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PRESIDENT'S COMMISSION ON BIOETHICS

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BEFORE THE

SUBCOMMITTEE ON
HEALTH AND THE ENVIRONMENT

OF THE

COMMITTEE ON
INTERSTATE AND FOREIGN COMMERCE
HOUSE OF REPRESENTATIVES

NINETY-FIFTH CONGRESS

SECOND SESSION

ON

H.R. 13662

A BILL TO ESTABLISH THE PRESIDENT'S COMMISSION FOR
THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIO-
MEDICAL AND BEHAVIORAL RESEARCH

AUGUST 4, 1978

Serial No. 95-147

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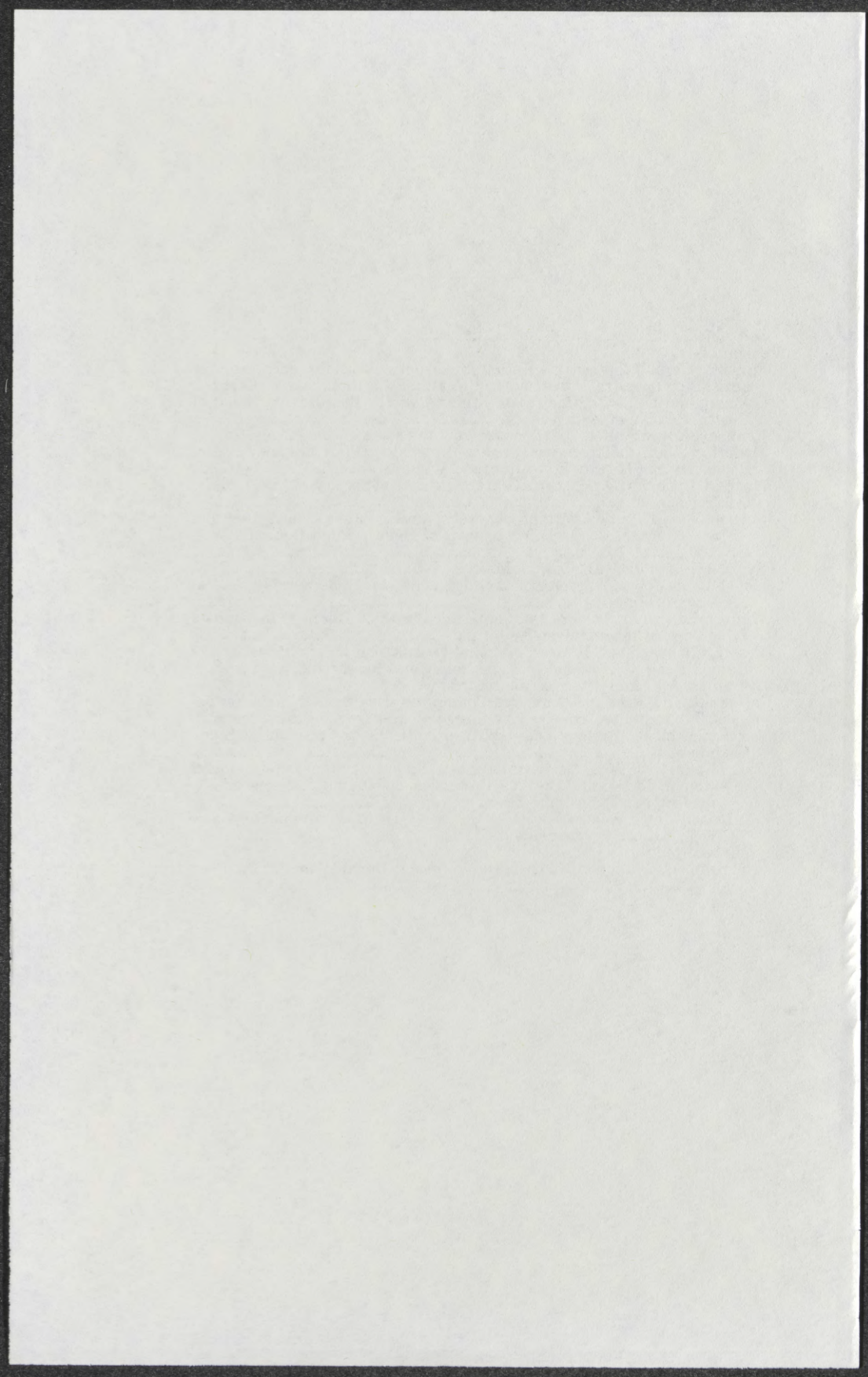
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PRESIDENT'S COMMISSION ON BIOETHICS

FRIDAY, AUGUST 4, 1978

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The subcommittee met, pursuant to notice, at 2 p.m., in room 2123, Rayburn House Office Building, Hon. Paul G. Rogers, chairman, presiding.

Mr. ROGERS. The subcommittee will come to order, please.

This afternoon the Subcommittee on Health and the Environment is holding a legislative hearing on H.R. 13662, a bill to establish the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. The proposed Commission would succeed the present National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research which goes out of existence on October 31, 1978.

The studies of the National Commission have been of great value to the Department of Health, Education, and Welfare and to Congress in developing policies which would take into account the ethical aspects of research involving human subjects and guarantee that the rights of such individuals be fully protected.

The Commission's reports concerning the conduct of research on prisoners and children, on psychosurgery, on informed consent and a variety of other difficult topics dealing with human research subjects were produced by a very able and hard-working group of outstanding individuals whose efforts deserve our highest praise.

While ethical problems connected with research on human subjects still are very much with us, our society is currently grappling with many very difficult ethical dilemmas in the practice of medicine and in the conduct of biomedical and behavioral research which go far beyond the protection of the rights of the research subject.

It is time that we begin to deal with these problems directly and as expertly as possible. Our experience with the National Commission has demonstrated that the concept of a working study commission is a valid one and has provided a model which may now be applied to the study of these areas at a time when Congress and the administration are having to make crucial policy decisions.

This afternoon we will explore the need to establish a study commission to succeed the present National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and what we should require of such a commission.

We have a distinguished group of witnesses to address this question and to comment on the proposed legislation.

Without objection the text of H.R. 13662 will be printed at this point in the record:

[Testimony resumes on p. 10.]

[The text of H.R. 13662 follows:]

95TH CONGRESS
2D SESSION

H. R. 13662

IN THE HOUSE OF REPRESENTATIVES

JULY 31, 1978

Mr. ROGERS (for himself, Mr. PREYER, Mr. SCHEUER, Mr. FLORIO, Mr. MAGUIRE, Mr. MARKEY, Mr. WALGREEN, Mr. CARTER, Mr. BROYHILL, and Mr. SKUBITZ) introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

A BILL

To establish the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.

- 1 *Be it enacted by the Senate and House of Representa-*
- 2 *tives of the United States of America in Congress assembled,*
- 3 That, effective November 1, 1978, part A of title II of the
- 4 National Research Act (relating to the National Commission

I—E

1 for the Protection of Human Subjects of Biomedical and Be-
2 havioral Research) is amended to read as follows:

3 "PART A—PRESIDENT'S COMMISSION FOR THE STUDY OF
4 ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND
5 BEHAVIORAL RESEARCH

6 "ESTABLISHMENT OF COMMISSION

7 "SEC. 201. (a) There is established the President's
8 Commission for the Study of Ethical Problems in Medicine
9 and Biomedical and Behavioral Research (hereinafter in this
10 part referred to as the 'Commission') which shall be com-
11 posed of fifteen members appointed by the President. The
12 members of the Commission shall be appointed as follows:

13 "(1) Five of the members shall be appointed from
14 individuals who are or were distinguished in biomedical
15 or behavioral research.

16 "(2) Five of the members shall be appointed from
17 individuals who are or were distinguished in the prac-
18 tice of medicine or otherwise distinguished in the provi-
19 sion of health care.

20 "(3) Five of the members shall be appointed from
21 individuals who are distinguished in the fields of ethics,
22 theology, law, the natural sciences (other than a bio-
23 medical or behavioral science), the social sciences, the
24 humanities, health administration, government, and
25 public affairs.

1 No individual who is a full-time officer or employee of the
2 United States may be appointed as a member of the Commis-
3 sion. A vacancy in the Commission shall be filled in the
4 manner in which the original appointment was made.

5 “(b)(1) Except as provided in paragraphs (2) and (3),
6 members shall be appointed for terms of four years.

7 “(2) Of the members first appointed—

8 “(A) five shall be appointed for terms of three
9 years, and

10 “(B) five shall be appointed for terms of two
11 years,

12 as designated by the President at the time of appointment.

13 “(3) Any member appointed to fill a vacancy occurring
14 before the expiration of the term for which his predecessor
15 was appointed shall be appointed only for the remainder of
16 such term. A member may serve after the expiration of his
17 term until his successor has taken office.

18 “(c) The Chairman of the Commission shall be appoint-
19 ed by the President, by and with the advice and consent of
20 the Senate, from members of the Commission.

21 “(d)(1) Members of the Commission shall each be enti-
22 tled to receive the daily equivalent of the annual rate of basic
23 pay in effect for grade GS-18 of the General Schedule for
24 each day (including travel time) during which they are

1 engaged in the actual performance of duties vested in the
2 Commission.

3 “(2) While away from their homes or regular places of
4 business in the performance of services for the Commission,
5 members of the Commission shall be allowed travel expenses,
6 including per diem in lieu of subsistence, in the same manner
7 as persons employed intermittently in the Government serv-
8 ice are allowed expenses under section 5703 of title 5 of the
9 United States Code.

10 “DUTIES OF THE COMMISSION

11 “SEC. 202. (a) The Commission shall, on an on-going
12 basis, conduct studies of the legal, ethical, and social implica-
13 tions of—

14 “(1) the allocation of Federal resources for bio-
15 medical and behavioral research and for health care
16 delivery;

17 “(2) the requirements for informed consent to par-
18 ticipation in research projects and to otherwise undergo
19 medical procedures;

20 “(3) the establishment of a uniform definition of
21 death;

22 “(4) counseling and testing for genetic diseases;

23 “(5) the differences in the availability of health
24 services as determined by the income or residence of
25 the persons receiving the services;

1 “(6) the requirements and guidelines applicable to
2 clinical trials;

3 “(7) the establishment of standards of efficacy ap-
4 plicable to medical procedures performed on humans;

5 “(8) human in-vitro fertilization; and

6 “(9) such other matters relating to medicine or
7 biomedical or behavioral research as the President may
8 designate for study by the Commission.

9 “(b)(1) Upon the completion of each study undertaken
10 by the Commission, it shall report its findings to the Presi-
11 dent and the Congress.

12 “(2) Not later than November 1 of each year the Com-
13 mission shall report to the President and the Congress on the
14 activities of the Commission during the fiscal year ending on
15 September 30 of such year. The Commission may include in
16 such report such recommendations for legislation and admin-
17 istrative action as it deems appropriate.

18 “(3) The Commission may at any time publish and dis-
19 seminate to the public reports respecting its activities.

20 “ADMINISTRATIVE PROVISION

21 “SEC. 203. (a) The Commission may for the purpose of
22 carrying out this part hold such hearings, sit and act at such
23 times and places, take such testimony, and receive such evi-
24 dence, as the Commission may deem advisable.

1 “(b) The Commission may secure directly from any de-
2 partment or agency of the United States information neces-
3 sary to enable it to carry out this part. Upon request of the
4 Chairman of the Commission, the head of such department or
5 agency shall furnish such information to the Commission.

6 “(c) The Administrator of General Services shall pro-
7 vide to the Commission on a reimbursable basis such admin-
8 istrative support services as the Commission may request.

9 “(d)(1) The Commission may appoint and fix the pay of
10 such staff personnel as it deems desirable. Such personnel
11 shall be appointed subject to the provisions of title 5, United
12 States Code, governing appointments in the competitive ser-
13 vice, and shall be paid in accordance with the provisions of
14 chapter 51 and subchapter III of chapter 53 of such title
15 relating to classification and General Schedule pay rates.

16 “(2) The Commission may procure temporary and inter-
17 mittent services to the same extent as is authorized by sec-
18 tion 3109(b) of title 5 of the United States Code, but at rates
19 for individuals not to exceed the daily equivalent of the
20 annual rate of basic pay in effect for grade GS-18 of the
21 General Schedule.

22 “(3) Upon request of the Commission, the head of any
23 Federal agency is authorized to detail, on a reimbursable
24 basis, any of the personnel of such agency to the Commission
25 to assist it in carrying out its duties under this part.

1 “(e) The Commission shall not disclose any information
2 reported to or otherwise obtained by the Commission which
3 is exempt from disclosure under subsection (a) of section 552
4 of title 5, United States Code, by reason of paragraphs (4)
5 and (6) of subsection (b) of such section.

6 “(f) Section 14 of the Federal Advisory Committee Act
7 shall not apply with respect to the duration of the Commis-
8 sion.

9 “AUTHORIZATION OF APPROPRIATIONS

10 “SEC. 204. To carry out this part there are authorized
11 to be appropriated \$4,000,000 for the fiscal year ending Sep-
12 tember 30, 1979, \$4,000,000 for the fiscal year ending Sep-
13 tember 30, 1980, \$4,000,000 for the fiscal year ending Sep-
14 tember 30, 1981, and \$4,000,000 for the fiscal year ending
15 September 30, 1982.”.

Mr. ROGERS. Our first witness this afternoon is Dr. Kenneth J. Ryan, who is the Chairman of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and professor of Obstetrics and Gynecology, Harvard Medical School, Boston Hospital for Women.

We welcome you to the committee. We appreciate your presence, and your statement will be made a part of the record in full, and you may proceed as you desire.

STATEMENT OF KENNETH J. RYAN, M.D., BOSTON, MASS., ACCOMPANIED BY MICHAEL YESLEY, STAFF DIRECTOR, NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

Dr. RYAN. Thank you, Mr. Chairman, members of the committee. I would like to point out that I am speaking as an individual.

Mr. ROGERS. We had understood that you would appear before us to express your personal viewpoint, and not necessarily those of the National Commission or of Harvard.

Dr. RYAN. I am pleased to be given the opportunity to express my views on the creation of a Presidential Commission.

As you have already stated, the present National Commission for the Protection of Human Subjects, which has been in existence for 4 years, will be terminated in October of this year, and it filled an apparent need that is well documented by the legislative history that preceded its creation.

Anyone who was in Congress at the time of the debates over fetal research must realize the emotional nature of the debates that occurred.

The mandate for the Commission included specific studies in areas such as research on fetuses, prisoners, children, the institutionalized mentally infirm, the medical practice of psychosurgery, the function of institutional review boards, ethical principles governing research, and health services provided by the Department of HEW, as well as the impact of technological advances on society.

Congress added two additional requests for assistance from the Commission after its formation, one on freedom of information and the other on the swine flu program.

The Commission has also consulted with CIA on its research guidelines.

I have brought a summary of the Commission's activities for the record, and I believe copies have been submitted to the committee. [See p. 13.]

Mr. ROGERS. Yes. Thank you.

Dr. RYAN. A judgment of the quality of the Commission's work can only be made over time by Congress and the people, but I believe its utility can be measured now by the translation of most of its recommendations into regulations by the Department of HEW.

It is also my personal belief that these regulations have more legitimacy and credibility than they would have had were they generated by HEW itself.

I believe there is a need for a successor body; and in a pending report which the Commission was asked to prepare for the Con-

gress—this report is on the Impact of Advances in Technology on Society—this will undoubtedly be part of the final recommendation.

From a study that includes a report of a panel of 121 experts from diverse fields of interest, a national opinion poll done for us by the Harris Corp., and a scholarly colloquium, we have been advised that there is an urgent need for programs that can assess the impact of technical advances and the need for facilitating public information and public participation before policy decisions are made. A commission could serve this function.

The strengths of this mechanism can be optimized by having diverse membership, not dominated by science or medicine, and a commission which is independent from any specific governmental agency or private institution.

The strongest component of the present Commission's operation was the requirement that its recommendations be published in the Federal Register for additional public comment, and that the head of the agency to whom the recommendation was sent had to respond in a fixed period of time.

I urge the inclusion of such a provision in any bill establishing a new commission.

I might say, parenthetically, that the only time where Commission recommendations have been neglected was when there was no requirement in the mandate that we be responded to. One of them was brought up this morning, and that is the Task Force on Compensation, which was an in-house task force that worked for 2 years, published a report, the Commission reviewed it, urged the Secretary to put it into force, so that there would be some policy on compensation for people harmed by research, and to my knowledge no response has come of that as yet.

The other interaction that we had was with the CIA, and there, on their initiative, we reviewed for them their guidelines for the conduct of human research under their auspices. We made specific recommendations, but, again, to my knowledge, these have not been followed up by any governmental agency or body of government. There was no requirement to do so.

I would recommend a small commission. I don't know that there is anything magical about the numbers, but having worked with a group of 11, I would think that anything much larger than that would be difficult.

I would recommend provision for nonvoting representation from those Federal agencies most clearly affected, and those that conduct research in which there are ethical questions being raised, such as HEW, the Department of Defense, that has a provision for consideration of this, the CIA, the Veterans Administration and so on.

I do not feel that an advisory board within any specific agency can serve the same function, for many of the reasons I have described above. I think individual agencies need such ethical advisory boards, but I don't think that they would have the independence or the requirement that the head of the agency respond.

One also needs a strong staff. Mr. Yesley, our staff director is here with me. We had a staff about equivalent to the size of the Commission. We could not have done our work without these very

skilled individuals. By incorporating a strong staff, a full-time staff, into its operation, by regular meetings at no less than monthly intervals—the Commission has met, sometimes more than once a month when we were under pressure to get a report out—by having the opportunity to have scholarly studies performed, to go on site visits—as we did to prisons and to institutions for the mentally infirm—to hold public hearings—and I might say, the Commission has never denied anyone the opportunity to speak before it whenever we have advertised these public hearings—and by holding open meetings as we are required to do under the sunshine laws, I think all of these things would create a commission which would exemplify the democratic process at its best.

I would like to add in concluding that I don't think such a commission should have regulatory or oversight functions. I do not believe that private citizens functioning in this capacity could do so effectively.

And I would like to also say in regard to the matters discussed this morning that the Commission was not requested to consider in-vitro fertilization. Our mandate was full and it was for that reason we did not. None of the present regulations or the present rules under which it is done or not done came from our deliberations.

That is the end of my prepared testimony, Mr. Chairman. I would be willing to answer any questions.

[Testimony resumes on p. 22.]

[The report referred to by Dr. Ryan follows:]

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

August 1, 1978

SUMMARY OF ACTIVITIES

The National Commission for the Protection of Human Subjects was established in 1974 under Public Law 93-348. Since coming into existence, the Commission has forwarded to Congress and to the Secretary of Health, Education and Welfare six reports with recommendations on various aspects of biomedical and behavioral research. These include four reports and recommendations on the circumstances under which investigators may include as research subjects human fetuses, children, prisoners, and patients institutionalized as mentally ill or retarded. In addition, the Commission has issued reports and recommendations on conditions under which psychosurgery may be performed, and the disclosure under the Freedom of Information Act of information contained in applications for research grants and contracts. Four more reports are in the final stages of development: (1) a statement of the basic ethical principles and guidelines for the conduct of biomedical and behavioral research with human subjects (the Belmont Report); (2) recommendations for the performance of Institutional Review Boards (which provide ethical review of proposed research at the local level); (3) recommendations for the protection of patients receiving health services under DHEW programs (such as the Indian Health Service, Community Mental Health Centers, Medicaid and Medicare); and (4) the "Special Study," a report on the implications of advances in biomedical and behavioral technology.

The Secretary of Health, Education and Welfare is required under Public Law 93-348 to publish the recommendations of the Commission within 60 days of receipt, and to publish his proposed regulatory response for implementing those recommendations within an additional 180 days. If the Secretary decides not to adopt the Commission's recommendations on a particular topic, he must publish his reasons for declining to do so.

In preparing its reports, the Commission has followed a systematic approach that includes collection of empirical data and scholarly analysis of the scientific, legal, moral and social issues. In addition, the Commission has held public hearings to solicit opinions from members of professional societies, representatives of federal agencies, public interest groups and concerned individuals, and convoked a Minority Conference to assure that it would receive the views of minorities on topics under consideration. The Commission members also went on site visits to prisons, facilities for the mentally retarded, and an Indian Health Service Clinic. Finally, the Commission has conducted extensive deliberations at open meetings, leading to the adoption of its recommendations. Brief summaries of the Commission's published reports follow.

Research on the Fetus

The Commission affirmed its belief that the fetus, as a human subject, should be treated with respect and dignity regardless of its life prospects. Because some information that is in the public interest and that provides significant advances in health care can be attained only through the use of the human fetus as a research subject, however, the Commission recommended

that research involving the human fetus should be conducted and supported under limited conditions and with careful ethical review.

The Commission recommended that therapeutic research involving the fetus may be conducted if it conforms to appropriate medical standards and has been approved by an Institutional Review Board. Nontherapeutic research directed toward the fetus in utero may be conducted if: (1) the knowledge to be gained is important and cannot be obtained by alternative means, (2) appropriate investigations on animals have been completed, (3) the research presents no more than minimal risk, and (4) the research has been approved by an Institutional Review Board; if such research is in anticipation of abortion and there are problems in applying these guidelines, it may be conducted if approved by a national ethical advisory body. Nontherapeutic research during abortion or directed at the nonviable fetus ex utero must satisfy three additional guidelines: (1) the fetus must be less than 20 weeks gestational age, (2) no significant procedural changes may be introduced into the abortion procedure in the interest of research alone, and (3) no intrusion should be made that alters the duration of fetal life. All research involving the fetus should require the consent of the mother and the absence of any objection by the father, in view of his possible ongoing responsibility for the care of the fetus.

The Commission transmitted its report and recommendations on research involving the fetus on May 21, 1975. The recommendations were subsequently incorporated into DHEW regulations without significant change (45 CFR 46 subpart B).

Research Involving Prisoners

The Commission recommended that prisoners should not be the subjects of research that is unrelated to their status as prisoners and is of no benefit to them (e.g., drug testing, research involving infectious diseases) unless there is an important social and scientific need and there are compelling reasons for involving prisoners in the research. In addition, a prison proposed as the site for such research should meet standards regarding health and safety conditions, free communication with persons outside the prison, prisoner representation on review boards, and effective grievance procedures. Further, research participation should not be a factor in parole considerations.

The Commission recommended that research designed to study the causes and effects of prison life may be conducted provided the risks are minimal and there are adequate procedures to assure informed consent, protect the subjects' privacy, and maintain confidentiality of data. In addition, research on new or accepted methods of diagnosis or treatment that are intended to improve the health or well-being of the individual prisoners participating as subjects may be conducted providing the research has undergone appropriate review.

Central to the Commission's recommendations was the provision that all research involving prisoners should undergo review by an Institutional Review Board that includes among its members prisoners or prisoner advocates. Further, before any research is performed in a prison, the head of the responsible federal agency should determine that the investigators are competent and the research facilities are sufficient and suited to the particular research project.

The Commission's recommendations were transmitted on October 1, 1976 and were adopted by the Secretary of Health, Education and Welfare in proposed rule-making on January 5, 1978, with the modification that "nontherapeutic" research would not be permitted at all unless it involves no more than minimal risk and is designed to study the possible causes, effects and processes of incarceration, or the nature of prisons as institutional structures and of prisoners as incarcerated persons.

The Use of Psychosurgery

Based upon the data collected regarding the potential benefit of at least some forms of psychosurgery and the apparent absence of significant long-term risks, the Commission concluded that an absolute ban on all psychosurgical procedures was unwarranted. However, because of the innovative nature of the surgery and the possibility that the intervention might be misused, the Commission recommended a number of procedures to protect the rights of individual patients.

The Commission recommended that psychosurgery should never be performed against the wishes of an adult patient (even one adjudicated mentally incompetent) or a mature minor. In addition, it recommended that such surgery be performed only after a review board, specially approved by DHEW for the purpose, has reviewed the proposed procedure and determined: (1) that the surgeon and his team are competent to perform the operation; (2) that adequate pre- and postoperative evaluations will be performed; (3) that the procedure is medically indicated for each particular patient; and (4) that

each patient has given valid informed consent. In the case of patients unable to give informed consent and those who are minors, prisoners or involuntarily confined mental patients, psychosurgery should be performed only after approval by a court of competent jurisdiction and a finding by a national psychosurgery evaluation board that the proposed procedure has demonstrable benefit in the treatment of particular symptoms. Such a finding would be based on the performance of the procedure on adults who are able to consent and not involuntarily confined.

The Commission also recommended that a registry be established for collection of information regarding every psychosurgical operation performed in the United States, so that demographic characteristics of patients undergoing such surgery will be available and, in addition, to facilitate the accumulation of data regarding the safety and efficacy of various forms of psychosurgical interventions.

The Commission's report and recommendations on the use of psychosurgery were transmitted on March 14, 1977 and printed in the Federal Register for comment on May 23, 1977. DHEW has not yet issued proposed regulations on psychosurgery.

Research Involving Children

The Commission concluded that the participation of children in research is important to safeguard the health and well-being of all children and that such research can be conducted in an ethical manner. It recommended that proposed research involving children be reviewed by an Institutional Review Board

to determine that: (1) the research methods are suited to the objectives of the research and methods of the discipline; (2) relevant studies have been conducted on animals and adult humans, as appropriate; (3) risks are minimized to the extent possible; (4) the privacy of subjects and their families, and confidentiality of data will be maintained; and (5) subjects will be selected fairly. If the research includes an intervention that presents more than minimal risk but holds out the prospect of direct benefit for the subjects, the risk should be justified by the anticipated benefit. If the intervention presents more than minimal risk and does not hold out the prospect of direct benefit, the risk should represent only a minor increase over minimal risk, and the anticipated knowledge to be gained should be of vital importance for understanding the subjects' disorder. Research that cannot satisfy the foregoing conditions may under limited circumstances be conducted if approved by a national ethical advisory body.

The Commission further recommended that in addition to the consent of a child's parents or guardian, the agreement of the child also be required if the child is able to understand the procedures to be used and to make a choice regarding his or her participation. As a guideline, the Commission recommended that the assent of all children aged seven or older be required and that the objection of a child of any age be binding (unless the research involves an intervention that holds out the prospect of direct benefit to the child's health and is available only in the context of research).

The Commission transmitted its report and recommendations on research involving children to the Secretary, DHEW, on September 29, 1977; it was printed in the Federal Register for public comment on January 13, 1978. DHEW has not yet responded with proposed regulations.

Research Involving Those Institutionalized as Mentally Infirm

The Commission observed that in no other area of its mandate was the need for research as clearly manifest than in the care and treatment of mental retardation and conditions known as mental illness. At the same time, individuals institutionalized as mentally infirm are especially vulnerable to exploitation. Thus, although research is absolutely essential to improving their condition, the protection of their rights, welfare and dignity is equally important.

The Commission noted that the category of persons comprehended in this report includes individuals with a wide range of capacities for self-determination as well as individuals whose capacities in this regard fluctuate over time. The Commission recommended, therefore, that no such persons who cannot give informed consent be involved in research unless it is relevant to their condition, and that no person institutionalized as mentally infirm be included in research over his or her objection unless the research involves a therapy not otherwise available and a court specifically authorizes that person's participation. Further, no institutionalized individual should be approached to participate in research unless a person responsible for his or her care determines that such participation will not interfere with such care.

Because institutionalized individuals may lack the capacity for informed consent but nevertheless be able to understand what sort of procedures will be involved in a research project and to make a choice regarding participation, the Commission recommended that the "assent" of such persons be sufficient for research that presents no more than minimal risk and that is

relevant to their condition. Assent of such patients should also be sufficient to authorize research involving a therapy from which the subjects may derive direct benefit.

Research presenting more than minimal risk and no foreseeable benefit to the subjects may involve institutionalized persons if the risk is no more than a minor increase over minimal, the anticipated knowledge is of vital importance for understanding or alleviating the disorder or condition of the subjects, and the subject does not object. For this category of research, the Commission recommended that the review board appoint a consent auditor to determine whether each potential subject consents, assents or objects to participation. Finally, the Commission recommended that a national ethical advisory body review research proposals that the local review board believes should be supported but cannot approve under the constraints of the previous recommendations.

The Commission transmitted its report and recommendations on those institutionalized as mentally infirm on February 8, 1978; it was published in the Federal Register for public comment on March 17, 1978.

Disclosure of Research Information Under the Freedom of Information Act

Not contained in the National Research Act was a request, made subsequently by Congress, for the Commission to recommend the extent to which information contained in research grant applications should be made available under the Freedom of Information Act. After reviewing the arguments pro and con, and receiving the opinions of many investigators, professional societies and public interest groups, the Commission determined that information contained in applications for research grants and contracts should be available at the time of funding, but not before. The Commission based this recommendation by balancing considerations of the investigators' right to privacy against the public interest in knowing what research is being conducted with federal support. The resolution of these competing claims, it was determined, came at the point that federal funds are committed to a particular research project. At that time, the investigator's interest in privacy must give way to the public interest.

Mr. ROGERS. Thank you very much, Dr. Ryan. Mr. Yesley, we are also pleased to have you with us.

Dr. Carter?

Mr. CARTER. Thank you, Mr. Chairman.

Are there adequate educational programs in our universities on bioethics at the present time?

Dr. RYAN. They are beginning. It is a new field. The Commission stimulated a lot of interest. We had graduate students coming and studying the operation of the Commission as part of their thesis, so it is a field that is developing; and in one of the recommendations we are making to the Secretary, we are urging support for education, both public and professional education, in these areas.

Mr. CARTER. Thank you, sir.

How frequently and in what form should the proposed commission issue its reports?

Dr. RYAN. It is a difficult question to respond to.

We were given a deadline for the fetal research report and that was 4 months, and we met it. We were given an initial life of 2 years, and it was extended by the Congress twice.

I think the Commission should be under some pressure to get on with its work. One of the things that I think helped us was the fact that we had specific things to do and a specific time span in which to do it.

There are some of these issues which could be discussed and debated without a limit of time. I cannot respond specifically to that. It would depend on the questions being asked.

Mr. CARTER. Do you think the Senate bill is better, in that it provides for continuity of the Commission and the House bill does not?

Dr. RYAN. I can't speak for all the Commissioners, but we have been working long and hard in this endeavor and we would like not to be a lame-duck body. The Commission has to prepare a staff, develop a technique of operation, and it would be inappropriate to ask the present group to start gearing up when we were going to be replaced very soon.

I think most of the people have worked long and hard and really would look forward to being relieved of their responsibility.

Mr. CARTER. I want to thank you for a very fine statement. Thank you, Mr. Chairman.

Mr. ROGERS. Thank you.

Mr. Preyer?

Mr. PREYER. Thank you, Dr. Ryan, for your statement.

I understand that you feel this Commission should not have any regulatory authority?

Dr. RYAN. That is correct; I do not feel a commission should have regulatory authority, that is this type of commission.

Mr. PREYER. I am glad to hear that. I think when we deal with Federal regulations of ethics we are walking on some pretty difficult ground.

One other question that concerned me is how the recommendations of such a Commission would fall in line with court decisions. Presumably, you would deal with questions on which there will be judicial decisionmaking, ethical issues, moral issues, involving death, for example.

Would any of the Commission's recommendations be binding in a way that would put you in conflict with judicial decisions?

Dr. RYAN. We had three attorneys on our Commission. Our staff director is an attorney, and part of the work which the Commission would ask to have done would be a legal review of the matters that we were studying.

We were very much aware of State laws and Federal laws that pertain to the areas under consideration, such as the age for majority consent for medical care and whether that was appropriate for a similar age to consent for research, participation in research, things of that nature.

But in all of the areas that we looked at, the legal aspects were an important one and that is why it is so important to have diverse membership and a very qualified staff, so that we are not making recommendations that are in conflict with existing statutes.

Mr. PREYER. Thank you very much. I think it is an excellent statement.

Mr. ROGERS. Thank you.

Mr. Scheuer?

Mr. SCHEUER. Thank you, Professor Ryan. We did enjoy your statement and benefited from it.

I have no questions directly relating to your testimony, which was very clear and to the point.

I do have a question for you though. A relative of mine in his eighties just passed away a few months ago—cancer of the bladder—and it was a painful, horrifying experience for those around him. He was brain-dead for several days before he finally passed on, and it was an extraordinarily trying experience for his family.

It seems to me that society ought to have a way of short-circuiting that and there ought to be a way of terminating life when brain function has terminated.

Has your Commission investigated the subject of death with dignity?

Dr. RYAN. That was not part of the existing Commission's mandate, and it did not discuss those matters.

Mr. SCHEUER. I don't suppose we ought to get into it today. Thank you very much, Mr. Chairman.

Mr. ROGERS. Mr. Maguire?

Mr. MAGUIRE. I have no questions.

Mr. ROGERS. I think, if you could submit for the record your views about some specific provisions in the Senate and House bills which you think are good or are ill advised, it would be appreciated. You might also let us know what problems you think a new Commission should address, and perhaps you could let us know whether you think the issues as set forth in the bills are those that are adequate to cover the field, and whether eight issues are too many or not enough.

[The following information was received for the record:]

HARVARD MEDICAL SCHOOL

KENNETH J. RYAN, M.D.
*Kate Macy Ladd Professor of
 Obstetrics and Gynecology
 Chairman of the Department*



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August 8, 1978

Congressman Paul G. Rogers
 Chairman
 Subcommittee on Health and the Environment
 of the Committee on Interstate and Foreign
 Commerce
 Room 2415
 Rayburn House Office Building
 Washington, DC 20515

Subject: HR 13662
 "President's Commission for the
 Study of Ethical Problems"

Dear Congressman Rogers:

In response to your request at the Public Hearings on HR 13662 for a written statement to be submitted later, I am enclosing replies to the specific questions you posed.

- 1.) A Comparison of the House (HR 13662) and Senate (S. 2579) Versions for the Creation of a Presidential Commission
 There are more similarities than differences between the House and Senate bills and the comments listed below can easily be accommodated within the common concept of an independent advisory Commission.
 - a.) The Name of the Commission
 The choice of a name for the Presidential Commission depends on whether it is more important to designate the new body as a continuation of the preceding National Commission or whether it is more important to emphasize its new role and mandate and thus specify ethics and medicine as well as research in its title. While a minor matter, I prefer the House version which changes the name. As will be detailed below, it would be difficult to continue the present Commission during the transition period in any case.
 - b.) Composition of the Members of the Commission
 In establishing the composition for a new Commission, I would recommend a total number of no more than 11 (Senate

version) in preference to the larger more unwieldy number of 15 in the House Bill. The composition of the membership is well set out in the present National Commission and in the Senate version of the successor body. This establishes a majority of six members who are not involved in biomedical or behavioral research. I recommend further that the remaining five members could be selected from the three disciplines of biomedical research, behavioral research and the practice of medicine. For the other six members, selection should come from ethics (no more than two), law (no more than two) the humanities (sociology or history of science) and public affairs.

It is clear that the membership could not possibly be large enough to include experts in every area of concern to the Commission and still be a workable size. On the other hand, the Presidential Commission can easily draw on consultants to obtain facts and opinions relevant to the specific matter being considered at any given time, much as the National Commission has done in the past. In addition, the staff can complement as well as reinforce the areas of competence of the Commission members.

I recommend having nonvoting ex officio advisors to the Commission from the Department of Health, Education, and Welfare, CIA, FBI, VA and other federal departments involved in human research as suggested in the Senate Bill. This would facilitate communication and can easily be accomplished since each such department now has or should have individuals responsible for studies involving human research. The present Commission worked with individuals from the Defense Department and CIA at their request on matters related to human research.

I do not recommend that the present Commission be called upon to serve on an interim basis since, as a lame duck group, they would be in an awkward position to recruit staff and establish procedures for their successors. In addition, two of our Commissioners have unfortunately died and essentially all of our staff will have transferred to other positions since there has been no job security during the period in which the Commission's future has been considered. It is possible that former Commissioners or staff could be called upon to consult with the new Commission should this seem desirable.

In general, I prefer the Senate version of composition of members and the House version which does not require continuation of the present Commission members.

c.) Duties of the Commission

Some combination of the House and Senate versions of the mandate for the Commission would be appropriate since they overlap

considerably. Any ambiguity on a regulatory role should be removed. I recommend no oversight on regulatory function. It would be a courtesy to avoid the topics chosen by the DHEW Ethical Advisory Board for the study of In Vitro Fertilization and Clinical Research until they prepare a report on these issues. The Congress could add these same subjects for review later if additional work appears to be needed.

d.) Reports of the Commission

The single most important provision for a Presidential Commission would be the requirement that its recommendations be published in the Federal Register for public comment and that a written response from the head of the appropriate federal agency be required within a fixed period as is the case in the Senate version of the bill and as is the case for the present National Commission. There is little hope that Commission reports will be considered on a timely fashion without this provision.

The National Commission will recommend to the Congress, in an upcoming report on Institutional Review Boards, that DHEW be the lead agency in all regulations on federal guidelines for human research. If this is accepted, most interaction of a Presidential Commission would be with the Secretary of DHEW. It remains to be seen whether the Congress via legislation or the President by executive order, favorably consider the upcoming National Commission suggestion that would require all federal agencies and departments to establish regulations for the conduct of human research along the model now used by DHEW. If this is accomplished, there would be little need for a Presidential Commission to interact with other individual departments on this matter unless exceptions to standard practice were requested or consultation was sought by an individual department. The federal departments and agencies and the Congress could thereafter work out mechanisms for oversight and compliance with such common regulations. I do not believe a Commission could effectively serve an oversight function. The upcoming National Commission Report on Institutional Review Boards does, however, include suggestions on how accreditation and compliance responsibility can be made uniform and centralized for all federal agencies. This recommendation is in accord with a report of the Commission on Federal Paperwork.

e.) Confidentiality

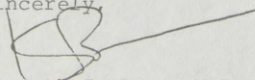
The Senate Bill has a section on confidentiality which should be reviewed for inclusion in any final legislation.

2.) Problems of a New Presidential Commission

Any successor body to the National Commission will have as a guide the precedent of a format and style of operation which has proven reasonably effective. The major challenges will be to organize an effective full-time staff, to establish a timetable for reporting out specific studies and to develop a working relationship among Commission members which will allow the development of useful recommendations. There is a period of education required for the Commission members to achieve some common base of knowledge and to develop a process in dealing with ethical matters and public policy for a very diverse constituency.

I thank you for the opportunity to offer these suggestions.

Sincerely,


Kenneth J. Ryan, M.D.

Mr. ROGERS. I think you have articulated for us your concern about an in-house ethical commission and I presume you think that is not the way to proceed.

Dr. RYAN. I don't think it will serve the functions that we have been describing.

I think there is a role for the ethical advisory boards and they have, in fact, been in existence.

Mr. ROGERS. But are there problems for which we will need a commission that will cut across all agencies and departments, which simply could not be effectively addressed by an in-house ethical advisory committee?

Dr. RYAN. We will be issuing a report in September, which will go to the Secretary and to your committee as well, Mr. Rogers, which will cover some of these concerns about how various Federal agencies should relate one to another with respect to guidelines, ethical guidelines, covering research.

In point of fact, we agree with the Paperwork Commission, which also made a recommendation in this regard, and I think the interaction between any body deliberating on ethics of research in various Federal agencies can only come from an independent body. It would be very difficult if it were in only one agency, I believe.

Mr. ROGERS. I think the committee shares that concern. I am not sure that that is understood by the Office of Management and Budget. From the pressure that we are getting, I am not sure they understand the difference between an in-house advisory committee and an independent Presidential Commission which would go across the board in making recommendations to the Congress and to the President.

I presume, too, in the law we could make sure of the proper membership balance. One cannot always assure that balance in an in-house commission. In fact, I think there is only one theologian on the advisory group of HEW, and I say that is fine. I agree with you, that each agency should have an advisory board. However, I don't think it would necessarily address universal problems adequately.

Dr. RYAN. If I may just add, as the Commission has been in existence for some time, the Congress has had problems that have come before it that they themselves have directed to our Commission, and I think the Congress will have to make the determination of whether that is useful to them, having a sitting commission that is trained to consider some of these problems and can give them an appropriate report.

Mr. ROGERS. I would ask unanimous consent that this comparison prepared by the staff be put in the record: "Comparison of Ethical Advisory Board With a National or Presidential Study Commission."

Without objection it is so ordered.

[The following information was submitted for the record:]

COMPARISON OF ETHICAL ADVISORY BOARD
WITH A NATIONAL OR PRESIDENTIAL STUDY COMMISSION

CMB and others within the Administration argue that a National or Presidential Study Commission to address ethical problems in medicine and Biology is redundant since an ethical advisory board exists within DHEW. Below is a brief comparison of the significant differences between a study commission and the DHEW ethical advisory board.

DHEW Ethical Advisory Board	Presidential Study Commission
1. Mandates at discretion of Secretary of DEHW (no Congressional input).	Mandates directed by Congress or the President.
2. Advisory to Secretary of DHEW only.	Advisory to the President and Congress.
3. Could only deal with DHEW matters.	Could address issues which involved any Federal agency.
4. Would deal with details of Departmental policy, including DHEW regulations and a review of individual grants, in addition to broad policy issues.	Would deal principally with broad policy issues, could review agency policy but would not review individual projects.
5. Would be just another DHEW advisory Committee.	Would have public credibility and visibility.
6. It's recommendations would affect only DHEW, could be ignored by other agencies or Congress.	It's recommendations would have government-wide effect.
7. No guarantees of balanced membership. Present board seven M.D.'s, three lawyers, one Ph.D. and one theologian.	Congress has input into balance of membership, as specified in authorizing statute.
8. Ethical Advisory Board is more likely to be subject to Departmental pressures than an independent body.	Comission would be independent of any Federal agency.

Mr. ROGERS. Are there any other matters you think we should be alert to as we consider this legislation?

Mr. SCHEUER. Mr. Chairman, may I ask a question, assuming you are finished?

Mr. ROGERS. Yes. Yes, I am.

Mr. SCHEUER. Can you see any legal, ethical or social implications that would be appropriate for this Commission to look into in comparing today's tertiary, hospital-based, high-technology-based, sickness-care system, with perhaps an alternative health-care system that would be neighborhood based, outpatient care, ambulatory care based, low technology, counseling oriented.

Dr. RYAN. I am sorry.

Mr. SCHEUER. What I mean is, there are two quite different models of delivering health care. One depends on tertiary hospital beds, CAT scanners, open-heart surgery, kidney dialysis machines, and a lot of specialties, and most of it in hospital beds. It is a sickness-care system. Another is a preventive health-care system that would have as its focus preventive health care delivered in the neighborhood, with a lot more paraprofessional input, counsel input, essentially an outpatient, ambulatory-care model.

Do you see any ethical implications with such a dramatic contrast of organizing health care?

Dr. RYAN. It is hard to put everything in an ethical perspective, but let's put it this way: I think that there is a responsibility for society to address that, and through the legislature that is the Congress, because there are things that you can do which will, in fact, influence the extent to which we have unneeded and inappropriate duplication of tertiary care centers.

Mr. SCHEUER. Would you think that subject would be an appropriate subject for this Commission?

Dr. RYAN. The question of assigning priorities in the health-care field, I think, would be.

Mr. SCHEUER. How about the American lifestyle and the health effects of our lifestyle. Do you see an ethical and moral implication there that would merit study by this Commission as to what extent the Government would jawbone people into changing behavior in terms of alcohol, tobacco, exercise, drugs, violence, and things that directly impinge on that?

Dr. RYAN. There are ethical implications in that, anytime you set about to change people's behavior or infringe on individual freedoms; and the question of community responsibility is on the other side of the coin, so one can derive ethical considerations from this in terms of what the Government does, and the individual responsibility of citizens with respect to health. But, for example, if you want an ethical consideration, what about one Federal agency pushing tobacco and another Federal agency saying you shouldn't smoke, now, that is an ethical consideration.

Mr. SCHEUER. I am sorry you said this in the presence of my colleagues from North Carolina and Kentucky; but you did raise a very real question, and, I take it, you think this would be an appropriate subject for consideration by this commission?

Dr. RYAN. Yes, I think we are a diverse society and sometimes human welfare comes into conflict with other perceived needs, such

as economic and so on, and I think those are ethical issues that we as a society have to address. I don't pretend they are simple.

Mr. SCHEUER. Thank you very, very much.

Mr. ROGERS. Any other questions or comments?

Doctor, thank you so much for being here; and Mr. Yesley, we are grateful to you. We also appreciate the outstanding job you have done in devoting your time to the Commission. We are looking forward to your report.

Dr. RYAN. Thank you very much.

Mr. ROGERS. I think we anticipated at this time that Senator Kennedy would be present. He has a very limited time and we told him we would try to accommodate his schedule.

[Brief recess.]

Mr. ROGERS. The subcommittee will come to order.

Mr. Gaither is Chairman of the Ethics Advisory Board at HEW, who is accompanied by Joel Mangel, Deputy Assistant General Counsel, Public Health Division, Office of General Counsel; Charles McCarthy, Executive Director-Designate, Ethics Advisory Board, and Carol Emmott.

If Senator Kennedy does come in, we may have to interrupt your testimony.

STATEMENT OF JAMES C. GAITHER, J.D., CHAIRMAN, ETHICS ADVISORY BOARD, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, ACCOMPANIED BY CHARLES McCARTHY, PH. D., EXECUTIVE DIRECTOR-DESIGNATE, ETHICS ADVISORY BOARD; JOEL MANGEL, DEPUTY ASSISTANT GENERAL COUNSEL, PUBLIC HEALTH DIVISION, OFFICE OF GENERAL COUNSEL; AND CAROL B. EMMOTT, SPECIAL ASSISTANT TO DEPUTY ASSISTANT SECRETARY FOR LEGISLATION (HEALTH)

Mr. GAITHER. Thank you very much, Mr. Chairman. I must confess at the outset a little embarrassment at the complexity of the message that I have to deliver to the committee on this subject. I, as you know, am serving the Department on a part-time basis as Chairman of the Ethics Advisory Board. I wish to express my own views, as Secretary Califano has requested me to do, as well as those of the Department and the administration.

I would first like to address the views of the Department and the administration with respect to Senate bill 2579, and then turn to your bill, Mr. Chairman, if I might. Again, from the administration's point of view and then express my personal views.

The new Presidential Commission proposed by the Senate bill would be required to evaluate on a continuing basis and report on the adequacy of the protection for human subjects of biomedical and behavioral research in the rules, policies, guidelines, and regulations of each Federal department or agency that conducts or supports such research. The proposed Commission would have authority to review in detail any program or project of any Federal department or agency to determine whether human subjects are adequately protected.

The new Commission would also be expected to undertake general studies concerning the ethical, social, and legal implications of advances in biomedical and behavioral research and technology, and to conduct special studies of informed consent to medical treat-

ment, uniform definition of death, the ethical, moral, and legal implications of voluntary testing, counseling, information, and screening programs on genetic diseases and conditions, and the adequacy of current procedures for safeguarding the privacy of research subjects.

As you know, Mr. Chairman, promoting the consideration of the ethical aspects of issues facing health policymakers has been one of Secretary Califano's highest priorities. I agreed to help carry out this strong commitment by serving as Chairman of the new Ethics Advisory Board. In this capacity, I closely followed the development of the Senate bill and the extensive efforts of departmental officials to develop appropriate legislation. The Secretary and I deeply regret that such efforts failed to produce a bill the Department could support.

I would like to summarize briefly the deficiencies which the Department believes seriously impair the usefulness of the Commission proposed by the Senate bill.

The primary concern of the Department relates to section 1802 of the Senate bill, which would require a Presidential Commission of private citizens devoting a small portion of their time each year to public service to assume responsibility for insuring the adequacy of the protections for human subjects of all federally supported biomedical and behavioral research. Both the administration and the Department are deeply troubled by that first provision set forth in section 1802. While Secretary Califano has from the very start given the very highest priority to ethical problems facing the Department, and has supported the National Commission in every way, he is concerned about giving such a Commission this kind of supervisory or regulatory responsibility. The Department strongly believes that the responsibility for the protection of human subjects of federally supported research should remain with accountable Federal officials, as Dr. Ryan has just said. Part-time nongovernmental advisers can provide invaluable assistance in studying complex issues, airing differences, and bringing divergent views and experiences to bear on a problem. But it is a far different thing to add to an already complex governmental structure a part-time Commission with this extraordinary responsibility.

The Department views such a step to be unnecessary in light of the capabilities of the General Accounting Office, congressional oversight committees, and the thorough work already completed by the National Commission for the Protection of Human Subjects. More importantly, the Department regards such a step as dangerous, in that assigning responsibilities to a Presidential Commission often prompts bureaucracies to do nothing during the course of a Commission study. Advancing protections for human subjects is too important a task to risk such a response.

The Department has other, somewhat less significant, concerns about the Senate bill. It questions, for example, whether the prescribed membership, largely devoted to research on human subjects, is appropriate given the emphasis in the bill on health care and medical practice. The Department is concerned about providing ex officio membership to some but not all interested Departments and agencies.

The Department is also concerned that the bill will require duplication of studies nearing completion by the National Commission.

Last, the Department is troubled by the requirement that the Commission work separately with each one of some 20 Federal agencies which support research involving human subjects in order to implement its recommendations. The result could be the multiplication of overlapping and conflicting Federal regulations for the protection of human subjects.

An entirely different approach to the research problems throughout the Executive agencies has been recommended by the National Commission. The Commission urged that the Department of Health, Education, and Welfare act as a lead agency in organizing an interagency task force to promulgate, either directly or through Executive order, governmentwide regulations on the protection of human subjects. The Department believes that the approach recommended by the Commission is sound and likely to result in a uniform Federal policy for the protection of human subjects.

Despite the importance which the Department has given to the ethical aspects of health policies and practices, it has concluded that it cannot, for the reasons just cited, support the Senate bill.

I would now like to turn to your bill, Mr. Chairman, H.R. 13662, which would establish a Presidential Commission for the study of ethical problems in medicine and biomedical and behavioral research. Due to the significant progress made by the National Commission and the broad agenda of the Ethics Advisory Board, which I am chairing, and concern about proliferation of advisory groups, the administration cannot support this bill, and would prefer that no legislation be enacted at this time. Should the Congress choose to act, however, the Department would prefer the defined and more appropriate role required of the Commission by the House bill.

This legislation mandates studies into important ethical questions in the health field, while avoiding both the institutional and organizational problems found in the Senate bill which I described earlier.

It would mandate studies concerning: (1) the allocation of Federal resources for biomedical and behavioral research and for health care delivery; (2) the requirements for informed consent to participate in research projects and to undergo medical procedures; (3) the establishment of a uniform definition of death; (4) counseling and testing of genetic diseases; and (5) the differences in the availability of health services to persons who live in certain areas or who fall into certain income brackets.

The Department believes that these studies could provide, not only for the Department but for the entire executive branch and the private sector as well, new insights into the ethical dimensions of health care research and delivery.

The House bill also requires three other studies which the Department believes should be deleted because of ongoing efforts in the Department. The first, a study of in-vitro fertilization, is as discussed this morning presently before the Department's Ethics Advisory Board. Once its deliberations are completed and departmental action taken, the Congress could consider whether further study or hearings are in order.

The second and third studies relate to Federal guidelines for clinical trials and standards of efficacy for medical procedures. These matters are already on the agenda of or under study by the Ethics Advisory Board, the Office for Medical Applications of Research at the National Institutes of Health, and the new Office of Health Technology within HEW. Should Congress establish a statutory health technology center, these issues would also presumably come under its mandate. Again, the Department questions the need for additional studies in these areas at this time.

In summary, Mr. Chairman, while the administration does not support legislation, H.R. 13662 would be preferable to S. 2579.

Mr. Chairman, I would like to note that, while the Ethics Advisory Board has not taken a position on these bills, Dr. David Hamburg, vice chairman of the Ethics Advisory Board, and I have carefully reviewed both bills, and have been involved in this deliberation for some months now. While we commend the Senate leadership in focusing attention on this important issue, we do concur in the Department's preference for the House bill.

Dr. Hamburg and I are particularly concerned that the legislation reflect our strong opinion that the most appropriate role of a Presidential Commission is to bring a variety of independent viewpoints to bear on troublesome policy issues. To charge such a Commission with oversight or supervisory responsibility would be, not only counterproductive, but inappropriate. I can assure you, Mr. Chairman, that both the Ethics Advisory Board and the Secretary would give serious and thoughtful consideration to the recommendations of such a Commission. Policy implementation, however, should be left to responsible executive officials, whose performance is subject to a number of existing review mechanisms and controls.

Further, Dr. Hamburg and I would urge that our efforts to launch an effective Ethics Advisory Board at HEW not be duplicated by the charge to a new commission. We believe collaboration between our Board and a new Commission can be productive, but would not be fostered by overlapping mandates. I think there is a role, as Dr. Ryan has said, for both the Presidential Commission and an Ethics Review Board. Secretary Califano feels very strongly that the ethical issues that are constantly coming across his desk require the presence of a group of independent people who can advise him on those issues. He also personally supports the utility of and need for groups like the Commission just completing its work that can take an independent look, a more detached look, do longer term studies, focus on issues that are not sitting on his desk at that particular time, but who would be of great service to him in dealing with those particular issues.

I appreciate the opportunity of appearing before you, Mr. Chairman, to share both the Department's and my own views on these bills. I would be glad to answer any questions you may have.

Mr. ROGERS. Thank you very much for your helpful statement. Are you an employee of the Department of HEW?

Mr. GAITHER. No, sir, I am an attorney from San Francisco. I am here at the Secretary's request.

Mr. ROGERS. I understand that. Are any of the members of your commission employees?

Mr. GAITHER. No, they are not.

Mr. ROGERS. That is why I was interested in the argument evidently advanced against the legislative proposal by the Office of Management and Budget. I presume that HEW^W individually might agree with us but OMB has set the policy. I understand that. We have been through years of this.

But I thought it was interesting that the primary concern of the Department as stated in the statement approved by—the Office of Management and Budget—I do not know who that invisible person over there is writing this—relates to section 1802 of the Senate bill which would require” * * * a Presidential Commission of private citizens devoting a small portion of their time each year to public service to assume responsibility for insuring the adequacy of the protection of human subjects of all federally supported biomedical and behavioral research. The Department strongly believes that the responsibility for the protection of human subjects of federally supported research should remain with accountable Federal officials.”

I do not think anybody debates that. I presume you are not spending all of your time in this field, either.

Mr. GAITHER. No, I am not.

Mr. ROGERS. Nor is the Commission.

Mr. GAITHER. But I think the point is, Mr. Chairman, that I do not think that I or any group that I might want to work with has the capability to monitor as required by that provision in the Senate bill.

Mr. ROGERS. Oh, I agree. Congress and the National Commission should do the work, plus the General Accounting Office—

* * * the Department is troubled by the requirement that the Commission work separately with each one of some 20 Federal agencies which support research involving human subjects in order to implement its recommendations. The result could be the multiplication of overlapping and conflicting Federal regulations for the protection of human subjects.

I thought that the purpose of the overall mission, would be to set one policy for all agencies. Would that not be your interpretation of it?

Mr. GAITHER. It is possible. I think the concern is being expressed with the provision in the Senate bill that requires each Cabinet officer to respond independently rather than the administration as a whole, to each recommendation and without any provision for uniformity of the kind you have stressed this afternoon.

Mr. ROGERS. I assume you would get uniformity through the OMB.

Mr. GAITHER. One might hope so.

Mr. ROGERS. I am not sure that we should count on that.

Mr. MAGUIRE. Does this subcommittee have oversight over OMB with respect to health matters, Mr. Chairman?

Mr. ROGERS. I think we could ask. I think they might assert executive privilege, but we could try.

Mr. MAGUIRE. I think it would be interesting to find out whether or not they would or not. This is not the first time we have had this kind of development before you.

Mr. ROGERS. We will look into that.

Dr. MCCARTHY. Mr. Chairman, the National Commission has recommended that HEW, which supports approximately 40 percent

of all research involving human subjects, exercise a lead role among Federal research agencies. Now that leadership would be presumably under the guidance of a commission or some other body. Rather than have the Presidential Commission deal independently with each of the Federal research agencies, it would deal with all of them through the leadership of HEW. OMB would play no part in this procedure.

Mr. ROGERS. Thank you.

Dr. Carter, do you have any questions?

Mr. CARTER. Thank you, Mr. Chairman. Dr. Gaither, if a Presidential Commission is established under either the House or Senate bill, do you think the Ethics Advisory Board should continue; and if so, in what relationship to the Commission?

Mr. GAITHER. Dr. Hamburg, I, along with Secretary Califano, believe strongly that it should. We would work very closely with it to make sure that we were mutually supportive and were focusing on different problems. There are certainly more than enough very difficult ethical issues faced by this Government for two bodies to split up. I think it could be very destructive, however, of our work were we asked to do the same things. I think, as you will note, apart from myself the members of the Ethics Advisory Board are very distinguished people who are willing to devote time to the service of their country, but I do not think to engage in duplicative efforts with equally distinguished people in another advisory body.

Mr. CARTER. Thank you for a very fine statement.

Mr. ROGERS. If the witness will bear with us, we will have to interrupt his testimony. I see our distinguished colleague, Senator Kennedy, is here and we are anxious to hear his testimony. He does have a tight schedule.

We are very pleased to welcome the chairman of the Health Subcommittee, knowing of his great work and leadership in the health field, and particularly in the subject matter of these hearings. I think we have heard so much today already of the need for some action to be taken. We are very pleased to have you with us and to share your viewpoint.

STATEMENT OF HON. EDWARD M. KENNEDY, A U.S. SENATOR FROM THE STATE OF MASSACHUSETTS

Senator KENNEDY. Thank you very much, Mr. Chairman and members of the committee. First of all, I express my appreciation for the opportunity to present some views briefly to this committee, to say how much I have enjoyed working with you, Mr. Chairman, and the other members of this committee on this particular subject matter in times gone past. I respect the leadership you are providing, insuring that this concept of a panel for the protection of human subjects will be continued after this Congress.

I am very mindful, as we get into the waning days of this Congress, that all of us are increasingly reminded of your decision not to continue as the chairman of this committee and return to the Congress of the United States to address the issues of health. As I have said to you privately and as I have reminded our friends on the other side of the Congress, we are going to miss your leadership, and the American people are in your debt for what you have done for the health of the American people.

Mr. ROGERS. That is very kind.

Senator KENNEDY. I appreciate the chance to come here this afternoon.

If I could, I have worked out a talking paper, but actually I think I would be almost as quick if I went through this program.

Mr. ROGERS. Certainly.

Senator KENNEDY. With your permission, I will, Mr. Chairman.

Mr. ROGERS. Certainly.

Senator KENNEDY. It's a pleasure to be here today to testify on H.R. 13662, a bill designed to establish a successor commission to the present National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research which goes out of existence on October 31, 1978.

When Congress enacted legislation establishing the National Commission in 1974, it was truly landmark legislation.

It marked the first time the country established an independent group to be primarily concerned with the protection of human research subjects.

It marked the first time that an interdisciplinary group of professionals—doctors, lawyers, ethicists, theologians—were given a mandate to work together and try to give the society guidance of some of the most difficult, complex, ethical and moral problems of our time.

The legislation recognized the new challenges and dilemmas posed by the continuing expansion and development of biomedical knowledge and technology. It provided a forum where ideas and issues could be debated and analyzed—always in public, but outside the political arena. And the result has been some of the most important analyses of ethical issues ever developed—on fetal research, on psychosurgery, on research on prisoners, children, and the mentally retarded.

These reports have earned this Commission the respect and appreciation of the scientific community, the medical profession, the pharmaceutical industry, consumer groups, ethicists and theologians. Its reputation is impeccable. Its work is of high quality.

In this era of abundant regulation, it is interesting to note that this Commission has had a profound effect on public policy without a shred of regulatory authority. Where they have had impact, it has been because of the force of their ideas and their powers of persuasion. The quality of their work has determined the fate of their recommendations.

The Commission was structured to make recommendations to the Secretary of HEW. The Secretary has to publish them, and respond to them, but not accept them unless persuaded to do so.

The Commission has affected the Department's policies. It has significantly raised the standards for the protection of human research subjects. It has helped formulate policy in difficult ethical areas. And it has done so solely on the basis of the merit and quality of its work.

We all know that commissions come and go; that our shelves are cluttered with unread reports that make no difference. This Commission's reports are living documents. They have made and continue to make a difference.

But their work today remains unfinished. Their mandate expires in October. But the need for a commission is as great today as it ever was, as Chairman Rogers and the other cosponsors of H.R. 13662 recognize. It was most heartening for all of us who are deeply concerned with these issues when the Senate on June 26 passed S. 2579, a bill to establish the President's Commission for the Protection of Human Subjects of Biomedical and Behavioral Research by a vote of 68 to 10.

Turning to the specifics of H.R. 13662, I support most provisions of the bill, many of which are incorporated in S. 2579. I strongly support studies of the legal, ethical, and social implications of those matters listed in section 202 of the bill.

However, my main concern is that the bill does not go far enough. I am most distressed that the Commission does not have a specific mandate to investigate, study, and report on the protection of human subjects of biomedical and behavioral research.

It would be a major step backward to eliminate the only independent focus on protecting human research subjects at a time when our clinical research budgets are expanding to break all records—in government and the private sector.

It is a sad, but true, fact that biomedical research progress has too often been achieved at the expense of individual rights—of free choice, of informed consent.

The Senate Health Subcommittee has documented a wide range of abuses in 17 days of hearings since 1973. They are a blight on the otherwise proud record of American science and medicine.

We have seen:

How treatment was withheld from syphilis victims for years after an appropriate therapy had been developed;

The use of an experimental supercoil intrauterine device, without informed consent, result in grievous harm to unsuspecting subjects;

The use of Depoprovera, at that time an experimental, long-term injectable contraceptive with profound side effects, on thousands of women throughout the State of Tennessee without informed consent;

The use of that same product on the mentally retarded, without informed consent;

The abuse and misuse of psychosurgery on children;

The sterilization of two retarded teenage girls without the consent or knowledge of their parents;

The testing of experimental drugs in "locked" nursing homes, without consent, without proper medical supervision, without proper recordkeeping;

The testing of drugs on prisoners without following appropriate ethical safeguards;

The testing of respiratory depressants during labor with consent obtained under duress and unjustifiable risks to the newborn infant;

The inconsistent and ineffective record of university-based institutional review board in protecting human research subjects;

Widespread abuses in the human research programs of the Department of Defense;

The inexcusable, intolerable abuses of human rights by the Central Intelligence Agency's testing of hallucinogenic drugs on unwitting Americans on both coasts, of all social classes;

The death of a CIA employee after he was given an hallucinogenic drug without his knowledge;

The use of prostitutes by the CIA to lure Americans to safe-houses where they became the unwitting subjects of drug experimentation.

The list is endless. It covers abuses from 1922 to 1978.

In considering the testimony at these hearings, the subcommittee and subsequently an overwhelming majority of the U.S. Senate became convinced that all human subjects who participate in biomedical and behavioral research programs under the auspices of any Federal agency deserve protection. There is no reason to justify the elimination of the important monitoring work that a Presidential Commission can do, and I strongly urge this subcommittee to incorporate into H.R. 13662 provisions similar to those contained in S. 2579.

I am also concerned that H.R. 13662 does not contain certain administrative provisions found in current law and S. 2579 that would require the Commission to make recommendations directly to a department or agency; require the head to publish them, and respond to them, but not accept them unless persuaded to do so. These provisions have worked extremely well with the current Commission. They have not conferred upon the Commission any regulatory authority but merely forced a public discussion of extremely difficult ethical and moral issues. If the Commission causes changes, it will be due to the quality of its work.

In the weeks ahead I look forward to working with members of this subcommittee in enacting legislation that will establish a commission to continue and enhance the work of the current Commission. As biomedical and behavioral research becomes more and more sophisticated, the ethical and moral dilemmas connected with it becomes more and more complex and difficult. The recent birth in England of a "test-tube" baby is clear evidence of this. And while the United States has long been recognized throughout the world as the leader in biomedical and behavioral research, unfortunately, the time and attention which has been given to the development of our biomedical and behavioral research programs has not been matched by efforts aimed at the development of policy adequate to protect human subjects of that research.

I am hopeful that we can work together and establish a new high quality commission to focus on these important issues.

Let me just say, for example, I knew HEW has problems about the establishment of a commission that is going to in effect look at other standards by other agencies in the ethical area. Let me just point out I do not think ethics belongs alone to HEW. It belongs to other regulatory agencies and other departments of government. It does to the Defense Department, and to the Central Intelligence Agency, to the Food and Drug Administration and to the other agencies.

We saw in the course of our hearings where the FDA had arrangements with the standards for informed consent that they had worked out with the Department of Defense and CIA. The fact of

the matter is those rules and suggestions sounded pretty good, but no one was overlooking whether they were being implemented or being enforced.

It just seems to me there is this concern.

I know the views of our distinguished representatives from HEW, and I spent a good deal of time with my good friend Secretary Califano wondering about the administrative mish-mash between whether we have a superagency, and how is that going to relate with HEW. If they are promulgating rules and regulations, what is going to happen here, and what is going to happen in the other agencies?

The fact of the matter is what we would hope with that Commission is that they would review the various ethical standards that would be promulgated by the other agencies to make sure that they conform to protect human subjects and informed consent.

Then, second, if they do find areas where there are abuses, they should publish those, not interfere, not regulatory interference, but just publish those, and that the head of that particular agency is going to make a response to it. He can either say they are so or not so, and that is it—no other kind of interference.

I have great confidence in the desire of Secretary Califano to establish an absolutely superb Commission, but I am concerned about future secretaries and future administrations about what is going to happen.

I think having at least this type of Commission that has been by proven example really demonstrated that it has worked to encourage the scientific inquiry—I think the work that was done in the area of psychosurgery; for example, there were important abuses. It was as a concept heavily condemned. The guidelines that had been established on it actually meant there is more, but under circumstances under which the American people have been reassured.

On the vote that took place in the Congress of the United States on fetal research, I do not think there were 25 or 30 Members who opposed a complete prohibition on fetal research. Guidelines were published by this Commission whereby scientific inquiry is being done and has benefited directly both the fetus and the mother.

It seems to me we are not talking about abstract ideas in these circumstances. We are talking about a system that has functioned and is working. What we are really hopeful about is that we can try to insure that that function, particularly as I mentioned as we are coming into more and more with the expansion of technology, and in all of its implications in terms of the health care process, all the moral and ethical issues that are going to come crashing down on us in the Congress, to at least be able to have an agency that is going to be thinking about these matters and guiding us and guiding the various agencies of the Government in a thoughtful compassionate human way that conforms with the great Judeo-Christian ethics of this Nation.

Mr. ROGERS. Thank you very much for a very excellent statement, and for really articulating the different concerns you have and what I think is probably the main difference between the approaches of the House and Senate bills. I think we are all agreed we need a Commission to get into these very severe ethical prob-

lems. I think the principal question is how much of an oversight function the Commission should have.

As you explained it here, as I understood it, you felt it would be realistic to have the Commission recommend the ethical standard or policy and simply have each agency respond as to how they were carrying out that recommendation. You would further expect the Commission to comment on the appropriate rules and regulations.

Senator KENNEDY. What I would hope is that each of the agencies would develop their own—I suppose they might consult—but you give to each of the agencies the flexibility to develop, given their particular, as they view them, ethical and moral questions which are before the agencies, which may very well be somewhat different in each of the areas, and that the Commission have a chance to review with them the fashioning of these.

I basically believe that as a matter of conformity there really won't be a problem of each of the agencies developing their own but should there be an issue or problem, that at least this commission will in the Federal Register just publish the points of difference and will expect a response.

If there are arrangements, if they publish these rules and regulations and it comes to the attention of the Commission that those rules are not being conformed with, they again can go to the Federal Register and publish. They have no sanction whatsoever but purely the raising of those factors. I think all of us understand here that with the exception of those that have the very serious interests and intricacies of government function, there are not a lot of people that read through that Register, but that process has worked to date. There are many who thought it would not work, but on moral issues and questions it has.

Mr. ROGERS. The only concern I have is how the Commission would actually police the agencies' actions. In other words, should we think of directing the General Accounting Office to do that for us, to actually check in to see how that policy is being carried out in those instances and to make a report to us.

I just wonder what personnel it would require to do the policing?

Senator KENNEDY. I am not interested in establishing or providing investigators and the rest. I do think if that becomes necessary after a period at the expiration of the act, that they can make the case they were unable to get it because they did not get support, then we could consider. I am not for having a police function or having investigative functions on this. My own sense is that in this particular community, in the ethical community which we are talking about, there is broad-based communication and fertilization of ideas. I would not establish that. In the review of those when matters come to their attention where a particular agency is not conforming, then they make the publication.

Mr. ROGERS. We may not be as far apart as we thought.

Dr. Carter, do you have a question? The Senator is going to have to leave very shortly.

Senator KENNEDY. Dr. Carter, thank you for coming to our convention and conference. I got your nice note on that. We missed Paul.

Mr. CARTER. I was certainly happy to be there, and I found your statement to be informative and interesting.

I have no questions at this time.

Mr. ROGERS. Mr. Preyer.

Mr. PREYER. I too want to thank you for your leadership, Senator, in this area.

Just one quick question. You mention that you strongly supported the provision in the Senate bill dealing with the general studies of ethical, social, and legal implications.

In the House bill we do not have general studies, but we list a series of eight areas.

Senator KENNEDY. That is right.

Mr. PREYER. Then in the report we spell out those areas in more detail. Our theory was, intellectuals being what they were, there may be 2 years taken to decide what particular general studies they will study, and that we thought it might be better if we told them rather specifically what to study, rather than let them examine their own ethical feelings and so forth on that.

Would you have any great difficulty with the House approach?

Senator KENNEDY. I think we are very close, Mr. Congressman. We had both. We had a general and a specific, and as you will notice on your first four, they were all areas where we hoped there would be study as well. I do not have my bill in front of me, but I think we had a feature in terms of genetic diseases which we added, and one or two others. I do not think we would have any difficulty whatsoever in agreeing on those particular areas, and we would welcome what comments you would have on our more general kinds of provisions to see if we could provide some degree of focus. I think these areas which you have identified are of enormous importance and value. I think we could agree on that, and would welcome whatever reaction you would have to our more general language to see if we might provide some degree of flexibility, but also be sensitive to the points you make now. I would welcome what suggestions you have.

Mr. PREYER. Thank you.

Mr. ROGERS. Mr. Scheuer.

Mr. SCHEUER. Senator, I want to ask you a question or two about some additional items that I think might be covered and get your point of view. You have been quite an articulate exponent of the concept of preventive health care. Our system is heavily weighted toward tertiary hospital care, high technology, CAT scanners, open-heart surgery. It is essentially a sickness system as compared to an alternative that some of us were talking about, and you certainly have too, a system that would be community oriented, preventive in nature, mostly ambulatory and outpatient, with a lot of counseling and a lot of paraprofessional output, a great deal cheaper and a great deal more cost-effective.

Do you think that the moral and ethical and social implications of this contrast would be worthy of study by such a Commission?

Senator KENNEDY. I see you have it down here already. My first reaction would be positive, Congressman. The question is how you define it and target it in such a way where it could really be meaningful as a working document, either for the Congress or for policymakers. Clearly we ought to know more about it, and I am absolutely convinced that what you add into that or I would add into that is the reimbursement.

Mr. SCHEUER. Of course.

Senator KENNEDY. The impact on those particular questions and how that has impacted, as well as the other question. Then it gets to the point where it is best that this Commission do this or whether we have another study, whether there would be health care research or another agency do it, I would think is the issue.

But there are profound ethical and moral questions that are involved, the failure of some to be able to get health care treatment, and other questions. I think the job ought to be done. Whether this panel would have the kinds of resources to do it, given the fact of its particular membership best able to do it, I suppose would be something we ought to think about.

Mr. ROGERS. Mr. Maguire.

Mr. SCHEUER. One more question.

Mr. ROGERS. Quickly, please.

Mr. SCHEUER. Yes. How about the ethical implications of our lifestyle and the health implications of our behavior and the degree to which government has the right to intrude on our behavior, issues such as alcohol, exercise, drugs, diet, the whole bit?

Senator KENNEDY. I think as you well know, the models that have been developed show very clearly, Breslou studies, DeBakey, Finland study, all indicate clearly what can be done.

Now the question is, what is the appropriate role of the central authority in that? My own sense is the heaviest responsibility is going to be on the local community and on the individual.

My sense is, with regard to occupational health issues and with regard to water, air, other factors, the Federal Government, but the rest is a local question. But I think it is reasonable to say how are we going to get people from smoking too much? What does it cost us, maybe \$14, \$16 billion a year for hospitalization, for people that smoke too much? Should the other people pay for it? How are we going to get them to stop it?

Mr. SCHEUER. You are right on target.

Senator KENNEDY. Yes, as to those tough issues, I wish I knew. We need attention to it; whether this is again the panel to do it, I agree it ought to be done.

Mr. ROGERS. Mr. Maguire.

Mr. MAGUIRE. Thank you very much, Senator. I think you have made a compelling case.

My concern is not that the Commission you propose might do too much, but rather, that it might not be able to do enough given the enormous range of issues and dilemmas which you outlined in your discussion.

My question would be, do you envision any problem with this being a part-time Commission given the enormity of the range of issues and Federal agencies involved? Do you think there might be a problem of having the Commission actually do the job within the period of time which we would specify in view of the fact that the Commission would be comprised of citizens giving a bit of their time, et cetera?

Senator KENNEDY. They have done awfully well so far. I think that it has been limited. We have not gotten into the broader kind of issues that Congressman Scheuer and others have mentioned.

I would think that what we have outlined on this plate they probably could do. I think there is a very important advantage, the types that we have gotten have been able to dip in and out of both academia and the universities, as philosophers, theologians, and as ethicists, and they are able to bring those very special strengths from their interaction.

Whether we would be able to get that standard—the quality on that first group was absolutely superb. Whether you could get them out of that is a tough kind of question. It is one that we ought to pursue with them and find out, for example, the members of the panel, whether they would have done it, taken the time off. I think that is a fair question. Maybe they would have.

I think, given the success of this panel and the interest on these issues by the people we have involved—I find that this is one of the most exciting areas for people, ethicists, doctors, and the rest. Maybe we could get it, maybe we could get them to do it full time.

Mr. ROGERS. Thank you very much.

Senator KENNEDY. Thank you very much.

Thank you, gentlemen.

Mr. ROGERS. Thank you so much.

Could we have the HEW witnesses back in case there are further questions?

Senator KENNEDY. This is the man to ask on that last question [indicating Dr. Ryan].

Mr. ROGERS. Are there further questions of HEW? I think we have gotten the viewpoint of the administration, of OMB, and individual views. I think we understand.

Mr. SCHEUER. No questions, Mr. Chairman.

Mr. ROGERS. Mr. Maguire.

Mr. MAGUIRE. Well, I just want to invite Mr. Gaither to comment on the testimony which he has heard.

Mr. ROGERS. Certainly. I am not sure he heard that.

Mr. MAGUIRE. I was going to suggest Mr. Gaither might comment on the testimony that we just heard, if he would care to do so.

Mr. ROGERS. You can do that personally, if you like.

STATEMENT OF JAMES C. GAITHER, J.D.—RESUMED

Mr. GAITHER. I would be happy to do that as a private citizen.

I basically share, and I believe Secretary Califano does as well, the things that Senator Kennedy has said, and I guess the one difference relates to method and what a group like this can really accomplish.

I would endorse wholeheartedly everything he has said about the present Commission. It is a superb group, it has worked enormously hard and has been very effective. But if you focus on what they were asked to do, they were given very specific tasks, and they did them very well. They were not asked either to define their own charter or to regulate across the board.

That is what I believe Senator Kennedy is suggesting now; the model for specific studies which worked so well can be applied to, in effect, regulate the protection of all human subjects, and I just question that point.

Mr. MAGUIRE. With all due respect, I think the Senator made clear—as I have reviewed my briefing material it seems clear to me, unless I am missing something, that this is not a proposal for regulatory authority; he very specifically says studies, which would then be published in the Federal Register and which would have to be taken account of by the relevant agencies and actors, but it would not be a regulatory situation, at least as I understand that word, unless you see something there that I do not.

Mr. GAITHER. I think the question is more than just semantics, Mr. Maguire I think if you read the language of section 1802, the Senator is suggesting that the Commission have responsibility for reporting on the adequacy of all Federal policies and guidelines in terms of the adequacy of protection of human subjects.

The sanction he speaks of is publication. One can certainly say that is not regulation but I think the responsibility for insuring the adequacy of protection of human subjects is placed quite squarely on that Commission by section 1802, and I believe that that is a questionable way to run the Government. I think it is taking responsibility away from the Cabinet officers and agency heads who ought to be held accountable for doing that very thing.

Mr. MAGUIRE. You do not have any quarrel I take it with the breadth of coverage that is proposed with respect to agencies or programs?

Mr. GAITHER. No, not at all.

Mr. MAGUIRE. It is simply the mechanism you are worried about?

Mr. GAITHER. That is right. It is the regulatory versus the study. Indeed, I think Dr. Ryan said earlier that he supports the study mechanism but not the regulatory.

Mr. MAGUIRE. But they both call for studies, only in one case—

Mr. GAITHER. Review and monitoring, I think, and insuring the adequacy of everything the Federal Government does is a very different thing from studying research on prisoners, fetal research, or a limited area like that. But let that not cloud the basic point that I am trying to make.

I am very supportive of the notion, of the need, of the ethical concerns that have arisen in this country and in this committee which have been needed and continue to have a very important place in the Federal health program.

Mr. MAGUIRE. Specifically, you agree with the notion that it ought to be broadly concerned with human subjects wherever they are being dealt with, by whatever agencies; therefore, it ought to be a presidential as opposed to a strictly HEW unit, is that correct?

Mr. GAITHER. I have no disagreement with that at all, just that the charter ought to be clearly defined so they know what they are expected to do.

Mr. MAGUIRE. Thank you.

Mr. ROGERS. It is my understanding that both you and Dr. Hamburg of the Institute of Medicine personally feel that the House approach is probably superior to that of the Senate, regarding oversight functions and regulatory responsibilities.

Mr. GAITHER. Yes, sir.

I will, however, have to say that I personally support what the Senator said and what Dr. Ryan said earlier about the report

mechanism that has been developed, that has been effective, something that I think makes sense.

I think there ought to be a government-wide response to promote uniformity, but I think some kind of mechanism like that does make commissions more meaningful.

Mr. ROGERS. Thank you very much. Your testimony this afternoon has been helpful and we are grateful for your bearing with the committee and testifying twice. Thank you for being here.

Mr. GAITHER. Thank you, sir.

Mr. ROGERS. I might say that I know there is a group of young people here from the Boca Raton, Fla., Sea Explorers. I would like for them to stand and let these people see what good Floridians look like. We are glad to have you with us.

Our next witness will be Dr. Seymour Siegel, Rabbi Siegel, who is from the Jewish Theological Seminary of America.

We are very pleased to have you with us and we are grateful for your being willing to give us the benefit of your thinking.

Your statement will be made a part of the record in full, and you may proceed.

I presume Mr. Scheuer may like to have some comment before you begin.

Mr. SCHEUER. Yes. Just very briefly, Mr. Chairman.

Dr. Siegel is, to my knowledge, one of the eminent theologians and moral teachers and ethicists, if I may use that word in America today. He is a very distinguished intellectual. He honors us by appearing here today. I want to wish him welcome.

Rabbi SIEGEL. Thank you.

Mr. ROGERS. Also, if we may ask Dr. Ruth Macklin, of the Hastings Center, Institute of Society, Ethics and the Life Sciences to come and join us. We will ask her to make the second statement, and Dr. LeRoy Walters, director of the Center for Bioethics at the Kennedy Institute of Georgetown University, if you will also please join the Rabbi.

All of these are distinguished persons that we need to hear from. If you would begin.

STATEMENTS OF RABBI SEYMOUR SIEGEL, PROFESSOR OF ETHICS AND THEOLOGY, JEWISH THEOLOGICAL SEMINARY OF AMERICA; RUTH MACKLIN, PH. D., HASTINGS CENTER, INSTITUTE OF SOCIETY, ETHICS AND THE LIFE SCIENCES; AND LeROY WALTERS, PH. D., DIRECTOR, CENTER FOR BIOETHICS, KENNEDY INSTITUTE OF ETHICS, GEORGETOWN UNIVERSITY

Rabbi SIEGEL. Thank you very much, Mr. Chairman, and thank you very much for those kind words. As one of the great teachers once said, "You can compliment me, I can take it."

My testimony here will be very brief. I have submitted a statement. [See p. 47.]

Mr. ROGERS. Your statement will be made a part of the record in full.

Rabbi SIEGEL. I just want to say that I personally have been enormously enriched by a year of study at the Kennedy Institute for Bioethics, which Dr. Walters directs, and also had some advisory capacity with the Commission on Experimentation of Human

Subjects with regard to fetal research. So that I am, as the members of this panel are, extremely impressed with the work that is now being done in various centers on this very important question of bioethics, which, as we have seen this week, after the birth of the baby in England, is a matter not only of governmental interest but of interest to the entire world.

I was interested to see that in the discussions of this particular event in the news magazines, newspapers, and on television, the ethical questions seem to play as much or a more important role than the actual scientific events that took place.

I was pleased, for example, to hear the Chairman of this Commission on one of the TV programs make that clear. So that I think it is not necessary to belabor the point that a Commission on Bioethics is not only necessary, but is required and desired by the American public and by the Congress which represents the American public.

Therefore, I come here to endorse the creation of such a Commission as both the Senate and the House bills mandate.

I would personally prefer the House Resolution 13662, which is sponsored by the chairman and his colleagues on this committee, for the reasons that have already been stated. Although the Senate resolution does not say anything about regulation, it does say that the Commission will investigate what is going on in various agencies and will comment on them. This does give it, if not a regulatory function, a semiregulatory function, and does seem to envisage the creation of a big bureaucracy to see what is going on in all the other agencies and to comment on them. And one thing which I think the American people and this Congress seem to endorse is that the less bureaucracies created, the better.

I would envisage the Commission on Bioethics which I hope will be created or continued as being a resource advisory body to those who have to make policy; it should leave the legislative and regulatory functions to those agencies which already exist. Therefore, when Congress feels the need to formulate legislation in the area of the definition of death or problems of informed consent, it can turn to the Commission for guidance as to the ethical issues involved. This could prove to be most important to the efficacy and the enforceability of any new legislation or regulation.

Personally, I would think it would make the work of the Commission cumbersome if it had the responsibility, as the Senate resolution seems to indicate, of actually going in to see what is happening and commenting on it, even though it may not have the power to stop it or to modify it.

Therefore, in summary I believe that we are on the threshold of great new breakthroughs in the history of medicine and biology and therefore, and as history has shown, the more solutions we find, the more problems have ethical dimensions to them. It is a tribute to our form of government I think that we are worried about the ethical and moral implications of these breakthroughs as we are concerned about their scientific and technical aspects. Therefore I would heartily endorse the creation of a Commission on Bioethics as envisaged in the House bill, which will be an important step toward helping those who are applying their genius, ingenuity, and daring to the lifting of the human condition.

Thank you very much, Mr. Chairman, and members of the subcommittee.

[Testimony resumes on p. 54.]

[Rabbi Siegel's prepared statement follows:]

TESTIMONY OF SEYMOUR SIEGEL, PROFESSOR OF ETHICS AND THEOLOGY, JEWISH THEOLOGICAL SEMINARY OF AMERICA, NEW YORK, N.Y.

on H.R. 13662 , A Bill to establish the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research

August 4, 1978.

Mr. Chairman:

It is a great honor and privilege for me to be able to appear before you and the members of your Subcommittee. I am also pleased to be able to participate in these hearings together with distinguished colleagues Professor LeRoy Walters of the Kennedy Institute for Bioethics where I spent a fruitful and exciting year as Senior Research Fellow during the Academic Year 1976-77 and Doctor Ruth Macklin of the Hastings Center.

I have been concerned with the issue of bioethics for several years teaching ethics at a great institution of learning. I also serve as Chairman of the Committee on Jewish Law for the Conservative movement within Judaism which numbers more than a million members. This Committee decides questions of ethics within the realm of traditional Jewish concepts and teachings. As a chairman I have been called upon to discuss and analyze important bioethical questions. As I mentioned previously, I am grateful to the Kennedy Institute for Bioethics in Washington for the opportunity and leisure to research problems relating to the interaction between ethical traditions and scientific developments during a whole academic year.

* * *

Reinhold Niebuhr, America's greatest thinker on the relation of ethics and public policy wrote: "The realm of politics is a twilight zone where ethical and technical issues meet." We are proposing here to enter this twilight zone hoping to dispel the obscurity which sometimes characterize our discussions. Until now the politicians and bureaucrats avoided the discussion of ethics, except in the most general terms. The sometimes difficult academic style of philosophers, theologians and social critics seemed far away from the

real world where the real decisions are made. Many times it was not only politicians who felt that they were entering a twilight zone when they confronted ethicists, but scientists themselves were resentful that the busybodies representing ethical traditions were interfering in their important work.

Happily, this attitude of segregation is now being overcome. There is an old Hebrew proverb which says: What good sense cannot accomplish, time will accomplish. The dramatic events of our time have called the ethical consideration forth from academic discussion into the realm of policy making.

The world was stunned last week when a baby was born who had been conceived outside the womb of her mother. Time magazine in a rather sardonic remark observed that the birth of the Brown baby was the most eagerly awaited "blessed event" in almost two thousand years. The dazzling achievement of the scientists were rightfully hailed and celebrated all over the world. It is interesting, however, that there seemed to be almost as much interest--in the media at least--as to the ethical dimensions of this startling event as in the scientific parameter. People are beginning to sense that the greater the scientific achievement, the more we need to consider the ethical guidelines which should guide our thrust into the unknown. More and more the realization has been achieved that a creative partnership between the scientific community and those who are responsible for guarding the values of our civilization is vitally necessary if both science and humanity are to go forward.

The application of our notions of right and wrong to medical and biological research and practice is of very ancient origin. Physicians have been asked to guide their activities by oaths they undergo from dim antiquity. Dealing as they do with the most basic of human concerns and with the most intimate of human relationships, those who engage in healing need guidelines to guard themselves. There must have been researchers in dim antiquity as there are men of science today who resent the fact that their activities are being monitored and sometimes even hampered by groups which claim to speak for the values of the society in which they work.

They feel that unreasonable and dogmatic restraints are being imposed upon them. Sometimes they are, of course, correct. However, it is neither in the interests of the public nor science to let only self-policing prevail. This is not because scientific researchers are somehow more likely^{to} cut corners than do other groups in our society. My own observation is that the morality of scientists is usually as good or even better than that of professional moralists. However, as Oscar Wilde once observed, morality is the attitude we adopt toward people we personally dislike. This sarcastic remark reflects a basic truth: good people usually do not need explicit moral restraints. Moral guidelines and rules are needed when our own self-interest, our own passions are involved. While it is sometimes difficult to fool others, it is relatively simple to fool oneself. Therefore the application of guidelines to scientific research is necessary to restrain those who may misunderstand the issues involved or whose self-interest may becloud their judgment. While guidelines might cause some hardship to those who^{do} not need them, they will, on balance enhance the community of science rather than hamper it.

In a modern complex society such as ours, it is the government which frequently is the best means to express the moral consensus of the community in realistic concrete terms. This is because government is the main financial support of scientific research. Therefore, its decisions are more readily listened to--they have to be, otherwise the research cannot go on. There is another aspect of government which is important to point out. In a democratic society, it is through government that the diverse views which make up our society can be expressed. When politics is really working, these diverse views contend with each other and are adjudicated in the give-and-take of democratic procedure. Thus, only rarely, do extreme views which do not represent the broad consensus of the people hold sway. It is hard to find a modus vivendi without some compromise. That is why, there is great truth in the old saw that politics is the art of the possible.

What this means is that the moral viewpoint of the American people in the area of bioethical dilemmas can best be expressed in concrete terms if it is filtered through a responsive and responsible political structure.

An instructive example of the way a constructive partnership between the scientific community and those who express the value-structure of our society has been demonstrated in the issue of Recombinant DNA research, in which Doctor Walters played such an important role. Whereas in September 1973 the leading scientists of our country were warning us about the procedure, in July, 1977 the same scholars were urging that the research go on unhampered as much as possible. It is my opinion that this basic change of opinion within the scientific as well as the public-policy community was brought about at least partially by the successful way in which guidelines were formulated for DNA research, stimulating the development of methods to reduce to almost nil any potential danger.

A creative partnership between ethics, science, and government can help us avoid some of the pitfalls as we march forward in our quest to wrest from nature her secrets so that we can improve the human estate.

It is for these reasons that I appear before you to testify on behalf of House Resolution 13662 sponsored by Congressmen Rogers, Preyer, Schuer, Florio, Maguire, Markey, Walger, Carter, Broyhill and Skubitz.

It is important that ^{the}~~a~~ Commission envisioned by ~~this~~ bill be set up. This commission will coordinate and centralize the important work that is being in various institutes such as the Kennedy Institute, the Hastings Institute, the Harvard Center for Medical Ethics and by various individuals in the field of bioethics.

I am pleased that the membership of the proposed commission will represent a broad spectrum of interests including those who are actually engaged in research as well as those who devote themselves to the study of the ethical and public policy implications of scientific research.

The range of topics which will be assigned to this Commission cover the basic issues of bioethics at this time. I would urge the broadening of the discussion of item #8: human in vitro fertilization. The Brown case illustrates the urgency with which we must act to analyze the ethical and policy issues involved in the area of human reproduction. Very soon we will have to decide whether our ethical tradition permits not only the fertilization in vitro, but also the gestation/^{of humans}in vitro. We will have to face the issue of host wombs, frozen embryos, etc. These procedures represent awesome possibilities which can radically change the entire nature of man. Our viewpoint toward these developments both as a society and as a government will radically affect what will happen in the future. It is also important that we coordinate our efforts and conclusions with similar bodies overseas, so that we will not have the situation where that which is banned in the United States is then done in England or South America.

This Commission might also coordinate the activities in the bioethics field that is taking place at HEW, the NIH, etc.

In my judgment the new commission should not be envisioned along the model of the regulatory agencies which have the power to supervise and enforce their findings. To convert the proposed Commission into another FDA would lay this Committee open to the fear that it is creating yet another giant federal bureaucracy.

The new Commission should act as a resource and advisory body to those who have to make policy. It should leave the legislative and regulatory functions to those agencies which already exist. Therefore, when Congress feels the need to formulate legislation in the area of the definition of death or

problems of informed consent it could turn to the Commission for guidance as to the ethical issues involved. This could prove to be most important to the efficacy and the enforceability of any new legislation or regulation.

In summary, therefore, I believe that we are on the threshold of great new breakthroughs in the history of medicine and biology. Undreamed of blessings await us and our posterity. As is the cunning of history, each new breakthrough requires more and more vigilance so that our humanity be preserved. This means the entrance into that twilight zone where technology and ethics meet. The creation of a new commission will make the creative partnership necessary for reasoned and beneficial progress. Government, as in many other areas, is the coordinator, the convenor of the interests of the public ^{so that they can} as they apply to the various developments within our society. The creation of a Commission on Bioethics as envisioned in the Bill under consideration will be an important step toward helping those who are applying their genius, their ingenuity, and their daring to the lifting of the human condition.

"If the righteous desire it they could be creators (like God).^v This quotation from the Talmud, the ancient repository of Judaic wisdom pays high tribute to human endeavors. It echoes the famous lines emanating from another source of ancient insight--the Greek poet Sophocles "Wonders are many and none is more wonderful than man."

The wonders of nature are great. The skill of the human mind that can unlock nature's secrets is the greatest of the wonders of nature. With recognition of the need for a creative partnership between men of science and those responsible for the promotion of the values of our society, the future promises even greater wonders.

Mr. ROGERS. Thank you very much for a very, very helpful statement.

Dr. Macklin.

STATEMENT OF RUTH MACKLIN, PH. D.

Dr. MACKLIN. Thank you, Mr. Chairman.

Let me please add for the record that in addition to my work at the Hastings Center, I am also on the faculty of the Albert Einstein College of Medicine in New York City where I teach biomedical ethics and confer on a regular basis with physicians who are engaged in research and also patient care.

Not a day goes by when some ethical concerns are not voiced about advances in the biomedical and behavioral arena. Within the last 2 weeks alone, we have witnessed striking advances in biomedical technology.

In the days immediately before and after the birth of the Brown baby in England, the Hastings Center received dozens of telephone calls and requests for staff members to speak to the public over television and radio about ethical issues surrounding in-vitro fertilization. These appearances led to a flood of additional calls about ethical issues in a broad range of biomedical and behavioral topics unrelated to in-vitro fertilization.

At the same time, a breakthrough in human genetics was announced, enabling detection of hereditary birth defects in unborn babies. This technique is one of the first applications of recombinant DNA research—an area that has received a striking amount of attention among scientists, policymakers, and the public over the past several years.

On the same day—July 27, 1978—that these scientific breakthroughs were announced, the New York Times reported an appeal by Mr. Califano to medical specialists to help rebuild public confidence in flu immunization in the hopes of urging a somewhat skeptical public to get flu shots.

It is clear without a doubt that advances in theoretical knowledge and technological applications in broad areas affecting human health and well-being will continue to occur. All of these gains pose ethical dilemmas concerning the assessment of risks and benefits.

Even in cases where it is shown that biomedical and behavioral research is likely to bring more benefits than harms, problems still exist in the effort to distribute such benefits equitably among the population.

Since technological advances in these areas will continue at an ever-increasing pace, and since policies are best developed in a systematic manner, there is no better approach than the creation of a President's commission to oversee developments in this crucial area.

In the past 10 years we have witnessed a giant leap in public awareness and concern about ethical matters related to medicine and health. Increased consciousness on the part of the public and their elected representatives about moral issues has now moved beyond the narrower realm of biology and medicine into a number of broader social arenas.

For almost 10 years now, the work of the Hastings Center, similar activities by the Kennedy Institute at Georgetown University,

and a wide range of efforts by individual scholars in biology, medicine, law, philosophy, religion, and the social sciences have all contributed to bringing ethical issues in the biomedical and behavioral sphere to the attention of policymakers and the public at large.

This is all by way of asserting a need for such a Commission. The time has come to move beyond that narrower focus and consider the protection of human subjects in a wider domain. It makes excellent sense, therefore, to create a President's Commission, whose mandate would be broadened to include the kinds of general studies described in the Senate bill, as well as the specific studies noted in the somewhat narrower version before us in the House bill.

The need for such a Commission is further demonstrated by the excellent work of the National Commission for the Protection of Human Subjects, now nearing its completion. The National Commission conducted its studies with careful attention to details, with scholarly rigor, and with a sensitivity to the pluralism that exists in our society on ethical and religious matters.

I won't repeat the accolades previous speakers have uttered. I agree with all of them.

Anyone who has read their reports and recommendations or attended any of the Commission's working sessions cannot fail to be impressed, as I have been, with the commendable results of this interdisciplinary group.

An exceptional virtue of the National Commission's reports is that they are clear and understandable to a concerned public, as well as satisfying to those of us who work professionally in the field of biomedical ethics and health policy.

The bill enacted by the Senate explicitly calls for followup of the National Commission's work—a feature omitted from the House bill in the form in which it now exists.

I find that omission disappointing, as well as a further difference between the two bills relating to the existing National Commission. S. 2579 provides for continuity between the existing National Commission and the proposed Presidential Commission by having present Commission members serve on the new commission until the President acts to appoint members of the newly-created body.

The House bill contains no such provision helping to ensure continuity without a reduplication of work already accomplished. Anyone who has spent long hours in deliberation and discussion of topics in biomedical ethics knows that such issues are exceedingly complex and that debate proceeds most efficiently in groups that have had some experience working together.

Both the interdisciplinary composition of the present National Commission and the experience of its members suggest that the newly-formed Presidential Commission could best profit in its assigned tasks by having as much continuity as possible with the distinguished work of the present National Commission.

There is one final point to be made about the need for a Presidential Commission. Dr. Ryan referred earlier to a study subcontracted by the Commission entitled "A Comprehensive Study of the Ethical, Legal and Social Implications of Advances in Biomedical and Behavioral Research and Technology."

As Dr. Ryan noted, there were two components to that study: (1) a policy study, in which a consultant panel of about 125 persons from 5 broad categories responded to structured and open ended questions; and (2) a national opinion survey, with questions administered to a probability sample of 1,679 Americans in individual face-to-face interviews. I served as a member of the consultant panel, and was struck by a number of the results of this comprehensive inquiry, which I want very briefly just to mention.

First, there was an overwhelming response on the part of the consultant panel that an urgent need exists for a permanent national commission of some sort, although panelists were divided as to what was called for.

Sixty-two percent of the panelists who responded to the second evaluation instrument considered the establishment of such a commission to be an urgent policy. Forty-seven percent ranked this among the top 3 most urgent policies, and 44 panelists ranked it first in importance.

A variety of needs for this Commission were noted, but those most frequently mentioned pertained to the national coordination of research and the establishment of standards at a national level.

Second, although the national opinion survey did not specifically address the creation of a permanent national commission, the findings of the survey were nonetheless instructive in this regard. The public and consultant panelists both were asked to name good and bad effects of recent advances in biomedical and behavioral technology and projections into the future.

In both groups, health advances dominated the good predictions, while ethical, political, and social effects dominated the bad. The public saw treatment for mental illness—specially, proliferation of tranquilizers—and selection of sex of offspring as the advances most likely to produce bad effects.

Consultant panelists predicted control of behavior as the item most likely to lead to bad effects in the future.

A Presidential Commission with a broad mandate would have to examine these subjects as well as numerous others to which consultants and the public responded in this study.

I shall say a bit more about the findings of this study in my remarks about the differences between the House and the Senate bills to establish a President's Commission.

DIFFERENCES BETWEEN THE HOUSE BILL AND S. 2579

It is disappointing to note that the House bill before us lacks the scope and breadth of the bill enacted by the Senate. The Senate bill appears to have a broader base, leading to consideration of ethical, social, and legal concerns that go beyond the narrower confines of biomedical and behavioral research and allocation of resources for these activities.

There are three chief areas in which the broader scope of the Senate bill merits serious consideration for inclusion in a bill brought before the House: First, the interagency aspect, about which former speakers and Senator Kennedy spoke at length. In my consideration I have not got in mind any regulatory authority

that would be given for the interagency function as noted in the Senate bill.

Second, there are aspects related to public understanding of and attitudes toward advances in biomedical and behavioral technology; and

Third, sections pertaining to privacy and confidentiality.

I shall address each of these briefly in turn.

(1) The interagency aspect. The Senate bill makes explicit provision for review of programs in other departments or agencies, including the Department of Defense and the Central Intelligence Agency. The House bill omits this oversight provision.

The biggest danger is, of course, that some human subjects of research would go unprotected if a President's Commission is not granted oversight of the sort provided for in the Senate bill. Not only does this omission from the House bill leave potential subjects open to the sorts of abuses—by now well-documented—that have occurred in military and CIA research projects involving drugs and other modes of behavior control. It is also patently unjust.

To make careful provision for review and oversight of some biomedical and behavioral research while avoiding similar efforts that may be conducted outside the auspices of the Department of Health, Education, and Welfare is to allow a double standard to exist in the ethics of research on human subjects.

The subjects of biomedical and behavioral research deserve equal protection under the law, in accordance with widely accepted precepts of social justice.

With due acknowledgement of the need for secrecy involving national security matters, I remain disturbed about the possibility for abuse or inadequate protection of research subjects.

The virtue of establishing a national commission under the auspices of the executive branch is precisely that it can enable the kind of interagency oversight provided for in the Senate bill but lacking in the House version. This is all the more troubling in light of recent, rapid advances in psychopharmacology, newly developed techniques of neurological surgery, and other refinements in the field of neuroscience.

Who will look out for the interests of those who serve as research subjects for biomedical and behavioral investigations conducted by the Department of Defense and the CIA? If not a Presidential Commission, the answer is probably "nobody."

The deletion of this provision from the bill enacted by the Senate results in narrowing the scope of protection of human subjects and thereby allowing vulnerable groups to be subjected to different ethical standards.

(2) Aspects related to public understanding of and attitudes toward advances in biomedical and behavioral technology. Section 1804 of S. 2579 includes a number of "general studies" that are omitted in the House bill. The most significant lack lies in the failure of the House version to address public understanding of and attitudes toward implication of advances in biomedical and behavioral research, laws, and moral principles governing the use of technology in medical practice, and implications for public policy.

We are no longer dealing with a naive public. The ever-increasing public awareness of ethical aspects of biomedical research and

treatment calls for a concerted effort to inform and gather responses from the citizens of our democracy. Some people are surprised to learn that residents of the Nation's slums and ghettos are often reluctant to enter teaching hospitals—where they do receive high-quality care—but are reluctant to enter from fear of becoming human guinea pigs.

Patients' advocacy groups have sprung up all across the Nation, and many who enter hospitals refuse to sign the forms required for gaining their informed consent because they have not been adequately informed.

Recent studies demonstrate a high degree of noncompliance on the part of patients in treatment regimens ordered by physicians. In the interest both of preserving and promoting the health of patients, and of fostering more efficient and effective medical care, it is crucial to have data on public understanding of and attitudes towards advances in biomedical and behavioral technology.

The omission of this provision from the House bill leaves open to chance and haphazard channels of information what should properly be a systematic effort on the part of a President's Commission.

The public opinion survey part of the comprehensive study I cited earlier reveals a relatively high degree of sophistication and some rather strongly held attitudes on the part of the public.

It is a mistake to ignore these facts in establishing a President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.

(3) Sections pertaining to privacy and confidentiality. Sections 1805 and 1807 of S. 2579 make detailed and explicit provision for studying, evaluating, and maintaining the privacy of research subjects and the confidentiality of patient records. The House bill, as I studied it, refers only to disclosure under subsection (a) of section 552 of title V, United States Code. The omission of the broader considerations included in the Senate bill is especially striking in light of the current climate.

At a time when first amendment rights in other domains are being subjected to serious and prolonged debate, it is surely a grave error to ignore these traditional concerns of biomedical practice and research. The public is worried these days—perhaps with good reason—about increasing inroads into their privacy, widespread use of data banks and computer storage of personal information, and the need to reveal a range of personal data to insurance companies and other third party payers.

It would set an unfortunate precedent for other professional areas, such as law and journalism, if a Presidential Commission in the biomedical and behavioral sphere failed to spell out in detail provisions required for protecting the privacy and confidentiality of subjects of research and treatment.

One of the five subject areas selected for examination in the comprehensive study conducted by the present National Commission was that of data banks and computer technology. A large number of consultant panelists raised questions about increasing inroads into privacy and confidentiality brought about by technological advances in this area.

I would recommend, therefore, that such provisions be included or added to the House bill.

Now considering the composition of the President's Commission, the 15-member Commission described in the House bill is excessively weighted in the direction of biomedical and behavioral experts. It is a well-known fact that professionals with expertise in scientific or clinical matters often fail to exhibit awareness of and sensitivity to ethical aspects of their work.

This is not to imply that biomedical and behavioral researchers or clinicians are likely to engage in patently immoral practices. It is, however, important to recall that awareness of moral implications and the ability to address such concerns in a thorough and rigorous manner requires some training and experience in the practice of moral reasoning.

Technical expertise does not transfer automatically into the arena of moral decisionmaking. Two-thirds of the proposed Commission, in the House bill, need have no previous acquaintance or experience with matters pertaining to ethics or health policy. The remaining third may include persons distinguished in the natural sciences other than biomedical or behavioral science. They, too, may lack experience in dealing with moral and policy concerns.

Since the President's Commission is mandated specifically to study ethical problems in medicine and biomedical and behavioral research, the imbalance in its proposed composition is most unfortunate.

On this point, the Senate bill is superior. It requires that more than half of the Commission's members be persons who are not and have not been engaged in biomedical or behavioral research involving human subjects. This provision insures that past and current practices in biomedical and behavioral research will not hold sway simply because a majority of the Commission's members accept those practices uncritically and as a matter of course.

While I was on the faculty of Case Western Reserve University, I served for several years on an institutional review board—one that reviewed research protocols in the social and behavioral sciences. As most people know, there is a great deal of deception of human subjects practiced in the course of much social science experimentation.

When I raised questions about the morality of this deception in connection with informed consent requirements, I was greeted almost uniformly with disdain by the social scientists on the committee who accepted widespread deception as standard practice in the field and saw no presumption of anything morally questionable about this practice.

The composition of a National Commission was an issue that drew considerable attention from the consultant panelists in the comprehensive study mentioned earlier.

The most frequently expressed position was that the Commission should be composed of both scientists and nonscientists and that it should be multidisciplinary.

Beyond that, panelists differed on the question of whether the Commission should include all and only distinguished personnel, whether there should be representation by ordinary consumers and if so, what percentage, and whether there should be specific selections made from the poor and minority groups.

There was a broad range of views concerning the composition of the Commission, but a distinct minority of panelists thought that the group should be composed mainly of distinguished researchers or clinicians in the biomedical and behavioral sciences.

When the proposed composition of the President's Commission is considered together with the fact that the House bill lacks provision for studying public understanding of and attitudes toward advances in biomedical and behavioral technology, it suggests that this Commission is likely to be controlled by those who already wield power in the health care delivery and health research systems.

A President's Commission should be a balanced group. It should surely be composed in such a way that its members will suffer a minimum of conflicts of interest.

It is hard to see how the composition of this important body, as proposed in the House bill, would lead to anything but a perpetuation of the status quo regarding ethical problems in medicine and biomedical and behavioral research.

Thank you, Mr. Chairman.

Mr. ROGERS. Thank you so much.

Dr. Walters.

STATEMENT OF LeROY WALTERS, PH. D.

Dr. WALTERS. Thank you, Mr. Chairman. My remarks today will be brief. They will be divided into three parts. First, I will attempt to summarize the achievement of the National Commission for the Protection of Human Subjects. Second, I will present the case for the establishment of a Presidential Commission to continue the work of the current National Commission when the National Commission's work terminates in October of this year. Third, I will comment specifically on some of the strengths and possible weaknesses of H.R. 13662 as currently drafted.

I. THE ACHIEVEMENT OF THE NATIONAL COMMISSION.

In July of 1974 Public Law 93-348 was enacted.¹ Title II of the law provided for the establishment of a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. At that time, and even in December 1974 when the Commission held its first meeting, no one could be sure how the Commission would approach the difficult issues assigned to it, whether the commissioners would be able to achieve consensus on any of the issues, or whether the Commission's findings and recommendations would be acceptable to the Congress, the Department of Health, Education, and Welfare, the research community, and the general public.

Today, after 3½ years of work, the Commission has compiled a solid record of achievement. It has issued six major reports, and plans to issue four additional reports prior to its termination in October of this year. During its existence the Commission has served as the focal point for national discussion of ethical issues in biomedical research and, to a more limited extent, in behavioral research and the delivery of health care.

¹ U.S. *Statutes at Large*, vol. 88, pp. 352-354.

Evidence of the broad acceptance of the Commission's work can be found in two editorials, the first published in the *New England Journal of Medicine*, the second in the *New York Times*. In January of 1977 Franz Ingelfinger, then editor of the *New England Journal of Medicine*, wrote:

When Congress created the National Commission for the Protection of Human Subjects * * *, its goals were recognized as laudable, but its practical usefulness seemed doubtful to some * * *.

Now, 2 years later, the skeptics have had to swallow most of their doubts. In the context of the formidability of its assignments, the commission has been remarkably successful * * *¹

In June of this year a *New York Times* editorial supported congressional initiatives to create a Presidential Commission for the Protection of Human Subjects by pointing to the achievements of the current National Commission:

The commission has performed splendidly. Its guidelines for the conduct of research on fetuses, children, prisoners, and hospitalized mental patients have shaped research practices and have often been incorporated into government regulations. Fears that the commission would block valuable research have proved largely unwarranted.²

II. THE CONTINUING NEED FOR A PRESIDENTIAL COMMISSION

Prior to the creation of the current National Commission, as well as during its existence, other Government agencies conducted or sponsored important studies of issues in biomedical ethics. Among the most important of these studies are the following:

1. A report on the Tuskegee Syphilis Study by a committee appointed by the U.S. Public Health Service (1973).³

2. A technology assessment of the totally implantable artificial heart by a panel appointed by the National Heart and Lung Institute (1973).⁴

3. A report and recommendation on the compensation of injured research subjects by an interagency DHEW task force (1976).⁵ In my view this is the finest report to come out of any agency—conducted by the agency members themselves—that we have had to date in the whole field of biomedical ethics.

4. A report and recommendations on national immunization policy by work groups appointed by the Assistant Secretary for Health (1977).⁶

One possible approach in the future would be to create similar ad hoc committees, each of which would be assigned by one or more executive agencies to study a particular ethical or public policy issue. The advantages of such an approach are that it fosters accountability within executive agencies and that it maintains maximum proximity between the study and implementation func-

¹ F. J. Ingelfinger, "Ethics of Human Experimentation Defined by a National Commission [Editorial]," *New England Journal of Medicine* 296(1): 44-45, Jan. 6, 1977.

² "Keeping Scientists Humane," *New York Times*, June 18, 1978, sec. 4, p. 18.

³ U.S., Public Health Service, "Final Report of the Tuskegee Study Ad Hoc Advisory Panel" (Washington, D.C.: U.S. Government Printing Office, 1973).

⁴ U.S. National Heart and Lung Institute, Artificial Heart Assessment Panel, "The Totally Implantable Artificial Heart: Economic, Ethical, Legal, Medical, Psychiatric, and Social Implications" (Bethesda, Md.: National Heart and Lung Institute, June 1973).

⁵ U.S., Department of Health, Education, and Welfare, "HEW Secretary's Task Force on the Compensation of Injured Research Subjects" (3 vols.; Bethesda, Md.: National Institutes of Health, January 1977).

⁶ National Immunization Work Groups, "Reports and Recommendations of the National Immunization Work Groups, Mar. 15, 1977" (McLean, Va.: JRB Associates, 1977).

tions of the agencies. Disadvantages of the ad hoc committee approach are the lack of continuity from one study to another and the lack of visibility of the committees and their findings.

A second possible approach would be to create ongoing commission-like groups within individual agencies. The best-known such group is the Ethics Advisory Board within the Department of Health, Education, and Welfare. In the summer of 1977 Secretary Califano appointed 11 distinguished persons to this Board, which is responsible for advising the Secretary on a broad range of ethical issues raised by biomedical or behavioral research conducted or supported by the Department. The Board is currently conducting a review of the scientific, ethical, and legal aspects of in-vitro fertilization.⁷

I have nothing but the highest regard for the members of the Ethics Advisory Board and its staff. Without question the board will provide valuable advice to the DHEW Secretary on a variety of important topics in biomedical ethics.

However, the existence and anticipated contribution of the DHEW Ethics Advisory Board do not, in my view, render superfluous the creation of the proposed President's Commission. The establishment of a President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research remains a high priority for at least three reasons:

1. The number of topics in biomedical ethics which require detailed study at a national level is sufficiently large that no single board or commission will be able to cover all of them, even in several years' work. On this point I would therefore agree with Mr. Gaither.

2. The proposed President's Commission could complement the work of the DHEW Ethics Advisory Board by including the activities of all executive agencies within the scope of the Commission's attention. The fact that 20 Federal agencies other than DHEW are involved, at least to some extent, in the conduct or support of research involving human subjects⁸ illustrates the need for such an interagency perspective.

3. The proposed President's Commission, like the current National Commission, would provide a highly visible national forum for the presentation of divergent viewpoints on major issues in biomedical ethics. The public discussion fostered by the Commission might in turn, contribute toward the achievement of a national consensus on those issues.

III. SPECIFIC COMMENTS ON H.R. 13662

A. Strengths of the bill: 1. The bill, even in selecting a name for the Commission, includes within the Commission's purview both ethical issues in clinical medicine and issues in biomedical and behavioral research. The mandate of the proposed President's Commission is thus significantly broader than that of the current National Commission.

⁷ Personal communication from Charles R. McCarthy, Ph. D., Executive Director-Designate of the Ethics Advisory Board.

⁸ U.S., National Commission for the Protection of Human Subjects, staff, "The Protection of Human Subjects in Research Conducted or Supported by Federal Agencies" (Bethesda, Md.: National Commission for the Protection of Human Subjects, Feb. 10, 1978), p. 1.

2. The bill provides for a Commission of mixed composition, which would include health professionals, biomedical and behavioral researchers, and members of numerous nonbiomedical and non-behavioral fields.

3. The bill assumes that the proposed Commission would conduct business in public and explicitly provides for the dissemination of Commission reports and recommendations to the President, the Congress, and the public.

4. The bill requires all executive agencies to provide pertinent information requested by the Commission Chairman.

5. The bill identifies eight issues of national importance and asks the Commission to conduct studies of their legal, ethical, and social implications. Among these issues are the allocation of scarce biomedical resources, informed consent, genetic counseling, in-vitro fertilization, and the definition of death.

B. Reservations about the bill: 1. The proposed composition of the Commission—and here I echo the sentiments of Dr. Macklin—is too heavily weighted toward scientists and health professionals and does not allow for sufficient representation of ethicists, lawyers, social scientists, and members of the public. Since both technical and normative aspects of the designated topics will be discussed, I would recommend that the number of scientists and health professionals, on the one hand, and experts in other fields, on the other, be approximately equal.

2. The bill should include explicit provision for the publication of Commission recommendations in the Federal Register, as well as a stipulation that recommendations directed to a particular agency—perhaps through the President's Science Adviser—must receive a formal response, also to be published in the Federal Register, within a specified time period. The requirement of a formal published response has been a key to the success of the current National Commission and distinguishes the fate of its recommendations from the perpetual silence accorded the recommendations of many past commissions.

3. Several issues in biomedical ethics which have received national attention are omitted from the list of topics to be studied by the Commission. These include:

a. Euthanasia and the prolongation of life.⁹ Here I would note that the U.S. Congress has held hearings on death with dignity, the right to survival of handicapped newborn infants, and extraordinary health care in 1972, 1974, and 1975, respectively. In addition, it is noteworthy that eight States have recently enacted laws concerning appropriate treatment for seriously ill or dying patients, and that no fewer than 27 State legislatures considered death-with-dignity legislation during their 1978 sessions.

b. The compensation of injured research subjects.¹⁰

c. National immunization policy, especially with respect to the immunization of children.¹¹

⁹ The source for these statistics is the *Legislative Newsletter* of the Society for the Right to Die, Summer 1978, p. 1.

¹⁰ See the reference cited in footnote 5 above. Although this excellent report was forwarded to the Office of the Secretary, DHEW, in January 1977, no action on the issue of compensating injured research subjects has been taken by DHEW.

¹¹ See the reference cited in footnote 7 above. The Federal Government is heavily involved in providing funds to the States in support of their immunization programs, especially among children. See for example, the "Disease Control Amendments of 1976," Title II of Public Law 94-317.

d. Epidemiological research and the confidentiality of medical records.¹²

e. Ethical issues in behavioral research and therapy, which the current National Commission admittedly was not able to cover in as much detail as biomedical issues.

4. In the final version of the bill the Congress should indicate which issues it considers to be of the highest priority and should set reasonable deadlines by which it expects the Commission to complete its reports on those issues.

In summary, H.R. 13662 is an important bill: The Presidential Commission envisioned in the bill would perform a vital national service not likely to be performed by any other group.¹³

Thank you.

Mr. ROGERS. Thank you very much. I think some of the suggestions you have made are good. We are grateful to the panel for bringing our attention to them. I think both bills probably are deficient in making sure that enough ethicists are included on the Commission. For instance, I think you could end up maybe with only one ethical person under the Senate bill, because it says—

Rabbi SIEGEL. Ethicists. They are all ethical persons.

Mr. ROGERS. Ethicists, I am sorry, ethicists. And I am not sure everybody is ethical, may I say.

Rabbi SIEGEL. Maybe we should have a Commission to discuss that.

Mr. Rogers. I don't think we have to have a commission. Just look around in Washington, or perhaps even New York. I think probably both bills are deficient with respect to ethicists, because I see ethics mentioned only once—neurology, medicine, biological and physical sciences, health administration—so I presume the criticism applies both to the Senate and the House versions.

Would you agree to that?

Dr. MACKLIN. I would agree, if it were a question of insuring it. My remarks were really addressed to the balance of the members, and in the Senate bill there is explicit provision that there be six members who are not, and have not, been engaged in biomedical and behavioral research, and I think that affords a different perspective.

I think you are quite right to point out that there is no requirement that there be a large number of people from the field of ethics.

Mr. ROGERS. I think if you will analyze the House bill, you will see that only 5 members be appointed from individuals distinguished in biomedical and behavioral research; 10 would not be. So perhaps that is even a heavier balance against the researchers. However, I really don't think it is that important. But we do need to give more attention to including individuals who are neither from medical or scientific disciplines.

Rabbi SIEGEL. Could I say one thing?

Since listening to my colleagues here, it just occurred to me that a lot of these legislative decisions on bioethical issues are made in

¹² See the recommendations on this issue compiled by the U.S. Privacy Protection Study Commission in *Personal Privacy in an Information Society: the Report of the Privacy Protection Study Commission*. (Washington, D.C.: U.S. Government Printing Office, 1977), *passim*.

¹³ I acknowledge with gratitude the excellent research assistance of Emilio Jaksetic in the preparation of this statement.

State legislatures rather than in the Federal Congress, and that some thought should be given to how to either make available the findings of this Commission or some kind of formal relationship with the 50 States to help them in their legislative and regulatory functions.

Mr. ROGERS. I think that is an excellent suggestion to look at, too. I presume that the three of you, judging from your testimony, do not believe that the Commission should be in a regulatory function; is that correct?

Dr. MACKLIN. Correct.

Rabbi SIEGEL. Correct.

Dr. WALTERS. Correct.

Mr. ROGERS. And should it have a continuing oversight function or should it be more concerned with the setting of policy?

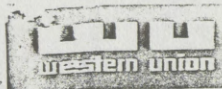
Rabbi SIEGEL. I think if the Commission took up the agenda that this bill, or even the Senate bill, sets before it, plus the additions that we have heard, that they would have quite enough to do in the course of their deliberation, unless they would be made use of by various agencies and departments and Congress itself, unless there was some specific request of them.

Mr. ROGERS. Thank you.

Your testimony has been very helpful to the committee. We appreciate your presence here. You were kind to give your time, and I express, again, the appreciation of the committee.

I believe that concludes the list of witnesses, and the committee is adjourned.

[The following telegram was received for the record]


Telegram

LLAC51 WAC057(0751)(4-008926E216)PD 08/04/78 0745

ICS IPMBNGZ CSP

8C53273807 IDBN BAKERSFIELD CA 693 08-04 0745A EST

PMS CHARLES PLANTE, DLR IMMY THERE IS A CONGRESSIONAL MEETING
BEING HELD AND THIS HAS TO BE DLRD IMMEDIATELY TO MAKE THIS HEARING,
MR PLANTE'S PHONE NUMBER IS 2026591373 TO LET HIM KNOW YOU HAVE
THE MSG TO BE DLRD, DLR

2000 K ST NORTHWEST

WASHINGTON DC 20006

AS THE HONORABLE PAUL G ROGERS CHAIRMAN, SUBCOMMITTEE ON HEALTH AND
THE ENVIRONMENT HOUSE OF REPRESENTATIVES RAYBURN HOUSE OFFICE
BUILDING ROOM 2415 WASHINGTON DC 20515

DEAR CHAIRMAN ROGERS

THE AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS WHICH IS THE

ACKNOWLEDGED LEADER AND SPOKEPERSON FOR PRACTICALLY ALL AMERICAN
NEUROLOGICAL SURGEONS WHO NOW NUMBER NEARLY 3,000, ENDORSES THE BILL
WHICH YOU, MR ROGERS, HAVE INTRODUCED IN WHICH THIS SUBCOMMITTEE ON
HEALTH AND THE ENVIRONMENT IS PRESENTLY HEARING.

AS NEUROLOGICAL SURGEONS WE HAVE THE PRIVILEGE AND RESPECTFUL DUTY
TO SERVE THE NEURO-SURGICAL AND MEDICAL NEEDS AND WANTS OF THE
AMERICAN PUBLIC. IT IS THIS MOST HUMAN AREA OF MEDICINE AND OF
BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BRAIN AND MIND, THAT
CONTAINS SO MANY OF THE ETHICAL PROBLEMS TO WHICH THE PROPOSED
LEGISLATION IS DIRECTED. BECAUSE OF THESE CHALLENGING INVOLVEMENTS
WE HAVE CHOSEN TO DEDICATE OUR EFFORTS AND TIME TO THE PRINCIPLES
CONTAINED IN THIS BILL ENTITLED "TO ESTABLISH THE PRESIDENT'S
COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND

**Telegram**

BIOMEDICAL AND BEHAVIORAL RESEARCH".

ALL EIGHT OBJECTIVES LISTED IN THIS BILL TO ESTABLISH A PRESIDENTIAL COMMISSION SEEM RELEVANT. SPECIFICALLY, WE DEAL ACTIVELY WITH THESE VARIOUS OBJECTIVES, BY EXAMPLE,

1. UNIFORM DEFINITION OF DEATH
2. HUMAN BEHAVIORAL AND BIOMEDICAL RESEARCH
3. INFORMED CONSENT FOR SAME
4. PSYCHOSURGERY
5. DETERMINATION OF REQUIREMENTS AND GUIDELINES THAT SHOULD APPLY TO HUMAN CLINICAL TRIALS
6. ETC

WE HAVE BEEN PARTICULARLY INVOLVED WITH MANY OF THE MATTERS REVIEWED BY THE NATIONAL COMMISSION ON PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH AND HAVE OFFERED ADVICE ON A NUMBER OF OCCASIONS. WE HAVE AGREED WITH THE PRINCIPALS DECLARED IN THE LEGISLATION WHICH ORIGINALLY CREATED THAT NATIONAL COMMISSION. WE ENDORSE THIS LEGISLATION WHICH YOU ARE INTRODUCING NOW AS COMPLEMENTING THE WORK OF THE PREVIOUS NATIONAL COMMISSION. THIS LEGISLATION HEIGHTENS THE IMPORTANCE OF THOSE PRINCIPLES AND WORK INY CREATING A PRESIDENTIAL COMMISSION TO REPLACE THE PRESENT NATIONAL ONE; IT PROVIDES FOR NEEDED CONTINUITY TO THE IMPRESSIVE START ALREADY MADE BY THE NATIONAL COMMISSION.

THIS LEGISLATIVE PLAN ACCOMPLISHES THESE GOALS BY STRUCTURING AN EXEMPLARY AND EFFECTIVE ADVISORY GROUP OF 15 PERSONS EQUITABLY


Telegram

DIVIDED IN THREE GROUPS OF FIVE EACH. FIVE MEMBERS ARE DISTINGUISHED EXPERTS IN THE FIELD OF BIOMEDICAL AND BEHAVIORAL RESEARCH ITSELF. ANOTHER FIVE MEMBERS ARE DISTINGUISHED PHYSICIANS WHO ARE NOT DIRECTLY INVOLVED IN THOSE RESEARCH FIELDS AND WHO DO UNDERSTAND IN THE FULLEST THE MEDICAL NEEDS OF THE AMERICAN PUBLIC. THE REMAINING FIVE MEMBERS SHALL BE DISTINGUISHED IN THE FIELDS OF ETHICS, MORALITY, LAW AND PHILOSOPHY, AND IN ESSENCE, TRULY UNDERSTAND THE NEEDS OF THE CONSUMER. THIS GROUP OF 15 PERSONS WOULD BE, BY DEFINITION, ADVISORY BUT, IN EFFECT, BY VIRTUE OF THEIR DEDICATION AND EXPERTISE AND BY VIRTUE OF THE ULTIMATE EXCELLENCE OF THEIR DELIBERATIONS AND ACCOMPLISHMENTS, WOULD BECOME EFFECTIVE AND THEREFORE AUTHORITATIVE.

THERE WOULD BE NO NECESSITY OF INVESTING THIS COMMISSION WITH

REGULATORY AUTHORITY. SUCH A PROPOSED COMMISSION OUGHT NOT, IN ANY CASE, RESORT TO THAT REGULATORY POWER TO ACCOMPLISH ITS GOALS BUT RATHER IT SHOULD BE ABLE TO IDENTIFY FOR ITSELF AND THEN TO DEMONSTRATE ANY NEEDS TO THE VARIOUS AGENCIES AND DEPARTMENTS (AND TO THE PUBLIC AS WELL). IT IS APPARENT TO US THAT THE DHEW, FDA, FTC, CIA, DOD, JUSTICE DEPARTMENT, ETC HAVE ENOUGH EXISTING AUTHORITY TO ADMINISTER, TO IMPOSE APPROPRIATE SANCTIONS AND TO DEAL WITH MATTERS CALLED TO THEIR ATTENTION BY THIS PRESIDENTIAL COMMISSION WITHOUT CREATING YET ANOTHER UNNECESSARY LAYER OF REGULATORY AUTHORITY. THEREFORE, THIS BILL WITH ITS GOOD PLANNING OBVIATES THAT CRITICISM.

TO PROVIDE REGULATORY AUTHORITY OR THE POWER OF SUBPOENA WOULD OBVIOUSLY INVEST THIS PRESIDENTIAL COMMISSION WITH AN INQUISITORIAL


western union

Telegram

CLOAK THAT WOULD QUICKLY ACHIEVE THE UNDESIRABLE POLARITY OF AN ADVERSARY, QUASI-JUDICIAL, PUNITIVE AGENCY; WISELY, THIS BILL AVOIDS THAT.

THIS PROPOSED BILL PROVIDES FOR A PRESENTLY NEEDED PRESIDENTIAL COMMISSION FOR A FINITE PERIOD OF UP TO FOUR YEARS ONLY. THIS PROPOSAL WOULD PERMIT A TIMELY REVIEW OF ITS CONTINUATION THEREAFTER BUT DOES NOT IMPOSE THE COMMISSION AS A PERMANENT BODY BEFORE THE CONGRESS IN ITS WISDOM MAY CHOOSE TO DO SO.

WE APPLAUD THE CONTINUATION AND STRENGTHENING OF THE PRINCIPALS OF THIS PRESIDENTIAL COMMISSION AS THEY ARE EMBODIED IN THE LEGISLATION BEING INTRODUCED AND HEARD.

RESPECTFULLY,

THE AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS
DONALD DORN, M.D., PRESIDENT

GEORGE ABLIN, M.D.
NNNN

[Whereupon, at 4:20 p.m. the subcommittee adjourned.]

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