: Toolman, to prepare analysis of preliminary d drafts of essays prepared by the Commission. That is someone to try to put it all together, point out points of compatability among various views, irreconcilable differences probably, present your own views on the subject matter from the broad philosophical perspective from the committee on social thought.

DR. COOKE: So moved.

MR. JONSEN: Second.

MR. RYAN: All in favor say, aye; opposed, no.

The next one I find is someone associated with my hospital. I suppose indirectly I work for him and indirectly there could be a conflict of interest.

I will not participate and I will ask Dr. Brady to present the scope of the work of Dr. John Wilson.

DR. BRADY: To prepare a report to analize statutory

provisions, regulations and case law bearing on research in the fetus, the statutory material will cover the use of human beings in research, et cetera.

Your report should be received not later than March 7 so it will be circulated,and the other requirements are essentially the same.

In addition, we request you attend a one-day meeting. He will come to the meeting in March. I entertain the motion for approval.

MS. HEIGHT: I so move.

MS. LEBACQZ: Second.

DR. COOKE: How does this differ?

MR. YESLEY: This was in response to a request for a redundant contractor on legal issues. It is similar to but not identical with Mr. Capron's contract.

DR. BRADY: Is there further discussion?

All in favor say, aye; opposed, no. You have the chair back, Mr. Chairman.

MR. RYAN: It is now 5 minutes to four. We will try to get all of the information to you on the basis that Miss King has indicated. We will try to hold open an extra day on Sunday for work or Thursday if you want to come in a day early, with desks.

We will, at that time, set aside time in the agenda for bringing up substantive issues for the drafting of the

Commission report.

MR. LOUISELL: I would like to mention I don't recall we ever considered any research in the area of fetal experimentation with problems of the alcoholic mother or drug addicted mother. I don't know if it is necessary to enter into that field but I think we maybe should be thinking about that because there is so much, at least in the attention of popular psychology today as being a significant thing.

MR. RYAN: Having brought that up, how do we deal with that?

MR. LOUISELL: I would be content at this late hour to refer it to the staff for consideration as to whether it is feasible at all, and if so, whether we should tackle it at the next meeting.

MR. RYAN: I don't know whether Dr. Mahoney's material will cover any aspect of that but we could keep our eye open for it. The instruction to the staff is to star it and see if we can pay special attention to that area.

DR. BRADY: I want to bring up one additional matter which has to do with extra days. There are developing, as most of us know, at least two rather key conferences related to issues that are central to our concern here.

The National Academy of Science is meeting next week, as a matter of fact, and I talked to Mike about a similar affair being held in Texas under the sponsorship of the law school,

I believe.

I presume that the staff will cover a good part of the National Academy of Science one. I think it is extremely important at least on some of these conferences that the Commission be encouraged, or at least members of the Commission be encouraged to attend.

I don't know how many others intended to go to the National Academy one but it is conceivable that could be one of the extra type duties.

DR. LOWE: As you wish.

DR. BRADY: We should encourage xome Commission members to go.

MS. KING: I am going to one here so it is obviously no expense. If I wanted to go to the one in Texas, if I thought it would add something other than I will get the next two days, can the Commission pay for air fare?

DR. LOWE: As far as I know you have the right to do whatever you do to fulfill your mandate. If it got out of hand financially we wil get back to you.

DR. BRADY: A couple of these look like key matters. Did you intend to go to the National Academy?

MR. STELLAR: I can't.

MR. TURTLE: I have two points, one relatively short and one requiring a vote. I think we ought to have a budget and I move the staff give us the proposed budget for the

next two years and give us an idea what contracts we have already let will cost and the proposed expenditure.

If there is some problem with making this information public it would fall under the confidentiality laws but I think we ought to go ahead and know what we will be spending.

DR. LOWE: We are preparing an implementation document which you will all see. We can project next year's budget but the implementation docket will show this year's budget and how much we have spent and will spend up to July 1.

MR. TURTLE: The second point is I would like to review my request to send out a letter to the Comptroller General to ascertain the authority of this Commission and its relationship, if any, to HEW.

I raised the matter I think at the last meeting as I recall. It was put off to allow the general counsel of HEW to have an opportunity to look at the draft and give us some comments. I have not seen any of those comments.

What I have in fact seen is a letter appearing at page 3 of our book which raises the issue in my mind again, and this is a letter from the executive director of our Commission to the general counsel of HEW, acting in a way that I believe is inconsistent with the independence of this Commission.

Basically our legislative mandate says we have the right to request information from any executive agency and that

information should be provided. In fact, what we are doing here is we are acting almost as a subset of HEW, and we are going to the general counsel of HEW to find out from him if he will allow us permission to ask for information from FDA.

To my mind this kind of relationship can only serve to damage the credibility of the Commission. I think it is becoming important again that we get the relationships resolved once and for all.

MR. LOUISELL: Did you refer to the general counsel of the Comptroller General?

MR. TURTLE: I wanted to ask him and his general counsel's office about the relationship of this organization and the HEW agency as set forth in the draft letter circulated at the last meeting.

MR. RYAN: It seems to me that the draft letter was to be modified, is that correct?

DR. LOWE: We have received no modification.

MR. RYAN: You were going to modify it, Mr. Turtle?

MR. TURTLE: If you read the minutes, the way the matter was left the general counsel would come up with some comments. The opportunity was there for him to review the matter and see what he thought about sending out the letter.

My point was intended not to be bound by anything the general counsel of HEW said but would allow him the month to make the comments. He has not made any comments and I am

just concerned about the letter of February 7, 1975 that raises the issue to my mind again. We are not acting as an independent organization in this request.

MR. RYAN: What was your recommendation?

MR. TURTLE: I would recommend the Commission send out the letter on its own letterhead, by the way, too.

MR. RYAN: First let the chairman respond by saying he is caught between general counsels and attorneys and interpretations of laws which he personally is not competent to judge on.

I will turn to our executive director and ask him for any comments he wishes to make and then the Commission can act in any way it so desires.

DR. LOWE: May I deal with the second issue first, the stationery. We have requested independent stationery. It is the process of review. The request has been turned down. We have moved it to higher echelons. We will report to you hopefully on our own stationery as soon as we get a ruling.

I have made inquiries with respect to the first item and the information I received informally from general counsel is as follows:

If the charter of a commission, however identified, however is established, is received by OMB on the stationery of an agency of the government and OMB acting for the White House, signs off on that charter and it is then published in

the Federal Register, this in fact establishes the authority of the agency and the commission.

If you wish to pursue this further you are, of course, at liberty to do so. This is the information I have obtained. Our charter is on departmental stationery.

MR. TURTLE: I can't believe that. I don't have anything to respond to that. I request permission or I move that this Commission request the advice from the Comptroller General as to the standing and relationship of this Commission to HEW in a format or in a manner basically set forth in the draft.

I think it can be cleaned up and some minor modifications made.

MR. RYAN: Would you accept from the Commission if it goes to vote affirmative on it and I don't know that they will, will you accept then the responsibility for preparing the draft and submitting it?

MR. TURTLE: I have already prepared the draft but I would like to clean it up.

MR. RYAN: And send it to the Comptroller General as a representative of the Commission?

MR. TURTLE: Yes, sir.

MR. RYAN: Is that the motion?

MR. TURTLE: Yes, sir.

MR. RYAN: Is there a second?

MR. LOUISELL: I will second it.

MR. RYAN: Is there discussion?

MR. LOUISELL: I think I can see very distinctly the theoretical basis of the motion. I wonder if in the experience we now have had over the past several months you still feel there is a realistic need of pursuing this as distinguished from a purely theoretical structural concept.

MR. TURTLE: Let me refer you to your minute book, item 3 which is a letter from the Commission to the general counsel of HEW which deals with the request for information as set forth in our legislative mandate.

Instead of making a request, we start out with the fact that we might make a request and in doing so we presumably would be operating under our authority. We go down to informal discussion with representatives of FDA.

They tell us they cannot provide any information until they get an opinion from HEW general counsel. Then we go back and request the opinion of the HEW general counsel as to the information that should be disclosed by the FDA pursuant to our request.

That raises in my mind very clearly the question of whether or not we are active as an independent commission or whether or not anybody reading this letter would suspect very strongly that we were acting as an agency of HEW and requesting an advisory opinion as to what our duties and perogatives were

under the statute.

As a result of this letter, I feel more strongly about it than I did in the past.

MS. KING: I hope I will now be accurate. If we indeed have resolved the theoretical problem of this being an independent commission and we wanted information from the FDA, I want it understood that we still would have made a request to FDA that would have been referred to the FDA general counsel before they acted. So, we have not done anything differently as an independent commission.

Now, what is a different process is if the general counsel decides we are not entitled to that information, we are in a different posture if we are considered under the umbrella of HEW than if we would be considered if we were considered an independent commission that is not subject to the authority of the general counsel.

I think that is the point Mr. Turtle is trying to make.

MR. TURTLE: I agree up to a point. If we requested information from FDA they might refer our request to their general counsel but we did not go and ask if we had a right to go to them for information.

MS. KING: We would be in a different posture, however, if we were bound by the decision, the general counsel's interpretation and if we were not bound by the general counsel's interpretation.

If we were presumably an agency of HEW, then we have to abide, as I understand by his interpretation. If we are not, we can challenge his interpretation. Other groups have challenged it and if necessary, we can challenge it in court.

Therefore, I am speaking in favor of that motion but I want people to understand our posture. I think that is important. It may not be as theoretical as Professor Louisell indicated.

Secondly, I found it is a lot better to deal with things when they are somewhat theoretical than in the height of controversy in the event we cannot get the FDA information.

For that reason, I would support the motion. Having heard the interaction over the last meetings, it seems to me this is something we should resolve. It seems a reasonable request except we are asking one of the Commission members to do the work for us.

If you are going to vote affirmatively on this, I would presume Mr. Turtle would make a draft, submit it to the Commission members and with your indulgence, I think, he could at the same time submit it to the general counsel of OMB, unless the Commission wishes to review and try to approve it ahead of time.

MR. TURTLE: Speed it up, I should clean up the draft, send it out and I can contact them by telephone for comments.

DR. RYAN: Is that acceptable?

MR. TURTLE: For those in the geographic area--

MS. KING: Let me explain why. It is a touchy issue. Further, I understand the basis for this and I realize it places us in a difficult position with the Department with whom we are still working. I would, therefore, propose before we send any letter that we each have the benefit of the others' views. We are in a political thicket. I did not want to be contacted individually without having heard, for example, Professor Louisell's viewpoint or Dr. Jonsen's viewpoint, because I think it is critical to all of us even though we want to get out of here fast.

I think we should exchange comments at a meeting rather than having individual telephone conversations. I think it is too important to risk individual discussions.

DR. RYAN: Mr. Turtle, could you have a final draft for the commission as the first item of business the next time we meet?

MR. TURTLE: I believe we are going to be running short of time, and that is the reason I provided a draft at the meeting prior to this. It would not be acceptable to me to operate in that manner, but I am certainly willing to be guided by the commissioners' vote.

MS. HEIGHT: I was wondering whether Mr. Turtle might furnish that to us in advance so that we may be able to

formulate any comments and get them back to him.

MR. TURTLE: You should have a draft from me at the present time.

M S. HEIGHT: If there is any comment to go to him, he might have it in advance sothat he could come in with a draft reflecting his opinions.

DR. RYAN: Since both of you are in Washington -- do you want all of the input from the rest of the commissioners?

DR. COOKE: I think some of the commissioners are about as ignorant as you can find in this area.

MS. KING: I understand that, but if we ever get into a debate about the independence of this commission, and I feel strongly that the commission, just as I have had to learn the legal terms, you may have to learn the medical terminology. That is why I don't want it done individually.

MS. HEIGHT: If we send any comments to Mr. Turtle he and we could come into the next meeting already having registered something that he can take into account that would foreshorten the discussion. Then we would still open the meeting to discuss it.

MR. TURTLE: In the interim, I will agree to that if we get a new letter out to the FDA saying basically we would like this information under our statutory authority to request this information, and let it go at that. We can get started on that tack and the next thing we can take up is the

letter at the next meeting.

DR. RYAN: We just taken one item at a time. We have a motion before us and if we can redraft the motion that Mr. Turtle will prepare a draft; that it will go out to all of the commission members as rapidly as possible, that they will write to him any comments or suggestions they have with respect to this; that we will put it on the agenda as the first item of business so it can be voted on at the next meeting and acted on immediately.

Is that a motion?

DR. SELDIN: I so move.

DR. BRADY: Second.

DR. RYAN: All in favor say, "Aye." Opposed, "No."

The motion is carried.

Do you have another recommendation, Mr. Turtle?

MR. TURTLE: Yes, I believe if we are really interested in obtaining information from FDA, the staff should be directed to write to FDA a letter directed to the head of FDA, not the HEW General Counsel, and that letter simply state pursuant to our statutory authority we are hereby requesting final information, period.

DR. RYAN: May I have a second to that motion .

DR. SELDIN: I will second that as a motion.

DR. RYAN: All in favor, say, "Aye." Opposed, "No."

The motion is carried.

Is there any other item of business that the commission would like to discuss at this time?

If not, I would like to thank the staff as usual for their tremendous effort.

This meeting is now adjourned.

[The meeting was adjourned at 4:15 p.m.]

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

Summary Minutes
March 14-15, 1975

Conference Room 6
Building 31
9000 Rockville Pike
Bethesda, Maryland

(Entire meeting open to the public)

Friday, March 14, 1975

1. The meeting was called to order by Chairman Kenneth J. Ryan, M.D., at 9:15 a.m.

2. Commission members heard testimony on Federal agency roles in research on the fetus, given by the following public officials:

    1. Dr. Louis Hellman, Deputy Assistant Secretary for Population, Health, Education and Welfare.

    2. Dr. Norman Kretchmer, Director, National Institute of Child Health and Human Development, (representing National Institutes of Health).

    3. John Jennings, Associate Commissioner, Food and Drug Administration, accompanied by Dr. Frances Kelsey, Dr. Carl Leventhal, and Mr. William Vodra.

3. A final report to the Commission on legal issues in research on the fetus was presented by Professor John Wilson (1). During discussion of Professor Wilson's report, members unanimously voted to request that he and Mr. Alex Capron (2) who also prepared a report on legal issues in research on the fetus, be present at the April Commission meeting.

4. Commission members took part in a roundtable discussion with the following ethicists: Drs. Sissela Bok, Leon Kass, Marc Lappe, Paul Ramsey, LeRoy Walters, Richard Wasserstrom, Arthur Dyck, Stephen Toulmin, and Seymour Siegel. (3) The discussion was based on contracted papers by some of these and other ethicists,(4) as reviewed in a written summary by Dr. Toulmin. Dr. Kass outlined a related report to the Commission on philosophical issues in determining fetal viability, non-viability, and death. Commission members and the panel of ethicists engaged in a general discussion of ethical issues related to research on the fetus.

5. A final report to the Commission on the role of research involving living fetuses in advances in medical science and technology was presented by the following members of Battelle Institute:(5) Drs. R. I. Leininger (Principal Investigator), D.A.Axler, A.D. Barker, R. D. Falb, and D. L. Gardner.

6. The meeting adjourned at 6:30 p.m.

Saturday, March 15, 1975

7. The meeting was called to order by Chairman Kenneth J. Ryan, M.D. at 9:15 a.m.

8. Members voted unanimously to have a letter (drafted by Mr. Turtle) sent on their behalf to the Comptroller General requesting information on the relation of the Commission to the executive and legislative branches of government.

9. Following discussion of the contracting for the special study (6), members voted unanimously to adopt the policy of affirmatively seeking out minority and female contractors, in the process of awarding contracts, and of judging for each contract the appropriateness of using the 8(a) contracting process or any other mechanisms for insuring minority and female participation in its contracting process.

10. Members heard a final report to the Commission, by Dr. Richard Behrman(7) on guidelines for determining fetal viability and death; Dr. Leon Kass commented on this topic.

11. A final report on the nature and extent of research on the fetus was presented by Dr. Maurice Mahoney(8) and co-workers Drs. Walters, Bender, Frigoletto, and Fost.

12. Following Dr. Mahoney's presentation, staff suggested that Drs. Mahoney and Behrman be requested to attend the April Commission meeting to assist in deliberations.

13. Returning to administrative matters, members voted to issue an RFP for the special study, as drafted by staff, with modifications indicating the interest of the Commission in obtaining complementary points of view by multiple contracting.

14. After a staff presentation of the background and rationale for the study on Institutional Review Boards, members voted unanimously (with Mr. Turtle abstaining) to have staff develop a draft RFP for this study.

15. Following discussion of the April agenda and the possibility of an additional meeting in April, staff was requested to obtain from each Commission member an itemization of prior commitments during that month, so that such a meeting could be scheduled, if necessary.

16. Members voted unanimously to hold the next meeting on April 11, 12, and 13.

17. Members discussed mechanisms for the preparation of their report on research on the fetus.

18. The meeting was adjourned at 4:45 p.m.

Members Present

Kenneth John Ryan, M.D.
Joseph V. Brady, Ph.D.
Robert E. Cooke, M.D.*
Dorothy S. Height
Albert R. Jonsen, S.J., Ph.D.
Patricia King, J.D.
David W. Louisell, J.D.
Donald Wayne Seldin, M.D.
Eliot Stellar, Ph.D.
Robert H. Turtle, LL.B.

Staff Members Present

Charles U. Lowe, M.D.
Michael S. Yesley, J.D.
Duane Alexander, M.D.
Robert J. Levine, M.D.
Edward Dixon, J.D.
Bradford Gray, Ph.D.
Miriam Kelty, Ph.D.
Barbara Mishkin, M.A.
Anne Ballard
Bonnie M. Lee

*Did not attend full session

(Approximately 100 members of the public attended.)

CERTIFIED BY:

Kenneth John Ryan, M.D.

April 11, 1975
(Date)

Materials Provided

The following materials were provided to Commission members: a sample letter of invitation to 13 Federal officials to testify at the March 14 meeting; a memo to Commission members relating to the ethicists' roundtable discussion at the March 14 meeting; a memo from staff outlining a tentative timetable for the Commission through August 1976; a draft for the Request for Proposals for the Special Study; a staff paper related to an empirical study of institutional review boards; a staff-prepared outline of positions on research on the fetus; correspondence to the Commissioner of the Food and Drug Administration and response; a staff paper related to legal aspects of parental or guardian consent for children to participate in non-beneficial research; correspondence received from the public; news clips related to the Commission's mandate; and an up-date on the staff-prepared case register.

In addition, the final reports by the following consultants and contractors were distributed:

Dr. Sissela Bok
Dr. Joseph Fletcher
Dr. Marc Lappe
Dr. Richard McCormick
Dr. Paul Ramsey
Dr. Seymour Siegel
Dr. LeRoy Walters
Dr. Richard Wasserstrom

Battelle Institute
Dr. Richard Behrman
Dr. Leon Kass
Dr. Maurice Mahoney
Dr. Stephen Toulmin
Mr. Alex Capron
Professor John Wilson

Footnotes

(1.) Refer to January 10-11, 1975 minutes, item 5.

(2.) Refer to January 10-11, 1975 minutes, item 5.

(3.) Refer to January 10-11, 1975 minutes, item 4.

(4.) Refer to January 10-11, 1975 minutes, item 4. Other ethicists are Richard McCormick and Joseph Fletcher.

(5.) Refer to January 10-11, 1975 minutes, item 17.

(6.) Refer to January 10-11,1975 minutes, item 8.

(7.) Refer to January 10-11, 1975 minutes, item 3.

(8.) Refer to December 3-4, 1974 minutes, item 9.