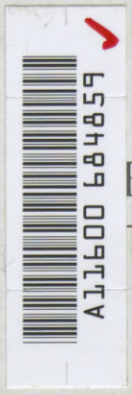
FETAL RESEARCH, 1974



HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON

LABOR AND PUBLIC WELFARE

UNITED STATES SENATE

NINETY-THIRD CONGRESS

SECOND SESSION

ON

EXAMINATION OF THE VARYING AND SOMEWHAT CONTROVERSIAL ISSUES INVOLVED IN REGARD TO THE BAN ON FETAL RESEARCH CONTAINED IN THE NATIONAL RESEARCH ACT

JULY 19, 1974

Printed for the use of the Committee on Labor and Public Welfare

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FRIDAY, JULY 19, 1974

U.S. SENATE,
SUBCOMMITTEE ON HEALTH OF THE
COMMITTEE ON LABOR AND PUBLIC WELFARE,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:05 a.m., in room 4232, Dirksen Senate Office Building, Hon. Edward M. Kennedy, subcommittee chairman, presiding.

Present: Senator Kennedy.

Senator KENNEDY. The subcommittee will come to order.

Last Friday President Nixon signed into law the National Research Service Awards and Protection of Human Subjects Act. This truly landmark piece of health legislation establishes a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

Last month this subcommittee began a series of hearings on subjects of unusual public interest that will be studied by the Commission. The purpose of these hearings is to bring about widespread public discussion of these issues.

In order for the extraordinarily important work of the Commission to be successful, there must be significant public input to it. It is my hope that these hearings will generate public interest which will be translated into public participation in the works of the Commission.

The topic we are focusing on today became one of the most highly charged, emotional issues confronting our society. Yet fetal research is a complicated subject. The harsh rhetoric of opposing viewpoints, which has characterized much of the public debate thus far, has done little service to the development of a complete understanding of the issue.

For example, our mail shows that there has been a widespread misinterpretation of the ban on fetal research contained in the National Research Act. That ban, which is temporary in nature, pertains to research on a living fetus before or after induced abortion, unless such research is done for the benefit of the fetus.

This is not the equivalent of a ban on all fetal research—far from it, as we will hear today. Yet the widespread impression is that the Congress has voted a temporary ban on all fetal research.

I am hopeful that these hearings will result in the widest possible dissemination of information which will enable the public to adequately and accurately become informed on this issue. That has not been the case to date.

I hope today's hearing will place this issue more in its proper perspective. We want to find out what fetal research is, what forms it takes, what benefits have been and will be derived from it, and what ethical and moral considerations are raised by such research. We want to know where if at all, this issue overlaps with the abortion issue.

We want to know on what points differences of opinion exist and where there really is widespread agreement.

I do not mean to imply that an understanding of the true dimensions of the issue will result in agreement about the proper course of action to be followed. But I do hope that such an understanding will enable us to focus constructively on the real differences, rather than on imagined ones.

As medical technology continues to advance society will be repeatedly confronted with ethical, moral and even legal dilemmas. These dilemmas will be potentially divisive and highly emotional.

The National Research Act establishes a mechanism to help us anticipate these problems and focus the best minds in the country on them before they become divisive. I hope we can all learn to consider these difficult problems in an atmosphere that permits their resolution without leaving deep and unnecessary scars upon our society.

This morning we will hear from a panel of witnesses who will address themselves to the questions and concerns surrounding the issue of fetal research. Dr. Frederick Robbins is Dean of the School of Medicine at Case Western Reserve University.

In 1954 Dr. Robbins was awarded, along with Dr. John Enders and Dr. Thomas Weller, the Nobel Prize in Physiology and Medicine for his work in the cultivation of polio virus in tissue culture.

Dr. Richard E. Behrman is Carpentier Professor and Chairman of the Department of Pediatrics of the College of Physicians and Surgeons of Columbia University. He is the author of many scientific publications concerned with fetal and neonatal problems.

Dr. Andre E. Hellegers, director of the Kennedy Institute for Bioethics at Georgetown University, is also Professor of Obstetrics-Gynecology and Physiology-Biophysics at Georgetown. He was a member of the National Advisory Child Health and Human Development Council of the NIH, as well as being a member of many other distinguished organizations in this area.

Ms. Patricia Policastro is an executive board member of the U.S. Coalition for Life. She is also a member of the Pennsylvania Association for Retarded Children and a representative of the East Hills Chapter of People Concerned for the Unborn Child.

I want to welcome you to our meeting here this morning. We have had a number of you appear before us. Dr. Robbins is on our Advisory Committee of our Office of Technology Assessment.

The Senate and the Congress have benefited by his participation in that endeavor.

So we have four very distinguished public spirited and concerned witnesses this morning, who I know can help us, help the public to have a better understanding of this issue.

Dr. Robbins.

STATEMENT OF FREDERICK C. ROBBINS, M.D., DEAN OF THE SCHOOL OF MEDICINE, CASE WESTERN RESERVE UNIVERSITY, CLEVELAND, OHIO; RICHARD E. BEHRMAN, M.D., DIRECTOR OF BABIES HOSPITAL, THE CHILDREN'S MEDICAL AND SURGICAL CENTER, COLUMBIA-PRESBYTERIAN MEDICAL CENTER, NEW YORK, N.Y.; ANDRE E. HELLEGERS, M.D., DIRECTOR, JOSEPH AND ROSE KENNEDY INSTITUTE FOR THE STUDY OF HUMAN REPRODUCTION AND BIOETHICS, GEORGETOWN UNIVERSITY, WASHINGTON, D.C.; AND PATRICIA POLICASTRO, U.S. COALITION FOR LIFE, MURRAYSVILLE, PA., A PANEL

Dr. ROBBINS. Thank you, Mr. Chairman. I will address myself primarily to some aspects of the benefits of fetal research and what it is.

I have to admit to certain biases since as a virologist and pediatrician for many years I have been actively concerned with diseases that occur in utero or in early life, particularly infections.

Not only have I been concerned with the immediate effects such as death or illness but even more with the long term consequences that may not become evident until late in life.

I am making the assumption that all of us meeting here have the same goal in mind, namely, improvement of health and the quality of life.

We may disagree as to the means to be employed but not as to the ultimate purpose. I suspect that we can also agree that through the pursuit of biomedical research we have been able to make some progress toward this goal.

But, in my opinion, we have only scratched the surface and at a time when emotions are running high, it is incumbent upon all of us to exercise sound judgment in the formulation of policies and procedures affecting the future of biomedical research.

Let us be very careful that in our concern about some actual or imagined abuses that we do not do more harm than good.

In the brief time available to me for formal testimony I should like to touch upon the following points concerning fetal research.

1. The wisdom of legislatively prohibiting or severely limiting fetal research.
2. What do we mean by fetal research?
3. Why is fetal research done?
4. What benefits have resulted from fetal research?
5. What benefits might reasonably be expected from fetal research in the future?

Since my field of interest has been infectious diseases my examples will be drawn largely from this area. Dr. Behrman will approach the matter from a different point of view and deal with a variety of other conditions.

1. Why do I raise any question in principle about the appropriateness of specific legislation prohibiting fetal research?

My concern arises from a feeling that it is difficult to deal in the political arena with an issue so fraught with emotional overtones, particularly in view of the close association in many people's minds between the conduct of fetal research and the abortion issue.

Laws, once passed, are difficult to alter and in today's changing world it is wise to keep one's options open.

Senator KENNEDY. Are these really separate issues?

Dr. ROBBINS. Abortion and fetal research?

Not entirely, no, sir, because certain research probably could not be done unless there were abortions.

On the other hand, they philosophically have some differences in my opinion. Research can be done on spontaneous abortions, and as you will hear later, some fetal research is done in utero.

So there is overlap. Nobody can deny that.

The kind of deliberative approach that will be possible under H.R. 7724 seems to be highly desirable although the four month period allowed for the commission to consider recommendations on the conduct of fetal research is not very long.

Now what is meant by fetal research? I will not go into it in great detail. If questions come up later, I will be glad to try to answer them.

It really refers to many different types of activities and some are not at issue here really as some could hardly be called research.

There are noninvasive techniques which are used to monitor the fetal condition in utero, such as the fetal electrocardiogram or electroencephalogram to determine heart function and brain waves, or the use of ultrasound and other physical methods to determine fetal position and conformation before delivery.

Amniocentesis is a type of fetal research. Dr. Behrman will deal with that.

In another highly important investigative area, it is essential either to obtain a small piece of fetal skin or other tissue for examination or culture, comparable to doing a biopsy which is often done in later life for diagnostic purposes.

This may be used to establish cultures, which are later used for viruses growth, which I will illustrate a little bit later in my testimony.

Senator KENNEDY. Is area "c" which you have mentioned here, concerning a small piece of fetal skin or other tissue for examination or culture, comparable to doing a biopsy? It is on a living fetus, is this correct?

Dr. ROBBINS. It could be living or—I frankly find it a little difficult to always know which we are talking about and what the definitions are.

Living in the sense that the cells are still alive and capable of reproducing, not living in the sense that the organism has the capability of functioning as an integrated whole anymore.

Senator KENNEDY. Do they do that in utero?

Dr. ROBBINS. It has been done in utero as well. Of course by amniocentesis one gets cells which one can culture and that is used to examine the chromosomes, and also by use of amnioscopy——

Senator KENNEDY. You just lost me.

Dr. ROBBINS. Dr. Hellegers is the obstetrician in the crowd. Amnioscopy consists of inserting a small tube into the uterus and under direct vision taking a small piece of skin that can be used to culture. It is being used for a variety of diagnostic purposes, but not very widely at the moment.

Cultures are usually derived either from artificially aborted or naturally aborted fetuses or with amniotic cells obtained by withdrawing fluid.

In certain other kinds of examinations, such as when the physiological or biochemical properties are being studied one may have to examine portions of organs or the entire organ. This is the kind of experiment that has aroused much more concern.

Now why do we need research on the human fetus?

An important reason is that since we are interested in human health and disease we must, in the last analysis, examine the situation in the human. Much groundwork can be done in animals and this avenue always should be explored to its fullest before turning to man—although there are people who would prefer we work first in humans and then in animals.

However, it is rarely if ever possible directly to transpose findings in animals to man.

Our interest in understanding more about the fetus is related to the great importance of the intrauterine period of development for the future health of the individual. It is during this period that many hereditary diseases first become evident. Short of controlling conception it is here that many defects will have to be corrected or treated if we are to prevent disability.

Although reasonably well protected within the womb the fetus is subjected to a variety of environmental insults due to drugs, chemicals, radiation, the nutritional state of the mother, et cetera.

The fetus is peculiarly vulnerable to such insults since they are likely to cause an arrest of development with the tragic effect of causing congenital abnormalities or preventing the individual from ever achieving his biologic potential.

There is reason to suspect that a significant proportion of congenital anomalies and mental retardation can be ascribed to injuries sustained during fetal existence or early infancy.

It is during fetal life that certain infections such as rubella are most devastating. Some infections may become established in the fetal period and persist for long periods with deleterious effects of

varying degree whereas the same organisms would cause only acute short-lived infections in older individuals.

On the basis of animal models it is possible that certain human cancers may result from infection of the fetus with specific viruses which would have no such effect in later life.

An area of great importance is the response of the fetus to drugs. We know generally that the fetus handles drugs differently than older persons but our ignorance in this area is profound. We badly need to be able to determine how various drugs and antibiotics are dealt with by the fetus at various stages of development and indeed whether or not the drug crosses from the mother to the fetus. This can only be determined by direct tests.

What benefits have been derived from fetal research?

Senator KENNEDY. On the use of these drugs, this requires tests on the living fetus, is that what you are saying here?

Dr. ROBBINS. I guess in the definition that most people are using, yes.

Senator KENNEDY. Is it possible to tell in advance whether the drugs will harm or benefit the fetus?

Dr. ROBBINS. Most of the experiments I am aware of, sir, have been done with drugs where there is very, very little likelihood where any harm will come to the fetus.

Actually I would personally consider it quite unethical to do anything with a drug or substance where there was strong likelihood of any damage to the fetus.

Now, that is an argumentable point, I realize, but that would be my own feeling.

Senator KENNEDY. At this time, who is giving the consent? Are the parents?

Dr. ROBBINS. Parent or guardian, usually the parent. Of course that is a point of issue.

The right of a mother who has determined to have an abortion, to make decisions of this sort is seriously questioned.

Senator KENNEDY. Can you give us, doctor, some idea why this type of research is so important?

Dr. ROBBINS. The most important issue is whether or not potentially useful or harmful substances do reach the fetus.

The problem of treating infections of the brain or central nervous system is somewhat comparable because the brain, like the fetus, is somewhat segregated. With many drugs you do not know whether they will reach the spinal fluid. for instance, and be effective. One can only determine this by testing.

Similarly, certain antibiotics, for instance, which one might use to treat an infection in the fetus, may or may not cross from the mother's circulation to the fetal circulation, so they will be available to treat the infection.

That was the kind of experiment which the physicians in Boston were doing which got them in trouble.

Senator KENNEDY. For a lay person's understanding, what are the health benefits that can be derived from research on the fetus that

is not necessarily directly beneficial to that particular fetus. If such research is done and carried on, can it really benefit future fetuses?

Dr. ROBBINS. I think in the case of the experiments in Boston, the drug which they were concerned about could be used to treat syphilitic infection of the fetus. This is very destructive to the fetus and may either result in death or serious disability, so that there could be benefit to future fetuses. But the subjects tested did not have syphilis.

Many of the infections that present a particular problem for the fetus at the moment are viral, and we do not yet have any really good drugs for virus infections, but we must consider the reverse side of the coin, namely the damage drugs or vaccines given to the pregnant mother can do to the fetus.

Unfortunately, here one cannot do very many experiments in man, but it is important to determine whether or not these do in fact cross the placenta.

An example in the area of vaccination is that of rubella—German measles. You know that rubella vaccine is a live virus.

When one is vaccinated against rubella, one has a very mild infection, which does not do you any harm.

Now obviously the issue here is: Will this harm the fetus if inadvertently a pregnant woman in the first trimester is vaccinated?

Now you cannot determine whether it will harm the human fetus——

Senator KENNEDY. What are the considerations? If she has had contact with and then develops measles, the impact on the fetus can be mental retardation or other kinds of difficulties, can it not?

Dr. ROBBINS. Yes. I have provided you a few pictures here——

Senator KENNEDY. Yes. First, though you say if we do not do this procedure there is a chance that the mother may get German measles and that the child may be born mentally retarded?

Dr. ROBBINS. Yes.

Senator KENNEDY. Then if you give the vaccine, it might have some kind of effect on the fetus, is that correct?

Dr. ROBBINS. We have no assurance that the vaccine would not harm the fetus.

Senator KENNEDY. We are trying to establish a balance. Is it correct to assume that if the vaccine does work and does not have an adverse impact on the fetus that one could conceivably have a healthy baby?

Dr. ROBBINS. Right.

Senator KENNEDY. It may still have an adverse impact on the fetus?

Dr. ROBBINS. Through fetal research we have shown that the vaccine virus can reach the fetus.

Senator KENNEDY. Would that type of research be banned at the present time?

Dr. ROBBINS. Yes.

[The prepared statement of Dr. Robbins and the exhibits referred to follow:]

Friday, July 19, 1974

TESTIMONY

PRESENTED TO:

Subcommittee on Health
Edward M. Kennedy, Chairman

Senate Labor and Public Welfare Committee

WITNESS:

Frederick C. Robbins, M.D.
Dean, School of Medicine
Case Western Reserve University
Cleveland, Ohio

(Biographical Sketch Appended)

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

Thank you for offering me the opportunity to meet with you this morning to discuss the value of fetal research. You realize, of course, that I have certain biases since as a virologist and pediatrician for many years I have been actively concerned with diseases that occur in utero or in early life, particularly infections. Not only have I been concerned with the immediate effects such as death or illness but even more with the long term consequences that may not become evident until late in life. I am making the assumption that all of us meeting here have the same goal in mind, namely improvement of health and the quality of life. We may disagree as to the means to be employed but not as to the ultimate purpose. I suspect that we can also agree that through the pursuit of biomedical research we have been able to make some progress toward this goal. But, in my opinion, we have only scratched the surface and at a time when emotions are running high, it is incumbent upon all of us to exercise sound judgment in the formulation of policies and procedures affecting the future of biomedical research. Let us be very careful that in our concern about some actual or imagined abuses that we do not do more harm than good.

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Since my field of interest has been infectious diseases my examples will be drawn largely from this area. Dr. Behrman will approach the matter from a different point of view and deal with a variety of other conditions.

1. Why do I raise any question in principle about the appropriateness of specific legislation prohibiting fetal research?

My concern arises from a feeling that it is difficult to deal in the political arena with an issue so fraught with emotional overtones, particularly in view of the close association in many people's minds between the conduct of fetal research and the abortion issue. Laws, once passed, are difficult to alter and in today's changing world it is wise to keep one's options open. Furthermore, the variety of situations that arise make it difficult to generalize and each case presents special problems. The kind of deliberative approach that will be possible under H.R. 7724 seems to be highly desirable although the 4 month period allowed for the commission to consider recommendations on the conduct of fetal research is not very long.

2. What is meant by fetal research? The term has been applied to many different types of activities, and some are not even at issue here.

a. There are the non-invasive techniques which are used to monitor the fetal condition in utero, such as the fetal electrocardiogram

or electroencephalogram to determine heart function and brain waves, or the use of ultrasound and other physical methods to determine fetal position and conformation before delivery.

b. Amniocentesis is a type of fetal research which is a relatively harmless procedure of removing some of the fluid bathing the fetus. The material can be examined biochemically and microbiologically and cells from it can be cultured or examined. This technique has made possible prenatal diagnosis of many serious conditions, including infections, hereditary disease or such acute conditions as hyaline membrane disease or Rh incompatability. Many of these, if not prevented or treated, can result in mental retardation or death.

c. In another highly important investigative area, it is essential either to obtain a small piece of fetal skin or other tissue for examination or culture, comparable to doing a biopsy which is often done in later life for diagnostic purposes. But to be able to understand the cause and possible prevention of many seriously disabling or potentially lethal conditions which can develop later in life, it is necessary to study whole organs, or portions thereof, in order to learn about the peculiar biochemical and physiological properties of the developing organism.

3. Why do we need to do research on the human fetus? An important reason is that since we are interested in human health and disease we must in the last analysis examine the situation in the human. Much groundwork can be done in animals and this avenue always should be explored to its fullest

before turning to man. However, it is rarely if ever possible directly to transpose findings in animals to man.

Our interest in understanding more about the fetus is related to the great importance of the intra-uterine period of development for the future health of the individual. It is during this period that many hereditary diseases first become evident. Short of controlling conception it is here that many defects will have to be corrected or treated if we are to prevent disability.

Although reasonably well protected within the womb the fetus is subjected to a variety of environmental insults due to drugs, chemicals, radiation, the nutritional state of the mother, etc. The fetus is peculiarly vulnerable to such insults since they are likely to cause an arrest of development with the tragic effect of causing congenital abnormalities or preventing the individual from ever achieving his biologic potential. There is reason to suspect that a significant proportion of congenital anomalies and mental retardation can be ascribed to injuries sustained during fetal existence or early infancy.

It is during fetal life that certain infections such as rubella are most devastating. Some infections may become established in the fetal period and persist for long periods with deleterious effects of varying degree whereas the same organisms would cause only acute short lived infection in older individuals. On the basis of animal models it is possible that certain human cancers may result from infection of the fetus with specific viruses which would have no such effect in later life.

An area of great importance is the response of the fetus to drugs. We know generally that the fetus handles drugs differently than older persons but our ignorance in this area is profound. We badly need to be able to

determine how various drugs and antibiotics are dealt with by the fetus at various stages of development and indeed whether or not the drug crosses from the mother to the fetus. This can only be determined by direct tests.

4. What benefits have been derived from fetal research?

I will not be able to be encyclopedic but will provide a few examples of concrete benefits that have resulted from the use of fetal tissues and fetal research.

The first example is that of polio, one of the more impressive success stories in modern medicine and one with which I have some direct relationship. The breakthrough that made the conquest of polio possible occurred in the laboratory of Dr. John F. Enders in 1948. It was found that the polio virus could be grown in tissue cultures of human embryonic tissues. These cultures consisted of tiny fragments of tissue floating in about a tablespoonful of fluid all contained in a small stoppered flask. Exhibit #1 shows the flasks used in this research. It is material from cultures such as these that was used as the base for the original "Salk" vaccine. Once we had learned the trick, other more effective methods were developed and it was found that the virus could be grown equally well in monkey tissues; and up until recently most vaccine was produced in cultures of monkey kidney. However, because of continued problems with contaminating viruses and shortage of supply much of the vaccine used today is grown on human embryonic lung cell cultures.

The results of polio vaccination are familiar to all but it might be worth reviewing what has happened since 1948 when polio virus was found to grow in these simple little cultures of human fetal tissues.

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Photographic exhibit #2 shows a plain brick building that from 1922 was the contagious disease wing of Cleveland City Hospital. It had more than 100 beds and in the late '40s and '50s it was largely filled with acute polio cases during the summer and fall and during the winter and spring with the respirator patients and severe cripples. In exhibit #3 one sees a polio ward filled with severely paralyzed patients and in #4 a patient in an iron lung, a horrendous though life saving contraption that some of you may remember. This was taken in 1954 and the sign on the wall which says the vaccine works was placed there at the insistence of the patients who were overjoyed even though it came too late to help them. In exhibit #5 we see a severely paralyzed patient eating with mechanical aids. In exhibit #6 one sees the curve of the incidence of paralytic poliomyelitis in the United States before and after the introduction of vaccination. One could hardly imagine a more dramatic and satisfying result. Indeed, in exhibit #7 we see a pile of rubble that is all that is left of the contagious disease unit which was being demolished in 1965. With polio a disease of the past it was no longer needed.

Rubella (German measles) is an infectious disease that presents a peculiar need to study the fetus. As you are no doubt aware rubella presents little threat to anyone except to the fetus in the first trimester of pregnancy. Although it has long been known that rubella during pregnancy could result in abnormal offspring it is only within the last 10-15 years that we have been able to show that the fetus was infected by the virus and to define the wide spectrum of disease that it may cause. Exhibit #8 shows a baby born with

severe generalized infection. Such infants have a high mortality and the survivors are often seriously impaired. The eyes may be affected as seen in exhibit #9 where one can see the opacities (cataracts) in the lens. Finally, exhibit #10 shows a child left spastic and retarded in development due to fetal rubella infection. The elucidation of the involvement of the virus and the extent of damage was made possible only by testing fetal tissues for the presence of virus. It is to be hoped that with widespread use of the vaccine that is now available this type of fetal damage can be prevented.

Another important application of fetal tissues in the field of virology is the use of cultures of fetal trachea for the cultivation of a group of common cold viruses and certain types of influenza virus. These studies have contributed to our understanding of the cause of common respiratory illnesses and are important in the efforts to develop preventive measures for respiratory diseases including influenza which is still one of the more important causes of death and disability and continually poses the threat of becoming more virulent. The disastrous epidemic of 1918 still haunts us particularly since we do not know why it was so deadly.

Fetal cells show some of the characteristics of cancerous cells and thus studies of their behavior in tissue culture throws light upon why cancerous cells behave as they do.

Thus, it should be evident that fetal research has contributed significantly to our understanding of disease and normal development.

5. What benefits might reasonably be expected from fetal research in the future?

The contributions of fetal research in the future promise to be even greater than already made.

I have not touched upon past and potential contributions in areas such as endocrinology, metabolism and immunology. We are beginning to recognize that arteriosclerosis, the underlying cause of coronary disease, and a variety of disabilities associated with aging, has its origins in very early life. It becomes important to study fetuses for evidence of early signs of arteriosclerosis and to learn more about the development of arterial walls and how fetal cells deal with fatty substances such as are associated with the characteristic changes of arteriosclerosis. The promise of such studies leads me to emphasize once again how important events may be during the fetal stage in regard to the health and competence of the individual in later life. This is a big subject the importance of which we are just beginning to comprehend.

The remaining photographs in your packet are of children with a few of the many kinds of congenital and hereditary abnormalities that are of unknown cause and about which we can do little or nothing at present. Improved diagnostic methods frequently lead to their recognition before birth. However, upon their recognition we are presented with only two alternatives, both highly unsatisfactory. Either abortion must be performed or the family must decide to bring into the world a severely handicapped person with the attendant problems for the affected individual, the family and society. Most would agree that neither is satisfactory. But if we are to learn how to prevent or treat such conditions during the intra-uterine period in order to permit the birth of a normal functional person, there is no alternative, in my opinion, but to be able to conduct appropriate research upon the fetus.

Frederick Chapman Robbins

Frederick Chapman Robbins, M. D., Dean of the School of Medicine, Case Western Reserve University, Cleveland, Ohio was born in Auburn, Alabama on August 25, 1916. He received the A. B. degree in 1936 and the B. S. in 1938, both from the University of Missouri, and the M. D. from Harvard in 1940. He served in the United States Army from 1942-1946, received the Bronze Star for Distinguished Service and was discharged with the rank of Major.

From 1948 to 1950 he held a Senior Fellowship in Virus Diseases of the National Research Council and worked with Dr. John F. Enders in the Research Division of Infectious Diseases, Childrens Hospital Medical Center. During this time he was concurrently on the faculty of the Harvard Medical School as Research Fellow in Pediatrics.

Here he investigated mumps, herpes simplex and vaccinia viruses. His main effort was the cultivation of poliomyelitis virus in tissue culture and the application of this technique. It was for this research that Dr. Robbins was awarded, jointly with Dr. Enders and Dr. Thomas H. Weller, the Nobel Prize in Physiology and Medicine in 1954, as well as the First Mead Johnson Award and the Kimble Methodology Research Award.

In May, 1952 he became Professor of Pediatrics, Western Reserve University School of Medicine and Director of the Department of Pediatrics and Infectious Diseases. Among his responsibilities was the care of polio victims. In 1966, he became Dean of this School of Medicine.

Dr. Robbins is a member of the American Philosophical Society, the National Academy of Sciences and the Institute of Medicine of the National Academy of Sciences. He is immediate past president of the American Pediatric Society. He holds membership in the American Academy of Pediatrics and is past president of the Society for Pediatric Research.

Dr. Robbins is a member of the Advisory Council of the Office of Technology Assessment of the Congress. He has served as consultant in virology to the Department of Health, Education and Welfare. He was a member of the Infectious Diseases Committee of the National Institute of Allergy and Infectious Diseases of the National Institutes of Health. He is co-chairman of the National Academy of Sciences Academy Forum on Human Experimentation. Dr. Robbins is chairman of the Ohio Comprehensive Health Planning Advisory Council.

In 1969 Dr. Robbins was presented the Medical Mutual Award of the Academy of Medicine of Cleveland and he was a recipient of the 1971 Ohio Governor's Award.

July 1974

EXHIBITS REFERRED TO BY

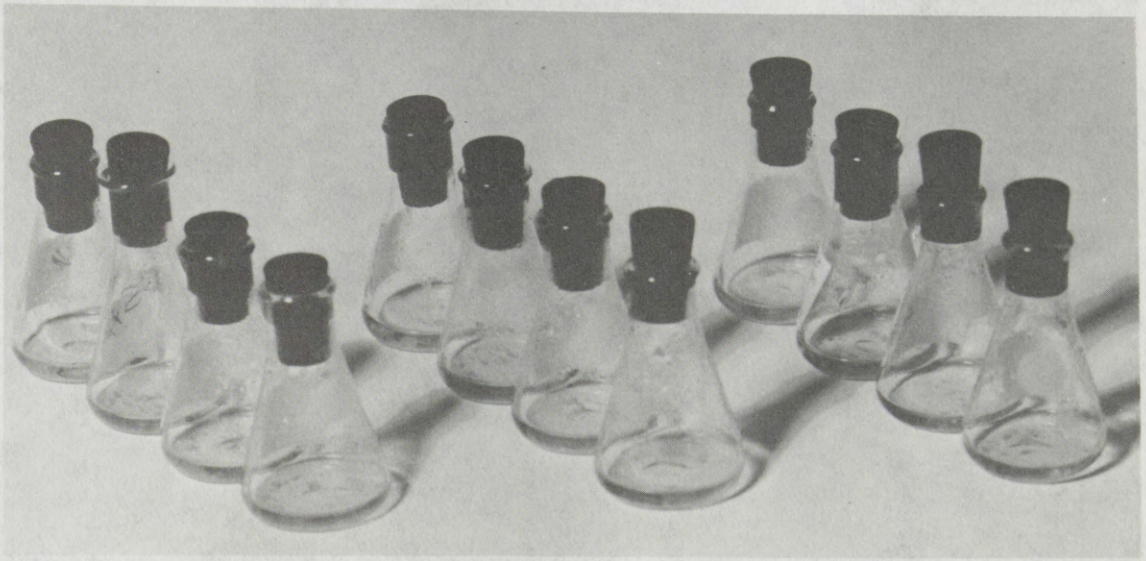
DR. FREDERICK C. ROBBINS

IN TESTIMONY ON FETAL RESEARCH

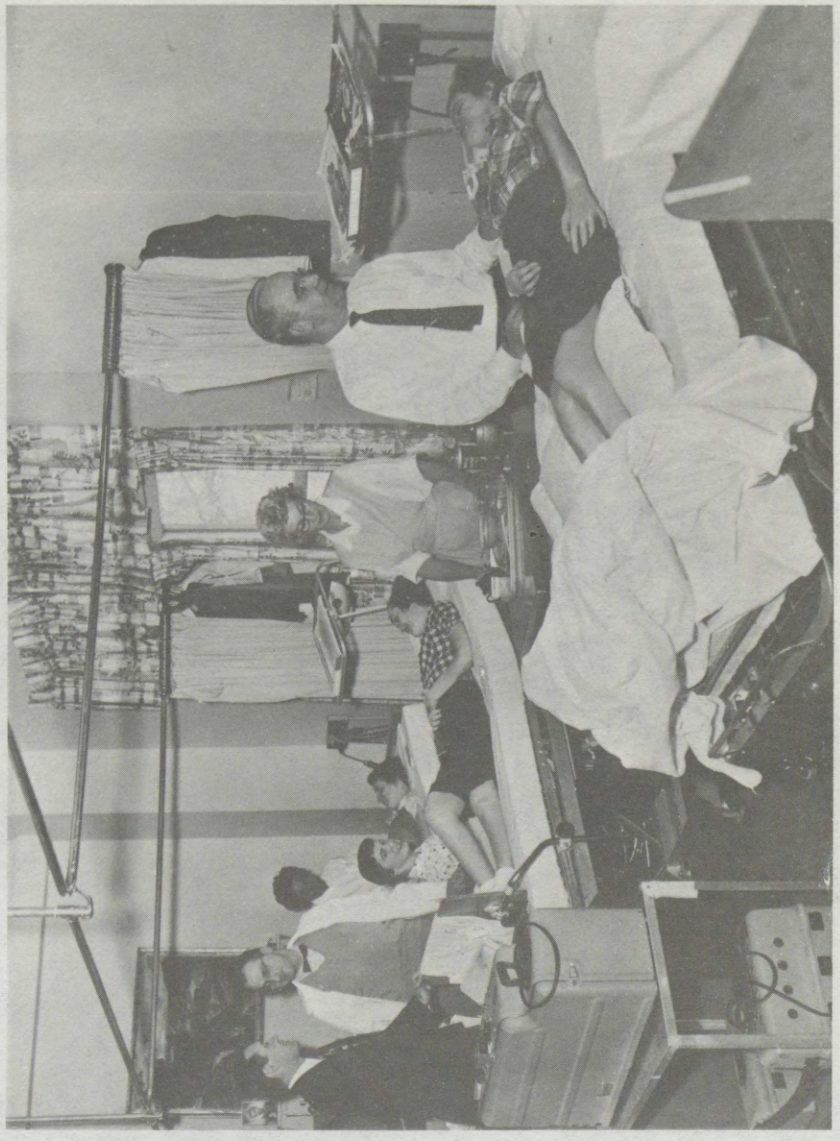
PRESENTED TO SENATE SUBCOMMITTEE ON HEALTH

FRIDAY, JULY 19, 1974

1. THE ORIGINAL TISSUE CULTURES IN WHICH POLIO-VIRUS WAS SUCCESSFULLY GROWN.



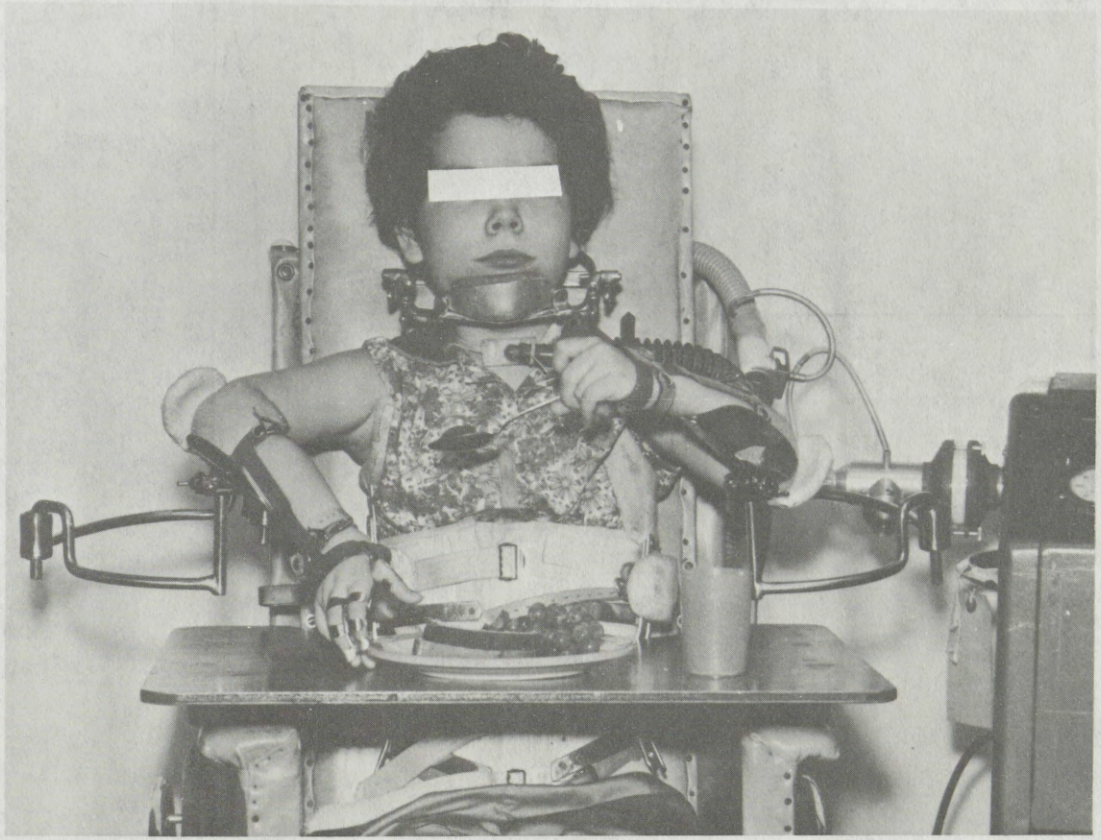
2. THE TOOMEY PAVILION: POLIO TREATMENT CENTER FOR NORTHEAST OHIO, ERECTED 1913



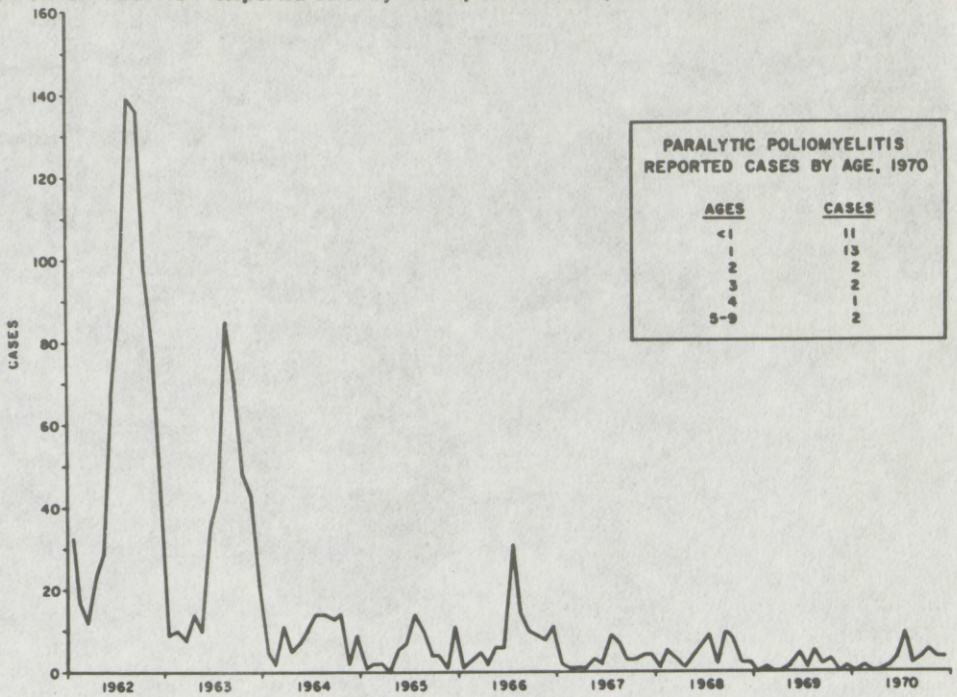
3. A POLIO WARD

4. IRON LUNG (RESPIRATOR) UNIT IN TOOMEY

5. POLIO VICTIM WITH MECHANICAL AIDS



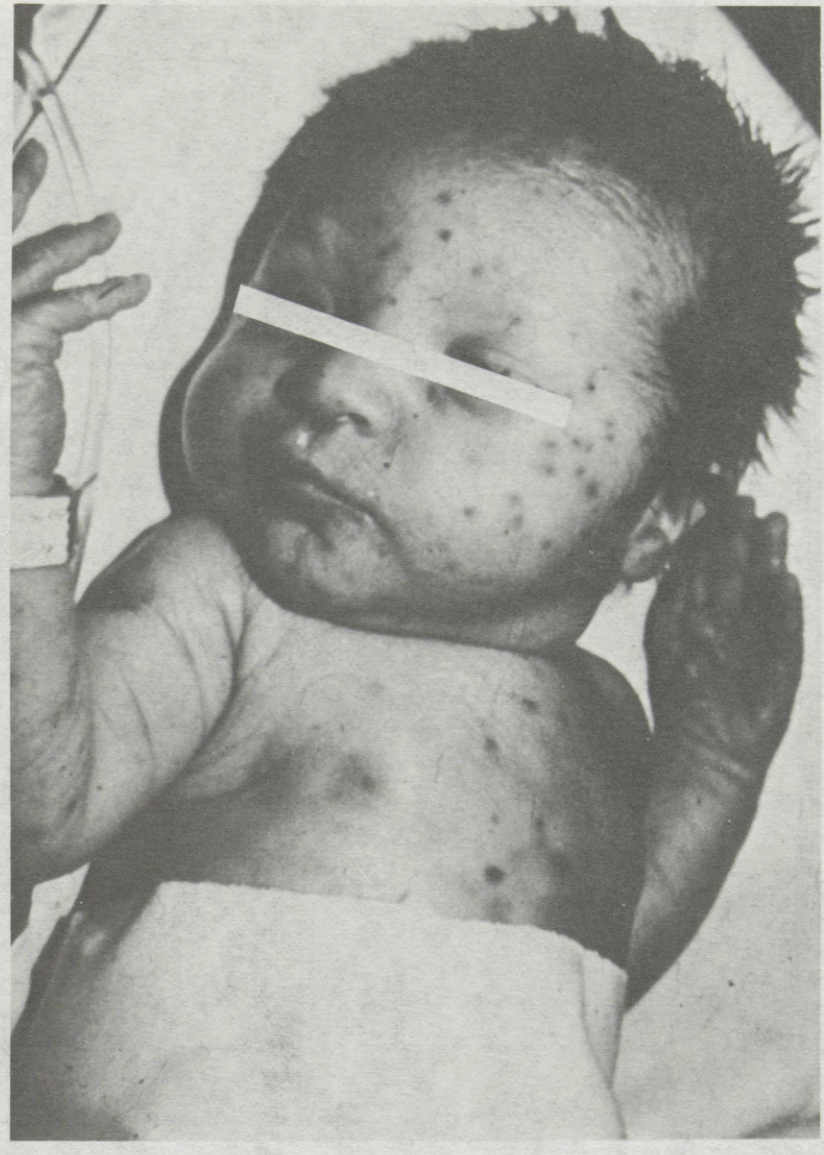
PARALYTIC POLIOMYELITIS — Reported Cases by Month, United States, 1962-1970



PARALYTIC POLIOMYELITIS REPORTED CASES BY AGE, 1970

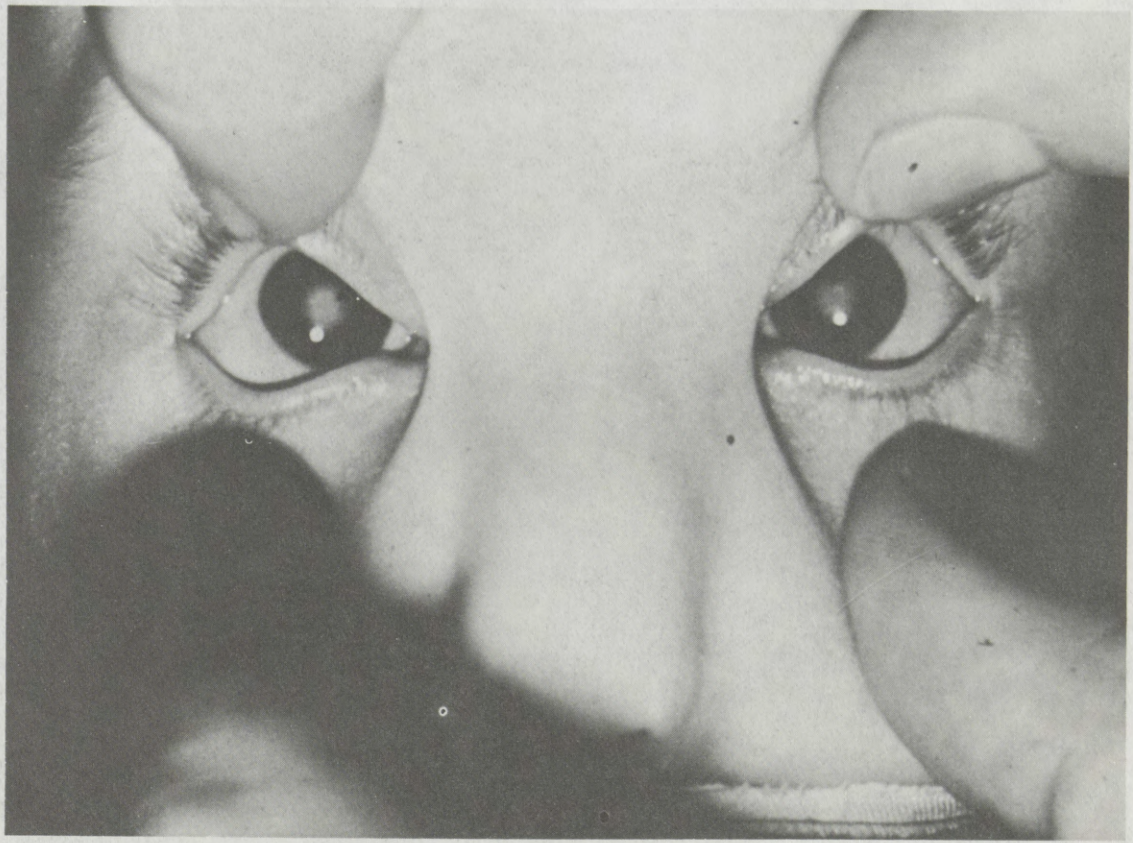
AGES	CASES
<1	11
1	13
2	2
3	2
4	1
5-9	2

7. HEALTHY CHILDREN DO NOT NEED TOOMEY'S

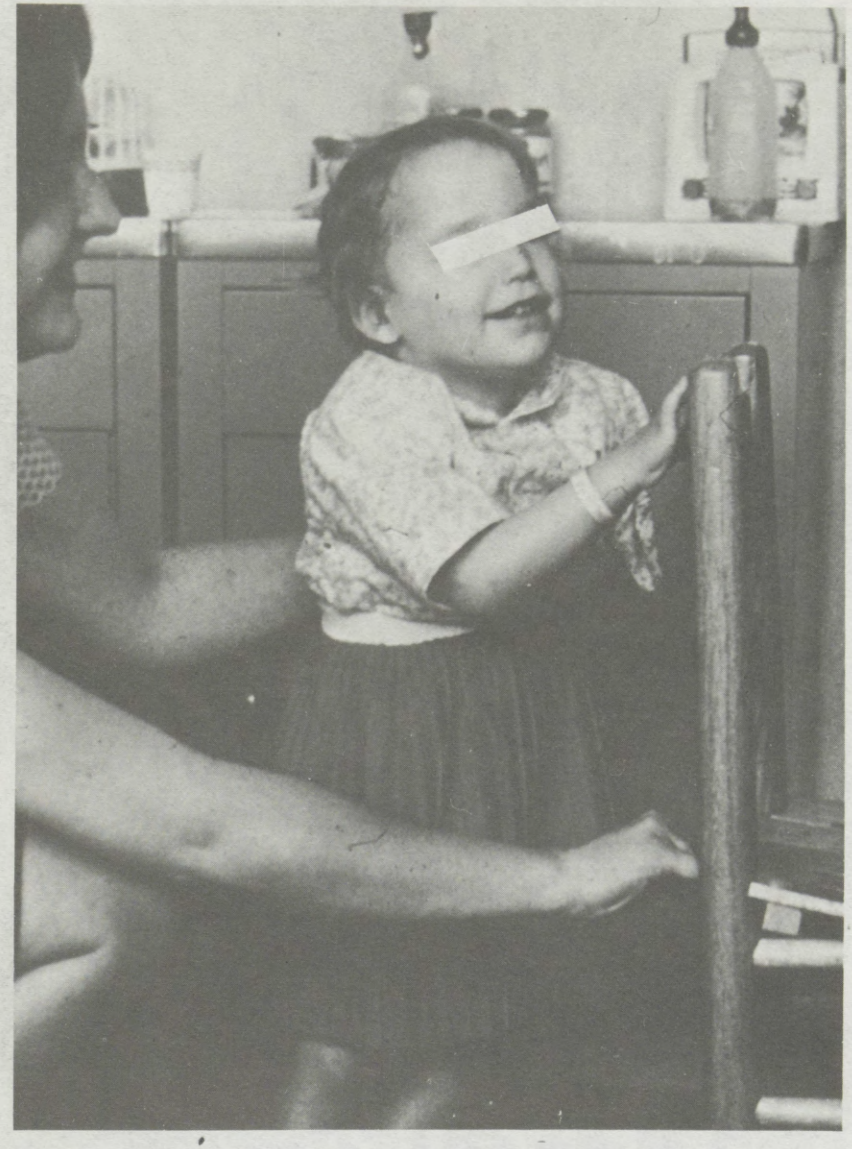


8. CONGENITAL RUBELLA - 30% FATAL

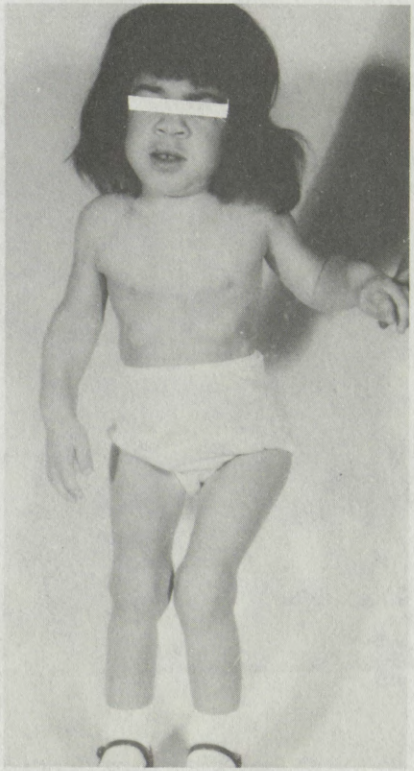
9. BLINDNESS FROM RUBELLA (CONGENITAL CATARACTS)



10. CHILD PERMANENTLY AFFECTED BY RUBELLA (SPASTIC)

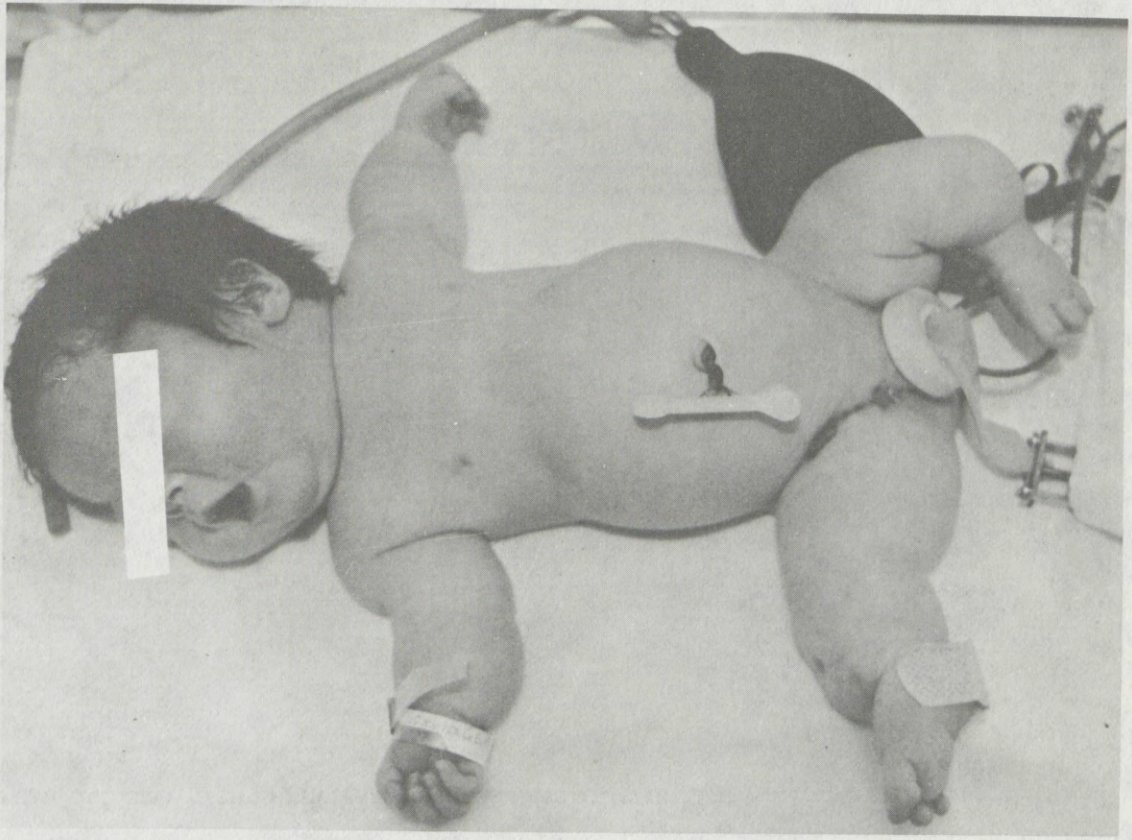


11. 11-YEAR OLD GIRL WITH HEREDITARY DISEASE RESULTING IN BLINDNESS AND RETARDATION

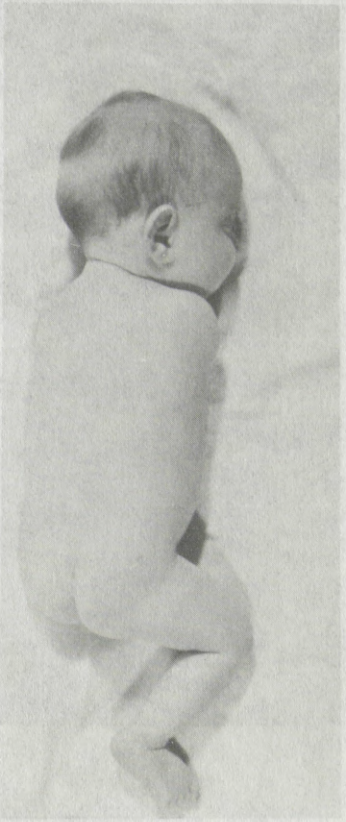


39-475 O - 75 - 3

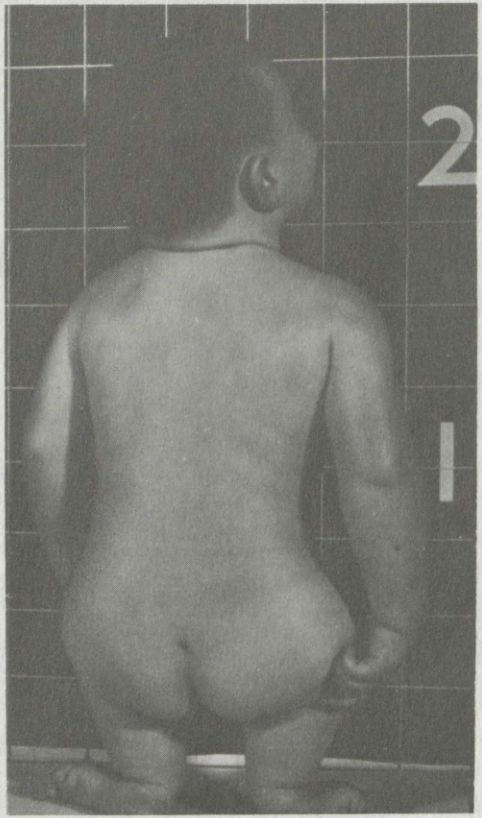
12. INFANT WHO DIED FROM ACHONDROPLASIA (BONE AND CARTILEGE DISORDER)

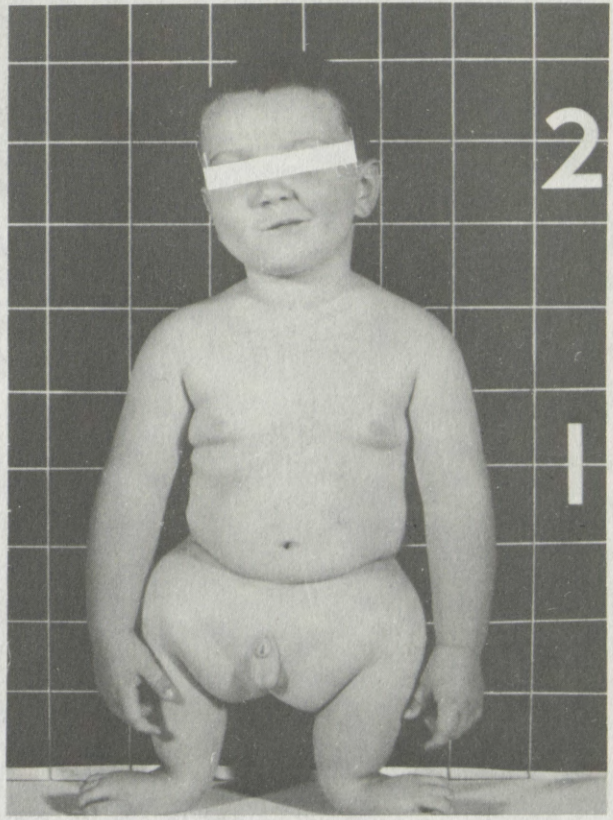


13. INFANT WITH CONGENITAL ABSENCE OF LIMBS



14. MALE INFANT WITH CONGENITAL ABSENCE OF LONG BONES OF HIPS AND FEET





Senator KENNEDY. Now let us hear from some of the other members of the panel on this.

Should this procedure be banned, Dr. Hellegers?

Dr. HELLEGERS. I would say if the circumstance is such that you know the damage which is done by the untreated or unvaccinated disease, you have on one side of the ledger certain danger to that fetus, and if you now develop a vaccine which you believe that it stands to benefit the fetus as much as to harm the fetus——

Senator KENNEDY. How are you going to know that?

Dr. HELLEGERS. You will not know it until you have given it, but the intention at that point is therapeutic. So, let us say there is always a first time when a given drug has to be given.

Senator KENNEDY. Are we really talking about drugs then?

Are we saying if the intention is good, you can go ahead and do it?

But, if you are not quite really sure, then you cannot?

Dr. HELLEGERS. I think that is predominantly what the ethical issue is about, to say would you use that fetus for the purposes of other people?

Are people to be used as objects?

And the answer there generally has been no, we shall not use people as objects even for the benefit of others.

Senator KENNEDY. Are you going to find very many researchers that are that disdainful in terms of human life?

Dr. HELLEGERS. No.

That is why I say there would be no problem with what Dr. Robbins suggests, namely one would say here is a situation, we know the damage of nonvaccination, and here we have a sufficient knowledge in other than the human about the vaccine.

Sooner or later, the patient has to see it, but in this patient the intention is for that fetus to benefit more than it would stand to lose.

Senator KENNEDY. You don't think the ban would apply?

Dr. HELLEGERS. I do not think the ban would apply.

Dr. ROBBINS. I think there is a misunderstanding of what I have been talking about.

The experiments in question were to vaccinate mothers who were known to be susceptible to German measles—women, excuse me, not mothers.

These women were scheduled for abortion. Their fetuses were examined to see if the vaccine virus indeed caused infection of the fetus.

Now, we were quite sure that the vaccine virus would not cause greater damage than if they had had regular measles. We were not certain that it would not damage the fetus if they survived. But we did show that the virus crossed the placenta—obviously, we never had a chance to see if it did any harm.

The conclusion from those experiments was that every effort should be made to avoid giving a pregnant woman, at least in the first trimester of her pregnancy, German measles vaccine. As a result this has been the policy, even though it is quite possible that even though the virus did reach the fetus that it would do no harm. Even in natural infection, it does not always do harm.

This kind of experiment does raise ethical issues.

But it did solve an important problem and has laid a firm foundation, we think, for the protection of fetuses in the future.

Senator KENNEDY. Dr. Behrman.

Dr. BEHRMAN. Those individual fetuses that Dr. Robbins indicated were affected by a virus given intentionally by the investigator had no potential for being benefited at the time that the virus was given.

I think that is the answer to the narrow question raised.

The only way one could subsequently decide if another given fetus was at risk would be by experiments to be able to diagnose that infection in utero and thus distinguish the group that were actually infected from those who were exposed but not infected.

The whole potential for developing a vaccine that effectively could protect the fetus would depend on that kind of information, which, at the time it was obtained would be of no benefit because it would not even be therapeutic.

Mrs. POLICASTRO. I am somewhat familiar with the type of investigation to which Dr. Robbins is alluding.

I feel that something has been introduced, and I will talk about this further in my statement, which we know would harm a child, if this child were to continue living.

When such a medication was introduced, when the virus was introduced through the mother, they were trying to study a transplacental type of involvement to the fetus. Therefore, that fetus would, given percentages where rubella affects a child, be injected also.

Nevertheless, they were deliberately intending to infect for the purpose of further studying the fetus at a later date after the abortion had been completed.

Senator KENNEDY. Dr. Behrman, do you agree with that?

Dr. BEHRMAN. I agree. In that instance that is exactly what was being done.

There is no way in which that individual fetus, I think, can be conceived of having potential for being benefited from that experiment.

The benefit is to the population of unborn fetuses who subsequently would benefit from the vaccine, very much like the polio situation of several years ago.

Dr. ROBBINS. This kind of experiment very clearly raises the ethically difficult issues. There is no doubt about it.

Senator KENNEDY. The issue then is that although you may be risking some additional harm to the fetus, there is sufficient evidence that the research could benefit fetuses in the future. In other words, you are attempting to balance these two factors.

Dr. ROBBINS. Absolutely.

Senator KENNEDY. Mrs. Policastro, if that is the purpose, this poses for you and for many people a particular dilemma, as I understand it?

Mrs. POLICASTRO. Yes, that is true.

Dr. ROBBINS. I might say it causes a particular dilemma for those of us who feel this is the appropriate thing to do. It is not just something we do offhand by any means.

This is a matter of great soul searching, and one wants to be extremely sure that you have exhausted the various avenues other than this.

There were experiments done in monkeys, extensive studies, before any was done in man. The bare minimum was done in man, I assure you.

So those who have done such experiments are not always as cocksure that they are right as they may appear to be.

Senator KENNEDY. I suppose this is complicated as well by the decision of a woman to have an abortion, amounting to a decision to extinguish life. From your vantage point, Dr. Robbins, if you are convinced that life is going to be extinguished, should you proceed to do this type of research?

Dr. BEHRMAN. If I could follow up on that thought of yours.

The thing to appreciate is that actually this kind of information is what would give another woman at another time—who does want pregnancy but who has been exposed to rubella and does not want the pregnancy if her baby is infected—gives her the option, as a result of these types of experiments, for one to diagnose whether or not that particular fetus is infected. This would thus decrease abortions by really removing the only reason why that particular woman might want the abortion in the case of a potentially infected fetus.

I think there, it becomes a very individual decision, because many abortions that are done at the desire of a woman are because of her fear of the risk of infection to her fetus and damage to its subsequent development.

Senator KENNEDY. Dr. Hellegers?

Dr. HELLEGERS. I would like to say there was one other consideration that was brought forward by the so-called Peel Commission in Britain which dealt with this.

Under the Peel Commission rules, this would have been prohibited on the grounds that once the virus had been given, the woman would no longer be able to change her mind about not having the abortion.

So, the route that the British went was to say do not remove from any woman prior to the actual abortion her ability to change her mind at the last moment.

So that happened to be the British approach. Nothing like this exists in the United States yet.

The second problem is whether extinguishing of life or the knowledge of future death is a sufficient ground for use as experimental subjects. This is, of course, highly questionable. I think it is a big problem, just simply to say that just because you are going to die in 5 minutes, therefore I may use you now.

I think, fundamentally, what we are dealing with here is a problem of ends and means, and whether the end, however good, justifies the means.

Mrs. POLICASTRO. I understood some of this research, as with the rubella research, was to determine the transplacental involvement with the fetus, not to find out if there was a vaccine that could cure it at the time.

It was just to see the involvement with the fetus.

It would be wonderful if we could have a vaccine to counteract this in the first few months of pregnancy, but this is not the understanding I have of this type of research. There may be concurring research also being done along these lines for a vaccine to guard against this.

But, as I understand it now, some of this research was to introduce rubella virus to the fetus in order to study later to see what involvement that virus had on the fetus, which is a little different.

Dr. BEHRMAN. I agree entirely. That is what it was. It was a step.

The problem is that it is not possible to design experiments that in one fell swoop would take us from no understanding to a vaccine. Progress is a series of small opportunities to answer limited questions which, then, on the basis of very difficult judgments and reasoning, builds into a hypothesis on which you have a vaccine eventually being developed.

I would like to make one other comment regarding the Peel report.

One very critical point about the Peel Commission report, and I think it is particularly important for the Congress to understand this, is that it did not in law prohibit what Dr. Hellegers said.

What the report did was to say that the Commission makes the determination at this time, until further consideration by an administrative body, (i.e., the Commission itself) that at this moment in time, it seems that the potential benefit is too distant for the gain.

Now, I think none of us think that is the type of judgment that should be made in legislation. It should be made by investigators and probably should be made by other groups monitoring investigations, and so on.

What we are concerned about here is the question of what is to go into Federal legislation—and I do not mean H.R. 7724—but a potential absolute ban on research which allows no reconsideration easily on an administrative level as to when that research might become reasonable to do.

Dr. ROBBINS. I would like to make another point that does not really have to do with the fetal research issue particularly. It is only part of it.

That is, there seems to be a misunderstanding as to what is required in order to achieve certain benefits. We are never able to introduce a new vaccine, a new drug, a new treatment of any kind, without some attendant risk.

Society usually has made up their minds that they are willing to accept some risk in order to achieve a better drug. And this has been going on for a very long time.

I was reading very recently the whole history of the development of innoculation against smallpox during the 18th Century in England.

Smallpox was a very serious problem and its mortality was quite high.

They were willing to accept the risk of being purposely innoculated with smallpox virus, not vaccine. The risk was something like

20 to 30 percent, if you got the disease naturally, and something like 5 to 10 percent if you were innoculated.

There was a serious risk of dying.

We face this kind of risk all the time in everything we do. Of course, we also face it when we drive in our automobile, and we take our child in our automobile, or pregnant wife, we are presenting them with a serious statistic risk.

Senator KENNEDY. What you are saying, I gather, doctor, is that in these areas of research it is very difficult to determine when risk outweighs benefit and vice versa. There are serious ethical dilemmas involved here.

But I suppose that over a period of time we can expect a careful review of procedures that will ultimately lead to better protection of future fetuses.

Dr. ROBBINS. Yes.

Senator KENNEDY. The dilemma that could be created by any kind of legislation is that if you ban a particular or precise action, you are interrupting what you see as a necessary stream of research that has the likelihood and potential of leading toward further protection of fetuses?

Dr. ROBBINS. Yes, but I would also like to make it very clear that any good scientist is fully aware and must always be concerned with the fact that his own judgment is not infallible.

The principle of subjecting his judgment to scrutiny by others is well established in science and good science should be done this way.

The fact that we are not infallible is very clear in that we have to set up double blind studies because the mere fact that an investigator may want an experiment to come out a certain way may influence how he views the data. That is nothing new to a person in politics, people can look at the same question, the same data, and get entirely different answers.

So that science, good science, goes to great lengths to guard against these kinds of biases, and I hope that the same kinds of assurances apply in the area we are talking about.

Senator KENNEDY. Dr. Hellegers.

Dr. HELLEGERS. Just so we will not confuse things too much. I would disagree with Dr. Robbins on his approach to the smallpox vaccine in its first use, for the simple reason that it could be first used in an adult who was capable of giving consent on behalf of undergoing a certain risk, and the particular problem we are faced with is that we are dealing with proxy consent giving on behalf of another, and may that other be used on behalf of mankind?

I would find it considerably easier to accept something myself and find out what its medical effects are than to give it to one of my minor children and say I want that child used as the vehicle.

Dr. ROBBINS. That is an interesting aside. The first experiments that were done with the Jenner vaccine were done on prisoners, in London, and the proxy there was the king.

Senator KENNEDY. That raises, of course, obviously the issue about who does have a right to give consent or not consent. That, in and of itself, is an issue.

Okay, let us move ahead.

You think, Dr. Robbins, that actually the rubella vaccine could have been developed in Great Britain under the Peel Commission?

Dr. ROBBINS. Rubella vaccine could have been developed.

Senator KENNEDY. Could have been developed?

Dr. ROBBINS. The question we were discussing as to the use of the vaccine in pregnant women could not have been answered unless you could convince the Peel Commission that there was no significant threat to the fetus.

The particular experiments I am talking about had been preceded by experiments in primates, that is, monkeys, and there was evidence that the vaccine virus was much less likely to cross the placenta than was the natural virus that causes the disease.

So that at least we had reason to believe that. The vaccine virus was much more benign, we knew it was more benign in other respects, but it was much more benign in this respect in monkeys.

There was a feeling that it was probably statistically fairly remote, even if the mother changed her mind, that there would be much likelihood of damage to the fetus.

Furthermore, the numbers involved were such that there was a very small chance of actually getting serious involvement of many fetuses even if you used wild virus.

However, I realize that there is disagreement among people at this table as to the way that the decision was finally made.

Senator KENNEDY. We want to make sure we hear from the others. Could you outline for us which areas affect infants most directly, which diseases or disabilities would really necessitate fetal research. We want people to have some understanding of what is involved here—the types of illness, disease, or infections.

Also, do you believe that the necessity of some type of fetal research is generally accepted by the scientific community?

Dr. ROBBINS. I will mention some and then I will let Dr. Behrman mention others.

Senator KENNEDY. As you know, the National Research Service Awards Act does not ban all fetal research.

So it would be helpful if you could summarize for us the principal diseases that affect infants and whether you think that the ban which has been developed really prohibits the kind of research that will make progress in those particular areas, just so that we understand what we are doing here in the Congress and the Senate. I am not sure we do.

Dr. ROBBINS. There are about five or six infections which present a serious problem in infancy and occur in utero.

One of the more important ones in which work might be impaired by the present ban is cytomegalo virus. It happens to be a virus related to the one that causes fever blisters.

Anywhere from 1 to 2 percent of live born infants are infected with this agent. Originally we thought that this agent always caused very serious injury, particularly of the brain.

By careful experimentation, which does not involve at the moment fetal research, it has been shown that although a great many in-

fants are born infected, only a small proportion of these are demonstrably affected, although subtle effects may occur.

Now in order to study this virus, the best cells are human fetal cells. It has been important, also, to examine fetuses—either aborted spontaneously or artificially—to see how frequent this infection is within intrauterine, and how often it is the cause of serious disease in utero.

This disease is a very interesting problem and illustrates how hard it is sometimes to arrive at a clear definition of how serious a particular infection is.

Rubella we have already talked about and there is little more we need to say.

Senator KENNEDY. Prior to the vaccine, what percent of the children were affected by it?

Dr. ROBBINS. Less than 50 percent had any serious effects.

Senator KENNEDY. Less than 50 percent?

Dr. ROBBINS. Less than 50 percent of those born to mothers who had rubella. Now they might have had some minor effects, but any serious effect was less than 50 percent.

But the effect, when it did occur, was pretty devastating. It seemed to vary with epidemics to some extent. Not every epidemic had exactly the same experience.

In the last major epidemic in this country, there was something like 20,000 affected children in the United States. When you consider that many of these will live out a full life's span, that is a fairly significant burden.

Senator KENNEDY. The effects can be mental retardation and other defects?

Dr. ROBBINS. Yes, right.

Maybe Dr. Behrman would like to take up some of the other areas.

Dr. BEHRMAN. If I could give maybe one example.

Senator KENNEDY. You understand what we are trying to get at here, Doctor?

Dr. BEHRMAN. Yes. I think one of the—really, statistically, the greatest cause of death is respiratory distress syndrome in the first week of life in newborn infants, known as hyaline membrane disease.

At the moment, both for premature infants and for those full-term infants who are afflicted, the major way of managing them involves respirators, where something analagous to our treatment of polio, when we had respirators before we had any type of preventive measures.

The respirators are of benefit in that we decrease the chance of the child's getting brain injury if we can keep their blood oxygenated. But the use of respirators also increases the chance of getting significant disease both in the lungs and in the eyes. The next logical step, which people have been pursuing in experimental animals principally, is to develop a heart-lung bypass machine very similar to that used in open-heart surgery, that would allow you to perfuse this child without using a respirator, keeping his brain oxygenated

for prolonged periods of time. At the moment this can only be done for a short period of time, only long enough to do surgery. But if one could develop such a bypass machine one could decrease the morbidity associated with respirators and decrease the mortality for some of the premature infants who, despite the use of respirators, cannot be kept oxygenated.

Now the steps necessary to get to that point:

The first step was animal work. We are in the process of doing that animal work now. Success is by no means around the corner. But it is easy to foresee that within the next 4 to 5 years engineering feats might enable us to use a heart-lung bypass for as long as a week or 10 days, instead of a respirator, on an animal with poor lung function or lung damage similar to hyaline membrane disease.

The next step would then be to take a child with hyaline membrane disease and put him on this bypass machine. Experience indicates there is such a broad difference between animals, in this instance sheep and some monkeys, and a child, that the risks for the first child to be put on the machine are almost certainly going to be death, if you choose a child that has a severe disease.

On the other hand, one would not be justified in choosing a child with mild disease because there the chances of being able to pull him through with a respirator would certainly be much better than the chances of using a totally untested new device, even though it had been tried out on animals.

The logical step would be to take what has been referred to in the various materials presented to the committee as a fetus that has a 100-percent chance of dying, with absolute certainty, and using that machine on him. You know that with a respirator he has 100-percent chance of dying and you know that with a heart-lung bypass machine he has probably 100-percent chance of dying, since the first fetuses that are done would probably die. One could pretend that maybe you were increasing the chance of that baby, but if you took a baby that you really thought had a reasonable chance to survive, you would probably not be justified in using a new machine. You would have to use the respirator.

However, there are a number of steps before you got to that point. You would then choose to use a fetus, who, although alive, had a 100-percent chance of dying if not extraordinary means were used, and in general one would not use extraordinary means.

For example, take a 250-gram fetus, a half-a-pound fetus. In that situation, you are weighing benefits down the line by a series of experiments, even before putting the fetus on the machine, some of which may involve measuring volume of blood in that previable fetus, or measuring the normal clotting of the blood, to make sure that when you put him on the machine the blood will not clog in the tubes of the machine.

All of those experiments would have to be done and most reasonably have to be done on the very small fetus.

Now what you would be measuring there is a potential gain in an area where respiratory disease is the major cause of death for a large group of newborn infants. You would be weighing the gain for that population, even though the first set of infants that you

used the new device on would clearly derive no therapeutic benefit themselves.

Now we are kind of in the area of imagination, of the unknown. There is a judgmental factor in deciding, when you are at the point when the technology is really good enough to justify taking a small risk on a population that has no chance to benefit, for the sake of a population which has a large chance to benefit. That is a judgment that is very difficult to make, very difficult both for technical people to make, as well as for lay people to make, in terms of the ethical part of that judgment. I think one of the very intelligent things the British Government did was to set the Peel Commission up so that such issues could be constantly reviewed rather than to have prohibited a whole area of investigation, which may then preclude one from really ever changing the outlook for that group of infants.

Now, also, you have to remember the outlook is not just life or death for that group of infants. It may involve morbidity of the lung, it may involve blindness, and clearly, for a certain group of them, it involves significant mental retardation.

I guess what we are talking about is where are those kinds of judgments best made and who should participate in making them?

I think that is a reasonable question for Congress to try to solve. I think if we make the choice that we are going to ban fetal research entirely, essentially we are making the choice that we are going to give up the opportunity to improve our way of taking care of children with these kinds of maladies.

Instead, we will go the route of caring for those who survive, hopefully most humanely as caretakers in society. I think that is a very fundamental choice that has to be made.

Senator KENNEDY. Well stated. Dr. Hellegers.

Dr. HELLEGERS. I would like to add a third possibility. Dr. Behrman raised a question, where should these decisions be made and who should make them?

I would like to suggest that the third possibility is: should they be made at all?

The simple saying that because we have 100-percent certainty that the fetus small enough is going to die, therefore it makes sense to use that fetus, buys the principle that impending death is warranty for experimentation.

I think I am not going to buy that immediately because it has been bought before, and I would suggest that in the first case it should be used, should be the case in which the physician honestly feels that the respirator is not going to save that baby and that at that point he would, on that baby, use the heart-lung machine, in which case that baby maybe would stand possibly to benefit as much as to lose.

But I am not quite sure we ought to use one category of live people, just because they are going to die, for the benefit of others.

I think we get in the danger of using people as objects regardless of the benefit.

Dr. BEHRMAN. I wonder if I could address that question directly.

I suppose the first example of nontherapeutic investigation was Adam and Eve when she gave him the apple and, frankly, the results were devastating.

The theologians have not successfully really resolved this one yet.

It has been argued, as Dr. Hellegers has just argued, that if we allow experiments on live fetuses that have no chance of survival, the same reasoning could be used to do experiments on other doomed human beings; for example, adults, terminally ill adults on respirators with no brain function.

This is really, I think, a specious argument because, at the present time—and I think this is ethically justified—such an adult or his relative would have the opportunity to give informed, uncoerced consent to be the subject of such investigation.

We do not preclude that adult from making the decision to participate in that investigation. If he decides to participate, experiments could and perhaps should be done, depending upon the evaluation of the scientific and law community as to whether the benefit to be gained was worth allowing him to do this.

The human experiment in the fetus or the aged legally and ethically should not be inconsistent with treatment used to sustain life. No one is arguing that. That is the implication of Dr. Hellegers' argument.

However, in contrast to the terminal adult, little is being done to sustain the life of these previable fetuses we are talking about at the moment of birth. It is generally considered unethical to use vigorous attempts to transiently sustain such previable fetal life. It would be considered extraordinary attempts, comparable to extraordinary attempts to sustain life in an adult who is terminal and has no brain function.

In this instance, the two are very different situations. We are not saying that anything should be done that would be inconsistent with the treatment used to sustain that fetal life. We are saying that anything that is consistent with that should be done.

It so happens under these circumstances that very little is ethically justifiable to be done for that fetus.

For example, it would be unethical to put such a fetus on a respirator, and it would generally not be done, similar to situations in adults where a decision is made not to put an adult on the respirator.

Now, those decisions are not made by the physician alone. They are made in consultation with the family. Often the family makes them in consultation with other members of the family, with religious people, with friends.

These decisions are the kinds of life decisions people make all the time.

Frankly, I think individuals involved are probably the best people, supplemented by appropriate safeguards and monitoring, to make these kinds of life decisions.

So I do not think it is really a fair argument to say that the fetus is analogous to a person in a concentration camp.

[The prepared statement of Dr. Behrman follows:]

Statement of

Richard E. Behrman, M.D.
Chairman, Department of Pediatrics
College of Physicians and Surgeons, Columbia University
and
Director, Babies Hospital
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at the
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The health and welfare of our children and of our children's children is currently being placed in serious jeopardy by efforts to prohibit or significantly limit research on fetuses. Instead of providing adequate safeguards from abuses by a few individuals, these efforts are likely to severely limit our ability to protect children from serious illness.

Most of us in this country place a high value on the desirability of each person exercising his own judgment about how his (or her) life will be lived. The right not to have anyone touch our bodies or threaten to touch them without our permission is one important aspect of this right. However, this right is not absolute. We require children to have certain immunizations before going to school whether or not they or their parents want them because the health risk to the community in this circumstance is considered to outweigh the value we place on the very basic right not to be touched by another person without our consent.

The doctrine of informed consent to the necessary assaults and batteries of physicians in the course of caring for the sick is based, in large measure, on the idea that the interests and well-being of the individual patient are best protected by delegating to this individual the decision as to whether or not to allow the physician to proceed. Ideally, the patient thus makes the ultimate judgment as to the individual's, the family's and, in some instances, the general

societal risks and benefits. This is a just and practical right even though there are times when serious adverse consequences for the patient and his family occur which could have been avoided but were not because the patient's own decision was obviously not the best decision; and there are times when society may, as a consequence of such a decision of a patient, have to assume enormous human and financial burdens of long-term care. Nevertheless, the risks to the individual and his family are considered to be still greater if others are made responsible for these decisions.

However, this legally guaranteed ethical right of the patient to exercise informed consent prior to medical procedures and treatments is also not absolute. There are circumstances in which the individual patient's capacity to protect his or her own interests is limited or non-existent. For example, an adult in coma after cerebral vascular accident may not be able to consent to a necessary treatment. In this situation we accept a substitute consent by a closely related family member whose interests, love and concern for the patient are such that reasonable men and women might rightly assume that the relative will be making judgments for the patient, often with enormous implications for the family and society, with a perspective similar to, but obviously not identical with, the viewpoint we imagine the patient might have had. Again, society as well as the family and patient may be profoundly affected by these decisions which the substitute patient, the parent or relative,

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is empowered to make.

Research on the human fetus should also be considered in the context of our accepted framework of individual decision making, social justice and the right of patients to protect themselves through an obligation for informed consent by the patient or by a reasonable substitute. Further, when we think about the health and welfare of children, another idea emerges as fundamental. Individual decisions must be placed on a time scale that measures their impact not only on the individual living today but also on what a particular decision will mean to the child or adult twenty or fifty years later, and what it implies for other individuals living at this time, as well as for future generations. This is what John Rawls refers to as "justice between the generations." If we are willing to accept the fruits of past research, such as immunization against polio, we in turn have a very real obligation to continue substantial efforts to investigate our current health problems for the sake of our children's children.

What then is the nature of the decision which must be made when a parent is asked to give permission to a physician to operate on a child with suspected appendicitis? Assuming reasonable efforts to inform the parents about the medical risks and benefits, is it basically different from the parents giving permission to a hematologist to use a new antimetabolite to treat leukemia as part of an investigation of the efficacy of the unproven drug? As far as the parents' decision is concerned, is this significantly different from an expectant

mother giving informed consent to allow ultrasound (a form of sonar) to be used on her fetus for the purpose of determining normal fetal growth? In each instance, we are asking the parent to make a moral-ethical judgment as a substitute for that of the child or fetus, in part on the basis of the physician's presentation of the risks and benefits for the individual fetus or child which he has an ethical duty to relate to the parents and, in part, on the basis of the parents' life experience and general human understanding in making independent decisions that affect themselves, their families, and others in society, as well as future generations. The issue is not whether physicians should make these decisions. They should not now make these decisions for parents and should not in the future. Rather, the issue is: should we limit the right of the parents to make these decisions?

When permission for human investigation is at issue, rather than a question of generally accepted choices of treatment, the moral-ethical decision of giving informed consent for therapeutic or non-therapeutic research which involves the invasion of the body of the fetus or child should continue to be a decision for parents, or in unusual circumstances, someone else substituting for the parents. This has not been the rightful domain of the physician or physician-scientist in the past and should not be. To wrongly accuse physicians in general of usurping this role, as some are doing, is dishonest and merely obscures an important problem. A more relevant issue is to decide whether

society needs to provide parents with some additional safeguards in making their own decisions.

Should parents and/or others substituting for a fetus be allowed to consent to the fetus being included in therapeutic and non-therapeutic investigation? What are the consequences for the development of the human species if we do not allow research on fetuses? What risks or diseases for our children as adults could be avoided by investigations during fetal life? Major advances in the prevention of coronary heart disease may depend on our understanding of fetal and infant metabolism and nutrition. Our ability to prevent and treat certain central nervous system disorders, such as multiple sclerosis, as well as a variety of cancers of adult life, and even our ultimate ability to ameliorate the aging process are likely to be dependent in part, upon investigations of fetal life. Do we limit the right to life of fetuses by delegating their consent to others? Or do we increase the opportunity to exercise their right to life and subsequent freedoms, if we investigate their health and disease on the basis of consent given by others? We do require children to go to school regardless of their wishes or those of their parents because of a judgment that this is in their and society's best interests. It oversimplifies the problem of consent to assume that the sole basis for allowing informed consent by parents to substitute for that of the fetus is to protect the particular fetus from any conceivable bodily harm. This is, of course, the major consideration, but there are other ethical interests to be taken into account, such

as the protection of future generations and society.

The principle that governs medical investigation of adults should also continue to be applicable to children and to fetuses, i.e., the decisions should be made by an uncoerced and reasonably adequately informed individual or individuals whose interests are substantially overlapping or identical to those of the proposed subject and include an awareness of the ramifications for the family, society and future generations. Basically, the substitute or supplemental consent of a parent for a child's or fetus' consent to participate as a subject of research should be a matter left to the judgment of a concerned, loving, and mature individual who will evaluate the situation from the parental perspective as well as from the point of view of the child's or fetus' immediate and long-term best interests as if he or she were in the fetus' place. The interests of society and future generations may also be given adequate consideration in this context. The ultimate judgment should not be made in a vacuum or without safeguards to increase the opportunities to gain a reasonable understanding of the implications and possible consequences of the decision. As with most medical decisions, the patient or parents, in the case of a child, consult with friends, relatives, ministers, family physicians, etc. Further, the community should require some evidence that consent was truly informed, that the individual and general benefits were honestly presented relative to the risks. It may well be desirable to formally provide the decision making adult with additional advice or consultation beyond

what he or she seeks out for himself. Very little other than therapeutic research or non-therapeutic research with little or no risk is likely to occur under this system. For the most part, it has not occurred in the past. I believe this way of proceeding will assure not only that life is protected, but that there is optimal opportunity for an individual child and other generations of children to fully exercise a right to life.

Now, I'd like to turn specifically to the problem of abortion and the investigation of existence before birth which I believe should be considered from the perspective we have just discussed. The problem is best introduced by an example. The technique of amniocentesis involves placing a needle through the abdomen of a pregnant woman into the amniotic cavity surrounding the fetus and withdrawing a sample of this fluid; the pressure of the fluid can also be measured. These techniques of pressure measurement and sampling have had significant health benefits for individual fetuses and infants. The pressure measurements are an important adjunct to monitoring heart rate during labor and thus have played a major role in improving survival and decreasing brain injury from asphyxia in newborn infants. Analysis of the fluid obtained has provided a means for improved management of Rh disease with resulting increases in survival and decreases in morbidity. Similarly, other tests on this amniotic fluid determining the lecithin to sphingomyelin ratio have improved the quality of obstetrical decisions in managing immature fetuses with a resultant decrease in deaths and injury from prematurity; this decrease in

injury may have a substantial impact on the incidence and severity of cerebral palsy in the future.

When the technique was first used to measure intrauterine pressure during human labor, amniocentesis was not established as a procedure which would be of benefit for the individual fetus. Further, preliminary investigations of such advances in animal species are not always possible or practical, although generally desirable. The problem of treating and preventing Rh disease could not have been adequately investigated in animals before human studies were undertaken. By going ahead with the human fetal investigation through amniocentesis enormous benefits have accrued in the treatment of fetal asphyxia, Rh disease, prematurity and hyaline membrane disease. I will not even go into the potential impact of this technique on over forty familial disorders of intracellular metabolism or its implications for individual families, society and future generations in managing chromosomal aberrations such as Down's Syndrome (mongolism). In my opinion this important advance would not have been at all likely to occur under the various proposals for federal legislation to prohibit human fetal investigation. It is critical to keep in mind that the issue to be considered is not whether the proposed language to prohibit fetal research will allow amniocentesis or other recent advances to continue to be available, but rather the issue is whether now unknown and unimagined advances with similar substantial benefits for our children are unlikely to be developed because of a ban on fetal research.

We could decide not to have any investigation of the fetal stage of human development and accept this limitation on our ability to enhance the opportunity for our children to grow and develop in a way that will maximize their potential as adults and thereby abdicate our responsibility to future generations. Alternatively, we can attempt to devise a social mechanism to provide a substitute or supplementary judgment for the fetus consistent with the high value we rightly place on each individual's freedom to make decisions and judgments that most closely affect himself. In my opinion the latter approach best preserves our fetuses' and children's right to life, liberty, and the pursuit of happiness. Some other mechanism for decision-making should be devised to cover this situation which takes into account the interests of the individual fetus, the parents, society and future generations of children who have a substantial stake in this matter.

If abortion or miscarriage occurs accidentally, decisions about the disposition of the dead fetus should be the prerogative of the parents, as would be the situation after a child dies. This would be consistent with the foregoing principles and with the general rules governing disposition of cadavers.

If a fetus is alive after delivery, the ethical obligation, as in the case of the infant and child, is to sustain life so far as reasonably possible, and it is both unethical and illegal to carry out any investigation which is inconsistent with generally accepted treatment necessary to promote life. There is no real issue about this, although there may be a substantive medical problem of

deciding when a fetus is dead. If a live fetus unintentionally results from the parents' decision to have an abortion, a substitute judgment about consent to human therapeutic investigation could be devised to supplement the parents' judgment. If it is a wanted pregnancy, the principle governing informed consent by parents of infants or children should apply. It should be kept in mind that as a practical matter the premature infant will be considered a fetus under proposed laws and regulations, and much of the therapeutic research that has led to dramatic decreases in mortality and morbidity of premature infants in past decades might not continue if fetal research is prohibited.

A major problem centers on the question of experimentation on a fetus who although living is judged at a given point in time to have no chance of survival, no matter what is done therapeutically, called a previable fetus. If investigation is permitted, it is conceivable that sooner or later such a fetus may survive. Investigation on such a fetus should be subject to informed consent of the parent with appropriate supplemental procedures to provide reasonable safeguards to assure informed consent and adequate consideration of the rights of the fetus and parents.

Investigations of such previable fetuses may be particularly vital to improving the biologic quality of our children in the future; this interest of society in these fetuses is of even more concern if the population growth is limited. Therefore, a real effort should be made to provide reasonable

procedures that will allow such knowledge to be acquired.

Our ability to accurately diagnose early in gestation a severely affected fetus with rubella (and thus avoid aborting an unaffected wanted infant when a mother has had the infection and legally desires to abort an infected but not an unaffected fetus) is directly dependent on research on previable fetuses directed at developing new methods of diagnosis. To make these diagnoses, one needs to compare the normal with the abnormal fetus. Further, the use of tissue from a previable fetus may be particularly important to cancer research, studies to prevent birth defects and the development of vaccines such as those now available to prevent polio and measles.

It has, however, been argued that if we allow experiments on live fetuses who have no chance to survive, the same reasoning could be used to do experiments on other doomed members of the human species -- such as terminally ill adult patients. It is argued that since both have no chance of survival and it would be wrong to do an experiment that has no therapeutic benefit for the patient on a dying adult, it would also be wrong to do such experiments on dying fetuses. However, this is really a specious argument since such an adult or his relative would have to give informed, uncoerced consent to being the subject of such an experiment; if he did, the experiment could and perhaps should be done, depending on the particular problem. Of course, the human experiment in the fetus or the aged, legally and ethically, should not be in-

consistent with the treatment being used to sustain life. However, in contrast to the terminal adult, little is being done to sustain the life of these fetuses at the moment of birth. Vigorous attempts to transiently sustain such previable fetal life would be considered similar to unreasonably extraordinary attempts to keep an adult alive who is terminal and has no brain function.

If we do not promote human investigation as it pertains to fetuses, the welfare of our children and our society may be put in substantial jeopardy. Those who have the responsibility to provide needed additional safeguards for the patient subjects of human investigation should not choose to prohibit certain types of investigation in fetuses rather than to provide reasonable substitute procedures for an informed, uncoerced judgment as to whether or not it is in the best interests of the fetus and society that he or she be included as a subject of investigation. Instead of protecting fetuses from abuse, a ban on such research will seriously limit our ability to protect children from serious illness and compromise our efforts to promote optimal growth and development of fetuses and children. The goal of research into fetal life is to preserve the right to life in its fullest sense by preventing and curing human disease. We must develop reasoned and thoughtful solutions to this problem which will minimally limit each individual's freedom to make his own decisions about his life and his family while giving adequate consideration to his responsibilities to others in the community and to future generations.

Senator KENNEDY. Dr. Hellegers.

Dr. HELLEGERS. I would not wish to make that argument in whatsoever way.

I would simply say that I think that the fetus is entitled to more protection than an adult. I agree with Dr. Behrman that the adult can volunteer and give consent.

I think the less a person is able to give consent, the more they require protection and not the other way around.

Dr. BEHRMAN. I agree with that.

I think the issue is to find the most rational and reasonable kind of protection to afford the fetus in situations like this, not to abrogate the responsibility for coming up with a creative social solution that will enable us to move ahead in certain areas.

Dr. ROBBINS. I will agree with that. That is the crux of the problem, a good social solution.

Senator KENNEDY. Dr. Robbins, do you want to summarize the remainder of your testimony and we will move on?

Dr. ROBBINS. I think, Senator Kennedy, I would perhaps not proceed with any testimony any further. I see no point in it.

Most of the issues have been covered.

I did point out what resulted from the work with polio, which was initially done with human fetal tissues, and I think we have all got to agree the results were rather impressive and gratifying.

There are many promising areas for the future.

I would point out the work which is being done with arteriosclerosis in the hopes of preventing coronary disease, and other diseases of the blood vessels, which are associated largely with aging. It would seem quite probable that this start in utero and studies on fetal cells will be important in approaching this problem.

Cultures of fetal trachea have been the principal means of growing the common cold viruses, an important advance, and even studying certain variants of influenza virus.

The influenza studies are especially important. Influenza is one of the most serious illnesses on a worldwide basis that we face and, of course, the disastrous epidemic of 1918 haunts us, particularly since we do not really know why it was so deadly. Studies in cancer are most important and fetal research is critical.

I would like to reemphasize that one is able now to diagnose prenatally, many hereditary diseases and some congenital abnormalities. At the moment when a diagnosis is made—there are only two alternatives: accept the consequences, or perform a therapeutic abortion. Neither, in my opinion, is a very desirable solution.

Without studies, some of which will involve the live fetus, we have little chance at arriving at that point which would allow for prevention or therapy of some of these disabilities which are so devastating.

Our goal is to eliminate abortion as a therapeutic tool but it will be quite some time before we can achieve that.

Senator KENNEDY. Mrs. Policastro, we will proceed with you next.

Mrs. POLICASTRO. Mr. Chairman, thank you for the opportunity to present our views before the Health Subcommittee on the issue of experimentation using human subjects.

I am Patricia Policastro, executive board member for the U.S. Coalition for Life.

At this moment, I would like to ask your permission to enter into the record further documentation that, due to the brevity of an oral dissertation, I cannot include. Will you accept it.

Senator KENNEDY. All the testimony will be printed, and you may submit any other documents you wish.

[The documents referred to follow:]

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STUDENTS PICKET STANFORD EXPERIMENTS ON LIVE ABORTED FETUSES

DOCTOR ADMITS MOTHERS OF SOME CHILDREN WERE NOT INFORMED

A student protest at Stanford University today led to a dramatic confrontation between student leaders and Dr. Robert Goodlin, the man whose experiments they were trying to ban. During the confrontation, Dr. Goodlin admitted that some children were experimented on without their mothers' consent.

The Student Pro-Life Federation organized picketing in front of Stanford Medical Center in protest of what they termed "abominable acts" which took place when Dr. Goodlin conducted experiments on live aborted fetuses in his attempt to develop an artificial womb. Commenting on the student protest was Mark Swendsen, a Director of the Student Pro-Life Federation and organizer of the rally: "While an artificial womb would be an unquestionably useful article, we object to the means Dr. Goodlin has taken to achieve his ends. His experiments have involved cruel acts, such as slicing open the rib-cages of still-living aborted fetuses in order to observe their hearts. We hold that the abortions which killed these children, as well as Dr. Goodlin's experiments on them in their dying moments, constitute violations of human rights. No human being should be made into an involuntary guinea-pig, no matter how much a doctor wants him as a subject. This is especially true when the child is as helpless as Dr. Goodlin's victims, and when the experiment involves such cruelty. We are demanding a permanent ban on the experiments, an end to secrecy in Dr. Goodlin's lab, and an investigation by government authorities for possible prosecution."

Dr. Goodlin, absent during most of the student picketing, rushed to Stanford.

2/Experiment protest

Goodlin met in his lab with three student leaders: Swendsen, Jim Babcock, Chairman of the Student Pro-Life Federation, and Debbie Wiggins, Southern California Co-ordinator for the group. During the meeting, Dr. Goodlin denied that any secrecy had been attached to his laboratory, but gave in to one of the student demands: that their representatives be allowed be allowed to visit his lab at any time. However, he rejected a second demand of a permanent ban on his experiments. Explaining that his experiments have not been conducted since 1969 due to a lack of funding, Goodlin expressed the hope that he would be able to obtain enough money to begin experimenting on aborted children once again. "I think that this is an important area of study," Goodlin said.

Swendsen said that the students would continue to press their demands that the authorities conduct an investigation for possible prosecution of Goodlin.

Goodlin contended that he had done nothing wrong; however, under intense questioning from Swendsen, he admitted that the mothers of the children used in his experiments were at times not informed that their children would be removed from them alive for use in his lab. Goodlin also stated that some children from premature deliveries were experimented on, too, and contended bitterly that the ultimate objective of his experiments was the development of an artificial womb to save the lives of premature infants. While admitting that fetuses up to 24 weeks of gestation had been used, Goodlin said: "Those that were very late were actually miscarriages, and we were trying to see whether we could keep them alive." Goodlin's novel experiments involved attempts to get the fetuses to breathe solely through the skin while in a jar filled with a liquid under high pressure, through which oxygen was pumped. Swendsen stated that Goodlin's argument was absurd: "To say that it is legitimate to kill someone in order to learn how to save his life just doesn't make sense," Swendsen said. Swendsen also asked Goodlin: "Do you feel that it is legitimate for a doctor to perform medical experiments on an involuntary human subject?"

"Of course not!" Goodlin replied. He explained that he had never been able to resolve the question of whether a fetus is human. Debbie Wiggins, speaking

for the student group, retorted: "It is incredible to me that a man of such tremendous knowledge, such tremendous scientific curiosity, can't establish a most basic fact."

Miss Wiggins continued: "This is a monstrous disregard of human life. Even if you make the scientifically absurd assumption that human life does not begin at conception, the fact that the mothers of these children at times did not consent to the experiments indicates a ghastly arrogance on Dr. Goodlin's part."

Babcock added: "The protection of those who because of their tender age have no voice to cry out against injustice is of paramount importance. The medical profession is disgraced by those who arrogantly assume the right to experiment as they please with involuntary human victims."

In a private statement to news media, Goodlin said, "I think they're nuts!" The opinion was apparently somewhat mutual.

STUDENT PRO-LIFE FEDERATION
May 19, 1972

SUBMISSION BY THE SOCIETY FOR THE PROTECTION OF UNBORN CHILDREN (S.P.U.C.) TO THE GROUP ESTABLISHED BY THE MINISTER OF HEALTH AND SOCIAL SECURITY TO CONSIDER THE ETHICAL, MEDICAL SOCIAL AND LEGAL IMPLICATIONS OF USING FETUSES OR FETAL MATERIAL IN RESEARCH.

Introduction

The referral of the problem of research on fetuses obtained at abortion for consideration by an independent, expert group provides a much needed opportunity for the Government to receive advice from an informed source on several aspects of the badly framed abortion legislation. Many of the most unsatisfactory features have direct bearing on the problem of fetal research.

The ethical difficulties of this matter do not exist in isolation. The problems of utilisation of human tissue dealt with by the Human Tissue Act and the question of determination of death are examples of closely related issues.

S.P.U.C. does, of course, accept that abortion is justified when continuation of the pregnancy would carry real risk to the life or health of the mother. But in common with most informed medical opinion, it believes that such circumstances are comparatively rare in Britain in the present day.

It is a consequence of abortion that a fetus will be separated from the mother at an age when it will usually be incapable of survival (non-viable). Since the Abortion Act it has happened that "abortion" has been done at a stage where the fetus proved to be capable of independent existence.

Fetal tissues have been used for research in the past and this has been without reasonable doubt to the benefit of humanity in general. They have also been utilised in connection with routine diagnostic work and even, to a limited extent, for therapy. S.P.U.C. would certainly not wish to see these uses stopped.

[illegible] however, is the question of research on live human fetuses - or babies as they in fact are. The Society is of the view that every step should be taken to ensure that this is not only prohibited but that safeguards are introduced to make it impossible that it could happen.

Below some of the problems and dangers which are involved are referred to and possible safeguards suggested.

PROBLEMS AND DANGERS OF THE PRESENT SITUATION

Since we now accept that human corpses may properly be obtained for medical education and research, sometimes by payment, there can be no objection in principle to this being done with aborted fetuses. But clearly, it would be quite wrong to allow doctors and clinics to have a vested financial interest in the disposal of any legal abortions for which they are responsible.

Determination of Life and Viability

A viable infant is regarded as one born after 28 weeks' gestation. If born before that and dead, it is an abortion; if after a stillbirth. A live born infant, however, is one which breathes or shows other signs of life after complete expulsion from the mother regardless of the stage of pregnancy. Any infant showing such signs which subsequently disapear should be registered as a live birth and the death also registered. The most widely acknowledged "other sign of life", is, of course, a heart beat. Modern developments have made it possible to detect the baby's heart beat down to as early as 12 weeks' gestation. The fact is, of course, that at this early gestation period there is at present no realistic prospect of extra-uterine survival and it is widespread practice for doctors not to seek evidence of heart action in babies which are hopelessly small.

With advances in neonatal care the earliest gestational age at which a child may be reared after delivery from the uterus is steadily declining. Quite apart from errors in gestation calculation

which have always made it possible that a baby calculated to have a sub-28 week gestational age would transpire to be of a maturity four weeks in advance of this and therefore achieve survival, it is now becoming increasingly possible, with the aid of sophisticated scientific aids, to achieve survival of children delivered before a true 28 weeks' gestation period. Some different arbitrary dividing line between "viable" and "non-viable" is needed.

Other countries have set lower limits of viability, e.g. in the recent abortion legislation in New York State this is 24 weeks. Any arbitrary figure is likely to require downward revision before long in the light of medical progress. Babies with weights approximating to a 24 week gestational age have already been reared.

If every tiny fetus with an electronically detectable heart beat were given the full attention of the resuscitation facilities little would be gained yet much would be lost by diversion of the limited resources from babies standing a reasonable chance of benefitting. The situation is akin to that in the very elderly when the good doctor will avoid dramatic resuscitative procedures which he would utilise in a young adult. The idea, however, that because no action is taken to resuscitate the hopelessly young or the hopelessly old, the human body should be an available specimen for research is unthinkable. Before any human baby material is utilised for research, it must be made certain that death in the strictest sense has definitely occurred.

Fetal Suffering

The possibility exists of the fetus having neurological activity and experiencing pain. Fresh evidence has become available strongly supporting the concept of fetal neurological activity (e.g. Hon,E.H. in "Diagnosis and Treatment of Fetal Disorders", ed. by Karlis Adamsons, New York, 1968; Grimwade, J. Walker, D. and Wood, C., Lancet 1, 1970, 1936; Wedenberg, E. and Westin, B., World Medicine, 19.5.70, p.24). This work has involved assessing the response of the fetal heart rate to the transmission of sound waves through the maternal abdomen. The baby responds to these by increased cardiac rate. Wedenberg and Westin say that the hearing organs and neurological channels are completely formed and operative by the 24th week of intra-uterine life. If the relatively refined auditory system is functioning in the fetus it seems certain that the relatively crude pain sensation is also operative. Pain, of course, is in scientific terms indefinable. It is only assessable by the individual experiencing it. In relation to clinical practice and animal research practice, it is appropriate always to give the individual the benefit of any doubt. It is a horrific situation that the human baby is denied the protection against research procedures which might cause pain yet this is given to laboratory rodents.

POSSIBLE SAFEGUARDS

In dealing with some of the related problems such as certification of death in adults, there is little need to spell out everything in legalistic terms or to build in controls; the common-sense ethic of the doctor can be relied upon. However experience has now shown that it is unwise to rely wholly upon the ethical conduct of individual doctors engaged in abortion practice, particularly in the private sector, and that in this matter the law needs to be clearly stated and firmly enforced if abuse is to be prevented.

1. Remove the 28 week arbitrary distinction and redefine viability

The law could be reworded to cover "Termination of Pregnancy on Medical Grounds". This would immediately remove the anomalous distinction between termination of pregnancy at 195 and 197 days. The group might care to consider (a) that for the time being a 20 week limit for fetal viability be accepted; (b) that a weight figure be introduced, e.g. 500G. It would, however, be essential to legislate that even below these standards no fetal tissues could be used for research unless death had been certified by an independent doctor (see below).

2. Appointment of independent arbiter

Some form of financially independent medical arbiter should be involved in every case. By "financially independent" is meant one who would in no circumstance receive money from the patient and would not stand to lose or gain if the abortion was performed or if the fetus survived. This arbitration should not be performed by any doctor who has any involvement in possible research utilising the baby's tissue. The precise status of such a person could take several forms, e.g. an N.H.S. whole-time consultant; similar to that of a medical cremation referee; that of a Government inspector as in relation to animal research or that of a medical "ombudsman".

3. Commission for control of fetal research.

The conduct of research on fetal material should be strictly controlled by a Commission. Without its specific permission no fetal research of any type would be permitted.

4. Abolition of research on babies showing cardiovascular or neurological manifestations of life.

This Society believes that all research should be totally banned on babies which show any manifestations of life on assessment of function of the neurological or cardiovascular systems. The most stringent, sophisticated, modern, electronic methods of exclusion of activity should be obligatory in every case under the scrutiny, as indicated above, of an independent arbiter.

5. Consent of parent

Research on fetal material should not be permitted without the express consent of one or other parent.

6. Registration of disposal of fetuses

All institutions which are licensed in relation to abortion operations should be required to account for the disposal of all fetuses.

'Live' abortus research raises

Both Congress and the California legislature plunged into regulation of medical research in recent weeks in a way that has alarmed scientists and clinicians. The specific legislative target in both capitals, Washington and Sacramento, was research on "live" aborted fetuses.

Acting in the charged atmosphere that surrounds both the abortion issue and that of informed consent for experimentation, the legislators took these actions:

Dr. Rich: 'Fetal research is a must if fetal surgery is to have a future.'

- Congress attached a rider to the National Science Foundation's authorization bill for fiscal 1974, barring use of NSF funds for research on abortuses with beating hearts. The law was signed by President Nixon August 16 as PL 93-96.
- The Senate voted September 11 to put a similar rider on the NIH fund-authorization bill for research fellowships and training, prohibiting the HEW Secretary from conducting or supporting research on live products of induced abortion except to "insure survivability of that fetus." The bill, HR 7724, was expected to go to conference to iron out differences with the House version (passed May 31) and then to the President, probably by early October.
- The same week the U.S. Senate acted, the California legislature approved a bill making it unlawful for any physician in the state to do scientific or laboratory studies on a live abortus except to preserve its life. Adopted unanimously by both chambers, SB 1046 was expected to be signed by Gov. Ronald Reagan and take effect immediately as an "urgency" statute. It carries the penalty of suspension or revocation of a physician's license for "unprofessional conduct," should the state's Board of Medical Examiners find him in violation of the provisions.

Significantly, the congressional legislation bars federal funding of such research both in the U.S. and abroad—a provision that would bar American investigators from using federal grants to conduct fetal research in northern Europe or other areas where live abortuses are generally more available than in the U.S. (MWN, June 8, p. 21).

But the NSF law and the NIH riders are limited in time. The former applies to the current fiscal year only and would have to come up for renewal next spring. The House version of the NIH restriction is also for fiscal 1974 only, while the Senate adopted Sen. Edward M. Kennedy's (D-Mass.) proposal that the fetal-research amendment be in force only till a national study commission could come up with an alternative.

The California law, on the other hand, would be a permanent addition to the state code and quite possibly a model for other states. Dean Clayton Rich of the Stanford University medical school told the Assembly health committee that he "understood the benevolent motivation for SB 1046, but the bill is potentially more harmful than beneficial."

Fetal research, he said, is needed if new methods of diagnosis and treatment for critically ill newborns are to be developed. "While maternal mortality has decreased remarkably since 1935, neonatal mortality remains disappointingly high. One of the reasons . . . is our ignorance of fetal physiology. Simply stated, we need new knowledge."

The technique of amniocentesis, Dr. Rich pointed out, "would not have been developed without studies of human fetuses." Similarly, he argued, "Fetal surgery, now in its infancy, can be regarded as experimental. Is its development to be foreclosed?" And on the "rare occasions" when diagnostic amniocentesis induced abortion or damaged the fetus, he said, "Physicians would want to study the fetus to learn how a recurrence could be prevented."

Stanford pediatrics professor Philip Sunshine added other warnings of the bill's possible effects. Progress in treating respiratory distress syndrome "could not have been made without techniques developed in conjunction with fetal research," said Dr. Sunshine. The bill appeared to set up barriers to research on sickle cell anemia, he added, particularly studies to determine how fetal hemoglobin production is switched to sickle hemoglobin.

Representatives of Stanford, the University of California, the American Civil Liberties Union, and Zero Population Growth did succeed in getting the California bill amended. A criminal penalty clause was deleted, as was a total ban on study of "conception outside the womb." Speaking of the latter proposal, Dr. Sunshine asked, "Do you mean to keep women who are not fertile from any hope of motherhood?"

The bill's opponents also got a clause put in to permit fetal research "to protect the life or health of the fetus"—i.e., to allow physicians to use experimental approaches in the newborn nursery if standard ones fail.

But a suggestion by the Stanford faculty members to have the whole issue referred to a special commission of clergymen, laymen, and scientists, as was done several years ago in Britain, was turned down flat. Instead,

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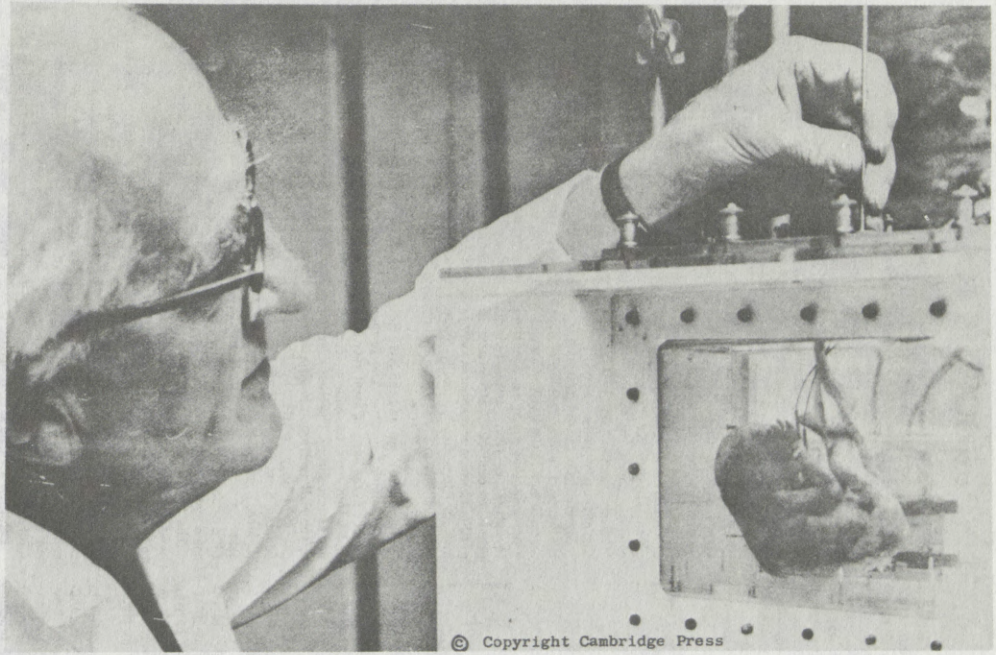


THE LAST HOURS OF AN ABORTED BABY. Dr. Lawrence Lawn, of Cambridge University's Department of Experimental Medicine at work experimenting on a living, legally aborted, human fetus. Some British doctors have been vigorously defending their experiments on live aborted babies after a storm of protest blew up in England when a Member of Parliament told the press that private abortion clinics had been selling live aborted babies for research. Dr. Lawn was quoted in the Cambridge Evening News as saying "We are simply using something which is destined for the incinerator to benefit mankind. . . Of course we would not dream of experimenting with a viable child. We would not consider that to be right". The Langham Street (abortion) Clinic admitted sending aborted fetuses to the Middlesex Hospital (The People, May 17, 1970). A spokesman for the clinic said that the fetuses 'were aged between eighteen and twenty-two weeks. . . Our doctor had to give some special attention to the operation. He did this at his own expense and dispatched the fetuses to his colleague at the Middlesex Hospital. It had to be done pretty promptly, but the hospital is only a couple of minutes away.' In the News of the World, for the same date, this same man, Mr Philip Stanley, is also quoted as saying "The position is quite clear. A foetus has to be 28 weeks to become legally viable. Earlier than that it is so much garbage".

Wednesday, October 24, 1973 MEDICAL TRIBUNE

California Bans Medical Testing On Living Fetuses

Medical Tribune Report

SACRAMENTO, CALIF.—The State of California has banned medical experimentation on living, aborted human fetuses in the wake of charges made to a state legislative committee that investigators at several California universities were engaging in "grotesque torturing" of live aborted fetuses.

Among the schools mentioned were Stanford University and branches of the University of California.

Physicians who violate the ban face revocation of their licenses.

The sponsor of the legislation, Assemblyman Mike Antonovich of Los Angeles, told MEDICAL TRIBUNE that he had reports of medical experimentation on living fetuses up to six months of age—which subsequently died—and he called such testing "murder."

His bill passed both houses of the California Legislature without a single dissenting vote and was signed into law by Gov. Ronald Reagan.

The California Medical Association took a "no opposition" stand on the bill.

It is expected that similar legislation will be offered in other states.

Before the California legislative action, the National Institutes of Health moved to halt three instances of such experimentation that, although not directly funded by the NIH, used laboratory facilities partially supported by Federal grants.

A spokesman for the NIH reported that the agency had uncovered experiments on living fetuses that were carried out in Finland, with subsequent laboratory work in the United States, and in each instance the NIH had negotiated a voluntary cessation of such experimentation.

The NIH is currently holding in abeyance proposed grants for fetal experimentation, pending a report by an advisory committee on the ethical problems at issue. The committee's report is expected in January, and although the NIH declined comment on any recommendations the committee may have already drafted, it was learned that the advisory group was, at one point, suggesting that such experimentation be sanctioned and supported on fetuses up to 20 weeks of age and weighing up to 1.1 lbs.

Packed in ice,' hearing told

Pittsburgh Catholic 3/17/72

'Laboratory' gets bodies of aborted, nurse claims

By PATRICIA BARTOS

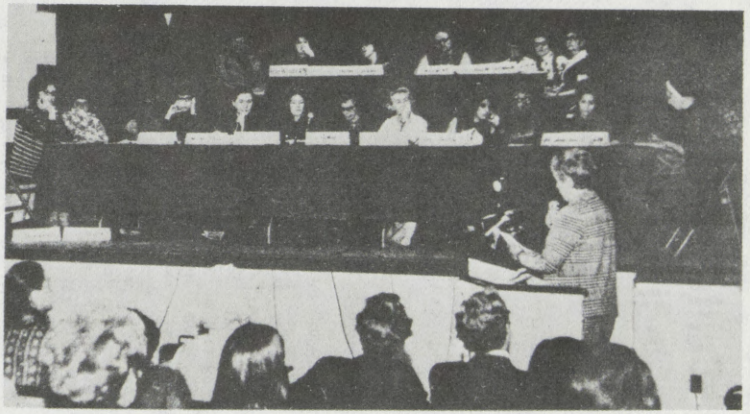
"I was no longer able to accept seeing tiny arms and legs considered routine specimens," stated former Magee-Women's Hospital nurse-anesthetist Mrs. Wilhamine Dick in testimony before the Abortion Law Commission meeting Tuesday in Chatham College chapel auditorium. Mrs. Dick reported being required to assist in induced abortions at Magee despite written and verbal objections to the operations.

"It was repulsive to watch live fetuses being packed in ice while still moving and trying to breathe, then being rushed to some laboratory; and hear a medical student later discuss the experience of examining various organs of a once-live baby."

Mrs. Dick, now a resident of California where she works as a nurse anesthetist, described herself as an Independent Baptist. She worked at Magee from 1967-71.

She was among invited speakers addressing the 23-member all-woman commission appointed by Governor Shapp to study the possible liberalization of Pennsylvania's present abortion law.

She related that a request by her to be excused from helping in induced abortions "was denied. This denial was further enhanced with threats of being fired, harassment, intimidation, restrictions in assigned duties and alterations of previously practiced personnel policies. The conditions of continued employment made it impossible for me to properly care for my children; therefore, forcing me to seek employment elsewhere."



Abortion Law Commission, Governor Shapp's 23-member, all-woman panel, hears testimony Tuesday from former Magee nurse-anesthetist Mrs. Wilhamine Dick, lower right.

ISOLATION OF ATTENUATED RUBELLA-VACCINE VIRUS FROM HUMAN PRODUCTS OF CONCEPTION AND UTERINE CERVIX

ANTTI VAHERI, M.D., TIMO VESIKARI, M.D., NILS ÖKER-BLOM, M.D., MARKKU SEPPÄLÄ, M.D., PAUL D. PARKMAN, M.D., JORGE VERONELLI, PH.D., M.D., AND FREDERICK C. ROBBINS, M.D.

Abstract To evaluate the fetal hazard of accidental administration of live rubella vaccine during pregnancy, the vaccine was given to 35 women certified for legal abortion. Twenty-four of these were rubella seronegative.

Various specimens, including the products of conception, were tested for rubella virus independently in three collaborating laboratories. Rubella virus was recovered from the placenta in six cases and from the fetus in one case. Virus was also found in 13 of 22 uterine cervical swabs taken nine to 25 days after vaccination of seronegative mothers. Virus was not isolated from comparable specimens obtained from women with pre-existing antibody. The results indicate a hazard of placental and fetal invasion by the vaccine virus and emphasize the need to observe precautions when post-puberal female patients are vaccinated.

SINCE their introduction in 1969, live, attenuated rubella-virus vaccines have been extensively used, both for mass vaccination of children and for the selective vaccination of post-puberal women. There has been concern that infection of pregnant women with rubella-vaccine virus might result from exposure to a vaccinated contact. Thus far, however, only two presumable cases of transmission from a vaccinated person to a susceptible contact have been reported.[1,2] Several studies specifically designed to test the contagiousness of rubella-vaccine virus for susceptible pregnant women exposed to vaccinated children participating in field trials gave no evidence of contact infection.[3-5]

The practice of vaccination of post-puberal women, however, may lead to inadvertent vaccination during pregnancy. Indeed, a number of such occurrences have been reported,[6-9] stressing the need for greater knowledge of the possibility of transplacental transmission of vaccine virus.

The collaborative project described below was designed to study the transplacental passage of live, attenuated rubella-vaccine virus (HPV-77 strain, derivatives DK-12 and DE-5) by examination of the products of conception obtained after certified legal abortion in women who had volunteered for vaccination. A preliminary report on the first 10 cases studied has been published,[10] and data from these cases are included in the present paper.

MATERIALS AND METHODS

Study Population and Clinical Observations

The study population was recruited from women applying for abortion at the Department of Obstetrics and Gynecology, University of Helsinki, or at the State Institute of Midwifery, Helsinki, Finland. The criteria for inclusion into the study were as follows: that they be certified for legal abortion by the National Board of Health; that they volunteer for the study after a full explanation of what was involved; that there be no contraindication to vaccination; that the gestational period be less than 14 weeks; that adequate specimens be secured; and that the serum hemagglutinin-inhibition (HI) antibody titer be low, preferably less than 1:10.

The final study population consisted of 35 women between the ages of 15 and 43 years, of whom 24 were seronegative and 11 had antibody titers ranging from 1:10 to 1:80. As in other studies,[4] the susceptible group was found to be younger (average age of 28.3 years) than the immune group (average age of 34.1 years), although no selection for age was applied.

The gestational age at the time of vaccination (counted from the first day of the last menstrual period) ranged between 49 and 107 days. The interval between vaccination and abortion (VA interval) was between 11 and 30 days.

All patients were interviewed six weeks after vaccination concerning any reaction to the vaccine. Leukocyte and platelet counts were done on all patients at the time of operation.

Vaccines Employed

Twenty-nine women received 1 ml of HPV-77 DK-12 vaccine prepared in dog-kidney cell cultures (Philips Roxane, Incorporated, St. Joseph, Missouri), and six received HPV-77 DE-5 vaccine grown in duck-embryo cell cultures (Merck Sharp and Dohme, West Point, Pennsylvania).

Collection Handling and Testing of Specimens

Serum specimens were obtained from each subject before vaccination, two to three weeks later and again six to nine weeks after vaccination.

Throat and nasopharyngeal swabs for virus isolation were collected from eight days after vaccination up to 36 days after vaccination. An average of four samples were obtained from each patient. Cotton-tipped applicators were used to obtain the throat swabs, and calcium alginate swabs (Calgiswabs) for the collection of nasopharyngeal secretions. Swabs were rinsed in 6 ml of Eagle's basal medium con-

From the departments of Virology and Obstetrics and Gynecology, University of Helsinki, Helsinki, Finland, the Division of Biologics Standards, National Institutes of Health, U. S. Public Health Service, Bethesda, Md., and the Department of Pediatrics, Case Western Reserve University School of Medicine and Cleveland Metropolitan General Hospital (address reprint requests to Dr. Robbins at Case Western Reserve University School of Medicine, 2119 Abington Road, Cleveland, O. 44106).

Supported by research grant from the United Cerebral Palsy Research and Educational Foundation, Inc., New York City.

taining 0.2 per cent bovine serum albumin, 100 μg per milliliter of gentamycin sulfate and 50 international units per milliliter of nystatin.

A single blood sample was drawn at the time of surgery, and either the whole heparinized blood or the buffy coat was employed for virus studies.

Immediately before surgery the uterine cervix was swabbed with a cotton-tipped applicator, which was then handled as described for the throat and nasopharyngeal swabs.

Pregnancy was terminated in 30 cases by hysterotomy and in five cases by curettage. Specimens from 15 prophylactic appendectomies performed at the time of hysterotomy were also made available for virologic studies. After repeated washings with balanced salt solution these surgical specimens were homogenized in a Ten Broeck tissue grinder. The resulting suspension (20 per cent v/v) was clarified by low-speed centrifugation.

Tissue suspensions were similarly prepared from placental and fetal specimens and from segments of extra-embryonic membranes. Most of the samples, obtained by hysterotomy, were delivered to the laboratory still surrounded by intact membranes. Repeated washings with balanced salt solution were performed before and after dissection.

In one of the testing laboratories (Helsinki) many of the specimens for virologic studies were immediately inoculated into RK-13 cells cultures.[11] When this was not possible, specimens were stored at −70°C before testing. Two additional aliquots of the same samples were frozen and shipped in dry ice to the laboratories in Cleveland, Ohio, and Bethesda, Maryland, where they were tested in primary grivet-monkey-kidney cultures by the ECHO-11 interference technic.[12]

In addition, primary cell cultures were established from the fetal specimens and were maintained through two subcultures. Supernatant fluids from these cultures were collected and tested, as were the rest of the samples for virologic studies. Occasionally, because of delays in transit samples were thawed when received in the United States laboratories.

Virus isolates were identified by neutralization with rubella-hyperimmune rabbit antiserum.

Serologic tests consisted of the rubella hemagglutination inhibition assay carried out in Helsinki according to the modification of Halonen et al.[13] and in Cleveland and Bethesda by methods previously described.[4,14]

Results*

Clinical Reactions to Vaccination

The only complication of vaccination noted involved the joints. Two of 18 susceptible women who received HPV-77 DK-12 vaccine reported pain or stiffness of joints approximately two weeks after vaccination. Symptoms lasted for about two weeks and in one case were associated with objective swelling of a joint. One of the six subjects who were given HPV-77 DE-5 vaccine complained of mild arthralgia two weeks after vaccination that lasted for only a few days.

Serologic Response to Vaccination

Seroconversion was observed in all the 24 initially susceptible vaccinated women. Among the 11 patients with low prevaccination antibody titers, a booster response, defined as a fourfold or greater rise in HI antibody titer, was observed in five.

Virologic Studies

The results of virus isolations in the three laboratories were, for the most part, in agreement, but some discrepancies were noted. Many isolates became detectable only after passage, suggesting that such samples contained very low concentrations of virus. These presumably low titers, inactivation during transit and the different methods used in Helsinki, as opposed to Cleveland and Bethesda, are all factors that may have contributed to the discrepancies noted.

Respiratory secretions. Virus was isolated from throat or nasopharyngeal swabs (or both) collected from 11 of the 24 seronegative women (46 per cent). The intervals after vaccination when these isolations were recorded are shown in Figure 1.

A single positive specimen was obtained from each of two of the 11 participants with low initial antibody titers. No other virus isolations were made from any source from the seropositive women.

Cervical secretions. Of the 22 cervical swabs collected from patients without prevaccination immunity, virus was isolated in 13 (59 per cent) over the interval of nine to 25 days after vaccination.

Blood and appendix. Viremia was documented in five of the 24 patients who underwent seroconversion (21 per cent). Appendixes from 10 susceptible women and from five with pre-existing immunity were tested for virus. Two specimens, obtained 13 and 24 days after vaccination from susceptible patients yielded virus.

Placenta, amniotic fluid and extra-embryonic membranes. Placental tissue from each patient was studied, and six virus isolations were made, all from women without prevaccination immunity (isolation rate, 25 per cent). The time after vaccination that these positive specimens were obtained is shown in Figure 1.

No virus was recovered from any of a number of other extra-embryonic samples tested from susceptible subjects even when the placenta was positive. These specimens were 16 amniotic fluids, 14 decidua, four amniotic membranes, two umbilical cords and five pooled membranes.

Fetal specimens. A single virus isolation was made from fetal tissue. This was obtained from the kidney homogenate of a fetus obtained from a 22-year-old woman vaccinated on the 55th day of gestation and aborted 24 days later. Virus was recovered in two laboratories and not in the third.

*For more detailed information order NAPS Document 01786 from National Auxiliary Publications Service, c/o CCM Information Corporation, 866 3d Ave., New York, N.Y. 10022; remitting $2 for each microfiche copy reproduction or $5 for each photocopy. Checks or money orders should be made payable to CCM Information Corporation–National Auxiliary Publications Service.

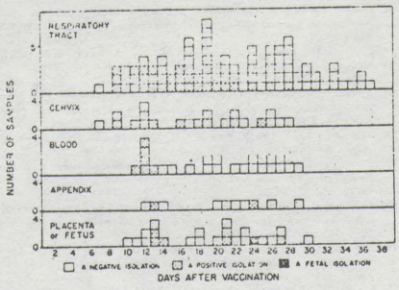


Figure 1. Virus Isolations after Vaccination of Seronegative Mothers.

Specimens of eye, brain, lung, liver, intestine, skin-muscle and a mixed homogenate of tissues from the same fetus were negative as was a primary culture of fetal skin-muscle. Virus was isolated from the mother's appendix and respiratory tract but not from the mother's blood, cervix or placenta.

Discussion

Although the primary purpose of this study was to determine whether or not rubella-vaccine viruses administered to the mother in routine fashion are capable of causing infection of the human fetus, there are a number of other aspects deserving comment.

It was of interest to determine if pregnant women respond to vaccination in the same manner as non-gravid subjects. In the group of rubella-susceptible pregnant women joint symptoms occurred in approximately 12 per cent, being mild in all. This figure is to be compared with results of various studies concerning the frequency of arthritis and arthralgia in young women who are not pregnant, with proportions as high as 56 per cent after administration of HPV-77 DK-12 vaccine[15] and 14 to 44 per cent in those receiving HPV-77 DE-5.[16-18] Our findings are from a small sample and must be interpreted cautiously but do suggest that pregnant women are less likely to experience post-vaccine arthritis and arthralgia than nonpregnant women, and when such cases do occur, they are less severe.

The serologic response, the pattern of vaccine-virus excretion and the frequency of viremia are not appreciably different in the pregnant subjects from those observed among nonpregnant vaccinated women, suggesting that pregnancy has no marked effect on the extent of viral multiplication within the host.

An unusual observation is the finding of virus in the appendix. In one case virus was recovered 24 days after vaccination at a time when circulating antibody was present and no virus could be isolated from the blood, providing evidence that the vaccine virus persists in the tissues for a substantial period.

The recovery of vaccine virus from 39 per cent of the cervical swabs obtained from the susceptible group was unexpected. Virus shedding seems to occur at this site during the same interval after vaccination as it does in the respiratory tract. Although the virus content of the cervical samples was not quantitated, the frequent positivity of first-passage isolations and the reproducibility of cervical virus isolations in the three testing laboratories suggest that virus is present in considerable quantity. Similar observations have been reported by Seppälä et al.[19] in natural rubella infections. The pathogenetic importance of rubella-virus excretion in the female genital tract is not known at present but would be compatible with the hypothesis that intrauterine infection can occur in a retrograde manner.

The finding of vaccine virus in 25 per cent of the placental samples from women undergoing seroconversion is similar to what occurs when natural rubella complicates pregnancy.[20] The absence of detectable virus in extra-embryonic tissues and fluids other than the placenta indicates that this organ is preferentially infected.

In any attempt to assess the importance of the single virus isolation from fetal tissue it is first necessary to establish that the observation is not a laboratory error. The fact that the same results were achieved in two of the three testing laboratories, and that virus was recovered from the kidney and not from other organs of the same fetus, argues strongly against laboratory contamination or other errors such as improper labeling.

The failure to recover virus more frequently from the fetus cannot be taken to mean that the vaccine strains are less likely than unmodified ones to cause such infection. Alford et al.[20] found that fetal involvement is infrequent when natural rubella infection occurs after the eighth week of gestation. Unfortunately, none of the women in the study reported here received vaccine until the eighth week, and only five of the 24 susceptible subjects before the ninth week. Furthermore, the intervals between vaccination and abortion were of necessity relatively short.

Similar difficulties may explain the failure of Furukawa et al.[21] to demonstrate intrauterine infection in 10 women vaccinated with Cendehill and RA 27/3 strains.

Our data do not provide any evidence concerning the persistence of fetal or placental infection due to vaccine viruses. Virus has been recovered by Larson et al.[9] from the placenta 69 days after inadvertent vaccination, indicating that intrauterine infection with vaccine virus probably behaves similarly to natural infection. However, no data are available concerning the teratogenic properties of any of the vaccine viruses.

The failure to isolate virus (except to a minor degree from the respiratory tract) from any of the 11 vaccinated women who had low prevaccination antibody titers suggests that even low levels of immunity can afford protection.

In conclusion, the evidence presented here supports the present recommendations of the United States Public Health Service that vaccination of post-puberal women should be undertaken with ex-

treme caution.[22] These are as follows: limit vaccination to women in whom susceptibility has been proved by a previous antibody determination; exclude pregnancy to the extent possible; and assure that the recipient is capable of following a reliable contraceptive program for at least two months following vaccination.

Since diagnostic laboratory assistance, in cases of inadvertent vaccination during pregnancy, is usually hampered by the unavailability of prevaccination serum samples, it seems advisable to obtain and store such samples before vaccination of any postpuberal female patient.

The practice of rubella vaccination in the immediate post-partum period[23] offers the possibility of extending the benefits of protective immunization to a sizable proportion of susceptible women of childbearing age. Recent reports, however, stress the desirability of enforcing a reliable contraceptive program when vaccine is administered during the early puerperium.[24,25]

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OFFICIALS WINK AT LAWS

Infants Aborted Alive

By JAMES LONG
Journal Staff Writer

On Nov. 3, 1970, an expectant mother at City of Roses Hospital was injected with a salt solution to induce a legal abortion.

Instead of producing a dead fetus, the mother expelled a gasping, 28-ounce premature infant.

The infant was removed to the University of Oregon Medical Center where it survived 5½ hours. (The file number at the Medical Center is 44-6313.)

Mrs. Jerry Ghiglieri of the Oregon Right-To-Life (RTL) organization says her group has documented no fewer than 33 incidents of infants being aborted alive in the state.

"MOST OF THEM died within a few minutes," she said. "Usually, the medical staff just leaves them alone. The babies may try to breathe. They go into convulsions."

Although Right-To-Life claims there is no distinction between killing premature infants inside or outside the womb, it points to some of the live births as evidence that Oregon's abortion laws are being winked at by district attorneys and some doctors.

The law, RTL points out, forbids the abortion of infants beyond the 150th day of gestation — about 21 weeks — except when a physician believes in good faith that the life of the (mother) is in imminent danger," to quote ORS 435.445.

YET, NOTES RTL, the State Board of Health's own statistics indicate that 18 infants of 23 weeks' or more gestation were aborted during the first six months of 1971.

The same document, obtained by The Journal, listed only one of 3,459 abortions during that time span as an "emergency."

Richard Barton, chief criminal deputy district attorney for Multnomah County, confirmed to The Journal that his office was asked to investigate the Medical Center "preemie" case. "We dropped it because we were satisfied the obstetrician had been misled about the duration of the pregnancy," said Barton.

According to Barton, the district attorney's office was convinced that the obstetrician — a top man in his field — was unable to determine that the mother was less than three months from full-term delivery.

TWO PORTLAND obstetricians, Associate Prof. John de Maria of the University of Oregon Medical School and Dr. Paul E. Zuelke, agreed that a well-trained doctor might reasonably be expected to err by two weeks — either way — in judging a baby's prenatal age.

Another obstetrician, Asst. Prof. Burritt W. Newton of UOMS, placed the margin of error at three weeks. Even after the fetus is aborted, he said, a good pathologist can't judge the age "any closer than about two weeks."

Dr. Zuelke commented, "I would think most doctors would want to err on the side of conservatism if there is doubt. It is hard to understand why there is ever any excuse (for aborting an infant older than 150 days) except once in a great while."

DR. NEWTON said the two- to three-week margin for error causes him to doubt the value of Board of Health statistics showing 18 abortions over the age limit in January-June, 1971.

Marian Marin, state registrar of vital statistics, said no information is available to indicate the specific estimated ages of the 18 fetuses in question.

The figures supplied by her office showed that approximately 5 per cent of the total abortions involved fetuses of age 126 days or older, thus coming within possible range of error for the 150-day limit.

Dr. William Brady, Oregon state medical investigator, told The Journal that "the question of an over-age aborted infant has never been referred to our office."

"THERE ARE a lot of babies aborted over 150 days, but the cases are never brought up because people would have to answer a lot of awkward questions," added Brady, a forensic pathologist.

Dr. Russell Secco, a Portland urologist and anti-abortion leader, shrugged: "Nobody has to pay attention to the law. What we've got in Oregon is abortion-on-demand. You don't need a reason in this state. All you need is $250."

Mrs. Eleanor Fixen, a nurse-anesthetist at Good Samaritan Hospital, told The Journal that many nurses who attend abortions "don't like it" but are afraid of losing their

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jobs if they refuse — despite a clause in the abortion law to protect their freedom of choice.

"I WAS IN FAVOR of abortions at first," Mrs. Fixen said. "But after I saw a fetus come out in pieces, I thought to myself, 'Good gosh, that was a human life.' I refused to do it anymore. Nobody said anything to me."

Two Emanuel Hospital nurses, who would not allow their names to be used, agreed that there is subtle pressure to take part in abortions despite moral objections "because it's just part of the OB (obstetrics) department now."

One nurse said: "If you want to work, you don't have any choice except changing jobs."

(A spokesman for Emanuel Hospital said 27 per cent of "deliveries" in the hospital's OB department were abortions, at last count. The figure given at Good Samaritan was 31 per cent.)

ANOTHER OB NURSE, who participates reluctantly in abortions, commented: "They say you get hardened to it. But you don't. And I don't think I ever will."

"This isn't a religious thing," emphasized Mrs. Fixen. "I'm not a Catholic. I'm a Lutheran — and not even a good Lutheran. I just think it's murder."

Mrs. Ghiglieri said she is especially concerned about the plight of reluctant OB nurses "because they are the ones who are usually involved most directly in abortions. The doctor is seldom around to see the results."

According to Board of Health statistics, 2,050 of the 3,459 abortions in the first six months of 1971 were by the "suction" method. Another 577 were by saline injection, 657 by "D&C" — surgical dismemberment — with 126 removed by hysterectomy, 16 by hysterotomy, and three by "other" methods.

(THE REASONS given were: 127 for physical health, 33 for infant defect, 15 for felonious intercourse, and 3,383 for mental health.)

Mrs. Ghiglieri pointed out that a hysterotomy, equivalent to a "caesarian section," usually produces a live fetus.

Legally aborted fetuses, which may range up to seven months' gestation according to cases documented by Right-To-Life, are usually turned over to the hospital's pathology department for examination and disposal.

Dr. Homer Harris, head of pathology at Emanuel Hospital, said all of Emanuel's fetuses are sent to the anatomy department of the University of Oregon Medical School.

DR. ROBERT BACON, acting chairman of the department, said he knows of no case in which the school has received a live fetus for experiments similar to recent ones at Cambridge University in England.

At Cambridge, well-formed fetuses from legal abortions were kept alive for several hours in studies employing an artificial uterus.

"I don't know what my position would be on this type of research," said Dr. Bacon. "Personally I think the information from it would be important. It's an area in which we are absolutely blank. But I am happy that I have not been presented with the problem to deal with."

Dr. Bacon said the medical school's donated fetuses are used for microscopic tissue studies, particularly the development of the human nervous system.

DR. SACCO told The Journal that he isn't particularly disturbed by the reports of experiments on live fetuses. "It isn't much more grotesque than killing them," he said.

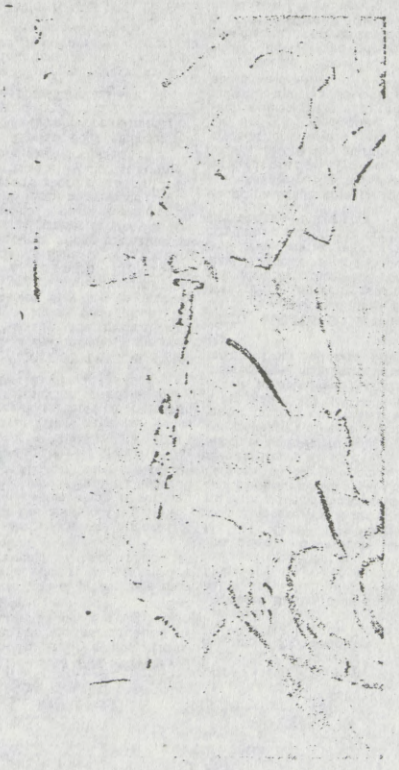
Sacco added: "If the abortion is well done, we don't have to watch the baby die. So we inject a salt solution. The result is like putting salt on a slug, but we don't have to watch it."

A medical school spokesman said patients are given a choice of having the aborted fetus buried if it is more than 20 weeks old.

An official of a large Portland funeral home told The Journal, "We don't get many requests for this. Maybe [illegible] a year."

U.S. Doctors in Europe

Operations on Live Fetuses



N. Y. Times photo

Research on live, aborted fetuses received a setback last week with a ruling by the National Institute of Health

DR. Jerald Gaull in periodic trips to Finland injects a radioactive chemical into the fragile umbilical cords of fetuses freshly removed from their mothers' wombs in abortions.

The fetus in each case is far too young to survive, but in the brief period that its heart is still beating, Gaull — chief of pediatrics research at the New York State Institute for Basic Research in Mental Retardation on Staten Island — then operates to remove its brain, lung, liver and kidneys for study. First, he emphasizes, he severs the nervous connections that link the brain to the body "to make sure the fetus will feel no pain."

Dr. Robert Schwartz, chief of pediatrics at Cleveland Metropolitan General Hospital, goes to Finland for a similar purpose. After a fetus is delivered, while it is still linked to its mother by the umbilical cord, he takes a blood sample. Then, after the cord is severed, he, "as quickly as possible," operates on this aborted being to remove other tissues and organs.

The fetuses in all these cases are yet so small and undeveloped that their lungs are not fully formed. They cannot breathe, and their brains undoubtedly die within a matter of minutes, though their hearts beat much longer.

But if Schwartz continues to perform his procedures in advance of brain death, while the fetus by all definitions is still alive, he will be violating a new rule just pronounced by the scientifically powerful National Institutes of Health.

Last Thursday the NIH stated: "We know of no circumstances at present or in the foreseeable future which would justify NIH support of research on live aborted human fetuses." Schwartz is an NIH grantee who will have to abide by this rule if he is to get future support.

"What needs to be said," said Gaull, "is that we need to get information that will help the unborn who are going to be born, not aborted. Rather than it being immoral to do what we are trying to do, it is immoral — it is a terrible perversion of ethics — to throw these fetuses in the incinerator as is usually done, rather than to get some useful information."

This position was quickly rejected last week as at least a part of the public and top NIH leadership reacted to the first public report that NIH for more than two years has been considering the matter of guidelines for scientists who do indeed study live, aborted fetuses.

No vast number of American scientists are interested in these operations. Some, however, have been going abroad for various studies or at least removal of fetal samples.

There is "a relatively minimal amount," in the United States, according to Dr. Kurt Hirschhorn of New York's Mount Sinai Medical School. There is emotional objection to even removing fetal samples by many American doctors as well as much of the public. And the main U.S. methods today of abortion — suction removal early in pregnancy and, later, injection of saline solution ("salting out") — produce only fragmented or dead fetuses.

Americans are doing research on fetuses in Denmark, Sweden, Japan, and Britain, scientists report. And some at least are either doing so with federal funds or bringing tissues back for study in federally funded programs.

This seems obvious despite an NIH memorandum: "We . . . find no documentation in current NIH research grants or contracts reflecting the use of live fetuses as a research tool," the memo said.

Dr. David Gitlin of the University of Pittsburgh-Children's Hospital is an NIH grantee. "We used to do research on the intact fetus," he said. "Now we take tissues — the brain has stopped functioning but the tissues are still alive. I very frequently go to friends in Scandinavia. Without them I couldn't work."

Other scientists do not believe some tissues are really "alive" enough if the brain has stopped working. This is one reason some scientists have preferred to work while the fetus is still attached to the mother.

NIH, said Dr. Robert Berliner, deputy director of science, last Thursday, "does not contemplate approving the support of such research."

What is more, said Berliner, a respected scientist in his own right, "there is no scientific justification" for work on living human fetuses because "you can do the same studies with animals."

Developmental specialists disagree. As much as possible can and should be studied in animals, they concede, but, as Gaull put it, "our understanding of human development must be based on understanding of human tissues rather than monkey or rat or rabbit."

Washington Post Service

Aborted Fetuses Used In Dental Experiments

By FRANK MORRISS

(Special to The Wanderer)

DENVER — Colorado dentists are fortunate to live in a State where there is an abundance of "material" for research, the Denver Metropolitan Dental Society was told recently. The "material" referred to by Dr. Charles Tobin are aborted fetuses.

Dr. Tobin, who is on the staff of the Colorado University Medical Center and that center's proposed dental school, has done research on some 300 aborted fetuses. His experimentation is continuing on the mandible (lower jaw) of fetuses in efforts to determine the reasons for the sequence of eruption of teeth, solutions to blood-clotting problems connected with dental surgery, etc. The early eruption process of teeth, it seems, begins, unseen in the jaw as early as six weeks after fertilization and extends to the fourteenth and

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fifteenth week. Fetuses provide the chance to study this process at its very start.

Dr. Tobin's headquarters are in the Veteran's Administration Hospital in Denver. He told this reporter that he had "several sources" for obtaining the fetuses, but apparently his main source is Denver's General Rose, a private hospital that in 1971 led the State with 993 abortions.

Dr. M. Ovitz, pathologist at General Rose, confirmed the supplying of fetuses for the research, and said they would be available to anyone doing responsible research. According to the pathologist, the fetuses are supplied under the general release of "tissue" which a patient permission form makes. "In this case the tissue would be the fetus," Dr. Ovitz said. They are supplied at no charge and all have been dead "several hours," according to the pathologist. That fact would make blood-clotting experimentation questionable in result, he believes. He knew of no special permission that would inform mothers the fetuses would be the subjects of experimentation.

A check with the Colorado and Denver departments of health revealed no regulation covering such experimentation with fetuses. Spokesmen for both departments agreed that it is a matter between the researcher and the hospitals themselves.

Dr. Tobin assured this reporter that he had done similar research in New York, that he knew the legal requirements and abided by them. "The fetuses are cremated when I am finished," he said.

Colorado was the first State to let down the legal barriers against abortion, when it liberalized its abortion statute in 1967. In that year, between April and December, there were 140 abortions reported to the Colorado Department of Health. In 1968 there were 497; 1969, 946; 1970, 2,091; 1971, 3,759. The vast majority of these were done under the new laws provision for abortion to protect the mother's "mental health." In December, 1971, for example out of 418 abortions reported, 404 were under the maternal mental-health provision.

More abortions in Colorado are done on children nine to twelve weeks old than any other gestation period. However, twenty-four were done last year on children twenty-five weeks and over, and 132 on children twenty-one to twenty-four weeks old.

The Wanderer, 3-2-72

A Thymus for Maggie

Medical and ethical debate over liberalized abortion laws has centered on the woman and the unborn child. A by-product of legal abortions, however, can affect the vital interests of a third party: a desperately ill youngster who can be helped by a transplant from an aborted fetus. Such operations are still rare. But Dr. Arthur Ammann of the University of California's San Francisco Medical Center has performed two gland transplants that may encourage increasing use of fetal tissue.

Magdalena Vozaites, 5, is the daughter of a Greek immigrant family living in Daly City, Calif. The victim of a birth defect that prevented her from resisting infection, Maggie has had illness as her constant companion since infancy. During one 18-month period, she was hospitalized nine times with serious infections, including pneumonia. It was questionable whether she would survive childhood.

Vital Gland. Last summer, Maggie was referred to Ammann, a specialist in pediatric immunology. When she failed to respond to injections of a white blood cell extract as a means of arousing immunity, Ammann realized that the problem was in her thymus gland—a butterfly-shaped bit of tissue that lies just behind the breastbone. The gland has a key role in the development of the body's immune responses. In one previous case, Ammann knew, implantation of a thymus from a miscarried fetus stimulated this process in a child born without the gland.

Hopeful that a similar operation could help Maggie, Ammann took advantage of California's liberalized abortion law to search for an appropriate fetal thymus. The task proved difficult. For best results, Ammann needed a transplant from a healthy fetus 14 to 20 weeks old. These are rare because most California abortions are performed before the twelfth week of pregnancy. But in December, Ammann found a woman who was having a late abortion on psychiatric grounds and got permission to use the fetus' thymus.

Moral Question. Flown to San Francisco in an insulated container, the thymus was implanted during a three-hour procedure. That proved relatively easy. Many other transplants must be hooked up to the circulatory system in order to function properly; the thymus, requiring no connection, is merely placed in the abdominal cavity. Maggie's liver and spleen, which had become enlarged during her illnesses, have decreased in size. She is now at home, and her immunological system appears to be working normally.

Last month, Ammann tried the operation again on Matthew Octavio of Petaluma, four weeks old, who suffered from an immune defect that had killed six of his cousins. He was sent home, then returned to hospital with a possible respiratory infection, which the transplant might help him to overcome.

Despite its success, the operation is likely to come under fire from opponents of abortion who question the morality of using tissue from aborted fetuses. But Ammann sees no ethical problems in his operation. "We don't go around soliciting abortions," he says. "These are abortions that are already being done for other reasons." Dr. Samuel Kountz, a kidney specialist at the U.C. Medical Center, would like to try an even bolder operation—the transplant of a fetal kidney.

Time, 2-28-72, p. 54

Post-abortion fetal study stirs storm

The Supreme Court's landmark abortion decision may have eased one legal and ethical dilemma for American medicine while creating another. The issue is fetal research, and it is a subject every bit as emotionally charged as the abortion controversy itself.

To Right to Life and other anti-abortion groups, the use of the aborted fetus for biomedical research only adds insult to injury—following one crime against life with another. To Rep. Angelo D. Roncallo (R-N.Y.), the matter is serious enough to require legislative prohibition.

The congressman's bill, introduced in April, would make it a federal crime to carry out any research activity on a human fetus or to intentionally take any action to kill or hasten the death of a human fetus in any federally supported facility or activity. The penalty would be ten to 20 years in prison.

But last month, while the National Institutes of Health pondered a rational policy on fetal research—and held in abeyance any requests for support of such research—conferees at the combined meeting in San Francisco of the American Pediatric Society and the Society for Pediatric Research heard at least four reports on work involving human fetal tissue.

No one even raised an eyebrow when Dr. Peter A. J. Adam, associate professor of pediatrics at Case Western Reserve University in Cleveland, reported on a study of "cerebral oxidation of glucose and D-beta hydroxy butyrate (BOHB) in the isolated perfused human fetal head." Dr. Adam's work was done in collaboration with Drs. Niels Raiha, Eeva-Liisa Rahiala, and Martti Kekomaki at the University of Helsinki last summer—and was supported in part by NIH funds.

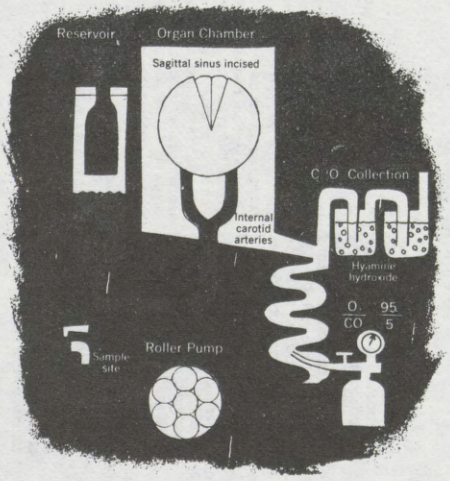
In a study to examine mechanisms by which the fetus is protected in both normal and abnormal pregnancy, the Finnish-American team decided to tackle the question of whether glucose and BOHB can serve equally well as energy sources early in human development. They can, Dr. Adam concluded in his report, adding that the findings also indicate there is no effective physiologic competition between the two fuels and that oxidated brain metabolism apparently accounts for about a third of the total fetal metabolism.

To produce those data, the investigators severed the heads of 12 previable fetuses obtained by abdominal hysterotomy at 12 to 20 weeks' gestation. The heads were then perfused through the internal carotid arteries with recirculating Krebs-Ringer bicarbonate medium containing labeled substrates, and were equilibrated continuously with a gaseous oxygen-carbon dioxide mixture. Venous return was obtained from the incised sagittal sinus, and carbon 14-labeled CO_2, evolved from the labeled substrates, was collected in hyamine hydroxide solution.

According to Dr. Adam, no member of the research team participated in decisions regarding the method of abortion; these were made solely by the attending gynecologist. While hysterotomy used to be a common abortive method in Finland, he says, the more recent use of prostaglandin has reduced the supply of suitable fetuses and has caused the researchers to abandon this line of investigation. Neither ethical nor legal considerations entered into that decision, adds Dr. Adam.

In the view of the Cleveland physician, a policy that would permit abortion but prohibit fetal research would be unethical as well as irrational. "There's still a dearth of information on fetal mortality," he says, "and once society has declared the fetus dead and abrogated its rights, I don't see an ethical problem. . . . In fact, a much greater problem lies in experimentation with infants and children." (See cover story, page 37.)

He considers resistance to fetal research a kind of "ritualistic absolution" but believes much of it can be dispelled if such research is carried out in full public view. "People need to understand that the fetus doesn't have the neurologic development for consciousness or pain and that it also doesn't have the pulmonary system to survive." Legal considerations and the principles of informed consent are irrelevant, declares Dr. Adam. "Whose right are we going to protect when we've already decided the fetus won't live?" ■



With this system of perfusion, the Helsinki team was able to study the metabolism of the human fetal brain.

THE USE OF FETUSES AND FETAL MATERIAL FOR RESEARCH

We appreciate the opportunity of commenting on the Report of the Advisory Group on "The Use of Fetuses and Fetal Material for Research".

We accept the Report as a reasonable document with the exception of paragraphs 32-35 concerning "Research on the Pre-viable Fetus". We have comments to make on paragraphs 6 and 16.

The definition of Fetal Material in paragraph 6 on page 2 of the Report is confusing, in that no distinction is made between extra-embryonic material of fetal origin associated with a living fetus in situ (i.e. placenta, fluids and membranes - the use of which for research involves the death of the fetus, and which therefore presents exactly the same ethical problems as for the use of fetal tissues, as defined, and living placental tissue of fetal origin expelled naturally after the birth of a living infant. The use of living afterbirth material for any purpose is, of course, entirely legitimate, and we would hope that research into the possibility of replacing fetal tissues by afterbirth material for routine virology(see paragraph 9 of the Report) will be actively pursued. We would not regard the use of fetal material obtained by amniocentesis for research as legitimate, excepting insofar as it is directly related to the medical welfare of the child or the mother concerned, since amniocentesis is not wholly without risk to the child and its mother.

The definition of Fetal Death in paragraph 6 of the Report is badly worded, in that it implies that a fetus which "is incapable of being made to function as a self-sustaining whole" is by definition in a state of "Fetal Death". But no pre-viable fetus is capable of functioning as a "self-sustaining"whole, since it has to be sustained by its mother. The precise definition of death is difficult, but defining the death of a fetus would seem to involve no special difficulties, and to require no special terminology, beyond that for defining death in other human beings.

Paragraph 16 of the Report, in speaking of research involving the whole pre-viable fetus being carried out after delivery in "certain countries" may be read to imply that such work has not as yet been carried out in Great Britain. This would in fact be incorrect, since Dr. Lawrence Lawn M.D., of the Cambridge University Department of Investigative Medicine, has for a number of years been experimenting with artificial placentas, using living aborted human fetuses of up to 18 - 20 weeks gestation. Evidence to this effect has already been submitted to the Lane Committee, and also to the Peel Committee, and its truth is not in question, since Dr. Lawn has himself admitted as much in press interviews.

In connection with paragraph 32 of the Report, it should be made clear that fetal lungs are normally solid at birth, and only by movement of the baby's own muscles, or by active resuscitation by the attendant, can inflation of the lungs be achieved. It follows therefore that the only acceptable evidence from the state of the lungs of non-viability is that all artificial attempts at inflating them have been tried and have failed, and not simply that the lungs appeared solid on delivery.

In paragraph 33 we would point out that, with the rare exception of abortion because of risk of fetal abnormalities, the only lawful reasons for procuring an abortion are that continuance of the pregnancy would involve risk to the mother's life or health or that of any existing children. It is a result of aborting a pre-viable fetus that the child is killed, but that is not the purpose of the operation, and it is always the duty of a medical practitioner terminating a pregnancy under the Act to do all that is possible to save the child.

In paragraph 34 the argument that work on the "whole pre-viable fetus" offers an opportunity for making observations that "cannot be

obtained in any other way" is an absurdity. Exactly the same can be said for sacrificing experimentation on the adult human.

The most serious criticism relates to paragraph 35 which states "that only fetuses weighing less than 300 grammes should be used". A fundamental principle of dealing with the immature newborn who is not breathing is to avoid exposure to the chilling and hypoxia, associated with weighing, by placing in an incubator or on a heated platform and giving positive pressure oxygenation. To deny the child this in order that weighing may be performed to assess eligibility for the experimenter's chamber is ethically quite unacceptable.

To say, as under paragraph 35 (2), that responsibility for deciding whether or not the fetus is appropriate for use in this type of research must lie with the medical attendant and not the research worker is no safeguard; he may be one and the same person.

Sections (3) and (4) of paragraph 35 on the role of ethical committees would seem to pre-empt their proper role - to decide whether research on a live, pre-viable fetus <u>is</u> ethical.

The problems which arise in the wording of this section of the <u>Report</u> indicate that the Group were trying to provide for something which was likely to be unacceptable to the national ethical sensibility.

Mrs. POLICASTRO. The U.S. Coalition for Life is a national-international research agency and clearinghouse with a broad range of interests, including abortion, euthanasia, infanticide, population control, and genetic engineering.

We are honored to have an outstanding international advisory board. Included is the world-renowned fetologist Sir William Liley of New Zealand, the "Father of Fetology," who practices as a fetal pediatrician.

Also included are specialists in the fields of maternal health care, medical ethics, and so forth, fields which are directly related to the topic at hand, experimentation on human subjects, more specifically experimentation on the human fetus.

Implicit in all Coalition activities is our concern for human life, a concern which extends not only to the unborn child, but to all members of society, particularly the poor, the young, the mentally retarded, those individuals whose life and liberty are made even more vulnerable to attack by those who have become forgetful of basic moral and ethical beliefs.

We support the formation of a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. I emphasize the words "protection of human subjects" lest members of such a Committee see as its primary orientation the mere identification of regulatory procedures or clinical guidelines geared toward the protection of researchers and institutions engaged in experimental research rather than the protection of the human subjects.

With regard to the specific ethical, medical, social, and legal implications of using fetuses or fetal material in research, we would hope that the Commission will take every step to insure that research on live human fetuses, inside the womb or outside will be prohibited except when the experimental procedure is to safeguard the life of the child.

Senator KENNEDY. Your position is if it benefits the child, or the doctor believes it will benefit the child, it is all right?

Mrs. POLICASTRO. Yes.

Referring to Dr. Behrman's statement, where there is an experimental procedure that can be used on a child, we have certainly no argument with that, even though obviously it is experimental and there may be no benefit to that particular child. That child may die anyhow.

If it is for the use of that child and, hopefully, to help others that have the same situation, such as hyaline membrane disease, that would certainly be acceptable.

Senator KENNEDY. So, it is not only the benefit to the particular child. You are not opposed if it has some risk to the child, under certain conditions?

Mrs. POLICASTRO. No.

I am sure that most experimental procedures, particularly at the beginning, do involve a great deal of risk.

But I think in the children we are discussing there is a great risk anyhow, such as hyaline membrane disease, and as Dr. Behrman has stated, they would be using children who had chances of 100 percent death.

If anything can be done to save them, fine, even though it may be of an experimental nature. They are trying to do something. This is much to their credit.

Senator KENNEDY. I conclude from the bulk of the testimony here today that the number of procedures on which there is really strong disagreement is rather small.

Mrs. POLICASTRO. We hope that such a prohibition would be supported by practical guidelines to insure that such abuses could not happen.

In the past, we have been willing to justify the use of a commonsense ethic in which legalistic terms or built-in controls were waived in favor of the individual or collective judgment of a particular researcher or research institution. This singular criteria is no longer acceptable.

Experience in this country and abroad has shown that it is unwise to rely wholly upon the ethical conduct of individuals engaged in abortion practice or the collective judgment of medical boards whose institutions are engaged in mass-produced abortions.

Senator KENNEDY. Are you distinguishing between those that are concerned primarily with abortion or those that are concerned primarily about research?

Mrs. POLICASTRO. In this instance, research, I am using more or less an analogy here showing that in boards that might have been making decisions on abortion, their ethics might leave a little to be desired. This could possibly also apply to research.

Laws need to be clearly stated and firmly enforced if abuses of the live fetus are to be prevented. This would also hold true of various governmental agencies.

We would note that the National Institute of Child Health and Human Development has issued grants for the purpose of developing new techniques of destroying the unborn child rather than insuring his health and development.

In this category we might also include those commercial firms who may view the aborted child as a profitable source of material.

Experimentation on live aborted children is not a science fiction dream but a present day reality. As a matter of record, there are instances where such experimentation has taken place. I wish to cite just a few classic examples of such practices.

In 1972, Denver, Colorado, already had a good supply of research "material."

Dr. Toben, a staff member of the Colorado University Medical Center, used aborted fetuses for dental study. While not having particular argument with his manner of research, it was, however, interesting to note that at no time was there any permission requested from the mothers or any knowledge given to them that their children were later to be used in such manner.

It is my understanding that permission must be attained for the use of a body after death for autopsy report. What right does an outside party have to a body?

Senator KENNEDY. Is your objection, then, that research took place on the dead fetus?

Mrs. POLICASTRO. Yes.

Senator KENNEDY. Or is it your objection that they did not have permission by the parents to do so?

Mrs. POLICASTRO. Well, the research was taking place on the dead fetus, however, but at the same time no permission was ever asked from anyone.

Senator KENNEDY. It is really the permission in this instance?

Mrs. POLICASTRO. Right.

This is the point I am trying to make in this instance.

In Pittsburgh, a young anesthetist at Magee-Women's Hospital at the time Mrs. Wilhamine Dick, in testimony before the Abortion Law Commission 1972, testified:

> It was repulsive to watch live fetuses being packed in ice while still moving and trying to breathe, then being rushed to some laboratory; and hear a medical student later discuss the experience of examining various organs of a once-live baby.

Again, in 1972, we saw a student protest staged at Stanford University against the experimentation by Dr. Goodlin on live fetuses, again without anyone's given consent.

Senator KENNEDY. You mean these fetuses were kept alive for medical student laboratory work?

Mrs. POLICASTRO. I have no evidence to say they were kept alive. However, when they were delivered at birth, they were packed in ice, still alive, and shipped off.

Whether or not they were still kept alive, or how much longer, I have no evidence on that.

Dr. Goodlin was attempting to develop an artificial womb.

Commenting on the experiments, Mark Swendsen, organizer of the demonstration, said:

> While an artificial womb would be an unquestionable useful article, we object to the means Dr. Goodlin has taken to achieve his ends. His experiments have involved cruel acts, such as slicing open the rib cages of still living aborted fetuses in order to observe their hearts. We hold that the abortions which killed these children, as well as Dr. Goodlin's experiments on them in their dying moments, constitute violations of human rights. No human being should be made into an involuntary guinea pig, no matter how much a doctor wants him as a subject. This is especially true when the child

is as helpless as Dr. Goodlin's victims, and then the experiment involves such cruelty.

We read in the May 18, 1972, issue of the New England Journal of Medicine of another but certainly related aspect of fetal experimentation.

This work involved the administering of a live rubella vaccine to women scheduled for abortions for the purpose of evaluating fetal hazard of accidental administration.

The fetus, after delivery, was studied for traces of the rubella virus. To condense this procedure, a virus was introduced which, by its nature, could harm the developing child so anticipating its destruction by abortion, it would be further studied.

These are but four examples, the seedlings of a growing problem.

Senator KENNEDY. If I understood you, you do not object to research on dead fetuses when permission is obtained?

Mrs. POLICASTRO. No.

I will, however, later qualify that a little further.

We may see in this type of research the tips of an iceberg, the results of a medicine without an ethic. Throughout our discussion we can only see irony in the concern that is displayed for improvement of the health outlook for maternal and fetal patients by many people who are willing to do away with lives to attain such advances.

In addition to the more apparent abuses already discussed, let us try to foresee other adversities.

We may find researchers requesting abortions performed according to immediate need of a particular state of development of the fetus.

Senator KENNEDY. Can you summarize the point you are making?

Mrs. POLICASTRO. I am suggesting here that in cases if such things could be possible, as a kidney transplant, they could have a kidney at a certain stage of development that would be able to be transplanted, not so much ordering the abortion, but saying let us keep this woman and have the abortion performed at 2½ months or 3½ months, at what point they desired it.

Senator KENNEDY. Is this taking place now, to your knowledge?

Mrs. POLICASTRO. No. This instance I am citing, I am trying to foresee problems that may arise.

Senator KENNEDY. This type of thing concerns you?

Mrs. POLICASTRO. Yes.

With research funds dwindling, the overzealous researcher may give in to abuses.

If a researcher is waiting in line for a fetus, or just a particular organ, what attempts will be made to sustain life if the abortion produces a living child?

Rather than shown due respect after death, the human body may become no more than a supply of "spare parts."

There is a real sense of immediacy about the establishment of a commission to draw up guidelines for research on human subjects. England has previously done a great deal of study in this area.

We can give credit to the Society for the Protection of the Unborn from that country for their insights in this area and ideas which we wish to include with our own.

The U.S. Coalition for Life submits the following considerations that we feel necessarily must be part of the set of guidelines.

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2. Terminology must be correctly defined.

3. Permission must be obtained from parent, parents, or guardians, as for autopsy studies.

4. No research should be done other than to protect the life of the fetus until all signs of neuorological or cardiovascular function have ended.

5. Viability cannot be used as a criteria to arbitrarily deny the fetus protection as a living human being.

6. Funds would be withheld from any researcher or research agency or institution that does not strictly adhere to the policies as set forth in the guidelines.

7. There should always be present at an abortion that may result in a live fetus being born, an advocate for the child to insure that his rights would be protected and everything would be done to sustain his life. That advocate should in no way profit, financially or otherwise, from the use of the fetus, dead or alive.

8. Laboratories should keep accurate files showing where a fetus was obtained, how it was used, and how a dead fetus was disposed.

9. Respect should always be shown, the same as afforded any other human body.

This briefly summarizes our suggestions for the Commission's study. We will elaborate on these guidelines at appropriate hearings conducted by the Commission.

The U.S. Coalition for Life encourages concern on the subject of human experimentation. Knowing that much of this research will be done on the child who has been aborted, we in no way compromise our belief that all human life is to be protected from conception to the time of natural death. It is our strong intention to support a human life amendment to our Constitution as well as any legislation which guarantees and protects the right to life for all.

[The prepared statement and bibliography of Mrs. Policastro follows:]

Testimony of

Patricia Policastro

Executive Board Member of the

U. S. Coalition for Life

Prepared for

the Senate Health Subcommittee

on Human Experimentation

July 19, 1974

Mr. Chairmen:

Thank you for the opportunity to present our views before the Health Subcommittee on the issue of experimentation using human subjects. I am Patricia Policastro, Executive Board Member for the U. S. Coalition for Life.

The U. S. Coalition for Life is a national-international research agency and clearinghouse with a broad range of interests including abortion, euthanasia, infanticide, population control and genetic engineering. We are honored to have an outstanding international advisory board. Included is the world-rekowned fetologist, Sir William Liley of New Zealand, the "Father of Fetology" who practices as a fetal pediatrician. Also included are specialists in the fields of maternal health care, medical ethics and so forth, fields which are directly related to the topic at hand, experimentation on human subjects, more specifically experimentation on the human fetus. Implicit in all Coalition activities is our concern for human life, a concern which extends not only to the unborn child, but to all members of society, particularly the poor, the young, the mentally retarded, those individuals whose life and liberty are made ever more vulnerable to attach by those who have become forgetful of basic moral and ethical beliefs.

We support the formation of a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. I emphasize the words protection of human subjects lest members of such a commission see as its primary orientation the mere identification of regulatory procedures or clinical guidelines geared toward the protection of researchers and institutions engaged in experimental research rather than the protection of the human subjects. With regard to the specific ethical, medical, social, and

legal implications of using fetuses or fetal material in research, we would hope that the commission will take every step to insure that research on live human fetuses, inside the womb or outside will be prohibited except when the experimental procedure is to safeguard the life of the child. We hope that such prohibition would be supported by practical guidelines to insure that such abuses COULD not happen. In the past we have been willing to justify the use of a common-sense ethic in which legalistic terms or built in controls were waived in favor of the individual or collective judgment of a particular researcher or research institution. This singular criteria is no longer acceptable. Experience in this country and abroad has shown that it is unwise to rely wholly upon the ethical conduct of individuals engaged in abortion practice or the collective judgement of medical boards whose institutions are engaged in mass-produced abortions. Laws need to be clearly stated and firmly enforced if abuses of the live fetus are to be prevented. This would also hold true of various governmental agencies. We would note that the National Institute of Child Health and Human Development has issued grants for the purpose of developing new techniques of destroying the unborn child rather than insuring his health and development. In this category we might also include those commercial firms who many view the aborted child as a profitable source of material.

Experimentation on live, aborted children is not a science fiction dream but a present day reality. As a matter of record, there are instances where such experimentation has taken place. I wish to cite just a few classic examples of such practices. In 1972, Denver, Colorado already had a good supply of research "material." Dr. Toben, a staff member of the Colorado University Medical Center, used aborted fetuses for dental study. While not having particular argument with his manner of research, it was however

interesting to note that at no time was there any permission requested from the mothers or any knowledge given to them that their children were later to be used in such manner.[1] It is my understanding that permission must be attained for the use of a body after death for autopsy reports. What right does an outside party have to a body? In Pittsburgh, a young anesthetist at Magee-Women's Hospital at the time, Mrs. Wilhamine Dick in testimony before the Abortion Law Commission in 1972 testified: "It was repulsive to watch live fetuses being packed in ice while still moving and trying to breathe, then being rushed to some laboratory; and hear a medical student later discuss the experience of examining various organs of a once-live baby."[2] Again in 1972 we saw a student protest staged at Stanford University against the experimentation by Dr. Goodlin on live fetuses again without anyone's given consent. Dr. Goodlin was attempting to develop an artificial womb. Commenting on the experiments Mark Swendsen, organizer of the demonstration said, "While an artificial womb would be unquestionable useful article, we object to the means Dr. Goodlin has taken to achieve his ends. His experiments have involved cruel acts, such as slicing open the rib-cages of still-living aborted fetuses in order to observe their hearts. We hold that the abortions which killed these children as well as Dr. Goodlin's experiments on them in their dying moments, constitute violations of human rights. No human being should be made into an involuntary guinea-pig, no matter how much a doctor wants him as a subject. This is especially true when the child is as helpless as Dr. Goodlin's victims, and when the experiment involves such cruelty."[3] We read in the May 18, 1972 issue of the New England Journal of Medicine of another but certainly related aspect of fetal experimentation.[4] This work involved the administering of a live rubella vaccine to women scheduled for

abortions for the purpose of evaluating fetal hazard of accidental administration. The fetus, after delivery, was studied for traces of the rubella virus. To condense this procedure, a virus was introduced which by its nature could harm the developing child, so anticipating its destruction by abortion, it would be further studied. These are but four examples, the seedlings of a growing problem.

We may see in this type of research the tips of an iceberg, the results of a medicine without an ethic. Throughout our discussion we can only see irony in the concern that is displayed for improvement of the health outlook for maternal and fetal patients by many people who are willing to do away with lives to attain such advances. In addition to the more apparent abuses already discussed, let us try to forsee other adversities. We may find researchers requesting abortions performed according to immediate need of a particular state of development of the fetus. With research funds dwindling, the over-zealous researcher may give in to abuses. If a researcher is waiting in line for a fetus or just a particular organ, what attempts will be made to sustain life if the abortion produces a living child. Rather than shown due respect after death, the human body may become no more than a supply of "spare parts."

There is a real sense of immediacy about the establishment of a Commission to draw up guidelines for research on human subjects. England has previously done a great deal of study in this area. We can give credit to the Society for the Protection of the Unborn from that country for their insights in this area and ideas which we wish to include with our own.[5] The U. S. Coalition for Life submits the following considerations that we feel necessarily must be part of the that set of guidelines.

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5) Reprint of Submission by the Society for the Protection of Unborn Children (S.P.U.C.) to the Group Established by the Minister of Health and Social Security to Consider the Ethical, Medical, Social, and Legal Implications of Using Fetuses or Fetal Material in Research.

Senator KENNEDY. Dr. Hellegers?

Dr. HELLEGERS. Senator, I would like to say first of all I am testifying on behalf of my own, and not on behalf of any organization.

Second, I hope I can enter the statements as submitted into the record, and read only parts of it. So I would like to submit the whole document if I could.

Let me say briefly that I am heartily in favor of fetal research, child research, adult research, but I think the problem is not just whether any research will be done, but how it will be done.

Let me begin by stating that I believe that people are not opposed to research. However, the fetus represents the smallest member of the human race, not to be compared to a tooth or a tonsil.

I wish to make it crystal clear that these groups of people should not be artificially represented as representing the so-called "pro" or "anti" abortion forces respectively.

I do not think that anybody is opposed to research on placentas or afterbirth.

What I think people have qualms about is use of the fetus itself.

Often research reports say a sample of fetal blood was obtained, and I have procured literally hundreds of samples. They are usually taken from the placentas which contain fetal blood, and I think many, many of the people erroneously visualize the body of the fetus being stuck.

Let me say that I doubt if the opponents of fetal research mean to include the dead fetus. I am sure they would not, by and large, be opposed to a dead fetus being used.

Senator KENNEDY. Can you give us an idea of how much fetal research is done on dead fetuses—and is thus nonobjectionable—and how much is done on living fetuses?

If we could grasp this in layman's terms, it would be helpful.

Dr. HELLEGERS. Exceedingly little research is done on the fetus that is alive, or what is called by the average man someone he thinks alive.

I think what people are worried about is a fetus that is moving, has a heartbeat, has brain waves. They would be fairly easily recognized.

Senator KENNEDY. Have you any idea how much is done on living tissue, and how much is the kind that is done on the placentas that, i.e., is not objectionable?

Dr. HELLEGERS. I will have to give you an obstetrician's answer.

Senator KENNEDY. Just an expression from the panel.

Dr. HELLEGERS. I would say when I was on the obstetrical service at Johns Hopkins before the Supreme Court decision, we would perform three hysterotomies per year, and hysterotomy is the method of obtaining live fetuses. That is to say all of the abortions done by suction, D. & C., most of the ones that are done by salt solution yield dead fetuses.

We are talking about something that is a very small fraction of all abortions going on.

If we exclude the fetus in utero. They all may be alive prior to the abortion.

Senator KENNEDY. I do not think we can. In terms of the layman's understanding can you distinguish for us between what is being

done with the live fetus in utero, outside the mother, and the dead fetus? What is the percentage of research, particularly on live fetuses?

Dr. HELLEGERS. Let me give you figures—100 percent.

Senator KENNEDY. Give it so that we understand the dimension of this particular problem.

Dr. HELLEGERS. I can start by saying 100 percent of the fetuses in utero are alive, or the abortion would not have been done.

Senator KENNEDY. But how much research is done on live fetuses in utero?

Dr. HELLEGERS. In terms of administration of agents I would say a fair amount is done.

If we qualify further and say administration to the mother of substances that can harm the fetus, then it is very little, so I agree with Dr. Robbins' statement that the Boston experiment I would not at all consider unethical.

In fact, I offered to testify on behalf of the defendants in Massachusetts.

Dr. ROBBINS. I would tend to agree with this, but I would say the danger of giving drugs that we do not know anything about to the pregnant woman is probably greater than the danger to the fetus that occurs from the planned experiment, and I am not aware of large numbers of experiments of any kind that are going on in this country or abroad. There is some, but not very much.

Dr. HELLEGERS. That is right.

Senator KENNEDY. It is difficult, I know, to pinpoint numbers, but are we talking about thousands, or tens of thousands, or hundreds a year?

Dr. ROBBINS. I might think there would be three or four investigators—probably none right now.

Dr. HELLEGERS. You mean with the administration of harmful agents.

Senator KENNEDY. I am trying to get as clear a breakdown as I can on live in utero fetal research so that the layman and also the Congress, can grasp the dimensions of what we are talking about.

I gather from your testimony that just a handful of researchers were doing it, and that today none is being done.

I suppose this research was in the form of taking various drugs, is that correct? Also, what other procedures were being used?

Dr. HELLEGERS. Yes. I have done many in the terms of administration of oxygen, and taking a sample of the fetal blood to find out whether or not the oxygen gets across to the fetus, but this is where you say the fetus had as much to benefit as it had to lose.

Senator KENNEDY. How much research is banned by the Congressional action?

Dr. BEHRMAN. I am not sure how you get at an answer.

One way to get at that answer is to calculate that there is approximately $83 billion that has been spent on health in general by the Federal Government, and about 2 to 3 percent of that is for research.

Of that research, 2.5 percent, I would be amazed if we were talking about more than one-thousandths of that. We have to look at it in terms of what is being funded through NICHD, and you have to take a fraction of that. I cannot imagine 10 percent of the

NICHD budget involving fetal research. You then have to fractionate that as to what percentage of that really had anything to do with the type of in utero situation you are asking about.

I guess we are talking about ten-thousandths. I just do not know how to get at the answer.

Dr. HELLEGERS. Perhaps I can give you some enlightenment.

Senator KENNEDY. I would like to get the answer to that. I would also like to know, if the percentage is so minute why the scientific community is so outraged about the ban?

Dr. HELLEGERS. That is precisely what I do not understand.

With 3 years on the National Council of the NICHD, and 4 years on the Study Section that dealt with that, in those 7 years I cannot recollect a single project that was funded of this kind. That is in the 7 years that I have served on the committee. I think your point is well taken.

I do not think it does any harm, Senator.

Dr. ROBBINS. I do not think that is a valid point.

I think there is a very good reason why there is not much going on, and there are some people who feel that there is too little going on, not because of legal restrictions necessarily, but of the problems that are attendant with doing this kind of work, and also, I think that many of the people who do it, as I have suggested before, have concerned themselves about the ethical aspects, and are loathe to do it.

Perhaps if we had reasonable guidelines and people felt a little more secure, there would be more.

Now, you do not have to do large numbers of experiments to achieve your goal.

The initial polio work was done in one laboratory and with a very small budget. But I do not think we can answer your question quantitatively at this time.

Let me ask you a question. When one, let us say, removes a piece of trachea (the tube that supplies the air to the lung) from a fetus, the lining cells of that trachea have to be alive in order for you to use it for testing and/or growing a virus.

Now, you do not have to remove it from a fetus that has all of those criteria we generally use to define life such as a beating heart, respirations or brain waves. Of course, a pre-viable fetus does not have brain waves anyway, so that is not a good criteria.

Is one dealing here with a live or a dead fetus?

Dr. HELLEGERS. I understand that to be what the average man in the street would understand to be a dead fetus, without heartbeat, without EEG, and so on.

Senator KENNEDY. That would be my understanding.

Dr. ROBBINS. That would be mine, but I am not sure it would be everybody's.

Senator KENNEDY. It might not be everybody's. I think that this legislatively was certainly the intention.

Dr. Behrman, is there anything you want to add on this point?

Dr. BEHRMAN. Only a general comment about what research is about.

The nature of research is not how many get grants and do projects and do experiments, and publish them, but the nature of it is

to find out whether or not that one good idea comes out of it that has any significance.

As to the polio work, there must have been hundreds of thousands of papers on questions that had some bearing on cell development up to that point that really were of no benefit, until the right idea came along, and the benefit could be adequately demonstrated.

We are talking about a human endeavor in which the efficiency is low for really lasting ideas, and this has to be kept in mind.

Senator KENNEDY. Dr. Hellegers?

Dr. HELLEGERS. Next, then, there is the problem of the live fetus outside the mother. This is what I think the public debate is all about. It is not sufficient to analyze the problem in the light of the Supreme Court's abortion decision. Such an extrauterine fetus can no longer interfere with a woman's privacy or health.

The case can no longer be argued under such slogans as "Every woman has a right to control her own body" since this fetus is no longer inside her body. It can no longer be argued under the slogan "No woman should be forced to bear a child" because once the fetus is removed from the woman she is no longer forced to bear it. It can no longer be argued that such a fetus can interfere with its mother's health.

In brief, there is no longer any possible conflict between the fetus and its mother. The issue now squarely becomes whether that live fetus is to be treated as a tooth or a tonsil, and that I think is where the lines are drawn.

It is also at this point, as with other live extrauterine children, that the serious problem of consent giving for experimentation comes in. If the live extrauterine fetus is only tooth or tonsil there would seem to be little problem. But if it is more than that, and no longer even theoretically capable of interfering with an adult's rights (such as to privacy or health), then the question is a new one. It becomes the key question in all proxy consent giving (for example, consent giving on behalf of another who cannot give consent). The question is: Who can give consent on behalf of another and for what?

Usually, the proxy consent giver is philosophically required to have the interest of the experimental subject at heart. This is what makes the parents of the aborted fetus questionably appropriate consent givers, if not outright disqualified for the task.

After all, given the problem of deciding between the fetus' welfare and their own in the abortion decision, they chose their own welfare. It is agreed that their decision may have been agonizing. And I would hold that the agony of the decision may well qualify them to refuse permission for the use of their live fetus.

But I do not see how their position in anyway qualifies them as suitable consent givers for granting permission for the experiment. There lies the rub both in cases where the fetus is alive or dead.

In a sense, then, the aborted fetus may be analogized to the abandoned child or adult. In the case of the dead fetus, or the dead child, or the dead adult, I think the issue may well differ from the live ones.

There are States which assign dead and abandoned adults to medical schools for dissection. There are counties and States with

"Uniform Anatomical Gift Acts" which hold that body parts of the deceased belong to the community unless appropriately qualified next of kin object.

I think the issue of the dead fetus can well be analyzed in this light. What seems to me to be a key consideration, in assuring ourselves of the appropriate qualifications for proxy consent givers, is that they stand to lose as much as to gain from the consent giving.

In proxy consent giving for minors this qualification usually holds in that parents will protect their offspring from damage since they are still held responsible for raising the minor or incompetent.

It is in the absence of this natural guarantee that the fetus is particularly vulnerable to adults who might want to use it as a means only, as an object only, and not in the light of some benefit which might accrue to that fetus itself.

Let me say finally that the problems I have discussed do not preclude all experimentation with fetuses. Strong voices have been raised suggesting the Nation's future health is in great peril unless live fetuses are used.

Nothing in our past history supports the suggestion. We have done very well in medical research on behalf of children and others before the Supreme Court decision.

Indeed, the National Institutes of Health have asserted that no live fetus research was supported in the United States before or after the Supreme Court decision. My close to 15 years service as a consultant to the NIH confirm this assertion.

Live fetuses are simply not that commonly procured as to be significant in research. Moreover, if it were ever shown that there was an absolute national imperative to use live fetuses, there are mechanisms for ethically incorporating such needs in society.

I remind the subcommittee that occasionally a national defense need of such magnitude arises that human beings are drafted to serve the survival of the Nation. The issue then becomes how to do such drafting equitably and ethically. Our present method is one of random lottery, which assures that no one is considered more or less socially worthy than another.

It is conceivable that we might postulate such a fetal draft on behalf of a national health need. But I doubt that any proponent of the scientific imperative to perform research on the live fetus would even wish to suggest it.

It is self-evident from the track record of fetal physiology research in the United States and elsewhere that no such imperative need exists and I am at a loss to think where it would arise in the foreseeable future.

I think the issue before us today is one of resisting sloganeering among proponents and opponents of live fetal research. In real scientific fetal physiology research these are largely nonissues.

I am quite confident that principles (not just procedures) can be established which will safeguard both the live fetus and scientific research. We have no need for either "antiscience" or "scientism."

Several years ago I testified in favor of the so-called Mondale bill. I said then that I did so not just for the protection of patients and society but even more so for the protection of science. It simply will not wish to push a scientific imperative to the exclusion of humanitarian concerns.

When the sciences and the humanities begin to understand each other's point of views, both will be better served. I am grateful for the opportunity to testify, and perhaps to have helped clarify what the issues are, and even more what they are not.

Senator KENNEDY. The Buckley Amendment, Dr. Hellegers, would not be inconsistent with your position, then.

Dr. HELLEGERS. I do not think the Buckley Amendment would have done any harm to fetal research in the United States if it had been properly interpreted to not apply to amniotic fluid, dead organs and placentas, and if we were focusing only on that very small group of the alive, non-viable fetuses.

I am not saying better language could not have been found, but I think it is necessary.

Senator KENNEDY. You confuse me a bit. It seems to me to be a semantic difference. I realize there could be important professional differences here. For example, Dr. Behrman might suggest that you not put the fetus on a respirator, and you are fairly sure also that it will not survive. However, you have a ray of hope that it might survive, although he looks at it differently. But the actual results seem to me to be pretty much the same.

Dr. HELLEGERS. I think where the dichotomy might lie between Dr. Behrman and I would be on the choice of the first case in which to apply the new technique.

Now, I think Dr. Behrman might say let us use the live, non-viable fetus because he cannot live anyway.

I would go the reverse route and say, let us use the viable one, and use on one who might benefit by it.

Senator KENNEDY. If it were my child and we discussed it with both of you I do not think I would let it go ahead.

Dr. HELLEGERS. Pardon me, but if you were told your child without it would die, would you still then?

Senator KENNEDY. Then aren't we really confusing the parents? Both of you arrive at the same conclusion but I would think you would cause a good deal of anguish with the parents.

Dr. HELLEGERS. I would begin by saying I would never start in the first case with a live fetus only because it was going to die.

Senator KENNEDY. Whose child are you going to use then?

Dr. HELLEGERS. The first child that will stand to benefit from going on the machine as much as to lose from it.

Senator KENNEDY. But by definition his chances of using the other kind of procedures are what?

Dr. HELLEGERS. Then I would not use them.

Senator KENNEDY. Pardon me?

Dr. HELLEGERS. If another therapy is available you would not use the new.

Senator KENNEDY. Is not that a difficult dilemma.

Dr. HELLEGERS. That is right. That is always the dilemma, who will be the first patient who stands to benefit more than be harmed; and that is a very tough first patient choosing procedure. But I would not forego the agonies by saying let me use one that is going to die anyway, because that is worth some very serious consideration on principle.

Senator KENNEDY. As far as I understand Dr. Behrman's description—and he can speak for himself—the fetus you would use is

from a scientific point of view, almost assuredly not going to survive. Is that correct?

Dr. BEHRMAN. That is correct.

Senator KENNEDY. Dr. Behrman knows it is not going to make it.

Dr. HELLEGERS. That is right.

Senator KENNEDY. How do you differ?

Dr. HELLEGERS. I differ with him in the fact that if you are not going to make it anyway it is not a warranty to be experimented upon.

Senator KENNEDY. But the results are going to be the same, are they not? You put the child on the respirator yourself.

Dr. HELLEGERS. No, no. Excuse me. I would only put the child on the respirator if I thought that by doing so it would have a chance of surviving, however small.

If I understand the feeling correctly of Dr. Behrman, he would do it only if he thought the child was not going to survive. That is a big difference.

Mrs. POLICASTRO. There is a slight difference from this.

Here we are talking about children who in some cases may be spontaneously aborted. In other cases it would be an induced abortion.

Given the fact that it is an induced abortion you do not expect to come up with a live child so therefore you think, well, this child is going to die and therefore we can experiment on this child by using any number of experimental procedures.

Dr. Behrman, however, is interested in if you are given a case of a fatal membrane disease you have another experiment and procedure that might help this child because of this experimental procedure and therefore it helps in saving that child with that disease and let us go through with it.

Dr. BEHRMAN. Some of the difference may be a little bit ambiguous and I am not talking about a theoretical situation. These are decisions that come up every day in which I am involved and the question comes up, if I could use an example very specifically, where you have a baby of say 3 pounds on a respirator with a very severe disease and all of the indices we have make us think that this is a fatal disease and that he is not going to survive. We are rarely in a situation until the last minute or two to be able to tell a parent absolutely that the child is going to die. Because we are not in that situation, because there is always the possibility of life, even if it is 2 percent we cannot switch to a totally new approach which we are almost certain or absolutely certain is not going to help the first child, particularly if there has been absolutely no work done on humans before that and it just cannot be done adequately.

Now, we can pretend, and I think that is what Dr. Hellegers was saying, if we want to play with words we can pretend the child has a chance, you know, or let the impression be that we have a possibility of getting help from the new procedures, et cetera.

There is no issue. If we honestly think that we would use the procedure then it is not really a very difficult ethical question, but I think there are many situations in practice where you cannot honestly make that judgment and these are usually the situations

when you are moving from a known therapeutic approach to one that before this was never used in humans. That is really what we are concerned about here.

I do not know if that pinpoints it a little more closely but I am saying that from my own experience it is better to be able to go to a mother who has a fetus and is going to be aborted because the decision has been made independently of the investigator, has been made after the father has been talked with, after the relatives have been talked with, in light of her religious views. These decisions are not made in a vacuum.

At that point she has made the decision and we have taken measurements with ultra sound and we know the fetus is in the category that has absolutely no chance of survival. It seems to me more sensible with the scientists, with monitoring by a lay board, a very complicated judgment being made by other people as well as the scientists, to be able to approach the mother in the presence of the other people and get her permission to use that fetus at that point for a procedure we know is not going to benefit that individual fetus but which may benefit her next child or somebody else's child. That is a much more sensible way to arrive at a judgment in society than to pretend in the other situation.

I guess what I am really trying to say is if the fetus is alive from the moment of conception then we have really a moral obligation to optimize through research all of his chances for a healthy survival and it is unethical and immoral not to use fetal research as a way of optimizing the chances for that fetus to develop normally.

Now, that may involve really interjecting cells or chemicals in a 5th- or 12th-stage fetus after fertilization in order to correct an inborn error of metabolism. That is not science fiction. That is on the horizon, maybe not in our lifetime but our children's lifetime.

If you end up setting up a rigorous congressional decision that this area of human endeavor will not be allowed to go on you really do preclude these possibilities and even though these possibilities are slight I think it is wrong for a nation to preclude itself from being able to have progress in these areas.

Senator KENNEDY. Dr. Hellegers?

Dr. HELLEGERS. I would like to say it is not a question of pretending, as Dr. Behrman said, because in no ethical system I know of is there a demand for absolute certainty on the part of the moral agent.

The issue is, do you have moral certainty that this child will be better off; not scientific certainly, because all moral decisionmaking is done by moral agents who have certain things they do not know about.

The question here is honesty, and it is moral integrity, and not do we have absolute certainty that this one will die, because we do not have that from anybody.

I would like to differentiate the use of fetal research from the use of fetuses, which is a different issue.

I am heartily in favor of Dr. Behrman's statement that we must use certain research but the question becomes, do we use fetuses on behalf of another?

[The prepared statement of Dr. Hellegers follows:]

STATEMENT OF ANDRE E. HELLEGERS, M.D.

Mr. Chairman and members:

For purposes of identification I am Dr. Andre E. Hellegers, Professor of Obstetrics-Gynecology and Physiology-Biophysics at Georgetown University and Director of its Joseph and Rose Kennedy Institute for the Study of Human Reproduction and Bioethics. My research work has been overwhelmingly in the area of fetal physiology and I have been president of the Society for Gynecologic Investigation and of the Perinatal Research Society--two of the country's major societies interested in fetal physiology research.

For the past few months we have all been exposed to opinions which extend in range from a need to ban all fetal research to a need to put no restrictions on it whatever. In the process all fetal research has been lumped together in the most simplistic fashion so that both proponents and opponents have resorted to such absurd slogans as that we would never have developed the Salk vaccine or will never cure cancer unless we "allow fetal research" all the way to the proposition that fetuses are being tortured by pseudoNazis. These propositions are totally absurd and I hope today to shed some light on what I believe some of the true issues to be.

Firstly, I am heartily in favor of fetal research, child research, adult research--in brief, I do not believe medical research needs any defense from me. It has been going on for centuries to the benefit of mankind and I have no doubt it will continue formany more centuries to come. What is at issue is not whether research will be done, but how it will be done.

Because of the issue of abortion, the words "fetal research" can have an emotional impact akin to the emotion caused after the second World War, when the how of German research in concentration camps came to light. But this is an appalling oversimplification. We therefore do well to survey simply what the issues are, and especially what they are not.

There are those who consider the human fetus no more than a tooth or a tonsil. For them, quite logically, fetal research presents no more of a problem than research on a removed tooth or tonsil.

For others, however, the fetus represents the smallest member of the human race, not to be compared to tooth or tonsil. I wish to make it crystal clear that these groups of people should not be artificially represented as presenting so-called "pro" and "anti" abortion forces respectively. It would, I believe,

clarify thinking greatly if we thought not about fetuses obtained from induced abortion, but fetuses obtained from spontaneous miscarriages. No one believes a spontaneous miscarriage is immoral and so we do well to first consider fetal research with spontaneously miscarried fetuses so that we separate the whole emotional issue of induced abortion from fetal research.

Let me begin by stating that my belief as to what people are not opposed to. I do not think anyone is opposed to research on amniotic fluid. I do not think anyone is opposed to research on placentas (afterbirths). I believe what people have qualms about is the fetus itself. So often research reports say that "a sample of the fetal blood was obtained." I myself have procured literally hundreds of such samples. But I think people don't realize that fetal blood samples are usually obtained in such experiments from the placenta (which contains fetal blood, not maternal) rather than from the body of the fetus. I think they visualize the fetal body being stuck, rather than the placenta.

So I think the first assertion I would make is that I doubt that "opponents of fetal research" are interested in protecting amniotic fluid or placentas. I should perhaps say a special word about amniotic fluid. The word "amniocentesis" has only recently appeared in popular magazines like Time and Newsweek. To many, the word "amniocentesis" means a new procedure to determine whether a fetus is abnormal in order to abort it if it is. Nothing could be further from the truth. Amniocentesis simply means the removal of amniotic fluid and has been carried out for decades by obstetricians to relieve women who had a condition called "polyhydramnios" which means "too much amniotic fluid." It was a procedure designed to help women; not to abort abnormal fetuses. And, even in recent years, amniocentesis is overwhelmingly carried out for the purpose of saving fetal life. It is done to determine whether the fetus is mature enough to be delivered or whether it should be left in utero a little longer to mature further instead of dying of prematurity. And it is used to determine whether fetuses about to die of Rh disease should be delivered early and receive exchange transfusions of blood, or even receive a blood transfusion in utero, in order to allow them to survive. In brief, Mr. Chairman, I am trying to point out that procedures such as amniocentesis are ethically neutral. It is the purpose for which they are carried out which determinesthe ethics of their performance.

If then amniotic fluid and placental research are not, ipso facto, to be prohibited, what else can we probably agree on? I think that we can perhaps agree on the dead fetus. I doubt that the "opponents of fetal research" mean to include the dead fetus. I am sure they would not by and large be opposed to autopsy of dead adults or of dead children. If they include the fetus in the human family, as I do, I can see no fundamental reason not to do with the fetus what one would do with the child or with the

adult. Let me extend my argument even to the fetus resulting from an induced abortion rather than just from "spontaneous miscarriage". Let us take an adult killed by homicide. I have heard no great outcry against the performance of an autopsy on a victim of murder, homicide, assassination, suicide, a hit and run accident or any of such methods of death production, of which we might disapprove. Our performance of the autopsy in no way denotes approval of the cause of death.

Perhaps a word of caution is in order(as the ethicist LeRoy Walters has pointed out). I doubt the American public would wish to see us draw a systematic advantage in medical research from systematic abortion. That is to say, I do not believe the general public would wish us to start thinking of abortion as a good because it offers us research opportunities. But I do not think that this is what we are at. Right now I do not believe the American public objects to use of a dead fetus more than it objects to use of a murder victim for the gathering of medical information which might benefit others. By the same token I do not believe the American public would object to the transplantation of fetal organs to babies, providing the donor of the organs was dead.

To recapitulate up to this point: it is not amniotic fluid which is at issue, nor the placenta, nor fetal blood taken from placentas, nor dead fetuses, nor their organs.

What is at issue is the living fetus.

Let us for a moment consider this category. The fetus, of a certain size, outside of its mother is called a premature baby, and I think the average American would wish to see the premature baby treated with the same respect and under the same rules as the more mature baby.

What we are left with as a problem then is the fetus which is alive but whose prognosis for survival is hopeless. Such a fetus is commonly called nonviable or previable. Technically, it is also sometimes called an abortus. I think however people confuse the words viable and alive. The term viable denotes a prognosis, i.e., this fetus will not live in future. It is certain to die in future. On the other hand, the term alive denotes a diagnosis, i.e., this fetus is alive now, regardless of its future.

I believe the entire medical debate revolves around this alive, but not viable fetus. I have been quoted in the press as not buying the notion that one can experiment with anyone simply because they are known to be dead shortly. I remain opposed to accepting such a principle. I do not think impending and certain death, ipso facto, makes you common property for the performance of medical experiments. Now the question becomes: how do you tell whether a fetus is alive? Personally, I have never had great

difficulty with that and I do not believe others have great difficulty unless they are interested in obfuscating matters. I think we can very well draw analogies to adults. If the fetus moves any of its parts or has a heart beat or tries to breathe or has brain waves it would look rather obviously alive to what Lord Justice Devlin in Britain would wisely call"the average man on the Clapham bus". So I really do not think that "twelve men and true" would have great difficulty in arriving at a description of the criteria for diagnosing death in a fetus.

Now I must make clear that the issue of experimentation on the live fetus can arise when the fetus is still in utero or after it has left the uterus. A British committee headed by the Queen's obstetrician, Sir John Peel, arrived at the conclusion that there should be no experiments on the undelivered or unaborted fetus. Their reasoning was that agents damaging to the fetus might be administered to the mother. Once this was done, they felt, she had in large measure lost the option of changing her mind at the last moment about undergoing an abortion. I agree with this conclusion where it concerns agents which may harm the fetus. I do not agree if the agent cannot harm the fetus and consequently does not affect the woman's free decision making ability regarding the abortion.

Next, then, there is the problem of the alive fetus outside the mother. This is what I think the public debate is all about. It is not sufficient to analyze the problem in the light of the Supreme Court's abortion decision. Such an extrauterine fetus can no longer interfere with a woman's privacy. The case can no longer be argued under such slogans as "Every woman has a right to control her own body" since this fetus is no longer ins e her body. It can no longer be argued under the slogan "No woman should be forced to bear a child" because once the fetus is re oved from the woman she is no longer forced to bear it. It can no longer be argued that such a fetus can interfere with its mother's health. In brief, there is no longer any possible conflict between the fetus and its mother. The issue now squarely becomes whether that live fetus is to be treated as a tooth or a tonsil, and that I think is where the lines are drawn.

It is also at this point, as with other live extrauterine children, that the serious problem of consent giving for experimentation comes in. If the live extrauterine fetus is only tooth or tonsil there would seem to be little problem. But if it is more than that, and no longer even theoretically capable of interfering with an adult's rights (such as to privacy or health), then the question is a new one. It becomes the key question in all proxy consent giving (i.e.,consent giving on behalf of another who cannot give consent). The question is: who can give consent on behalf of another and for what?

Usually, the proxy consent giver is philosophically required

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to have the interest of the experimental subject at heart. This is what makes the parents of the aborted fetus questionably appropriate consent givers, if not outright disqualified for the task. After all, given the problem of deciding between the fetus' welfare and their own in the abortion decision, they chose their own welfare. It is agreed that their decision may have been agonizing. And I would hold that the agony of the decision may well qualify them to refuse permission for the use of their live fetus. But I do not see how their position in any way qualifies them as suitable consent givers for granting permission for the experiment. There lies the rub both in cases where the fetus is alive or dead. In a sense, then, the aborted fetus may be analogized to the abandoned child or adult. In the case of the dead fetus, or the dead child, or the dead adult, I think the issue may well differ from the live ones.

There are states which assign dead and abandoned adults to medical schools for dissection. There are countries and states with "Uniform Anatomical Gift Acts" which hold that body parts of the deceased belong to the community unless appropriately qualified next of kin object. I think the issue of the dead fetus can well be analyzed in this light. What seems to me to be a key consideration, in assuring ourselves of the appropriate qualifications for proxy consent givers, is that they stand to lose as much as to gain from the consent giving. In proxy consent giving for minors this qualification usually holds in that parents will protect their offspring from damage since they are still held responsible for raising the minor or incompetent. It is in the absence of this natural guarantee that the fetus is particularly vulnerable to adults who might want to use it as a means only, as an object only, and not in the light of some benefit which might accrue to that fetus itself.

Let me say finally that the problems I have discussed do not preclude all experimentation with fetuses. Strong voices have been raised suggesting the nation's future health is in great peril unless live fetuses are used. Nothing in our past history supports the suggestion. We have done very well in medical research on behalf of children and others before the Supreme Court decision. Indeed, the National Institutes of Health have asserted that no live fetus research was supported in the U.S. before or after the Supreme Court decision. My close to fifteen year service as a Consultant to the N.I.H. confirm this assertion. Live fetuses are simply not that commonly procured as to be significant in research. Moreover, if it were ever shown that there was an absolute national imperative to use live fetuses, there are mechanisms for ethically incorporating such needs in society. I remind the Subcommittee that occasionally a national defence need of such magnitude arises that human beings are drafted to serve the survival of the nation. The issue then becomes how to do such drafting equitably and ethically. Our present method is one of random lottery which assures that no one is considered more or less socially worthy than another.

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It is conceivable that we might postulate such a fetal draft on behalf of a national health need. But I doubt that any proponent of the scientific imperative to perform research on the live fetus would even wish to suggest it. It is self evident from the track record of fetal physiology research in the United States and elsewhere that no such imperative exists and I am at a loss to think where it would arise in the foreseeable future.

I think the issue before us today is one of resisting sloganeering among proponents and opponents of live fetal research. In real scientific fetal physiology research these are largely non-issues. I am quite confident that principles (not just procedures) aan be established which will safeguard both the live fetus and scientific research. We have no need for either "anti-science" or "scientism". Several years ago I testified in favor of the so-called Mondale Bill. I said then that I d d so not just for the protection of patients and society but even more so for the protection of science. It simply will not wash to push a scientific imperative to the exclusion of humanitarian concerns. When the sciences and the humanities begin to understand each other's views, both will be better served. I am grateful for the opportunity to testify and perhaps to have helped clarify what the issues are, and even more what they are not.

Senator KENNEDY. Dr. Behrman, you have testimony here. Would you like to include it or summarize it?

Dr. BEHRMAN. I will try to summarize it, as I realize we are running late.

Senator KENNEDY. That is all right. We do have time.

Dr. BEHRMAN. I think most of us in this country place a high value on the desirability of each person exercising his own judgment about how his or her life will be lived. The right not to have anyone touch our bodies or threaten to touch them without our permission is one important aspect of this right. However, this right is not absolute. We require children to have certain immunizations before going to school, whether or not they or their parents want them, because the health risk to the community in this circumstance is considered to outweigh the value we place on the very basic right not to be touched by another person without our consent.

The doctrine of informed consent to the necessary assaults and batteries of physicians in the course of caring for the sick is based, in large measure, on the idea that the interests and well-being of the individual patient are best protected by delegating to this individual the decision as to whether or to not allow the physician to proceed. Ideally, the patient thus makes the ultimate judgment as to the individual's, the family's, and, in some instances, the general societal risks and benefits. This is a just and practical right even though there are times when serious adverse consequences for the patient and his family occur which could have been avoided but were not because the patient's own decision was obviously not the best decision; and there are times when society may, as a consequence of such a decision of a patient, have to assume enormous human and financial burdens of long-term care. Nevertheless, the risks to the individual and his family are considered to be still greater if others are made responsible for these decisions.

However, this legally guaranteed ethical right of the patient to exercise informed consent prior to medical procedures and treatments is also not absolute. There are circumstances in which the individual patient's capacity to protect his or her own interests is limited to nonexistent. For example, an adult in coma after cerebral vascular accident may not be able to consent to a necessary treatment. In this situation we accept a substitute consent by a closely related family member whose interests, love, and concern for the patient are such that reasonable men and women might rightly assume that the relative will be making judgments for the patient, often with enormous implications for the family and society, with a perspective similar to, but obviously not identical with, the vewpoint we imagine the patient might have had. Again, society as well as the family and patient may be profoundly affected by these decisions which the substitute patient, the parent or relative, is empowered to make.

Research on the human fetus should also be considered in the context of our accepted framework of individual decisionmaking,

social justice, and the right of patients to protect themselves through an obligation for informed consent by the patient or by a reasonable substitute. Further, when we think about the health and welfare of children, another idea emerges as fundamental. Individual decisions must be placed on a time scale that meaures their impact not only on the individual living today but also on what a particular decision will mean to the child or adult 20 or 50 years later, and what it implies for other individuals living at this time, as well as for future generations. This is what John Rawls refers to as "justice between the generations." If we are willing to accept the fruits of past research, such as immunization against polio, we in turn have a very real obligation to continue substantial efforts to investigate our current health problems for the sake of our children's children.

What then is the nature of the decision which must be made when a parent is asked to give permission to a physician to operate on a child with suspected appendicitis? Assuming reasonable efforts to inform the parents about the medical risks and benefits, is it basically different from the parents giving permission to a hematologist to use a new antimetabolite to treat leukemia as part of an investigation of the efficacy of the unproven drug? As far as the parents' decision is concerned, is this significantly different from an expectant mother giving informed consent to allow ultrasound—a form of sonar—to be used on her fetus for the purpose of determining normal fetal growth? In each instance, we are asking the parent to make a moral-ethical judgment as a substitute for that of the child or fetus, in part on the basis of the physician's presentation of the risks and benefits for the individual fetus or child which he has an ethical duty to relate to the parents and, in part, on the basis of the parents' life experience and general human understanding in making independent decisions that affect themselves, their families, and others in society, as well as future generations.

Senator KENNEDY. One of the very basic kinds of questions is balancing the interest of future generations with the interest of a given child in a given situation, is it not?

Dr. BEHRMAN. Yes, it is.

Senator KENNEDY. This is a delicate problem. I suppose what we are interested in is what should guide us in this circumstance, especially when a child cannot decide for himself.

Dr. BEHRMAN. I think the nature of the decision we are talking about is similar when we as phyicians ask the parents for permission for an appendicitis operation.

A fair number of those operations will prove that there was no appendicitis and the physician's judgment was wrong. But in advising surgery the physician is telling the parents that on the basis of his experience there is a significant chance that appendicitis will be present which warrants the risk of surgery.

The issue is not whether physicians should make these decisions. They should not now make these decision for parent and should not in the future. Rather, the issue is: Should we limit the right of the parents to make these decisions?

When permission for human investigation is at issue, rather than a question of generally accepted choices of treatment, the moral-ethical decision of giving informed consent for therapeutic or non-therapeutic research which involves the invasion of the body of the fetus or child should continue to be a decision for parents, or in unusual circumstances, someone else substituting for the parents. This has not been the rightful domain of the physician or physician-scientist in the past and should not be. To wrongly accuse physicians in general of usurping this role, as some are doing, is dishonest and merely obscure an important problem. A more relevant issue is to decide whether society needs to provide parents with some additional safeguards in making their own decisions.

Should parents and/or others substituting for a fetus be allowed to consent to the fetus being included in therapeutic and nontherapeutic investigation? What are the consequences for the development of the human species if we do not allow research on fetuses? What risks or diseases for our children as adults could be avoided by investigations during fetal life? Major advances in the prevention of coronary heart disease may depend on our understanding of fetal and infant metabolism and nutrition. Our ability to prevent and treat certain central nervous system disorders, such as multiple sclerosis, as well as a variety of cancers of adult life, and even our ultimate ability to ameliorate the aging process are likely to be dependent in part, upon investigations of fetal life. Do we limit the right to life of fetuses by delegating their consent to others? Or do we increase the opportunity to exercise their right to life and subsequent freedoms, if we investigate their health and disease on the basis of consent given by others? We do require children to go to school regardless of their wishes or those of their parents because of a judgment that this is in their and society's best interests. It oversimplifies the problem of consent to assume that the sole basis for allowing informed consent by parents to subtitute for that of the fetus is to protect the particular fetus from any conceivable bodily harm. This is, of course, the major consideration, but there are other ethical interests to be taken into account, such as the protection of future generations and society.

The principle that governs medical investigation of adults should also continue to be applicable to children and to fetuses, that is, the decisions should be made by an uncoerced and reasonably adequately informed individual or individuals whose interests are substantially overlapping or identical to those of the proposed subject and include an awareness of the ramifications for the family, society, and future generations. Basically, the substitute or supplemental consent of a parent for a child's or fetus' consent to participate as a subject of research should be a matter left to the judgment of a concerned, loving, and mature individual who will evaluate the situation from the parental perspective as well as from the point of view of the child's or fetus' immediate and long-term best inter-

ests as if he or she were in the fetus' place. The interests of society and future generations may also be given adequate consideration in this context.

Senator KENNEDY. If a mother has decided to abort a child should she then still be allowed to make the decision about what happens to the fetus?

Dr. BEHRMAN. I think in that situation she should not be given the right to be the sole person to give consent.

I also do not think she should be excluded from the discussions that go on about that, but I think there we need to develop some type of mechanism on a local level in which a physician and nonphysician people who are concerned about the care of the mother and the child and who are not at all concerned with the investigation should be a party to making that decision.

I think those decisions will be made rarely, practically never unless there is a potential therapeutic gain but I think there are occasions when we would want to have those decisions made and I think we ought to be smart enough to design a way to do it that will enable us on those occasions to take advantage of the situation because of the benefit for future generations.

I am not going to go into the amniocentesis problem because of the late hour except to make the point that the issue is not as Dr. Hellegers has defined it, that certain things can be excluded.

The issue really, to my mind, is whether the given proposals to prohibit fetal research will still allow now unknown and unimagined advances with substantial benefits similar to those that we now get from amniocentesis to accrue to our children.

That is the issue and to a certain degree it is not sufficient to narrow it down by excluding all of the things you can presently identify. I am really concerned about that.

We are concerned obviously that presently identifiable areas of research would be prohibited but what the scientific community is most concerned about are those unimagined and unknown areas of research that might be excluded if the wrong language is used and focuses only on what is presently known rather than giving us the potential for moving onto things that are presently unknown.

The ultimate judgment should not be made in a vacuum or without safeguards to increase the opportunities to gain a reasonable understanding of the implications and possible consequences of the decision. As with most medical decisions, the patient or parents, in the case of a child, consult with friends, relatives, ministers, family physicians, etc. Further, the community should require some evidence that consent was truly informed, that the individual and general benefits were honestly presented relative to the risks. It may well be desirable to formally provide the decisionmaking adult with additional advice or consultation beyond what he or she seeks out for himself. Very little other than therapeutic research or nontherapeutic research with little or no risk is likely to occur under this

system. For the most part, it has not occurred in the past. I believe this way of proceeding will assure not only that life is protected, but that there is optimal opportunity for an individual child and other generations of children to fully exercise a right to life.

Now, I would like to turn specifically to the problem of abortion and the investigation of existence before birth which I believe should be considered from the perspective we have just discussed. The problem is best introduced by an example. The technique of amniocentesis involves placing a needle through the abdomen of a pregnant woman into the amniotic cavity surrounding the fetus and withdrawing a sample of this fluid; the pressure of the fluid can also be measured. These techniques of pressure measurement and sampling have had significant health benefits for individual fetuses and infants. The pressure measurements are an important adjunct to monitoring heart rate during labor and thus have played a major role in improving survival and decreasing brain injury from asphyxia in newborn infants. Analysis of the fluid obtained has provided a means for improved management of Rh disease with resulting increases in survival and decreases in morbidity. Similarly, other tests on this amniotic fluid determining the lecithin to sphingomyelin ratio have improved the quality of obstetrical decisions in managing immature fetuses with a resultant decrease in deaths and injury from prematurity; this decrease in injury may have a substantial impact on the incidence and severity of cerebral palsy in the future.

When the technique was first used to measure intrauterine pressure during human labor, amniocentesis was not established as a procedure which would be of benefit for the individual fetus. Further, preliminary investigations of such advances in animal species are not always possible or practical, although generally desirable. The problem of treating and preventing Rh disease could not have been adequately investigated in animals before human studies were undertaken. By going ahead with the human fetal investigation through amniocentesis enormous benefits have accrued in the treatment of fetal asphyxia, Rh disease, prematurity and hyaline membrane disease. I will not even go into the potential impact of this technique on over 40 familiar disorders of intracellular metabolism or its implications for individual families, society and future generations in managing chromosomal aberrations such as Down's Syndrome (mongolism). In my opinion this important advance would not have been at all likely to occur under the various proposals for Federal legislation to prohibit human fetal investigation.

It is critical to keep in mind that the issue to be considered is not whether the proposed language to prohibit fetal research will allow amniocentesis or other recent advances or now unknown and unimagined advances with similar substantial benefits for our children are unlikely to be developed because of a ban on fetal research.

We could decide not to have any investigation of the fetal stage of human development and accept this limitation on our ability to enhance the opportunity for our children to grow and develop in a way that will maximize their potential as adults and thereby abdicate our responsibility to future generations. Alternatively, we can attempt to devise a social mechanism to provide a substitute or supplementary judgment for the fetus consistent with the high value we rightly place on each individual's freedom to make decisions and judgments that most closely affect himself. In my opinion the latter approach best preserves our fetuses' and children's right to life, liberty, and the pursuit of happiness. Some other mechanism for decisionmaking should be devised to cover this situation which takes into account the interests of the individual fetus, the parents, society and future generations of children who have a substantial stake in this matter.

If abortion or miscarriage occurs accidentally, decisions about the disposition of the dead fetus should be the prerogative of the parents, as would be the situation after a child dies. This would be consistent with the foregoing principles and with the general rules governing disposition of cadavers.

If a fetus is alive after delivery, the ethical obligation, as in the case of the infant and child, is to sustain life so far as reasonably possible, and it is both unethical and illegal to carry out any investigation which is inconsistent with generally accepted treatment necessary to promote life. There is no real issue about this, although there may be a substantive medical problem of deciding when a fetus is dead. If a live fetus unintentionally results from the parents' decision to have an abortion, a substitute judgment about consent to human therapeutic investigation could be devised to supplement the parents' judgment. If it is a wanted pregnancy, the principle governing informed consent by parents of infants or children should apply. It should be kept in mind that as a practical matter the premature infant will be considered a fetus under proposed laws and regulations, and much of the therapeutic research that has led to dramatic decreases in mortality and morbidity of premature infants in past decades might not continue if fetal research is prohibited.

A major problem centers on the question of experimentation on a fetus who although living is judged at a given point in time to have no chance of survival, no matter what is done therapeutically, called a previable fetus. If investigation is permitted, it is conceivable that sooner or later such a fetus may survive. Investigation on such a fetus should be subject to informed consent of the parent with appropriate supplemental procedures to provide reasonable safeguards to assure informed consent and adequate consideration of the rights of the fetus and parents.

Investigations of such previable fetuses may be particularly vital to improving the biologic quality of our children in the future; this

interest of society in these fetuses is of even more concern if the population growth is limited. Therefore, a real effort should be made to provide reasonable procedures that will allow such knowledge to be acquired.

Our ability to accurately diagnose early in gestation a severely affected fetus with rubella (and thus avoid aborting an unaffected wanted infant when a mother has had the infection and legally desires to abort an infected but not an uninfected fetus) is directly dependent on research on previable fetuses directed at developing new methods of diagnosis. To make these diagnoses, one needs to compare the normal with the abnormal fetus. Further, the use of tissue from a previable fetus may be particularly important to cancer research, studies to prevent birth defects and the development of vaccines such as those now available to prevent polio and measles.

It has, however, been argued that if we allow experiments on live fetuses who have no chance to survive, the same reasoning could be used to do experiments on other doomed members of the human species—such as terminally ill adult patients. It is argued that since both have no chance of survival and it would be wrong to do an experiment that has no therapeutic benefit for the patient on a dying adult, it would also be wrong to do such experiments on dying fetuses. However, this is really a specious argument since such an adult or his relative would have to give informed, uncoerced consent to being the subject of such an experiment. If he did, the experiment could and perhaps should be done, depending on the particular problem. Of course, the human experiment in the fetus or the aged, legally and ethically, should not be inconsistent with the treatment being used to sustain life. However, in contrast to the terminal adult, little is being done to sustain the life of these fetuses at the moment of birth. Vigorous attempts to transiently sustain such previable fetal life would be considered similar to unreasonably extraordinary attempts to keep an adult alive who is terminal and has no brain function.

If we do not provide human investigation as it pertains to fetuses, the welfare of our children and our society may be put in substantial jeopardy. Those who have the responsibility to provide needed additional safeguards for the patient subjects of human investigation should not choose to prohibit certain types of investigation in fetuses rather than to provide reasonable substitute procedures for an informed, uncoerced judgment as to whether or not it is in the best interests of the fetus and society that he or she be included as a subject of investigation. Instead of protecting fetuses from abuse, a ban on such research will seriously limit our ability to protect children from serious illness and compromise our efforts to promote optimal growth and development of fetuses and children.

The goal of research into fetal life is to preserve the right to life in its fullest sense by preventing and curing human disease. We must develop reasoned and thoughtful solutions to this problem

which will minimally limit each individual's freedom to make his own decisions about his life and his family while giving adequate consideration to his responsibilities to others in the community and to future generations.

Senator KENNEDY. What are the different kinds of experiments that require live fetuses now?

Dr. BEHRMAN. I would think very few. They tend to be those experiments in which your advance has come to the point where you move from the tissue and the cell level to the organ system, to the whole being. It is at that level where you are at a transition, where you are moving from whole animal experiments to trying something therapeutically on a human. Such experiments make up a very small percentage, I am sure, but it is the key percentage these experiments allow you to move research into something that is medical progress. So although such experiments are few they are vital and I think it is important to construct a language in a way that will allow us to make judgments as to the appropriate experiments proposed rather than to prohibit and discourage people from thinking in this direction and developing possible experiments.

Thank you, Senator.

Senator KENNEDY. Do any of you care to make a final comment?

Dr. HELLEGERS. I would like to make a couple.

First, I was trying to start off by informing the public where they believe there are certain capital issues, where the word research is bandied about, and that is just the information process.

The second is a much trickier issue, frankly. We must keep in mind someplace along the line a fairly fundamental ethical question, which is whether something wrong, in principle, can be righted by setting up procedures for judgment.

I think that is something the Commission will have to address itself to at some time. It is not quite clear to me that the institution of 122 committees of review makes a given procedure more or less acceptable in principle.

Senator KENNEDY. Dr. Behrman?

Dr. BEHRMAN. The issue really is how the Commission should give appropriate balance to the various principles involved—in other words, and I agree with Dr. Hellegers, obviously heavy weight has to be given to the principle which he is espousing here. I would say, however, that the other principles, if you will, which Dr. Robbins has referred to as justice between the generations, that other principles have to enter into the ultimate judgment and because of those other principles it would be wiser not to make a prohibition but rather to set up the way in which judgments can be made as the occasion arises to see whether the benefit is worth the risk to the individual.

Senator KENNEDY. Dr. Robbins?

Dr. ROBBINS. I would just like to make a comment here.

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I tend to agree very much with what Dr. Behrman said in his last statement but I would like to point out that although the present Federal regulations do not inhibit or prevent a great deal of the kinds of research that we have been talking about, some of the State and local ordinances do.

Indeed, in Cleveland the ordinance states that no person shall experiment upon or sell the product of human conception which is aborted, irrespective of the duration of pregnancy. This does not just deal with the fetus but includes all the things that Dr. Hellegers said are excluded.

This is not such a minor issue in the country as a whole.

Senator KENNEDY. You would all agree that kind of a ban would really be catastrophic, is that right?

Dr. HELLEGERS. Yes.

Senator KENNEDY. Mrs. Policastro do you have any concluding comment?

Mrs. POLICASTRO. I think I have said everything. I want to emphasize again that we must afford the fetus or the child protection either before it is born or after it is born.

Senator KENNEDY. I think this has been an enormously helpful and useful hearing this morning, certainly to me, and I believe to the other members of the committee who will familiarize themselves with the record.

As I stated at the outset, there has been a great deal of misconception and misunderstanding about this issue.

I think this was evident in the discussion on the floor of the U.S. Senate.

It was evident during the conference committee in which many of us participated.

I think it was evident in the reports of the results of the conference as well.

You are not the only forum in the country whose views differ on this difficult matter, but you have given a good deal of attention to it.

We have elicited a recognition that there are some broad areas of agreement about what should be continued under appropriate safeguards and consent procedures and which would continue to permit the scientific research and medical community to move ahead in their important areas for the preservation of human life; that there is an area of fundamental disagreement but that at least it is relatively narrow; and that there are important emotional and strongly held views about this particularly narrow area.

I hope these are the kinds of questions that will be examined by this committee so that they and other public-spirited groups can bring to the discussion their own views and opinions.

Again, I want to thank all of you.

At this point I order printed all statements of those who could not attend and other pertinent material submitted for the record.

[The material referred to follows:]

Statement of

Msgr. James T. McHugh

U.S. Catholic Conference

Before

the Senate Health Subcommittee

on Human Experimentation

On behalf of the United States Catholic Conference, I wish to take this occasion to add to the continuing discussion concerning research and experimentation on human fetuses and infants. In reality, the basic ethical norms governing experimentation on human beings apply as well to the unborn, the neonate and children, and the moral question is essentially the same. However, research and experimentation on the fetus is definitely linked to the question of abortion, and attitudes toward abortion tend to cloud the issue of the ethics of fetal experimentation.

At the outset it may be well to list the types of experiments and procedures that are commonly described as fetal experiments.

1. Injection of drugs or chemical substances into the fetus to monitor fetal reaction or to examine effects on the fetus after an abortion. This includes drugs or chemicals given to the mother to find out if they reach the fetus.

2. Surgical procedures on a fetus or aborted infant (viable or previable) to examine specific fetal organs.

3. Diagnostic procedures to determine the size and placement of the fetus in the womb. This includes sampling of the amniotic fluid to diagnose blood disorders, etc.

4. Tissue cultures using tissue from a living infant, a spontaneously aborted fetus or a fetus obtained by induced abortion.

5. Alterations of the RNA/DNA content so as to change the genetic structures of the embryo or fetus.

No doubt there are other possible experiments, and a careful scientific explanation of these is necessary for informed judgement. Although in vitro fertilization touches on the area of fetal experimentation, it is not included in this analysis.

Unfortunately, a clear delineation of the question of fetal experimentation has been inhibited by the very poor handling of the issue in the press, and by the rather rigid position taken by spokespersons on both sides of the debate. Reports of and reference to pending cases in Boston are a classic example of obfuscation, and these cases have been used by scientists and by the general press to create an atmosphere of panic. A brief description of these two cases may serve to clear up some of the confusion and enable us to more sharply pinpoint the ethical questions regarding experiments on human fetuses.

Presently, there are two separate cases under Grand Jury investigation. The first involves charges against one physician for the death of an aborted infant of 24-28 weeks of gestational age. The doctor is reportedly charged with manslaughter for causing the death of this infant by neglect or by some positive act that killed the infant. In this case, the essential question is whether doctors are obligated to preserve the life of a living aborted child, or whether, since abortion is legally permissible, the doctors may kill or abandon the living aborted child.

The second case involves charges that a team of four doctors violated a Massachusetts grave-robbing statute by performing experiments on aborted fetuses. 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, and is it consistent with a "broad interpretation" of the Geneva Protocol of 1925 proposed by Senator Humphrey barring the use of chemical and bacteriological substances in warfare. Innocent unborn children deserve at least as much protection as combatants in war. Moreover, such experiments practically eliminates any possible change of mind for the woman. Secondly, should not experiments on dead aborted fetuses be subject to the same ethical or legal restrictions applicable to other human cadavers? If not, why?

Unfortunately, these cases have been grouped together, and 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.

These cases are instructive because they clearly raise the question of the humanity of the fetus, and the judiciousness of ethical and/or legal restraint on experiments on the fetus.

First of all, the humanity of the fetus is assumed by all concerned, 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, ie, the elimination or treatement of disease.

However, the good intention does not resolve the problem, and thus the need for discussion of the methods used, ie, 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 ongoing effort of NIH to formulate regulations for fetal research. Other private foundations were attempting to do the same thing. However, the NIH discussions did not center on permitting or prohibiting fetal research, but on the appropriate criteria under which NIH would fund such research. For practical purposes, 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 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 is no doubt that the opinions of the U.S. Supreme Court in Wade and Bolton (January 22, 1973) have created confusion in regard to the human rights of the unborn. The Court ignored or overlooked the scientific evidence that the human fetus is a human being who possesses basic human rights. The Court offered no philosophic justification for its moral judgement that the fetus is not a person in the whole sense and represents only the potentiality of life. In the absence of a thorough examination of the evidence and a totally unsatisfactory rationale for the denial of personhood, there is no reason why anyone should accept the opinion of the Court in regard to the humanity of the fetus.

Moreover, this particular opinion of the Court has been especially destructive because in denying personhood to the fetus, it tends to reduce the human fetus to the level of experimental animal. Precisely because of this, there is a more compelling need for regulation of fetal experimentation and fetal research. A reasonable precedent can be found for such government restriction in Senator Humphrey's amendment to the Military Procurement Authorization Bill banning chemical research on beagle puppies. The Senate, on basic humanitarian motivations, voted 76-12 to bar research on dogs. Certainly, then, government can reasonably prohibit research on live human beings, before or after abortion.

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 Mr. 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 forseeable 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 diseases. 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.

Moreover, the generalizations that permeate the present discussion fail to make necessary distinctions. We must distinguish:

a) Experiments on live or dead fetuses.

b) Experiments or procedures to save this particular fetus as compared to those that will presumably increase scientific knowledge so as to help others.

c) Experiments that simply verify existing scientific facts as compared to experiments calculated to prove a scientific hypothesis.

d) Surgical interventions on the dead fetus from induced abortion to compare fetal organs with those of children or adults, or the examination of a specific organ from a spontaneously aborted fetus to find the cause of the spontaneous abortion.

e) Surgical interventions to legitimately investigate some pathology as compared to surgical interventions that allow surgical residents an opportunity to sharpen their surgical skills.

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 judgements 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, eg, 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 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 judgements 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." We urge a similar attitude in regard to fetal experiments.

Msgr. James T. McHugh
United States Catholic Conference
July 23, 1974

Senator KENNEDY. The subcommittee stands adjourned.
[Whereupon, at 12:25 p.m., the subcommittee was adjourned.]

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