

Foreign Commerce, Subcommittee on Public Health and Environment.

BIOMEDICAL RESEARCH ETHICS AND THE PROTECTION OF HUMAN RESEARCH SUBJECTS

HEARINGS

BEFORE THE

SUBCOMMITTEE ON

PUBLIC HEALTH AND ENVIRONMENT

OF THE

COMMITTEE ON

INTERSTATE AND FOREIGN COMMERCE

HOUSE OF REPRESENTATIVES

NINETY-THIRD CONGRESS

FIRST SESSION

ON

H.R. 10403, H.R. 1111, H.R. 1112, H.R. 2655, H.R.
5371, H.R. 6852, H.R. 7850, H.R. 8778, H.R. 8779,
H.R. 9488, and H.R. 10573

BILLS TO PROVIDE FOR THE PROTECTION OF HUMAN
SUBJECTS WHO PARTICIPATE IN BIOMEDICAL OR BE-
HAVIORAL RESEARCH PROGRAMS, TO PROVIDE FOR A
STUDY AND EVALUATION OF THE ETHICAL, SOCIAL, AND
LEGAL IMPLICATIONS OF ADVANCES IN BIOMEDICAL RE-
SEARCH AND TECHNOLOGY, AND FOR OTHER PURPOSES

SEPTEMBER 27 AND 28, 1973

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Challoner, Dr. David R., counselor.

Association of American Medical Colleges:

Ball, Dr. Michael F., director of biomedical research.

Cooper, Dr. John A. D., president.

Health, Education, and Welfare Department:

Chalkley, Dr. D. T., Chief, Institutional Relations Branch, Division of Research Grants, National Institutes of Health.

Edwards, Dr. Charles, Assistant Secretary of Health.

Kelsey, Dr. Frances O., Director, Scientific Investigation Staff, Office of Scientific Evaluation, Bureau of Drugs, Food and Drug Administration.

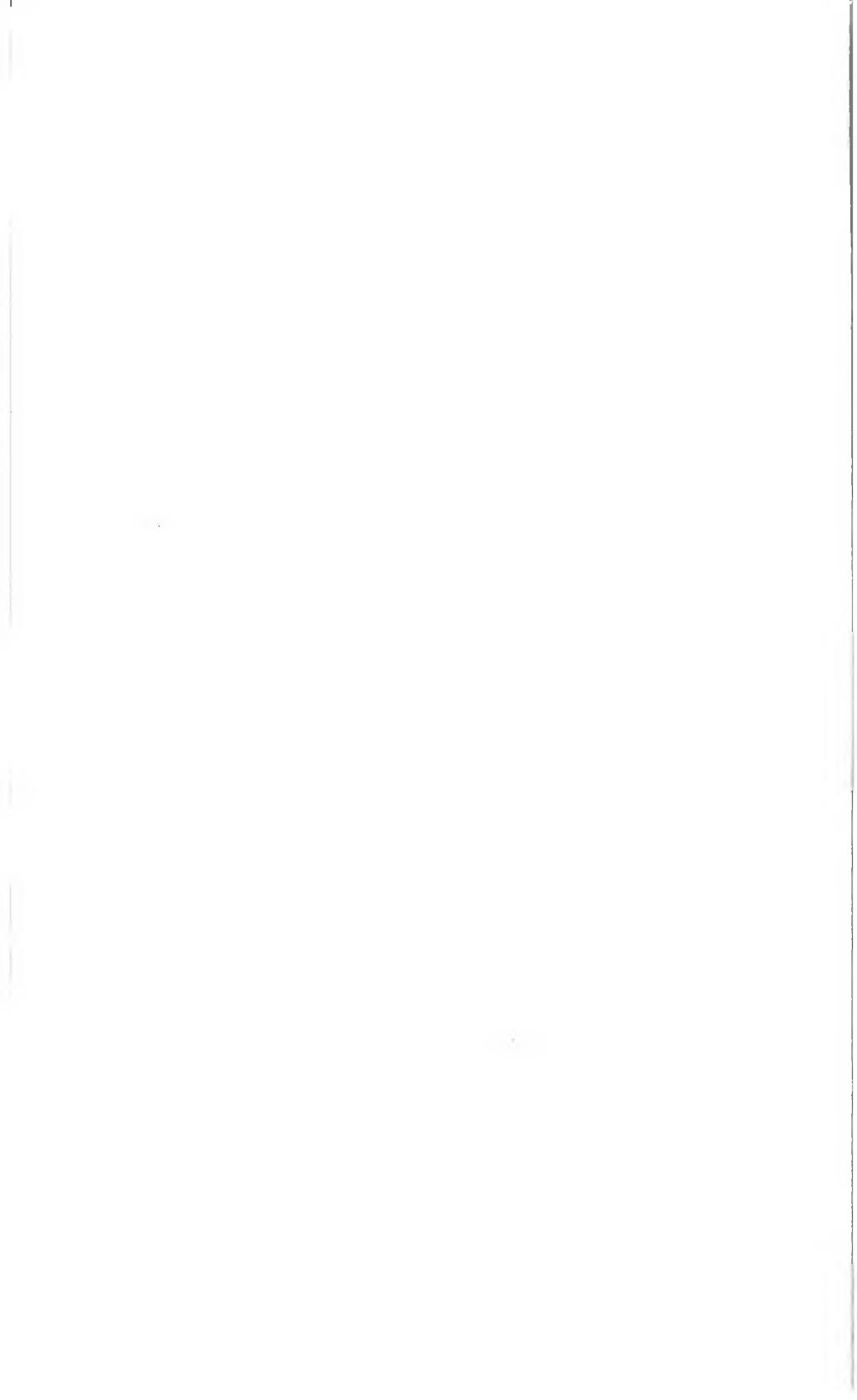
Lamont-Havers, Dr. R. W., Deputy Director, National Institute of Arthritis, Metabolism, and Digestive Diseases, National Institutes of Health.

Stone, Dr. Robert, Director, National Institutes of Health.

Zapp, Dr. John S., Deputy Assistant Secretary for Legislation (Health).

Institute of Society, Ethics, and the Life Sciences, Robert M. Veatch, Ph. D., Associate for Medical Ethics.

Joint Council of Pediatric Societies, Dr. Richard Behrman, professor and chairman, Department of Pediatrics, Columbia University.



BIOMEDICAL RESEARCH ETHICS AND THE PROTECTION OF HUMAN RESEARCH SUBJECTS

THURSDAY, SEPTEMBER 27, 1973

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

The subcommittee met, pursuant to notice, at 10 a.m., in room 2322, Rayburn House Office Building, Hon. Paul G. Rogers, chairman, presiding.

Mr. ROGERS. The subcommittee will come to order.

The hearings today and tomorrow are for the purpose of examining the provisions of H.R. 10403 and other bills which involve the problem of human experimentation. H.R. 10403 was introduced for purpose of discussion and has been passed in the Senate as part of legislation which deals with training and research grants.

The overall question of the ethical conduct of conducting experiments with human subjects received worldwide attention following World War II and was addressed at the Nuremberg trials. Since then there has been several national and international agreements passed.

I think there can be no question as to the need for experiments as part of the scientific process which give our medical storehouse new and valuable drugs and methods for the betterment of man.

The question most frequently posed in light of reoccurring stories about the misuse of human subjects is how we can best strengthen existing law to insure that these misuses do not occur.

During recent months hearings have documented that our system of surveillance on medical trails using humans has many shortcomings. I am not at all sure that the provisions of H.R. 10403, as well-meaning as they are, can fully guarantee our goal of protecting individuals who participate in medical research.

I am not convinced that in trying to write into law the proper ethical protocols for experimentation, we can limit ourselves simply to one area, that being the Department of Health, Education, and Welfare. Nor am I convinced that when addressing the question of ethics we can limit our concern to projects or programs which are federally funded.

I know that this committee is looking forward to hearing what corrections and recommendations have been made within HEW since the subject received attention earlier this year and what legislation the Department is supporting or opposing.

The report from the General Accounting Office has again brought our attention to the fact that some form of revision must be forthcoming.

If after the hearings are concluded we feel that the scope of legislation presented here is not broad enough, then it may be necessary for us to expand its scope beyond HEW to cover all other departments and agencies which are involved in human experiments. Yet, we may possibly have to move beyond this.

Science is the art which best exemplifies man's dedication to improving mankind's lot. But we cannot allow the individual's rights to be compromised or threatened in the name of science.

Without objection, the text of H.R. 10403 and all related bills and agency reports thereon shall be placed in the record at this point.

[Testimony resumes on p. 90.]

[The text of H.R. 10403, H.R. 1111, H.R. 1112, H.R. 2655, H.R. 5371, H.R. 6852, H.R. 7850, HR. 8778, H.R. 8779, H.R. 9488, and H.R. 10573, and agency reports thereon follow :]

93d CONGRESS
1ST SESSION

H. R. 10403

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 19, 1973

Mr. ROGERS introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

A BILL

To amend the Public Health Service Act to provide for the protection of human subjects who participate in biomedical or behavioral research programs, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 SHORT TITLE

4 SEC. 1. This Act may be cited as the "Protection of
5 Human Subjects Act".

6 SEC. 2. The Public Health Service Act (42 U.S.C.
7 201) is amended by adding after title XI the following new
8 title:

1 shall be appointed who are or who have been engaged in
2 biomedical or behavioral research involving human subjects.

3 “(e) The terms of each member shall be four years
4 except that—

5 “(1) the members first appointed shall serve as
6 designated by the President, three for a term of two
7 years, four for the term of three years, and four for a
8 term of four years; and

9 “(2) any member appointed to fill a vacancy occur-
10 ring prior to expiration of such term shall serve only for
11 the remainder of the term for which his predecessor was
12 appointed.

13 “(f) In appointing the members of the Commission con-
14 sideration shall be given to nominees from the National Acad-
15 emy of Sciences and other appropriate, independent, non-
16 governmental organizations.

17 “(g) No member shall serve for more than two full
18 terms.

19 “(h) A vacancy in the Commission shall not affect the
20 activities of the Commission and seven members thereof shall
21 constitute a quorum. Appointed members may serve after
22 the expiration of their terms until their successors have taken
23 office.

24 “(i) Members of the Commission who are not officers or

1 employees of the United States shall receive for each day
2 they are engaged in the performance of the duties of the Com-
3 mission compensation at rates equal to the daily equivalent
4 of the annual rate in effect for GS-18 of the General Sched-
5 ule, including traveltime; and all members while so serving
6 away from their homes or regular place of business, may be
7 allowed travel expenses, including per diem in lieu of sub-
8 sistence, in the same manner as such expenses are authorized
9 by section 5703, title 5, United States Code, for persons in
10 Government service employed intermittently.

11 “(j) The Secretary shall make available to the Com-
12 mission such staff, consultants, experts, information, equip-
13 ment, office space, and other assistance as it may require to
14 carry out its activities.

15 “(k) The Commission shall appoint an executive direc-
16 tor who shall serve full time and whose duty it shall be
17 to administer the daily activities of the Commission. Such
18 executive director shall be compensated at a rate equivalent
19 to the annual rate for a person serving at the level of GS-
20 18 of the General Schedule.

21 “DUTIES OF THE COMMISSION

22 “SEC. 1202. (a) The Commission shall—

23 “(1) undertake a comprehensive investigation and
24 study to identify the basic ethical principles and develop
25 guidelines which should underlie the conduct of biomed-

1 cal and behavioral research involving human subjects and
2 develop and implement policies and regulations to assure
3 that such research is carried out in accordance with the
4 ethical principles identified by the Commission in order
5 to assure the full protection of the rights of the subjects
6 of such research;

7 “(2) develop procedure for the certification of
8 Institutional Review Boards;

9 “(3) develop and recommend to the Congress the
10 implementation of an appropriate range of sanctions
11 (and the conditions for their use) for failure of certified
12 Institutional Review Boards to respond to Commission
13 rules, regulations, and procedures;

14 “(4) develop and recommend to the Congress a
15 mechanism for the compensation of individuals and their
16 families for injuries or death proximately caused by the
17 participation of such individuals in a biomedical or be-
18 havioral research program; and

19 “(5) develop and recommend to the Congress with-
20 in one year after the date of enactment of this section an
21 appropriate mechanism to broaden the scope of the Com-
22 mission’s jurisdiction in order to assure that all human
23 subjects in biomedical and behavioral research programs,
24 demonstrations, and activities are protected.

1 “(b) In fulfilling the mandate of subsection (a) the
2 Commission shall, among other subjects, consider—

3 “(1) developing appropriate guidelines for the se-
4 lection of human subjects for participation in biomedical
5 or behavioral research projects;

6 “(2) the nature and definition of informed consent
7 in various settings;

8 “(3) the role of assessment of risk-benefit criteria
9 in the determination of the appropriateness of research
10 involving human subjects;

11 “(4) the conditions and procedures by which ap-
12 peal of an Institutional Review Board decision may be
13 made to the Commission;

14 “(5) defining more precisely the boundary between
15 biomedical and behavioral research involving human
16 subjects and the accepted and routine practice of medi-
17 cine;

18 “(6) evaluating and responding to, when appro-
19 priate, requests from the biomedical and behavioral re-
20 search community and the public for clarification of par-
21 ticular ethical problems confronting society with regard
22 to biomedical and behavioral research;

23 “(7) the need for variation in the review procedures
24 carried out by the Institutional Review Boards;

25 “(8) evaluating and monitoring of the performance
26 of Institutional Review Boards;

1 “(9) the question of conflict of interest in the per-
2 formance of Institutional Review Board duties; and

3 “(10) conditions and procedures by which individ-
4 ual protocols may be referred to the Commission for
5 decision.

6 Wherever there are duplications, overlaps, or conflicts, this
7 title, and policies established by the Commission, and ap-
8 proved by the Secretary under this title, shall take prece-
9 dence over existing Department of Health, Education, and
10 Welfare policies governing biomedical and behavioral re-
11 search involving human subjects.

12 “(c) (1) In addition to its other duties, the Commission
13 shall conduct a study and investigation of the employment
14 of psychosurgery with a view to determining the number and
15 types of cases, during the five-year period ending Decem-
16 ber 31, 1972, in which psychotherapy has been performed
17 in all private and public hospitals in the United States, and
18 of compiling an analysis, on a case-by-case basis, of a suffi-
19 cient number of such cases (together with followup infor-
20 mation thereon) to provide the basis for an objective sci-
21 entific evaluation of psychosurgery performed during such
22 period with regard to the types of psychosurgery so per-
23 formed, the conditions for which it was performed, and the
24 results thereof. The Commission shall, not later than two
25 years after the date of enactment of this subsection, complete

1 such study and investigation and shall, on the basis of the
2 information gained therefrom, establish policies indicating
3 the circumstances (if any) under which the performance of
4 psychosurgery is appropriate.

5 “(2) As used in this subsection, the term ‘psychosur-
6 gery’ means brain surgery on (A) normal brain tissue of an
7 individual, who does not suffer from any pathological dis-
8 ease, for the purpose of changing or controlling the behavior
9 or emotions of such individual, or (B) on diseased brain tis-
10 sue of an individual, if the sole object of the performance of
11 such surgery is to control, change, or affect any behavioral
12 or emotional disturbance of such individual. Such term does
13 not include brain surgery designed to cure, or ameliorate the
14 effects of epilepsy; nor shall such term be construed to in-
15 clude electric shock treatments.

16 “JURISDICTION

17 “SEC. 1203. The policies and procedures developed by
18 the Commission pursuant to section 1202 shall to the max-
19 imum feasible extent be applied by the Secretary as appro-
20 priate to the delivery of health services in health service
21 programs funded in whole or in part by the Department of
22 Health, Education, and Welfare. Until such policies and
23 procedures are developed, the provisions of section 1207 (a),
24 (b), and (c) of this title shall be applied by the Secretary
25 as appropriate to the delivery of health services in health

1 service programs funded in whole or in part by the Depart-
2 ment of Health, Education, and Welfare.

3 CONSCIENCE AMENDMENT

4 "SEC. 1204. (a) (1) No individual shall be required to
5 perform or assist in the performance of any portion of a
6 health service program or research activity for which the
7 provisions of this title are applicable, funded in whole or in
8 part by the Department of Health, Education, and Welfare
9 if such performance or assistance would be contrary to his
10 religious beliefs or moral convictions.

11 "(2) No entity shall be required to make its facilities
12 available for the performance of any health service program
13 or research activity funded in whole or in part by the Depart-
14 ment of Health, Education, and Welfare if such performance
15 is prohibited by the entity on the basis of religious beliefs or
16 moral convictions.

17 "(3) No entity may (A) discriminate in the employ-
18 ment, promotion, or termination of employment of any phy-
19 sician or other health care personnel, or (B) discriminate
20 in the extension of staff or other services to any physician or
21 other health care personnel solely because he performed or
22 assisted in the performance of a lawful health service pro-
23 gram or research activity for which the provisions of this
24 title are applicable in an unrelated facility, or solely because
25 he refused to perform or assist in the performance of such

1 a health service program or research activity, in a facility
2 controlled by such entity on the grounds that his performance
3 or assistance in the performance of such health service pro-
4 gram or research activity would be contrary to his religious
5 beliefs or moral convictions.

6 “(b) The provisions of this section shall not be con-
7 strued as superseding the provisions of section 401 of the
8 Health Programs Extension Act of 1973.

9 “PROHIBITION ON RESEARCH

10 “SEC. 1205. Until such time after certification of Insti-
11 tutional Review Boards has been established and the Com-
12 mission develops policies with regard to the conduct of re-
13 search on the living fetus or infants, the Secretary may not
14 conduct or support research or experimentation in the United
15 States or abroad on a living human fetus or infant, whether
16 before or after induced abortion, unless such research or ex-
17 perimentation is done for the purpose of insuring the survival
18 of that fetus or infant.

19 “INSTITUTIONAL REVIEW BOARDS

20 “SEC. 1206. (a) No institution may receive Depart-
21 ment of Health, Education, and Welfare grants or contracts
22 to conduct biomedical or behavioral research involving human
23 subjects unless such institution has established an Institu-
24 tional Review Board certified by the Commission.

25 “(b) (1) The members and the Chairman of such In-

1 stitutional Review Boards shall be appointed by the chief
2 executive officer of the institution in accordance with policies,
3 regulations, and procedures of the Commission.

4 “(2) Such Institutional Review Boards must be com-
5 posed of sufficient members (including religious leaders, per-
6 sons schooled in ethics, and non-health-care professionals)
7 with such varying backgrounds of competence as to assure
8 complete and adequate review. No member of such Institu-
9 tional Review Boards shall be involved in either the initial or
10 continuing review of an activity in which he has a conflict of
11 interest as defined by the Commission, except to provide such
12 information as may be requested by such Institutional Review
13 Boards.

14 “(c) Each Institutional Review Board shall establish
15 two subcommittees as follows:

16 “(1) a Protocol Review Subcommittee, which shall
17 be responsible for approving, disapproving, or offering
18 suggestions for modifications of protocols for experimen-
19 tal procedures;

20 “(2) a Subject Advisory Subcommittee, which shall
21 be primarily concerned with the protection of the rights
22 of subjects of biomedical and behavioral research, and
23 shall assure that human subjects are as well informed
24 about the nature of the research as is reasonably possible.

25 “(d) The membership of the Institutional Review Board

1 and its subcommittees established under this section shall be in
2 accordance with regulations established by the Commission.

3 “(e) Nothing in this section shall prohibit or limit the
4 authority of the Secretary to make grants or enter into con-
5 tracts for biomedical or behavioral research prior to the
6 promulgation of procedures under section 1202 (a) (2).

7 “INTERIM PROVISIONS

8 “SEC. 1207. (a) Until such time as the certification of
9 Institutional Review Boards has been established, each insti-
10 tution engaged in biomedical and behavioral research involv-
11 ing human subjects shall determine that the rights and wel-
12 fare of the subjects involved are fully protected, that the
13 risks to an individual are outweighed by the potential bene-
14 fits to him or by the importance of the knowledge to be
15 gained, and that informed consent is to be obtained by meth-
16 ods that are adequate. Such informed consent shall be ob-
17 tained in all but exceptional cases.

18 “(b) For the purposes of this section only, the term ‘in-
19 formed consent’ shall mean the consent of a person, or his
20 legal representative, so situated as to be able to exercise free
21 power of choice without the intervention of any element of
22 force, fraud, deceit, duress, or other form of constraint or
23 coercion. Such consent shall be evidenced by an agreement
24 signed by such person, or his legal representative. The infor-
25 mation to be given to the subject in such written agreement
26 shall include the following basic elements:

1 “(1) a fair explanation of the procedures to be
2 followed, including an identification of any which are
3 experimental;

4 “(2) a description of any attendant discomforts and
5 risks reasonably to be expected;

6 “(3) a fair explanation of the likely results should
7 the experimental procedure fail;

8 “(4) a description of any benefits reasonably to be
9 expected;

10 “(5) a disclosure of any appropriate alternative
11 procedures that might be advantageous for the subject;

12 “(6) an offer to answer any inquiries concerning
13 the procedures; and

14 “(7) an instruction that the subject is free to either
15 decline entrance into a project or to withdraw his con-
16 sent and to discontinue participation in the project or
17 activity at any time without prejudicing his future care.

18 In addition, the agreement entered into by such person, or his
19 legal representative, shall include no exculpatory language
20 through which the subject is made to waive, or to appear to
21 waive, any of his legal rights, or to release the institution or
22 its agents from liability for negligence. Any organization
23 which initiates, directs, or engages in programs of research,
24 development, or demonstration which require informed con-
25 sent shall keep a permanent record of such consent and the

1 information provided the subject and develop appropriate
2 documentation and reporting procedures as an essential ad-
3 ministrative function.

4 “(c) The term ‘exceptional cases’ as used in subsection
5 (a) shall be strictly construed; shall permit the waiver only
6 of those elements of consent listed in subsection (b) as may
7 be justified by the circumstances of each case; and shall re-
8 quire the written concurrence in the acting physician’s deci-
9 sion by at least two other licensed physicians not involved in
10 the research project, unless in a life threatening situation, it is
11 not feasible to obtain such concurrence.

12 “DUTIES OF THE BOARDS

13 “SEC. 1208. It shall be the duty of the Institutional
14 Review Boards, established under section 1204, to—

15 “(1) establish local policies for the review of re-
16 search sponsored in whole or part by the Department
17 of Health, Education, and Welfare, consistent with the
18 national guidelines promulgated under section 1202;

19 “(2) advise the Commission with regard to pro-
20 cedural modifications deemed necessary for effective
21 research;

22 “(3) assume full responsibility to insure that bio-
23 medical and behavioral research involving human sub-
24 jects is carried out under the safest possible conditions
25 with the fully informed consent of the subject (or his

1 family) in a manner fully consistent with the ethical
2 principles developed by the Commission;

3 “(4) seek the consultative services of the Commis-
4 sion on any decision, or for the provision of information
5 needed to arrive at a decision; and

6 “(5) initiate, if appropriate, the referral of par-
7 ticular decisions to the Commission in accordance with
8 regulations promulgated by the Commission.

9 “INSPECTIONS

10 “SEC. 1209. (a) The executive director in consultation
11 with the Secretary may at any reasonable time order the in-
12 spection by the appropriate agency of the Department of
13 Health, Education, and Welfare of each institution involved
14 in a biomedical and behavioral research program involving
15 human subjects to determine if it is being operated in com-
16 pliance with this title, and rules and regulations promulgated
17 hereunder.

18 “(b) In the case of an institution inspected pursuant to
19 this section, the inspection shall extend to all things therein
20 (including records, files, papers, processes, controls, and facil-
21 ities) bearing upon the conduct of the research in question.

22 “RECORDKEEPING REQUIREMENTS

23 “SEC. 1210. (a) Every biomedical and behavioral re-
24 search program operated under the jurisdiction of the Com-
25 mission shall establish and maintain such records, make such

1 reports, and provide such information as the Commission may
2 reasonably require to enable it to determine whether such
3 program is being conducted in compliance with the provisions
4 of this Act and standards prescribed pursuant to this title and
5 shall, upon request of an officer or employee designated by
6 the Commission, permit such officer or employee to inspect,
7 verify, and copy appropriate books, records, and documents
8 relevant to determining whether such program is being con-
9 ducted in compliance with standards prescribed pursuant
10 to this section.

11 “(b) (1) The Commission shall not disclose any infor-
12 mation reported to or otherwise obtained by it pursuant to
13 this section which concerns any information which contains
14 or relates to a trade secret or other matter referred to in
15 section 1905 of title 18 of the United States Code, except
16 that such information may be disclosed to other officers or
17 employees of the Commission and of other agencies concerned
18 with carrying out this section, or when relevant in any pro-
19 ceeding under this section.

20 “(2) Records compiled pursuant to this section which
21 concern personal or medical information shall be confidential
22 and may be disclosed only for the purposes and under the
23 circumstances expressly authorized under paragraph (3) of
24 this subsection.

25 “(3) (A) If a person, with respect to whom any given

1 record referred to in this section is maintained, gives his
2 written consent, the content of such record may be disclosed
3 to medical personnel for the purposes of diagnosis or treat-
4 ment of such person, to governmental personnel for the pur-
5 pose of obtaining benefits to which the person is entitled, and
6 to such personnel as may be designated by the Commission
7 for the purpose of carrying out this section.

8 “(B) If a person, with respect to whom any given
9 record referred to in this section is maintained, does not give
10 his written consent, the content of such record may be dis-
11 closed (i) to medical personnel to the extent necessary to
12 meet a bona fide medical emergency; (ii) to such qualified
13 personnel as may be designated by the Commission for the
14 purpose of conducting scientific or epidemiological research,
15 but such personnel may not identify, directly or indirectly,
16 any individual in any report of such record, or otherwise dis-
17 close identities in any manner; or (iii) if authorized by an
18 appropriate order of a court of competent jurisdiction granted
19 after application showing good cause therefor. In assessing
20 good cause the court shall weigh the public interest and the
21 need for disclosure against the injury to the patient, to the
22 physician-patient relationship, and to the research program,
23 and shall determine that the disclosure will not unduly inter-
24 fere with the treatment of the patient or the conduct of the
25 research program. Upon the granting of such order, the court,

1 in determining the extent to which any disclosure of all or
2 any part of any record is necessary, shall impose appropriate
3 safeguards against unauthorized disclosure. This section shall
4 not supersede any other provisions of Federal law.

5 “(4) The prohibitions of this section shall apply to
6 records required to be maintained under this section con-
7 cerning any individual notwithstanding any statute of limi-
8 tations or other law which may apply.

9 “(5) Except as authorized under paragraph (3) of this
10 subsection, persons required by this section to maintain the
11 confidentiality of records may not be compelled in any Fed-
12 eral, State, or local civil, criminal, administrative, legislative,
13 or other proceedings to disclose such records.

14 “(6) Any person who unlawfully discloses the contents
15 of any record referred to in subsection (a) shall upon con-
16 viction be fined not more than \$500 in the case of a first
17 offense, and not more than \$5,000 in the case of each subse-
18 quent offense.

19 **“REVIEW**

20 “SEC. 1211. (a) In order to assess the efficacy of its
21 policies and those of the Institutional Review Boards, the
22 Commission shall annually evaluate its activities and duties
23 under this Act by contract with a qualified, independent
24 organization.

25 “(b) Not less than 1 per centum of the annual budget

1 of the Commission shall be devoted to carrying out the pur-
2 poses of subsection (a).

3 "PUBLICATION OF DECISIONS

4 "SEC. 1212. The Commission shall compile a complete
5 list of decisions pertaining to programs under its jurisdiction
6 and annually publish and distribute reports of important de-
7 cisions. The Commission shall establish such channels of
8 communication among Institutional Review Boards as it
9 determines necessary to carry out its responsibilities under
10 this Act.

11 "DEFINITIONS

12 "SEC. 1213. As used in this title the term—

13 "(1) 'Commission' means the National Commission for
14 the Protection of Human Subjects of Biomedical and Be-
15 havioral Research.

16 "(2) 'Institution' means any person or entity (includ-
17 ing Government departments or agencies) receiving De-
18 partment of Health, Education, and Welfare support for
19 biomedical or behavioral research involving human subjects.

20 "(3) 'Health service programs' means all programs
21 administered by the Secretary except the Social Security Act.

22 "AUTHORIZATION OF APPROPRIATIONS

23 "SEC. 1214. There are authorized to be appropriated
24 to carry out the purposes of this title \$3,000,000 for each

1 of the fiscal years ending June 30, 1974, and June 30,
2 1975.”

3 **AMENDMENT TO SPECIAL PROJECT GRANT AUTHORITY**

4 **SEC. 3.** Section 772 (a) (7) of the Public Health
5 Service Act is amended by inserting immediately before the
6 semicolon at the end thereof the following: “, or (C) provid-
7 ing increased emphasis on, the ethical, social, legal, and
8 moral implications of advances in biomedical research and
9 technology with respect to the effects of such advances on
10 individuals and society”.

11 **REVIEW OF GRANT AND CONTRACT AWARDS**

12 **SEC. 4.** Part G of title VI of the Public Health Service
13 Act is amended by adding at the end thereof the following:

14 **“REVIEW OF GRANT AND CONTRACT AWARDS**

15 **“SEC. 455.** The Secretary, after consultation with the
16 Director of the National Institutes of Health and, where
17 appropriate, with the Director of the National Institute of
18 Mental Health, shall, by regulation, provide for the proper
19 scientific peer review by assembled groups of qualified inde-
20 pendent scientific experts of the review of all grants and for
21 research and development contracts (except for grants under
22 sections 402 (b) and 419A (c) of this Act) administered by
23 the National Institutes of Health or the National Institute
24 of Mental Health, which will be awarded after the date of
25 enactment of this section. Such system of scientific peer re-

1 view shall be modeled after and shall utilize to the maximum
 2 extent possible appropriate peer review study section groups
 3 established by the National Institutes of Health or National
 4 Institute of Mental Health and shall be composed principally
 5 of non-Federal scientists and of no more than 20 per centum
 6 who are Federal employees in the scientific, biomedical, and
 7 behavioral research fields.”.

8 TECHNICAL AMENDMENTS TO THE PUBLIC HEALTH
 9 SERVICE ACT

10 SEC. 5. (a) Section 1 of the Public Health Service
 11 Act is amended by striking out “titles I to XI” and inserting
 12 in lieu thereof “titles I to XII”.

13 (b) The Act of July 1, 1944 (58 Stat. 682), is fur-
 14 ther amended by renumbering title XII (as in effect prior
 15 to the date of enactment of this Act) as title XIII and by
 16 renumbering sections 1201 through 1214 (as in effect prior
 17 to such date) and references thereto as sections 1301 through
 18 1314, respectively.

19 SPECIAL STUDY

20 SEC. 6. Title XII of the Public Health Service Act is
 21 amended by adding after section 1214 the following:

22 “SPECIAL DUTIES OF THE COMMISSION

23 “SEC. 1215. (a) In addition to the duties prescribed
 24 under section 1202, the Commission shall undertake a com-
 25 prehensive investigation and study of the ethical, social, and

1 legal implications of advances in biomedical and behavioral
2 research and technology, which shall include, without being
3 limited to—

4 “(1) analysis and evaluation of scientific and tech-
5 nological advances in the biomedical services, past, cur-
6 rent, and projected;

7 “(2) analysis and evaluation of the implications of
8 such advances, both for individuals and for society;

9 “(3) analysis and evaluation of laws, codes, and
10 principles governing the use of technology in medical
11 practice;

12 “(4) analysis and evaluation through the use of
13 seminars and public hearings and other appropriate
14 means of public understanding of and attitudes toward
15 such implications; and

16 “(5) analysis and evaluation of implications for
17 public policy of such findings as are made by the Com-
18 mission with respect to biomedical advances and public
19 attitudes toward such advances.

20 “(b) The Commission shall make maximum feasible use
21 of related investigations and studies conducted by public and
22 private agencies.

23 “(c) The Commission shall transmit to the President
24 and to the Congress, not less than once every twenty-four
25 months, a report containing detailed statements of findings

1 and conclusions of the studies conducted under subsection
2 (a), together with recommendations for needed legislation
3 or other appropriate action by public or private organizations
4 or individuals.

5 “(d) Each department, agency, and instrumentality of
6 the executive branch of the Government, including inde-
7 pendent agencies, is authorized and directed, to the extent
8 permitted by law, to furnish to the Commission, upon request
9 made by the Chairman or Vice Chairman, such information
10 as the Commission deems necessary to carry out its functions
11 under this section.”.

93^d CONGRESS
1st SESSION

H. R. 1111

IN THE HOUSE OF REPRESENTATIVES

JANUARY 3, 1973

Mr. ROYBAL introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

A BILL

To provide for a study and evaluation of the ethical, social, and legal implications of advances in biomedical research and technology.

1 *Be it enacted by the Senate and House of Representa-*
 2 *tives of the United States of America in Congress assembled,*
 3 That this Act may be cited as the "National Commission on
 4 Health Science and Society Act".

5 ESTABLISHMENT OF COMMISSION

6 SEC. 2. There is hereby established a National Commis-
 7 sion on Health Science and Society (hereinafter referred to
 8 as the "Commission").

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MEMBERSHIP

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SEC. 3. (a) The Commission shall be composed of fifteen members to be appointed by the President from among the fields of medicine, public health, mental health, law, theology, biological science, physical science, social science, philosophy, humanities, health administration, government, and public affairs, and from the public at large.

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(b) Any vacancy in the Commission shall not affect its powers.

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(c) The President shall designate one of the members to serve as Chairman and one to serve as Vice Chairman of the Commission.

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(d) Eight members of the Commission shall constitute a quorum.

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DUTIES OF THE COMMISSION

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SEC. 4. (a) The Commission shall undertake a comprehensive investigation and study of the ethical, social, and legal implications of advances in biomedical research and technology, which shall include, without being limited to—

(1) analysis and evaluation of scientific and technological advances in the biomedical sciences, current and projected;

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(2) analysis and evaluation of the implications of such advances, both for individuals and for society;

(3) analysis and evaluation through the use of

1 seminars and public hearings and other appropriate
2 means, of public understanding of and attitudes toward
3 such implications;

4 (4) analysis and evaluation of implications for pub-
5 lic policy of such findings as are made with respect to
6 the biomedical advances and public attitudes;

7 (5) analysis and evaluation of scientific and tech-
8 nological advances in the field of psychiatry, and psy-
9 chology, current and projected;

10 (6) analysis and evaluation of the use of human
11 subjects for purposes of experimentation or research;
12 and

13 (7) analysis and evaluation of the availability of
14 health services to all segments of the population with
15 particular emphasis on the health service needs of low-
16 income segments of the population.

17 (b) The Commission shall make maximum feasible use
18 of related investigations and studies conducted by public and
19 private agencies.

20 (c) The Commission shall transmit to the President
21 and to the Congress one or more interim reports and, not
22 later than two years after the first meeting of the Commis-
23 sion, one final report, containing detailed statements of the
24 findings and conclusions of the Commission, together with
25 its recommendations, including such recommendations for

1 title 5, United States Code, governing appointments in
2 the competitive service, and without regard to the pro-
3 visions of chapter 51 and subchapter III of chapter 53
4 of such title relating to classification and General Sched-
5 ular pay rates, but at rates not in excess of the maximum
6 rate for GS-18 of the General Schedule under section
7 5332 of such title, and

8 (2) procure temporary and intermittent services
9 to the same extent as is authorized by section 3109 of
10 title 5, United States Code, but at rates not to exceed
11 \$100 a day for individuals.

12 (d) The Commission is authorized to enter into con-
13 tracts with Federal or State agencies, private firms, institu-
14 tions, and individuals for the conduct of research or surveys,
15 the preparation of reports, and other activities necessary to
16 the discharge of its duties.

17 COMPENSATION OF MEMBERS

18 SEC. 6. Members of the Commission shall receive com-
19 pensation at the rate of \$175 per day for each day they
20 are engaged in the performance of their duties as members
21 of the Commission and shall be entitled to reimbursement
22 for travel, subsistence, and other necessary expenses incurred
23 by them in the performance of their duties as members of
24 the Commission.

1 **APPROPRIATIONS AUTHORIZED**

2 **SEC. 7.** There is hereby authorized to be appropriated
3 the sum of \$1,000,000 for the fiscal year beginning July 1,
4 1973; and \$1,000,000 for the fiscal year beginning July 1,
5 1973.

6 **TERMINATION**

7 **SEC. 8.** On the ninetieth day after the date of submis-
8 sion of its final report to the President and the Congress,
9 the Commission shall cease to exist.

93^d CONGRESS
1ST SESSION

H. R. 1112

IN THE HOUSE OF REPRESENTATIVES

JANUARY 3, 1973

Mr. ROYBAL introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

A BILL

To amend the Public Health Service Act to provide for a comprehensive review of the medical, technical, social, and legal problems and opportunities which the Nation faces as a result of medical progress toward making transplantation of organs, and the use of artificial organs a practical alternative in the treatment of disease; to amend the Public Health Service Act to provide assistance to certain non-Federal institutions, agencies, and organizations for the establishment and operation of regional and community programs for patients with kidney disease and for the conduct of training related to such programs; and for other purposes.

- 1 *Be it enacted by the Senate and House of Representa-*
- 2 *tives of the United States of America in Congress assembled,*
- 3 *That this Act may be cited as the "Artificial Organ, Trans-*
- 4 *plantation, and Technological Development Act of 1973".*

3

1 ized by law (5 U.S.C. 5703) for persons in the Govern-
2 ment service employed intermittently.

3 “(e) The Commission shall have an Executive Director,
4 who shall be appointed by the Chairman with the approval
5 of the President and shall be compensated at the rate pro-
6 vided by law for level IV of the Federal Executive' Salary
7 Schedule. The Executive Director shall have such duties and
8 responsibilities as the Chairman may assign.

9 “(f) In making appointments to the Commission, the
10 President shall assure that appointees are qualified by pro-
11 fessional training and accomplishment to appreciate the full
12 range of medical, legal, social, economic, technical, hu-
13 manitarian, and other problems which are relevant to present
14 and future decisions involving the role of the Federal Gov-
15 ernment in the prevention and treatment of diseases in which
16 the use of transplantation or artificial organs may be a factor.

17 “(g) The Commission shall (1) review present and
18 anticipated medical, technical, social, and legal problems as-
19 sociated with the development of the knowledge and tech-
20 nology necessary to make transplantation and the use of
21 artificial organs a practical and readily available alternative
22 in the treatment of disease; (2) make projections of the
23 public's need for readily available facilities and technology
24 for organ transplantation and utilization of artificial organs;

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1 (3) consider the economic, legal, and social ramifications of
2 alternative ways in which the Federal Government could
3 participate in developing the necessary knowledge and facili-
4 ties to make transplantation and the use of artificial organs
5 a practical and readily available alternative in the treatment
6 of disease; (4) review and report on the activities of Fed-
7 eral, State, and local government and private institutions in
8 this area of medicine; and (5) advise on such specific related
9 problems as may be referred to it by the President and the
10 Secretary.

11 “(h) The Commission shall consult with the Secretary
12 regarding its studies and shall furnish its proposed reports
13 and recommendations to the Secretary for review and com-
14 ment. The Commission shall submit to the President such
15 interim and final reports as it deems appropriate, and the
16 Secretary shall submit to the President his views on the Com-
17 mission’s reports. The President shall transmit the Commis-
18 sion’s final report to the Congress together with such com-
19 ments and recommendations for legislation as he deems ap-
20 propriate.

21 “(i) The Commission shall terminate not later than
22 three years from the effective date of the Artificial Organ,
23 Transplantation, and Technological Development Act of
24 1973.

25 “(j) The Commission may (1) hold such hearings, sit

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1 and act at such times and places, take such testimony, and
2 receive such evidence as it may deem advisable; (2) ac-
3 quire, furnish, and equip such office space as is necessary;
4 (3) use the United States mails in the same manner and
5 upon the same conditions as other departments and agencies
6 of the United States; (4) without regard to the provisions
7 of title 5, United States Code, governing appointments in
8 the competitive service, and the provisions of chapter 51 and
9 subchapter III of chapter 53 of such title relating to classifi-
10 cation and General Schedule pay rates, employ and fix the
11 compensation of such personnel as may be necessary to carry
12 out the functions of the Commission; (5) procure services as
13 authorized by section 3109 of title 5, United States Code, at
14 rates not to exceed \$100 per diem for individuals; (6) enter
15 into contracts or agreements for studies and surveys with
16 public and private organizations and transfer funds to Fed-
17 eral agencies to carry out such aspects of the Commission's
18 functions as the Commission determines can best be carried
19 out in that manner; and (7) incur such necessary expenses
20 and exercise such other powers as are consistent with and
21 reasonably required to perform its functions under this
22 section.

23 “(k) Subject to general policies adopted by the Com-
24 mission, the Chairman shall be the chief executive of the

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1 Commission and shall exercise its executive and adminis-
2 trative powers as set forth in subsection (j) of this section.

3 “(l) The Chairman may make such provision as he
4 shall deem appropriate authorizing the performance of any
5 of his executive and administrative functions by the Execu-
6 tive Director or other personnel of the Commission.

7 “(m) The Commission may, to the extent practicable,
8 utilize the services of existing Federal health agencies.

9 “(n) Upon request of the Commission, the head of any
10 Federal department or agency is authorized (1) to furnish
11 to the Commission, to the extent permitted by law and
12 within the limits of available funds, including funds trans-
13 ferred for that purpose pursuant to subsection (j) (6) of
14 this section, such information as may be necessary for carry-
15 ing out its functions and as may be available to or procurable
16 by such department or agency, and (2) to detail to tempo-
17 rary duty with this Commission on a reimbursable basis
18 such personnel within his administrative jurisdiction as it
19 may need or believe to be useful for carrying out its func-
20 tions, each such detail to be without loss of seniority, pay,
21 or other employee status.

22 “(o) Financial and administrative services (including
23 those related to budgeting, accounting, financial reporting,
24 personnel, and procurement) shall be provided the Com-
25 mission by the General Services Administration, for which

1 payment shall be made in advance, or by reimbursement from
2 funds of the Commission in such amounts as may be agreed
3 upon by the Chairman of the Commission and the Admin-
4 istrator of General Services: *Provided*, That the regulations
5 of the General Services Administration for the collection of
6 indebtedness of personnel resulting from erroneous payments
7 (5 U.S.C. 5514 (b)) shall apply to the collection of erro-
8 neous payments made to or on behalf of a Commission em-
9 ployee, and regulations of said Administrator for the admin-
10 istrative control of funds shall apply to appropriations of
11 the Commission: *And provided further*, That the Commission
12 shall not be required to prescribe such regulations.

13 "ESTABLISHMENT AND OPERATION OF REGIONAL AND COM-
14 MUNITY PROGRAMS FOR THE PREVENTION AND TREAT-
15 MENT OF KIDNEY DISEASE

16 "SEC. 320. (a) It is the purpose of this section to
17 provide financial support through grants to public and other
18 nonprofit schools of medicine, hospitals, agencies, and institu-
19 tions to assist in the establishment and operation of regional
20 and community prevention and treatment programs for
21 patients with kidney diseases and for training related to such
22 programs.

23 "(b) There are hereby authorized to be appropriated
24 the sums of \$20,000,000 in the fiscal year ending June 30,

1 1973; and \$30,000,000 for each succeeding fiscal year until
2 and including the fiscal year ending June 30, 1975, to enable
3 the Secretary to carry out the purposes of this section and
4 section 321 of this Act.

5 “(c) The Secretary shall, after consultation with the
6 National Advisory Committee on Kidney Disease Programs
7 (established pursuant to section 321 of this title), prescribe
8 general regulations and guidelines concerning (1) eligibility
9 of public or nonprofit agencies, institutions, or organizations
10 for grants under this section, (2) determination of costs
11 with respect to which such grants may be made, (3) the
12 terms and conditions under which such grants will be made,
13 and (4) the assurance that all grants are coordinated with
14 any existing regional plan for a kidney disease program in
15 a particular area.

16 “(d) There is hereby established in the Department
17 of Health, Education, and Welfare the Office for Kidney
18 Centers, for the purpose of administering sections 320 and
19 321 of this Act and providing coordination of Federal ac-
20 tivities in the prevention and treatment of kidney disease.
21 The Secretary is authorized to appoint a Director and such
22 additional personnel as are required to perform the re-
23 sponsibilities specified in this Act and such additional re-
24 sponsibilities as the Secretary may assign to the Office for
25 Kidney Centers.

1 “(e) Subject to the regulations and guidelines estab-
2 lished pursuant to subsection (c) the Office for Kidney
3 Centers shall assist in establishing kidney center programs.
4 This assistance shall consist of providing information, serv-
5 ices, and grants for planning, training, construction, renova-
6 tion, and percentage contributions toward the operation of
7 kidney centers.

8 “(f) A ‘kidney center’ for the purpose of this section
9 means:

10 “(1) A ‘regional kidney center’ established within
11 or as a part of a medical school or hospital that has dem-
12 onstrated a high level of professional competence in rele-
13 vant medical disciplines. The purpose of the regional
14 kidney center would be:

15 “(i) to train medical and supporting personnel;

16 “(ii) to provide transplantation treatment for
17 patients with chronic uremia where this form of
18 therapy is indicated;

19 “(iii) to provide dialysis treatment when medi-
20 cally indicated in connection with training, research,
21 and transplantation;

22 “(iv) to engage in research and the develop-
23 ment of new techniques;

24 “(v) to coordinate with and establish appro-

1 appropriate relations with one or more local community
2 dialysis units (described in subsection (f) (2)) ;

3 “(vi) and, to assure that knowledge and treat-
4 ment of kidney disease will evolve in a balanced
5 fashion;

6 “(2) A local ‘community dialysis unit’ established
7 in conjunction with and in continuing relationship with
8 a ‘regional kidney center.’ The purpose of a community
9 dialysis unit would be:

10 “(i) to provide a central training and treat-
11 ment facility for the care of persons having chronic
12 kidney disease;

13 “(ii) to provide training and supervision to
14 physicians, staff members, and to patients who are
15 candidates for home dialysis;

16 “(iii) to foster and promote the availability
17 and wider use of the equipment and techniques of
18 home dialysis.

19 “(g) The amount of any grant to carry out the purposes
20 of this section shall include:

21 “(1) 100 per centum of the costs directly related
22 to the training of physicians, staff members, patients,
23 and their families;

24 “(2) 100 per centum of the costs for construction
25 or renovation of existing facilities and for the necessary

1 equipment to establish a regional kidney center under
2 the provisions of subsection (f) (1) ;

3 “(3) 60 to 90 per centum of the costs for construc-
4 tion or renovation of existing facilities and for the neces-
5 sary equipment to establish a community dialysis unit
6 under the provisions of subsection (f) (2). The percent-
7 age contribution shall be determined on the basis of the
8 economic status of the particular community involved
9 pursuant to guidelines established by the Secretary.

10 “(4) 90 per centum in the first year of full opera-
11 tion, 60 per centum in the second year, and 30 per
12 centum in the third year and thereafter of the operation
13 and maintenance costs of regional kidney centers and
14 community dialysis units established pursuant to this
15 Act: *Provided, however,* That grants under this sub-
16 section may be in lesser amount if the Secretary deter-
17 mines that centers and units are capable of meeting a
18 larger share of costs of operation.

19 “(h) Three years after the Secretary formally publishes
20 notice in the Federal Register that applications will be re-
21 ceived for grants under this section, the President will trans-
22 mit to the Congress any recommendations he may wish to
23 make concerning the program. In the event that no changes
24 are made in the authorizing legislation, the program shall
25 continue as authorized under this section and section 321.

1 “SEC. 321. (a) There is hereby established a National
2 Advisory Committee on Kidney Disease Programs. The
3 Committee shall consist of four members currently in Gov-
4 ernment service and eight members, not otherwise in the
5 employ of the United States, appointed by the Secretary
6 and without regard to the civil service laws, who are leaders
7 in the fields of the basic medical sciences related to kidney
8 disease, kidney disease diagnosis and treatment, community
9 health programs, or public affairs.

10 “(b) Each appointed member of the Committee shall
11 hold office for a term of four years, except that any member
12 appointed to fill a vacancy prior to the expiration of the
13 term for which his predecessor was appointed shall be
14 appointed for the remainder of such term and except that
15 the term of office of the members first taking office shall
16 expire, as designated by the Secretary at the time of appoint-
17 ment, four at the end of the third year after the date of ap-
18 pointment. An appointed member shall not be eligible to
19 serve for more than two terms.

20 “(c) Appointed members of the Committee while at-
21 tending meetings or conferences thereof or otherwise serving
22 on the business of the Committee shall be entitled to receive
23 compensation at rates fixed by the Secretary, but not exceed-
24 ing \$100 per day, including traveltime, and while so serving
25 away from their homes or regular places of business they

1 may be allowed travel expenses, including per diem in lieu
2 of subsistence, as authorized by section 5703 of title 5,
3 United States Code, for persons in the Government service
4 employed intermittently.

5 “(d) The Committee shall advise and assist the Secre-
6 tary in the preparation of regulations for, and as to policy
7 matters arising with respect to, the administration of this
8 section insofar as it pertains to kidney disease, or the diag-
9 nosis, treatment, and care of patients suffering from such
10 diseases. After the Committee is established, it shall consider
11 all applications for grants under section 320 which pertain
12 to kidney diseases, or the diagnosis, treatment, and care of
13 patients suffering from such diseases and shall make recom-
14 mendations to the Secretary with respect to approval of
15 application for and the amounts of such grants.

16 “(e) The Committee shall also review and make recom-
17 mendations on kidney disease programs of departments and
18 agencies of the Federal Government, including, but not
19 limited to, those in the Veterans' Administration, the Public
20 Health Service, and the Vocational Rehabilitation Adminis-
21 tration, so that the methods, facilities, and programs of these
22 administrative agencies can best be utilized in supporting
23 programs for prevention and treatment of kidney disease.
24 Particular attention shall be paid to the coordination of
25 activities of these various agencies in a given region so as

14

1 to insure adequate geographical distribution of services and
2 avoid duplication of facilities and services.”

3 SEC. 3. The Secretary of Health, Education, and Welfare
4 is authorized and directed to study the effectiveness of the
5 coverage extended by the amendments made by section 3 of
6 this Act to individuals with kidney failure, giving particular
7 attention to the need for increasing the duration of the bene-
8 fits provided in the case of such individuals and for any
9 other adjustments which may be indicated because of the
10 unique nature of their condition and the treatment required.
11 Within six months after the effective date of this Act the
12 Secretary shall transmit to the President and the Congress a
13 report containing his findings of fact and any conclusions or
14 recommendations he may have.

15 SEC. 4. The head of each department, agency, and in-
16 strumentality of the United States is authorized and directed
17 to cooperate with the Secretary of Health, Education, and
18 Welfare, to the maximum extent possible, in carrying out the
19 provisions of this Act.

20 SEC. 5. Except as otherwise specifically provided by
21 any amendment made by this Act, there is authorized to be
22 appropriated such sums as may be necessary to carry out
23 the provisions of this Act.

24 SEC. 6. The foregoing provisions of this Act shall be-
25 come effective as of the first day of the first month which
26 begins after the date of enactment of this Act.

1 day (including traveltime) during which they are en-
2 gaged in the actual performance of duties vested in the
3 Commission.

4 (2) Members of the Commission who are full-time
5 officers or employees of the United States shall receive
6 no additional pay on account of their service on the
7 Commission.

8 (3) While away from their homes or regular places
9 of business in the performance of services for the Com-
10 mission, members of the Commission shall be allowed
11 travel expenses, including per diem in lieu of subsistence,
12 in the same manner as persons employed intermittently
13 in the Government service are allowed expenses under
14 section 5703 (b) of title 5 of the United States Code.

15 (d) QUORUM.—Seven members of the Commission
16 shall constitute a quorum but a lesser number may hold
17 hearings.

18 (e) CHAIRMAN.—The Chairman of the Commission
19 shall be elected from the membership of the Commission by
20 its members.

21 STAFF OF COMMISSION; EXPERTS AND CONSULTANTS

22 SEC. 4. (a) STAFF.—With the approval of the Com-
23 mission, the Chairman may appoint and fix the pay of such
24 personnel as he deems desirable.

1 hearings, sit and act at such times and places, take such
2 testimony, and receive such evidence, as the Commission may
3 deem advisable.

4 (b) **POWERS OF MEMBERS AND AGENTS.**—When so
5 authorized by the Commission, any member or agent of the
6 Commission may take any action which the Commission is
7 authorized to take by this section.

8 (c) **OBTAINING INFORMATION.**—The Commission may
9 secure directly from any department or agency of the United
10 States information necessary to enable it to carry out this
11 Act. Upon request of the Chairman of the Commission, the
12 head of such department or agency shall furnish such informa-
13 tion to the Commission.

14 (d) **MAILS.**—The Commission may use the United
15 States mails in the same manner and upon the same condi-
16 tions as other departments and agencies of the United States.

17 (e) **ADMINISTRATIVE SUPPORT SERVICES.**—The Ad-
18 ministrator of General Services shall provide to the Com-
19 mission on a reimbursable basis such administrative support
20 services as the Commission may request.

21 **REPORT**

22 **SEC. 6.** The Commission shall transmit to the President
23 for transmittal to Congress a report to the President not
24 later than one year from the date the Commission is or-
25 ganized. The final report shall contain a detailed statement

6

1 of the findings and conclusions of the Commission, together
2 with its recommendations for such legislation and adminis-
3 trative actions as it deems appropriate.

4

TERMINATION

5 **SEC. 7.** The Commission shall cease to exist sixty days
6 after submitting its final report pursuant to section 6.

[H.R. 5371, 93d Congress, 1st session, introduced by Mr. Stokes on March 7, 1973, and

H.R. 6852, 93d Congress, 1st session, introduced by Mr. Stokes (for himself, Mr. Badillo, Mr. Burton, Mr. Carey of New York, Mrs. Chisholm, Mr. Clay, Mr. Conyers, Mr. Corman, Mr. Dellums, Mr. Dent, Mr. Diggs, Mr. Edwards of California, Mr. Frenzel, Mr. Hawkins, Mrs. Mink, Mr. Mitchell of Maryland, Mr. Rangel, Mr. Rosenthal, and Mr. Thompson of New Jersey) on April 11, 1973

are identical as follows:]

A BILL

To prohibit psychosurgery in federally connected health care facilities.

1 *Be it enacted by the Senate and House of Representa-*
 2 *tives of the United States of America in Congress assembled,*

3 That (a) for purposes of this Act:

4 (1) The term "federally connected health care facility"
 5 means a hospital or other facility for the delivery of health
 6 care (A) which is under the jurisdiction of any department,
 7 agency, or instrumentality of the United States, (B) any
 8 part of which is constructed, renovated, operated, or main-
 9 tained with funds provided under a grant, contract, loan, or
 10 loan guarantee made after the date of the enactment of this
 11 Act by the United States, (C) which is a provider of services

1 qualified to participate under title XVIII of the Social Secu-
2 rity Act or is providing medical care and services under a
3 State plan approved under title XIX of such Act, or (D)
4 which is utilized to provide health care for inmates of prisons
5 or other correctional facilities any part of which is con-
6 structed, renovated, operated, or maintained with such funds.

7 (2) The term "psychosurgery" means those operations
8 currently referred to as lobotomy, psychiatric surgery, and
9 behavioral surgery and all other forms of brain surgery if
10 the surgery is performed for the purpose of—

11 (A) modification or control of thoughts, feelings,
12 actions, or behavior rather than the treatment of a
13 known and diagnosed physical disease of the brain;

14 (B) modification of normal brain function or nor-
15 mal brain tissue in order to control thoughts, feelings,
16 action, or behavior; or

17 (C) treatment of abnormal brain function or ab-
18 normal brain tissue in order to modify thoughts, feelings,
19 actions, or behavior when the abnormality is not an
20 established cause for those thoughts, feelings, actions,
21 or behavior.

22 Such term does not include electroshock treatment, the elec-
23 trical stimulation of the brain, or drug therapy, except when
24 substances are injected or inserted directly into brain tissue.

25 (b) No department, agency, or instrumentality of the

1 United States may make a grant, contract, loan, or loan
2 guarantee after the date of enactment of this Act for any
3 hospital or other facility for the delivery of health care
4 unless such facility agrees to prohibit the performance of
5 psychosurgery on its premises or for any prison or other
6 correctional facility unless such facility agrees to prohibit
7 the performance of psychosurgery on any of its inmates.
8 The Secretary of Health, Education, and Welfare shall
9 notify each hospital or other facility for the delivery of
10 health care described in paragraph (1) of subsection (a)
11 of the requirements of this Act.

12 SEC. 2. It shall be unlawful for (1) any person to per-
13 form psychosurgery in any federally connected health care
14 facility, and (2) for any federally connected health care
15 facility to permit any person to perform psychosurgery in
16 violation of clause (1) of this section.

17 SEC. 3. (a) (1) Any person who violates section 2 (1)
18 of this Act and any federally connected health care facility
19 (other than such facility under the jurisdiction of a depart-
20 ment, agency, or instrumentality of the United States or a
21 State) which violates section 2 (2) of this Act shall be
22 subject to a civil penalty of not more than \$10,000 for each
23 violation. Such penalty may be assessed by the Commission
24 established under section 4 (hereinafter in this section re-
25 ferred to as the "Commission") and collected in a civil

1 action brought by the United States in a United States dis-
2 trict court.

3 (2) In any proceeding by the Commission to assess a
4 civil penalty under this subsection, no penalty shall be as-
5 sessed until the person or facility charged shall have been
6 given notice and an opportunity to present his or its views
7 on such charge. If the Commission's determination that such
8 person or facility is liable for such penalty is made on the
9 record after notice and opportunity for hearing, then in any
10 civil action to collect such penalty (and in any other civil
11 action reviewing such determination of the Commission)
12 any findings of fact on which such determination is based
13 shall be conclusive if supported by substantial evidence on
14 the record considered as a whole.

15 (b) The Commission may bring a civil action in the
16 district courts of the United States to restrain violations of
17 section 2.

18 (c) (1) Any individual upon whom psychosurgery was
19 performed in violation of section 2 may bring a civil action
20 in the district courts of the United States for damages
21 against the person who performed such psychosurgery or
22 against the federally connected health care facility which
23 permitted it to be performed, or against both. The court in
24 such action shall, in addition to any judgment accorded to
25 the plaintiff, allow a reasonable attorney's fee to be paid by

5

1 the defendant and the costs of the action. The remedy pro-
2 vided by this subsection shall be in addition to and not in
3 substitution for any other remedies which such individual
4 may have under any other law or at common law.

5 (2) The Commission may, upon the written request of
6 any such individual or class of individuals made in accord-
7 ance with such requirements as the Commission shall pre-
8 scribe, bring such a civil action in the district courts of the
9 United States on behalf of any such individual or class of
10 such individuals.

11 (d) No person who performs psychosurgery in viola-
12 tion of section 2 (1) —

13 (1) may receive any funds under any grant made
14 by the United States or under any contract or loan made
15 by the United States after the date of enactment of this
16 Act, or

17 (2) shall be eligible to apply for any grant, con-
18 tract, loan, or guarantee made by the United States,
19 during the five-year period beginning on the date such per-
20 son is determined by the Commission to have violated section
21 2 (1). The Commission shall report to each department,
22 agency, and instrumentality of the United States which
23 makes grants, contracts, loans, or loan guarantees to which
24 this subsection may apply such information respecting deter-
25 minations by the Commission of violations of section 2 (1)

1 as may be necessary for such departments, agencies, and in-
2 strumentalities to enforce this subsection.

3 SEC. 4. (a) There is established the Psychosurgery
4 Commission (hereinafter in this section referred to as the
5 "Commission") which shall be composed of nine members
6 appointed by the President, by and with the advice and
7 consent of the Senate, from individuals who have an interest
8 and experience in the field of mental health and who are
9 not physicians or persons with a master's or doctor's degree
10 in psychology. At least three members shall be appointed
11 from individuals who are members of one or more minority
12 groups (as that term is defined in section 720 (9) (A) (i)
13 of the Emergency School Aid Act). A vacancy in the Com-
14 mission shall be filled in the manner in which the original
15 appointment was made.

16 (b) (1) Except as provided in paragraphs (2) and
17 (3), members shall be appointed for terms of three years.

18 (2) Of the members first appointed—

19 (A) three shall be appointed for terms of one year,

20 (B) three shall be appointed for terms of two years,

21 and

22 (C) three shall be appointed for terms of three
23 years,

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

25 (3) Any member appointed to fill a vacancy occurring

1 prior to the expiration of the term for which his predecessor
2 was appointed shall be appointed only for the remainder of
3 such term. A member may serve after the expiration of his
4 term until his successor has taken office.

5 (c) (1) Members of the Commission shall each be
6 entitled to receive the daily equivalent of the annual rate of
7 basic pay in effect for grade GS-18 of the General Schedule
8 for each day (including traveltime) during which they are
9 engaged in the actual performance of duties vested in the
10 Commission.

11 (2) While away from their homes or regular places of
12 business in the performance of services for the Commission,
13 members of the Commission shall be allowed travel expenses,
14 including per diem in lieu of subsistence, in the same manner
15 as persons employed intermittently in the Government serv-
16 ice are allowed expenses under section 5703 (b) of title 5 of
17 the United States Code.

18 (d) Five members of the Commission shall constitute a
19 quorum but a lesser number may hold hearings. The Chair-
20 man and Vice Chairman of the Commission shall be elected
21 by the members of the Commission.

22 (e) (1) Subject to such rules as may be adopted by the
23 Commission, the Chairman may appoint and fix the pay of
24 such personnel as he deems desirable.

25 (2) The staff of the Commission shall be appointed

1 subject to the provisions of title 5, United States Code,
2 governing appointments in the competitive service, and shall
3 be paid in accordance with the provisions of chapter 51 and
4 subchapter III of chapter 53 of such title relating to classi-
5 fication and General Schedule pay rates.

6 (f) Upon request of the Commission, the head of any
7 Federal agency is authorized to detail, on a reimbursable
8 basis, any of the personnel of such agency to the Commission
9 to assist it in carrying out its duties under this Act.

10 (g) (1) The Commission may for the purpose of carry-
11 ing out this Act hold such hearings, sit and act at such times
12 and places, take such testimony, and receive such evidence,
13 as the Commission may deem advisable. The Commission
14 may administer oaths or affirmations to witnesses appearing
15 before it.

16 (2) When so authorized by the Commission, any mem-
17 ber or agent of the Commission may take any action which
18 the Commission is authorized to take by this section.

19 (3) The Commission may secure directly from any de-
20 partment or agency of the United States information neces-
21 sary to enable it to carry out this Act. Upon request of the
22 Chairman or Vice Chairman of the Commission, the head of
23 such department or agency shall furnish such information
24 to the Commission.

25 (4) The Commission may use the United States mails

1 in the same manner and upon the same conditions as other
2 departments and agencies of the United States.

3 (h) (1) The Commission shall have power to issue
4 subpoenas requiring the attendance and testimony of wit-
5 nesses and the production of any evidence that relates to any
6 matter under investigation by the Commission. Such at-
7 tendance of witnesses and the production of such evidence
8 may be required from any place within the United States
9 at any designated place of hearing within the United States.

10 (2) If a person issued a subpoena under paragraph (1)
11 refuses to obey such subpoena or is guilty of contumacy, any
12 court of the United States within the judicial district within
13 which the hearing is conducted or within the judicial district
14 within which such person is found or resides or transacts
15 business may (upon application by the Commission) order
16 such person to appear before the Commission to produce
17 evidence or to give testimony touching the matter under
18 investigation. Any failure to obey such order of the court
19 may be punished by such court as a contempt thereof.

20 (3) The subpoenas of the Commission shall be served in
21 the manner provided for subpoenas issued by a United States
22 district court under the Federal Rules of Civil Procedure
23 for the United States district courts.

24 (4) All process of any court to which application may
25 be made under this section may be served in the judicial

1 district wherein the person required to be served resides or
2 may be found.

3 (5) For purposes of sections 6002 and 6004 of title
4 18 of the United States Code, the Commission shall be con-
5 sidered an agency of the United States.

6 (i) The Commission shall report on or before January 1
7 of each year to the President and the Congress respecting its
8 activities under this Act.

[H.R. 7850, 93d Congress, 1st session, introduced by Mr. Roncalio of New York on May 15, 1973;

H.R. 8778, 93d Congress, 1st session, introduced by Mr. Roncallo of New York (for himself, Mr. Addabbo, Mr. Archer, Mr. Burgener, Mr. Clancy, Mr. Cleveland, Mr. Dominick V. Daniels, Mr. Delaney, Mr. Denholm, Mr. Erlenborn, Mr. Fauntroy, Mr. Froehlich, Mr. Giaimo, Mr. Grover, Mr. Guyer, Mrs. Heckler of Massachusetts, Mr. Hillis, Mr. Hogan, Mr. Ketchum, Mr. Maraziti, Mr. Mazzoli, Mr. Mitchell of New York, Mr. Murphy of Illinois, Mr. Nedzi, and Mr. O'Brien) on June 18, 1973;

H.R. 8779, 93d Congress, 1st session, introduced by Mr. Roncallo of New York (for himself, Mr. O'Hara, Mr. Peyser, Mrs. Sullivan, Mr. Walsh, Mr. Won Pat, Mr. Young of Illinois, Mr. Wydler, Mr. Zablocki, and Mr. Zwach) on June 18, 1973, and

H.R. 9488, 93d Congress, 1st session, introduced by Mr. Roncallo of New York (for himself, Mr. Bafalis, Mr. Jones of Oklahoma, and Mr. Powell of Ohio) on July 23, 1973,

are identical as follows:]

A BILL

To prohibit the use of appropriated funds to carry out or assist
research on living human fetuses.

- 1 *Be it enacted by the Senate and House of Representa-*
 2 *tives of the United States of America in Congress assembled,*
 3 That no funds heretofore or hereafter appropriated for any
 4 department, agency, or instrumentality of the United States
 5 may be used to carry out any research activity on a human
 6 fetus which is outside the womb of its mother and which is
 7 alive with a beating heart or to assist (by grant, contract, or
 8 otherwise) any person in carrying out such research activity.

1 be appointed by the President by and with the advice and
2 consent of the Senate from among individuals who by virtue
3 of their service, experience, or education are especially quali-
4 fied to serve on the Board. At least one, but not more than
5 two, of the members of the Board shall be doctors of medicine
6 who have had experience in research on human beings. At
7 least one of the members shall be well schooled in the field
8 of medical law and ethics. The members shall select a chair-
9 man and a vice chairman from among their membership.
10 The terms of office of each member of the board shall be
11 three years except that—

12 (1) the members first appointed shall serve, as
13 designated by the President, one for a term of one
14 year, two for a term of two years, and two for a term
15 of three years;

16 (2) any member appointed to fill a vacancy shall
17 serve for the remainder of the term for which his prede-
18 cessor was appointed; and

19 (3) a member shall be eligible for reappointment
20 for one additional term.

21 (c) Any vacancy on the Board shall not affect its powers
22 and three members of the Board shall constitute a quorum
23 except that the Chairman may prescribe a lesser number to
24 constitute a quorum for the purpose of conducting hearings.

25 (d) The Commission shall appoint an executive director

3

1 who shall serve full time and whose duty it shall be to ad-
2 minister the daily activities of the Board.

3

ADMINISTRATIVE POWERS

4 SEC. 3. (a) In order to carry out the provisions of this
5 Act, the Board is authorized to—

6 (1) appoint and fix the compensation of personnel
7 of the Board in accordance with the provisions of title
8 5, United States Code;

9 (2) make, promulgate, issue, rescind, and amend
10 rules and regulations as may be necessary to carry out
11 the functions vested in the Board and delegate author-
12 ity to any officer or employee;

13 (3) employ experts and consultants in accordance
14 with section 3109 of title 5, United States Code;

15 (4) appoint one or more advisory committees com-
16 posed of such private citizens and officials of Federal,
17 State, and local governments as it deems desirable, to
18 advise it with respect to its functions under this Act;

19 (5) utilize, with their consent, the services, equip-
20 ment, personnel, information, and facilities of other
21 Federal, State, and local public agencies with or without
22 reimbursement therefor;

23 (6) accept voluntary and uncompensated services,
24 notwithstanding the provisions of section 3676 of the
25 revised statutes;

4

1 (7) accept on behalf of the Board unconditional
2 gifts or donation of services, money, or property, real,
3 personal, or mixed, tangible, or intangible;

4 (8) take such actions as may be required for the
5 accomplishment of the objectives of the Board; and

6 (9) make contracts with public or private nonprofit
7 entities to conduct studies related to the purposes of this
8 Act.

9 (b) Upon request made by the Board, each Federal
10 agency is authorized and directed to make its services,
11 equipment, personnel, facilities, and information (including
12 suggestions, estimates, and statistics) available to the great-
13 est practicable extent consistent with other laws to the Board
14 in the performance of its functions with or without reim-
15 bursement.

16 (c) Each member of a committee appointed pursuant
17 to clause (4) of subsection (a) of this section who is not
18 an officer or employee of the Federal Government shall be
19 compensated at the rate prescribed for GS-18 under section
20 5332 of title 5, United States Code, for each day he is
21 engaged in the actual performance of his duties (including
22 traveltime) as a member of a committee. All members
23 shall be reimbursed for travel, subsistence, and necessary
24 expenses incurred in the performance of their duties.

25 (d) (1) The Board or any duly authorized subcommit-

tee or member thereof may, for the purposes of carrying out the provisions of this Act, hold such hearings, sit and act at such times and places, administer such oaths, and require by subpoena or otherwise the attendance and testimony of such witnesses and the production of such books, records, correspondence, memorandums, papers, and documents as the Board or such subcommittee or member may deem advisable. Any member of the Board may administer oaths or affirmations to witnesses appearing before the Board or before such subcommittee or member. Subpoenas may be issued under the signature of the Chairman, or any member of the Board duly designated by the Chairman, and may be served by any person designated by the Chairman or by any other member of the Board.

(2) In the case of contumacy or refusal to obey a subpoena issued under paragraph (1) by any person who resides, is found, or transacts business within the jurisdiction of any district court of the United States, such court, upon application made by the Attorney General of the United States at the request of the Chairman of the Board, shall have jurisdiction to issue to such person an order requiring such person to appear before the Board or a subcommittee or member thereof, there to produce evidence if so ordered, or there to give testimony touching the matter under inquiry. Any

1 failure of such person to obey any such order of the court
2 may be punished by the court as a contempt thereof.

3

COMPENSATION

4 SEC. 4. (a) Section 5314 of title 5, United States Code,
5 is amended by adding at the end thereof the following new
6 paragraph:

7 " (59) Chairman, National Human Experimenta-
8 tion Standards Board."

9 (b) Section 5315 of title 5, United States Code, is
10 amended by adding at the end thereof the following new
11 paragraph:

12 " (96) Members, National Human Experimenta-
13 tion Standards Board (4)."

14 SEC. 5. (a) It shall be the function of the Board to
15 develop guidelines and to issue regulations, in accordance
16 with the provisions of the Administrative Procedures Act,
17 for the conduct of biomedical and behavioral research in-
18 volving human subjects. The regulations and guidelines
19 adopted by the Board shall be designed to insure that the
20 conduct of such research be conducted in accordance with
21 the highest ethical and moral standards, the constitutional
22 rights of all American citizens, and fully consonant with
23 the right of privacy and the dignity and integrity of the
24 human subject. Wherever there are duplications, overlaps,
25 or conflicts, this Act and policies established by the Board

1 shall take precedence over existing Federal or departmental
2 guidelines and policies governing biomedical and behavioral
3 research involving human subjects.

4 (b) No medical experiment involving human beings
5 which is funded in whole or in part with Federal funds, or
6 which is conducted in any facility or institution which is the
7 recipient of Federal funds, or is operated by or on behalf
8 of the Federal Government, shall be conducted except in
9 accordance with regulations adopted pursuant to section 5
10 (a) of this Act.

11 (c) The Board shall adopt specific and detailed guide-
12 lines and regulations to insure:

13 (1) That true informed consent is obtained from the
14 subject of each experiment. Among other things, they shall
15 provide—

16 (A) that written consent shall be obtained and
17 kept permanently on file for each subject of each experi-
18 ment;

19 (B) that a brief summary describing the process
20 through which that consent was obtained be kept per-
21 manently on file;

22 (C) that the Board shall have immediate access to
23 any and all information kept in those files;

24 (D) that the definition of informed consent shall

1 include, among other things, the provisions outlined in
2 section 12 (d) of this Act.

3 (2) That each experiment shall make provision for the
4 compensation of victims of experiments that do not comply
5 with the guidelines and regulations issued by the Board.

6 (3) That any research project may be terminated, upon
7 notice and hearing, for a violation of the guidelines and regu-
8 lations of the Board.

9 (d) The Board shall make a full and complete study of
10 the practice of psychosurgery to determine its medical reli-
11 ability, and under what, if any, conditions it should be per-
12 mitted to be performed. In making this study the Board shall
13 give highest priority to ethical and moral principles, constitu-
14 tional rights of citizens, and the privacy and personal integ-
15 rity of human beings.

16 (1) The Board shall make a report on psychosurgery
17 within two years of the date of the passage of this Act. The
18 report shall be made public and shall be transmitted to
19 Congress.

20 (2) The report shall consider in which cases and under
21 which circumstances psychosurgery may be permitted.

22 (e) The Board shall, not later than one hundred and
23 eighty days following the issuance of its report on psycho-
24 surgery, promulgate guidelines and regulations, in accordance
25 with the provisions of the Administrative Procedures Act, to

9

1 govern the practice of psychosurgery. The regulations shall,
2 among other things, provide—

3 (1) That psychosurgery may be performed only where it
4 has been proved to be a medically effective practice for a
5 designated physiological disorder.

6 (2) That psychosurgery may not be performed to alter
7 the personality or modify the behavior pattern of the subject
8 involved.

9 (3) That psychosurgery may be performed only in in-
10 stances where a physically diseased or damaged portion of
11 the brain endangers the life or health of the subject and no
12 other less permanent treatment can be used successfully.

13 (4) That no psychosurgery may be performed in any
14 experiment which is funded in whole or in part with Federal
15 funds, or in any facility or institution which is the recipient
16 of Federal funds, or which is operated by or on behalf of the
17 Federal Government, except in accordance with regulations
18 issued by the Board.

19 (5) That no psychosurgery shall be performed without
20 the specific sanction and official approval of the Board. The
21 Board shall grant no general or unlimited approvals.

22 (f) Until such time as the report and regulations re-
23 quired by subsections (d) and (e) of this section have been
24 issued, there shall be a moratorium on all psychosurgery

1 funded in whole or in part by Federal funds, or performed in
2 any institution which is the recipient of Federal funds, or
3 which is operated by or on behalf of the Federal Government,
4 except in the cases of epilepsy or Parkinson's disease where
5 psychosurgery has been proved to be a medically effective
6 treatment for a defined physiological disorder.

7 (g) (1) The Board shall review all planned medical ex-
8 periments that involve human beings which are funded in
9 whole or in part with Federal funds to determine if the guide-
10 lines established under subsection (a) of this section are being
11 complied with, and no such experiment may be conducted
12 without the express approval of the Board. In making its de-
13 cision, the Board shall give due consideration to the action of
14 the appropriate Institutional Review Committee under sec-
15 tion 9 (b).

16 (2) The Board shall report to the appropriate commit-
17 tees of Congress the details of each proposed grant and each
18 program of experimentation, including the persons conduct-
19 ing the program; the institution concerned, the amount of the
20 grant, the nature of the program, and whether the grant or
21 program has been approved or disapproved by the appro-
22 priate IRC and the National Board. No grant or program
23 shall be finally approved until at least ninety days after the
24 proposal has been reported to Congress. The National Board

1 shall provide such additional information on each proposal
2 as the Committee shall request.

3 (h) The Board shall obtain a report from each Federal
4 department or agency detailing the exact extent to which
5 experimentation on human beings is conducted within that
6 department, or agency, and require that the report be up-
7 dated on a yearly basis. Any department or agency that
8 conducts experiments on human beings must have its human
9 experimentation program approved by the Board before
10 Federal funds can be allocated for that department or agency.

11 (i) The Board shall prepare and submit an annual re-
12 port to the President, for transmittal to the Congress, rec-
13 ommending legislation, if required, and detailing the
14 performance of the Board during the preceding year.

15 (j) The Board shall develop procedures for the certi-
16 fication of Institutional Review Committees.

17 JUDICIAL REVIEW

18 SEC. 6. (a) The Board is authorized to institute for
19 or in the name of the United States a civil action or other
20 proceeding for preventive relief, including an application for
21 an injunction, restraining order, or any other order, against
22 any person for any violation of this title or any regulation
23 issued pursuant thereto.

24 (b) (1) Whenever any person is aggrieved as a result

12

1 of any act which is prohibited by this title, such a person
2 may bring a civil action for damages irrespective of the ac-
3 tuality or amount of pecuniary injury suffered.

4 (2) Whenever any person is threatened with injury as a
5 result of any act which is prohibited by this title, such a per-
6 son may bring a civil action for such equitable relief as the
7 court determines may be appropriate irrespective of the actu-
8 ality or amount of pecuniary injury threatened.

9 (c) A person may bring a civil action under this Act in
10 any district court of the United States for the district in
11 which the violation occurs, or in any district court of the
12 United States in which such person resides or conducts busi-
13 ness, or has his principal place of business, or in the District
14 Court of the United States for the District of Columbia.

15 (d) The district courts of the United States shall have
16 jurisdiction of proceedings instituted pursuant to this title
17 and shall exercise the same without regard to whether any
18 aggrieved person shall have exhausted any administrative or
19 other remedies that may be provided by law. Any action
20 pursuant to this section shall be in every way expedited.

21 JURISDICTION

22 SEC. 7. Any individual, organization, department, or
23 agency, public or private, that receives funds from the Fed-
24 eral Government to be used for biomedical or behavioral
25 research on human beings, whether it be through congres-

1 sional allocation or departmental grant, shall be subject to
2 the provisions of this Act.

3 **INSTITUTIONAL REVIEW COMMITTEES**

4 **SEC. 8. (a)** No institution shall receive Federal grants
5 or contracts to conduct biomedical or behavioral research
6 involving human subjects unless such institution has estab-
7 lished an Institutional Review Committee certified by the
8 National Board.

9 (b) Institutions funded in whole or in part by Federal
10 funds which are presently conducting biomedical or be-
11 havioral research on human beings shall submit, within
12 thirty days following the establishment of the National
13 Board, a report detailing the exact nature of all research
14 involving human beings presently being conducted at that
15 institution. That institution shall establish within one year
16 following the passage of this Act an Institutional Review
17 Committee or forfeit all Federal funds until such time as the
18 Institutional Review Committee is established.

19 (c) (1) The members and the chairman of such Insti-
20 tutional Review Committees shall be appointed by the chief
21 executive officer of the institution in accordance with poli-
22 cies, regulations, and procedures of the National Board.

23 (2) Such Institutional Review Committee must be com-
24 posed of sufficient members (including religious leaders, per-
25 sons schooled in ethics, and non-health-care professionals)

1 with such varying backgrounds of competence as to assure
2 complete and adequate review. No member of such Institu-
3 tional Review Committees shall be involved in either the
4 initial or continuing review of an activity in which he has a
5 conflict of interest as defined by the National Board.

6 (d) Each Institutional Review Committee shall establish
7 two subcommittees as follows:

8 (1) a Protocol Review Subcommittee, which shall
9 be responsible for approving, disapproving, or offering
10 suggestions for modifications of protocols for experi-
11 mental procedures;

12 (2) a Subject Advisory Subcommittee, which shall
13 be primarily concerned with the protection of the rights
14 of subjects of biomedical and behavioral research, and
15 shall assure that human subjects are as well informed
16 about the nature of the research as is reasonably possible.

17 The subject advisory subcommittee shall be responsible
18 for insuring that the written information is kept on file
19 as provided in section 5, subsections (c), (1), (A) and
20 (B) of this Act.

21 **DUTIES OF THE INSTITUTIONAL REVIEW COMMITTEES**

22 **SEC. 9. (a)** It shall be the duty of the Institutional Re-
23 view Committees, established under section 8, to—

24 (1) oversee all experimentation conducted on hu-
25 man beings in that institution by way of establishing local

1 policies for the review of research sponsored in whole
2 or in part by the Federal Government, consistent with
3 the national guidelines promulgated under section 5;

4 (2) report immediately to the National Board the
5 plan of any experiment involving psychosurgery;

6 (3) assume full responsibility to insure that bio-
7 medical and behavioral research involving human sub-
8 jects is carried out under the safest possible conditions
9 with the fully informed consent of the subject (or his
10 family) in a manner fully consistent with the ethical prin-
11 ciples developed by the National Board;

12 (4) seek the consultative services of the National
13 Board on any decision, or for the provision of informa-
14 tion needed to arrive at a decision;

15 (5) initiate, if appropriate, the referral of particular
16 decisions to the National Board in accordance with regu-
17 lations promulgated by the National Board.

18 (6) submit, at least four times a fiscal year, a report
19 to the National Board detailing in full the activities of
20 that institution, and enumerating present and planned
21 experiments. On the basis of these reports, the National
22 Board shall recommend funding for the institution on a
23 yearly basis.

24 (b) No experimentation on human beings may be con-
25 ducted in any institution unless the appropriate Institutional

1 Review Committee has reviewed the program of experimen-
2 tation to insure that it is consistent with this title, guidelines,
3 and regulations promulgated pursuant to section 5 of this
4 title, and local policies and protocols issued by the local
5 board. The committee's decision approving or disapproving
6 any such program shall be reported to the National Board,
7 together with such additional information as may be required
8 by the National Board.

9 **PUBLICATION OF DECISIONS**

10 **SEC. 10.** The National Board shall compile a complete
11 list of decisions pertaining to programs under its jurisdiction
12 and annually publish and distribute reports of important
13 decisions.

14 **INTERIM PROVISIONS**

15 **SEC. 11. (a)** Until such time as the Institutional Review
16 Committee of an institution is established and certified by
17 the National Board pursuant to the provisions of section 8
18 of this Act, all phases of biomedical and behavioral research
19 conducted at that institution shall be subject to the direct
20 supervision of the National Board.

21 **(b)** During the interim period between the passage of
22 this Act and the establishment of the National Board, each
23 institution engaged in biomedical and behavioral research
24 involving human subjects shall determine that the rights and
25 welfare of the subjects involved are fully protected, that the

1 risks to an individual are outweighed by the potential bene-
2 fits to him, and that informed consent is obtained by methods
3 that are appropriate and sufficient to insure full knowledge of
4 the nature and detail of the experiment to be performed,
5 pursuant to section 12 (d) of this Act.

6 (c) (1) The report required pursuant to section 8 (b)
7 shall contain detailed descriptions of all experiments that are
8 presently being conducted, or have been conducted since the
9 passage of this Act, at that institution.

10 (2) On the basis of this report, the National Board shall
11 have the power to suspend all experimentation conducted on
12 human beings at that institution pending further investiga-
13 tion by the National Board.

14 (3) Among other things, description of individual ex-
15 periments in this report shall contain a detailed accounting
16 of the extent to which the individual was informed prior to
17 the experiment and of the method by which written informed
18 consent was obtained.

19 (d) Effective with the passage of this Act, all institu-
20 tions conducting biomedical and behavioral research shall be
21 required to maintain the records provided for in section 5,
22 subsections (c) (1) (A), (B), and (C) of this Act.

23 DEFINITIONS

24 SEC. 12. (a) "Board" or "National Board" means the
25 National Human Experimentation Standards Board.

1. (b) "Institution" means any person or entity (including governing departments or agencies) receiving funds from the Federal Government to be used for biomedical or behavioral research involving human subjects.

5 (c) "Institutional Review Committee" or IRC refers to local review committees to be established at individual institutions as required by this bill.

8 (d) For the purposes of this Act, the term "informed consent" shall mean the consent of a person, or his legal representative, so situated as to be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, or other form of constraint or coercion. Such consent shall be evidenced by an agreement signed by such person, or his legal representatives. The information to be given to the subject in such written agreement shall include the following basic elements:

17 (1) a fair explanation of the procedures to be followed, including an identification of any which are experimental;

20 (2) a description of any attendant discomforts and risks reasonably to be expected;

22 (3) a description of any benefits reasonably to be expected;

24 (4) a disclosure of any appropriate alternative procedures that might be advantageous for the subject;

1 in compliance with standards prescribed pursuant to this
2 section.

3 (b) (1) The National Board shall not disclose any in-
4 formation reported to or otherwise obtained by it pursuant
5 to this section which concerns any information which con-
6 tains or relates to a trade secret or other matter referred
7 to in section 1905 of title 18 of the United States Code,
8 except that such information may be disclosed to officers or
9 employees of the National Board and of other agencies
10 when such information is necessary to carry out the pro-
11 visions of this section.

12 (2) Records compiled in the course of proposing or
13 conducting biomedical and behavioral research involving
14 human subjects funded in whole or in part by the Federal
15 Government which records concern personal or medical in-
16 formation shall be confidential and may be disclosed only
17 for the purposes and under the circumstances expressly au-
18 thorized under paragraph (3) of this subsection.

19 (3) (A) When expressly authorized by the written, in-
20 formed consent of the person, with respect to whom any
21 given record referred to in this section is maintained: *Pro-*
22 *vided*, That the content of such record is disclosed only (i)
23 to medical personnel for the purposes of diagnosis or treat-
24 ment of such person, or (ii) to governmental personnel for
25 the sole purpose of obtaining benefits to which the person is

1 entitled, or (iii) to such personnel as may be designated in
2 regulations promulgated by the National Board for the pur-
3 pose of carrying out this Act.

4 (B) When information contained in any given record
5 referred to in this section is necessary to meet a bona fide
6 medical emergency.

7 (4) The provisions of this section shall not be deemed
8 to prohibit the disclosure of statistical information for the
9 purpose of conducting scientific or epidemiological research,
10 provided that such disclosure does not identify directly or
11 indirectly any individual with respect to whom records
12 referred to in this section are maintained.

13 (5) The prohibitions of this section shall apply to
14 records required to be maintained under this section concern-
15 ing any individual notwithstanding any statute of limitations
16 or other law which may apply: *Provided*, That nothing in
17 this subsection shall be deemed to authorize the disclosure
18 of information which any other provisions of State or Fed-
19 eral law (including administrative regulations) require to be
20 kept confidential.

21 (6) Persons required by this section to maintain the
22 confidentiality of records may not be compelled in any
23 Federal, State, or local civil, criminal, administrative, leg-
24 islative, or other proceedings to disclose such records, unless

1 such disclosure is expressly demanded by the person with
2 respect to whom a given record is maintained.

3 (7) Any person who unlawfully discloses the con-
4 tents of any record referred to in subsection (a) shall upon
5 conviction be fined not more than \$500 in the case of a
6 first offense, and not more than \$5,000 in the case of each
7 subsequent offense and (b) shall be liable in damages to
8 any person injured by such disclosure.

DEPARTMENT OF DEFENSE,
OFFICE OF THE GENERAL COUNSEL,
Washington, D.C., November 9, 1973.

HON. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Reference is made to your request for the views of the Department of Defense on H.R. 5371, 93d Congress, a bill "To prohibit psychosurgery in federally connected health care facilities."

The purpose of the bill is stated in its title.

The term "psychosurgery" is defined in the bill as operational procedures currently referred to as lobotomy, psychiatric surgery, behavioral surgery, and all other forms of brain surgery, if the surgery is performed for the purpose of: (a) modification or control of thoughts, feelings, actions, or behavior rather than the treatment of a known and diagnosed physical disease of the brain; (b) modification of normal brain function or normal brain tissue in order to control thoughts, feelings, actions, or behavior; or (c) treatment of abnormal brain function or abnormal brain tissue in order to modify thoughts, feelings, actions, or behavior when the abnormality is not an established cause for those thoughts, feelings, actions, or behavior. Such terms, however, exclude electroshock treatment, the electrical stimulation of the brain, or drug therapy, except when substances are injected or inserted directly into brain tissue.

While the Department of Defense supports measures which would enhance the nation's health care delivery system, we oppose H.R. 5371 for the following reasons: We believe the bill lacks a firm qualifying definition of "psychosurgery." As defined, it is too broad in scope and would deny a competent surgeon from performing several medically accepted surgical procedures which would, among other things, relieve pain, modify the acute and chronic aspects of convulsive disorders and spastic conditions. In each of these cases, when such procedures are appropriately administered by a competent, well-trained and skilled specialist, they legitimately modify control of thoughts, feelings, actions or behavior. The resultant relief of undue human suffering caused by these complex maladies is in keeping with good accepted medical principles and practices.

Our military surgeons do not perform the "classic" psychosurgery on active duty personnel. Normally such sophisticated operative procedures only would be required for persons not on active duty. In this regard, specific severe medical conditions requiring surgical correction or relief by psychosurgical methods would almost in every case be limited to our dependent and retired population, including other authorized beneficiaries.

For the reasons stated above the Department of Defense recommends no action be taken on H.R. 5371.

The Office of Management and Budget advises that, from the standpoint of the Administration's program, there would be no objection to the presentation of this report for the consideration of the Committee.

Sincerely,

L. NIEDERLEHNER,
Acting General Counsel.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., August 3, 1973.

HON. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This letter is in response to your request of February 9, 1973, for a report on H.R. 1111, a bill "To provide for a study and evaluation of the ethical, social, and legal implications of advances in biomedical research and technology."

This bill would provide for the establishment of a National Advisory Commission on Health Science and Society, which would conduct a comprehensive investigation and study of the ethical, social, and legal implications of advances in biomedical research and technology.

This Department has long supported dialogue concerning social, legal, and ethical implications of present and projected medical advances, believing that such dialogue can be a positive contribution to the task of public policymaking in these areas. However, title III of the Public Health Service Act provides

the Secretary with ample authorities to secure the assistance of scholars and consultants, to collect and publish information, and to utilize the administrative facilities and structures that may be necessary for investigation of a broad range of subjects relating to science research and its applications.

For example, the Department created a nine-member panel of distinguished consultants to evaluate the ethical and scientific aspects of the Public Health Service's study of syphilis in the non-infectious stage. Furthermore, a study group composed of representatives of various health components of the Department is currently reviewing policies on protection of human subjects in biomedical research. These groups are illustrative of ways in which the concerns of H.R. 1111 are being met by administrative activities within the Department.

Public sector activities also include a new program on the ethical and human value implications of science recently undertaken by the National Science Foundation in conjunction with the national endowment for the humanities. The program seeks to cover the whole spectrum of science and technology in terms of the ethical and human value issues of greatest current concern and consequently covers a much broader spectrum than scientific and technological advances in the biomedical sciences.

Several distinguished groups already in existence have broad missions similar to those outlined for the proposed Commission. These include the National Academy of Sciences, with its newly established Institute of Medicine and its National Research Council; the American College of Surgeons; the National Academy of Engineering; the American Academy of Arts and Sciences; and the American Philosophical Society.

Also in the private sector, the IBM Company has funded a program on technology and society at Harvard University. The World Council of Churches sponsors, from time to time, conferences on technology and its relationships to society. The Smithsonian Institute recently sponsored a symposium to evaluate the ethical use of drugs, and the American Medical Association is about to sponsor its Fourth National Congress on Medical Ethics. The Joseph P. Kennedy, Jr., Foundation continues to sponsor research and other activities dealing with the social impact of biomedical science.

The public and private initiatives mentioned above are representative of the large number of relevant activities already underway by institutions concerned with social, ethical, and legal issues raised by health research advances.

While the Department supports the concepts behind H.R. 1111, it is opposed to the bill because the Secretary already has ample authority and indeed is already engaged in efforts to achieve, in coordination with efforts in the private sector, all of the purposes of this piece of legislation. Accordingly, we recommend that H.R. 1111 not be enacted.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

FRANK C. CARLUCCI,
Acting Secretary.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., November 20, 1973.

HON. HARLEY O. STAOERS,
*Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives,
Washington, D.C.*

DEAR MR. CHAIRMAN: This letter is in response to your request of March 19, 1973, for a report on H.R. 5371, a bill "To prohibit psychosurgery in federally connected health care facilities".

The bill would make it unlawful for anyone to perform psychosurgery in any "federally connected" health care facility or for such facility to permit anyone to perform psychosurgery within its walls. Violators (other than a Federal health care facility itself) may be subject to a civil fine of up to \$10,000, assessed by a Psychosurgery Commission appointed by the President and collected in a civil action brought by the United States in any United States district court. The Commission may also bring civil actions in Federal District Courts to restrain performance of psychosurgery or class action suits on behalf of persons up whom psychosurgery was performed. Persons who unlawfully perform psychosurgery may not receive funds under any Federal grant, contract, or loan and

are not even eligible to apply for a Federal grant, contract, loan, or loan guarantee for a five-year period after the date the Commission found them in violation of the psychosurgery prohibition.

The bill also requires the Secretary of Health, Education, and Welfare to exact an agreement from any health care facility to prohibit psychosurgery on its premises as a prerequisite to receipt of Federal grant, contract, loan, or loan guarantee funds.

The definition of "federally connected health care facility" encompasses the great majority of providers of the United States. If any part of the facility was constructed, operated, renovated, or maintained with Federal funds—including Medicare and Medicaid reimbursements—the facility is subject to the prohibition. The term "psychosurgery" is also given a broad definition. It includes all types of brain surgery if performed for the purpose of modifying or controlling thoughts, actions, feelings, or behavior unless such modification or control is incidental to "the treatment of a known and diagnosed physical disease of the brain".

The Department certainly shares the opinion that psychosurgery is an extremely hazardous procedure and that the state of the art has not advanced sufficiently as yet to justify psychosurgical operations except under carefully controlled conditions and in the most extreme circumstances. In recent testimony before the Congress, Department witnesses made it clear, however, that few such operations are directly supported with Federal funds. Many dedicated men and women are daily conducting painstaking scientific research to enlarge the body of knowledge about the complex structure known as the brain. We see no justification for provisions that would seriously handicap this whole area of research, even though its direct support was provided through non-Federal sources, since virtually all hospitals receive some form of indirect assistance through Federal resources. We know of no other instance in which the Federal Government has prescribed the parameters of permissible and impermissible surgery for the medical profession.

The definition of psychosurgery is so broad as to bar most types of brain surgery not directly designed to remove a growth or a tumor. It is not clear, for example, that surgery to correct the abnormal brain function known as epilepsy is permissible under section (2) (C) of the bill. Moreover, modification of abnormal actions or reactions frequently results from brain surgery and may indeed be the primary purpose of the operation. We are not prepared to say that such modifications are never justified. The therapeutic value must be judged on a case-by-case basis.

Finally, the judicial system provides ample opportunity for injunctive relief before psychosurgery is performed and to assess damages if its performance was unwarranted or the circumstances amounted to a violation of patients' rights. There is no need for a new quasi-Federal agency to bring class action suits and assess civil fines.

For the above reasons, we would recommend against enactment of H.R. 5371.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

CASPAB W. WEINBERGER,
Secretary.

EXECUTIVE OFFICE OF THE PRESIDENT,
OFFICE OF MANAGEMENT AND BUDGET,
Washington, D.C., August 3, 1973.

HON. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request of February 9, 1973 for the views of this Office on H.R. 1111, a bill "To provide for a study and evaluation of the ethical, social, and legal implications of advances in biomedical research and technology."

In its report to your Committee the Department of Health, Education, and Welfare states its reasons for recommending against enactment of H.R. 1111. The Department mentions numerous activities being sponsored by public and private organizations which would achieve the objectives of the legislation. The Department also notes that the Public Health Service Act provides ample

authority for the Secretary of Health, Education, and Welfare to undertake the types of studies and investigations which H.R. 1111 would authorize.

We concur with the views expressed by the Department in its report. Accordingly, we recommend against enactment of H.R. 1111.

Sincerely,

WILFRED H. ROMMEL,
Assistant Director for Legislative Reference.

EXECUTIVE OFFICE OF THE PRESIDENT,
OFFICE OF MANAGEMENT AND BUDGET,
Washington, D.C., November 26, 1973.

HON. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request of October 23, 1973 for the views of this Office on H.R. 10403, a bill "To amend the Public Health Service Act to provide for the protection of human subjects who participate in biomedical or behavioral research programs, and for other purposes."

In testimony before your Committee on September 27, 1973 the Department of Health, Education, and Welfare stated its reasons for recommending against enactment of H.R. 10403.

We concur with the view expressed by the Department in its testimony that it would be inappropriate and unworkable to establish a new Commission to develop and implement mechanisms and procedures for the regulation of biomedical research while simultaneously making a study of the most appropriate way to regulate the protection of human subjects.

For the reasons stated by the Department of Health, Education, and Welfare in its testimony, we recommend against enactment of H.R. 10430.

Sincerely,

WILFRED H. ROMMEL,
Assistant Director for Legislative Reference.

EXECUTIVE OFFICE OF THE PRESIDENT,
OFFICE OF MANAGEMENT AND BUDGET,
Washington, D.C., January 9, 1974.

HON. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce, House of Representatives, 2125 Rayburn House Office Building, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request of March 19, 1973 for the views of this Office on H.R. 5371, a bill "To prohibit psychosurgery in federally connected health care facilities."

In reports to your Committee, the Department of Health, Education, and Welfare and the Department of Defense state their reasons for recommending against enactment of H.R. 5371. Both agencies express the view that the bill is far too restrictive and would result in barring most types of brain surgery not directly designed to remove a growth or tumor, regardless of therapeutic necessity or value. The Department of Defense also states its belief that H.R. 5371 "would pose a serious threat to the effective operation of the Department of Defense, including its efforts to reshape and increase the overall quality of health care being given to members and eligible former members and their families of the armed forces."

We concur with the views expressed by both Departments in their reports. Accordingly, we recommend against enactment of H.R. 5371. For the information of the Committee, we are also attaching a copy of a letter this Office has received containing the views of the Department of Justice on the bill.

Sincerely,

WILFRED H. ROMMEL,
Assistant Director for Legislative Reference.

Enclosure.

DEPARTMENT OF JUSTICE,
Washington, D.C., December 21, 1973.

HON. ROY L. ASH,
Director, Office of Management and Budget,
Washington, D.C.

DEAR MR. ASH: This is in response to your request for the views of the Department of Justice on H.R. 5371, a bill "To prohibit psychosurgery in federally connected health care facilities."

H.R. 5371 would render psychosurgery as defined therein "unlawful," per section 2, when performed in a federally connected health care facility or with the permission of such a facility. Section 1 of the bill defines "federally connected health care facility" and "psychosurgery" and directs the Secretary of HEW to notify such facilities of the requirements of the Act.

Section 3 would establish civil penalty sanctions of "not more than" \$10,000 to be assessed by the Commission established in section 4 of the bill. Such a penalty could be assessed both against the individual performing the "psychosurgery" and against the facility. Section 3(a) (2) contemplates an administrative proceeding by the Commission to assess such civil penalties. Findings of fact supported by substantial evidence in the record of such proceedings, after notice and opportunity for a hearing, would be conclusive in either a suit to collect the penalty or in any civil action by an accused to obtain court review of the Commission's determination. Section 3(b) authorizes Commission action to obtain a court order to restrain violations of the Act. Section 3(c) (1) would authorize the person upon whom "psychosurgery" is performed to sue the person performing the "psychosurgery" and the facility which permitted such for damages. Other court remedies are expressly preserved. Section 3(c) (2) would authorize the Commission to bring informer type actions per the preceding subsection, if requested to do so in writing. Section 3(d) renders persons performing "psychosurgery" ineligible to receive any money under a grant, contract or loan from the United States. Such a person would be ineligible to apply for such during a five-year period beginning on the date of the Commission's determination of violation. No bar to a grant, loan or contract is provided for those performing "psychosurgery" who do not perform such surgery in or for a federally connected health care facility.

Section 4 establishes a nine member completely lay "Psychosurgery Commission" composed of people who have "an interest and experience in the field of mental health." One third of the members would be from minority groups. Section 4(g) (3) requires the head of a Federal department or agency to furnish information necessary for the Commission to carry out its functions under the Act upon the request of the Chairman or Vice Chairman. Provision is made for immunity for witnesses in certain situations and an annual report to the Congress.

The Department of Justice defers to the Veterans Administration and the Department of Health, Education and Welfare as to basic scientific judgments involved in determining whether "psychosurgery" as defined in the bill should be banned. We have no information concerning the number of such operations performed or the incidence of adverse effects as a result thereof. Even if the instant bill is enacted into law, it is likely that "psychosurgery" will continue to be performed in certain private medical and mental institutions. Thus, if there is any merit in such surgery from a curative, palliative or experimental standpoint, the instant bill would restrict the benefits thereof to those who have sufficient money to afford treatment in certain private health and mental institutions.

The following are our reservations relevant to other provisions of the bill.

Section 1(b) of the bill would require hospital and other facilities for the delivery of health care, including prisons and other correctional facilities, to agree to prohibit the performance of "psychosurgery" on their premises, or on their patients or inmates, as a condition of eligibility for grants, contracts, loans or loan guarantees. This interdiction does not extend to the insurance of loans however.

Section 3 presents several problems. Executive Order 6166 localizes responsibility for the conduct of all Federal litigation in the Attorney General. Compare 28 U.S.C. 516. Subsections (b) and (c) (2) of section 3 of the bill attempt to dilute the Attorney General's authority and place litigation responsibility in a lay commission. We are opposed to authorizing a multiplicity of Federal agencies to conduct their own litigation because of the duplication of staff involved, the extra expense incurred and because it is important for the Government to be consistent in the legal positions which it takes in the courts.

Turning to the potential liability of Government employees who might participate in "psychosurgery," 38 U.S.C. 4116 and 42 U.S.C. 233 appear to immunize employees of the VA and the Public Health Service from personal liability insofar as negligence or malpractice are concerned. It would be an anomaly if such employees could be held personally liable under the proposed legislation for actions which do not constitute negligence or malpractice while being freed from personal liability if more serious conduct is involved.

Subsection (c) (1) would establish a cause of action for damages over and above any action which might arise under conventional tort law, but it does not establish a measure of damages. If the person involved has a remedy in tort that would appear to be the remedy with which the statute should leave him. We fail to see why a person subject to the Act should be saddled with double liability when persons not in federally connected health care facilities would not be subject to more than the usual liability for negligence or malpractice. Further, the negligence bar has been diligent in obtaining liberal awards in tort litigation. We do not believe that there needs to be provision for informer type suits by a Government agency. In any event, exclusive jurisdiction for suits arising from "psychosurgery" should not lie in the overcrowded Federal Courts. Rather the normal rules as to Federal jurisdiction should apply.

Turning to the administrative adjudication of civil penalty liability and the possible review of such adjudications in court proceedings, the bill fails to establish a time limit, such as thirty days, within which court review before a United States District Court must be sought. The additional sanctions imposed by subsection (d) are inconsistent. Subsection (d) (1) barring receipt of funds is without time limit and does not include a prohibition against receiving the benefit of a loan which is guaranteed or insured by the United States as distinguished from one which guaranteed or insured by the United States as distinguished from one which is made by the United States. Subsection (d) (2) limiting eligibility "to apply" for a grant, contract or loan guaranty is confined to a period of five years.

Section 4 would establish an independent nine member commission to administer the provisions of the Act but doctors and persons with an advanced degree in psychology would be expressly barred from membership on the Commission! We fail to see the need for the addition of yet another independent agency with so many commission members, particularly when the commission is not authorized to do more than enforce the standards which would be frozen by the statute.

For the reasons stated herein, the Department of Justice does not recommend enactment of H.R. 5371.

Sincerely,

MALCOLM D. HAWK,
Acting Assistant Attorney General.

Mr. ROGERS. We are very honored today to have as our first witness our colleague, Hon. Edward M. Kennedy, a U.S. Senator from Massachusetts and the chairman of the Senate Committee on Health. He has been a leader in this entire area and in the health field. We are very anxious to hear his testimony today.

I might say this bill was introduced exactly as the Senate has written it from his committee, so we could then proceed to determine on this side what we think should be done as well.

So we welcome you to the committee and are anxious to hear your testimony.

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. I am stirred by your opening statement and the challenge which you have presented to your committee and to those of us in the Senate as well. Your statement raises a great challenge in this area. We must work together to provide protection to human subjects, not only of HEW-sponsored research, but of research in the other service programs as well. I am hopeful that the Commission

which the Senate bill would establish would go far toward accomplishing this goal.

We hope that the Commission will make recommendations to the Congress as to how that best can be done. The Senate Health Subcommittee has wanted to proceed cautiously in expanding its application to other programs. I said if we had extended it beyond medicare and medicaid we would have had to refer it to the Finance Committee. If we had applied it to the Armed Forces, to the Armed Services Committee. It seemed to us it would be best to hold off, not only because of complications in the jurisdictional question, but also because this Commission is going to have to walk before it runs. To get into all these other areas before the Commission gets off the ground would seem to be a bit premature.

Also, you have raised a question about nonfederally funded programs to which I think the same response is appropriate. At the present time I think we will have met the most important challenge and hopefully we will be able to move into other areas at a later date.

Mr. ROGERS. May I just say that I just think we need to address ourselves to some consideration of this and I understand as you have explained the approach the Senate has taken. I do think, for instance, that in the veterans hospitals where so much research is done we would have some jurisdictional problems perhaps as you say, although we may be able to get them to go right along on the floor in action of this type. This, however, is something we can have discussions on.

Senator KENNEDY. I would certainly hope that we would be able to persuade our colleagues in a conference to embrace this. There does exist some record of cooperation. In our Health Committee we had a joint hearing with the Veterans Committee in the Senate on the issue of psychosurgery. The VA is involved in psychosurgery. They have, to their credit, in the last year propounded what I think are creditable guidelines. But we are in a difficulty in that we have a variety of different agencies with a variety of different guidelines all under a Federal policy and I feel that we ought to have the best minds together to suggest the best overall general policy. Obviously, there are going to be various interpretations as to application to different agencies, but at least we are going to have a uniform national policy.

Mr. ROGERS. Thank you.

Senator KENNEDY. I want to express my appreciation for testifying here in support of the Protection of Human Subjects Act. Your committee has always given the Nation's biomedical research community the support it has needed to become preeminent in the world. Your prompt scheduling of these hearings so soon after introducing this legislation is consistent with your commitments both to the biomedical and behavioral researchers, and to the human subjects of their research.

Mr. Chairman, as we meet here today, scientists may stand on the threshold of being able to recreate man. Techniques have already been developed that have the power to modify and control man's behavior.

In the last decade, we have witnessed an unparalleled expansion of our technological capabilities. The technology of biomedical and behavioral research is the technology of man. Today, we have more biomedical research scientists at work on more kinds of projects than

at any time in our history. Our scientists have been, and must continue to be, the most productive in the world. But their unparalleled success has taken us beyond the frontiers of man's understanding. And the gap between the development of the technology of man, and our capacity to understand the nature and implications of that technology, widens every day.

In the last decade, we have seen a surgeon hold a human heart in his hands and transplant it into another person's body; we have seen scores of surgeons renew life to thousands of people by the transplantation of kidneys; we have seen scientists unravelling the mysteries of the genetic code, learning how to alter the very structure of the building blocks of life; we have seen scientists begin to unlock the mysteries of the brain and begin to understand the physical basis of feelings—of sorrow and joy, of pain and pleasure, of anger and understanding; we have seen a breakthrough in the treatment of Hodgkins disease, a dreaded cancer of the lymph nodes; we have seen a vaccine developed to eliminate measles. We have all been touched by, and have all profited from the fruits of biomedical research.

But in the last decade, we have also seen the zeal for new knowledge and the overwhelming desire to utilize the new technology result in serious medical and ethical abuses. We have seen the Federal Government conduct the Tuskee syphilis experiment without adhering to the principles of informed consent; the sterilization of two black teenage girls in Montgomery, Ala. without their or their parents' understanding or permission; the widespread use of experimental drugs in the routine practice of medicine; the unjustified use of the supercoil—an experimental IUD, developed in isolation by a single practitioner without any professional review which resulted in serious medical injury to several patients; and the performance of psycho-surgery for the purposes of behavior modification without proper peer review and without an experimental protocol.

In 12 days of hearings before the Senate Health Subcommittee witnesses detailed the widespread nature of the abuses. Dr. Robert Veatch presented a summary of 12 studies out of his collection of 43 which raised significant ethical questions. Dr. Bernard Barber demonstrated that not even the university review committees were able to adequately address the problems. He reported that 350 physician-researchers judged their own work to have more risk than benefit for their experimental subjects in 18 percent of the cases. Eight percent of the studies were judged to have more risk than benefit for both present or any conceivable future subject.

As Dr. Jay Katz, perhaps the world's leading authority on human experimentation, testified:

Suffice it to say that the research community has made no concerted effort either to impose any meaningful self-regulation on its practices or to discuss in any scholarly depth the permissible limits of human research. Therefore, I submit, regulation has to come from elsewhere.

The Protection of Human Subjects Act has received considerable support from the Nation's biomedical research community. The Association of American Medical Colleges and the American Federation for Clinical Research were both supportive. Far from fearing Government intrusion into the research process these groups welcomed the idea of the Commission. They pointed out that the Nation's top

researchers have nothing to fear and everything to gain from a Commission that will help them grapple with the complex ethical dilemmas presented by their work. Dr. Albert Sabin, one of the Nation's most distinguished scientists and the developer of the oral polio vaccine, summed up the consensus of witnesses by saying "this legislation is needed—no ifs, ands, or buts."

The Commission has been structured to achieve maximum flexibility. It is directed to identify the basic principles underlying the conduct of biomedical research involving human subjects. It is directed to develop policies to provide maximum protection for human subjects of that research. But it has wide discretion in how to proceed. It works through institutional review boards formed at the local level. It is directed to provide maximum flexibility for these local boards.

Although I believe this Commission should eventually have jurisdiction over all federally sponsored research involving human subjects, its jurisdiction would be initially limited to HEW-funded research.

But the legislation requires the Commission to report to the Congress within a year to recommend a mechanism to expand jurisdiction.

The legislation also directs the Secretary to apply the policies of the Commission to the maximum feasible extent, where appropriate to the delivery of health services in HEW-funded health service projects. This is particularly important. It means, for example, that the principles of informed consent would be applied for an appropriate medical procedure—such as sterilization.

The OEO experience with sterilization guidelines shows why this provision of the legislation is so necessary. In May, 1971, OEO informed its health service projects that funds could be used to carry out voluntary sterilizations. Guidelines for this procedure were drawn up. But they were never sent out and the Relf sterilization case may have been a direct result of that.

During his confirmation hearing, OEO Director Arnett promised to furnish the committee a full report on the sterilization guidelines—why they were developed and why they were not released. I am today making public a copy of that report [see p. 95]. It details White House involvement in the decision to withhold the guidelines. Dr. Leon Cooper, Medical Director of OEO at the time, opposed the issuance of the guidelines. So did the White House, although apparently for different reasons. As the report quotes Cooper, "my purposes served their needs."

It is interesting to speculate what would have happened if Cooper had favored the release of the guidelines. The clear implication of this report is that they would never have been issued under any circumstances. Now that the Relf tragedy has occurred with its attendant publicity, HEW has proposed guidelines.

I submit that once an activity is supported, the decisions as to whether or not to issue guidelines, and what to include in those guidelines, should never be made on political grounds. In fact, in many cases, the decision to support or not support an activity in the first place should not be made on political grounds. Complex moral, ethical and religious principles must be weighed and balanced. The Commission will focus the most creative minds in the Nation on these problems, and will help clarify them both for society as a whole and for the individual investigator.

Mr. Chairman, this Commission is designed to help us find the critical balance required to satisfy society's demands for the advancement of knowledge while abiding by its strictures to protect the dignity, privacy, freedom, and health of its individual members. Scientific research must be supported. It must be encouraged. But it must go forth with the minimal possible risk to research subjects.

This Nation has had and must continue to have a biomedical research program second to none. But it must also have, and will have, a system for the protection of human subjects of that research which is second to none.

This legislation is a step, and an important step, in that direction.

[Testimony resumes on p. 103.]

[The OEO report referred to follows:]

ADMINISTRATIVELY CONFIDENTIALEXECUTIVE OFFICE OF THE PRESIDENT
WASHINGTON, D.C. 20506OFFICE OF ECONOMIC
OPPORTUNITYOFFICE OF PROGRAM AUDIT
(Inspection and Audit)MEMORANDUM

July 19, 1973

TO : Eric Biddle *EB*

THRU : Robert Slonager *RS*

FROM : John Myers & Peter Spalding *PM*

SUBJECT: OEO Instruction 6130-2 on Voluntary Sterilization Services
Background reference: Office of Program Audit
Memo from Inspector Vitez dated July 11, 1973,
Attached as Exhibit #3

PROBLEM

Inspection was asked to continue the inquiry pursued by Inspector Vitez for the purpose of determining why OEO Instruction 6130-2, dated January 11, 1972, was not released to family planning programs.

CHRONOLOGICAL SUMMARYMay 18, 1971:

On May 18, 1971 OEO issued a memorandum entitled "Family Planning Activities," signed by OEO Deputy Director Wesley L. Hjernevik, which announced a change in OEO's policy to permit payment for voluntary sterilization with OEO funds. The memorandum continued an OEO prohibition against the payment for abortions with OEO funds. (Exhibit #1)

This memo was forwarded to all Regional OEO Directors with a cover memo signed by George Contis, M.D., Director Family Planning Program, Office of Health Affairs, OEO. This memo contained the following sentence:

This document may not be reproduced without permission of the Inspection Division. It includes unevaluated investigative data, as well as material furnished in confidence by sources of untested reliability.

"Please do not consider any funding requests for sterilization services until you receive...guidelines."

November - December, 1971:

Dr. Leon Cooper, Director, Health Affairs, OEO, objected to the guidelines which had been written by the Family Planning Division, Health Affairs, OEO. Cooper felt that their implementation would result in the focus of all family planning grants on sterilization as opposed to family planning methods which would not result in permanent sterility. He also objected to the impact sterilization would have on the overall family planning budget.

January, 1972:

OEO Deputy Director Wesley Hjernevik was contacted by Paul O'Neill, Director, Human Resources Programs Division, Office of Management and Budget (OMB) who informed him that the White House was interested in withholding the dissemination of the guidelines pending a review of their contents. Hjernevik determined that the guidelines had been printed, but not disseminated. A copy of OEO Instruction 6130-2 was sent to O'Neill for review by the White House. (Exhibit #2)

Approximately February, 1972:

In approximately February 1972, Dr. Cooper and Mr. Hjernevik met with Mr. Paul O'Neill and Mr. James Cavanaugh of the Domestic Council of the White House. At this time Cooper voiced his objections to the guidelines. Dr. Cooper's objections were concurred in by O'Neill and Cavanaugh. Cooper said O'Neill and Cavanaugh felt that his objections would "serve their purposes." The White House objection to the issuance of the guidelines was based on the feeling that the performance of sterilization operations was not in consonance with the President's expressed opposition to the performance of abortions with Federal funds. The guidelines (OEO Instruction 6130-2, dated January 11, 1972) were never disseminated to any OEO grantees.

DETAILS

OEO issued Instruction 6130-1 (Exhibit #1) on May 18, 1971, amending Community Action Memo 37A as follows:

"1. Delete the following:

No project funds shall be expended for any surgical procedures intended to result in sterilization or to cause abortions.

2. Substitute the following:

No project funds shall be expended for any surgical procedures intended to cause abortions."

Attached to this Instruction was an undated memo from George Contis, M.D., Director of the Family Planning Program, to all OEO Regional Directors, which stated:

"...we are developing a set of guideline and clinical standards for the provision of sterilization services to OEO patients which will incorporate the necessary safeguards. We plan to have these available for use by family planning projects and your office by Sept. 1, 1971. Please do not consider any funding requests for sterilization services until you receive these guidelines."

In November 1971 Dr. Leon Cooper became Director of the Office of Health Affairs. He reviewed a new draft instruction, subsequently numbered 6130-2, which laid down guidelines governing sterilizations. Cooper told Inspection he had reservations about this instruction based upon questions about internal operating plans, program priorities and possible impact upon the program budget which would result from opening the door to sterilization services. Cooper said he suspected that demand for such services would redirect program emphasis away from providing contraceptive counseling and related services and would severely limit the program's research mission. Cooper said he discussed his reservations with Deputy Director Wesley Hjernevik, who agreed not to

disseminate the instruction until the questions had been resolved. This decision was also conveyed to Cooper's subordinates, Drs. George Contis and Warren Hern.

Wesley Hjernevik told Inspection he didn't become involved in the sterilization question until January 1972 when Contis and Hern came to see him, in Dr. Cooper's absence, with the draft of Instruction 6130-2. Hjernevik thought the Instruction was well-done but he also had reservations based upon his understanding that the original decision (May 1971) to permit sterilizations had been sold on the basis of male sterilization (vasectomy) rather than on the more serious surgical processes involved in female sterilization. Hjernevik said he sent a copy of the draft Instruction to the General Counsel's office, which approved its issuance. He also conferred with OEO Director Phillip Sanchez, who told him to use his own judgement. Hjernevik signed the Instruction and a cover memorandum dated January 10, 1972. Only after signing did he notice that the issuance did not bear the approving signature of Dr. Leon Cooper.

Hjernevik said he believes he referred the signed Instruction and cover memorandum back to Cooper with a note saying that he had reviewed and signed both contingent upon Cooper's concurrence. About ten days later Hjernevik said he received a call from Paul O'Neill of the Office of Management and Budget, who said there had been an inquiry from the White House Counsel's office. Hjernevik told O'Neill that he thought the Instruction had already been released, whereupon O'Neill was distressed and said White House was definitely interested in holding up dissemination if release had not yet been made. Hjernevik called Cooper, who told him the Instruction had not been disseminated. Hjernevik requested a copy for OMB and the White House. Cooper also expressed some of his own reservations about the Instruction based upon patient confidentiality and permission procedures, Hjernevik said. Cooper cited a program located

"somewhere in the South," according to Hjernevik, where OEO had specifically authorized a trial run on sterilizations and the issues of confidentiality and permission had arisen (probably Anderson County, Tennessee). Shortly after terminating this conversation, Cooper called Hjernevik to advise that the Instruction had gone to the printer without his approval. Hjernevik said it was later determined that none of the copies had been distributed to funded programs, although there had been some dissemination within OEO. As reported in the Vitez memorandum, Dr. Hern had received 200 advance copies of the printed instruction, most of which were retrieved and locked in the safe of Ernest Russell, OEO Director of Administration.

Hjernevik sent a copy of Instruction 6130-2 to O'Neill at OMB as requested. During the next two or three months, according to Hjernevik, Contis and Hern "had considerable emotional input" to him advocating the release of the Instruction. Hjernevik said he talked with Cooper and ascertained that all family planning grants contained a special condition against all sterilization activities, with the exception of the Anderson County, Tennessee grant. During this time it became clear to Hjernevik that Contis and Hern were generating correspondence from their family planning constituency throughout the country urging release of the Instruction. Hjernevik began to feel this pressure and felt that he and Cooper were caught between that force and the possible implications of the President's earlier statement disapproving abortions. Hjernevik also said that Cooper, a Negro, was feeling pressure from black groups who felt that sterilization was racially motivated. For this reason, Hjernevik called Paul O'Neill at OMB and asked for a meeting with him and a White House representative to clarify the situation. Hjernevik and Cooper met with O'Neill and Jim Cavanaugh, Associate Director of the White House Domestic Council.

Dr. Cooper told Inspection that he outlined his reservations to O'Neill and Cavanaugh, both of whom agreed that it would serve the White House's purposes for the Instructions to be withheld for awhile for Cooper's stated reasons. Cooper said that neither O'Neill nor Cavanaugh stated that the White House wanted the Instruction held up, but rather listened and concurred

with his own concerns. However, Hjernevik told Inspection that O'Neill and Cavanaugh were concerned with whether it was "sound public policy given the President's position on abortions" and questioned whether it was "necessary for OEO to go operational" with sterilizations, rather than carry on with research.

"We let them know we were content to sit on it," Hjernevik said. "The White House definitely didn't want us to go ahead. We (Hjernevik and Cooper) agreed coming back from the meeting that we would stress Cooper's concerns rather than the White House interest."

Martha Blaxall, former Budget Examiner for OEO Health Programs at OMB, was interviewed by telephone. She advised that sometime in February 1972 she was contacted by Dr. Warren Hern who told her that he had called a press conference to issue sterilization guidelines. Blaxall said Hern described the guidelines and his conviction that they should be issued expeditiously to preclude unguided sterilization activities by funded agencies. Hern said he had heard that someone at the White House had held up the guidelines and asked Blaxall to check into it. Blaxall agreed to do so because she knew Hern and because his concerns seemed reasonable. Blaxall took the matter to O'Neill, who checked and informed her that the Domestic Council's office had held up the Instruction. Blaxall did not recall that the name of the Domestic Council staff member was mentioned by O'Neill.

Inspection contacted O'Neill's office and learned that he was out of town on vacation until July 31.

Inspection contacted James Cavanaugh, Associate Director, Domestic Council at the White House, who agreed to attempt to make time available for an interview by Inspectors this week.

On July 13, 1973, Dr. E. Leon Cooper, M.D., the former Director of Health Affairs, OEO, who is currently the Executive Director, National Medical Association Foundation (NMAF), Washington, D. C., was interviewed regarding his knowledge of the circumstances surrounding the decision not to disseminate OEO Instruction 6130-2 (Voluntary Sterilization Services), dated January 11, 1972.

Cooper stated that he had never approved OEO Instruction 6130-2. (This instruction outlined procedures to be followed by grantees in the conduct of voluntary sterilizations by OEO funded family planning agencies and specified that a special condition be included in all grants which would protect the legal rights of the individuals who volunteered to undergo sterilization operations).

Cooper recalled that between November and December 1971 he had voiced various oral objections to the promulgation of the instructions to Wesley L. Hjernevik, Deputy Director, OEO, and to George Contis, Director of Family Planning, OEO. Cooper's objections were based on his conviction that approval of voluntary sterilization by OEO would focus all family planning grants on sterilization methods as opposed to family planning methods which do not result in permanent sterility. He also felt that the acceptance of voluntary sterilization would have significant impact on the 15 million dollar OEO family planning budget, an impact which had not been adequately considered by the OEO Family Planning Division. Cooper felt that an emphasis on sterilization would serve to convert family planning grants from research and demonstration grants to service grants. Cooper did not feel such a radical change in focus could be approved without additional consideration of the impact involved. Cooper added, that as far as he was concerned Instruction 6130-2 could not be considered to be an official document because he as Director of Health Affairs had not signed off on it.

Cooper recalled that in January 1972 he had met at the Office of Management and Budget (OMB) with Paul O'Neill, Director, Human Resources Programs Division, OMB, and James Cavanaugh of the Domestic Council of the White House. At this time Cooper explained his objections to the OEO instructions on voluntary sterilization. Cooper stated that both O'Neill and Cavanaugh concurred with his objections. Cooper did not care to speculate on any additional White House objections, but added "my purposes served their needs."

Though Cooper stated that he had never reduced his various objections to the instructions to writing, he did recall that he had replied to several Congressional inquiries on OEO policy regarding voluntary sterilization and added that this correspondence would reflect his position on the matter.

Cooper did not know who authorized the printing of the 25,000 copies of OEO Instruction 6130-2. He felt that, in any event, such authorization was premature in light of his and OMB's oral objections to the instructions. Cooper said that in February 1972 he had ordered Dr. Warren Hern, M.D., former Chief of Program Development and Evaluation Branch, Family Planning Division, OEO, to refrain from discussing the instructions outside of OEO and requested that Hern return the 200 advance copies of the printed Instructions which he had been furnished. Cooper took this action because he felt that the Instructions were not "official."

Cooper did not believe that any of the Instructions had been disseminated by OEO to any grantees.

NOTE: Exhibits not printed.

Mr. ROGERS. Thank you very much for an excellent statement. We are grateful to you for being here and giving it to us.

Mr. KYROS.

Mr. KYROS. Thank you, Mr. Chairman.

I certainly want to welcome the Senator here.

Senator, I do have a question for you. One of the basic parts of this legislation as it passed the Senate, as I understand, is to establish a commission which will undertake a comprehensive investigation and study to identify "basic ethical principles and develop guidelines." What information do you have that makes you believe that such principles and guidelines can be established so that laymen throughout the United States like ourselves understand it?

Senator KENNEDY. Well, I think the principles are established. Hopefully, a commission made up of theologians, medical personnel, and others, will be able to help identify them. We have seen some of the results that occur when we, either in the Congress or the executive, do not really deal with them. I am convinced that these questions should not be left just to legislative action. These issues are enormously complicated, for professional as well as lay people. Consider the issue of informed consent in a case of terminal cancer. Do we want to insist on getting the patient's informed consent if he is in a coma, and if research on his particular strain of the disease would directly benefit future victims?

Are you going to refuse to permit any research on an infant when it appears very clearly that that infant cannot survive and the research might benefit other children?

What we clearly need are the best minds from the biomedical community as well as input from others from whom society accepts moral guidance and who are going to be sufficiently sensitive to ethical considerations on this.

I think it is an extremely difficult challenge, but I think it is one that should be undertaken.

Mr. KYROS. Thank you.

Thank you, Mr. Chairman.

Mr. ROGERS. Dr. Carter.

Mr. CARTER. Thank you, Mr. Chairman. Certainly, Mr. Chairman, I support the formation of such a commission to establish guidelines on experimentation. I think it is very necessary and also I feel that the commission's work should probably be expanded to assist physicians who are handling or are caring for terminal patients, obviously terminal, for whom there is no hope, patients who are fed by tubes and are really alive, although actually they are dead. I think that this commission probably should be called upon to assist such physicians, give them direction, as to what to do at that time.

I am quite interested in this Relf tragedy, Senator. Could you tell me a little about that?

Senator KENNEDY. Well, Doctor, the factual situation was that the Relf children and the family were enrolled in an OEO-sponsored program on family counseling in Alabama. When use of the birth control drug Depo Provera was discontinued two Relf girls were sterilized. The mother was asked permission for the sterilization and she signed her name as an X. Then the two children were admitted to the hospital.

You know, there is rather a tragic personal story here, with their

being frightened at night, wanting to leave and being unable to do so. They were sterilized early in the morning and it was only after the operation that they became aware of the overwhelming implications of the operation. As a matter of fact, one of the little girls when asked whether she wanted to have children in the future said, "Yes," and when asked further, do you think you will be able to have them, answered, "Yes."

These people were not well educated. There is some indications that one of the girls is actually retarded. One was 12, and the other 14. This is, I think, a crystal illustration of the problems that surround the issue of adequate informed consent or lack of it.

HEW has now issued some very stringent guidelines affecting the sterilization.

Mr. CARTER. Were either or both of these children mentally retarded? Senator KENNEDY. There is evidence that one of them is retarded.

Mr. CARTER. But one was not.

Senator KENNEDY. One was not, but had a limited education.

Mr. CARTER. Well, in a case like that, of course, I think there could be no reason at all for such action to be taken if the child was normal, subjected to sterilization.

Senator KENNEDY. If I could, I would like to add to the testimony. I met with the children in private in my office. The parents and their attorneys were the one who actually testified before the committee, but I would like to add their total testimony as an addendum.

Mr. ROGERS. Certainly. Without objection, it will be made part of the record.

[Testimony resumes on p. 109.]

[The testimony referred to follows:]

STATEMENT OF JOSEPH LEVIN, ESQ., GENERAL COUNSEL, SOUTHERN POVERTY LAW CENTER, MONTGOMERY, ALA., ACCOMPANIED BY MR. AND MRS. RELF, MONTGOMERY, ALA., AND WARREN M. HERN, M.D., M.P.H., DENVER, COLO.

Mr. LEVIN. Thank you, Senator.

I am here in response to the call of this subcommittee in my capacity as general counsel, Southern Poverty Law Center, Montgomery, Ala.

I represent Minnie and Mary Alice Relf, whose testimony you have already taken this morning.

On June 14, 1973, Mary Alice Relf, age 12, and Minnie Relf, age 14, were surgically sterilized in a Montgomery, Ala., hospital.

These tubal sterilizations took place under the direction of the Family Planning Clinic of the Montgomery Community Action Committee, an OEO funded project.

In addition to Minnie and Mary Alice, the Relfs have one other daughter, Katie, who is 16 years of age. When Community Action moved the Relfs to a public housing project in 1971, the Family Planning Service began the unsolicited administration of birth control injections to Katie. No parental permission was sought or given. As a matter of fact, the agency sought out the Relf children as good subjects for their family planning program.

At a later date, the clinic began the unsolicited administration of the same shots to the two younger girls.

Senator KENNEDY. May I interrupt for a moment to ask whether the family sought out the services of the Family Planning Program or did the Family Planning Program seek out the family?

Mr. LEVIN. I think it is clear from the conversations that I have had with the Relfs that it was the Center seeking out the Relfs.

They were already under this Community Action program, and Community Action, having moved them into the project, was aware of their existence and sought them out.

I know the children themselves would have had no concept of family planning, and I certainly do not believe that the Relfs would have had—the parties would have had any concept of what family planning was all about.

Senator KENNEDY. If I may interrupt, the report says, "At a later date, the clinic began the unsolicited administration of the same shots to the two younger girls."

Do you know what the "shots" were?

Mr. LEVIN. We do not know.

Senator KENNEDY. Can you speculate as to whether the drug was Depo-provera?

Mr. LEVIN. That is what the Relfs think it was. I do not think there is sworn testimony to that effect, but I understand that is what it was.

In March 1973, Katie Relf was taken to the family planning clinic for insertion of an I.U.D. Once again, her parents were not asked if they had any objection.

After arriving at the clinic, Katie did object to the procedure, but was told by the nurse that she needed it.

On June 13, 1973, a family planning nurse picked up Mrs. Relf and the younger girls and transported them to a doctor's office. Mrs. Relf was told the girls were being taken for some shots. She thought the shots were the same as those all three children had been receiving for some time.

Neither Mrs. Relf nor the girls spoke with anyone at the office.

From the doctor's office, the children and their mother were transported to the hospital where the girls were assigned a room.

It was at this time that Mrs. Relf, who neither reads nor writes, put her mark on what we later learned was an authorization for surgical sterilization.

Mrs. Relf was then escorted home.

Minnie and Mary Alice were left by themselves in a ward in the hospital. So far, neither child had even seen the physician who was to perform the operation nor had either child been told what was going to happen to them.

Later in the afternoon of the 13th, or early on the 14th, Minnie got out of bed, borrowed some change from another patient, and telephoned a neighbor's house to speak with her mother. The Relfs do not have a telephone.

Minnie asked her mother to bring her sister and her home, but her mother had to tell her she had no transportation to get the girls home.

It was the next morning that both children were placed under a general anesthetic and surgically sterilized. At no point prior to the surgery did any physician discuss with the girls or their parents the nature or consequences of the surgery to which Minnie and Mary Alice were about to be subjected.

The girls were released from the hospital after 3 days.

As a footnote, I should point out that on the afternoon of the day Minnie and Mary Alice were taken to the hospital, the same family planning nurse returned to the Relf home and attempted to take Katie to the hospital to undergo sterilization. Katie locked herself in her room and refused to go. At that time no one else was home but Katie.

I was told by persons who spoke with the director of the clinic and the nurse on the day of the surgery, that the reason for the operations was the existence of new policies which prevented nurses from going out into the community to administer shots and birth control devices; that boys were "hanging around" the girls, and that the only way to insure against pregnancy was sterilization.

Senator KENNEDY. Did you ever find out what these new policies were?

Mr. LEVIN. Senator, I think the new policies revolved around HEW. This unit was about to come under HEW funding and I think HEW, under possibly an FDA regulation of some sort, I think possibly as the result of some of the work of this committee, had refused to permit the use of these particular shots, birth control shots. And I believe that is the policy to which they referred.

Two items are of paramount importance in considering the events I have just related. First, no doctor ever spoke with any member of the Relf family before the tubal sterilizations occurred. Second, the Relfs never, at any time, sought the services of the family planning clinic—not for the injections, not for the I.U.D., and certainly not for the sterilizations.

I decline to engage in debate over the relative merits of sterilizing children. I see no justification for permanently depriving any child of her right to conceive, regardless of the child's present mental or physical condition; nor do I believe that agencies, by committee or other means, have the right to sterilize any person, regardless of age, unless that person, intelligently and with full and complete knowledge of the consequences, desires to be permanently stripped of his ability to create life.

Passing the age of 21 is not necessarily a barometer for gaging the ability of an individual to comprehend the effects of sterilization.

I think I heard some testimony this morning revolving around the age of 18 as being an adequate age for consent.

My statement applies to the age of 18 also. That is no gage to determine that a person understands what is happening to them.

In order to begin to understand why it happened to these children, I think one must examine the social services system under which they and their family exist.

They receive \$156 per month from the Alabama Department of Pensions and Security; they receive food stamps; they receive subsidized medical assistance; and, I suppose, there are other forms of aid unknown to me at this time. In other words, each member of this family lives his or her existence under a microscope.

They are visited on an almost weekly basis by some social service person who either functions under the direction of the State or Federal Government, or whose salary is paid, directly or indirectly, through some combination of local, State and Federal funding.

They are surrounded by a welfare state upon which they depend for their very existence, and they are easily "coerced" into doing what the welfare people recommend to them.

It is a very sophisticated, probably unintentional, form of coercion, but it is extremely effective.

One must ask whether or not the hospital, the doctor, the nurses, and the anesthesiologist would have as quickly participated in the sterilization of a "paying customer."

Would this medical complex have permitted a middle-class white or black parent to so easily sign away his child's ability to procreate?

Would the middle-class parent, absent the kinds of dependency pressures exerted on a welfare family, have even considered surgical sterilization for his children?

I believe this subcommittee will find that the sons and daughters of middle America are not sterilized, regardless of physical or mental condition.

It is the "free clinic" patient who is fair game for this most final of birth control methods.

I recently spoke with an employee of the agency which wrote the proposal which will eventually provide HEW funding for the Montgomery Family Planning Clinic.

In response to a remark of mine condemning sterilization of minors, he asked if I would also be opposed to sex education in the schools since minors are affected there.

It is this apparent complete inability to draw lines, to make distinctions, to instinctively recognize the difference between a birth control pill and surgery, which forever halts the ability to participate in conception, which frightens me.

Sterilization is not "birth control" when applied to minors and incompetents—it is mayhem, and it should be stopped now.

Severe guidelines for sterilization should be established and distributed to all agencies, hospitals, or individuals who, in any way, participate in Federal- or State-funded sterilization programs.

I have every reason to believe that what happened to the Relf's is not uncommon; that for sometime now, OEO-funded and HEW-funded family planning projects have been securing sterilization operations for the minor children of poverty-stricken families, and I know that the decisions about who shall or shall not receive this so-called service must have been based upon only the most general criteria.

Senator KENNEDY. That is a very serious charge. On what evidence do you base it?

Mr. LEVIN. Senator, the legislation which set up the family, the whole community program, recommends in it—and I do not have the section right now—that family planning clinics be set up as one of the few itemized services that are asked to be set up under community action programs.

I know that there were some 5—somewhere in the neighborhood of 500.

Dr. Hern may be able to answer it better than I. Five hundred planning—500 family planning units that participated in family planning somewhere around 1971. I have read interoffice memos which indicate that about 80 percent of those units at that time, 2 years ago, desired to perform sterilization operations.

Well, we are talking about a lot of units.

I also have seen a report, a press report, quoting—and I have forgotten the man's name; he is in charge of operations, I think, for OEO—quoting this gentleman as stating that there are 40 to 60 units in the country performing sterilizations.

I do not think that is accurate, but if it is, that is remarkable that it has brought that many. Mr. Teague makes that statement.

But I do not think that is accurate. I think there are many more than that. This is my belief.

Senator KENNEDY. Your point is that whether the figure is 40 or 80—and you believe it to be more—there are no guidelines at the present time for the performance of the sterilization procedure.

Mr. LEVIN. And I think for each one of those, there have to be as many different procedures determining who gets sterilized as there are clinics offering the service, since there are no guidelines established by OEO, and apparently not by HEW.

I do not know but I am told that the unit in Montgomery is to receive a specific amount of money budgeted, sterilization money, and they had no procedures that I am aware of in order to guide the physicians and the members of the units, or anyone else as to how the sterilization is to be conducted.

In summary, I would like to say I think a look into the whole field of beneficent Government medical services and the treatment accorded poor people in the administration of such services is long overdue.

On behalf of the Relf family and the thousands of other families who require governmental assistance in order to fulfill the most basic needs of life, I implore you to give this matter your closest attention.

Senator KENNEDY. Thank you very much, Mr. Levin.

I have a few brief questions.

Is it your testimony that neither the mother of the girls, nor the girls themselves, understood the procedures which were to be performed?

Mr. LEVIN. Yes.

Senator KENNEDY. Is it your understanding that they were receiving Depo-provera prior to the time that they were sterilized?

Mr. LEVIN. I am not familiar with the drug, but I am told that is the only birth control injection available. So I assume that that is the only injection they received prior to the sterilization.

Senator KENNEDY. Did you know that Depo-provera was an experimental drug?

Mr. LEVIN. I have since been informed of that.

Senator KENNEDY. Thank you. Mr. and Mrs. Relf, we want to welcome you to the committee.

We had a nice visit in my office earlier with your daughters.

Mr. RELF. Yes.

Senator KENNEDY. And we want to tell you how much we appreciate your being here this morning.

Mr. RELF. I appreciate it.

Senator KENNEDY. As you probably know, we are trying to consider legislation so that what happened to your children will not happen to other children.

We know it is not easy to share with us the concern and sadness which you feel about this tragedy, but I want you to know how much we appreciate the fact that you are willing to come here and talk with us about it.

Perhaps you could tell us, in your own words, a little bit about what happened to your daughters.

Take all the time that you would like.

Mr. RELF. Well, I did not know what happened. See, I was off that day, I come in that evening. My wife was talking, she said the children are good, but they are in the hospital.

Senator KENNEDY. Your two daughters were in the hospital?

Mr. RELF. Yes.

Senator KENNEDY. That is Minnie and Mary Alice, is that right?

Mr. RELF. Yes.

Senator KENNEDY. Were you surprised at that?

Mr. RELF. I told her—I went down there.

Senator KENNEDY. Why did you think they were in the hospital?

Mr. RELF. I did not know.

Senator KENNEDY. Did you ask your wife?

Mr. RELF. The only thing I know about it is that they were taking shots.

Senator KENNEDY. As I understand your testimony you thought your daughters went to the hospital to be given some shots?

Mr. RELF. Yes; that is what I am talking about. To get shots. That is all I know about it. That is what she said.

Senator KENNEDY. They had not been receiving shots at other times?

Mr. RELF. They had been taking shots at the hospital.

Senator KENNEDY. Then what happened?

Mr. RELF. Then I came and went down there that night, see, and soon I walked in, they said the visiting hours was over,.

Senator KENNEDY. They said what?

Mr. RELF. The visiting hours was over. The children had gone to bed.

I did not know what happened to them, and I turned around and went back home.

Senator KENNEDY. What time was that?

Mr. RELF. Just about 9 o'clock, or 10 o'clock.

Senator KENNEDY. You wanted to see your children?

Mr. RELF. I saw them, I turned around, see, and they said they had to go to bed. I turned around and went on back home.

I went on back home, and the next morning my wife went. She went. I did not go. So when she come back, she said that they had an operation.

And this got all over me.

Senator KENNEDY. You what?

Mr. RELF. This got all over me then. I did not want it done.

Senator KENNEDY. You did not want it done?

Mr. RELF. No.

Senator KENNEDY. Were you upset?

Mr. RELF. Yes. I am still upset about it.

Senator KENNEDY. Would you tell us, Mrs. Relf, if the first time that you knew they were going to perform an operation was after it was done?

Mrs. RELF. Yes.

Senator KENNEDY. Mrs. Relf, why do you not tell us a little bit about what happened in your own words?

Mrs. RELF. Well, I went up there that morning, and they had operated on them.

Senator KENNEDY. Just bring the microphone up a little closer, and tell us a little bit about when you first found out that they were going to the hospital.

Mrs. RELF. The nurse came out and she told me that she was going to give them shots.

Senator KENNEDY. Did the nurse come out to your home?

Mrs. RELF. Yes, to my home.

Senator KENNEDY. What did she say?

Mrs. RELF. She said they were going to give them some shots.

Senator KENNEDY. Then what happened? Did your daughters go to the hospital?

Mrs. RELF. Then she took them to the doctor's office.

Senator KENNEDY. And then, at some time later, did your daughters go to the hospital?

Mrs. RELF. They went in the evening.

Senator KENNEDY. Did you know they were going into the hospital?

Mrs. RELF. I did not know they was going. They said to come back and pick them up at 1:30. The nurse said to pick them up, they were going to pick them up at 1:30.

Senator KENNEDY. When was that?

Mrs. RELF. That was in the afternoon.

Senator KENNEDY. So some time that afternoon they went to the hospital?

Mrs. RELF. Yes.

Senator KENNEDY. And was that the first time that you knew that they were going to the hospital? When did you find out that they had gone to the hospital?

Mrs. RELF. That afternoon.

Senator KENNEDY. Did you sign a form?

Mrs. RELF. I put an X on a piece of paper.

Senator KENNEDY. When did you put an X on a piece of paper?

Mrs. RELF. When I went down to the hospital.

Senator KENNEDY. Do you remember what the nurse asked you or why you signed that piece of paper?

Mrs. RELF. She told me. I put an X on a piece of paper, and she told me that they were going to give them some shots. That is what she told me.

Senator KENNEDY. So you put the X on the piece of paper because you thought they were going to get some shots, is that right?

Mrs. RELF. Yes.

Senator KENNEDY. And then you went home that evening?

Mrs. RELF. Yes, I went home that evening.

Senator KENNEDY. And then what happened?

Mrs. RELF. After I went home, I do not know.

Senator KENNEDY. They operated on them?

Mrs. RELF. They operated on them, and called me, and told me that they were at the hospital, so I went.

Senator KENNEDY. What did your daughters tell you when you saw them?

Mrs. RELF. They told me they had been operated on.

Senator KENNEDY. Was that the first you knew about it?

Mrs. RELF. That was the first I knew about it.

Senator KENNEDY. What was your feeling when you heard that they had operated on your children?

Mrs. RELF. I felt very bad about it. I got mad.

Senator KENNEDY. You felt what?

Mrs. RELF. I felt angry about it.

Senator KENNEDY. Why were you angry?

Mrs. RELF. Because I did not like it.

Senator KENNEDY. Would you have permitted it if you had known about it?

Mrs. RELF. No, I did not know it.

Senator KENNEDY. You would not have let them do it?

Mrs. RELF. I would not have let them do that. They said that they was going to give them shots.

Senator KENNEDY. Do you still use that clinic now, Mrs. Relf?

Mrs. RELF. No.

Senator KENNEDY. Do you think you will ever go back to it?

Mrs. RELF. I do not know if I will ever be going back there.

Senator KENNEDY. Very well.

As I mentioned earlier, what we are trying to do is to make sure that this never happens again, Mrs. Relf.

We met your three wonderful daughters this morning. They came to talk with us, and we showed them around my office. We showed them some of the pictures of my children. They are very lovely people.

We are going to do our very best to make sure that this does not happen to anybody else. We have just seen too much of this kind of thing in this country. There is no reason for it, and I for one am not satisfied with the explanation. "Well, accidents will happen, and therefore we should not alter what is happening at the present time." We have seen too many mothers and fathers that have been saddened by these kinds of occurrences.

As I said, we are going to do our very best to make sure that it does not happen again, and I believe that we can succeed in this effort.

We have a very deep sense of gratitude to you for coming here and sharing your personal experience with us. Very good of you.

Do you have anything else that you would like to say, Mr. Relf?

Mr. RELF. I believe she said everything.

Senator KENNEDY. It took a lot of courage for you to come up here and tell us about your experience, and we want to thank you.

We want now to hear from Dr. Hern.

Senator KENNEDY. If I could, I would like to add an interesting point. The initial target of our legislation had just been on the research programs. But after this experience dealing with the sterilization we added the service programs, but in a limited fashion. The phrase that we use is "whenever feasible and where appropriate." We want the Secretary to look very closely at programs like this, but we obviously need to exclude the great majority of other HEW service programs from these provisions.

Mr. CARTER. Do you think this particular case neither parent actually understood the operation that was to be undergone by the two children? Is that correct?

Senator KENNEDY. That was my impression.

Mr. CARTER. I want to say further that I agree with the Commission idea. However, in the treatment particularly of cancerous conditions today, almost every drug which is used, different chemicals and chemotherapy, may either kill or cure. In most cases or in many they have a very beneficial effect in that they have a great affinity for malignant cells, but in many cases also they have a disastrous effect upon other parts of the human body. Much of this is being—much work like this is being carried on throughout the country and I would hope that a commission that would be established would not interfere too much in these particularly specialized fields. And I happen to know from the feel—the effect of this because of reasons which I cannot state at the present time, but a Commission could be of great assistance but yet it should not go so far as to define the medicines always that a doctor should give to his patients. Any medicine can have a very serious effect and in the treatment of cancer particularly, the medicines are highly toxic but fortunately in most cases they are more toxic to the malignant cells. So I hope that the Commission would not hamstring our researchers in this area.

Thank you, Mr. Chairman.

Senator KENNEDY. If I could just respond, I concur completely with the doctor and Congressman about the Commission. What would actually be established by the Commission is a method to assure that the patients themselves had full knowledge and understanding of the drugs they were going to take and that there exists adequate institutional peer review. Any of those working in this research area would obviously be sensitive to the legitimate concerns that Dr. Carter has outlined here. I would certainly encourage the best kind of medical practice and the best use of the drugs would be made applicable.

Mr. ROGERS. Yes. I think it is a point well raised and we are fortunate, as you know, having two doctors on this committee. So, as Dr. Carter says, where there is a dangerous drug which can be lethal, particularly in the cancer field, with which they are experimenting, we have to be very careful in handling it. I think as you have suggested, Senator, if we will make this clear in the intent and in the record that this must be handled very carefully, I think this will be helpful in giving some guidance to the Commission.

Mr. CARTER. Mr. Chairman, I think the Commission's work would be too greatly expanded because this is going on all over our country every day and the different clinics from Sloan, Kettering to Cleveland, M. D. Anderson, and by and large, I think these people are doing a tremendous job and I feel that the people in this field should not be too closely bound because it would stultify work and keep them from going forward.

Mr. ROGERS. Well, I think the intent is to make sure that the patient has full knowledge and is fully aware of the consequences. I think that mainly is what the thrust of this is.

Senator KENNEDY. That is right.

Mr. CARTER. I certainly would agree with that. I think the Senator has made a good statement.

Mr. ROGERS. Thank you.

Mr. Preyer.

Mr. PREYER. Thank you, Mr. Chairman.

Senator Kennedy, I congratulate you not only for this bill but all you have done in the health field. You point out very properly that this is an extremely difficult and delicate area in which you have to reconcile the needs of scientific progress with individual liberties. I think that because this is difficult is no reason why we should not address ourselves to the question. I commend you for charging right ahead.

This is not the time to go into a lot of details but I did have two questions I would like to ask.

First, I notice that your bill establishes the national Commission within HEW. Do you see any merit in establishing that Commission as an independent agency in the executive branch so that you would avoid any possible conflict of interest which might arise from the regulatory function being under the same agency that approves grants?

Senator KENNEDY. I think that is a possibility, Congressman, and I think we could give some consideration to it. As one who has been interested in separating those particular functions in the past in regard to other agencies, I am sure of many of the compelling reasons for doing so, although I felt that the development of the Commission was best suited to HEW. But I think this is a worthwhile point to consider and I think we certainly ought to examine it.

Mr. PREYER. I introduced a bill (H.R. 10573) yesterday on this subject which sets up an independent agency. I hope the bill will make a contribution in this area.

Senator KENNEDY. I would like to work with you on that.

Mr. PREYER. The other question I would like to ask, because I think it is very important at this time, deals with the subject of psychosurgery. Such surgery is irreversible.

Senator KENNEDY. That is right.

Mr. PREYER. And also, apparently, there are real questions about the value of it. I wonder if from your hearings on this subject you felt that the evidence on psychosurgery showed it to be of such dubious worth in many cases that a moratorium on it would be warranted until such time as the national commission could set down guidelines in this area? Such a moratorium, of course, would not apply to cases where psychosurgery has proven its value.

Senator KENNEDY. Well, we heard from Bert Brown, who is the head of the National Institution of Mental Health, that they had very serious reservations about awarding grants in the field of psychosurgery. As a matter of fact, NIMH funds only one research program, and that is in my State. We have also heard from Dr. Aandy, who performs a great deal of psychosurgery in Mississippi. He also has published a number of evaluative articles. He estimates that between 800 and 1,000 such procedures a year are carried out in this country. Dr. Aandy has performed psychosurgery on children as young as 8 to 10 years of age. In some instances he has performed three or four operations on children under 15.

He defended his position. He was not interested in hiding it. He feels strongly about it. According to his own analysis, he has a very mixed success and failure record. This was a matter of considerable concern to a number of the members of the committee, Senator Beall in particular. He offered an amendment on the floor to carry through

your intention to bar any psychosurgery until the Commission had actually drawn up some criteria.

I was willing to accept that amendment at that time. He modified it to some extent. It did not quite come out as a complete ban. But I think considering Dr. Brown's very legitimate concern about it, that this would not be an unreasonable position to take, to ban it until the Commission had a chance to consider it.

Since we have only one program involving psychosurgery now being funded by the Federal program, its impact would be very limited because we are affecting physicians in private practice. It is questionable whether we would have the authority to do so. So as it stands, I would not be opposed to such a provision.

Mr. PREYER. Thank you very much, Senator, and again let me thank you for this major contribution.

Mr. ROGERS. Senator, let me just ask you one question here. Congressman Carter has introduced a bill to establish a Commission on Medical Technology and Dignity of Dying (H.R. 2655) which is a subject I think we have not properly thought through or addressed.

Now, in his legislation, he would propose setting up a Commission. I wondered if you thought in this legislation it might be well for us to consider in this legislation where we are setting up this Commission on ethics. It would also prescribe for them the duty as set forth here, or similar duties at set forth here, or similar duties that the Commission shall study under what circumstances modern medical technology is being used to deny individuals the right to die with dignity. In addition, it would determine under what circumstances the availability of governmentally funded benefits contribute to denying individuals the right to die with dignity.

What would be your reaction to perhaps including this as a charge to the Commission to look into this with possible recommendations?

Senator KENNEDY. I think it would strengthen the legislation. It is a matter of very considerable concern to millions of people. And I think this is the kind of concern to which this Commission should rightfully address itself. I would like to work with the doctor, with this committee, on how it best could be included in the legislation.

Mr. ROGERS. Thank you.

Mr. Hastings.

Mr. HASTINGS. Thank you, Mr. Chairman.

On a light note, first—there have been an awful lot of heavy ones here so far—I would like, through you, to greet the other body which we respectfully refer to as the House of Lords, and I would like to join the gentleman from North Carolina in complimenting you on your extreme activity in the area of health with the possible exception of HMO's which I guess we will have the opportunity to discuss later, and perhaps health insurance.

Senator KENNEDY. I do not think we will be talking about that for some time.

Mr. HASTINGS. On the serious vein, Mr. Chairman, I think we also ought to acknowledge over and above the fact that we have two doctors of medicine, of very great and pertinent interest to this subject is a doctor of theology, Dr. Hudnut, who I think will add his expertise as we consider this most serious problem.

I know, Senator, that you probably share the viewpoint I do, but I want to make certain, that in fact we have a great overriding concern

that the public be totally protected. At the same time, I am sure we do not want to leave the impression that there has been a great deal of irresponsible action coming from HEW and NIH.

Senator KENNEDY. That is right.

Mr. HASTINGS. And I cite the figures that of 650,000 projects involving programs which had been approved for funding by NIH since 1947, less than 12 have been challenged from any source. And of the present system of standards established in 1966, 28 have been approved and only one has been challenged. So I just want to make that part of the record, that, in fact, surely we are very interested in pursuing a course of action that is rapid. At the same time, I think we should make eminently clear what the track record has been overall.

Senator KENNEDY. I think that is a worthwhile addition to the record. As a matter of fact, in the legislation we incorporate the present guidelines in NIH, until the commission itself has a chance to develop its own.

Mr. HASTINGS. Those would be the interim provisions?

Senator KENNEDY. Yes. So we embrace those. Many experts have suggested many strengthening provisions, and we have incorporated those we felt wise and practicable.

Mr. HASTINGS. I know my position certainly is that of full protection for the public but at the same time, not to stultify the research field.

Thank you very much.

Mr. ROGERS. Mr. Symington. I might say that the Senator's time is—

Senator KENNEDY. We vote on the Trident at 11. Whether you are for it or against it will be indicated by whether I get out of here or not.

Mr. SYMINGTON. I think a member of my family is interested in that vote and if he thinks I held you here, he will cut off my allowance.

One quick question, Senator Kennedy. In our State recently there has come to light what might possibly be malpractices involving experimentation on mental patients and I have asked for the documents that I have seen to be turned over to the GAO and FDA to check them out. But the question arises in our minds how could a mental patient give consent to experimentation in a legal sense if his only guardian is the State institution itself which, of course, enjoys certain funding from sometimes private sources trying to test their drugs and sometimes through Government. Do we not need some kind of a committee or commission that reviews any such experimentation?

Senator KENNEDY. The Congressman, as usual, has put his finger on the dilemma. The problem of informed consent, as I indicated in earlier testimony, is one that could occupy the full time of a Member of Congress, or even a congressional committee. It is just for that reason that the commission would be established.

Mr. SYMINGTON. Thank you, Senator. Thank you for your statement.

Mr. ROGERS. Mr. Hudnut.

Mr. HUDNUT. Thank you, Mr. Chairman and Senator Kennedy. We appreciate your taking the time to come before this committee. We might have opposite views on the Trident, so I have a half hour's worth of questions.

I would like to ask you two questions: One specific, one general. The specific question is this. In your testimony, and perhaps in the

other testimony that we have received and the background materials on this subject, it is not clear that there is a need for this kind of legislation. It is in my opinion, not clearly indicated that the establishment of this new commission would provide new authority for the Secretary of HEW that he does not now have. Could you speak to that? In other words, is this giving him something that he does not now have?

Senator KENNEDY. Well, I am sure the Secretary will speak to this subject in detail. The Secretary could set up a commission. Whether it could be of this description and have these responsibilities is doubtful. There is no doubt that this legislation is needed if the job is to get done. This is not just my conclusion—it is the conclusion of who I consider to be the top research people in the country. You are going to hear from them in the course of your deliberations and I think it is their very strong feeling that their efforts in research can be strengthened and be even more effective with the help of this commission.

If the question is—could the Secretary set up a commission, give them the challenge, come on up here and request the \$3 million which we do on this—the answer is he probably would have the power. He can request anything. But I do say that the job is not—at the present time, being done. You have, as we have seen over the course of these hearings, a variety of different policies carried forth by governmental agencies. Obviously, the thrust of this legislation is only the one area of HEW but my very clear hope is that it would soon apply as a general governmental policy. Even in HEW there are different policies in different agencies.

In NIH you have different criteria than in VA. The guidelines which have been issued by Mr. Weinberger are different than what you have over in the VA. So I think what we need is uniformity of the highest standards—that is what I think the commission would offer the best opportunity to do.

Mr. HUDNUT. That leads to the general question I have. Reference was made to my theological background and it is very hard to get any kind of consensus on these exceedingly complex questions. The only thing two theologians can agree on is what a church should give to charity. What you are doing and what this bill is doing is asking us in a sense to legislate morality or freeze into an institutionalized position a particular ethical or religious point of view on, say, the subject of sterilization. Part of the essence and genius of American culture is its pluralism and heterogeneity, which it seems to me require that we go very slowly in saying that this is the point of view on genetic manipulation, or this is the point of view on sterilization. Once these 11 men can institutionalize their position through a regulation it would seem as though they would be mandating morality on a particular issue for all Americans.

Senator KENNEDY. Just let me, if I could—it is for that very reason we want the commission established. It is for the very reason that the good Congressman states. What we do not want to do is have the Congress, for political reasons, and I use it just in the broadest sense, making decisions about these particular issues. The commission would set up the best possible guidelines for informed consent. Second, it would require high quality peer review at the local level. The Commission doesn't do the review, it is all done in the local community.

We don't want to have to debate on political terms whether we should do experiments on live fetuses. That is the real political question—whether we in the Congress are going to debate that. Are you going to permit that or are you going to prohibit it? The answer should not be a political one. We can't tackle the issue of consent for such research. The Commission will make sure that the consent issue is fully aired. This way the country is going to be able to at least get the best kind of information available on a complex subject.

Remember whatever decision is going to be made will be subject to careful review at the local level. We are trying to do just what the good Congressman has mentioned, to take it out of the political debates and discussions about what we are going to permit and what we are going to prohibit.

So it is in an attempt to achieve what I think is the very legitimate concern of the Congressman, that this commission is devised, and I hope as a result of hearings and talking to some of the witnesses that you will hear that this point can be fully aired.

Mr. ROGERS. Dr. Roy, do you have a quick question?

Mr. ROY. I have no questions. I would like to thank the Senator for coming here and I appreciate the political courage that it takes to become involved in this area and I think that has been typical of your career as a public servant. I would say I share the feelings that these questions are too important to be left to scientists alone, even though I think the NIH and scientists generally have had excellent deportment in this area. But I thank you for bringing this to our attention and I welcome the opportunity to consider your bill, Dr. Carter's bill and others.

Thank you.

Mr. ROGERS. We are very grateful for your being here. It is most helpful.

Senator KENNEDY. Thank you very much, Mr. Chairman.

Mr. ROGERS. And we hope you will make your hearing.

Without objection, the chair wishes to place in the record, as though read, statements submitted by Congressmen Edward R. Roybal of California, John N. Erlenborn of Illinois, John M. Zwach of Minnesota, and Angelo D. Roncallo of New York.

STATEMENT OF HON. EDWARD R. ROYBAL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

H.R. 1111

Mr. ROYBAL. Today, the Nation is confronted with a problem of medical ethics of complicated magnitude. This problem has evolved with startling suddenness as a byproduct of miraculous advances in medical technology. This rapidly accelerating technology has not only increased the length of man's life, but has radically altered its quality. But most important, these advances demand a reassessment of the very meaning of human life. While improving man's overall medical health, medical technology has introduced a whole range of unique social, legal, and ethical issues. These issues affect human life from its very conception to its end and deserve immediate legislative attention.

Beginning with the conception of human life, we are confronted with a highly ambiguous medical technology which on the one hand can enhance human fertility while on the other hand can inhibit or totally eliminate life. This is made possible through the use of direct surgery, drugs, or devices whose number and efficacy increase at an ever quickening rate. The very existence of this technology, let alone its practice, raises many social, legal, and ethical questions. A good example of this dilemma is the well-publicized social and legal controversy surrounding the sterilization of poor people in a Southern State during June.

Other problems which confront us deal with the failure of entire organs and the capability of replacing those organs either with an artificial analog or a counterpart organ from another human body. These transplants and analogs are now a fact of every day life as a result of advances in biomedical technology only a decade or more old. Scores of heart transplants have already been conducted. Thousands of people now receive kidneys and even have their vision restored thanks to the medical technology which makes it possible to transplant an organ or tissue from one body to another. Even the human brain is not immune from modern medical technology; its very function and intellectual performance can be altered through the use of psychotropic drugs, psychological and psychiatric approaches, electrical currents, and indeed the scalpel.

These developments have now subjected the whole human body to medical experimentation. Clearly man has become man's perfect guinea pig. While many of these advances have proven beneficial to man, others have raised a host of serious problems. When is it, for instance, appropriate to radically alter the mental function of human beings through surgery, psychotropic drugs, or other means? How should the use of behavior modification drugs be regulated and who should control the administrator of those drugs? Is human experimentation acceptable if it affects the comfort, health, or lifespan of the subject?

Finally, advances in medical technology have not even spared the final end of human life. For it has given man the tools to prolong life indefinitely through the use of drugs, life-giving chemicals, and surgical intervention, even long after the body and mind can perform usefully.

These are but some of the issues confronting us today. And even more complicated issues will confront us with increasing frequency as medical technology continues into new horizons. These issues basically involve ethics and social responsibility. And to cope with them, the entire spectrum of human talent, concern and imagination must come into play. The arts and humanities, the natural and social sciences, religion and philosophy, and the specialties of law, medicine, and above all, public service must be summoned because, ultimately, it is man's own fate which is involved.

In recognition of these extremely complex issues, H.R. 1111 would establish a National Commission on Health, Science and Society. That Commission would be specifically structured to analyze and evaluate present and future biomedical and psychological advances and their implications for individuals, society, and public policy. It is but a

starting point which will vitally affect not only the present generation, but many generations to come. But most important, it initiates a long-overdue attack on issues which man clearly cannot continue to ignore.

H.R. 1112

I would like to submit to the Subcommittee on Public Health and Education, the Artificial Organ, Transplantation, and Technological Development Act of 1973—H.R. 1112. This piece of legislation has the extremely important purpose of coordinating the national effort against kidney disease and, more generally, of reviewing the implications and possibilities of transplantation and the use of artificial organs as alternatives in the treatment of disease.

The importance of the goals of this bill will most certainly be manifested with the initiation of the program authorized during the last Congress by our passing H.R. 1 (Public Law 92-603) to provide financial support for people suffering from end-stage kidney disease. Our intent with H.R. 1 was to help to make treatment of disabling kidney disease financially possible for the people of the Nation. The coverage provided through medicare instantly swelled the population qualified to receive transplantation or dialysis treatment. My bill, H.R. 1112, will help, in several ways, to ease the management of kidney disease for this large group of people. It proposes the establishment of the National Advisory Committee on Kidney Disease programs which will assist in the preparation of regulations and policy concerning kidney disease and patients. The committee will review and make recommendations concerning kidney disease programs for all of the agencies and departments of the Federal Government.

This committee will also help in the selection of recipients of grants awarded as a result of this bill, for the establishment of regional and community kidney centers. Regional kidney centers, as a part of a medical school or hospital, will provide training for medical and support personnel, provide transplantation treatment, support research to develop new techniques and serve a watchdog function to assure that knowledge and treatment of kidney disease evolve in a balanced fashion.

Grants will also be awarded for the establishment of community dialysis units in conjunction with regional kidney centers. These regional and community dialysis centers will help to provide facilities and trained personnel for treatment of the thousands of people now eligible for chronic kidney disease treatment.

Moreover, H.R. 1112 provides for at least two significant means by which the future costs to the Federal Government for treatment of renal patients may be greatly reduced. The first is through the bill's emphasis and provisions for research and training in the area of prevention of disabling and costly kidney disease. Second, the community dialysis units to be established are to promote the use of home dialysis through the training of physicians, staff members and patients and through the availability of equipment. The cost differential between home dialysis and that in the hospital ranges from about \$10,000 to \$16,000 per patient per year. The financial integrity of the new Federal kidney program may depend upon features such as the increased use of home dialysis as fostered by H.R. 1112.

The Artificial Organ, Transplantation, and Technological Development Act of 1973 would help to establish need, eliminate duplication, and, in general, provide the best known means of preventing, diagnosing, and treating kidney disease and other diseases for which transplantation or use of artificial organs are a possible treatment. A national coordinated attack on kidney disease and increased understanding of the state of the art of transplantation and the use of artificial organs will bring treatment into the reach of all people and, perhaps more importantly, provide a concentrated but balanced effort in preventing kidney disease or in finding the most effective treatment or cure for this disabling affliction.

**STATEMENT BY HON. JOHN N. ERLBORN, A REPRESENTATIVE
IN CONGRESS FROM THE STATE OF ILLINOIS**

Mr. ERLBORN. I am grateful to your chairman for inviting my comment on these bills by the Honorable Angelo Roncallo of New York and cosponsored by myself and other Members of Congress.

We like our scientists to be inquisitive and to probe the frontiers of knowledge. We recognize that good scientists have a thirst for knowledge which is an admirable trait.

There are some places, however, where we don't want them to probe. Inquiry in these areas offends our moral sense, and we often criticize scientists for venturing there. Our criticism ought not be severe, however, unless we have clearly drawn the perimeters beyond which they are not to venture.

One of the places where scientists should not make inquiry is research on a live human fetus. We previously have expressed our views in this regard, the House of Representatives having approved an amendment to H.R. 7724, which we passed May 31, 1973.

That amendment, however, was necessarily limited to the National Institutes of Health. In order to make sure there is no misunderstanding, H.R. 8778 proposes to extend this mandate to the other Federal agencies—20 in all, I believe—which receive funds for life-science research.

H.R. 8778, would draw the line where it ought to be drawn. It would prohibit the use of the Federal funds to carry out or to further research on living human fetuses.

I believe we owe it to our scientists, we owe it to humankind and, most of all, we owe it to ourselves to pass this bill.

Again, let me express my thanks for the privilege of submitting this statement.

**STATEMENT OF HON. JOHN M. ZWACH, A REPRESENTATIVE IN
CONGRESS FROM THE STATE OF MINNESOTA**

Mr. ZWACH. Mr. Chairman, on June 18, 1973, I joined with Congressman Roncallo of New York, and others, in cosponsoring H.R. 8779, a bill to prohibit the use of appropriated funds to carry out or assist research on living human fetuses.

Back on May 10, 1973, Mr. Roncallo, myself, and others had introduced H.R. 7725, to amend title 18 of the United States Code to make it a crime to carry out any research activity on a human fetus or to intentionally take any action to kill or hasten the death of a human fetus in any federally supported facility or activity.

Twice, we have been successful in attaching amendments prohibiting research on a live fetus to legislation before the House.

On May 31, the House voted 354-9 to add the Roncallo amendment to H.R. 7724, the biomedical research bill. The Senate has passed the bill also, but has amended key sections. To date the House has not agreed to go to conference with the Senate to iron out the differences.

On June 22, the House voted 288-73 for another Roncallo amendment, as amended, to H.R. 8510, the National Science Foundation authorization. The biomedical research bill amendment applied only to HEW research, while the amendment to H.R. 8510 dealt only with National Science Foundation research. H.R. 8510 is now public law.

However, HEW and the National Science Foundation are not the only agencies that conduct research on human beings. Thus, the need for an all-exclusive blanket coverage to pertain to all agencies that receive Federal funds still remains.

Most of this research is presently being carried on in foreign countries namely London, England. However, the research is being concluded here at the George Washington University Medical School. Under the leadership of Dr. Geoffrey Chamberlain of Kings College Hospital in London, live fetuses are connected to an artificial placenta. The longest "experiment" under this project has lived 5 hours and 3 minutes.

Undoubtedly this whole experiment raises some ethical and legal questions. The case studies used in these experiments are live human fetuses, that is, they are outside the womb of its mother and are alive with a beating heart. One of the living human fetuses was taken from a 14-year-old girl. The question is whether this type of experiment is morally right or legally sound. I, for one, do not think so.

To guard against this ghoulish practice in America, I introduced the legislation we are holding hearings on today. I believe it should be a Federal crime to carry out any research activity on a human fetus or to take action to kill or hasten the death of a human fetus in any federally supported facility or activity.

H.R. 8779 used the best weapon we can use against an agency, department, or instrumentality of the United States—the power of the purse. We should cutoff funds to any research effort that uses a human fetus which is outside the womb of its mother and which has a beating heart. Money is the only word they hear.

I believe the overwhelming support by the House—354-9, and 288-73—on the two past Roncallo amendments indicate the position of this Congress, a position of prolife, and not one of cruel and inhuman punishment that these live human fetuses are subjected to.

We have already written into the books a "conscience clause" which allows hospitals receiving Federal funds to decide for themselves whether abortions will be performed in their facilities. Public Law 93-45 also allows individual doctors, nurses, et cetera, to abstain from these types of operations if a hospital should decide to perform abortions.

We are trying desperately to get 218 signatures on a petition to discharge House Joint Resolution 261 from the Judiciary Committee, in order to get an up or down vote on a constitutional amendment to prohibit abortions. I believe it is imperative that people know just exactly where every Member of Congress stands on this issue.

Over 8 months have passed since the January 22 Supreme Court decision to allow abortions during the first 6 months of pregnancy. In

those 8 months thousands of unborn babies, yes, little human beings, have been destroyed forever. Life is too precious a thing to be denied to anyone, especially one so young and innocent, and unable to protect himself.

Congressman Roncallo says "H.R. 8779 is not antiabortion bill." In his "dear colleague" letter of May 1, 1973, he continues, "No matter what our feelings on the recent Supreme Court decision on that subject, we can all share equally in our revulsion at the practices this bill would allow. Certainly, if we can get upset about vivisection of dogs and other laboratory animals, we can take steps to protect our own kind."

If H.R. 8779 is not an antiabortion bill, it is at least a prolife piece of legislation. Research on live human fetuses certainly does not lend itself to prolong life. And life is all we have.

I urge favorable consideration of H.R. 8779 by your subcommittee so we can continue to recover the ground that was lost by the Supreme Court decision on January 22.

**STATEMENT OF HON. ANGELO D. RONCALLO, A REPRESENTATIVE
IN CONGRESS FROM THE STATE OF NEW YORK**

Mr. RONCALLO. Mr. Chairman, I appreciate the opportunity to present this statement to you and the distinguished members of the subcommittee. At a time when public awareness demands a greater concern for ethical values by those who are privileged to serve in the political sphere, it is particularly appropriate that the Congress consider carefully the legislation before us today.

The protection of human subjects of research and experimentation is one of these important ethical areas in which the country will be watching to see how we weigh the innate worth of each individual against his utilitarian value to society as a whole.

Although the announcement of these hearings which the chairman inserted into the Congressional Record indicated only that they would deal with his introduction of title II of the Senate-passed version of H.R. 7724, the written notice received by my office included my bills to prohibit support of live human fetus research on a Government-wide basis. Since then, the subcommittee staff has informed me that you do not believe that it is within your jurisdiction to consider legislation which would bind agencies other than those under the umbrella of the Department of Health, Education, and Welfare. I wish that I could have been told about this last April, when H.R. 7850 was first introduced. Since then, reintroductions of this legislation (H.R. 8778, 8779, and 9488) have gathered the support of nearly 40 cosponsors. We have lost nearly 6 months during which another committee—your staff suggested Government Operations—could have been considering these bills. If it is indeed the case that they lie outside your jurisdiction, I respectfully request that you or the distinguished chairman of the full committee seek to have the committee discharged from further consideration and asked to have the bills re-referred.

I will therefore restrict this statement to the provisions of H.R. 10403, which has been introduced by the chairman to afford the subcommittee the opportunity to hold hearings on protection of human subjects before going to conference with the Senate on H.R. 7724. If

the committee does retain jurisdiction over H.R. 7850, however, I most respectfully request that additional hearings be held on this and related bills as separate legislation, so that I might have the opportunity to testify fully as to their merits.

I believe that the Senate has done a great service by proposing a Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In their wisdom, they included a provision banning HEW support of live human fetus research and experimentation until that Commission develops policies on the subject. Although I would have preferred a permanent ban, as passed by the House and proposed in the other body by Senator Buckley, I am willing to accept the temporary measure and wait to see what the Commission comes up with, assuming the idea of a Commission is itself accepted. However, if the Commission fails to promulgate policies which adequately protect the sanctity of the lives of these tiny human experimental subjects, I want to put this subcommittee and the public at large on notice that I will be back here at that time to insist that the will of Congress be carried out through specific, permanent legislation.

The Senate version of the prohibition on research, contained in section 1205 of the new title XII of the Public Health Service Act as proposed in H.R. 10403, differs slightly from that passed by a 354-9 vote in the House on May 31. Essentially the differences, which are not overly significant, are as follows:

The Senate refers to "fetus or infant," whereas we only say "fetus." This is merely a layman's semantic distinction, as the term "fetus" is used by the medical profession to include delivered humans who are not considered to have a chance of viability. I have no problem with the change, however.

The Senate language refers to a "living human fetus or infant" without definition, whereas the House version spells out that the presence of a beating heart is to be used to decide if life is present.

The Senate limited its prohibition to cases of induced abortion and does not consider spontaneous abortion. The House bill is not concerned with how the fetus gets into the hands of the researcher, but rather concentrates on the fetus itself.

The Senate language contains a provision specifically permitting research and experimentation to insure the survival of the particular fetus or infant involved. This was part of the legislative history of the House bill as debated on the floor, although it is not contained in the actual language as passed.

In order to assist the conferees in reconciling the differing versions of this prohibition on research, I have conferred with Senator Buckley, and we have arrived at the following compromise language which carries out the intent of both Houses and which we suggest for inclusion in the conference report on H.R. 7724:

"PROHIBITION OF RESEARCH

"SEC. 1205. Until such time after certification of Institutional Review Boards has been established and the Commission develops policies with regard to the conduct of research on the living fetus or infants, the Secretary may not conduct or support research or experimentation in the United States or abroad on a human fetus or infant which has a beating heart or other sign of life:

“(a) before, during, or after induced abortion; or

“(b) during or after a spontaneous abortion; unless such research or experimentation is done for the purpose of insuring the survival of that fetus or infant.”

Of course if the committee decides not to accept the Senate proposal to establish the Commission, then I believe our conferees have a duty to insist on the language of my amendment as passed by the House or at least the language offered above without its first clause. The provision would then begin with “The Secretary may not * * *” and return to the permanent prohibition overwhelmingly supported by the House.

I have been informed that due to the respective votes on this subject in both Houses, the conference does intend to report out a restriction on live fetus research. I very much appreciate this honorable attitude of the members of the subcommittee. I would like to caution, however, against the inclusion of any language which would dilute the effectiveness, and thus the spirit, of the prohibition. I want to particularly warn the House conferees against accepting any language which would allow such research with the so-called informed consent of the mother or other person. I must point out most emphatically that no one has the moral right to give such consent because no one has the interests of the fetus in mind—least of all its mother, who has already consented to its destruction. This tears at the very fabric of what consent is all about and, I am sure, would be summarily rejected by both Houses.

I wish to commend the chairman and the members of this subcommittee for their praiseworthy and dedicated work on the original bill and their willingness to consider the importance of finding a remedy for the many abuses in the use of human subjects of research that so tragically mark the current utilitarian view of human life among many of our researchers today. I stand in strong support of Federal assistance to biomedical research which seeks to preserve and improve the quality of human life in the future while not jeopardizing the human lives of its present subjects. I urge swift enactment of H.R. 7724 into law, so that this country can continue even more strongly its efforts to do just that.

Thank you.

Mr. ROGERS. Our next witness is Dr. Charles Edwards, Assistant Secretary for Health, Department of HEW. He is accompanied by Dr. John S. Zapp, the Deputy Assistant Secretary for Legislation (Health), and Dr. Robert Stone, the Director of the National Institutes of Health.

STATEMENT OF DR. CHARLES EDWARDS, ASSISTANT SECRETARY OF HEALTH, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, ACCOMPANIED BY DR. JOHN S. ZAPP, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION (HEALTH); DR. ROBERT STONE, DIRECTOR, NATIONAL INSTITUTES OF HEALTH; DR. R. W. LAMONT-HAVERS, DEPUTY DIRECTOR, NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES, NATIONAL INSTITUTES OF HEALTH; DR. FRANCES O. KELSEY, DIRECTOR, SCIENTIFIC INVESTIGATION STAFF, OFFICE OF SCIENTIFIC EVALUATION, BUREAU OF DRUGS, FOOD AND DRUG ADMINISTRATION; AND DR. D. T. CHALKLEY, CHIEF, INSTITUTIONAL RELATIONS BRANCH, DIVISION OF RESEARCH GRANTS, NATIONAL INSTITUTES OF HEALTH

Mr. ROGERS. We welcome you gentlemen and will be pleased to receive your statement.

Dr. EDWARDS. Thank you, Mr. Chairman. I would like to introduce one of my colleagues whom you did not introduce, Dr. Lamont-Havers, the Deputy Director of the National Institute of Arthritis, Metabolism, and Digestive Diseases, and also is the Chairman of our HEW study group that has been developing guidelines and regulations for the protection of human rights.

Mr. ROGERS. Doctor, we welcome you to the committee.

Dr. LAMONT-HAVERS. Thank you, Mr. Chairman.

Dr. EDWARDS. Mr. Chairman, we do appreciate this opportunity to meet with you and members of the committee to discuss the administration's views concerning these two pieces of legislation; namely, H.R. 10403 and H.R. 1111.

I would like to say that the administration is opposed to both of these bills.

Mr. ROGERS. Opposed?

Dr. EDWARDS. Opposed.

Mr. ROGERS. To both.

ADMINISTRATION'S POSITION

Dr. EDWARDS. Right. Let me make it very clear that we agree with the intent of both of these pieces of legislation, but we feel very strongly that the intent is being accomplished by the Department of HEW. We have arrived at this position after, I can assure you, very extensive discussions with many, many knowledgeable scientists and nonscientists, both in and out of the Government.

But before discussing the reasons for—the specific reasons for our opposition to these bills which address the many issues raised in titles 2 and 3, respectively, of the Senate version of H.R. 7724, I would like to review the development of the Department's policy with respect to protection of human subjects of research.

DEVELOPMENT OF EXISTING POLICY

We believe that if we are to continue to progress in conquering diseases which afflict man, we must accept the fact that in the final analysis, we must understand the cause of disease in man. We must determine the best methods of diagnosis in man, and we must determine what is the most effective—and least harmful—treatment in man. No amount of research on cells, tissues, and animals can obviate the need for a final experimental assessment in man. We believe that if progress is to be made, then some risks must be taken. There is no way to eliminate all of the danger from biomedical and behavioral experimentation. These dangers, however, we all agree must be kept at a minimum. Human subjects of research must be protected from unreasonable or unnecessary risk and must have the opportunity to give their informed consent to experimental procedures which are for the patient's benefit. The support of such research by public funds imposes particularly compelling requirements for protection of human subjects.

The existing DHEW policy is a direct descendant of a policy study initiated in 1962, first implemented in 1966, and repeatedly amended and revised since then. This mechanism presently requires institutional review committees located at each institution where the research is being done. These committees must have reviewed and approved proposals involving human subjects before a grant or contract award can be made by DHEW, and they have the duty to monitor them when the project is awarded funds.

In addition, the HEW policy requires additional review by internal departmental committees. Within the Public Health Service, these include the initial review groups and advisory councils for various institutes. Of course, the staffs of HEW funding agencies also scrutinize research proposals and follow projects involving humans.

Finally, any unfavorable recommendations of any Department review group, or any instance of apparent disregard of the policy's provisions, is brought to the attention of the Institutional Relations Branch of the NIH, which continually monitors institutional performance and can propose appropriate sanctions.

These methods of protecting the rights of individuals have proved to be the most effective means that we believe are available. Present policies are time-tested and, on the whole, have served the public and the research community very well. However, we recognize that no system is perfect or not subject to abuse. We are certainly very anxious to do whatever we can to improve the protection of human subjects. Policies have been updated on a number of occasions, as I mentioned. At present, a study group composed of members from various components of the Department is once again subjecting them to exhaustive review. The study group is particularly concerned with protection of the rights of those who have limited freedom of choice, and it is also examining the question of compensation to those who suffer injury in such experiments. It is hoped that the study group will complete its work early in 1974.

H.R. 10403 would amend the Public Health Service Act to establish in the Department of Health, Education, and Welfare an 11-member, presidentially appointed Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission would have a number of functions. It would :

1. Undertake a comprehensive investigation of the ethical, social, and legal implications of advances in biomedical and behavioral research to develop the basic ethical principles for research of this nature involving human subjects;

2. Develop procedures for certification of institutional review boards;

3. Develop and recommend to Congress an appropriate range of sanctions for failure of certified institutional review boards to respond to Commission rules, regulations and procedures;

4. Develop and recommend to Congress a mechanism for compensation of individuals and their families for injuries or death caused by participation in a biomedical or behavioral research program; and

5. Develop and recommend to Congress an appropriate mechanism to broaden the scope of the Commission's jurisdiction.

The bill further requires that the Secretary, HEW, apply to the maximum extent feasible, policies and procedures developed by the Commission to health services delivered by any agency of the Department of Health, Education, and Welfare.

OBJECTIONS TO H.R. 10403

The provisions of H.R. 10403 are inconsistent and unworkable from, we believe, a practical point of view. A single Commission would be expected to develop and to put in place regulatory mechanisms and procedures while simultaneously making a study of the ethical, social, and legal implications of advances in biomedical research, including a study of ways to regulate research in order to assure full protection of the rights of the subjects of biomedical and behavioral research experimentation. It short, the Commission would be expected to develop and, with congressional approval, put in place a regulatory apparatus, including sanctions for violators, at the same time that it is conducting a study of the most appropriate way to regulate the protection of human subjects.

Mr. Chairman, the two major responsibilities of the Commission would be conflicting if not contradictory. To ask the Commission to regulate research involving human subjects while studying the question is likely to produce several undesirable results. First, it would make operative a new regulatory mechanism that has not been adequately studied, second, it is likely to prejudice the outcome of the study required by section 1215 since the members of the Commission will be motivated to research conclusions that support the regulatory decisions it has already made.

Development of the DHEW policy for protection of human subjects has drawn upon the experience of the Center for Disease Control, HSA, NIH, the NIMH, and the FDA. Other components of the Department, notably the Social and Rehabilitation Service and the Office of Education, have also played a role in the formulation of this policy, particularly as it applies to behavioral research.

Section 1202 applies to research grants and contracts and is extended by section 1203 to health service programs as feasible but would provide less comprehensive protection than current HEW policy. The existing DHEW policy applies to all grant and contract supported programs in which subjects are considered to be at

risk. The scope of the policy includes research and development programs and has been extended in selected areas to certain service programs where it has been determined that the protection of human subjects is needed, such as the hospital improvement programs of the Social and Rehabilitation Service. In addition, the FDA extended certain provisions of the existing DHEW policy to the regulatory area, a step only vaguely contemplated in H.R. 10403.

Section 1202 would also require the "development of an appropriate range of sanctions." The existing DHEW policy already includes provision for the termination of grant and contract support, the termination of eligibility of institutions to receive grants and contracts, and for the termination of the eligibility of individuals to receive grants or contracts.

In addition to the problems that I have just discussed, the Administration finds objectionable other provisions of H.R. 10403.

1. The proposed division by law of institutional review boards into two subcommittees, a protocol review subcommittee and the subject advisory subcommittee, is an implicit polarization of "science" and "ethics" that is likely to generate unnecessary antagonism between subcommittees, within research institutions (section 1206). Introduction of adversary elements should be limited to special circumstances such as those found in organ transplantation. Experience with the present DHEW mechanism has demonstrated that these variables require substantial flexibility in committee arrangements if they are to be meaningful and if they are to be effective. While institutional review committees should be required to assure both scientific soundness and protection of subjects, the means by which they exercise these functions should be left to the discretion of the review committees.

2. Assigning to the national commission the responsibility to apply all policies, procedures, and regulations adopted for protection of human subjects involved in research experimentation to health service delivery, would open, we believe, a Pandora's box of problems.

a. It would duplicate the responsibility of professional standards review organizations at the very time that they are beginning to function.

b. It would apply research standards to medical practice. Such research standards are based on no direct legal precedents. The standards of medical practice are well recognized in malpractice law.

c. It would blur the distinction between research and recognized therapy.

d. It would apply standards developed for one area of concern to problems that are generated by a different area.

3. The bill would take responsibility for ethical questions involved in research away from those agencies responsible for conducting the research. This would further separate "science" and "ethics" since the persons responsible for ethical surveillance would be in an entirely different agency than those responsible for the advancement of science. In our view, this separation would tend to create an irresponsible attitude among researchers. It would be

much more effective to hold research administrators responsible for the ethics as well as the science of their operations and insure adequate monitoring of their performance.

4. Section 1207 of H.R. 10403 would allow exceptions to the requirement of informed consent only in narrowly construed cases which require written concurrence of the attending physician. This provision would prohibit a large segment of behavioral science research, where no physician would normally be in attendance. For example, studies designed to determine them cost effective conditions for learning and perception as well as the retention of learned materials, studies of the effects of environmental and motivational factors on performance, and use of participant observational techniques in the study of naturally occurring social phenomena. In such cases, it is reasonable to expect the present review process to protect the rights of the subject while he remains unaware of the particular objectives and procedural details of the particular experiment.

H.R. 10403 fails to take into consideration this sort of low-risk, high-benefit behavioral research. It applies inflexible standards to every situation in which human subjects are involved in experimentation, both medical and behavioral. It would, in fact, require the participation of physicians in types of behavioral research outside of their purview. This emphasizes the necessity for careful review of specific research situations before the existing DHEW policy—which explicitly covers this kind of problem—is replaced by an untried approach.

H.R. 1111

H.R. 1111 would provide for the establishment of a National Advisory Commission on Health Science and Society, charged with conducting a comprehensive investigation and study of the ethical, social, and legal implications of advances in biomedical research and technology. This study would include an analysis of scientific and technological advances in biomedical sciences; an evaluation of their implications; an analysis of public understanding and attitudes through seminars and public hearings; and evaluation of advances in the fields of psychiatry and psychology; an analysis of the use of human subjects involved with research experimentation; and an evaluation of the availability of health services to all segments of the population, particularly to the needs of low income persons. The Commission would be directed to make maximum feasible use of all other relevant studies, whether public or private, and to make its final report, with conclusions and recommendations, to the President and to Congress not later than 2 years after its first meeting.

ADMINISTRATION OPPOSITION TO H.R. 1111

This Department has long supported dialog concerning social, legal, and ethical implications of present and projected medical advances, believing that such dialog can be a positive contribution to the task of public policymaking in these areas. However, title III of the Public Health Service Act provides the Secretary with ample authorities to secure the assistance of scholars and consultants, to collect and publish information, and to utilize the administrative facilities and structures that may be necessary for investigation of a broad

range of subjects relating to science research and its applications.

For example, the Department created a nine-member panel of distinguished consultants to evaluate the ethical and scientific aspects of the Public Health Service's study of syphilis in the noninfectious stage. Furthermore, as I indicated earlier, a study group composed of representatives of various health components of the Department is currently reviewing, and has been for the last year, policies on protection of human subjects in biomedical research. These groups are illustrative of ways in which the concerns of H.R. 1111 are being met by administrative activities within the Department of HEW.

Public sector activities also include a new program on the ethical and human value implications of science recently undertaken by the National Science Foundation in conjunction with the national endowment for the humanities. The program seeks to cover the whole spectrum of science and technology in terms of the ethical and human value issues of greatest current concern and consequently, covers a much broader spectrum than scientific and technological advances in the biomedical sciences.

In addition, several distinguished groups already in existence have broad missions similar to those outlined for the proposed Commission. These include the National Academy of Sciences, with its newly established Institute of Medicine and its National Research Council; the American College of Surgeons; the National Academy of Engineering; the American Academy of Arts and Sciences; and the American Philosophical Society.

The public and private initiatives mentioned above are representative of the large number of relevant activities already underway by institutions concerned with social, ethical, and legal issues raised by health research advances.

While the Department supports, as I mentioned, the concepts behind this legislation, namely, H.R. 1111, it is opposed to the bill because the Secretary already has made ample authority and, indeed, is already engaged in efforts to achieve, in coordination with efforts in the private sector, all of the purposes of this piece of legislation. Therefore, we recommend that H.R. 1111 not be enacted.

SUMMARY AND CONCLUSION

Mr. Chairman, we are in agreement with the need for protection of human subjects and for consideration of ethical issues of biomedical research and we are conducting, we believe, as a matter of fact, the most aggressive effort to protect human subjects that is being pursued anywhere in the world. Many distinguished outside groups as well as the Department itself are already engaged in the considerations and activities outlined for study in H.R. 1111.

We believe it would be a serious mistake to replace workable and, we believe, obviously effective mechanisms for protecting human subjects with an untried and uncompromising system such as that proposed by H.R. 10403 or to delay activity in this area because of the study proposed by H.R. 1111. We consider it far more effective and advisable to evaluate and to make changes in the present system as they are warranted.

The administration has recognized its responsibility to insure the protection of human subjects of experimentation. We are trying to

meet that responsibility most effectively through administrative controls and through constant review and updating of the DHEW policy for the protection of human subjects. The existing study group, as I have mentioned, reflects the discharge of our responsibilities.

For all of the reasons mentioned above, Mr. Chairman, the administration is opposed to H.R. 10403 and H.R. 1111. At this point we would certainly be delighted to attempt to answer any questions that you or members of your committee might have.

Thank you.

Mr. ROGERS. Thank you very much, Mr. Secretary, for your statement. I might say we will try the 5-minute rule if we may, if members will cooperate with that, and then we will come back.

Mr. KYROS.

Mr. KYROS. Thank you, Mr. Chairman.

Dr. Edwards, nice to see you again, sir.

Just a couple of questions. In your testimony on page 2, in the first paragraph at the top of the page, you say :

Human subjects of research must be protected from unreasonable or unnecessary risk and must have the opportunity to give their informed consent to experimental procedures where such consent procedures are for the patient's benefit.

Now, I do not quite grasp that. What if the consent procedures are not for the patient's benefit? Do they give their informed consent?

Dr. EDWARDS. Well, I think what we were referring to here, Congressman, is in some of the behavioral studies where the patient's well-being is not at question and where certain studies are ongoing that has no relevance to the patient's own well-being.

Mr. KYROS. I see. On the same page, at the bottom, you say :

Within the Public Health Service these include the initial review groups. and then you say :

The staffs of HEW funding agencies also scrutinize research proposals and follow projects involving humans.

Now, does this mean just a general scientific review or is this also an ethical review?

Dr. EDWARDS. I think I should say both. The initial review groups, and Dr. Stone might want to add to that, the initial review groups and advisory councils are mere review groups of outside scientists. In addition, the staffs of the various Institutes of the NIH monitor these studies, monitor them both from the scientific point of view and in recent years have paid more attention to monitoring in terms of the issues we are discussing today. Dr. Stone?

Dr. STONE. Your answer is accurate and I can say from personal experience from having attended some meetings recently, that that process is going on. Not only is scientific review made but issues relative to the ethics involved are raised in these scientific reviews.

Mr. KYROS. Does that mean, Dr. Stone, that there are as is proposed in the bill before us, theologians and philosophers, let us say, people that work in social work, and so forth, or are they all medical scientists?

Dr. STONE. On the initial review groups those are scientists and on the council some such individuals would be represented.

Mr. KYROS. On page 2, Dr. Edwards, at the very top, you say :

Finally, any unfavorable recommendations of any Department review group, or any instance of apparent disregard of the policy's provisions is brought to the attention of the Institutional Relations Branch of the NIH which continually monitors institutional performance and can propose appropriate sanctions.

What sanctions?

Dr. EDWARDS. Well, of course, cutting off funding support of the particular project would be the main sanction.

Mr. KYROS. Has the NIH ever done that?

Dr. STONE. Dr. Lamont-Havers could speak better.

Dr. LAMONT-HAVERS. Yes, sir. We certainly questioned actions being taken in some projects which were brought to our attention and have indeed limited funds to them. On the other hand, the Secretary also has the power to consider the general protection of all human subjects within that institution, whether the projects are being supported by Federal funds or not. We have considered some of these. As yet we have never cut off funds to such an institution.

Mr. KYROS. Well, to get back to your own programs, have you ever cut off funds for any programs as a sanction because there was a violation of your policies in dealing with human research?

Dr. LAMONT-HAVERS. Have we ever terminated one?

Mr. KYROS. Yes.

Dr. LAMONT-HAVERS. It is my impression that we have at least in the one case.

Mr. KYROS. Tell me all about that case.

Dr. LAMONT-HAVERS. That, I cannot do. We can supply that for the record.

[The information requested was not available to the committee at the time of printing—September 1974.]

Mr. KYROS. Tell me about one of the cases where you cut off most of the funds. Tell me any case where you began to impose a sanction and what happened.

Dr. LAMONT-HAVERS. This is Dr. Chalkley, who is in charge of the institutional relations branch.

Dr. CHALKLEY. There have been two occasions on which we became aware in midcourse of a project, that the project was being carried out in an inappropriate fashion. Unfortunately, perhaps for the creation of an example, both of these came to light as the grant was being terminated. In one of these instances we became aware of a study involving some extensive cardiopulmonary procedures. On inquiry we were informed that the individual was definitely not obtaining informed consent. He was avoiding it. He was told that all use of human subjects would stop, which it did, and the grant terminated within a matter of months.

Mr. KYROS. How did this come to light and who told you?

Dr. CHALKLEY. A request was made for renewal of the grant. As part of the review, a site visit was made and brought the matter to light.

Mr. KYROS. That is a pretty tenuous way for bringing that to light. I am not criticizing your agency. What I am suggesting is that there might be a need for some bill like this so you would not have to wait until a program is all the way through and the subject has been made the target of research that he should not have been.

Dr. CHALKLEY. We have fielded numerous public inquiries but none of these have as yet actually turned up any improprieties.

Mr. KYROS. Thank you very much. Thank you, Mr. Chairman.
Mr. ROGERS. Mr. Nelsen.

Mr. NELSEN. You point out that the Administrator has the power to deal with these problems and I presume the question would be does he exercise the power adequately to meet what the public might expect or demand? This is the No. 1 question. And I note, too, that in the testimony you are in total agreement with the need for protection of human subjects and for consideration of ethical issues.

Sometimes we face a problem here on the Hill where there seems to be a concern about an issue, and so to give it some recognition and the motivation to resolve the situation we in the Congress will put together a program that pushes a cause.

Now, would there not be merit to some activity on our part that ties in with what you say you are already doing, in order to give recognition to the problem. And at the same time accelerate it a little bit?

Dr. EDWARDS. Congressman Nelsen, let me answer your first question first, whether we have exercised the power that we claim we have.

I suspect, you know, that would depend, partially, on who was interpreting the extent of our power. I think if you look back over the last 20 years and see what the National Institutes have done, and the indirect effect they have had on research institutions in the United States, you would find that they really have exercised a lot of power. We also have to recognize that it just has been in the last few years that real emphasis has been placed on some special areas of interest, like the mentally retarded, prisoners, et cetera. Perhaps over the years we have not exercised all of the power that we legitimately have, but the situation has certainly been changing in the last several years, at least since I have been around.

For example, the FDA has eliminated a number of investigators over the years for not following protocol, et cetera. So I think we are making progress. We have the feeling, nevertheless, that adequate recognition is not being given to the high priority that we in the Department have placed on protection of subjects. A priority similar to that of the Congress. I have just left a meeting with the Secretary. We have what we call operational objectives which we review with the Secretary on a monthly basis. One of the main operational objectives we have is the implementation of policy and regulations on human experimentation.

The last time we met, the Secretary said he was not satisfied with Dr. Stone's time schedule on the development of these particular regulations, so he made him squeeze his time schedule down a little. We feel we are really doing a tremendous amount. We also feel quite strongly that one commission cannot deal with all this problem. You have got to involve the specialty groups. I mean, when you talk about neurosurgery, the experimentation on the brain, it takes a totally different kind of group than it might discussing some other particular subject. So I think those are our particular problems with the proposed Commission.

Mr. NELSEN. Off the record.
[Discussion off the record.]

Mr. NELSEN. Thank you, Mr. Chairman.

Mr. ROGERS. Mr. Preyer.

Mr. PREYER. Thank you, Mr. Chairman.

Dr. Edwards, explosion of interest in this whole field of behavior modification and the application of its techniques in prisons, schools, veterans hospitals, the whole application of it to violent behavior in general, raises some of the most profound questions about the relationship of the coercive power of the State to the individual that we have ever faced in this country. I would agree with Dr. Roy that those issues are too important to be left just to the scientists or to advisory committees at HEW.

These are the kinds of issues that require a public dialog and a public consensus.

Let me ask you some specific questions. At present how many agencies and divisions fund in whole or in part projects that involve human subjects in biomedical or behavioral research? That might be a hard one to answer offhand.

Dr. EDWARDS. You are talking about institutions within the Federal Establishment?

Mr. PREYER. Yes. Within the Federal Establishment.

Dr. EDWARDS. I would have to sit down with paper and pencil but I would suspect eight or nine, maybe more than that. FDA, NIH—all of the Institutes of the National Institutes of Health, if you take that as one, the Center for Disease Control, of course, the VA, Agriculture, DOD.

Mr. PREYER. A substantial number.

Dr. EDWARDS. I think I would like to correct one statement, too, that Senator Kennedy made, and that is that all of these institutions are operating under different rules and regulations. I do not believe that is correct. I think they are all utilizing as a basic document the guidelines drawn by the National Institutes of Health on the use of human subjects.

Mr. PREYER. Well, is there any Federal clearing house of some type where this kind of information is pulled together and where it is easily retrievable?

Dr. EDWARDS. When you say this kind of information, Congressman, you mean our guidelines, what we hope to make regulations within the very near future, or do you mean the various research projects?

Mr. PREYER. I mean the various research projects, such as Mr. Kyros was asking about.

Dr. EDWARDS. No. We try obviously, to coordinate that within HEW and to perhaps a small degree in other agencies outside of HEW, but that is not done, no.

Mr. PREYER. Well, if it is not done, would you not agree that a centralization of recordkeeping would be good?

Dr. EDWARDS. I really would have no objection to it. I think it would be very good for reasons probably for reasons other than the reasons you think it would be good, I mean, I think it would be great to help us eliminate some of the duplication that we know is going on in the Federal establishment in biomedical and other kinds of research, and it might have some payoff, too, along the lines you are suggesting. I had not thought about it just in that light.

Mr. PREYER. Let me ask one last question along another line. Is it true that HEW is at the moment revising its guidelines with respect to biomedical and behavioral research?

Dr. EDWARDS. Well, we are developing new guidelines for—perhaps Dr. Lamont-Havers could speak to that because he is the one that is doing it.

Dr. LAMONT-HAVERS. Yes, sir. At the present time we are adding modifications to the present policies and procedures, particularly as they relate to children, prisoners and institutionalized mentally ill and mentally retarded, those populations in which there are problems in obtaining the fully informed consent.

Mr. PREYER. How about psychosurgery?

Dr. LAMONT-HAVERS. The psychosurgery issue is being dealt with by the National Institute of Neurological Diseases and Stroke and by the National Institute of Mental Health. An extensive report has been presented to the Council of the Neurology Institute in which the background of psychosurgery, the need for research, is outlined and also recommends with regard to protection of such individuals which might be done.

Mr. PREYER. While there is not time to go into it now, Mr. Chairman, I think we would be interested in how these new guidelines will differ from the old ones in these specific areas, like informed consent, captive populations, and how they will be enforced.

Mr. ROGERS. I think that is—

Mr. PREYER. I hope he can give us that.

Mr. ROGERS. Also, we may want to go into some questioning on that in the second round.

Dr. EDWARDS. We would be delighted.

[A copy of the publication, "Report on the Research Aspects of the Neurological Bases of Aggressive (Violent) Behavior," prepared by the National Institute of Neurological Diseases and Stroke, Aug. 20, 1973, was submitted to the committee and may be found in the committee files.]

Mr. ROGERS. Dr. Carter.

Mr. CARTER. Thank you, Mr. Chairman. Is there any way to eliminate all danger from biomedical experimentation?

Dr. EDWARDS. Absolutely not, Dr. Carter.

Mr. CARTER. I notice that the Department of HEW has a policy group to make decisions along biomedical research, outlining what they can do with their patients and what they cannot do, is that true?

Dr. EDWARDS. That is correct.

Mr. CARTER. And then you have others at lower levels participating. Along that same line, do you not think that professional standards review organizations will be extremely helpful, which this—this became law last year as part of the social security amendments.

Dr. EDWARDS. Yes. I think that it is obviously too early to state specifically the impact of PSRO, but as I mentioned, I think it will have an impact.

Mr. CARTER. Yes, sir. And unethical practices will be brought out by this review board.

Dr. EDWARDS. They will be highlighted, that is right.

Mr. CARTER. All right. Now, at the present time, if we should adopt one of these bills, forming this 11-man commission, then, of course, they could establish guidelines, but to make this effective, there would have to be commissions in every State and members of that commission in every county throughout the country. Is that approximately true, do you think?

Dr. EDWARDS. I think probably that would be true, or at least there would have to be more than one.

Mr. CARTER. How does a layman look at—do really many laymen have an understanding of what physicians really have to do?

Dr. EDWARDS. Well, most physicians would say they did not.

Mr. CARTER. Yes, sir.

Dr. EDWARDS. No. I think more and more as our public becomes more sophisticated and more knowledgeable, they have a right to know more and more about what the physician is doing, but obviously, they do not fully understand, and we perhaps have not done as much as we could to educate the public in some of these areas.

Mr. CARTER. For instance, just to take an example, if an average layman saw a physician giving a patient ether, what would his reaction be to that. Anesthetizing him. You would almost think he was killing him, would you not?

Dr. EDWARDS. Could be, depending on how he was giving it.

Mr. CARTER. That has been testified in cases previously.

Dr. EDWARDS. Yes.

Mr. CARTER. So really, this would envision a great superbody to determine what experimentation doctors should do and should not do. Am I correct in that?

Dr. EDWARDS. Yes.

Mr. CARTER. Now, to go into the subject of psychosurgery, of course, we do admit that we have had people who have carried this too far, perhaps. You have not funded any people such as, you might say, Freeman, have you?

Dr. EDWARDS. No. We have made no psychosurgery grants.

Mr. CARTER. That is a rather celebrated case. He was supposed to have done some 4,000 cases, I believe. But a patient with a sudden change in his mental attitude and way of thinking, and who sometimes becomes psychotic, might well have a brain tumor, is that correct?

Dr. EDWARDS. Right.

Mr. CARTER. Or he might have had an injury to his brain, trauma, or something, which has caused this, and this can be relieved and must be in the case of brain tumor by surgery, is that correct?

Dr. EDWARDS. Absolutely correct.

Mr. CARTER. And in a sense this could be called very well psychosurgery, am I not correct?

Dr. EDWARDS. Interpreted literally, yes, you are absolutely right.

Mr. CARTER. OK. I think that concludes my questions.

Thank you, Mr. Chairman.

Mr. ROGERS. Mr. Symington.

Mr. SYMINGTON. Thank you, Mr. Chairman.

Dr. EDWARDS, thank you for visiting with us today. On page 11 of your statement, you refer, first, to a nine-member panel that was created. That panel was created last year, was it not, roughly?

Dr. EDWARDS. Roughly, yes.

Mr. SYMINGTON. And it was created because of a critical problem that arose. In other words, it was a spontaneous reaction of the Department to this syphilis research project that more or less got out of hand and was not properly governed?

Dr. EDWARDS. That is correct, Congressman. I think, though, it is only fair to say that this syphilis research project had been started a

long time ago, something like 25 years, and we have come a long way since in what we are demanding of our people in research. So I cannot point the finger at anybody specifically, and it was recognition on our part that we had been in error.

Mr. SYMINGTON. Just to follow that line, going to Mr. Preyer's question to you about how many research projects you have and is there a central clearinghouse parlaying information, sharing it, et cetera, you said, no, it might have some payoff, but you did not have it yet. In a way, to paraphrase that response, we might almost say knowing what you are doing might have some payoff. With that we would agree. And we look, of course, to the manner in which you do inform yourself of what is happening with public research moneys.

So going on, on page 11, you refer to a study group composed of representatives of various health components. Would it be possible to submit a list of its members, copies of the studies, recommendations, and reports that such study group has made, because we must take it that this study group is your idea of an appropriate substitute or alternative to the kinds of mechanisms we are attempting to create in this legislation. And so what we really need to know is whether that is a valid alternative. Would that be possible?

Dr. EDWARDS. Yes. We will provide that for the record. As I mentioned earlier, Dr. Lamont-Havers on my far right is the chairman of that group.

Mr. SYMINGTON. All right. Together with—what questions does it ask, what variety of questions, where did it put those questions, what were the answers, and does it meet regularly? I mean, how does it function?

Dr. EDWARDS. We can provide that.

Mr. SYMINGTON. What has it done and when was it created and why?

[Testimony resumes on p. 139.]

[The following information was received for the record:]

ESTABLISHMENT OF THE STUDY GROUP FOR REVIEW OF POLICIES ON THE PROTECTION OF HUMAN SUBJECTS IN BIOMEDICAL RESEARCH

The DHEW policies relating to the protection of human subjects in biomedical and behavioral research are under continual review in order that they can be kept as effective as possible. In addition, during 1972 Dr. Robert Q. Marston, who was then Director of the NIH, undertook a personal review of many of the ethical problems involved in clinical research. His concerns were articulated in a major policy speech entitled "Medical Science, the Clinical Trial and Society" which he presented at the University of Virginia on November 10, 1972. As a result of this activity within the Office of the Director, NIH, the "Study Group for Review of Policies on the Protection of Human Subjects in Biomedical Research" was established on January 22, 1973.

On February 15, 1973, in a memorandum from the Acting Assistant Secretary for Health to the Acting Director, NIH, it was requested that this study group which had been formed by NIH should also extend its considerations to all applicable programs throughout the Department of Health, Education, and Welfare.

Charge to the Study Group

The study group was originally charged specifically to examine the following issues and questions (later extended to encompass DHEW-wide policies):

1. Current policies and guidelines with special reference to:

- (a) NIH review of applications involving human subjects
- (b) the role of effectiveness of institutional review committees
- (c) continuing review of projects in progress
- (d) the problems of informed consent and subjects at risk, including children including children and normal subjects

- (e) the scientific validity of clinical research protocols
 - (f) the protection of subjects having "limited civil freedom," and
 - (g) the overall value and effectiveness of the NIH policy to date.
2. The role, organization, and inter-relationships of the Institutional Relations Branch, DRG, to OD, B/1/Ds, DHEW, and other agencies.
 3. Compensation of persons injured in clinical investigations.
 4. Analysis and significance of current legislative proposals.
 5. Legal/ethical responsibilities and liabilities.

In order to accomplish these objectives, "subgroups" were appointed by the chairman of the full study group, with each subgroup concentrating on a specific area of concern.

Because of the special problems relating to minors, pregnant women, and the fetus, the Director, NIH, had requested Dr. Charles Lowe, Scientific Director of the NICHD, to be in charge of this area of concern. This action also took cognizance of the related deliberations of the National Advisory Child Health and Human Development Council and the Human Embryology and Development Study Section.

Membership of Study Group

As per attached roster.

Utilization of Consultants

Individual consultants were utilized, primarily in the development of the concepts which led to the recommendations with regard to children. These concepts were later modified to apply to the institutionalized mentally ill and prisoners. A list of the consultants used in developing the recommendations with regard to children is attached.

Meetings

The primary work of the study group to date has been accomplished through its various subgroups which developed draft positions for presentation to the full study group for its consideration. The full study group has met at approximately monthly intervals to consider the draft proposal and reports presented by the subgroups. The various subgroups met at such intervals as they considered necessary in order to carry out their assignments.

Reports

The document which was forwarded from the Study Group to the Office of the Director, NIH, on September 27, 1973, encompasses recommendations relating to subject groups in which there are limitations of informed consent. The groups specifically addressed were (a) children participating in "nontherapeutic" research and the involvement of the fetus and abortion in biomedical research, (b) the institutionalized mentally ill and mentally retarded, and (c) prisoners. The report is in two parts: (a) an exposition of the problems and suggested actions and (b) a restatement of these actions as proposed regulations. It is the intent that, after the recommendations of the Study Group have been approved by the Department of Health, Education, and Welfare, they will be published in the Federal Register as "proposed rule making." Through this mechanism public discussion of these recommendations can be initiated. The result of this discussion will be taken into consideration to modify the recommendations in order that they can be put into final regulations.

In addition to the above, the recommendations of the Study Group with respect to modification of the present policies and procedures were presented to the Office of the Director, NIH, on May 17, 1973. Most of these recommendations have subsequently been included in the issuance of the proposed policy on the "Protection of Human Subjects," as published in the Federal Register on October 9, 1973.

To fully explain the activities of the Study Group, it is necessary to sketch in the background of current policies and practices dating from the mid-sixties when the Public Health Service compiled and issued guidelines on the protection of human subjects. These policies have governed the activities of NIH grantees since that time, though they were not formalized as Departmental Regulations.

Proposed formal regulations, based on a tightened version of the current DHEW policy, were first published in the Federal Register on October 9, 1973, under rule-making procedures. The proposed new rules are basic and encompass all research activity involving human subjects. However, we recognize the desirability of, if not the necessity for further elaboration of policy with respect to the validity of informed consent by or on behalf of children, prisoners, and the mentally infirm.

The Study Group was set up to deal with the policy issues related to informed consent and to propose appropriate additional regulations. A draft report by the group has been submitted to the Office of the Director, NIH. After preliminary discussions, it was decided to redraft the introductory and explanatory section of the Study Group's submission. This redraft and the proposed regulations will be subjected to final review and amendment by the NIH Director's staff, and submitted to the Assistant Secretary for Health, DHEW, and subsequently to the Secretary of Health, Education, and Welfare for final approval and publication in the Federal Register under rule-making procedures.

The "redraft" will be made available to the Subcommittee as soon as it is completed, but it seems quite likely that this document will be subjected to extensive modifications in the review process. We will ask, therefore, that the Subcommittee consider it as preliminary and tentative and subject to revision as to form and content.

The draft policies now being reviewed by the NIH are supplemental to the above-mentioned proposed regulations and are concerned almost exclusively with the issues surrounding consent. The philosophical approach of the working group to the problems of consent is stated in the introduction to its draft report.

"An uncoerced person of adult years and sound mind may consent to the application of standard medical procedures in the case of illness, and when fully and properly informed, may legally and ethically consent to accept the risks of participating in research activities. Parents and legal guardians have authority (in fact, a duty) to consent on behalf of their child or ward to established therapeutic procedures when the patient is suffering from an illness, even though the treatment may involve some risk to the patient.

"There is no legal basis, however, for parental or guardian consent to participation in research on behalf of subjects who are incompetent, by virtue of age or mental state, to understand the information provided and to formulate the judgments on which valid consent must depend. In addition, current guidelines for clinical research afford them inadequate protection. Nonetheless, to proscribe research on all such subjects, simply because existing protections are inadequate, would be to deny them potential benefits, and is therefore no solution. Knowledge of some diseases and therapies can be obtained only from those subjects (such as children) who suffer from the disease or who will be receiving therapy. Without their participation in research, progress in those fields of medicine cannot be made. These subjects need protection not currently offered, when their participation in research is considered.

"There are other individuals who may be able to comprehend the nature of the research, but who are involuntarily confined in institutions. Insofar as incarceration may diminish their freedom of choice, and thus limit the degree to which informed consent can be freely given, they too need protection. Current regulations do not recognize the limitations on voluntariness which emanate from incarceration."

The draft regulations prescribe an additional step in the review process when the research proposal involves human subjects. Supplemental to the review by advisory groups concerned with the merit and other scientific considerations related to the individual proposal, the draft regulations call for review by committee to be established at the Federal and institutional level. The new committees would approve proposals and monitor research performance in the light of ethical considerations.

Under the proposal, the consent of these new Institutional Committees would be required for research involving children, in addition to parental consent. When the subjects are more than six years of age, they too must consent.

Similarly, additional protections are proposed for prisoners through the establishment of committees concerned with the conditions under which prisoners' consent is elicited.

The proposal would limit research involving the mentally infirm to projects which deal with the diagnosis, treatment, prevention, or etiology of the disability from which the subject may suffer or to studies concerning institutional life *per se*.

While extended discussions of the proposals have been conflued so far to the working group, it appears that subsequent review will focus on the proposed mechanisms for carrying out the agreed-upon objective; that is, to provide better protection for research subjects whose ability to give voluntary and informed consent may be impaired or unclear.

Additional Actions by the Study Group

The subgroups of the primary study group are continuing to examine such complex problems as (a) compensation of persons injured in clinical investigation and (b) protection of machine-stored data relating to individuals taking part in clinical investigations. There is also continuing review of the interrelationship within DHEW and the Federal Government as a whole with regard to policies and procedures on the use of human subjects.

(Study Group for Review of Policies on Protection of Human Subjects in Biomedical Research)

ROSTER

- Dr. Ronald W. Lamont-Havers, Chairman; Deputy Director, NIAMD, NIH; Building 31, Room 9A52 (496-6623).
 Mr. Seymour Bress, Executive Secretary; Division of Research Grants, NIH; Westwood Building, Room 204 (496-7178).
 Dr. Thomas Chalmers; Director, Clinical Center, NIH; Building 10, Room IN212 (496-4114).
 (or)
 Dr. Robert Black; Associate Director, Clinical Center, NIH; Building 10, Room IN216 (496-3515).
 Dr. Carl Douglass; Deputy Director, DRG, NIH; Westwood Building, Room 452 (496-7211).
 Miss Mary McEniry; Assistant to the Director for Regulatory Affairs, FDA (BD-30); Parklawn Building, Room 13B-20 (443-3640).
 Mr. Joel Mangel; Office of the General Counsel; Parklawn Building, Room 4A52 (443-2644).
 Dr. Murray Goldstein; Associate Director for Extramural Programs, NINDS; NIH-Westwood Building, Room 757 (496-7705).
 Dr. Leon Jacobs; Associate Director for Collaborative Research; Office of the Director, NIH; Building 1, Room 103 (496-3111).
 Dr. Carl Leventhal; Assistant to the Deputy Director for Science; Office of the Director, NIH; Building 1, Room 103 (496-3561).
 Mrs. Donna Splegler; Office of Program Operations; Office of the Assistant Secretary for Health; Parklawn Building, Room 17A40 (443-2650).
 Dr. Charles McCarthy; Office of Legislative Analysis, OD-NIH; Building 1, Room 224 (496-3471).
 Dr. Richard B. Stephenson; Training Officer, OD-NIH; Building 1, Room 117 (496-4186).
 Mr. David Kefauver; Assistant Director for Extramural Programs; National Institute of Mental Health; Parklawn Building, Room 17C24 (443-4266).
 Dr. Frances O. Kelsey; Scientific Investigations Staff; Food and Drug Administration; Parklawn Building, Room 14B-31 (443-1727).
 Dr. Franklin Neva; Chief, Lab. of Parasitic Diseases, NIAID, NIH; Building 5, Room 116 (496-2486).
 Dr. Charles Lowe;¹ Scientific Director, NICHD, NIH; Building 31, Room 2A50 (496-5035).

"CONSULTANTS" OR RESOURCE INDIVIDUALS

- Dr. Michael Ball; Associate Director for Biomedical Research; Association of American Medical Colleges; 1 Dupont Circle; Washington, D.C. 20036 (466-5152).
 Dr. Laurence Tancredi; Staff Officer; Institute of Medicine, NAS; 2101 Constitution Avenue; Washington, D.C. 20418 (IDS: 1224-724, Outside: 961-1724).
 Dr. Donald T. Chatkley; Chief, Institutional Relations Branch, DRG-NIH; Westwood Building, Room 303 (496-7005).

CONSULTANTS . . . used by group studying the use of minors, pregnant women, fetuses and abortuses.

- Dr. Richard E. Berman; Professor and Chairman; Dept. of Pediatrics; College of Physicians and Surgeons; 630 W. 168th Street; New York, New York 10032; 212-579-2934.

¹ Chairman of the committee studying the use of minors, pregnant women, fetuses and abortuses.

- Dr. Peter Braun, Director; Center for Evaluation of Clinical Procedures; Harvard University; Boston, Massachusetts 02115; 617-734-3300.
- Prof. Alexander Capron; University of Pennsylvania School of Law; 3400 Chestnut Street; Philadelphia, Pennsylvania 19174; 215-594-7852.
- Dr. Robert E. Cooke; University of Wisconsin; Madison Center for Health Statistics; Office of the Vice Chancellor; 10th Floor, WARF Building; 610 North Walnut Street; Madison, Wisconsin 53706.
- Dr. Arthur Dyck; Professor of Population Ethics; Harvard Divinity School; 45 Francis Avenue; Cambridge, Massachusetts 02138; 617-495-5742.
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- Charles Halpern, Esq.; Center for Law & Social Policy; 1751 N Street, N.W.; Washington, D.C. 20036.
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- Dr. Charles A. Janeway; Children's Hospital; 300 Longwood Avenue; Boston, Massachusetts; 617-566-4832 Office; 617-734-6000 Hospital.
- Dr. Lawrence Kohlberg; Professor of Education and Social Psychology; Harvard Graduate School of Education; Larsen Hall, Appian Way; Cambridge, Massachusetts 02138; 617-495-3546.
- Leon Kass, M.D.; 26 Franklin Street; Annapolis, Maryland.
- Dr. Melvin Lewis; Prof. of Clinical Pediatrics and Psychiatry; Child Study Center; Yale University; 333 Cedar Street; New Haven, Connecticut 06510; 203-436-8220.
- Dr. L. Mastroianni; 106 Duiles Building; Hospital of the University of Pennsylvania; 3400 Spruce Street; Philadelphia, Pennsylvania; 215-662-4000.
- Dr. John Noonan; Professor of Law; University of California, Berkeley; Berkeley, California 94720; 415-642-6646.
- Mrs. Mary Robinson; Executive Director; Martin Luther King Parent and Child Center; 560 North Broadway; Baltimore, Maryland 21205; 301-955-5451.
- Dr. Jens G. Rosenkrantz; Surgeon-in-Chief; Children's Hospital of Los Angeles; Department of Surgery; 4650 Sunset Boulevard; Los Angeles, California 90054; 213-663-3341, Ext. 256.
- Dr. Robert Shank; Professor and Head; Department of Preventive Medicine and Public Health; School of Medicine; Washington University; St. Louis, Missouri 63110; 314-367-6400.
- Dr. Roger L. Shinn; Rheinhold Niebuhr Chair of Social Ethics; Union Theological Seminary; 3041 Broadway; New York, New York 10027; 212-662-7100.
- Daniel Singer, Esq.; Suite 1000, The Watergate; 600 New Hampshire Avenue, N.W.; Washington, D.C. 20037; 202-965-9400. Vice President and Fellow; Institute of Society, Ethics & the Life Science; Hastings; New York.
- William Smith, Esq.; Washington Research Project & Children's Defense Fund; 1736 R Street, N.W.; Washington, D.C. 20009; 202-483-1477.
- Dr. Stewart Taylor; University of Colorado School of Medicine; 4200 East 9th Avenue; Denver, Colorado 80220; 303-390-1211.
- Dr. Raymond L. Vande Wiele; Presbyterian Hospital; 622 West 168th Street; New York, New York 10032; 212-579-2377.
- Dr. LeRoy Walters, Director; Kennedy Center for Bioethics; Georgetown University; Washington, D.C. 20007; 202-625-2371.

Mr. SYMINGTON. Finally, did I hear you correctly in a response to Mr. Nelsen that the FDA has eliminated a number of investigators for not following protocol established?

Dr. EDWARDS. That is right; yes. I cannot give you the exact number but they have over the years and they are constantly reviewing protocol.

Mr. SYMINGTON. Would it be possible, say, over the past 10 years to provide that number?

Dr. EDWARDS. I would think so. I will certainly try to provide you with that. I know certainly over the last several years we can give you a list.

Mr. SYMINGTON. Is there a difference between entirely disqualifying and reprimanding? Do you take two different—

Dr. EDWARDS. I am sure of that. In reviewing and monitoring studies, be it in the FDA, along the lines that FDA is interested or along the lines of the various Institutes of the National Institutes of Health, I think that certainly all deviation from protocol would not require an elimination of the funding.

Mr. SYMINGTON. I understand. Maybe some key examples of the differences would be helpful to the committee.

[The following statement was received for the record:]

Although several instances of questionable compliance with DHEW policy can be cited which the DHEW (Institutional Relations Branch of the National Institutes of Health) has given special attention, it has been possible to work with institutional administrators to resolve the issues.

The DHEW policy superseded the Public Health Service policy over two years ago. While most large grantee institutions have been able to respond with assurances acceptable to the DHEW, some have had difficulty in resolving internal problems with some aspects of the policy. For these institutions, assurances are now required on a more onerous project-by-project basis until an acceptable assurance has been negotiated.

Although there is every indication that the DHEW policy is now in full implementation at most medical schools, universities, and research hospitals, and other institutions, the possibility that rare failures in compliance may occur on individual projects should not come as a surprise. The DHEW offices responsible for accepting and enforcing institutional assurances are actively reviewing institutional performance in the light of the assurances and policy requirements.

Mr. SYMINGTON. Finally, we have run into a possible problem in the State of Missouri, Mental Health Division, and as far as I know, my staff has submitted to the FDA certain documents which were sent to me and I would appreciate any assistance or interest you might take in that.

Dr. EDWARDS. Certainly. We would be delighted to.

Mr. SYMINGTON. Because it involves the use of drugs, some of them without even names yet, just numbers, on mental patients with seemingly inadequate consent procedures.

Dr. EDWARDS. We are aware of your interest in this and we are pursuing it. If there are any problems, please let us know.

Mr. SYMINGTON. Thank you very much.

Mr. Chairman, at this point I would like to submit a short statement recounting the facts that have been brought to our attention in the Missouri case.

Mr. ROGERS. Certainly, without objection, it will be made a part of the record at this point.

[The statement referred to follows:]

STATEMENT OF CONGRESSMAN JAMES W. SYMINGTON ON HUMAN EXPERIMENTATION IN MISSOURI

Mr. Chairman, a few days before the start of our hearings on human experimentation, my office received documents which purport to detail testing of various drugs on mental patients in Missouri. These documents indicate that both children and adults were used in these experiments, that the patients themselves were asked to sign consent forms even though they were institutionalized for mental illness, that one patient died during a study of psychotropic drugs, and that some drugs were still in the experimental stage. Moreover, the announcement of these hearings and of the fact that these documents were in my possession was made earlier this week. Yesterday, two of the principal investigators, the two doctors directing some of this research resigned.

In light of these circumstances, my staff has been in contact with FDA and GAO officials. I now ask that the FDA in cooperation with GAO investigate the Missouri situation. I request that FDA determine:

1. if the documents in my possession are authentic ;
2. if informed consent was given before these experiments ;
3. who gave consent in each case ;
4. if patients or guardians were paid for participation ;
5. what persons or companies financed these experiments ;
6. whose funds were used in any reimbursement ;
7. if drugs used in the experiments are safe & effective ;
8. such experiments violated FDA regulations or Federal law.

My staff will turn over copies of the documents in question to FDA and GAO officials so an investigation can begin at the earliest possible time.

Mr. SYMINGTON. Thank you, Mr. Chairman.

Mr. ROGERS. Mr. Hastings.

Mr. HASTINGS. Thank you, Mr. Chairman.

Dr. Edwards, this question of psychosurgery, this week's blue sheet has a story—I do not know whether you have seen it or not. The story indicates an ad hoc advisory panel of NIMH has recommended there be a part ban on psychosurgery and, in fact, that by November you would call for recommendations; is that reasonably accurate?

Dr. EDWARDS. I am not sure of that.

Dr. LAMONT-HAVERS. I am afraid the blue sheet has got hold of the report before we have. I am not sure if they are accurate or not. Certainly, the National Institute of Mental Health is preparing such a report and they should be practically ready now. I imagine the blue sheet must have got hold of a pre-copy, as it were. I have not seen it.

Mr. HASTINGS. This makes a statement that psychosurgery is a dangerous experimental procedure needing careful observation and should be banned at least for 2 years according to the ad hoc panel.

Dr. EDWARDS. More than likely that is correct and, as Dr. Lamont-Havers said, we have not received that officially yet. I assure you we will be checking on it today because I suspect it is true and philosophically, I more or less agree with it.

Mr. CARTER. This refers to lobotomy.

Dr. EDWARDS. Yes.

Mr. HASTINGS. One of the reasons I bring it up is to indicate that in fact there is an ongoing review of these controversial subjects within the Department.

Dr. EDWARDS. Absolutely, and I think your point is well taken.

Mr. HASTINGS. I had some interest in the questions that my colleague, Mr. Hudnut, had directed to Senator Kennedy and I would like you to comment on them as to whether perhaps the legislation as drafted might possibly be an attempt to or have the indirect result of legislating morality, as I recall his language, or imposing elements of religious persuasions on the entire United States. Do you see a danger?

Dr. EDWARDS. Absolutely. I think that was a very profound question and it really comes to the heart of the issue. While we have no objection at all to a blue ribbon committee considering all of these ethical, moral, and other issues—that could be very helpful—we do not want a commission to come in and interfere with what we have, an ongoing program that is a very meaningful program. We do not want to slow it down. But the consideration of these broad issues, there is no question that it has to be done and I think the questions that Congressman Hudnut brought up were the real gut issues.

Mr. HASTINGS. I believe, then, in deference to the Congressman, who indicated to me that he was perhaps leaving, I would be delighted to yield at this point.

Mr. HUDNUT. I thank the gentleman for yielding.

Doctor, I am sorry I had to be out of the room during your testimony, although I have scanned it and I think that the real substantive issue here is the basic one that I addressed myself to when I asked Senator Kennedy a question earlier, that is, how can we freeze into institutionalized form a given moral position without jeopardizing and undermining and in a sense sapping the vitality of a culture that is essentially pluralistic and heterogenous as far as its moral, political, social, theological, and philosophical aspirations and commitments are concerned? That is the danger in this bill, as I understand it, and perceive it. That is not saying whether or not I would support the bill once we get that far after the hearings, but right now the danger as I see it, is that it would tend to institutionalize a given moral position. A second danger involved in that is that it would tend to institutionalize a consensus. We have seen with the debate on prayer in the public schools how it is impossible, without sapping the vitality of Judaism, Catholicism, Protestantism, to have a moral position based on consensus that does justice to any of the components in the consensus. This is the kind of theoretical or philosophical danger, it seems to me, inherent in the recommendation to establish a commission and yet I can perceive the necessity and need for establishing some kind of regulations that will help avoid the abuses that we are all concerned about here. |

Dr. EDWARDS. I think you certainly very well point out the concern of the thoughtful scientific community about this kind of institutionalization. I would like to ask Dr. Stone, in view of the fact that he is so closely involved in the process by which human subjects are protected.

Dr. STONE. It seems to me what you are saying is that in matters of consensus there ought to be a parsimonious use of the written law. I certainly subscribe to that. While I recognize the need for written law my suspicion is, but I cannot document it, that the publicity, the public discussion that surrounds each encroachment on other people's civil liberties or rights is far more powerful than what finally gets written down into a law. That is what really regulates our laws, and I think you are saying that. If you are, I subscribe to it.

Mr. HUDNUT. Well, I appreciate your support. At the same time, as I note that we stand on common ground, I do share with some other members of the committee a perception that so often it seems to me that this committee on both sides of the aisle is at loggerheads with the administration and you come up and tell us you are opposed to all these nice good pieces of legislation and it is something I think I as a Republican should say and I believe in parsimony but I do not want to be irresponsible but it seems to me sometimes we ought to be able to sometime get together with the administration rather than always be in an adversary position. I am glad there is a little common ground here.

Dr. EDWARDS. I think there is lots of common ground on this issue.

Mr. ROGERS. Mr. Symington.

Mr. SYMINGTON. Mr. Chairman, so that the record is clear on this point, the witness has responded, I guess affirmatively, to Mr. Hudnut's suggestion that this legislation in and of itself would establish with the force of law certain resolutions of questions of moral conscience, would tend in that direction should a commission be established to make

studies of this kind as our bill would require. But does that not really beg another question which is you are already doing this and you are doing it with a study group whose names we do not know and we—you are making these decisions more or less in camera, it would seem.

Now, it may be that the approach that this bill takes goes too far but I think there is far too little public understanding and knowledge and consent, if you will, because it is impossible to give meaningful consent without knowledge, of the kinds of guidelines and criteria that are being observed and it is all very well to say that we want to remain pluralistic and we inevitably will. At the same time, decisions are being made which many would disagree with, perhaps, do not know what they are, and I think at the very least there ought to be something out on the table so that the American people have a chance to make judgments.

Dr. EDWARDS. Perhaps, Congressman, we have not given adequate publicity to some of the things we are doing. Our guidelines certainly have been in the public domain and are available to all institutions throughout the country and the members of our task force are certainly public knowledge. We will provide you with the information you requested [see p. 135]. I might ask Dr. Lamont-Havers to speak to some of the issues that you brought up.

Dr. LAMONT-HAVERS. Yes, sir. We certainly are not proposing regulations in camera. We are at the stage now of proposing draft proposals which will be published in the Federal Register and elsewhere with a very adequate period for full discussion by the public. This is a central feature of the process.

We will evaluate those responses in turn and decide whether we should at that point have hearings or whether the consensus from the public is such that we can then propose our regulations. But inherent in our whole concept is the fact that there has to be public discussion of these modifications which we will be proposing.

Mr. SYMINGTON. In the establishment of these proposals, the adoption of these proposals, were there nonemployees of HEW involved in the discussions?

Dr. LAMONT-HAVERS. Up to date there have been individual advisors coming in. We have not had open meetings at this stage. We are at the stage, really, of coming up with something which can be discussed and will then be modified from the discussion itself.

Mr. SYMINGTON. That is quite important because you do want the full spectrum of society to have a chance to respond before these things are engraven in stone.

Dr. LAMONT-HAVERS. The other thing we are concerned with is the fact that although psychosurgery and other types of things may be ethically wrong to be done today, the advancements in research may make them quite legitimate and necessary 3, 5, 10 years from now. We need a mechanism by which these things can be reviewed in order that the particular research projects in the future can be considered in the context of knowledge at that time.

Mr. SYMINGTON. Thank you.

Mr. ROGERS. Well, I think the point that is being made, and I would agree with it, is that to say that the bill is going to zero in and make hard and fast moral and ethical standards may not be a legitimate criticism when you claim that the only reason you do not want this, is

that you are doing it already. The Department—just the mechanism by which it will be done basically, is in question here. You are saying you are going to get to all these problems. You are going to make sure people have given their informed consent. You are going to see that things are done properly but you simply say you do not want it done through that mechanism. I understand that.

Dr. EDWARDS. It is a little deeper than that.

Mr. ROGERS. How much deeper?

Dr. EDWARDS. Quite a little, we really think we have come quite a distance and we do not want to go back and have to start with square 1.

Mr. ROGERS. What do you mean? You say you have come quite a distance. Does that mean—

Dr. EDWARDS. We are very near making available new regulations for public comments—they are not final because I think they have to be constantly revised, we are ready to go for all practical purposes or will be in the next several months. I do not want to see a commission established and then have to start all over again in order to bring the commission into it.

Mr. ROGERS. I do not know why—what do you have to do to bring up a commission, simply give them what you have decided to date and let them make judgments. I do not think that is going to take long.

Dr. EDWARDS. Having had a fair amount of experience with commissions, I know it does not work that well.

Mr. ROGERS. I think it does. In fact, in the President's Commission we did that exactly. We got department feelings to date and we moved from that.

Now, let us see where we are. What are we talking about here? Is this mostly the investigational new drug subject—is this the main thrust of where your activities are involved?

Dr. EDWARDS. No.

Mr. ROGERS. Well, how much farther? How broad is the subject matter?

Dr. LAMONT-HAVERS. There are three primary subjects at the present time with a fourth just beginning. One of them dealing with a review of our present policies and regulations is pretty well finished.

Mr. ROGERS. Policies and regulations on what?

Dr. LAMONT-HAVERS. On the use of human subjects.

Mr. ROGERS. All right.

Dr. EDWARDS. Across the board.

Dr. LAMONT-HAVERS. In the areas of those problems in which there are problems with informed consent, namely, children, prisoners, and institutionalized mentally ill patients and the mentally retarded, we are at the stage now of having developed a document which we will send forward for clearance and which will be published for comment hopefully, within the next few months if clearance is achieved.

We are also looking into the problem of compensation of those individuals who may have been harmed by biomedical research. This is not as far along as we would hope because of problems of getting interaction with the insurance companies who are involved in this area. We are just beginning to look at the question of protection of information in data systems which might involve individual human subjects.

Mr. ROGERS. Now, what about investigational new drugs? What about—how many people are involved, say, when you let it go into human experimentation? What do you have, 5,000 or 6,000 IND's now? Would that be about right?

Dr. EDWARDS. It would be in that general neighborhood. Of course, this subject, as you well know, is being actively pursued by the FDA.

Mr. ROGERS. This is what I want to get into. I am not sure at what stage we are. This is why I want to get into this subject.

Now, first of all, when an investigational new drug comes in, we want to make sure if they are going to deal with humans, those humans are properly informed, do we not?

Dr. EDWARDS. Absolutely.

Mr. ROGERS. All right. Now, you require what for the first stage before they can touch humans?

Dr. EDWARDS. Perhaps.

Mr. ROGERS. All right. Anybody.

Dr. EDWARDS. This is Dr. Kelsey, who heads this particular unit in the FDA.

Mr. ROGERS. We welcome you to the committee. First of all, you make tests on animals for 2 weeks?

Dr. KELSEY. It would really depend on the type of drug and how it would be administered and how long.

Mr. ROGERS. You let them go straight to humans?

Dr. KELSEY. No; no. As you say, it might be 2 weeks or it might be much longer. I have not got the protocols here but we can easily supply—

Mr. ROGERS. Just generally.

Dr. KELSEY. We would want an acute toxicity in two or three species of animals, and some subacute studies in two species, as well as pharmacological studies.

Mr. ROGERS. Normally, it is about 2 or 3 weeks testing on animals.

Dr. KELSEY. Provided the use on humans is restricted to a short period of time, such as a single dose to several days.

Mr. ROGERS. For some time anyhow.

Dr. KELSEY. Yes, sir.

Mr. ROGERS. How long would you let humans be tested in phase 1?

Dr. KELSEY. I would have to refer to the guidelines which we have available rather than quote from memory which might be wrong.

Mr. ROGERS. Well, I am not going to hold you to the exact.

Dr. KELSEY. Sometimes these phase 1 studies are a single dose. Sometimes they may involve two or three doses a day. A study usually starts off with a pretty low dose.

Mr. ROGERS. Normally, how many people do you limit it to in phase 1?

Dr. KELSEY. In phase 1, again—

Mr. ROGERS. Twenty to fifty healthy people, about?

Dr. KELSEY. Yes.

Mr. ROGERS. All right. That is—

Dr. KELSEY. Not all at once. You would first test one or two subjects and then gradually pick up.

Mr. ROGERS. You may be having more than one investigator, might you not?

Dr. KELSEY. In phase 1 it is usually only about one or two.

Mr. ROGERS. He may be doing 20 at the same time, this guy is doing 20. Do you keep that strict control on them where you make them report to you what has happened on the first patient before they give it to the next one? I never knew that.

Dr. KELSEY. We have a requirement that the trials in humans cannot begin until 30 days after we have received the submission.

Mr. ROGERS. That is not what I am asking. I understand that. They file their protocol as to what they want to do. They cannot do any experimentation on humans for 30 days. They can if you have not done anything between that time, can't they?

Dr. EDWARDS. Correct.

Mr. ROGERS. Sure.

Dr. KELSEY. Certainly.

Mr. ROGERS. Normally you require a 2-week period, about, on animals before you let them go to humans, for the most part.

Dr. KELSEY. Yes.

Mr. ROGERS. For the most part you want it tested, checked out for toxicity, whether any cancer appear in the animals, et cetera, right?

Dr. KELSEY. In phase 1, and this, of course, is you realize one of the things we are discussing now, how extensive you can do them before complete animal studies are done.

Mr. ROGERS. I am not saying what you are studying. I am saying what you do now.

Dr. KELSEY. At the present time, an entire carcinogenic study does not have to be done before clinical studies start. In the case of the oral contraceptives, rat carcinogenity studies must be completed before phase 3 studies are started.

Mr. ROGERS. On other drugs.

Dr. KELSEY. On other drugs or oral contraceptives?

Mr. ROGERS. So you let them move into humans before it is tested that it might bring about cancer. That is amazing. I thought you required dose tests on the animals first. But you are looking at that.

Dr. KELSEY. Yes, sir.

Mr. ROGERS. That is amazing. Were you aware of that, Dr. Edwards? I was not.

Dr. EDWARDS. No; I was aware of exactly the way it was.

Mr. ROGERS. I think that ought to be looked at immediately.

Now, so that is 20 to 50 people; 6,000 times 20 is what?

Mr. KYROS. 120,000.

Mr. ROGERS. Thank you, Mr. Kyros. He is a graduate of an Academy of Science at Navy.

Now, if it were 50 people, that is 300,000 right? 300,000 people. Now, that is phase 1.

Dr. KELSEY. Are you having 6,000 IND's or 600—

Mr. ROGERS. I thought you said 6,000 IND's over all.

Dr. KELSEY. Well, per year I think about 600 come in.

Dr. EDWARDS. Per year.

Dr. KELSEY. So each year there is a new 600 undergoing phase 1.

Mr. ROGERS. You have got 5 to 6,000 going now, have you not?

Dr. KELSEY. That is right.

Dr. EDWARDS. Over all.

Mr. ROGERS. I realize everyone is not started each year.

Now, phase 2, what do you have to do? You have to have some animal testing before you let them go. That is where you test for cancer. Then, in phase 2, is it?

Dr. KELSEY. No. Phase 2 is the first time the drug is introduced into a subject suffering from the condition for which it is proposed. Phase 1 strictly speaking, is normal volunteers.

Mr. ROGERS. All right. Now, phase 2 is usually conducted with how many people, 100 to 200 people?

Dr. KELSEY. I would say about that, possibly.

Mr. ROGERS. 100 to 200 times 6,000 is what? A million, two. At the top. All right, now—

Dr. EDWARDS. Let me interject here. First of all, you are assuming that all of these IND's and NDA's are operational, are active, and they are not all active at the same rate and some are inactive for awhile.

Mr. ROGERS. Some of them are inactive, some phase 2, some phase 3.

Dr. EDWARDS. Some are inactive while additional data is being collected or the investigator is doing something else, so I do not think the figures are reliable.

Mr. ROGERS. It may be that they are continuing to give the drugs but just not doing much about them. We do not know.

Dr. EDWARDS. It could be—

Mr. ROGERS. No way for us to know. They do not report that to you. This is some of the things I am talking about, what is going on and what we know and what we do not know and whether we need something to be looked into.

Now, when you get up to phase 3, where they really are expanded you use large groups of people, do you not? Could be in the thousands, could it not?

Dr. KELSEY. Yes, sir.

Mr. ROGERS. So it could get up, you know, to 50,000 to 60,000 people involved in this. So just from investigational new drugs alone, it is rather significant, the number of people that will be involved.

Now, I am concerned about what we are doing on this. I notice that the General Accounting Office made a report. This has now been published, and released by Senator Ribicoff, I believe.

Let me have your comment on the criticisms. I realize they took only 10 of the more than 6,000 drugs and looked at those. I do not know whether they were keyed to those particular ones or whether you brought them out for them or how they selected them. But the ones they selected were pretty startling as to what was going on. And as I understand it, they have made some rather significant criticisms and I thought I might get you to comment on that for a minute after which I may have some specific questions.

Dr. EDWARDS. Well, let me say just a word, Mr. Chairman, and then perhaps Dr. Kelsey would like to say a word.

Of course, Dr. Kelsey has been sort of a voice in the wilderness for a number of years on this particular problem. She has felt for a long time that the FDA was not adequately monitoring drug investigations and when we took over the FDA several years ago it became too obvious to us immediately that we were not doing what we should be. And Dr. Simmons and his colleagues set up a new unit under Dr. Kelsey's direction to do exactly that. I know Dr. Kelsey would be the last to say this has been adequately funded but I think we share your concern. We are moving in the right direction. I think some of the criticism of GAO is probably very legitimate but we have moved a long way.

Dr. Kelsey, you might want to—

Dr. KELSEY. I have nothing to add to what Dr. Edwards has said.

Mr. ROGERS. Let me ask you this now. FDA, I understood, was responding to some of the recommendations. Have you made any changes since the General Accounting Office?

Dr. EDWARDS. Of course, we were aware of this situation long before GAO got into it. I mean, what they are reacting to is something we reacted to long before they reacted to it. And that is why we set up this special unit.

Dr. KELSEY might want to tell you how the unit works a little bit and just what your method of operation is which, as I say, has been underway for several years.

Mr. ROGERS. First of all, before we get into what you have been doing over the years, since this was a General Accounting Office study begun in October 1972, I presume, have you made any changes in your procedures or in your rules and regulations to carry out a correction of the criticisms made by the General Accounting Office?

Dr. KELSEY. I would have to review those criticisms. I am not sure what you are referring to.

Mr. ROGERS. Are you aware of the General Accounting Office report?

Dr. KELSEY. Yes; I am. I am aware of it but I cannot exactly remember.

Mr. ROGERS. I just wonder if you remember any corrective action.

Dr. KELSEY. We have certainly stepped up our program on monitoring clinical investigators or rather seeing that the sponsors of these IND studies are carrying out their duties in seeing that the investigators are conducting these trials in the way that gives optimum safety to the subject and also provides—

Mr. ROGERS. How have you done that?

Dr. KELSEY. We have been in operation since 1966 but in the last year we have greatly expanded our activities. We have five programs now in operation that involve visiting investigators, visiting the sponsors, visiting laboratories in which animal research is carried out, and also visiting institutions themselves to see how their institutional committees are operating.

Mr. ROGERS. Well, now, besides visiting, have you put out any regulations requiring that results must be in your office by a certain period of time?

Dr. KELSEY. What type of results are you referring to?

Mr. ROGERS. Well, for instance where it took a sponsor 7 months to analyze the results of a study which showed later cancer in rats, or where it took 8 months for a drug company to supply FDA with the results of a study showing cancerous tumors in rats, or where it was over a month before notifying another group, FDA, that cancer had been found in dogs treated with a drug, even though humans were being treated with that drug.

Dr. KELSEY. This prompt reporting is a requirement of the regulations and part of our survey devoted to animal laboratories is to make sure that adverse effects in animals are reported promptly, and—

Mr. ROGERS. Should you have a requirement that the report must be in before human experimentation should begin?

Dr. EDWARDS. We probably have that requirement, do we not? I think the important thing is that we have—

Mr. ROGERS. Well, now, I am not sure. Evidently you do not have that requirement.

Dr. KELSEY. Some—

Mr. ROGERS. I am not sure that you should but I want to know your feeling about it and whether we should—

Dr. KELSEY. Well, as we said at the onset, the requirements now are that all animal requirements are not required to be concluded before human trials start and it can be that animal results which may or may not have some bearing on human toxicity may show up while clinical trials are in progress, and we are preparing guidelines or regulations—I am not sure which they will be—to try and remedy this situation.

For example, to see whether we should have more prolonged animal trials and to see what followup procedures should be done, should human subjects be exposed to a drug that has had adverse effects in animals.

Mr. ROGERS. Do you make a written determination that a drug's benefit outweighs the possible risk of its experimental use before allowing clinical tests to begin or continue when serious safety questions concerning testing drugs in humans arise?

Dr. KELSEY. I would say every medical office review must really embody a judgment as to—

Mr. ROGERS. I am saying do you require that?

Dr. KELSEY. Do you mean me or the FDA?

Mr. ROGERS. FDA.

Dr. KELSEY. Well, I—

Mr. ROGERS. Health Department.

Dr. EDWARDS. I would have to check and see whether a written report on that specific issue was made but obviously, that is taken into consideration before allowing—

Mr. ROGERS. This is one of the recommendations of the General Accounting Office.

Dr. EDWARDS. Yes.

Mr. ROGERS. You do not know yet whether that has been done. Would you let us know?

Dr. EDWARDS. We certainly will.

[The information requested was not available to the committee at the time of printing—September 1974.]

Mr. ROGERS. Second, institute a program to insure IND sponsors timely performance in reporting of animal studies to FDA and emphasize to sponsors the need to proceed with clinical investigations in accordance with the Code of Federal Regulations.

Has that been done?

Dr. KELSEY. I think we are doing that in our various programs.

Mr. ROGERS. Evidently they did not think you were.

Dr. KELSEY. Well, these programs have started since the GAO began its investigation.

Dr. EDWARDS. Again, the GAO came in on this back in 1971 or 1972.

Mr. ROGERS. October 1972. Almost 1973.

Dr. EDWARDS. As a matter of fact, they came in when we were still there. Again, they did not—there is nothing in that report that we were not well aware of and did not try to do something and did not initiate programs.

Mr. ROGERS. I am sure it is not a conscious not doing. What I am saying is that here are things that we are talking about and having this Commission check into, whether it ought to be done, what these standards should be and what requirements there should be when you begin to deal with humans. Now, you are telling me that you are doing all this within the Department but here is a report that has just shown,

and this was published on September 19, 1973, that the in-house study or the in-house group maybe has not yet done everything that could be done. Maybe this is overkill. I do not know. But we want to have some informed judgments so that we can decide whether this is a good idea or not.

Dr. CARTER, I think you have a question.

Mr. CARTER. Yes, sir.

Dr. Kelsey, were you the lady physician who found that thalidomide caused deformed youngsters?

Dr. KELSEY. Yes.

Mr. CARTER. Let me congratulate you on that. Thalidomide was invented in Germany, I believe, was it not, first used there?

Dr. KELSEY. Yes.

Mr. CARTER. And yet whatever system they have in Germany similar to the FDA did not find out the ill effects of thalidomide, did it? But our FDA here in the United States did that with your help, is that correct?

Dr. KELSEY. Yes, sir.

Mr. CARTER. Well, let me congratulate you again. I think you have a distinguished body, a great body of people here, and it is difficult to be perfect. It is difficult for a wheel to be completely round. But I do not know—is there a body, really, Dr. Edwards, in the world as well equipped and composed of as many hard-working, dedicated people as this group here?

Dr. EDWARDS. No. The longer I was with the Food and Drug Administration the more respect I gained for the doctors, the professional people in the organization.

Mr. CARTER. Well, every once in a while—

Dr. EDWARDS. They are an outstanding group of people.

Mr. CARTER. Every once in a while we have to go through a great deal of grilling and—

Dr. EDWARDS. They are constantly faced—

Mr. CARTER. Perhaps to strive toward that 100 percent but I think we are 99.44,000. I hope so.

Dr. EDWARDS. Dr. Kelsey and her colleagues are constantly faced with exactly what we are talking about today and the chairman has brought it up, what constitutes overkill. Where do you overkill and where do you underkill?

Mr. CARTER. On the experimentation.

Dr. EDWARDS. As you know, they held congressional hearings last year because FDA restrictions or their regulations are so restrictive that we are depriving or keeping good drugs from the market in the United States.

Mr. CARTER. Yes, sir.

Dr. EDWARDS. If we started to—

Mr. CARTER. Actually, even now with the drugs we have, almost any drug you have can cause very serious effects, is that not true? Is that not correct? Almost any drug. Aspirin, for instance.

Dr. EDWARDS. Right.

Mr. CARTER. And it is recognized as being effective and used generally and the more dread the disease, the more dangerous the medicine in many, many cases, is that not correct?

Dr. EDWARDS. That is correct.

Mr. CARTER. The medicines which save many, many lives may, well, do cause serious—many deleterious effects. If we—on every medicine, on every one of these medicines, if we took weeks to see if they caused cancer in rats, or rabbits, how much longer would it take us really to develop these medicines and make them available to the public? Could you give us an estimate on that?

Dr. EDWARDS. No. I cannot give you an estimate but it certainly would increase the time and particularly—of course, the problem becomes more complex because after we find out whether there is cancer in rodents of various and sundry types we do not know what it means.

Mr. CARTER. Actually, is it always true that if it is carcinogenic in rabbits, it is carcinogenic to a human? Has that ever been proven?

Dr. EDWARDS. Proven—

Mr. CARTER. It has been presumed by an act in 1962, as I understand it. Really, has it?

Dr. EDWARDS. I think the point you are making is a very good one.

Mr. CARTER. All right. Many substances which are—all substances—maybe I should say it that way—which are carcinogenic to rodents, are they always carcinogenic to human beings?

Dr. EDWARDS. No.

Mr. CARTER. All right.

I think that answers the question. Certainly, we want you to continue with your good work. And again, I compliment you for your excellence and I want to particularly point out the wonderful work of Dr. Kelsey who has saved millions of children in this country from being deformed by banning thalidomide.

Thank you.

Mr. ROGERS. Thank you. As a matter of fact, I join Dr. Carter in that. As you know, we had the pleasure of having you here, I think, after you just had gotten your award. So we recognize your abilities.

I must say all of my colleagues to my left get on me a little bit when they feel I am getting a little bit too rough and this is acceptable to me, but I must proceed as I am sure they understand, because we want you to get to be like, what is it, Ivory soap? And we do not even have that in the Congress but we should strive for it nevertheless. Ninety-nine instead of less.

Mr. CARTER. I believe it is already 99.44 and that is Ivory soap. About 5600ths of a percent to go.

Mr. ROGERS. Well, this is what we are going to strive for if we can and I am sure you agree with me.

Let me ask you this. Have you established a patient followup policy which requires a written commitment in the IND application from the sponsor to provide appropriate followup before an IND exemption is granted and guidelines prescribing adequate performance and reporting requirements for followup?

Dr. KELSEY. We are in the process of drawing up such guidelines.

Mr. ROGERS. I would like to have you let us know when all of this is done, when you have responded to the GAO report, and in what manner.

Dr. EDWARDS. We could give you a report right now, Mr. Chairman, on what—on those.

Mr. ROGERS. That would be fine.

[The information requested was not available to the committee at the time of printing—September 1974.]

Mr. ROGERS. Now, what about establishing the efficacy or safety of investigational results? Do you consider the results of studies done in an unethical manner? Would you accept those? I understand that the journals will not publish any findings or studies based on unethical research.

Dr. KELSEY. Well, if you consider the work of people we have disqualified as improper investigators, we do not accept their work unless it shows some adverse effect and then we will take that into consideration, of course. If they, because of their dishonest studies, have revealed the toxic effect of a drug, we will certainly take that into consideration.

Mr. ROGERS. No. What I am saying is, where you have studies going on, maybe they have not gotten all the informed concepts. Do you accept that?

Dr. KELSEY. If we are aware that this has occurred.

Mr. ROGERS. Yes, but what do you do to be aware of it?

Dr. KELSEY. This is part of our program. I cannot say we can do it for all these thousands of studies that are coming in, but the investigator signs a statement he has gotten informed consent. The sponsor signs a statement that they have required the investigators to obtain informed consent.

Mr. ROGERS. Do you have a form that should be filled out for the proper consent to be given?

Dr. KELSEY. Not at the moment. That is something that is also under discussion.

Mr. ROGERS. Should that not be done?

Dr. KELSEY. I was supposed to be at a meeting this morning on that very thing, sir.

Mr. ROGERS. Well, we have delayed you. Hopefully, this hearing helped bring about that meeting.

Dr. KELSEY. It is coincidental, I am afraid.

Mr. ROGERS. Is it? Well, suppose you let us know, then, Doctor, when you have it judged and completed, when it is effective. The committee will be interested in that, because investigations into drugs has gone on for some time. I believe now we would have gone into that way back when you got your award for thalidomide.

What about the existing procedures now outside of NIH that are designed to protect human subjects in medical schools, in hospitals? Are we aware of what is going on?

Dr. EDWARDS. By and large, I think most of these medical schools and hospitals utilize our guidelines.

Mr. ROGERS. Well, how do we know that, Dr. Edwards?

Dr. EDWARDS. Well, we know that that is true certainly in the case of those—the grants and funds, the projects that are being funded by us. We know that that is true.

Mr. ROGERS. Well, how do we know that? We do not take action until something happens and then we cut off the grants. What do we do ahead of time before we make the grants?

Dr. LAMONT-HAVERS. For the past 4 years now the Institutional Relations Branch at NIH who have responsibility for monitoring the institutional committees and institutional assurances have visited such institutions on an irregular basis because of personnel shortages. We are now instituting that on a much more regular basis and hope to put more resources in that kind of surveillance.

Mr. ROGERS. You cannot possibly visit all the hospitals in this country. It is impossible.

Dr. LAMONT-HAVERS. No. But when we have checked, it is obvious that the system which has been set up for the monitoring of projects funded by Federal funds has a large amount of side effects for the institution itself and it is much easier really, and to their advantage to have all such projects go through such a—

Mr. ROGERS. Have you required a committee in the various institutions to have review of this standard? Is that a requirement?

Dr. LAMONT-HAVERS. Each institution in which Federal funds are used?

Mr. ROGERS. In each hospital where there might be Federal funds?

Dr. LAMONT-HAVERS. Yes.

Mr. ROGERS. In any research project they must have a committee?

Dr. LAMONT-HAVERS. As long as they have a research project funded by the NIH or HEW, at least must have an institutional review committee and, as a matter of fact, the VA and other Federal funding agencies utilize such requirements of the NIH.

Mr. ROGERS. And what happens to that committee? Who monitors what they do? Your visits do?

Dr. LAMONT-HAVERS. Well, this is done in a number of ways. First of all, since institutional committees have to give their approval and review projects submitted to HEW involving human subjects, we in turn review that application in our various levels of review within NIH. Obviously if it is seen that problems in that institution have been identified by our own review processes, that signals the fact that something needs to be investigated at that institution.

Mr. ROGERS. Who does more work using human subjects in the Federal Government than any other, would you think? Would it be NIH? Would it be the relationship in Food and Drug or what other agencies of Government?

Dr. LAMONT-HAVERS. The actual numbers of humans involved, the NIH and NIMH would support more fundamental clinical research, which would involve by far the largest number of individuals. How this number would compare to the number of individuals related to the FDA regulation of drugs, I do not know.

Mr. ROGERS. Would you let us know?

Dr. LAMONT-HAVERS. I am not quite sure—

Mr. ROGERS. For the record?

Dr. LAMONT-HAVERS [continuing]. Whether it is possible or not.

Dr. EDWARDS. We will see if we cannot get you answers to some of these questions.

Mr. ROGERS. We will not know how many humans are being used.

Mr. CARTER. Mr. Chairman, on that, every patient in the sense that the physician learns from treatment of his patients and from the patient's reaction to medicine really constitutes research projects.

Mr. ROGERS. I think we are speaking of specific research projects. Are we not?

Dr. LAMONT-HAVERS. Yes.

Mr. ROGERS. You are not speaking of doctors handling their patients outside of the actual research projects?

Dr. LAMONT-HAVERS. No. We are talking about clinical research projects.

Mr. ROGERS. Well, I was not. Would you say that more than half the subjects used in experimentation are detained or do they come from the general population?

Dr. EDWARDS. Say that again, Mr. Chairman.

Mr. ROGERS. Detained. In other words, prison population.

Dr. EDWARDS. I would doubt it but I would say no, but I could not say that with any authority.

Dr. LAMONT-HAVERS. As far as NIH is concerned, this would represent a very small amount.

Mr. ROGERS. Then you are drawing up regulations to improve this.

Dr. LAMONT-HAVERS. Yes, we are.

Mr. ROGERS. Is there any followup on people who are used in human experimentation in IND's, and so forth? What do we do? How do we assure a followup? Or could we?

Dr. EDWARDS. We do not, by and large.

Mr. ROGERS. Should that be done?

Dr. EDWARDS. We are—again, this is a very difficult subject to come to grips with and we have had a number of groups, the National Academy of Science, and others, that have been trying to help us resolve this question and if you do, how do you do it because it involves hundreds and hundreds of thousands of people that ultimately get involved in this and followups that involve many, many years, particularly the cancer, you know, a drug that perhaps ultimately proves to be carcinogenic and then to try to go back and pick up all those people involved in the IND investigation and then follow them over a period, you know, it is a horrendous job and how you do it I am not just sure.

Mr. ROGERS. Is there any responsibility on the investigator to have a followup?

Dr. KELSEY. Well, to the extent that he is required to keep all his records for a certain period of time after the IND itself is either stopped or terminated or becomes an NDA, this permits at least a 2-year period in which if adverse effects are noted, you have records of those persons and they can be traced.

The question as to—you mean, who bears the financial burden?

Mr. ROGERS. Whatever burden there is.

Dr. KELSEY. We feel the sponsor should see that the investigator makes adequate or suitable followups.

Mr. ROGERS. Do you have regulations to that effect?

Dr. KELSEY. These are being also worked on.

Mr. ROGERS. You are thinking about those, too.

Dr. KELSEY. Very definitely, in fact.

Dr. EDWARDS. We are thinking about them but I think we would be frank to say that they are about ready to go because they are far too complex. In the mobility of investigators going from one institution to another and one State to another, et cetera, trying to keep track of this patient population—until we develop some kind of a really drug-monitoring information system that is really far more sophisticated than we have been able to come up with at this point—

Mr. CARTER. Mr. Chairman, on the treatment of cancer is it not true that you have many IND's, many investigational new drugs, that you are trying in the different clinics throughout our country?

Dr. EDWARDS. This is combined between ourselves, FDA, and the National Cancer Institute and they are working together on I do not know how many drugs but I am sure the NCI would have a number of drugs in this chemotherapy program they are testing.

Mr. CARTER. Would that seem to represent an IND?

Dr. KELSEY. I am pretty sure it is, yes.

Mr. CARTER. Well, I am quite sure that it is and it is being used and records are being kept. I know that quite well. On many of the other drugs, very careful records are kept.

Thank you, Mr. Chairman.

Mr. ROGERS. Now, let me ask you this. Is there any reason in the IND process why all of this, the necessary safeguards cannot be taken rapidly and speedily? Is there any reason to allow the requirement, for instance, that you let us know when you have human concept? Can that be done quickly? Is there any reason there has to be delay? Is there any reason they should not report their findings immediately on animal studies or any adverse effects on humans? There is no reason for a delaying factor, is there?

Dr. EDWARDS. If we could monitor these things 100 percent there would not be any reason, but, unfortunately, we cannot or we do not. As a result there is always an investigator here or there who does not follow the regulations as he should.

Mr. ROGERS. Well, now, what can you do with such an investigator, with someone who simply is not going to do their research in an ethical manner? What do you do? How do you find him? When do you take action, before or after, and what effect does it have?

Dr. KELSEY. Well, we find him usually by going out and visiting his office and viewing his patients' records, not the material that he submitted to the company.

Mr. ROGERS. It is triggered by a review, mostly a visit, then.

Dr. KELSEY. Well, we have several ways. Sometimes we have reason to suspect that an investigator may be doing poor work either from our in-house reviewers, from outside information, or the fact that he appears to be doing a great deal of studies or the fact that he is doing studies not in his area of competence, et cetera. We have also now instituted a new program where we randomly visit a number of investigators and the sponsor of a given new drug application—there our studies are directed particularly toward how the investigator is instructed by the sponsor.

Mr. ROGERS. Do you have a regulation that says unethical research studies will not be accepted?

Dr. KELSEY. We have a regulation that indicates how a clinical investigator may be disqualified and if he is disqualified, his studies will not be acceptable. The whole IND must be re-reviewed to see if it can stand up in the absence of his data.

Mr. ROGERS. If everyone knew that you were not going to accept any study that was not done properly, like the journals, would that not be an incentive for less unethical research?

Dr. KELSEY. Well, it certainly is in our regulations. This is one way in which the investigator can be disqualified and the data will not be acceptable and the sponsors are well aware of this and the investigators should be. But this apparently is not a great enough deterrent for some individuals.

Mr. ROGERS. Well, that puts the burden on you. If you have a positive burden on the researcher that he should not submit, that he cannot submit, and we consequently find out something, then it will not be accepted. If they can sneak it by you, they can get it in.

Dr. KELSEY. Well, he does not submit his work, of course, directly to us but to the sponsor and——

Mr. ROGERS. Yes. Now, so it seems to me, you need to look at that mechanism and also a rule. What do you do if you find out he has not gotten consent from these people he did his research on?

Dr. KELSEY. I think we would at first determine why he did not get consent, whether he had determined that his patient was one in which it might be detrimental to him to get it. I cannot offhand think—I am sure there must be examples in which proper consent has not been gotten and there are some in which disqualified investigators failed to get proper consent. This is one of the bases for their disqualification.

Mr. ROGERS. You disqualify them?

Dr. KELSEY. What that means is that they may not receive further shipments of any other investigational drugs. They may not do investigational drug studies while they are disqualified and all the work they have done in the past regardless of whether they have found this to contain inappropriate data or not, is also disqualified as far as that IND or NDA is concerned. So it is a fairly comprehensive——

Mr. ROGERS. How many have you taken action against?

Dr. KELSEY. It is either 14 or 16.

Mr. ROGERS. Would you let us know that for the record and what action was taken and on what basis it was taken and how long it took to act?

Dr. KELSEY. I think we can get that information.

Dr. EDWARDS. We can provide that.

[The information requested was not available to the Committee at the time of printing—September 1974.]

Mr. ROGERS. Are your Federal fund regulations the same for research done here as abroad?

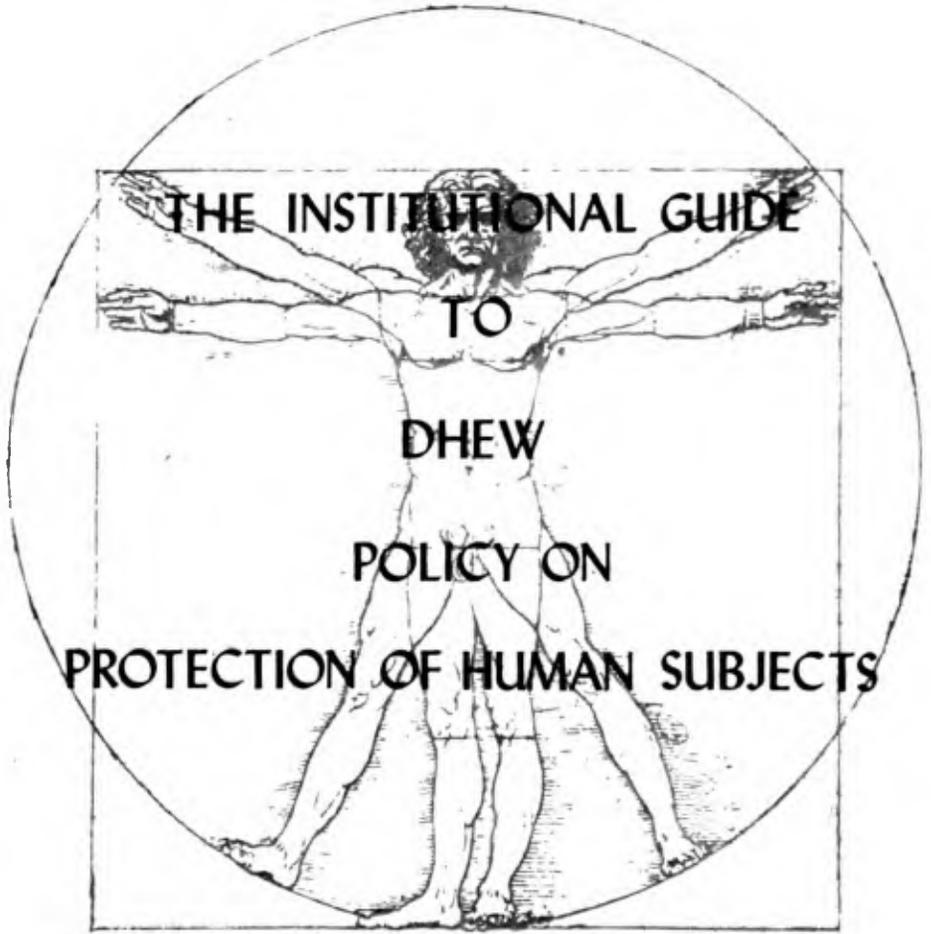
Dr. EDWARDS. No. I think the only—you mean in terms of patient consent, and so forth? We go by the Helsinki rules and regulations for studies that come in from overseas. We have, as you know, just published through—the Food and Drug Administration just published several weeks ago the new regulations as they relate to data that is acceptable from overseas.

Mr. ROGERS. Would you let us have for the record, the difference between the Helsinki requirements and our own?

Dr. EDWARDS. I think the main difference just in a general way is that they do not require—they require consent but not written consent is probably the major, and obviously that is not as easy to——

[Testimony resumes on p. 187.]

[The following information was received for the record:]



U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service **National Institutes of Health**

FOREWORD

The Department's basic policy, quoted in the first few paragraphs of this Guide, is simple in concept. However, simplicity in conception is not always easily translated into simplicity in application. Many of the basic terms of the policy, such as subject, risk, and informed consent, are differently understood in the several professions that participate in the varied grant and contract programs supported by the Department. This Guide provides working definitions of the policy's more critical terms, and outlines flexible operating procedures which can be adapted to a variety of grant and contract mechanisms.

A flexible policy is essential. Research, development, and the reduction to practice of new ideas are not carried out in a practical, ethical, or legal vacuum. The public interest obviously would not be served by an inflexible approach to what can or should be done. Ultimately, the decisions required by this policy must depend upon the common sense and sound professional judgment of reasonable men. The Department's policy and the Guide are intended to provide room for the exercise of this judgment.

In its present form, the Guide reflects several years' experience with an earlier Public Health Service policy. It incorporates many comments and suggestions by representatives of grantee and contractor institutions, and by consultants and staff of the operating agencies of the Department. Future experience in the application of the policy in the fields of health, education, and welfare will simultaneously raise questions and suggest changes. Correspondence should be addressed to the Chief, Institutional Relations Branch, Division of Research Grants, National Institutes of Health, Bethesda, Md. 20014.

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NOTE

Bold face indicates policy as stated in DHEW Grant Administration Manual Chapter 1-40.

Light face indicates interpretation of DHEW policy.

POLICY

Safeguarding the rights and welfare of human subjects involved in activities supported by grants or contracts from the Department of Health, Education, and Welfare is the responsibility of the institution which receives or is accountable to the DHEW for the funds awarded for the support of the activity.

In order to provide for the adequate discharge of this institutional responsibility, it is the policy of the Department that no grant or contract for an activity involving human subjects shall be made unless the application for such support has been reviewed and approved by an appropriate Institutional committee.

This review shall determine that the rights and welfare of the subjects involved are adequately protected, that the risks to an individual are outweighed by the potential benefits to him or by the importance of the knowledge to be gained, and that informed consent is to be obtained by methods that are adequate and appropriate.

In addition the committee must establish a basis for continuing review of the activity in keeping with these determinations.

The institution must submit to the DHEW, for its review, approval, and official acceptance, an assurance of its compliance with this policy. The institution must also provide with each proposal involving human subjects a certification that it has been or will be reviewed in accordance with the institution's assurance.

No grant or contract involving human subjects at risk will be made to an individual unless he is affiliated with or sponsored by an institution which can and does assume responsibility for the protection of the subjects involved.

Since the welfare of subjects is a matter of concern to the Department of Health, Education, and Welfare as well as to the institution, no grant or contract involving human subjects shall be made unless the proposal for such support has been reviewed and approved by an appropriate professional committee within the responsible component of the Department. As a result of this review, the committee may recommend to the operating agency, and the operating agency may require, the imposition of specific grant or contract terms providing for the protection of human subjects, including requirements for informed consent.

APPLICABILITY

A. General

This policy applies to all grants and contracts which support activities in which subjects may be at risk.

B. Subject

This term describes any individual who may be at risk as a conse-

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quence of participation as a subject in research, development, demonstration, or other activities supported by DHEW funds.

This may include patients; outpatients; donors of organs, tissues, and services; informants; and normal volunteers, including students who are placed at risk during training in medical, psychological, sociological, educational, and other types of activities supported by DHEW.

Of particular concern are those subjects in groups with limited civil freedom. These include prisoners, residents or clients of institutions for the mentally ill and mentally retarded, and persons subject to military discipline.

The unborn and the dead should be considered subjects to the extent that they have rights which can be exercised by their next of kin or legally authorized representatives.

C. At Risk

An individual is considered to be "at risk" if he may be exposed to the possibility of harm—physical, psychological, sociological, or other—as a consequence of any activity which goes beyond the application of those established and accepted methods necessary to meet his needs. The determination of when an individual is at risk is a matter of the application of common sense and sound professional judgment to the circumstances of the activity in question. Responsibility for this determination resides at all levels of institutional and departmental review. Definitive determination will be made by the operating agency.

D. Types of Risks and Applicability of the Policy

1. Certain risks are inherent in life itself, at the time and in the places where life runs its course. This policy is not concerned with the ordinary risks of public or private living, or those risks associated with admission to a school or hospital. It is not concerned with the risks inherent in professional practice as long as these do not exceed the bounds of established and accepted procedures, including innovative practices applied in the interest of the individual patient, student or client.

Risk and the applicability of this policy are most obvious in medical and behavioral science research projects involving procedures that may induce a potentially harmful altered physical state or condition. Surgical and biopsy procedures; the removal of organs or tissues for study, reference, transplantation, or banking; the administration of drugs or radiation; the use of indwelling catheters or electrodes; the requirement of strenuous physical exertion; subjection to deceit, public embarrassment, and humiliation are all examples of procedures which require thorough scrutiny by both the Department of Health, Education, and Welfare and institutional committees. In general those projects which involve risk of physical or psychological injury require prior written consent.

2. There is a wide range of medical, social, and behavioral projects and activities in which no immediate physical risk to the subject is involved; e.g., those utilizing personality inventories, interviews, questionnaires, or the use of observation, photographs, taped records, or stored data. However, some of these procedures may involve varying degrees of discomfort, harassment, invasion of privacy, or may constitute a threat to the

subject's dignity through the imposition of demeaning or dehumanizing conditions.

3. There are also medical and biomedical projects concerned solely with organs, tissues, body fluids, and other materials obtained in the course of the routine performance of medical services such as diagnosis, treatment and care, or at autopsy. The use of these materials obviously involves no element of physical risk to the subject. However, their use for many research, training, and service purposes may present psychological, sociological, or legal risks to the subject or his authorized representatives. In these instances, application of the policy requires review to determine that the circumstances under which the materials were procured were appropriate and that adequate and appropriate consent was, or can be, obtained for the use of these materials for project purposes.

4. Similarly, some studies depend upon stored data or information which was often obtained for quite different purposes. Here, the reviews should also determine whether the use of these materials is within the scope of the original consent, or whether consent can be obtained.

E. Established and Accepted Methods

Some methods become established through rigorous standardization procedures prescribed, as in the case of drugs or biologicals, by law or, as in the case of many educational tests, through the aegis of professional societies or nonprofit agencies. Acceptance is a matter of professional response, and determination as to when a method passes from the experimental stage and becomes "established and accepted" is a matter of judgment.

In determining what constitutes an established and accepted method, consideration should be given to both national and local standards of practice. A management procedure may become temporarily established in the routine of a local institution but still fail to win acceptance at the national level. A psychological inventory may be accepted nationally, but still contain questions which are disturbing or offensive to a local population. Surgical procedures which are established and accepted in one part of the country may be considered experimental in another, not due to inherent deficiencies, but because of the lack of proper facilities and trained personnel. Diagnostic procedures which are routine in the United States may pose serious hazards to an undernourished, heavily infected, overseas population.

If doubt exists as to whether the procedures to be employed are established and accepted, the activity should be subject to review and approval by the institutional committee.

F. Necessity to Meet Needs

Even if considered established and accepted, the method may place the subject at risk if it is being employed for purposes other than to meet the needs of the subject. Determination by an attending professional that a particular treatment, test, regimen, or curriculum is appropriate for a particular subject to meet his needs limits the attendant risks to those inherent in the delivery of services, or in training.

On the other hand, arbitrary, random, or other assignment of subjects

to differing treatment or study groups in the interests of a DHEW supported activity, rather than in the strict interests of the subject, introduces the possibility of exposing him to additional risk. Even comparisons of two or more established and accepted methods may potentially involve exposure of at least some of the subjects to additional risks. Any alteration of the choice, scope, or timing of an otherwise established and accepted method, primarily in the interests of a DHEW activity, also raises the issue of additional risk.

If doubt exists as to whether the procedures are intended solely to meet the needs of the subject, the activity should be subject to review and approval by the institutional committee.

INSTITUTIONAL REVIEW

A. Initial Review of Projects

1. Review must be carried out by an appropriate institutional committee. The committee may be an existing one, such as a board of trustees, medical staff committee, utilization committee, or research committee, or it may be specially constituted for the purpose of this review. Institutions may utilize subcommittees to represent major administrative or subordinate components in those instances where establishment of a single committee is impracticable or inadvisable. The institution may utilize staff, consultants, or both.

The committee must be composed of sufficient members with varying backgrounds to assure complete and adequate review of projects and activities commonly conducted by the institution. The committee's membership, maturity, experience, and expertise should be such as to justify respect for its advice and counsel. No member of an institutional committee shall be involved in either the initial or continuing review of an activity in which he has a professional responsibility, except to provide information requested by the committee. In addition to possessing the professional competence to review specific activities, the committee should be able to determine acceptability of the proposal in terms of institutional commitments and regulations, applicable law, standards of professional conduct and practice, and community attitudes.¹ The committee may therefore need to include persons whose primary concerns lie in these areas rather than in the conduct of research, development, and service programs of the types supported by the DHEW.

If an institution is so small that it cannot appoint a suitable committee from its own staff, it should appoint members from outside the institution.

Committee members shall be identified by name, occupation or position, and by other pertinent indications of experience and competence in areas pertinent to the areas of review such as earned degrees, board certifications, licensures, memberships, etc.

Temporary replacement of a committee member by an alternate of comparable experience and competence is permitted in the event a mem-

¹ In the United States, the regulations of the Food and Drug Administration (21 CFR 130) provide that the committee must possess competencies to determine acceptability of the project in these terms in order to review proposals for investigational new drug (IND) studies.

ber is momentarily unable to fulfill committee responsibility. The DHEW should be notified of any permanent replacement or additions.

2. The institution should adopt a statement of principles that will assist it in the discharge of its responsibilities for protecting the rights and welfare of subjects. This may be an appropriate existing code or declaration or one formulated by the institution itself.² It is to be understood that no such principles supersede DHEW policy or applicable law.

3. Review begins with the identification of those projects or activities which involve subjects who may be at risk. In institutions with large grant and contract programs, administrative staff may be delegated the responsibility of separating those projects which do not involve human subjects in any degree; i.e., animal and nonhuman materials studies. However, determinations as to whether any project or activity involves human subjects at risk is a professional responsibility to be discharged through review by the committee, or by subcommittees.

If review determines that the procedures to be applied are to be limited to those considered by the committee to be established, accepted, and necessary to the needs of the subject, review need go no further; and the application should be certified as approved by the committee. Such projects involve human subjects, but these subjects are not considered to be at risk.

If review determines that the procedures to be applied will place the subject at risk, review should be expanded to include the issues of the protection of the subject's rights and welfare, of the relative weight of risks and benefits, and of the provision of adequate and appropriate consent procedures.

Where required by workload considerations or by geographic separation of operating units, subcommittees or mail review may be utilized to provide preliminary review of applications.

Final review of projects involving subjects at risk should be carried out by a quorum of the committee.³ Such review should determine, through review of reports by subcommittees, or through its own examination of applications or of protocols, or through interviews with those individuals who will have professional responsibility for the proposed project or activity, or through other acceptable procedures that the requirements of the institutional assurance and of DHEW policy have been met, specifically that:

a. The rights and welfare of the subjects are adequately protected. Institutional committees should carefully examine applications, protocols, or descriptions of work to arrive at an independent determination of possible risks. The committee must be alert to the possibility that investigators, program directors, or contractors may, quite unintentionally, introduce unnecessary or unacceptable hazards, or fail to provide adequate safeguards. This possibility is particularly true if the project crosses disciplinary lines, involves new and untried procedures, or involves established and accepted procedures which are new to the personnel applying them. Committees must also assure

² Some of the existing codes or statements of principles concerned with the protection of human subjects in research, investigation, and care are listed in attachment C.

³ In the United States, the quorum reviewing investigational new drug studies must satisfy requirements of the Food and Drug Administration (21 CFR 130).

themselves that proper precautions will be taken to deal with emergencies that may develop even in the course of seemingly routine activities.

When appropriate, provision should be made for safeguarding information that could be traced to, or identified with, subjects. The committee may require the project or activity director to take steps to insure the confidentiality and security of data, particularly if it may not always remain under his direct control.

Safeguards include, initially, the careful design of questionnaires, inventories, interview schedules, and other data gathering instruments and procedures to limit the personal information to be acquired to that absolutely essential to the project or activity. Additional safeguards include the encoding or enciphering of names, addresses, serial numbers, and of data transferred to tapes, discs, and printouts. Secure, locked spaces and cabinets may be necessary for handling and storing documents and files. Codes and ciphers should always be kept in secure places, distinctly separate from encoded and enciphered data. The shipment, delivery, and transfer of all data, printouts, and files between offices and institutions may require careful controls. Computer to computer transmission of data may be restricted or forbidden.

Provision should also be made for the destruction of all edited, obsolete or depleted data on punched cards, tapes, discs, and other records. The committee may also determine a future date for destruction of all stored primary data pertaining to a project or activity.

Particularly relevant to the decision of the committees are those rights of the subject that are defined by law. The committee should familiarize itself through consultation with legal counsel with these statutes and common law precedents which may bear on its decisions. The provisions of this policy may not be construed in any manner or sense that would abrogate, supersede, or moderate more restrictive applicable law or precedential legal decisions.

Laws may define what constitutes consent and who may give consent, prescribe or proscribe the performance of certain medical and surgical procedures, protect confidential communications, define negligence, define invasion of privacy, require disclosure of records pursuant to legal process, and limit charitable and governmental immunity (see, e.g., the University of Pittsburgh Law Manual).

b. The risks to an individual are outweighed by the potential benefits to him or by the importance of the knowledge to be gained.

The committee should carefully weigh the known or foreseeable risks to be encountered by subjects, the probable benefits that may accrue to them, and the probable benefits to humanity that may result from the subject's participation in the project or activity. If it seems probable that participation will confer substantial benefits on the subjects, the committee may be justified in permitting them to accept commensurate or lesser risks. If the potential benefits are insubstantial, or are outweighed by risks, the committee may be justified in permitting the subjects to accept these risks in the interests of humanity. The committee should consider the possibility that subjects, or those authorized to represent subjects, may be motivated to accept risks for unsuitable or inadequate reasons. In such instances the consent procedures adopted should incorporate adequate safeguards.

Compensation to volunteers should never be such as to constitute an undue inducement.

No subject can be expected to understand the issues of risks and benefits as fully as the committee. Its agreement that consent can reasonably be sought for subject participation in a project or activity is of paramount practical importance.

"The informed consent of the subject, while often a legal necessity is a goal toward which we must strive, but hardly ever achieve except in the simplest cases."

(Henry K. Beecher, M.D.)

c. The informed consent of subjects will be obtained by methods that are adequate and appropriate.

Note.—In the United States, adherence to the regulations of the Food and Drug Administration (21 CFR 130) governing consent in projects involving investigational new drugs (IND) is required by law.

Informed consent is the agreement obtained from a subject, or from his authorized representative, to the subject's participation in an activity.

The basic elements of informed consent are:

1. A fair explanation of the procedures to be followed, including an identification of those which are experimental;
2. A description of the attendant discomforts and risks;
3. A description of the benefits to be expected;
4. A disclosure of appropriate alternative procedures that would be advantageous for the subject;
5. An offer to answer any inquiries concerning the procedures;
6. An instruction that the subject is free to withdraw his consent and to discontinue participation in the project or activity at any time.

In addition, the agreement, written or oral, entered into by the subject, should include no exculpatory language through which the subject is made to waive, or to appear to waive, any of his legal rights, or to release the institution or its agents from liability for negligence.⁴

Informed consent must be documented (see Documentation, p. 16).

Consent should be obtained, whenever practicable, from the subjects themselves. When the subject group will include individuals who are not legally or physically capable of giving informed consent, because of age, mental incapacity, or inability to communicate, the review committee should consider the validity of consent by next of kin, legal guardians, or by other qualified third parties representative of the subjects' interests. In such instances, careful consideration should be given by the committee not only to whether these third parties can be presumed to have the necessary depth of interest and concern with the subjects' rights and welfare, but also to whether these third parties will be legally authorized to expose the subjects to the risks involved.

⁴ Use of exculpatory clauses in consent documents is considered contrary to public policy. *Tunkl vs. Regents of University of California*, 60 Cal. 2d 92, 32 Cal. Rptr.33, 383 P. 2d 441 (1963), Annot., 6 A.L.R. 3d 693 (1966).

The review committee will determine if the consent required, whether to be secured before the fact, in writing or orally, or after the fact following debriefing, or whether implicit in voluntary participation in an adequately advertised activity, is appropriate in the light of the risks to the subject, and the circumstances of the project.

The review committee will also determine if the information to be given to the subject, or to qualified third parties, in writing or orally, is a fair explanation of the project or activity, of its possible benefits, and of its attendant hazards.

Where an activity involves therapy, diagnosis, or management, and a professional/patient relationship exists, it is necessary "to recognize that each patient's mental and emotional condition is important . . . and that in discussing the element of risk, a certain amount of discretion must be employed consistent with full disclosure of fact necessary to any informed consent."⁵

Where an activity does not involve therapy, diagnosis, or management, and a professional/subject rather than a professional/patient relationship exists, "the subject is entitled to a full and frank disclosure of all the facts, probabilities, and opinions which a reasonable man might be expected to consider before giving his consent."⁶

When debriefing procedures are considered as a necessary part of the plan, the committee should ascertain that these will be complete and prompt.

B. Continuing Review

This is an essential part of the review process. While procedures for continuing review of ongoing projects and activities should be based in principle on the initial review criteria, they should also be adapted to the size and administrative structure of the institution. Institutions which are small and compact and in which the committee members are in day-to-day contact with professional staff may be able to function effectively with some informality. Institutions which have placed responsibility for review in boards of trustees, utilization committees, and similar groups that meet on frequent schedules may find it possible to have projects re-reviewed during these meetings.

In larger institutions with more complex administrative structures and specially appointed committees, these committees may adopt a variety of continuing review mechanisms. They may involve systematic review of projects at fixed intervals, or at intervals set by the committee commensurate with the project's risk. Thus, a project involving an untried procedure may initially require reconsideration as each subject completes his involvement. A highly routine project may need no more than annual review. Routine diagnostic service procedures, such as biopsy and autopsy, which contribute to research and demonstration activities generally require no more than annual review. Spot checks may be used to supplement scheduled reviews.

Actual review may involve interviews with the responsible staff, or

⁵ *Salgo vs. Leland Stanford Jr. University Board of Trustees* (154 C.A. 2nd 560; 317 P. 2d 1701).

⁶ *Halushka vs. University of Saskatchewan*, (1965) 53 D.L.R. (2d).

review of written reports and supporting documents and forms. In any event, such review must be completed at least annually to permit certifications of review on noncompeting continuation applications.

C. Communication of the Committee's Action, Advice, and Counsel

If the committee's overall recommendation is favorable, it may simultaneously prescribe restrictions or conditions under which the activity may be conducted, define substantial changes in the research plans which should be brought to its attention, and determine the nature and frequency of interim review procedures to insure continued acceptable conduct of the research.

Favorable recommendations by an institutional committee are, of course, always subject to further appropriate review and rejection by institution officials.

Unfavorable recommendations, restrictions, or conditions cannot be removed except by the committee or by the action of another appropriate review group described in the assurance filed with the Department of Health, Education, and Welfare.

Staff with supervisory responsibility for investigators and program directors whose projects or activities have been disapproved or restricted, and institutional administrative and financial officers should be informed of the committee's recommendations. Responsible professional staff should be informed of the reasons for any adverse actions taken by the institutional committee.

The committee should be prepared at all times to provide advice and counsel to staff developing new projects or activities or contemplating revision of ongoing projects or disapproved proposals.

D. Maintenance of an Active and Effective Committee

Institutions should establish policy determining overall committee composition, including provisions for rotation of memberships and appointment of chairmen. Channels of responsibility should be established for implementation of committee recommendations as they may affect the actions of responsible professional staff, grants and contracts officers, business officers, and other responsible staff. Provisions should be made for remedial action in the event of disregard of committee recommendations.

ASSURANCES

A. Negotiation of Assurances

An institution applying to the DHEW for a grant or contract involving human subjects must provide written assurance that it will abide by DHEW policy. The assurance shall embody a statement of compliance with DHEW requirements for initial and continuing committee review of the supported activities; a set of implementing guidelines, including identification of the committee, and a description of its review procedures or, in the case of special assurances concerned with single projects or activities, a report of initial findings and pro-

posed continuing review procedures. Institutions that have not previously filed assurances should request instructions for the preparation of an assurance from the Division of Research Grants, National Institutes of Health.

Negotiation of assurances is the responsibility of the DRG, NIH. Negotiation will be initiated on receipt of a copy of a grant application, a contract proposal, or other documentation identifying the project and the offeror or sponsoring institution.

Assurances will not be accepted from institutions or institutional components which do not have control over the expenditure of DHEW grant or contract funds unless they are an active part of a cooperative project or activity.

An assurance will be accepted only after review and approval by the DRG, NIH.

B. Types of Assurance

Assurances may be one of two types:

1. *General assurance.*—A general assurance describes the review and implementation procedures applicable to all DHEW-supported activities within an institution, regardless of the number, location, or types of its components (see attachment A). General assurances will be required from institutions having a significant number of concurrent DHEW projects or activities involving human subjects.

2. *Special assurance.*—A special assurance will, as a rule, describe those review and implementation procedures applicable to a single project or activity (see attachment B). Special assurances may also be approved in modified forms to meet unusual requirements either of the operating agency or of the institution receiving a grant or contract. Special assurances are not to be solicited from institutions which have accepted general assurances on file.

C. Minimum Requirements for General Assurances

1. *Statement of compliance.*—A formal statement of compliance with DHEW policy must be executed by an appropriate institutional official.

2. *Implementing guidelines.*—The institution must include as part of its assurance implementing guidelines that specifically provide for:

a. The statement of principles that will assist the institution in the discharge of its responsibilities for protecting the rights and welfare of subjects. This may be an appropriate existing code or declaration or one formulated by the institution itself.

b. A committee or committee structure which will conduct initial and continuing reviews. Committee members shall be identified by name, occupation or position, and by other pertinent indications of experience and competence in areas pertinent to the areas of review such as earned degrees, board certifications, licensures, memberships, etc.

c. The procedures which the institution will follow in carrying out its initial and continuing review of proposals and activities to insure that:

- (1) The rights and welfare of subjects are adequately protected;
- (2) The risks to subjects are outweighed by potential benefits;
- (3) The informed consent of subjects will be obtained by methods that are adequate and appropriate.

d. The procedures which the committee will follow to provide advice and counsel to project and program directors with regard to the committee's actions as well as the requirement for reporting to the committee any emergent problems or proposed procedural changes.

e. The procedures which the institution will follow to maintain an active and effective committee and to implement its recommendations.

D. Minimum Requirements for Special Assurance

An acceptable special assurance covering a single activity consists of a properly completed statement of compliance, similar to that illustrated by attachment B. This assurance shall identify the specific grant or contract involved by its number, if known; by its full title; and by the name of the project or program director, principal investigator, fellow, or other person immediately responsible for the conduct of the activity. The assurance shall be signed by a committee of not fewer than three members and executed by an appropriate institutional official. The committee shall describe in general terms those risks to the subject that it recognizes as inherent in the activity. Consent procedures to be used are to be described. Any consent statement to be signed, heard, or read by the subject or responsible third parties should be attached. The assurance should outline the circumstances under which the director or investigator will be required to inform the committee of proposed changes in the activity, or of emergent problems involving human subjects. The assurance should also indicate whether the director or investigator will be required to submit written reports, appear for interview, or be visited by the committee or committees to provide for continuing review. It should also indicate the intervals at which such reviews will take place.

TIMING AND CERTIFICATION OF INSTITUTIONAL REVIEW

A. General Assurances

1. *Timely review.*—All proposals involving human subjects submitted by institutions with accepted general assurances should, whenever possible, be given institutional review and approval prior to submission to the DHEW. The proposal or application should be appropriately marked in the spaces provided on forms, or the following statement should be typed on the lower or right hand margin of the page bearing the name of the institutional official authorized to sign or execute applications or proposals for the institution:

"HUMAN SUBJECTS—REVIEWED AND APPROVED ON ____ (date) ____."
(This date should be no more than 90 days prior to the submission date, and must not be more than 12 months prior to the proposed starting date.)

2. *Pending review.*—If it will be necessary to delay the review, the

proposal is to be appropriately marked in the spaces provided on forms, or the following statement is to be typed in the lower or right hand margin of the page bearing the name of the institutional official authorized to sign or execute applications or proposals for the institution:

"HUMAN SUBJECTS—REVIEW PENDING ON ____ (date) ____."

(This date should be at least one month earlier than the proposed starting date of the project to avoid possible conflict with the award date.)

3. *Completion of pending review.*—Review should be initiated as soon as possible after the submission of the proposal so that final action can be completed prior to the pending review date. If this final action is disapproval, or is approval contingent on substantive changes in the proposal, the operating agency is to be notified promptly by telegram; an immediate confirmatory letter; and, where appropriate, by withdrawal of the application from further consideration by the agency.

4. *Institutional review of proposals lacking definite plans or specifications for the involvement of human subjects.*—Certain types of proposals are submitted with the knowledge that human subjects are to be involved within the project period, but definite plans for this involvement cannot properly be included in the proposal. These include (1) certain training grants where trainee projects remain to be selected, and (2) research, pilot, or developmental studies in which involvement depends upon such things as the completion of instruments, or of prior animal studies, or upon the purification of compounds.

Such proposals should be reviewed and certified in the same manner as more complete proposals. The initial certification indicates institutional approval of the applications as submitted, and commits the institution to later review of the plans when completed. Such later review should be completed prior to the beginning of the budget period during which actual involvement of human subjects is to begin.

5. *Institutional review of proposals not submitted with the intent of involving human subjects.*—If a proposal, at the time it is submitted to the DHEW, does not anticipate involving or intend to involve human subjects, no certification should be submitted. In those instances, however, where funds are awarded in response to the proposal and it later becomes appropriate to use all or parts of these funds for activities which will involve human subjects, such use must be reviewed and approved in accordance with the institutional assurance prior to the use of subjects:

a. Where support is provided by project grants or contracts, review and approval of such changes must be certified to the awarding agency or contracting agency, together with a description of the proposed change in the project plan or contract workscope. Subjects should not be used prior to receipt of approval from agency staff or from the project officer concerned.

b. Where support is provided by a mandatory grant or institutional grant, in which cases the institution determines within broad guidelines the project or activities supported, including the use of human

subjects (i.e., general research support grants, clinical research center projects), review must be carried out in accordance with the institutional assurance. Certification for individual projects need not be forwarded to the awarding agency.

Whenever the committee is uncertain as to whether a change should or should not be reported, the question should be referred to the operating agency concerned.

All certifications are subject to verification by DHEW representatives authorized to examine institutional and committee records.

B. Special Assurances

When a special assurance is submitted, it provides certification for the initial grant or contract period concerned. No additional documentation is required. If the terms of the grant or contract provide for additional years of support, with annual obligation or funds, the noncompeting renewal application or proposal shall be certified in the manner described in the preceding section.

COOPERATIVE ACTIVITIES

Cooperative activities are those which involve other than the grantee or prime contractor (such as a contractor under a grantee or a subcontractor under a prime contractor). In such instances the grantee or prime contractor may obtain access to all or some of the human subjects involved through the cooperating institution. Regardless of the distances involved and the nature of the cooperative arrangement, the basic DHEW policy applies and the grantee or prime contractor remains responsible for safeguarding the rights and welfare of the subjects. The manner in which this responsibility can be discharged depends on whether the grantee or contractor holds an institutional general assurance or an institutional special assurance.

A. Institutions with General Assurances

1. Initial and continuing institutional review may be carried out by one or a combination of procedures:

- By the grantee's or contractor's committee;
- By the committee reviews conducted at both institutions; or
- Through cooperation of appropriate individuals or committees representing the cooperating institution.

The procedures to be followed must be made a matter of record in the institutional files for the grant or contract before funds are released by the grantee or contractor for the cooperative project. There are three relationships that may govern in reference to the cooperating institution:

a. Cooperating institutions with accepted general assurances

When the cooperating institution has on file with the DHEW an accepted general assurance, the grantee or contractor may request the cooperator to conduct its own independent review and to report to the grantee's or contractor's committee the cooperating committee's recommendations on those aspects of the activity that concern indi-

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viduals for whom the cooperating institution has responsibility in accordance with its own assurance. The grantee or contractor may, at its discretion, concur with or further restrict the recommendations of the cooperating institution. It is the responsibility of the grantee or contractor to maintain communication with the cooperating institutional committees. The cooperating institution should promptly notify the grantee or contracting institution whenever the cooperating institution finds the conduct of the project or activity within its purview unsatisfactory.

b. Cooperating institution with no accepted general assurance. When the cooperating institution does not have an accepted assurance on file with the DHEW, the awarding agency concerned may request the DRG, NIH, to negotiate an assurance.

c. Interinstitutional joint reviews.—The grantee or contracting institution may wish to develop an agreement with cooperating institutions to provide for a review committee with representatives from cooperating institutions. Representatives of cooperating institutions may be appointed as *ad hoc* members of the grantee or contracting institution's existing review committee or, if cooperation is on a frequent or continuing basis as between a medical school and a group of affiliated hospitals, appointments may be made permanent. Under some circumstances component subcommittees may be established within cooperating institutions. All such cooperative arrangements must be accepted by the Department as part of a general assurance, or as an amendment to a general assurance, or in unusual situations as determined by the DRG, NIH, as a special assurance.

B. Institutions with Special Assurances

While responsibility for initial and continuing review necessarily lies with the contractor, the DHEW will also require acceptable assurances from those cooperating institutions having immediate responsibility for subjects.

If the cooperating institution has on file with the DHEW an accepted general assurance, the contractor shall request the cooperator to conduct its own independent review of those aspects of the project or activity which will involve human subjects for which it has immediate responsibility. Such a request shall be in writing and should provide for direct notification of the contractor's committee in the event that the cooperator's committee finds the conduct of the activity unsatisfactory.

If the cooperating institution does not have an accepted general assurance on file with the DHEW, the operating agency concerned must request the DRG, NIH, to negotiate an assurance.

INSTITUTIONAL ADMINISTRATION OF ASSURANCES

A. Institutional Responsibility

The grantee or contracting institution's administration is accountable to the Department for effectively carrying out the provisions of the institutional assurance for the protection of human subjects as ac-

cepted and recognized by the Department. Revisions in the institutional assurance, including the implementing procedures, are to be reported to the Department prior to the date such revisions become effective. Revision without prior notification may result in withdrawal of departmental recognition of the institution's assurance.

B. Executive Functions

Specific executive functions to be conducted by the Institutional administration include institutional policy formulation, development, promulgation, and continuing indoctrination of personnel. Appropriate administrative assistance and support must be provided for the committee's functions. Implementation of the committee's recommendations through appropriate administrative action and followup is a condition of acceptance of an assurance. Committee approvals and recommendations are, of course, subject to review and to disapproval or further restriction by institutional officials. Committee disapprovals, restrictions, or conditions cannot be rescinded or removed except by action of the committee or another appropriate review group as described and accepted in the assurance filed with the Department.

C. Assurance Implementation

Under no circumstances shall proposed activity plans, not approved by the committee, be implemented with Department funds. The principal Investigator, program or project director, or other responsible staff must be notified as promptly as possible of committee actions, including any restrictive recommendations made by the institutional committee or the administration. They must also be informed and reminded of their continuing responsibility to bring to the attention of the committee any proposed significant changes in project or activity plans or any emergent problems that will affect human subjects. Where continuing review of projects involves the channels of administrative authority in the institution, notification of committee actions should be sent through these channels. Establishment of mechanisms for consultation and appeal by investigators and subjects may be an important condition of acceptance of an assurance by the Department.

D. Documentation

1. *General.*—Development of appropriate documentation and reporting procedures is an essential administrative function. The files must include copies of all documents presented or required for initial and continuing review by the institutional review committee and transmittals on actions, instructions, and conditions resulting from review committee deliberations addressed to the activity director are to be made part of the official institutional files for the supported activity. Committee meeting minutes including records of discussions of substantive issues and their resolution are to be retained by the institution and be made available upon request to representatives of the DHEW.

2. Informed consent.—An institution proposing to place any individual at risk is obligated to obtain and document his informed consent; the terms "at risk" and "informed consent" will apply as defined previously.

The actual procedure in obtaining informed consent and the basis for committee determinations that the procedures are adequate and appropriate are to be fully documented. The documentation will follow one of the following three forms:

a. Provision of a written consent document embodying all of the basic elements of informed consent. *This form is to be signed by the subject or his authorized representative.* A sample of the form as approved by the committee is to be retained in its records. Completed forms are to be handled in accordance with institutional practice.

b. Provision of a "short" form written consent document indicating that the basic elements of informed consent have been presented orally to the subject. Written summaries of what is to be said to the patient are to be approved by the committee. *The "short" form is to be signed by the subject or his authorized representative and an auditor-witness to the oral presentation and to the subject's or his authorized representative's signature.* A copy of the approved summary, annotated to show any additions, is to be signed by the persons obtaining the consent on behalf of the institution and by the auditor-witness. Sample copies of the consent form and of the summaries as approved by the committee are to be retained in its records. Completed forms are to be handled in accordance with institutional practice.

c. Modification of either of the above two primary procedures. *All such modifications must be approved by the committee in the minutes signed by the committee chairman.* Granting of permission to use modified procedures imposes additional responsibility upon the review committee and the institution to establish that the risk to any subject is minimum, that use of either of the primary procedures for obtaining informed consent would surely invalidate objectives of considerable immediate importance, and that any reasonable alternative means for attaining these objectives would be less advantageous to the subject.

The committee's reasons for permitting modification or elimination of any of the six basic elements of informed consent, or for altering requirements for a subject's signature, or for signature of an auditor-witness, or for substitution (i.e., debriefing), or other modification of full, complete, written prior consent, must be individually and specifically documented in the minutes and in reports of committee actions to the institutional files. Approval of any such modifications should be regularly reconsidered as a function of continuing review and as required for annual review, with documentation of reaffirmation, revision, or discontinuation as appropriate.

3. Reporting to DHEW.—No routine reports to DHEW are required. Significant changes in policy, procedure, or committee structure shall, however, be promptly reported to the DRG, NIH, for review and acceptance. Review of these changes or of institutional and other records of performance under the terms and conditions of DHEW

policy, may require renegotiation of the assurance or such other action as may be appropriate.

ENFORCEMENT

The DRG, NIH, will follow up reports by reviewers, evaluators, consultants, and staff of the DHEW indicating concern for the welfare of subjects involved in approved and funded grants or contracts, and of subjects potentially involved in activities approved but not funded, and in disapproved proposals. On the basis of these reports and of other sources of information, the DRG, NIH, may, in collaboration with the operating agency concerned, correspond with or visit institutions to discuss correction of any apparent deficiencies in its implementation of the procedures described in its institutional assurance.

If, in the judgment of the Secretary, an institution has failed in a material manner to comply with the terms of this policy with respect to a particular DHEW grant or contract, he may require that it be terminated in the manner provided for in applicable grant or procurement regulations. The institution shall be promptly notified of such finding and of the reason therefor.

If, in the judgment of the Secretary, an institution fails to discharge its responsibilities for the protection of the rights and welfare of the individuals in its care, whether or not DHEW funds are involved, he may question whether the institution and the individuals concerned should remain eligible to receive future DHEW funds for activities involving human subjects. The institution and individuals concerned shall be promptly notified of this finding and of the reasons therefor.

DEPARTMENTAL REVIEW OF ASSURANCES

All assurances submitted for approval are to be forwarded to the DRG, NIH, for review and acceptance on behalf of the Department. Review will be principally concerned with the adequacy of the proposed committee in the light of the probable scope of the applicant institution's activities, and with the appropriateness of the proposed initial and continuing review in the light of the probable risks to be encountered, the types of subject populations involved, and the size and complexity of the institution's administration. Institutions submitting inadequate assurances will be informed of deficiencies. The appropriate operating agency will be kept informed, on request, of the status and acceptance of an assurance.

ATTACHMENT A

EXAMPLE OF A STATEMENT OF COMPLIANCE

PART ONE OF A GENERAL INSTITUTIONAL ASSURANCE

The (name of institution) will comply with the policy for the protection of human subjects participating in activities supported directly or indirectly by grants or contracts from the Department of Health, Education, and Welfare. In fulfillment of its assurance:

This institution will establish and maintain a committee competent to review projects and activities that involve human subjects. The committee will be assigned responsibility to determine for each activity as planned and conducted that:

The rights and welfare of subjects are adequately protected.

The risks to subjects are outweighed by potential benefits.

The informed consent of subjects will be obtained by methods that are adequate and appropriate.

This institution will provide for committee reviews to be conducted with objectivity and in a manner to ensure the exercise of independent judgment of the members. Members will be excluded from reviews of projects or activities in which they have an active role or a conflict of interests.

This institution will encourage continuing constructive communication between the committee and the project directors as a means of safeguarding the rights and welfare of subjects.

This institution will provide for the facilities and professional attention required for subjects who may suffer physical, psychological, or other injury as a result of participation in an activity.

This institution will maintain appropriate and informative records of committee reviews of applications and active projects, of documentation of informed consent, and of other documentation that may pertain to the selection, participation, and protection of subjects and to reviews of circumstances that adversely affect the rights or welfare of individual subjects.

This institution will periodically reassure itself through appropriate administrative overview that the practices and procedures designed for the protection of the rights and welfare of subjects are being effectively applied and are consistent with its assurance as accepted by the Department of Health, Education, and Welfare.

Official signing for the Institution

Signature _____

Title _____

Date _____

Enclosure: Implementing Guidelines, Part Two of a General Institutional Assurance.

ATTACHMENT B

**EXAMPLE OF A SPECIAL INSTITUTIONAL ASSURANCE
AND CERTIFICATION OF REVIEW OF
SINGLE PROJECTS INVOLVING HUMAN SUBJECTS**

- (0) The (name of institution) will comply with the provisions of the Department of Health, Education, and Welfare policy as outlined in the "Institutional Guide to DHEW Policy on Protection of Human Subjects." This institution has established a committee competent to review the project or activity identified below. The committee's membership, maturity, and expertise assure respect for its advice and counsel. No member of the committee has a vested professional interest in the project or activity that will conflict with the need for independent review for the purpose of safeguarding the rights and welfare of subjects.

The initial review of the proposal identified as (give proposed title, project director's or investigator's or fellow's name, and grant or contract or RFP number as applicable) indicates that:

- (1) In the opinion of this committee the risks to the rights and welfare of the subjects in this project or activity are:
The committee agrees that the following safeguards against these risks are adequate:
- (2) In the opinion of the committee the potential benefits of this activity to the subjects outweigh any probable risks. This opinion is justified by the following reasons:
- (3) In the opinion of the committee the following informed consent procedures based upon the six elements of informed consent as noted will be adequate and appropriate. Documentation is attached:
- (4) The committee agrees to arrange for a continuing exchange of information and advice between itself and the investigator or director, particularly to the criteria cited above. This exchange will be implemented by the following procedures:
- (5) The signatures, names, and occupations or titles of the members of the committee are listed below. None of these signatories have a vested or professional interest in this project or activity that conflicts with the need for independent review.

Signature	Name	Occupation or Title
Signature	Name	Occupation or Title
Signature	Name	Occupation or Title
Signature	Name	Occupation or Title

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(Add as many signature spaces as necessary. Review of projects involving investigational new drugs (IND's) requires a minimum of two persons licensed to administer drugs and one person not so licensed. Review for other purposes should utilize committees of equal or greater breadth.)

Date of Committee Approval _____

I certify that this review was carried out in accordance with the provisions of DHEW policy.

(6) Official signing for institution _____

Signature

Name

Title

Institution

Address

Telephone Number

Date

ATTACHMENT B INSTRUCTIONS

An acceptable special institutional assurance consists of a properly completed formal statement of compliance with Department of Health, Education, and Welfare policy (see attachment B), signed by a committee of not less than three members and by an official authorized to sign for the institution. The explanatory paragraphs which follow refer to the corresponding section of the attachment.

- (0) This should identify the application for a grant, contract, or award by its identifying number, where known, or by its full title. The name should be that of the investigator, program director, fellow, or other individual immediately responsible for the conduct of the work.
- (1) The committee should identify in general terms those risks that it recognizes as probable occurrences; i.e., "Aggravation of anxiety status through contact with interviewers," "Preservation of confidentiality of data," "Renal injury subsequent to multiple biopsy," "Possibility of side reactions to drugs," "Possible local hematosis and nerve injury associated with venipuncture."
- (2) The committee should identify the benefits to the subject or to mankind in general that will accrue through the subject's participation in the project. This should be followed by a brief discussion, weighing the risks against the benefits.
- (3) Consent procedures should be described and the minimum statement to be used should be attached. "Students responding to the attached advertisement will be interviewed." "The project outline will be submitted to the executive council of the PTA." "Individual teachers will be asked to allow an observer in the rooms chosen." "Superintendents of several State mental hospitals will be approached. The attached statement to the next of kin or guardian will be signed by the principal investigator and the superintendent." "The following special consent form will be signed by each subject and his or her spouse or next of kin before acceptance of the subject." "No prior consent will be sought. The following debriefing schedule will be followed within 30 minutes after completion of the test."
- (4) This should indicate whether the investigator or director will be required to submit written reports, or to appear for interviews, or will be visited by the committee or committee representatives, and at approximately what intervals these steps will be carried out.
- (5) No further explanation is necessary. (The committee must be composed of sufficient members with varying backgrounds to assure complete and adequate review of the project. The committee may be an existing one, or one especially appointed for the purpose. The institution may utilize staff, consultants, or both. The membership should possess not only broad competence to comprehend the nature of the project, but also other competencies necessary in the judgments as to acceptability of the project or activity in terms of institutional regulations, relevant law, standards of professional practice, and community acceptance. The com-

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mittee's maturity and experience should be such as to justify respect for its advice and counsel.)

(No individual involved in the conduct of the project shall participate in its review, except to provide information to the committee.)

(Committee members should be identified in the assurance by name, positions, earned degrees, board certifications, licensures, memberships, and other indications of experience, competence, and interest.)

The completed assurance should be attached to the application, or returned directly to the office requesting its submission.

ATTACHMENT C

Codes or statements of principles which are concerned with the protection of human subjects in research, investigation, and care have been issued by:

<u>Organization</u>	<u>Code; adoption date</u>	<u>Reference</u>
World Medical Association 10 Columbus Circle New York, N.Y. 10019 (code available from AMA; see address listed herein)	The Declaration of Hel- sinki; Recommendations Guiding Doctors in Clini- cal Research; 1964	J.A.M.A., 197(11):32, Sept. 12, 1966
Nuernberg Military Tri- bunals: U.S. v. Karl Brandt	Text from which the "Nuernberg Code" is derived.	Trials of War Criminals Before the Nuernberg Military Tribunals, vol. II, pp. 181-82; GPO 1949
American Medical Associa- tion 535 North Dearborn Street Chicago, Ill. 60610	AMA Ethical Guidelines for Clinical Investiga- tion; Nov. 30, 1966	←
(British) Medical Research Council 20 Park Crescent London W.1, England	Responsibility in Investiga- tions on Human Sub- jects; 1964	Report of the Medical Re- search Council for 1962- 1963, (Cmnd. 2382), pp. 21-25
(Canadian) Medical Re- search Council Montreal Road Ottawa 7, Ontario, Canada	Medical Research Council; Extramural Programme; 1966	←
American Association on Mental Deficiency 5201 Connecticut Avenue, N.W. Washington, D. C. 20015	Statement on the Use of Human Subjects for Re- search; May 1969	American Journal of Mental Deficiency, 74 (1):157, July 1969
American Nurses' Associa- tion 10 Columbus Circle New York, N.Y. 10019	The Nurse in Research; ANA Guidelines on Ethic- al Values; January 1968	←
American Personnel and Guidance Association 1607 New Hampshire Ave- nue, N.W., Washington, D.C. 20009	American Personnel and Guidance Association; Code of Ethical Stand- ards; no date specified	←
American Psychological As- sociation, Inc. 1200 17th Street, N.W. Washington, D.C. 20036	Ethical Standards of Psy- chologists; Copyrighted January 1963	American Psychologist, 18 (1):56-60, January 1963
International League of Societies for the Men- tally Handicapped 12 Rue Forestiere Brussels 5, Belgium	Declaration of General and Special Rights of the Mentally Retarded; Oct. 24, 1968	←

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<u>Organization</u>	<u>Code; adoption date</u>	<u>Reference</u>
National Association of Social Workers 2 Park Avenue New York, N.Y. 10016	NASW Code of Ethics; Oct. 13, 1968	←
American Anthropological Association 1703 New Hampshire Avenue, NW. Washington, D.C. 20009	Principles of Professional Responsibility; May, 1971	←
American Sociological Association 1722 N Street, NW. Washington, D.C. 20036	Code of Ethics September 1, 1971	←
Catholic Hospital Association St. Louis, Missouri 63104	Ethical and Religious Directives for Catholic Health Facilities September, 1971	←
Commission on Synagogue Relations Federation of Jewish Philanthropies of New York 130 East 59th Street New York, N.Y. 10022	A Hospital Compendium 1969	←

DECLARATION OF HELSINKI—RECOMMENDATIONS GUIDING DOCTORS IN CLINICAL RESEARCH ADOPTED BY THE WORLD MEDICAL ASSOCIATION IN 1964: AND AMA ETHICAL GUIDELINES FOR CLINICAL INVESTIGATION

[Publication of the American Medical Association]

DECLARATION OF HELSINKI—RECOMMENDATION. GUIDING DOCTORS IN CLINICAL RESEARCH

Introduction

It is the mission of the doctor to safeguard the health of the people. His knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of The World Medical Association binds the doctor with the words: "The health of my patient will be my first consideration" and the International Code of Medical Ethics which declares that "Any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest."

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, The World Medical Association has prepared the following recommendations as a guide to each doctor in clinical research. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Doctors are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

In the field of clinical research a fundamental distinction must be recognized between clinical research in which the aim is essentially therapeutic for a patient, and the clinical research, the essential object of which is purely scientific and without therapeutic value to the person subjected to the research.

I. Basic Principles

1. Clinical research must conform to the moral and scientific principles that justify medical research and should be based on laboratory and animal experiments or other scientifically established facts.
2. Clinical research should be conducted only by scientifically qualified persons and under the supervision of a qualified medical man.
3. Clinical research cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
4. Every clinical research project should be preceded by careful assessment of inherent risks in comparison to foreseeable benefits to the subject or to others.
5. Special caution should be exercised by the doctor in performing clinical research in which the personality of the subject is liable to be altered by drugs or experimental procedure.

II. Clinical Research Combined With Professional Care

1. In the treatment of the sick person, the doctor must be free to use a new therapeutic measure, if in his judgment it offers hope of saving life, reestablishing health, or alleviating suffering.

If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation. In case of legal incapacity, consent should also be procured from the legal guardian; in case of physical incapacity the permission of the legal guardian replaces that of the patient.

2. The doctor can combine clinical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that clinical research is justified by its therapeutic value for the patient.

III. Non-Therapeutic Clinical Research

1. In the purely scientific application of clinical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom clinical research is being carried out.

2. The nature, the purpose and the risk of clinical research must be explained to the subject by the doctor.

3a. Clinical research on a human being cannot be undertaken without his free consent after he has been informed: if he is legally incompetent, the consent of the legal guardian should be procured.

3b. The subject of clinical research should be in such a mental, physical and legal state as to be able to exercise fully his power of choice.

3c. Consent should, as a rule, be obtained in writing. However, the responsibility for clinical research always remains with the research worker; it never falls on the subject even after consent is obtained.

4a. The investigator must respect the right of each individual to safeguard his personal integrity, especially if the subject is in a dependent relationship to the investigator.

4b. At any time during the course of clinical research the subject or his guardian should be free to withdraw permission for research to be continued.

The investigator or the investigating team should discontinue the research if in his or their judgment it may, if continued, be harmful to the individual.

We, the undersigned medical organization, endorse the ethical principles set forth in the Declaration of Helsinki by the World Medical Association concerning human experimentation. These principles supplement the principles of medical ethics to which American physicians already subscribe.

American Federation for Clinical Research
 American Society for Clinical Investigation
 Central Society for Clinical Research
 American College of Physicians
 American College of Surgeons
 Society for Pediatric Research
 American Academy of Pediatrics
 American Medical Association

ETHICAL GUIDELINES FOR CLINICAL INVESTIGATION

(Adopted by House of Delegates, American Medical Association Nov. 30, 1966)

At the 1966 Annual Convention of its House of Delegates, the American Medical Association endorsed the ethical principles set forth in the 1964 *Declaration of Helsinki* of the World Medical Association concerning human experimentation. These principles conform to and express fundamental concepts already embodied in the *Principles of Medical Ethics* of the American Medical Association.

The following guidelines, enlarging on these fundamental concepts, are intended to aid physicians in fulfilling their ethical responsibilities when they engage in the clinical investigation of new drugs and procedures.

1. A physician may participate in clinical investigation only to the extent that his activities are a part of a systematic program competently designed, under accepted standards of scientific research, to produce data which is scientifically valid and significant.

2. In conducting clinical investigation, the investigator should demonstrate the same concern and caution for the welfare, safety and comfort of the person involved as is required of a physician who is furnishing medical care to a patient independent of any clinical investigation.

3. In clinical investigation *primarily for treatment*—

A. The physician must recognize that the physician-patient relationship exists and that he is expected to exercise his professional judgment and skill in the best interest of the patient.

B. Voluntary consent must be obtained from the patient, or from his legally authorized representative if the patient lacks the capacity to consent, following: (a) disclosure that the physician intends to use an investigational drug or experimental procedure, (b) a reasonable explanation of the nature of the drug or procedure to be used, risks to be expected, and possible therapeutic benefits, (c) and offer to answer any inquiries concerning the drug or procedure, and (d) a disclosure of alternative drugs or procedures that may be available.

1. In exceptional circumstances and to the extent that disclosure of information concerning the nature of the drug or experimental procedure or risks would be expected to materially affect the health of the patient and would be detrimental to his best interests, such information may be withheld from the patient. In such circumstances such information shall be disclosed to a responsible relative or friend of the patient where possible.

ii. Ordinarily, consent should be in writing, except where the physician deems it necessary to rely upon consent in other than written form because of the physical or emotional state of the patient.

iii. Where emergency treatment is necessary and the patient is incapable of giving consent and no one is available who has authority to act on his behalf, consent, is assumed.

4. In clinical investigation *primarily for the accumulation of scientific knowledge*—

A. Adequate safeguards must be provided for the welfare, safety and comfort of the subject.

B. Consent, in writing, should be obtained from the subject, or from his legally authorized representative if the subject lacks the capacity to consent, following: (a) a disclosure of the fact that an investigational drug or procedure is to be used, (b) a reasonable explanation of the nature of the procedure to be used and risks to be expected, and (c) an offer to answer any inquiries concerning the drug or procedure.

C. Minors or mentally incompetent persons may be used as subjects only if:

i. The nature of the investigation is such that mentally competent adults would not be suitable subjects.

ii. Consent, in writing, is given by a legally authorized representative of the subject under circumstances in which an informed and prudent adult would reasonably be expected to volunteer himself or his child as a subject.

D. No person may be used as a subject against his will.

Mr. ROGERS. Well, I have a letter here which is a copy sent to me from Dr. Dripps dated September 24, 1973, written to Commissioner Schmidt. This letter is critical, saying that the drug companies now are moving overseas to do their phase 1 research more and more because of the problems involved in time and expense and the fact that it takes so long to get action from the regulatory agency—FDA.

Now, he documents some of his criticisms, saying that because of the slow manner in which we are handling things, and consequently not making timely decisions, that we find research in the United States is diminishing. For instance, the moneys spent by U.S. companies in the drug field, are decreasing whereas the R. & D. expenditures in the United Kingdom are at 17-percent increase, in Japan, 22-percent increase, Sweden, 13.5-percent increase and ours is only a 10-percent increase.

Now, in all probability, he says, the U.S. increase is taken up just by inflation and by the need for retesting old products rather than the search for totally new products. Further evidence of this static condition of drug R. & D. in this country is reflected in R. & D. manpower which has not increased the last 4 years.

Now, comparable data is not yet available for foreign countries with the exception of Sweden whose R. & D. manpower has increased at the rate of 9 percent over the last 5 years, a rate comparable to the United States in the midsixties.

Dr. Dripps says it is also no secret that a number of countries are doing more and more of their clinical development overseas. He quotes the precedent of Squibb, claiming Squibb can reduce the cost and delay of introducing a drug in the United States by bringing it to foreign markets first. He gives some examples. One of our largest firms is reported to have discontinued most of its phase 1 studies in this country in favor of doing them abroad. Another firm, Cutter Labs, announced that it is stopping all drug research due to today's regulatory environment.

He also attaches a list of four drugs that were proved in the United Kingdom and I will submit all of this for the record (see p. 189). It was

produced 5 years before the United States. Another one, 11 years, 5 years, 11 years. And the time assessment in the United States for one is 2½ years, another is 6¼ years, 1 year, 9½ years. And there may be reasons why we have not. But we get this criticism and what I am wondering is along with this criticism, along with the fact that we are not requiring reports to come in timely, it seems to me what we need is a tightening up of requirements so that the drug studies and animal studies be in promptly. Then we can make some judgments quickly, because I think unless we do pick this up, if this trend is legitimate, it causes some concern.

Dr. EDWARDS. May I make a comment, Mr. Chairman, about Dr. Dripps? This is not the first contact we have had with Dr. Dripps over the past years. This letter, although I have not read it, appears to be about as reliable as most of the information we get from Dr. Dripps.

I think first of all, it is important to recognize that Dr. Dripps is very closely allied with the pharmaceutical industry. As a matter of fact, the last time we had dealings with him most of his information was coming from Smith Kline and French.

The fact that many pharmaceutical companies are going overseas is absolutely true, but why would they not? More and more sales are available for them overseas. The ability of investigators, the institutions, to do drug investigations overseas is improving. I think it is a very logical thing to have happen, but to attempt to blame all this on the FDA is a lot of nonsense because we do have the strictest—we have said that from the very beginning, that we have the strictest regulations in terms of proving new drugs, no question about it, but the important issue which Dr. Dripps never bothers to take into consideration is that most of the developed countries of the world are moving more and more in the direction of our kind of a regulatory system and we asked Dr. Dripps, and I do not know about the four drugs he lists there, but we asked him to provide a list to us of meaningful drugs that were marketed overseas that were not marketed in this country and I have never seen that list. As a matter of fact, we tried to get it. It may be available. There are drugs marketed overseas that are not marketed here, to be sure, but as I say, meaningful drugs marketed overseas that are not marketed here.

Mr. ROGERS. These are now approved here. These are all approved but it took 5 years to approve them here where it was 5 years less in the United Kingdom, it was 11 years less there than here in another case and similarly 5 years less and 11 years less in others.

Now, I will furnish this to you and would like comment on it for the record, because I might say this is not just Dr. Dripps. It is 19 other doctors and scientists.

Dr. EDWARDS. They are the same that wrote you earlier in the year and the same that when we got them all, set them down and invited them all to come in and air their difficulties with the FDA they were singing a far different story at that particular point in time.

For instance, I think Dr. Kelsey being here, I think, is a good case in point. Thalidomide was approved overseas five years before it was disapproved over here but that is the nature of our system and I think that is the real issue.

Mr. ROGERS. Is thalidomide approved here now?

Dr. EDWARDS. No.

Mr. ROGERS. I did not think we approved it. These are drugs we have approved but if we had not approved them, that is a different matter. I think the criticism here is that we have approved them but it has taken us 11 years to approve them. I think that is the point he is making.

Dr. EDWARDS. The real issue is not whether there is a drug approved here or it took 5 years longer. The real issue is are they meaningful drugs? I think we all recognize we have got far too many drugs around anyway. The real issue is these meaningful new chemical entities that are really adding something to the therapeutic armamentarium.

Mr. ROGERS. I cite that he gives this sales capability in the United Kingdom. It is the third leading product. The 14 leading products, 10th leading product, 46th.

Dr. EDWARDS. That does not always speak to their—

Mr. ROGERS. No; but it is some indication how well it is accepted by the medical profession in using it with the public.

Dr. EDWARDS. True, but I think there are certain analgesics in this country that are widely used by the medical profession but are no more effective than some other drugs.

Mr. ROGERS. Well, this may well be but have we approved those?

Dr. EDWARDS. Oh, yes.

Mr. ROGERS. So they are approved for use.

Dr. EDWARDS. Right. Again, these—

Mr. ROGERS. Of course, the doctors make those judgments.

Dr. EDWARDS. I think the only fair thing on these—as we have from the very beginning—that we are willing to meet head on any allegations that, Dr. Dripps makes.

Mr. ROGERS. Well, I think these ought to be looked into and I would appreciate comment for the record.

[Dr. Dripps letter referred to follows: HEW's comments were not available to the committee at the time of printing—September 1974.]

UNIVERSITY OF PENNSYLVANIA,
OFFICE OF VICE-PRESIDENT FOR HEALTH AFFAIRS,
Philadelphia, Pa., September 24, 1973.

HON. ALEXANDER SCHMIDT,
Commissioner of Food and Drugs, Department of Health, Education, and Welfare,
Washington, D.C.

DEAR COMMISSIONER SCHMIDT: As you know, a group of us in academic medicine have expressed concern about the future of drug development and regulation in this country. We have spoken to members of Congress and the FDA of the need for a thorough examination of the IND/NDA process. One basis for our concern can be seen in three important areas: (1) The drug lag—i.e., the extent to which important drugs are available overseas and not available here. (2) The drop-out rate of compounds which get lost in the IND/NDA process. (3) Evidence of loss of U.S. leadership in drug research.

Dr. Charles Edwards recognized, as FDA Commissioner, the need to improve regulatory assessment. In a speech last December 13, he specifically recommended certain steps be taken. I attach our letter to him and Deputy Commissioner Gardner's response. In the event this exchange of correspondence has not been brought to your attention.

Although we realize the difficulty involved in creating the kind of advisory committees Dr. Edwards has in mind, namely, those which would literally follow a compound through the IND/NDA process, we hope that his recommendations, as well as our suggestions about them, can be put into effect soon.

We were encouraged to read on the occasion of your taking office that while you believe in the need for regulation for public safety, you will be looking at

the balance between regulation and the need to avoid inhibiting R&D. This question of maximizing benefit to patients has been the central concern of our group.

We have also been encouraged to see that in the last two months FDA has cleared several important compounds which have long been available overseas. We would like to point out, however, that the timing of these FDA actions supports our belief that the U.S. has fallen behind the rest of the world. For these four compounds, the average time between NDA submission and approval in the U.S. was almost five years. Also, on the average, they were introduced into the U.S. almost eight years after being introduced in Britain (see table attached). We suspect that the delays seen with these compounds are not isolated cases but confirm the existence of a real drug lag. It is also significant to note that these four compounds originated with foreign owned firms and were initially marketed in foreign countries.

While an international comparison such as this enables us to define performance of the U.S. in relative terms, there remains the more fundamental and difficult question of measuring the absolute impact of excessively conservative regulatory policies on the process of drug development at all levels. How, for example, have FDA regulatory policy and action affected the entry rate or the drop-out rate of potential new therapeutic agents in the IND/NDA stages?

No one knows how many potentially useful compounds are bogged down in the IND process or are discarded even before this phase of development. The U.S. public is clearly experiencing a delay in benefits, but it may be experiencing a total loss of potential benefits which might have come from compounds that for one reason or another are lost by the wayside. The contribution of regulatory behavior to such attrition is an important area deserving immediate study.

Admittedly, evidence of loss in leadership in drug research is fragmentary, but we see certain symptoms which give us grave concern. For example, based on the most recent figures available, the U.K. industry has been increasing its R&D expenditures at the rate of 17%, the Japanese 22%, Sweden 13.5%, and U.S. owned companies less than 10%. In all probability, the U.S. increase is taken up just by inflation and by the need for retesting old products rather than the search for totally new products. Further evidence of this static condition of drug R&D in this country is reflected in R&D manpower, which has not increased in the last four years. Comparable data is not yet available for foreign countries, with the exception of Sweden, whose R&D manpower has increased at the rate of 9% over the last five years, a rate comparable to the U.S. in the mid-1960's.

It is also no secret that a number of companies are doing more and more of their clinical development overseas. Richard Furland, President of Squibb, is quoted as follows in the September 6 issue of the *Congressional Record*: ". . . Squibb can reduce the cost and delay of introducing a drug in the U.S. by bringing it to foreign markets first. Prolixin Decanoate was developed in the U.S., but its usefulness in the treatment of schizophrenia was proved in Britain."

One of our largest firms (Merck) is reported to have discontinued most of its Phase I studies in this country in favor of doing them abroad. And another firm, Cutter Laboratories, announced that it is stopping all drug research due to "today's research and regulatory environment."

These, then, are some of the reasons for our concern and why we went to the Congress in the first instance almost two years ago and asked for a study and review of the entire drug development and regulatory process.

We recognize that you have just assumed your new responsibilities, but we also want you to know of your continuing interest and of our willingness to help in any way we can.

As in the past, I am sending a copy of this letter to Representative Paul Rogers, Chairman of the Subcommittee on Public Health and Environment, of the House Interstate and Foreign Commerce Committee, and Members of his Subcommittee, so that they will be informed of our views on this vital subject.

Respectfully,

Robert D. Dripps, M.D., Robert F. Bradley, M.D., Eugene Braunwald, M.D., Julius H. Comroe, Jr., M.D., Michael E. DeBakey, M.D., James E. Eckenhoff, M.D., Edward D. Freis, M.D., Alfred Gilman, Ph. D., Nathan S. Kline, M.D., Louis Lasagna, M.D., Sherman M. Mellinkoff, M.D., Walter Modell, M.D., John Oates, M.D., Irvine H. Page, M.D., E. M. Papper, M.D., Burtrum C. Schiele, M.D., Robert W. Wilkins, M.D., William R. Wilson, M.D., Robert I. Wise, M.D., Ph. D., George D. Zuidema, M.D.

Product	Marketed in United Kingdom	NDA submission, United States	U.S. approval	Assessment time, United States (years)	Introduction lag, United Kingdom vs. United States (years)	Rank in total market acceptance in the United Kingdom
Cromolyn Na (Intal; Aarane ¹).	1958	December 1970.	June 1973....	2½	5	3d leading product.
Fenfluramine HCl (Pondimin ¹).	1963	March 1957...	June 1973....	6¼	11	14th leading product.
Trimethoprim-Sulfamethoxazole (Bactrim; Septra ¹).	1968	July 1972.....	July 1973.....	1	5	10th leading product.
Metaproterenol (Alupent ¹).	1962	January 1964.	July 1973.....	9½	11	46th leading product.

¹ U.S. trade name.

Note: Metaproterenol usage in foreign countries is steadily declining since 1959 in favor of newer agents that are even more-broncho selective than metaproterenol. Thus, after nearly 9 yrs the U.S. physician is obtaining access to a drug which is being superseded abroad by subsequent advances.

Source of data: William M. Wardell, M.D., Ph. D., assistant professor of pharmacology and medicine, University of Rochester.

Mr. CARTER. Mr. Chairman, on that very thing, the restrictions we ourselves place on FDA lengthen the time which is necessary for them to approve these drugs. Is that not true, Doctor?

Dr. EDWARDS. Absolutely true.

Mr. CARTER. And, that, if we pass some more legislation, it will take much longer, is that correct?

Dr. EDWARDS. Well, it certainly could be correct. It would not necessarily have to be but there is a possibility.

Mr. ROGERS. This is the point I want us to go into and I think this committee must know at what stage we are. Are we holding down the development or not? We have put restrictions on to protect the safety of the public and requiring safety and efficacy of drugs. We want that done. This committee wants that done. But what we are saying is, I think here in some of the information that has been brought to the committee's attention, it is that this can still be done if we will do it promptly. And that is what we are trying to get at, in addition to seeing that it is done ethically and properly.

Mr. CARTER. Mr. Chairman, we cannot have it both ways.

Dr. EDWARDS. I cannot let that go by. For instance, if it is done timely, but everything we have been talking about this morning, you were talking about not requiring more animal testing before we began phase 1. You cannot be timely and require—I mean, these studies all take time and the more studies we require, the more time is involved in the approval or disapproval of an investigation of a drug or new drug.

Mr. ROGERS. I think if you require 2 weeks of animal studies, which I understand you do in phase 1 for the most part, those results ought to be gotten to you right away, not waiting 7 or 8 months to be reported. That is what I am talking about. You cannot make proper judgments if those reports are not in.

Now, why can we not administer these programs in a timely fashion? That is what I am saying. Is it lack of personnel? Is it lack of requirements or what?

Dr. EDWARDS. Well, it is probably a lack of a lot of things.

Mr. ROGERS. Well, that is what we want to know so it can be corrected.

Dr. EDWARDS. The main thing is the investigator who is doing the drug. Most of them are doing a lot of different things. He may report his data, he may expedite the report and he may not. There is not very much we can do about that, I mean how rapidly he reports his information. You know, he may not evaluate the data for a month.

Mr. ROGERS. Well, I think you can require that. If you want those animal studies in before he starts human research that, I think, would speed it up. What does he care whether he gets his report in on animal studies if he goes ahead and can start human experimentation? He could not care less.

Dr. EDWARDS. I think anything that—I mean, any impositions like this on investigators, whether we like it or not, I think it is going to have a major effect in driving some of them away from doing investigations, drug investigations.

Mr. ROGERS. Well, I understand this may be true in your type of regulation but if it is geared to the safety and efficacy of the product, if it is geared to the protection of human beings, then maybe we have to consider it and weigh the advantages and disadvantages.

Dr. EDWARDS. I would agree with that, sir.

Mr. ROGERS. Dr. Carter.

Mr. CARTER. My only remark was that to say that we cannot have it both ways, if we have safe drugs we have got to have enough time for going through the different phases for animal experimentation. I regret that we are not as fast perhaps in recognizing these drugs as some countries in Europe are but I feel that the reason is that our restrictions are much greater. They more than likely do not have the 1962 law which we have and certainly I do not believe they take the time and the care and that is one reason why thalidomide came from outside the United States and not within.

Thank you, Mr. Chairman.

Mr. ROGERS. Thank you.

You have been kind to stay with us this long. I think what the committee is concerned with, is trying to set forth what we should do, whether it should just be done in HEW or whether we should try to approach it—what do you think? Should we approach it Government-wide? Would this be a better approach?

Dr. EDWARDS. Absolutely.

Mr. ROGERS. I assume you do not have control over the VA?

Dr. EDWARDS. No, but I think your point is well taken. I think any Government rules and regulations should be applicable to all.

Mr. ROGERS. Perhaps we could work it out where we can take the cooperation of the other agencies and committees to get this through. This would be a helpful step to broaden it from just the HEW complex.

Dr. EDWARDS. It is a very good suggestion.

Mr. ROGERS. Thank you very much. We appreciate your help.

The committee will stand in recess until 2:30 this afternoon. We have additional witnesses.

[Whereupon, at 12:55 a.m., the hearing was recessed, to reconvene at 2:30 p.m., this same day.]

AFTER RECESS

[The subcommittee reconvened at 2:30 p.m. Hon. Paul G. Rogers, chairman, presiding.]

Mr. ROGERS. The Subcommittee on Public Health and Environment will be in order, please. We are continuing our hearings on H.R. 10403 and other bills, protection of human subjects in research programs.

We are very pleased to have as our next witness Dr. Thomas C. Chalmers, Director of the Clinical Center, National Institutes of Health, and soon-to-be—I am not sure what date it is to be effective; maybe it's already become effective—president of the Mount Sinai Medical Center in New York.

So we are honored to have you and know of the good work you have done at the Clinical Center, and I am very pleased to welcome you back to the committee.

STATEMENT OF DR. THOMAS C. CHALMERS, BETHESDA, MD.

Dr. CHALMERS. I appear before you as a private citizen, rather than as Director of the Clinical Center—

Mr. ROGERS. We are glad to have you in any capacity.

Dr. CHALMERS. And I will be leaving, starting at about 5 p.m., I guess, for New York.

Mr. ROGERS. May I say, we do hate to see you leave. Your contributions have been very significant, and all of us are very much aware of what you have done for your Government and the services you have rendered at NIH. It is the Government's loss, but Mt. Sinai's gain to have you join them.

Dr. CHALMERS. Thank you very much.

Mr. ROGERS. You may proceed any way you wish.

Dr. CARTER. Mr. Chairman, I want to say that I regret that Dr. Chalmers is leaving the Clinical Center at NIH, but I think that our loss is Mt. Sinai's gain, and I wish you the utmost success.

And just in my going over what he has to say, he says something here that is most unusual. He says, "Because episodes of illness in individual people are so variable, every physician is carrying out a small research project when he diagnoses and treats a patient." And that is something I said this morning, even though I hadn't at that time read Dr. Chalmer's report. Thank you.

Dr. CHALMERS. Congressman, I thought what you said this morning had a real ring of truth about it.

I am speaking as a public witness, but also, at the same time, agreeing with Dr. Charles Edwards. And except for the fact that I personally think there should be a commission to study this problem with the rest of his objections to the bill. I think that most of the discussion this morning centered on the commission, and not on the rest of the bill, which I visualize, and as Dr. Edwards pointed out, as setting up regulations right from the start, before the deliberations of the commission could possibly be completed as to whether these regulations were good or bad.

It is these rather complex regulations, which are clearly designed to replace the regulations which have been operative in DHEW since 1966 and are still developing in DHEW that I believe as a clinical

investigator, I should object to, and I believe the majority of clinical investigators will object to them also.

Mr. Chairman, these remarks are based on an address I made before the American Medical Writers Association last week, a copy of which is available for the record if you wish it [see p. 198].

The background of my objection follows from the fact that 20 years ago I gave up the practice of internal medicine after 6 years, because it became apparent to me that so much of my practice was based on poorly tested assumptions. There was an obvious need for much more clinical research to evaluate "standard" practice and to develop new therapies that have a sound scientific basis. Since then I have been active in clinical research with a special interest in the interactions of science and ethics in the care of patients in a research setting, and I feel that we need much more rather than less clinical research, not only to lead to the better practice of medicine in the future, but also because I am convinced that good clinical research is synonymous with good medical practice. If we regulate clinical research too closely, we are in danger of driving innovative medicine toward practice that is not peer reviewed.

It is extremely hard to distinguish between clinical research and the practice of good medicine. Because episodes of illness and individual people are so variable, every physician is carrying out a small research project when he diagnoses and treats a patient. Progress in medical knowledge depends on more physicians being willing and able to systematize these many experiments and to ask questions of a clinical situation from which meaningful answers can be obtained. The elaborate committee structure called for in the second half of H.R. 10403 might very well diminish the enthusiasm of clinicians for clinical research, or even worse, might encourage them to carry out ill prepared innovative experiments without the advantages of careful prior thought and review by peer groups. I believe that if we are to have more of such desirable peer review rather than less, we must simplify rather than complicate the process.

The second point is that H.R. 10403 makes no distinction between the amount of regulation to be applied to what might be considered non-therapeutic and therapeutic research. In the former case, normal subjects or patients volunteer as subjects of experiments from which they have little personal gain. No one disagrees that there should be several levels of protection of the volunteer, especially when he may have limited powers of giving informed consent, as in the case of children or prisoners. However, when the research is therapeutic and carried out in an effort to help the individual patient, an elaborate review structure and a subject advisory committee interjected between the physician and his patient would be extremely unwieldy and ill-advised. It would place an artificial wedge between clinical research and the enlightened clinical practice.

The third point has to do with the fact that all but one of the examples cited in the public press and in the Halls of Congress of malfeasance or unethical research were experiments carried out without the benefit of the careful scrutiny than research projects funded by the Department of Health, Education, and Welfare. In other words, they would all have been prevented if the present policies had been applied to all clinical research. There have been 65,000 research

projects funded by DHEW since 1947, and 29,000 since 1966 when the present regulations were put into effect, and there are almost no examples of unethical practice in the public domain. This is a remarkable record. As Dr. Edwards has said, the existing DHEW policy is now being improved to make the process even more protective of the individual, while at the same time not impeding essential clinical research. The real problem is to find some way to apply adequate regulations to all clinical research rather than merely that supported by various governmental agencies, and that was also recognized this morning. That goal will not be accomplished by this bill other than through developments of the study commission, a part of the bill which I favor enthusiastically. We need time and experimentation to determine whether such entirely new instruments as a subject advisory subcommittee, interposed between the physician-investigator and his sick patient, will benefit or harm the welfare of that patient.

I should like to commend those who developed this bill for starting a process that is bound to benefit the individual. My plea is for more time to test the impact of the regulations proposed, to be sure that clinical research will become more rather than less a part of the practice of medicine.

Finally, let me emphasize that the views expressed in this statement reflect my personal and professional judgment and are in no way intended to reflect the official position of the Department.

I would like to add a recommendation which we wrote out this morning to crystalize what I said, and that is that the Congress agree to the establishment of a national commission for the protection of human subjects of biomedical and behavioral research as provided in section 1201 of the bill, or of several other bills, which call for a similar body; and that language be incorporated in the bill to provide that such a commission, within one year of enactment of the law, develop a report to the Congress on the necessity for changing the presently operated DHEW and other guidelines; and that during that year such a commission hold its own hearings and meetings, calling upon the leading advocates of all points of view to present their ideas.

Mr. ROGERS. Thank you very much, Dr. Chalmers.

Dr. Carter?

Mr. CARTER. Thank you, Mr. Chairman. Again, Doctor, I want to tell you I feel like it is a great loss to NIH that you are leaving. You will be associated with Dr. Holland at Mount Sinai; is that correct?

Dr. CHALMERS. Yes.

Mr. CARTER. Recently he has done some rather interesting work there. Would you care to say something about the work which he has done?

Dr. CHALMERS. Well, actually, he is just getting started. He has just moved from Buffalo to Mount Sinai by way of Moscow, where he was the representative of the Department of HEW to the Russian scientists working on cancer. Before that move, he set up what was called "the acute leukemia study group," which was the original cooperative study group of investigators that essentially, by their controlled clinical trials, discovered the modern multi-drug therapy of acute leukemia and brought the apparently permanent remission rate, from under 5 percent to somewhere around 40 percent in all patients, and even higher in selected groups. And I think Jim Holland, along with Frei, now in Boston, and Freireich in Texas have certainly been leaders in that group.

Mr. CARTER. I think 50 out of a group of 100 are living now, after 5 years. That is of the acute leukemia group, and without medications, as I understand it.

Dr. CHALMERS. Yes.

Mr. CARTER. I think that is tremendous.

Dr. CHALMERS. That is a remarkable difference.

Mr. CARTER. And I feel that you will be in excellent company there. Now, do you feel that this legislation, which is proposed, should apply only to the projects funded by NIH?

Dr. CHALMERS. No. As I indicated, almost all, if not all, of the examples of bad ethics applied to clinical research were projects not funded by NIH. If we are going to improve the situation, they are the ones we should be directing our attention to. We have to find some way to do that legislatively, and the NIH committee that Dr. Edwards has referred to has been discussing the various ways in which this can be done within the present law, for instance, by awarding money only to those institutions whose committees has reviewed not only those projects supported by DHEW, but also reviewed all grants, all research projects.

Mr. CARTER. NIH has no need, really, then for this legislation?

Dr. CHALMERS. I don't think it does, no. I think that the job can be done without the legislation and is being done quite well.

Mr. CARTER. The elaborate committee structure calls for in the second half of H.R. 10403 might very well diminish the enthusiasm of clinicians for clinical research or even worse, may encourage them to carry out ill-prepared innovative experiments without the advantage of careful prior involvement and review by peer groups. Now, would you care to elucidate on that?

Dr. CHALMERS. Well, there are a number of modes of therapies that have slipped into common usage in medicine because physicians thought they might be a good idea and began to use them in some patients and, when those patients responded well, reported them in the literature. If the patients responded badly, the physician usually forgot about the therapy and went on to something else. The difficulty with those studies is that those were, actually the practice of medicine in a systematic way in that the data were recorded while patients were being treated, but the studies were not research because there was nothing to compare the results with. The effect of the therapy may have been the results of selecting a patient who is going to get well anyway, or it might have been due to the drug, or it may have been due to other modalities of treatment given to the patient. There are many instances in which this procedure has resulted in general acceptance of the therapy, but finally someone has doubted it and has done a well-designed controlled trial—the kind that requires extensive peer review and extensive informed consent from the participants—and it has been shown in the trial that the therapy was worthless. If this had been done earlier, then a lot of maltreatment might have been avoided. If the rules and regulations for peer review and informed consent are made so complicated that doctors can't find the time to organize and conduct a well-controlled trial, we will end up with more and more innovative practice, as it is called, and that is bad medical care. I can cite some examples, if you wish.

Mr. CARTER. An elaborate review structure and a subsequent advisory committee interjected between a physician and his patient will be unwieldy and ill advised, do you think?

Dr. CHALMERS. Yes. I think the main difficulty I have with the projected regulations is that they are so rigid and inflexible with regard to variations that will be required in individual institutions. I visualize a small hospital or even a doctor in his office who plans one clinical experiment in the course of a year being totally stopped by the prospect of having to set up the kind of committees that are called for.

What he is going to do may be so benign that it doesn't require such extensive review, but still he would have to set up a committee. Now he can very well get a simple review from his university committee, which does not have to go through three layers and does not involve people coming and talking to his patients, if that is indicated.

He will be more interested in doing the research if he is not too encumbered in comparison to the fact that, if he wants to go ahead and give the drug to the patient and not find out whether it is working or not, he can just go ahead and do it without going through all of this procedure.

Mr. CARTER. Do you think we need more time and experimentation before we go through with this?

Dr. CHALMERS. Yes; I think so. I know of no instances in which the patient advisory committee structure has been tested to see how it works. There may be some, but I just haven't heard of any. And I think it would be critically important, before legislating, that some investigators in the country have such a mechanism in operation, in order to find out how it works. We may find that it is totally too cumbersome, both in the very small institutions that may have one or two research projects a year, and even more important, in the large teaching hospitals with 50 or 60 clinical projects going on in the course of a year.

Mr. CARTER. Do you think that you need no such group out at NIH? You had a very good record; is that correct?

Dr. CHALMERS. Yes. And we think that our peer review system, which is triple-layered for the normal volunteer and the usual double-layered for the sick patient is, as far as we can tell, entirely adequate and working very well.

Mr. CARTER. Thank you very kindly.

Thank you, Mr. Chairman.

Mr. ROGERS. Mr. Hastings?

Mr. HASTINGS. My colleagues have used most of the superlatives in expressing themselves as to your Mt. Sinai appointment and the Government's loss. I would just say I certainly share these views with them, and particularly as a Congressman from the State of New York, we welcome you back home and—

Dr. CHALMERS. Thank you.

Mr. HASTINGS. Mr. Chairman, in the beginning of Dr. Chalmer's testimony he made reference to an address that he made before the American Medical Writers Association and a copy of it is available for the record, if we wish it. I read that, and would ask unanimous consent that it be included.

Mr. ROGERS. Without objection, it is so ordered.

[The following document was received for the record:]

THE REGULATION OF THERAPEUTIC RESEARCH¹(Thomas C. Chalmers, M.D.²)

I am honored to have been asked to welcome you to Bethesda for the 33rd Annual Meeting of the American Medical Writers Association. The close proximity of your meeting to the National Institutes of Health, the National Naval Medical Center, the Walter Reed Army Institute for Research, and the National Library of Medicine fits well with the theme of your meeting: "Medical Communication—Bridging the Gap Between Research and Health Care."

As you may be aware, I have an intense personal interest in the interactions between ethics and science in clinical research, and the communications media are critically important in supplying the public with some insight into these problems. At the moment, research in humans is being criticized in the press and in the committee rooms of Congress because of a few published examples of poor judgment on the part of clinical investigators. No one disagrees that the public should be protected by workable regulations from investigators who might cause more harm than good by their ignorance of proper techniques or by their excessive zeal for answering major public health problems at the improper expense of a few volunteers or sick patients. The question at issue is whether or not minor changes in procedure and a broader and more careful application of our present regulations will be sufficient to do the job, or whether we must institute an entirely new and elaborate system, with an attendant risk of stultifying clinical research.

In the few minutes that I have available to welcome you to Bethesda I cannot resist taking this opportunity to make two points: First, you are experienced enough in these matters to appreciate the importance of knowing the prevalence or rate of any abuse that may need correction. How common are the malfeasances from which we must find some way to protect the public while at the same time fostering clinical research? About eight years ago, some 22 examples were quoted from the modern medical literature published up to that time. Recently, a few more examples have been uncovered. Most of these are instances of poor quality research that would not have been passed by current peer review committees. Dr. Donald Chalkley, from whom you will be hearing later on, tells me that of 65,000 projects involving humans which have been approved for funding by NIH since 1947, less than 12 have been challenged from any source as unethical. Since introduction in 1966 of the present system for protection of human subjects, 29,000 have been approved and only one challenged. It is not known how many research proposals have been modified or even stopped by the existing local committees. About 1% have been flagged at the national level and disapproved for ethical reasons.

The examples given such wide play in the public press represent an extremely small percentage of the clinical research that has been carried out in the last twenty-five years. We have to keep reminding ourselves that the great majority of clinical research, in fact, almost all clinical research now supported by the Department of Health, Education, and Welfare is ethical, has been reviewed by competent committees, and does include multiple procedures to protect the rights of the patient participants. Of course, not all clinical research is supported by DHEW, and we should work hard to see that the guidelines are applied to all. However, I do not feel that there is evidence that drastic changes in those guidelines are indicated.

There are some extremely difficult and sensitive areas in which protection must be strengthened, particularly in research involving children and the mentally infirm. Surer and more adequate means for securing informed consent are needed in some instances. However, we must not over-react and impose restrictions upon clinical research which can freeze present modalities of treatment—including many medications and procedures now accepted which may in fact be more hurtful than helpful.

To understand the implications of excessive restriction upon clinical research, one needs to appreciate that there is a continuous spectrum of activities between what might be considered pure practice and pure research. The rubrics may be summarized as follows:

¹ For presentation at the 33rd Annual Meeting of the American Medical Writers Association, Bethesda, Maryland, September 14, 1973.

² Associate Director for Clinical Care and Director of the Clinical Center, National Institutes of Health, Bethesda, Maryland 20014.

A SPECTRUM OF PROFESSIONAL ACTIVITIES FROM PRACTICE TO RESEARCH

A. Not Now Covered by any Regulations or Peer Review

I. Pure Practice of Medicine: Application of procedures established as safe and efficacious

II. Impure Medical Practice: Use of popular but unproven techniques

III. Innovative Medicine and Surgery: Uncontrolled trials of new ideas

B. Now Adequately Covered by NIH Guidelines (Minor revisions in process)

IV. Clinical Research that is Therapeutic or Diagnostic in Intent: Protocol guided studies in sick adults, children, and mentally ill

V. Research in Sick Patients that is not Intended Primarily to Benefit the Participating Patient: The patient acting as a volunteer

VI. Research in Normal Adult Volunteers

C. Revised Procedures being Develop

VII. Research in Normal Children and Institutionalized Populations with Limited Ability to Give Informed Consent

Even the first category can never be totally free of research. Most of us forget that every physician is conducting a small clinical research project whenever he treats every patient, because no two patients are alike. None react exactly as he is supposed to, and, in all treatment, the physician is required to use some judgment and necessarily, to experiment somewhat. No one is advocating a patient protection committee between the physician and his patient in such a circumstance. Sometimes innovative practice results in the compilation of a series without too much forethought in regard to experiment and design. Such series are often published in the literature. More misleading than helpful information can be obtained from that kind of clinical research, and it would benefit from a reasonable peer review before it is begun. To make the review much more stringent than at present would make it even more difficult to persuade physicians to consider designing clinical experiments in a way that meaningful answers can be obtained.

The major deleterious impact of excessive structuring of the review process in the conduct of clinical research, while clinical practice remains unsupervised, will be in the field of clinical trials, both those conducted by individual scientists and by cooperative groups. Much of what we now do to patients in diagnosis and therapy has never been established to be more efficacious than harmful and would not survive critical peer review. We need to multiply many-fold the number of trials aimed at documenting the relative efficacy of both old and new therapies. A major roadblock has been the reluctance of both physicians and patients to become involved in elaborate control procedures, when the doctors are primarily interested in practicing their art and the patients in being treated for their illnesses. Further elaborate procedures will make that situation much worse. This tends to lead to more rather than less research being done without protocols, and more poor research being done under the guise of practice. Both the patient participants and the public at large will suffer therefrom.

Let me cite two striking examples to illustrate how many hundreds of thousands of people may have suffered from too great emphasis on practice and too little on clinical trials. Since the 1880's, the standard operation for carcinoma of the breast has been a radical mastectomy. The slightly higher operative mortality and the significantly greater local morbidity has been assumed to be well worth it if recurrences were to be prevented and life were to be prolonged by more radical surgery. There have now been four randomized controlled trials to test this concept, and none have confirmed it. All clinical trials have been technical defects, and these are not free of them, but it does look as though simple mastectomy alone in the patient without palpable axillary metastases or simple mastectomy plus X-ray therapy may be just as effective in creating a recurrence-free interval and prolonging life as the much more radical and mutilating surgery that has been performed for 90 years. At least there is as yet no evidence favoring radical surgery. The four completed trials of radical surgery, all conducted outside the United States, employed varying treatments in the control patients. A definitive trial of several therapies is now underway in this country and, presumably, the answer will be forthcoming within a few years. Entrance of patients into this trial requires a detailed explanation of the pros and cons of each form of therapy and justification of randomization. This undoubtedly scares some patients away. Yet it is likely that patients in such a trial are better informed about the options and prospects than those treated according to the usual or ac-

cepted practice. At least in a trial, they have a 50-50 chance of receiving the correct therapy.

There is a similar example in medical therapy. When oral hypoglycemic agents were introduced, it was fervently hoped that their long-term use would reduce the increased vascular complications in patients with non-insulin dependent diabetes. Many uncontrolled series were reported, and approximately a million diabetics have been taking the drug for the last few years. A controlled trial carried out by the University Group Diabetes Program over the last ten years has revealed that not only do the drugs not diminish the incidence of cardiovascular complications, but they actually seem to increase them and to shorten life. Just as in the case of carcinoma of the breast, there is a great deal of controversy about this study, partly because there are defects in the study and disputes about how much the defects may invalidate the results, and also partly because its conclusions do not confirm preconceived notions held by most physicians. More such trials are needed to settle these important questions. A marked expansion of the committee reviews and extensive efforts, no matter how laudable, to reduce to absolute zero the element of risk will only diminish the chances of accomplishing similar studies.

Clinical research is irrevocably intertwined with the good practice of medicine.

My plea is that it not be stifled by an over-reaction to the abuses which concern us all. Obviously, the 100% safe course regarding research with human subjects is to do none at all—but this is certainly not the safest course for the practice of medicine. No one wants to go into the 1980's and 90's practicing 1970 medicine.

Mr. HASTINGS. I would like to say, I think your statement is in itself most clear as to your position and feelings on this proposed legislation. It does not really need a great deal of further elaboration as far as I'm concerned. You feel we should have a Commission, but the Commission should not be able to put its recommendations as regulations into effect without the Congress and HEW taking a very careful look at the ramifications, and that is essentially what you are saying?

Mr. CHALMERS. Yes. Practicing clinical investigators have not yet had enough input into what's been produced, and they ought to have more opportunity to go over the details and to see how they will work.

Mr. HASTINGS. Well, I am delighted that the chairman thinks so highly of your work, and I hope that perhaps we can accept your recommendations.

I have no further questions, Mr. Chairman.

Mr. ROGERS. Thank you very much.

Should there be any distinction, would you feel, in regulations governing research involving, say, volunteers on the one hand, and the sick patients on the other?

Dr. CHALMERS. Oh, very definitely so, and I think the failure to distinguish between these may be an important reason for the present wave of popularity for instituting very strict regulations.

Mr. ROGERS. Yes, because I thought that was a good point you made where if it is for a therapeutic result, rather than just for research, perhaps it wouldn't have to be as strict.

Dr. CHALMERS. Right.

Mr. ROGERS. So you would have different degrees of regulations in effect?

Dr. CHALMERS. The motivation of the investigator is bound to be different in the case of volunteers because he is trying to acquire knowledge for all mankind. One needs an adversary on the volunteer's side making sure that the investigator's enthusiasm doesn't run away with him. On the other hand, the good clinical investigator is trying to help the patient who is sick, and for whom he is responsible. There the more

one interferes too heavily with the way he is going about his therapy—assuming he is also a well-trained physician—the more trouble one gets into. You get to the point where you are trying to legislate all sorts of detailed actions in complicated situations such as clinical research would be like legislating everything a doctor does in treating a sick patient.

Mr. ROGERS. Do you feel present HEW regulations are sufficient regarding clinical research?

Dr. CHALMERS. I think they need to be modified in several ways, and I guess you will see this when the papers referred to by Dr. Lamont-Havers are sent to the committee.

The modifications for sick patients and normal volunteer are not very great. The modifications for children, prisoners, institutionalized people who can't give informed consent are much more stringent, and involve several layers of control.

To emphasize: A much greater advantage will be gained to find some way to apply the HEW regulations to all clinical research rather than just that research sponsored by grants.

Mr. ROGERS. In other words, should we give the function of this Commission a study responsibility and recommendation function Governmentwide, rather than just in HEW?

Dr. CHALMERS. Yes.

Mr. ROGERS. This is what you are telling us?

Dr. CHALMERS. Yes.

Mr. ROGERS. That we should broaden the thrust of its responsibility for its recommendations? You were saying it should not be a regulatory commission, but simply one to study the problem and make recommendations?

Dr. CHALMERS. Yes.

Mr. ROGERS. You object to the line function, in effect, of the commission in setting up regulations?

Dr. CHALMERS. Yes.

Mr. ROGERS. What again was your objection?

Dr. CHALMERS. I think if that Commission decides after a year of study and looking at the changes now going on in the DHEW guidelines that they really don't work—although I think they do work—that that may be the time to suggest the changes called for in this bill, but I think it is premature to bring the changes about now.

Mr. ROGERS. Do you have any experience or know of any experience with a patient advisory committee?

Dr. CHALMERS. No.

Mr. ROGERS. What do you envision would be its duty?

Dr. CHALMERS. As stated in the bill, its function is to be sure that the patient fully understands what is happening to him. In the case of therapeutic research, I worry a little bit about the fact that another group looks in on what the doctor is doing when he is doing clinical research with a patient, but they don't look in on what he is doing when he is treating the patient. The irony of that situation is the fact that when he is treating the patient, he may be doing the wrong thing, and when he is doing the research, he may well be doing the right thing. We don't know. And to put all of this structure between what may well be the right thing to do—I think is more often than not the right thing—and standard therapy, as if that standard therapy had

been proven as efficacious when, in fact, it often is not, I think that is not good.

Mr. ROGERS. I am not sure that I agree with the section's discussion of that matter by saying it would not be proper to have it in an adversary setting. In other words, I think there is perhaps some adversary setting between the person who is going to be experimented upon, as far as his rights go, and the clinician who is doing that research. There may be some rare situation where there should not be an adversary position, but really, I don't know whether this should be carried to the point of having these commissions set up and—

Dr. CHALMERS. May I say, it is fine when the subject is a normal volunteer.

When a subject is a sick patient who is going to be treated as part of the research or diagnosed as part of the research, the concept of an adversary relationship in the practice of medicine, the care of a sick patient, is one that would bother all doctors greatly. They can see where the ombudsman idea in a big hospital might be useful, but the concept of the patient and the physician as adversaries rather than working together to get the patient well is a horrible one to contemplate.

Mr. ROGERS. Yes; although it might be well for that patient to be aware of what could happen?

Dr. CHALMERS. Yes; as he should be for all therapy.

Mr. ROGERS. Is that always done?

Dr. CHALMERS. No; I think one can say unequivocally that it is not always, but to a varying degree.

Mr. ROGERS. Thank you. I think your thoughts have been most helpful, and the committee certainly will give great weight to your testimony.

Thank you for being with us today.

Our last witness today is Dr. John A. Cooper who is president of the Association of American Medical Colleges, and he will be accompanied by Dr. David R. Challoner, counselor, American Federation for Clinical Research, Visiting Scholar/Institute of Medicine.

I think you are a good friend of Congressman Hudnut?

Dr. CHALLONER. That is right, Mr. Chairman.

Mr. ROGERS. We are delighted to have you here, along with Dr. Cooper, and will be pleased to receive your testimony.

STATEMENTS OF DR. JOHN A. D. COOPER, PRESIDENT, ASSOCIATION OF AMERICAN MEDICAL COLLEGES; DR. DAVID R. CHALLONER, COUNSELOR, AMERICAN FEDERATION FOR CLINICAL RESEARCH; AND DR. MICHAEL F. BALL, PAST PRESIDENT, AMERICAN FEDERATION OF CLINICAL RESEARCH, AND DIRECTOR OF BIOMEDICAL RESEARCH, ASSOCIATION OF AMERICAN MEDICAL COLLEGES

Dr. COOPER. Thank you, Mr. Chairman.

We are very pleased to comment on H.R. 10403 and in general about other bills that have been introduced relative to medical ethics. I think we don't need to repeat before this committee the importance of biomedical research in advancing human welfare and health, nor the importance of making certain that that research can be carried forward with adequate protection of the humans who are involved in the research program.

We do support, in general, the provisions of H.R. 10403 and we do support the establishment of a Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

I do have a written statement which, with your permission we would like to have incorporated in the record.

Mr. ROGERS. Yes; the statement will be put in the record in full.

Dr. COOPER. I would like to make some comments in addition to those in the written statement with regard to some of our observations about provisions of H.R. 10403.

First, with regard to the composition of the Commission, because of the very important matters which it is going to deal with and because of the importance of having broad input from the biomedical research community that has been involved in research on human subjects, we would like to recommend that the subcommittee consider requiring that 5 of the 11 members of the Commission, which is less than a majority, must be individuals who have actually conducted biomedical or behavioral research involving human subjects, in order that the Commission will be able to make informed judgments.

We think that the details in the bill regarding to the composition of the nonbiomedical research portion of both the commission and the institutional review committees may be too restrictive. We have had a brief opportunity to study the bill H.R. 10573, which was introduced by Mr. Preyer of your subcommittee. We like the provisions that he has included regarding the other types of individuals who would be incorporated into the nonbiomedical membership of both committees.

We do believe along with Mr. Preyer that the membership of the commission or national board should be subject to Senate review and approval.

Next, Dr. Chalmers has talked about the activities of the commission and we really in essence agree with some of the things that he has said. We feel that the legislation, after reviewing it more completely, may possibly be too directive of the commission's activities. For example, section 1206 directs the commission to establish institutional review boards and directs the commission to certify these boards. Section 1206 requires that each institutional review board establish two subcommittees, one regarding protocol review and one regarding subject advisory review. Section 1208 of the bill establishes the duties of the institutional review boards. Section 1210 describes how every biomedical and behavioral research program involving human subjects shall establish and maintain records. Section 1211 requires the commission to annually evaluate the activities of institutional review boards.

Although we are in agreement that the bill provides one approach to implementation of the commission's norms and standards, we think it would be better—for some of the reasons that Dr. Chalmers has talked about—to allow the commission to develop for itself the mechanisms for institutional peer review and the institutional protection of subjects and recordkeeping. We would suggest that the legislation be modified to recommend the matters for consideration by the commission, but to give them authority and responsibility for developing the approach as Dr. Chalmers has said, with full involvement of the views of those who have been involved in biomedical research involving humans. We say that so that we may be as certain as possible that

the bill will protect individuals but will not impede biomedical research.

Third, we are concerned that the legislation does not require this commission to regularly report its activities to the Congress for its consideration. We think that this should be incorporated in the bill because this is a very extensive subject and one over which the Congress should have continuing review through annual reports and the opportunity to discuss programs with the commission members.

Fourth, the proposed legislation does not limit the activities of this commission or require public debate of its recommendations. We believe that many of the matters that are going to be considered by the commission may be very controversial, and recommend that the commission be required, first, to publish its findings and recommendations with adequate period for reaction by concerned groups and, second, on the major issues of policy to hold public hearings on the recommendations so that there can be debate on the substance of these policy issues. We also would recommend that an appeal mechanism be established where bona fide disagreements between the commission and concerned groups could be subject to resolution by a neutral third party, such as the courts. We are pleased to see that in H.R. 10573 Mr. Preyer does outline a judicial review process which we think would be an important factor in a revised bill.

Fifth, although it is quite clear that the commission, by definition, will be concerned with research involving human subjects and with research in proposed mechanisms for improving delivery of health care, we think the proposed legislation does not delimit the activities of the commission in a manner whereby it would be clear that the ordinary practice of medicine is not subject to the jurisdiction of this commission. We think it is very important, in order that the practice of medicine can be continued out in the tradition in which it has been carried out in this country, that it be made clear that the commission is concerned with organized research efforts supported by Federal funding, and that it does not involve the kinds of activities relating to doctor-patient relationships that Dr. Chalmers has referred to previously.

Mr. ROGERS. May I interrupt? I think it would be very helpful if the association would submit the language they think would accomplish some of these objectives.

Dr. COOPER. Yes, Thank you.

[The following proposed language was received for the record:]

PROPOSED NEW LANGUAGE FOR SECTION 1202(b) (5)

We would suggest that section 1202(b) (5), which concerns the duties of the Commission, be amended to read as follows:

... defining more precisely the boundary between biomedical and behavioral research involving human subjects and the accepted practice of medicine, provided that, in defining these boundaries, the Commission shall concern itself with organized research support by Federal funds, and shall not have jurisdiction over the ordinary practice of medicine;

Dr. COOPER. Finally, we suggest that the provisions in the proposed legislation to prohibit research activities involving fetuses and infants not be adopted in the form in the bill. Instead, we believe the national commission should be directed to undertake the task of studying fetal research and developing a proposal policy in the same

way it has been directed to develop a policy for psychosurgery. Until the commission has developed a national policy for fetal research, we would recommend that the proposed regulations of the NIH, which you heard about, be used as guidelines for the conduct of research on fetuses or on infants.

We think that the language of that section of the bill is not clear and may indeed prohibit research on all infants; so we think that it is important that some of this research, which is essential in improving the ability to have children live and correct some of our infant mortality problems, be continued.

That concludes, sir, the formal presentation.

[Dr. Cooper's prepared statement follows:]

**STATEMENT OF JOHN A. D. COOPER, M.D., PRESIDENT, ASSOCIATION OF
AMERICAN MEDICAL COLLEGES**

Mr. Chairman and members of the subcommittee, the Association of American Medical Colleges welcomes this opportunity to appear before the subcommittee during its consideration of legislation for federal protection of human research subjects.

Now in its 97th year, the Association represents the whole complex of persons and institutions charged with the undergraduate and graduate education of physicians. It serves as a national spokesman for all of the 114 operational U.S. medical schools and their students, 400 of the major teaching hospitals, and 51 learned academic societies whose members are engaged in medical education and research.

The Association is anxious to comment on this legislation because of the deep involvement of the nation's medical schools in assuring the highest ethical, moral, and social concerns in all scientific inquiry, particularly when it involves human subjects.

In the last decade, we have witnessed an unparalleled expansion of our technological capabilities. The technology of biomedical research is the technology of man. Today, we have more biomedical research scientists at work on more kinds of projects than at any time in our history. Their success in these endeavors has taken us beyond the frontiers of man's understanding. The gap between the development of biomedical knowledge and technology and our capacity to encompass fully the implications of such rapid progress widens every day.

As technology evolves, the need for a national research policy also increases in order to guide the use of our knowledge. It is essential that any Federal policy concerning the involvement of human subjects in research be flexible. Research, development, and application of new ideas are not carried out in an ethical or legal vacuum. Ultimately, the decisions required by this policy must depend upon the common sense and sound professional judgment of reasonable persons, permitted the opportunity to develop rules and guidelines in a flexible framework.

In fact, guidelines already exist for the use of human subjects in experimentation, and the nation's medical schools already are involved in a variety of efforts to impress undergraduate medical students with the need for a holistic, ethical, moral and social view of their responsibilities toward patients.

The Department of Health, Education, and Welfare publishes an institutional guide to DHEW policy on the protection of human subjects, which applies to all grants and contracts to support activities in which subjects may be at risk. On September 15, 1972, the Executive Council of the Association of American Medical Colleges adopted a policy statement on the protection of human subjects:

"The Association of American Medical Colleges asserts that academic medical centers have the responsibility for ensuring that all biomedical investigations conducted under their sponsorship involving human subjects are moral, ethical and legal. The centers must have rigorous and effective procedures for reviewing prospectively all investigations involving human subjects based on the DHEW Guidelines for the Protection of Human Subjects, as amended December 1, 1971. Those faculty members charged with this responsibility should be assisted by lay individuals with special concern for these matters. Ensuring respect for human rights and dignity are integral to the educational responsibility of the institutions and their faculties."

Furthermore, the medical schools of the nation have been active in the teaching of medical ethics. All of the nation's 114 medical schools provide practical instruction in medical ethics and the relationship of the practice of medicine to the individual patient and society. This instruction is consistently provided throughout all of the student's patient-oriented training. Medical educators strongly believe that such continual clinical exposure to a highly individualized approach to each patient is the most effective method of instilling in students a sense of responsibility and flexibility in the treatment of their future patients. In addition to this constant, firsthand, clinical observation of the proper ethical relationship between physician and patient, most medical schools also offer classroom instruction in the ethical practice of medicine. A recent curriculum survey conducted by the Association indicates that 32 of the U.S. medical schools require courses relating to medical ethics or the social aspects of medical practice. An additional 49 schools provide formal lectures and discussions of these topics as an integral and essential part of the student's introduction to clinical medicine. Thus, 81 schools provide formal classroom instruction in addition to clinical training in ethical conduct. Despite this record, the Association believes that more could be done, if additional funds were available to offset the additional costs involved.

There are a number of legislative proposals before the subcommittee dealing with the protection of human subjects in experimentation, each of the measures reflecting long-standing concern with this extremely complex issue. The Association, as part of its concern with the issue, has carefully and thoughtfully reviewed each of the proposals. The conclusion of the Association is that the measure introduced by Subcommittee Chairman Rogers, the Protection of Human Subjects Act, provides the best protection for human subjects in experimentation while preserving the flexibility so essential to productive research. At the same time, each of the other measures makes important contributions.

The Protection of Human Subjects Act includes many useful suggestions contained in the reports of the Secretary's Commission on Medical Malpractice and the Tuskegee Syphilis Study Ad Hoc Advisory Panel. The Association recommends enactment of the legislation as introduced, with four suggested amendments.

The association suggests that:

(1) The composition of the National Commission should be modified to require that members (but never a majority) of the Commission shall have conducted biomedical or behavioral research involving human subjects. (This recommendation is in addition to the requirement that at least the Chairman or the Co-Chairman shall have conducted such research.)

(2) The members of the National Commission should be subject to Senate confirmation to provide a searching well publicized review of their qualifications;

(3) A limit should be set on the length of time which records required to be maintained under the legislation must be retained; and

(4) There should be no prohibition on research activities involving fetuses and infants. Instead, the National Commission should undertake the task of studying fetal research and developing appropriate policy. Until the Commission has developed a national policy for fetal research, the Association recommends that such research be continued, using the current and proposed NIH regulations as guidelines.

The Association's first suggestion seems useful in the context of assuring that the Commission will have sufficient familiarity with the use of human subjects in experimentation to carry out wisely its powers and duties.

The Association's second suggestion is important in assuring at least some form of outside review of the selection process for members of the National Commission. In view of the power and authority the Commission is to have, it seems highly appropriate to make membership subject to more than mere unilateral selection by the President.

The Association's third suggestion—essentially technical in nature—is designed to avoid accumulation of an overwhelming volume of records which, in the absence of any time limitation, would present a serious storage problem.

The Association's final suggestion is essential if American medical science is to continue to make inroads against genetic diseases, such as sickle cell anemia or Tay-Sachs disease, and against such childhood diseases as Rubella. Our suggestion would place a high priority upon the establishment, under the aegis of the Commission, of a national ethical policy for fetal research which would take into consideration both the rights of the fetus and the crucial need for this type of research.

The Association also commends the legislation for its inclusion of two additional provisions: increased support for medical ethics training in medical schools

and statutory authority for scientific peer review of National Institutes of Health research grants and contracts.

Already confronted with mounting operating expenses and dwindling federal assistance, most schools cannot prudently expand their teaching operations without assurances of specific additional financial support. HR 10403 provides such support by expanding the special projects for which schools may receive federal assistance to include the establishment and operation of programs providing increased emphasis on the ethics, social, legal and moral implications of advances on biomedical research and technology with respect to the effects of such advances on individuals and society.

The Association has been deeply concerned with recent challenges by the Office of Management and Budget directed at the role and function of the NIH advisory committees whose sole function is to provide, through review by peers, a rigorous assessment of the scientific merits of research projects for which NIH grant support is being sought. This process of scientific appraisal carried out by disinterested and expert scientists organized into some 60-odd "study sections" or scientific review committees has assured high standards of excellence in the use of public funds for the support of biomedical research in non-Federal research institutions. External review groups which have studied the programs and operations of the NIH have uniformly had high praise for this scientific review procedure.

Dr. COOPER. I think Dr. Challoner wanted to add some comments to what I said.

Mr. ROGERS. We welcome your remarks, Dr. Challoner.

STATEMENT OF DR. DAVID R. CHALLONER

Dr. CHALLONER. Mr. Chairman, thank you. It is a pleasure to be here with you representing the American Federation for Clinical Research. As I believe the members of your committee know, this is the largest organization of clinical investigators in the United States, with some 7,000 members. Our organization has long had an interest, because of the occupation of our members, in the protection of human subjects, and has worked with no difficulty under the NIH regulations that were discussed previously, and we certainly support these.

We also, however, recognize that there is a significant public concern at this point in time that has really led to the legislative effort that this hearing is responding to today.

We would certainly support the commission approach, as Dr. Cooper has mentioned. We have some concern that its directions should not follow immediately, but only after consideration as to whether indeed the NIH guidelines may be satisfactory.

I think a couple of points that were brought up earlier deserve some further comment. You have a concern that an adversary proceeding of some kind may still be appropriate in protecting the subject, especially the normal subject.

Well, I would submit to you that you might consider that the very makeup proposed for the institutional committees with perhaps attorneys, ministers, and so forth, as well as the professional people at the local level being involved on the committee that initially looks on the proposal, may have an element, admittedly a degree removed from the research itself, but may have an element of an adversary proceeding right there, which takes place before the research is approved at the local level.

I would also have real concern with an adversary proceeding taking place at the level of the interaction of the physician and his patient, who may be participating in research, as Dr. Chalmers mentioned before.

Mr. ROGERS. What if it is a volunteer?

Dr. CHALLONER. A completely normal patient?

Mr. ROGERS. And is not therapeutic?

Dr. CHALLONER. There may be more of a role for it there. At least the local committee should make sure that the information is presented to the patient. It still could be done without having an adversary proceeding by the physician who is responsible, but I would agree that the local committee should make sure that it is done.

Mr. ROGERS. OK.

Dr. CHALLONER. One other point that our organization has had some interest in, and that is that not only should the research be looked at initially and approved, but that there should be some provisions considered by the Commission as to how the ongoing research can be evaluated as to whether it is complying with the initial approval.

Those are our comments, Mr. Chairman. Thank you.

Mr. ROGERS. Thank you. Thank you very much.

Dr. Ball?

STATEMENT OF DR. MICHAEL F. BALL

Dr. BALL. The only additional comment I would make is that in my position with the AAMC, I have been invited to participate in the deliberations of a committee of the Department of Health, Education, and Welfare that is reevaluating the NIH guidelines, and although it is not appropriate to specifically talk in too much detail about these guidelines, I think it is fitting to comment that these deliberations have been extremely thoughtful and are proceeding in a manner that will, I will say, update to 1973 guidelines that have been progressively improved over the years.

I am very impressed with the way, in an adversary type of situation, we have debated the pros and cons of the patient protection committee and the institutional review committee. I would be strongly in favor of not specifically legislating the development of these kinds of committees at this time, but rather feel that the commission itself, in consultation with the Department of Health, Education, and Welfare, could develop a set of guidelines that would be to the benefit of both patients and investigators.

Mr. ROGERS. Do you think they would come out with committees of that nature?

Dr. BALL. I am not sure. We have discussed these types of committees. One could carry the patient protection committee to the point where literally getting informed consent would require a full-time professional sitting in on every interview between a patient and a physician to be sure that the rights of the patient are protected. That is a very heavy time commitment. It might be appropriate in some circumstances, but I think that the idea of protecting the rights of the patient requires also a commitment to the fact that you have to also assume that the investigator is interested in the rights of the patient.

Dr. COOPER. We would certainly hope that the revised guidelines, if they are adopted, might really furnish the base from which the Commission would develop its program and continue to refine it over the years as changes occur as it becomes aware of parts of the guidelines which should be revised. They would be a good starting

point, and the Commission would have a very good start in doing its work.

Mr. ROGERS. Well, as I understand it, then, you favor the establishment of a Commission. You do not think that you get into the business of immediately regulating from the Commission itself, nor should they set up these committees as yet, but they could look into it and make recommendations when it should be done?

Dr. COOPER. Right.

Mr. ROGERS. Any questions?

Mr. CARTER. I am pretty much in agreement with what the gentlemen have said as to the functions of the committee. One thing that I was interested in was about the fetus—that there should be no prohibition on research activities involving fetuses and infants.

Dr. COOPER. At this time, sir, as specified in the bill.

Mr. CARTER. Yes.

Dr. COOPER. That is, that the guidelines which are now in the NIH policy or in the revised policy, should be implemented, or rather should be the guiding principles until the Commission can make a study of this matter and come to some specific recommendation about exactly what kind of control there should be.

We are not saying that research on fetuses or infants should be carried on without any restrictions. We didn't mean to imply that, and it may not have been clearly stated.

What we really mean is that the prohibition, as stated in the bill, is not very clear. For example, it says:

Until such time after certification of institutional review boards have been established and the commission develops policies with regard to conducting research on living fetuses or infants, the Secretary may not conduct or support research or experimentation in the United States or abroad on a living fetus or infant whether before or after abortion.

As you know, there are very few infants that result from induced abortions. I mean, the very language of it is not clear.

The definition of fetuses, infants, and so on, is not clear, so we think the language itself is not very clear.

[The following proposed new language was received for the record:]

PROPOSED NEW LANGUAGE FOR SECTION 1205

We would like to offer new language for section 1205, along with definitions. We would suggest that the present language in section 1205 be stricken, and that the following new language be substituted:

"Until the Commission develops policies with regard to the conduct of research on the living fetus and abortus, the Secretary shall regulate research conducted on the fetus and the abortus, both before and after abortion, in such a way as to recognize the need to protect the products of conception and at the same time permit the conduct of essential biomedical research."

The terms we have employed in this suggested language are often used rather loosely by the public. In order to clarify their meaning, some specific definitions of these terms would be very desirable. For the purposes of this legislation, we would define "fetus" as the product of conception from the time of implantation to the time of delivery from the uterus. We would define "abortus" as a fetus when it is expelled whole as a result of medical or surgical intervention undertaken with the intention of terminating a pregnancy, prior to viability. For the purpose of this legislation, this definition of abortus would exclude: fetal material which is macerated at the time of expulsion, the placenta, a dead fetus, and isolated fetal tissue or organs excised from a dead fetus. The "viability" of a fetus (which is determined after either a spontaneous delivery or an abortion), entails a subjective and objective judgment by the physician attending labor or

examining the product of conception. Viability is the ability of the fetus, given the benefit of modern therapy, to survive to the point of independently maintaining vital functions, in which case the fetus is a premature infant. In general, and all other circumstances notwithstanding, a beating heart is not sufficient evidence of viability; an additional necessary condition is the possibility that the lungs can be inflated. Lacking this feature, no currently available mechanisms to initiate or maintain respiration can sustain life; and in this case, though the heart is beating, the fetus or abortus is in fact nonviable.

Mr. CARTER. You explained it to my satisfaction. That would bear, almost, for example, on amniocentesis?

Dr. COOPER. Of course, it certainly would.

Mr. ROGERS. Mr. Hastings?

Mr. HASTINGS. Thank you. I think again your position was very well articulated here. The recommendation for changes in the makeup of the commission certainly are noted. I am not so sure I agree with the one that you made about Senate approval, you know, the bill says that the chairman, by advice and consent of the Senate, but your recommendation is that all members should be subject to that. That might cause me a little difficulty. Other than that, your approach is not too unlike that of Dr. Chalmers, if I understood it. You want the commission, but to slow down before we automatically write into the statute an acceptance of the recommendations?

Dr. COOPER. The reason that we recommend Senate confirmation is that this commission will be operating in an extremely sensitive area, and we think there ought to be full public debate on its membership, all of its membership. That was the reason for making that recommendation.

Mr. HASTINGS. I guess you just may have more confidence in the Senate than I do. Thank you very much. I do appreciate your contribution.

I noticed that in the last paragraph, the last couple of paragraphs of your statement, you mentioned that most schools cannot expand their teaching operations without assurances of specific additional financial support.

Dr. COOPER. We did make this point in our testimony. There is one further point I would like to call to the subcommittee's attention. We are terribly concerned about peer review and the challenges that are being made on the peer review system, which we think has served the Federal Government and the research establishment very well over the years. It has made possible the kind of cooperation between the public and the private sector which has been one of the greatest successes of this country. We are very concerned about maintaining this relationship and also the most appropriate expenditure of the funds that you appropriate. On the other hand, we are concerned that the private sector does have a way to involve and participate appropriately in the development of the administration of public policy on biomedical research. We do want to see that those who do it have some input into what the programs are. So we are terribly concerned about peer review.

Mr. HASTINGS. Well, I thank you very much, all three of you, and in the words of the chairman, I would add your testimony will be most helpful to this subcommittee.

Mr. ROGERS. Dr. Carter?

Mr. CARTER. What is your information about peer review? Would you elaborate on that?

Dr. COOPER. Well, sir, there have been a number of statements.

Mr. CARTER. Or is it PSRO?

Dr. COOPER. No. We were talking in this situation about the peer review of the study sections, the councils, and the other apparatus that has been so effective, we think, over the years.

Mr. CARTER. Yes, sir.

Dr. COOPER. In the National Institute of Health and in other programs of DHEW.

Mr. CARTER. Yes.

Dr. COOPER. No, sir, I hope we don't have to open up a discussion of PSRO's.

Mr. CARTER. You wouldn't want to take a position on that?

Dr. COOPER. No, sir. I don't know whether it is appropriate to take fifth amendments in front of subcommittees of Congress or not, but—

Mr. CARTER. Well, I am a believer in peer review. I am not so sure I am a believer in PSRO. Thank you very much.

Mr. ROGERS. I am sure you know that when we had the training research bill on the floor, an amendment was added by the House itself prohibiting research on a fetus?

Dr. COOPER. Yes, sir.

Mr. ROGERS. With a heart beat.

Dr. COOPER. Yes.

Mr. ROGERS. And it did not prescribe infants as well. What would you think if we left that as a policy until the commission made its recommendations; just restrict it to the live fetus?

Dr. COOPER. Well, it gets into a very complicated area. It depends on what the definitions are. I mean, as I think Dr. Carter has pointed out, one might extend this so that amniocentesis might be considered as some kind of experimentation on fetuses.

The NIH guidelines, it seems to us, particularly those developed recently, give adequate protection for experimentation on fetuses, and it would be our hope that those guidelines could serve as the basis for that kind of research until the commission could make a very thorough and deep study of this whole area to come up with, let us say, an approach which might be less based upon emotional feelings.

Mr. ROGERS. Yes, sir. But I think it may be difficult for this committee in conference not to recognize the House feeling on this particular matter where it is restricted to fetuses and not to infants. This could cause some problems.

Mr. CARTER. Mr. Chairman, on that very thing, amniocentesis, as Dr. Cooper stated, might be interpreted as experimentation. The fluid in which the fetus lives and cells from the fetus by which microscopic examination of the cells, by this method, it can be told if the fetus is normal or abnormal or what type of abnormality it might have. So I think that that should be considered.

Mr. ROGERS. That may have to be made clear in the conference report.

Dr. COOPER. Yes, sir; because, as Dr. Carter said, it is really a matter of the definition of exactly what you mean and the word "fetus," that word is not very definitive and clear. So that we see that as one of the problems.

Mr. ROGERS. It might be helpful for you to get us the definition, if it is appropriate.

Dr. Challenor, we are grateful for your being here, and I know William Hudnut would have liked to have been here. He had to catch a plane. He asked us to express his regrets.

[Congressman Preyer subsequently submitted written questions to Dr. Cooper—the question and answers follow:]

QUESTIONS SUBMITTED BY CONGRESSMAN RICHARDSON PREYER AND ANSWERS BY DR. JOHN A. D. COOPER, PRESIDENT, ASSOCIATION OF AMERICAN MEDICAL COLLEGES

1. "You may have heard me mention Dr. Bernard Barber's research in conjunction with the work on his book *Research on Human Subjects* indicates that 35% of those institutions where less than all clinical research is reviewed were medical schools. Is this cause for concern?"

Dr. Cooper: All of the nation's medical schools have established institutional human experimentation committees. The purpose of these committees is to consider research proposals before any research is even conducted. These committees are usually responsible directly to the Dean or to the executive faculty. Thus, to the best of our knowledge, all research involving human subjects is subject to careful review in every school. Thus, I do not think Dr. Barber's comments are accurate.

2. "What types of biomedical and behavioral research are the medical colleges involved in?"

Dr. Cooper: The nation's medical colleges conduct all types of biomedical and behavioral research. Their activities cover the full spectrum of such research, and reflect the same interest and activities of other types of research institutions.

3. "What standards must they adhere to? To whom do their researchers report?"

Dr. Cooper: Our medical schools have voluntarily adopted the DHEW policy guidelines as their operating standards for all of their research, whether or not it is federally supported. Researchers report to their principal investigators, who are responsible to the human experimentation committee, to which I referred in an earlier question.

4. "From where do the researchers draw their subject populations? Any medical students?"

Dr. Cooper: Medical school researchers draw their subjects from two basic population groups. The first is the general patient population at an academic medical center. The other, or "special" population group, consists of volunteer normals, prisoners, and individuals with unique traits, such as carriers of sickle cell disease. It is the policy of the schools to discourage participation of medical students in research projects, but there are occasionally a few students who will participate anyway, usually as volunteer normals.

5. "What is your feeling with respect to a National Board for the maintenance of uniform standards in human experimentation?"

Dr. Cooper: The Association could support the concept of a National Board to maintain uniform standards in human experimentation, if this Board could remain flexible enough to cope with constantly changing technology and knowledge. A Board that is composed of individuals highly qualified by training in the areas of medicine, law, ethics, etc., and that is open to public and scientific comment and accountability is an excellent first step. It would be imperative that this Board be able to constantly reevaluate its policies and regulations both to assure maximum protection, and at the same time, assure maximum advancement in our efforts to better the quality of life.

6. "What sorts of things should the local Institutional Review Committees be concerned with? What ideally should their relationship be to the National Board?"

primarily with the quality of the research conducted, and should function as the

Dr. Cooper: The local Institutional Review Committee should concern itself local unit which carries out and enforces the standards promulgated by the National Board. The National Board should provide an additional review mechanism whereby, at the request of the IRC, the National Board will offer consultation in cases where the IRC believes that the exact ethical issues are unclear, or wishes an additional level of decision making. Such a reference function would enable the Board to continually reevaluate its standards and carry out its statutory goals to the maximum extent possible.

7. "Is psychosurgery presently being taught in the colleges as a medically reliable technique?"

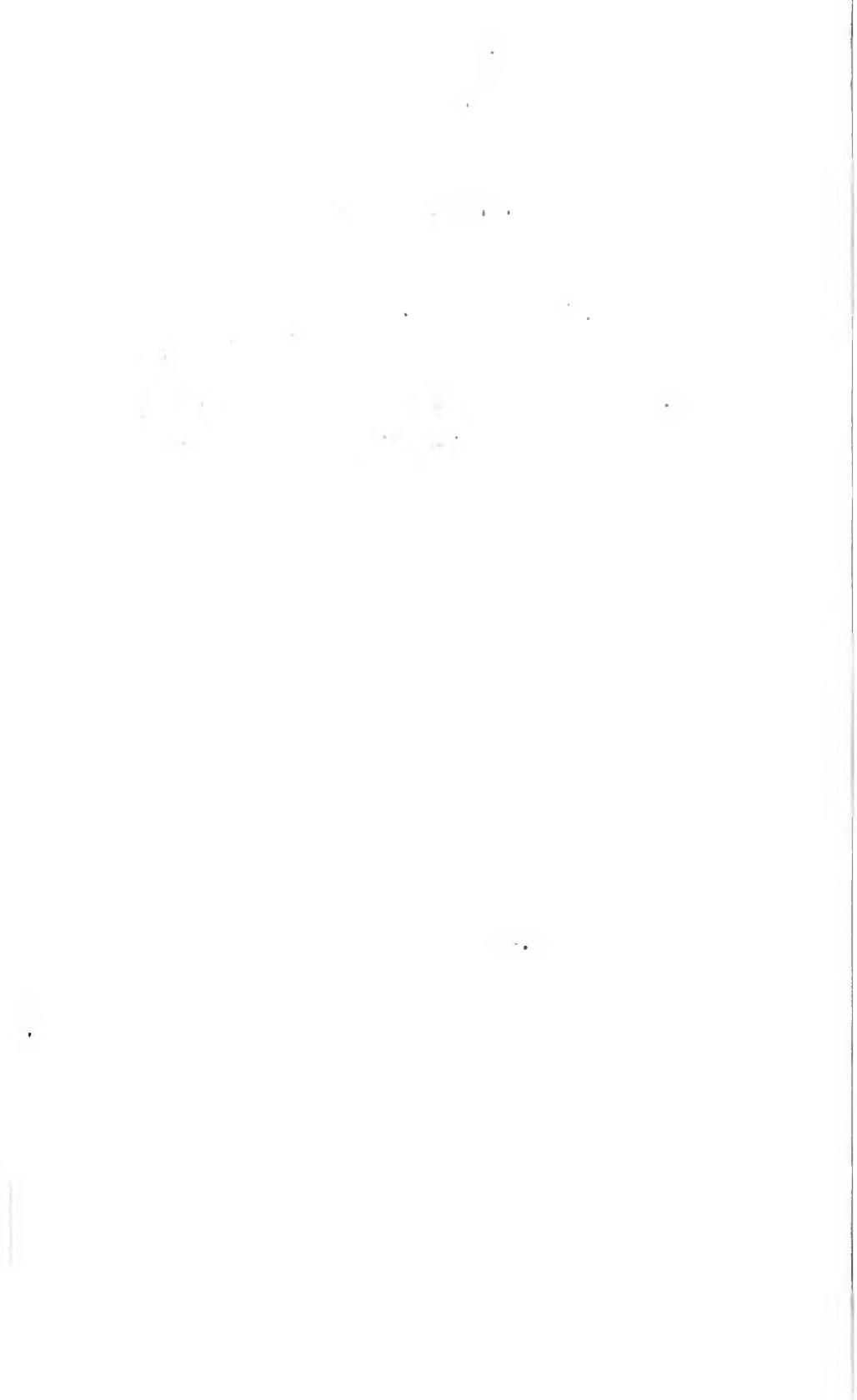
Dr. Cooper: Psychosurgery is a highly specialized technique which has been carried out in only a limited number of medical schools. Because of its highly specialized nature, it would ordinarily not be considered in undergraduate medical education. There are a variety of views on the effectiveness of psychosurgery depending upon various conditions for which it is proposed. The medical schools certainly would not consider it as a medically reliable technique for all conditions.

8. "What is your reaction to a moratorium on psychosurgery (except in those cases it has been shown to be medically effective, i.e. Parkinson's disease, epilepsy) until the Board is able to consider at length its efficacy?"

Dr. Cooper: We have no strong reactions to a moratorium on psychosurgery until guidelines can be developed by an appropriate review body. Such a surgical procedure should be allowed in such cases as epilepsy or Parkinson's disease, where a definite physiological disorder is involved.

Mr. ROGERS. The committee stand adjourned until tomorrow at 10 a.m.

[Whereupon, at 4 p.m., the subcommittee adjourned, to reconvene at 10 a.m., Friday, September 28, 1973.]



BIOMEDICAL RESEARCH ETHICS AND THE PROTECTION OF HUMAN RESEARCH SUBJECTS

FRIDAY, SEPTEMBER 28, 1973

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

The subcommittee met, pursuant to notice, at 10 a.m., in room 2322, Rayburn House Office Building, Hon. Paul G. Rogers presiding.

Mr. ROGERS. The subcommittee will come to order.

We are continuing our hearings on H.R. 10403 and other bills concerned with the protection of human subjects in research programs. The committee is pleased this morning to have as its first witness, Dr. Jay Katz, Yale University Law School, New Haven, Conn.

We welcome you to the committee. You may proceed in any way you desire.

STATEMENT OF DR. JAY KATZ, YALE UNIVERSITY LAW SCHOOL

Dr. KATZ. Mr. Chairman and members of the subcommittee, in two earlier appearances before the Senate Subcommittee on Health,^{1,2} I have urged Congress to consider drafting legislation for the control of human experimentation. It was only after prolonged reflection that I have come to the conclusion that such a step was necessary; for in theory I would have favored self-regulation by the professions. But it is an inescapable fact that all professions have an inherent incapacity to promulgate meaningful self-regulation,^{3,4} and the medical and behavioral science professions are no exception. They have been unable and unwilling to provide sufficient guidance to their investigators or sufficient safeguards for the subjects of research. Thus the establishment of a commission as proposed in Senate bill H.R. 7724 is essential, not only for the protection of research subjects but also for the protection of the research enterprise and of society. I shall limit my opening remarks to an expansion of this triple theme as well as to a few recommendations about revisions in the bill now before you.

¹ Katz, J.: Opening statement before Subcommittee on Health—subcommittee of Committee on Labor and Public Welfare (Mar. 8, 1973).

² Katz, J.: Opening statement before Subcommittee on Health—subcommittee of Committee on Labor and Public Welfare (June 30, 1973).

³ Tuskegee Syphilis Study Ad Hoc Advisory Panel: Final report of Subcommittee on Charge III (Jay Katz, chairman). Washington, D.C.: U.S. Department of Health, Education, and Welfare (1973).

⁴ Katz, J., and Capron, A. M.: Social Factors Affecting the Modern Treatment of Catastrophic Diseases (Contract No. HSM 110-69-219). Washington, D.C.: National Center for Health Services Research and Development (July 1973).

⁵ Katz, J., with the assistance of Capron, A. M., and Glass, E. W.: Experimentation With Human Beings. New York: Russell Sage Foundation, (1972).

PROTECTION OF SUBJECT, RESEARCH, AND SOCIETY

I do not wish to describe to you in detail once again examples of unconscionable or thoughtless abuse of research subjects. By now they must be well known to you. Indeed, an unremitting focus on such dramatic transgressions obscures the realization that they are only symptoms of an underlying disease which has wider ramifications and affects though in less obvious a fashion, many, if not most, research projects.

Let me instead discuss some of the issues which underly contemporary research practices. The recently aborted Detroit psychosurgery experiments were not stopped by DHEW regulations; in fact, they had passed the procedural hurdles laid down in the Department's guidelines. The experiments were halted through the efforts of an intrepid group of lawyers who petitioned the court for a review of the proposed study. But even more important, this type of research is neither an isolated case of mutilative brain investigations nor an isolated case of research with prisoners. Its dramatic quality and, in this instance, fortunate outcome should not deny the reality that research with prisoners is currently being conducted in our country at an unprecedented rate, unknown to the rest of Western society.

Yes, these projects are being "reviewed" by institutional review committees, and the prisoners are said to lobby for participation and to give their consent eagerly. But they do so because participation provides them with opportunities to earn some money, or to live for a time in research units superior to the squalor of their ordinary existence. These facts raise complex questions which extend beyond informed consent and even risk taking, though they are troublesome questions in their own right. What I have in mind are such questions as: To what extent should investigators be allowed to exploit the unfortunate conditions of prison life, or how widespread a use of prisoners should a society tolerate for research purposes, or what impact will the increasing participation of prisoners in research have on the administration of justice?

These are only some of the questions which, I submit to you, members of individual review committees have neither the capacity nor the time, interest, and resources to confront. To define the issues and to formulate meaningful regulations require the establishment of a Commission which can survey what is happening throughout our prison system and whose task it is to formulate specific guidelines for the employment of captive populations in research. And this group must consist not only of representatives of the biomedical and social science research professions, but of other segments of society as well.

The recent controversy over experimentation with fetuses also demonstrates the need for formulating overall research policies. Even though the likelihood of such research could have been predicted long ago, indeed DHEW must have known that it had already arrived on the scene, the Department left it solely to the 600 or more individual review committees to establish their own policies. This is not only an unnecessarily repetitive assignment, but also a responsibility to which these committees could not rise. Let me emphasize again that these committees have neither the time nor the interest nor the capacity to undertake this assignment. This is a most important point because DHEW relies so heavily and almost exclusively on these committees.

Moreover, such decisionmaking should not be made behind closed doors. The decisions arrived at deserve publication, so that not only the public can participate in approving, modifying, or proscribing such research practices, but also the scholarly community—for example, lawyers, doctors, historians of science—can contribute to the debate on the safeguards which should be provided for such activities. “From this,” as Professor Calabresi has put it, “a sense of what society at large deems proper in medical experiments might well arise * * * [taking] into account much broader sources of information as to societal values.”⁶ Senate bill 7724 provides for the creation of procedures which will insure publication and review.

I have recently been a member of the Artificial Heart Assessment Panel convened by the Heart and Lung Institute. We learned that before too long artificial hearts may be available for human implantation. The availability of such devices will require the resolution of such complex issues as subject selection, particularly since at first the devices will be in scarce supply; risk taking, and a calculus for balancing risks against expected benefits; the boundaries between experimentation and therapy, for labeling it either, will have significant consequences; et cetera. Under existing policies, all these decisions are left to individual review committees, and again I submit that they cannot handle these assignments. Indeed, the creation of the proposed Commission should provide the opportunity to study these problems and to propose rules and procedures long in advance of the first human trials.

Not so long ago coronary artery bypass surgery was introduced as a surgical treatment for certain heart diseases. The operation is now being employed in thousands of patients each year, though the merits of the procedure have not been established through prior careful clinical trials. At this time, with claims of therapeutic effectiveness drowning out doubts, it is difficult to conduct a double-blind study to test these assertions because patients cannot easily be asked to forgo a treatment that is advertised as being “effective.” The proposed Commission would be in an authoritative position not only to devise standards for the conduct of urgently needed double-blind experiments but, even more important, to establish standards for the conduct of careful clinical testing before any major biomedical innovation is introduced on a massive scale.

Let me underline here that in this instance, and it is one of many, the Commission can play a major role in improving clinical research practices which have long suffered from unsupported claims of therapeutic merits based on faulty and careless methodology. Moreover, double-blind studies, in which neither subjects nor investigators know which of two procedures are administered, or single-blind studies, in which subjects alone do not know, raise important issues for the informed consent process since in carrying out such studies at least some information must be kept from the participants. These decisions should not be left to the research community alone, since they involve fundamental issues of social policy; for example, the impact of such practices on “thoroughgoing self-determination,” a fundamental posit of our legal system. Again DHEW regulations do not address them-

⁶ Calabresi, G.: “Reflections on Medical Experimentation in Humans,” 98 *Daedalus* 400 (1969).

selves to these problems, nor do I believe that the underlying philosophy of these regulations readily permits their meaningful confrontation.

Finally, the widespread use of children for research raises many troublesome problems. The controversy over the Willowbrook hepatitis studies demonstrates the need for a searching inquiry into the widespread use of institutionalized children for experimental purposes; the exploitation of substandard conditions, which aggravate diseases from which children are suffering, as a felt necessity for the conduct of research; the use of children when adults might serve as subjects instead; et cetera. Moreover, who should give consent for research with children; are parents, superintendents of institutions, legal guardians always best situated to do so? One fact I have no doubt about; namely, that children are used for research with all too unnecessary and thoughtless frequency.

What are the significant features of the bill before you? I would single out three:

(1) A central group will be responsible for formulating policies instead of the hundreds of individual review committees which cannot be expected to assume this complex task.

(2) "Outsiders" who can represent and protect individual and societal values and interests will be included in policy formulation and review.

(3) Procedures are created for the publication and review of important decisions. These provisions will radically change the currently uniformed and secretive climate which pervades research decision-making.

RECOMMENDATIONS FOR REVISIONS

Section 1201(a) provides that the proposed Commission be "established within the Department of Health, Education, and Welfare." I believe that the Commission should be independent of DHEW, for the Agency which both conducts a great deal of research itself and supports much of the research that is carried on elsewhere, is not in the best position to regulate dispassionately the human experimentation process. If the Commission must remain within DHEW, every effort should be made to give it as much independence as possible and this should be reflected in the proposed legislation. For example, the National Transportation Safety Board, which is a part of the Department of Transportation is accorded such independence: "In the exercise of its functions, powers, and duties, the Board shall be independent of the Secretary and other offices and officers of the Department."⁷

By placing the Commission within DHEW, its authority may extend only to research supported by the Department (see also sec. 1203 (a)). I believe that at least all federally supported research involving human subjects should be covered by the act, whether such research is conducted in intramural or extramural settings, or sponsored by other governmental agencies, such as the Department of Defense. Moreover, serious considerations should be given to extending the authority of the Commission to all human research activities conducted throughout the United States, whether federally supported or not. I appreciate that section 1202(a)(5) asks the Commission "to recom-

⁷ Public Law 89-670 § 5(f). 80 Stat. 935, 936 (Oct. 15, 1966).

mend to Congress * * * an appropriate mechanism to broaden the scope of the committee's jurisdiction," but perhaps you can move in this direction already at this time.

Section 1205(b) (2) provides that the Institutional Review Boards "be composed of sufficient members, including religious leaders, persons schooled in ethics, and non-health-care professionals, with such varying backgrounds of competence as to assure complete and adequate review." I would suggest instead that the administration of research be left primarily to the researchers' professional peers. Once adequate research policies have been formulated by the Commission and satisfactory review mechanisms have been established—and it is at these stages of the process where the participation of a broadly representative membership is required—"outsiders" should intervene as little as possible in the administration of these policies. Thus, "outsiders" must be represented on the Commission but they should not interfere with the day-to-day professional decisionmaking; instead, the Institutional Review Boards should be advised, as provided in section 1207 (4) and (5) of the bill, to seek the assistance of the Commission whenever issues arise, not yet covered by existing policies, that require deliberation by the more broadly represented body. Therefore I would propose that "outsiders" on the Institutional Review Boards be limited to the Subject Advisory Subcommittees where they can make a valuable contribution to the supervision of the consent process.

Most important, the Commission should not be asked to undertake the duties specified under title III. As Senator Hughes pointed out so cogently during the Senate debate of H.R. 7724,

I am not entirely convinced that a single Commission, even with a staff of experts and consultants, can perform both tasks. It may well be that two separate commissions should be created. . . . Otherwise, we may find that the immediate task of devising appropriate standards and regulations will take precedence over the longer term intellectual exploration which could ultimately be far more significant.

The task of devising appropriate standards is a complex and difficult assignment in itself and I am afraid that both deliberations will be adversely affected if the Commission remains burdened with the dual assignment. I strongly urge you either to provide for the appointment to two separate commissions or, in the alternative, to specify that the National Commission for the Protection of Human Subjects only address the second assignment once it has its first assignment well in hand. Indeed the former assignment may benefit from the experience gained in devising appropriate standards and regulations.

One final point, since the Commission must address itself to complex issues, it would be advisable to give it sufficient time, perhaps 2 years, before it must report to the Congress on the various guidelines it has fashioned. I hope and expect that the Commission will have the capacity to make certain recommendations earlier, but it should not be forced to propose a complete set of recommendations hurriedly and unreflectively.

CONCLUSION

It has been insufficiently recognized that the major problems in human experimentation are not resolved by only defining the risks and injuries which subjects should or should not suffer from participation in research. The emphasis on risks has blinded the scientific com-

munity to safeguarding other values basic to our democratic society; for example, the right of individuals to thoroughgoing self-determination about anything which affects their mind and body. I submit that a scientist does not have an inherent right either for the sake of progress or for the sake of freedom of scientific inquiry to conduct, without consent, deception experiments, secret observations, double-blind studies, drug testing, et cetera. Society, through legislative action, may wish to delegate this right to him, but it has first to be so delegated.

None of what I have had to say should be construed as an attempt to stifle research. Medical research has made great contributions to the alleviation of human suffering in the past and should be encouraged to do so in the future.

Indeed, I believe that with greater public participation the demand for research will increase in intensity because society has always had an abiding interest in benefiting from the advances of medical knowledge—disease and death are enemies which the public dreads as much, if not more, than do the professionals. But at the same time I value respect for the dignity and integrity of man even more than the advancement of science. For progress, as the philosopher Hans Jonas has pointed out, “is an optional goal” and we have much more to lose, as we have lost already, from “the erosion of moral values”⁸ which inevitably follows any unauthorized invasion of man’s mind and body. The bill before you seeks to create rules and procedures for the protection of the rights of subjects, the welfare of society, and the claims of science, and it does so with the underlying intent of raising to consciousness a greater appreciation of the “social costs” we are willing to tolerate. This is all to the good.

Mr. ROGERS. Thank you very much, Dr. Katz, for a very excellent and a most helpful statement.

Mr. PREYER. Thank you, Dr. Katz. I bring you greetings from your colleague Alex Bickel whom I saw last night. I appeared with him on a program in Boston and I think I convinced him I need a refresher course in law school on courtroom procedures. I must say your testimony is as impressive as he led me to believe it would be. It is full of so many good things it is tempting to go through and point to one statement after another which you have made which I think are very important.

Certainly you make a powerful argument for a Commission rather than leaving this to the HEW as they ask. I certainly agree with you.

You mention the number of these individual agencies and divisions that have individual review commissions in this type of behavioral biomedical research. I gather there is no central clearinghouse. An HEW witness said that their guidelines are disseminated throughout all of these different groups and, therefore, there is some sort of unity to it. Are you aware of what sort of dissemination of these guidelines are available and what sort of enforcement mechanism is available to pull this together?

Dr. KATZ. Yes; I have sat on two review committees myself and we work with a yellow booklet of guidelines which HEW has prepared. But as we argued in our final report on the Tuskegee syphilis study, the guidelines are confusing, in part because they cannot be spelled

⁸ Jonas, H.: *Philosophical Reflections on Experimenting With Human Subjects*, 78 Daedalus 245 (1969).

out in a short booklet. And no procedures have been established for interpreting what the "terms of art" contained in the booklet mean. What do we mean by informed consent? What do we mean by risk-benefit equations? There are no provisions for the institutional review committees to get guidance with respect to interpretation. That is one problem.

The second problem, which I tried to address in my opening statement has to do with the fact that there are larger issues that are not even considered by the HEW guidelines.

I recently met with a member of a committee which reviews protocols of research projects conducted in prisons. When I started talking to him about some of the larger issues that required consideration before one can ever review an individual protocol; he was soon appalled because he had never thought about these issues and HEW has never addressed itself to them either in its guidelines.

Mr. PREYER. I think you make the point very well that these questions should not be decided behind closed doors. The rights of the individual involve more than just medical questions.

I would like to ask you one more specific question. You have indicated a real sensitivity to the problems of experimenting with captive populations—prisoners, mental health patients. The Butner Federal Corrections and Behavioral Research Facility in my home State of North Carolina is under construction. In your judgment, can we ever be truly successful in eliminating the coercive atmosphere of such an institution so that we have any such thing as a meaningful consent procedure? Can you set up guidelines that will work in that atmosphere?

Dr. KATZ. No; and that is a very, very important point. The whole issue of coercion needs to be studied in great detail because first of all, coercion is a fact of life. It surrounds all of us. In certain settings it becomes a more important issue. The more captive the population, the more important the problem. We have to begin to figure out when we will disregard coercion and under what circumstances we will assert that for certain kinds of experimentation the coercive aspects are too great, and therefore we do not wish to permit a particular experiment to be conducted. For example, I disagree with the decision of the Michigan court in the psychosurgery case because the Michigan court based its judgment on a reluctance to trust the consent of institutionalized prisoners. From all I have read about the case, I would argue that its investigators probably obtained as good a consent from the prisoner as they could get under any circumstances and that the Michigan court should have decided this case on the ground of public policy; namely that this type of mutilative surgery, while it is still so highly experimental, should not be inflicted on any institutionalized prisoners in our midst. We have to think these issues through very carefully and figure out in what directions we wish to move.

I submit there is nobody in HEW who addresses itself to these complex problems, and I hope that the Commission will do so because that will be their assignment.

Mr. PREYER. Thank you again. I think your recommended revisions are very interesting.

I have introduced a bill—H.R. 10573—which includes some of those. You mention that the Commission should be independent of HEW, with which I agree.

You also think we should consider extending the authority of the Commission to all human research activities. The bill I have introduced does extend the authority somewhat. You have made some other very interesting suggestions and your testimony will certainly be helpful to the committee.

Mr. KATZ. Thank you.

Mr. ROGERS. I was interested in following up on the question of coercion. For the most part, who are people who volunteer, not in therapy situation, but simply volunteer for research projects? Are they people who need money or mainly prisoners or is it someone who is just interested? Are they medical students? Are they nurses? Who have you found are those who would volunteer and what is the incentive?

Dr. KATZ. Mr. Rogers, the interesting point is, and I have talked about it at great length with scientists on many occasions. I have urged them to conduct studies on volunteering. We have relatively little data on this point. Surely medical students, members of the paramedical and parascientific communities have volunteered for experimentation. There is some data on this topic in mere therapeutic settings; for example, about organ donations. People apparently volunteer and some have been subjected to careful psychological examination. It was found that they were as healthy as most of us are and that there ceases to exist an altruistic motivation for volunteering. I think there will always be persons who will come forward for all kinds of reasons and who will volunteer. But we need more data on this. My hunch would be, from what I know about human psychology, that there is a much broader base within the population for participation in research than even the research community assumes. There exists a very curious situation within the research community; it suspects people who come forth and volunteer from the community at large, it does not trust their motivations. Even though all studies seem to indicate that their willingness to volunteer is trustworthy.

Mr. ROGERS. I just wonder, when we talk about the freedom of concept, say, in an institution, you then equate it with some one is in a very low economic group and he needs money. Is that a like pressure, even though he is not confined? Is there much difference of pressure? A man may want cigarette money for being in prison. This man may want it for food outside? Is there a difference?

Dr. KATZ. It is really not a qualitative difference. It may be a quantitative difference. Again, the Commission will have to address itself to this question, as the research community should have, because there has been a deliberate attempt to use primarily persons from the lower socioeconomic group as research subjects. The Commission will have to confront the question to what extent should a cross-section of the population be used for experimentation? At all research centers not only patients from the wards but also patients from private and semi-private pavillions should be approached and asked to participate in research that benefits all of us.

Mr. ROGERS. Should we have different rules and regulations and should we ask for it for research having to do with therapy? Should we ask for it for those involved in that type of research and the patients involved, and that research regarding a volunteer situation which is not in relation to therapy for the individual?

Dr. KATZ. Yes, Mr. Rogers, and that is a very, very complicated problem. One might argue that we need more stringent standards for research with patients than with volunteers because volunteers at least know that they are part of a research effort. Patients often do not know to what extent new procedures are being tried out for their benefit or to what extent they are also being used for the acquisition of knowledge. This is becoming an increasingly important problem. I think this issue may explode in our faces one of these years, because the research profession both wittingly and unwittingly are calling more and more studies therapeutic rather than experimental, because in the therapeutic setting they have much greater authority to proceed than they now have in the experimental arena. The Commission has to address this issue, too.

Mr. ROGERS. I understand you are addressing double-blind studies. Is not the problem there one where we may have some knowledge, some indication that a drug or what ever we may be using is beneficial or has a good chance to be beneficial and yet we are not using it purposely on these others to prove a point. Would that be a proper way to proceed?

Dr. KATZ. What I have in mind is, and this also requires further discussion, that at present double-blind studies are very difficult to carry out because as soon as a new procedure or a new drug comes on the market, it is immediately being tested out in clinical settings. Let us assume that the drug has some benefits, and that reports are published that there are good benefits, then it is very hard to carry out afterwards a double-blind study. I believe that serious consideration should be given to the proposition, and this may create new problems, that before any new therapy is introduced, a careful double-blind study must be carried out. At that point since one really does not know whether the therapy is beneficial or not, it is ethical to carry out a double-blind study. Today, it is hard to conduct a double-blind study on coronary artery bypass surgery because so many claims about therapeutic effectiveness have been made.

Mr. ROGERS. Did they carry on animal studies?

Dr. KATZ. Yes, although I am not familiar with all of the technical aspects.

Mr. CARTER. You think double-blind studies should be carried out to test the therapeutic effectiveness of various procedures; is that correct?

Dr. KATZ. I would think so but they raise problems.

Mr. CARTER. Would you consider the treatment of syphilitics down near Atlanta as being a double-blind study?

Dr. KATZ. No; it was not a double-blind study.

Mr. CARTER. In what way was it not?

Dr. KATZ. First of all, it was a single-blind study; they used controls and they used experimental subjects who knew nothing about what was being done to them and why they were participating in this project.

Mr. CARTER. You say you approved of the studies concerning the bypass operation of the human heart. Of course, we get into a very serious consideration from what I have read and what I have seen of this. I think the bypass procedure is quite effective in many cases. We have two groups and we deny the benefits to one and do not deny them to the other. If we do this, are we morally right?

Dr. KATZ. May I add two things. When I say I would have no problem with double-blind studies, this does not mean that society may not have different convictions about them; society may say no, we do not wish to have double-blind studies performed for x , y , and z reasons. In order to have double-blind studies, there needs to be first of all societal approval for the conduct of such studies. We do not have mechanisms for obtaining said approval at this time.

Two, when you do double-blind studies, you may be able to tell the persons involved, "Look, we want to conduct a double-blind study. We want to randomly assign you to one group or another. Do you wish to participate in this?" Consent is not completely ruled out by double-blind studies. Only certain aspects of the disclosure process has to be modified. This was not true in the Tuskegee syphilis studies. The subjects did not even know they were part of an experiment during the entire 40-year period.

Mr. CARTER. There were subjects treated and were not, did not know whether they were receiving treatment or not.

Actually I think, Mr. Chairman, there are many people who have these heart conditions and need bypass surgery, but refuse to have it because of fear. They could be in one class, those who do not choose to have it, and those who do choose. By that we can have a comparison of the relative effectiveness of treatment and not treatment.

Dr. KATZ. The research community would be dissatisfied with this procedure because it gets into the problem of who selects himself in and who selects himself out, and this selection factory complicates the evaluation of a research project.

Mr. CARTER. He is still master of his fate. Take those people who need bypass surgery but don't want it. They are willing subjects for your study and doing nothing to them, but you can compare them with those who do want it and most of them who have coronary insufficiency and whose life expectancy is short do want the surgery, then there you have your two ways of comparing this.

Dr. KATZ. Your points are very well taken, I think they illustrate the need for having public discussions and public airing of these issues, however, such opportunities are not available under the existing system.

Mr. ROGERS. Let me ask you, should there be an appeal mechanism of some type?

Dr. KATZ. Yes, there has to be.

Mr. ROGERS. When there is a ruling against the person they have some forum to go to to appeal.

Dr. KATZ. Yes, Mr. Chairman.

Mr. CARTER. Mr. Chairman, would this go down to every person undergoing research?

Mr. ROGERS. In other words, should this apply to all research projects: in other words, where the investigators—

Mr. CARTER. Not just the projects, but the individual cases.

Dr. KATZ. Individual subjects?

Mr. CARTER. Yes.

Dr. KATZ. Who may wish to do what?

Mr. CARTER. On which doctors are conducting research studies. Should our Commission consider each individual case throughout the United States?

Dr. KATZ. No, they should not.

Mr. ROGERS. I think what we are thinking of is where an investigator comes in to do something and the committee mechanism says no. Should he have the right to appeal it to have some other group discuss it with him.

Dr. KATZ. That is most important. History tells us that the conduct of important research has not been impeded by society, but by members of the profession. Therefore, the appeals procedure would serve the useful function of bringing rejected research to the attention of others.

Mr. ROGERS. Should there be research at all on uncomprehending patients, mental patients, maybe children.

Dr. KATZ. Yes, but the condition for their participation have to be very carefully worked out.

Mr. ROGERS. Thank you, Dr. Katz.

Dr. KATZ. Thank you.

Mr. CARTER. Thank you, Doctor. It is very nice to talk with you. I think a Commission for setting down guidelines would be perhaps all right, but I think it could certainly go too far if every case throughout the country were considered before research should be undertaken in this case. It would absolutely halt research in its tracks as I see it.

By the way, I was just trying to think of who used neoarsphenamine?

Dr. KATZ. Dr. Ehrlich.

Mr. CARTER. In developing arsphenamine up to that time, we had no adequate treatment for syphilis except mercurial rubs. Arsphenamine was quite a successful treatment.

Dr. KATZ. It was.

Mr. CARTER. In developing that, how many people died of the effects of arsphenamine or neoarsphenamine?

Dr. KATZ. I don't know, but I would think a considerable number of people.

Mr. CARTER. Well, of course, that is quite true.

Dr. KATZ. May I say something. It is a very important point. A price has to be paid for progress. I am not suggesting that research should be halted just because there may be risks to individuals, but we have to figure out what price we want to pay for progress and under what conditions.

Mr. CARTER. In these cases, of course, these people would have suffered different degrees of syphilis and probably eventual death or insanity.

Dr. KATZ. That is true.

Mr. CARTER. Some of them died, but he developed neoarsphenamine that saved thousands more; is that correct?

Dr. KATZ. That is correct.

Mr. CARTER. Do you remember the development of the vaccine BCG by the French? We had a rather bad effect from that; isn't that true?

Dr. KATZ. I am not familiar with that.

Mr. CARTER. That was a tubercular vaccine developed in Paris around the turn of the century. They had 106 deaths when they tried to immunize people against tuberculosis. Yet BCG is used perhaps with great success today in the treatment of cancer. We lost some lives, but we stand a chance of saving millions more; is that not correct?

Dr. KATZ. Yes.

Mr. CARTER. Thank you very much.

Mr. ROGERS. Dr. Katz, thank you so much. We are very grateful for you being here and sharing your views with us.

Our next witness is Dr. Bernard Barber, chairman of the Department of Sociology, Barnard College, Columbia University.

We welcome you to the committee. You may proceed as you wish, Mr. Barber.

**STATEMENT OF BERNARD BARBER, PROFESSOR AND CHAIRMAN,
DEPARTMENT OF SOCIOLOGY, BARNARD COLLEGE, COLUMBIA
UNIVERSITY**

Mr. BARBER. Mr. Chairman, members of the committee, thank you for the opportunity to express my approval and recommend your positive action on the bill which is before you today, the Protection of Human Subjects Act.

May I say just a few words, first, about my experience with this matter? As a sociologist, I have been concerned with the problems of medicine, the professions, and science during my whole professional career. As a result of this longstanding concern, I have written several books and articles on these problems. More recently, during the last 4 years, together with three colleagues, I have been engaged in intensive research on the ethics of human experimentation. Without support from the Russell Sage Foundation, my colleagues and I have done two studies: One on a nationally representative sample of 292 biomedical research institutions using human subjects; in the second, on a sample of 350 research physicians using human subjects in two institutions, one we called University Hospital and Research Center, the other Community and Teaching Hospital—two typical research settings.

Confidentiality was, of course, guaranteed all our respondents. Finally, during the years 1966-70, I was a member of the Drug Research Board, National Academy of Sciences—National Research Council, and had many occasions during that service to discuss with my medical colleagues on the Board, and with the Commissioner of the Food and Drug Administration, some of the problems before you in your present hearings.

Perhaps I can best express my approval of the act by the form of necessarily brief answers to three essential questions.

The first question is: Is there a need for control and regulation of the widespread and indispensable practice of using human subjects in biomedical and behavioral research? If one but scans the evidence now available from research studies, from testimony presented before the Senate committee in its March hearings, and from journalistic reports of the Tuskegee syphilis experiments, the answer to this question is "Yes." Although ethical procedures have improved since the NIH mandate of peer review in 1966, for all the research it funded, ethical practice in the use of human subjects is still unsatisfactory in the light of what the public demands and what the research profession proclaims to be its own humane standards. Among other defects, and evidence collected in our study and in that of Prof. Bradford Gray of the University of North Carolina on present practice, shows the following:

(1) At least a significant minority of research studies are still being done where risks exceed benefits to subjects.

(2) Where such less favorable studies are being done, they are more likely to be done on ward and clinic patients than on private patients even in our most distinguished university hospitals and research centers.

(3) The ignorant, the poor, and the ethnically despised are more likely to be used as subjects, partly just because they are more often ward and clinic patients, but partly also because their handicaps make them more available.

(4) Prisoners and other captive populations are not adequately protected against abuse in experimental studies.

(5) Training for the ethical problems raised by experimentation is either nonexistent or casual not only in medical and other graduate schools but in intern and residency programs.

Senator Javits has introduced in the Senate a bill to provide funds for medical schools to improve these ethical training programs in the medical fields.

(6) The widespread overemphasis on science as against humane treatment leads to questionable research by both the relative failures in science and by the excessively ambitious and competitive.

(7) In a whole series of ways, such as lack of continuing review and lack of appeal procedures, present peer review committees do not function as effectively as they might.

(8) In many institutions, even those which presumably review all research, at least 10 percent of the research is still not being reviewed. This is what our research has shown.

And finally, (9) the medical schools, which are the self-proclaimed ethical as well as scientific leaders in the profession, have failed to justify their claims to ethical leadership. This is seen in their educational defects, but also in the functioning of their peer review committees, where one would expect leadership and excellence, are certainly no better, and in some respects are worse, than committees in other types of research institutions.

The second question I want to answer is, does the bill you are considering promise to improve significantly present and future practice in the use of human subjects in research? I think it is indispensable for such improvement. There is neither time nor need to consider all its detailed provisions. I would like to single out some of its more general virtues.

Here I shall inevitably be repeating what Dr. Katz has said, and I would say I would be proud to associate myself with his statement.

One of these virtues is that the establishment of a National Commission for the Protection of Human Subjects would transform a fundamental moral problem from a condition of relative professional neglect and recurrent journalistic scandal to a condition of continuing public and professional alike, need to have our level of consciousness raised in this area. Acknowledging that we have a problem and that we now have a societally supported obligation to alleviate it is a prerequisite to the rational and cooperative program of improvement that the act prescribes in the duties of the Commission.

But good intentions and moral declarations are not enough. Another virtue of the act is that it provides, not only in the persons of the Commissioners but in those of a full-time Director and staff, the necessary resources for carrying out the high purposes of the Commission.

One of the defects of our present situation is that there is a gross shortage of personnel and resources, both within the Government and from the relevant professions on an ad hoc basis, to cope with the tasks which are presently prescribed. The peer review committees have not had face-to-face meetings in many cases, nor do they have continuing review, nor is an appeal procedure available. Regulation of the use of human subjects is too important to our values to be any longer deprived of the means necessary to make it truly effective. Adequate personnel and resources on the Commission will make possible not only proper attention to day-to-day tasks but to special problems as they arise. Right now, for example, we ought to have Commission-appointed and Commission-supported groups studying such problems as the use of prisoners as subjects, what is to be done about research on children, the dilemmas of experimental psychosurgery, and the use of humans for research in vitro fertilization. For lack of present resources there is a pileup of such problems right now, but it is in the nature of scientific progress to continue to raise new ethical problems in the use of human subjects. The Commission will always have to confront a mixture of novelty and routine.

Finally, a third general virtue of the Commission is that it recognizes explicitly that research on human subjects is too important to all of us to be left to the researchers themselves. For the proper regulation of the powerful professions of modern society, we need a combination of insiders and outsiders, of professionals and citizens. The act you are considering establishes this wise principle in a way that has never been done before.

And that principle brings me to my third and last question. Is Government regulation necessary? Why not leave control of these matters to the researchers themselves? I want to answer this question if only because I know it may be asked by some of the biomedical researchers who will appear before you and who will speak in favor of absolute professional autonomy. That is only to be expected. All powerful professional groups resist objective scrutiny and control by outsiders and pledge that their own wisdom, initiative, and compassion are sufficient to protect the interests and values of their clients.

But my answer is different. My answer is different because it is a fact, carefully demonstrated by the findings of my research group, that the biomedical professions—and I would add behavioral groups—have not taken the initiatives necessary for protecting their human subjects. They have tended only to respond, and then reluctantly, to Government mandate enforced by the power of the purse. They have been laggard in improving the ethical education of their students, undistinguished in using peer review to control questionable research, and, at least in recent years, relatively more interested in the demands of scientific achievement than in the obligations of humane treatment of subjects.

Considerable personal acquaintance with medical researchers has indicated to me that they tend to view law and all Government regulations as necessarily negative, restrictive, and punitive—and this despite their positive experience with NIH and other Government funding. Given this view, some of them are likely to declare that this bill is negative, hostile, and a dangerous infringement of their powers and autonomy. But I do not see the bill this way. I see it as a positive, con-

structive, creative effort to deal with some of the unintended and undesired consequences of that great advance of science which in our time has on the whole been so beneficial for all of us. I very much hope that my researcher colleagues will come to see the bill in this way and will give it the kind of imaginative and energetic support which they already give to their scientific research. Such support is as necessary for success in ethics as in science.

Mr. Chairman, members of the committee, I strongly favor this bill and wish only that it applied to all Government research, not just that funded by DHEW. Indeed, I would like to see it cover all medical research, however funded.

Mr. ROGERS. Thank you very much, Dr. Barber, for your statement and for your letting us have the benefit of your research on this question. It will be most helpful to the committee.

Mr. Preyer.

Mr. PREYER. Thank you very much, Dr. Barber. I think your book will be very helpful in this field by outlining the research you have done. It points to a somewhat alarming situation in the medical schools.

Concerning the national Commission, do you feel that Commission should be an independent one or do you think it would work if it were within HEW?

Mr. BARBER. I think more knowledgeable heads than mine would have to decide precisely where it should be located. I think it probably should not be in HEW. It should have oversight on other Government funded research as well as research generally. My expectation is that even if this Commission is set up just to scrutinize Government-funded research it will have whatever the opposite is of chilling effect, a warning effect on institutions elsewhere. I serve as a kind of ethical consultant to one of the large foundations and I notice, for example, they use the DHEW guidelines and would be glad to go further with Commission policies and procedures, so some of its effect will spread in any case.

I do feel that it should be located in a place where there are no conflicts of interest, but yet where it is somehow responsible to the larger social and political process. I think the last thing in the world the advocates of this bill would want to suggest is that this is somehow to be a court of last resort. I think the whole larger political and public process, of congressional and public discussions, and legal adjudication, have to be the courts of final resorts.

Mr. PREYER. Thank you very much, Dr. Barber. I appreciate your testimony.

Mr. ROGERS. Dr. Carter.

Dr. CARTER. From what you say, you are quite an exponent of ethical and moral values and I trust that that is true and I like to see people that way. I want to say to you that the medical profession is like all other professions. It has people within it who perhaps don't obey moral and ethical canons. I would say no greater percentage than in your profession or in the legal profession and in most schools the students are taught ethics. While they are not special courses, in many schools along this line, they are all given the oath of Hippocrates. That is just the beginning of it. If every class ethical standards and values are mentioned by our teachers. As a member of that profession, it is not entirely decadent in ethic and morals.

As a great exponent of ethic and morality, I would like to ask your view on abortions.

Mr. BARBER. Could I first address myself to your other remarks?

Mr. CARTER. You have made quite an attack on the medical profession.

Mr. BARBER. No, I have not. I would hope that the medical profession might construe these recommendations just in the opposite way, that it is a point of pride that the medical profession has got as far as it has but it is still falling short of its proclaimed standards. My own feeling would be, if you asked me, that the medical profession overall does better than any of the other professions.

Mr. ROGERS. I will have to challenge that here as a lawyer.

Mr. CARTER. I said the same.

Mr. BARBER. I hope it is very clear that as a sociologist I would say it is only to be predicted that those who have made the greatest advances are those who are held up to the highest standards, but in this case it is very clear that those standards, self-proclaimed, have not been fully maintained.

Mr. CARTER. We have not answered my question. As an exponent of high ethics and moral values, what is your position on abortions?

Mr. BARBER. I don't understand just what you are asking me.

Mr. CARTER. Do you believe that a woman should freely obtain an abortion if she wants to have an abortion and at any moment of pregnancy?

Mr. BARBER. I think you would have misconstrued what I have in mind.

Mr. CARTER. You are not answering my question. You are obfuscating.

Mr. BARBER. We are trying to stress that we are very desirous of recommending certain procedures by which in effect the committee can have a vital part of say—

Mr. CARTER. You still have not answered.

Mr. BARBER. I have no absolute answer on abortions. I can give you my views.

Mr. CARTER. Let me hear them.

Mr. BARBER. One of the things I would be very much happier with would be if the whole discussion about abortions, the laws and practices about abortion had been considered by some of the kinds of agencies which we are proposing to you. I would like to make up my mind from time to time—I have no absolute standards—in the light of what I consider to be certain kind of informed and rational public participation.

Now, I can speak to one issue on that. Such a Commission, I suspect, would point out first of all there are no absolute rights in society because rights come into conflict with one another and they are always competing with one another. I certainly would not say there is an absolute right for abortion. Society might want to put all kinds of restrictions. It may want to set age limits and term times. My own feeling is, for example, that right now some of the courts have handed down decisions about the absolute right of the woman to say something about abortion which seems to say that the husband has no right in those decisions. But whatever I feel about it, I would like to have it discussed, as I say, by knowledgeable, open discussion and then I

would make up my mind for the time being what my views would be.

Mr. CARTER. You have not answered yes or no, but would you recommend that the panel make decisions on this which would be authorized by this legislation and that individual decisions be made by it as to whether doctors would proceed with abortions?

Mr. BARBER. In the first place, this is understood to be a Commission only for research. For example, under such a Commission, and this question has actually been settled by this bill, research on live fetuses is banned for 2 years. My own feeling is in matters that are no longer experimental, but therapeutic, the Commission will have no say. This is only for experimental research.

Mr. CARTER. This legislation would ban research on fetuses to prevent amniocentesis whereby it can be determined if a child is a mongol and you favor banning amniocentesis which certainly involves a fetus.

Mr. ROGERS. I think his position was one where he did not necessarily approve of the bill's banning of the research on fetus.

Mr. BARBER. That is right. Amniocentesis is a standard procedure. It is not experimental.

Mr. ROGERS. Even so, you do not approve of the ban of research on fetuses in the bill. Do you think that should be considered by the Commission rather than being done by law?

Mr. BARBER. That is right, and psychosurgery similarly.

I think one of our problems is that too often before we have an open public discussion we take a polarized absolute stance, yes or no. We are recommending really open and public inquiry and discussion. Not just as a social scientist, but as a citizen. I think very often we need to accumulate the facts about what is actually going on before we make up our minds. Again and again I noticed this in response by Dr. Katz to one of your questions, we simply don't know who volunteers. We have only a little bit of information. We now have one study of volunteers that could be followed up by other studies. I would like very much to see this Commission sponsor key kinds of research to find out what the facts are before the qualified moral decisions are made.

Mr. CARTER. Thank you, Dr. Barber.

Mr. ROGERS. Thank you so much for being here. Would you submit for the committee's use a copy of your study that you mentioned and also just give us from what you have seen in your peer review description in medical schools—who is on them, how often do they meet, and so on.

Mr. BARBER. Those data are in our books and we will be glad to submit that for the committee's use.

Mr. ROGERS. Thank you and we are grateful for your being here.

Our next witness is Dr. Robert Cooke, Department of Pediatrics, University of Wisconsin Medical School.

The committee welcomes you and your statement will be made a part of the record. If you would like to summarize for us rather than going over points that have been covered, you may do so.

STATEMENT OF DR. ROBERT E. COOKE, VICE CHANCELLOR FOR HEALTH SCIENCES, UNIVERSITY OF WISCONSIN

Dr. COOKE. My statement is quite brief and I would like to read it and then I would be delighted to answer questions.

I am Dr. Robert E. Cooke, presently vice chancellor for health sciences of the University of Wisconsin, Madison, and for the past 17 years pediatrician-in-chief of the Johns Hopkins Hospital. During this period, I have served as chairman of the scientific advisory board of the Joseph P. Kennedy, Jr., Foundation as well as a member of a number of scientific and honorary societies. Pertinent to this legislation, last year I served as a visiting professor at the Harvard University School of Medicine as a member of the Harvard interfaculty program in medical ethics; I am appearing in support of this bill, the Protection of Human Subjects Act, and sincerely believe that it will warrant an important place in the list of significant contributions which the chairman has made to the health care field.

Over a period of 30 years I have had firsthand contact with the conduct and supervision of research ranging from intensive studies of water and electrolyte metabolism in young infants which significantly altered the treatment of diarrheal diseases throughout the world to behavioral studies of normal and mentally retarded infants and children which have led to widespread acceptance of programs such as Headstart which I engineered, and parent and child centers—the pre-school program for infants 1 to 3 years of age.

Over this period of time I have had the opportunity to witness a dramatic increase in the sensitivity of most investigators to the protection of the rights of human subjects. Twenty-five years ago, my colleagues and I carried out studies considered to be completely consistent with ethical research practice at that time, which neither I nor the rest of the scientific community would tolerate at the present time. Without any question the leadership provided by the National Institutes of Health in requiring, for funding purposes, the establishment of institutional review committees has prevented to a large extent most serious abuses of the rights of experimental subjects.

These local review groups conscientiously investigate essentially all research projects submitted for funding by the Department of Health, Education, and Welfare. Such reviews are concerned both with the benefit-to-risk ratio of the research and with the consent and privacy of the subjects. Even projects funded by private funds may be submitted to extensive review (in a number of institutions).

If so much has been accomplished in the protection of human rights, if most subjects are afforded a large measure of protection by existing mechanisms, why do I urge the passage of this title which establishes a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research which will undertake the duties clearly outlined in the legislation?

To answer properly this question I would like to digress briefly to explain what I consider to be the basic ethical aspects of the problem of human experimentation. In contrast with common opinion, decisions concerning the use of human subjects in research, covering the selection of human subjects, covering consent, covering protection, covering confidentiality, are moral or ethical decisions, not scientific decisions. A local review committee when it approves a project for research funding makes an ethical decision, not a scientific decision, even though on the surface it seems scientific. It is an ethical decision because it is concerned with "ought", not "is." Indeed, ethics is the considered reflection on what is right or wrong, on what ought or ought not to be done. An analogy may help clarify the distinction

between nonmoral, scientific, professional decisions, and moral or ethical decisions.

Thalidomide was an excellent sedative. It was also a very dangerous teratogen—and produced severe congenital defects. Both of these statements are nonmoral, scientific facts. However, the decision to ban thalidomide was a moral decision—essentially a decision that no drug, regardless of how effective and beneficial to many, ought to be used that produced serious injury even if only to a few.

The decision to operate on a mongoloid infant to save his life is a moral decision. The kind of surgical technique to use is a professional, scientific judgment.

Committees on human experimentation thus deal with ethical-moral questions.

From my comments, it might be presumed that scientists therefore have no part to play in ethical decisionmaking. Of course, that assumption is not correct, as I will now attempt to establish.

In deciding upon human experimentation, there is always to a greater or lesser degree some conflict of basic ethical principles. Of concern always is the principle of utility or benefit. Without question, the scientist is best prepared to supply information in regard to utility—essentially nonmoral data. Also, risk can best be evaluated by the scientist. However, other fundamental, irreducible, ethical principles arise in human experimentation. Has there been a just selection of subjects? Is noninjury a fundamental principle not to be violated by this investigation?

An eminent ethicist now in residence at Harvard, Prof. Roderick Firth, has described the clearest process, to my mind, for ethical decisionmaking. It is entitled "The Ideal Observer Theory." In essence Professor Firth argues that the best ethical decisions would be made by a person nearest to the image of God—or Ideal Observer—who would have the following characteristics:

1. Omniscient—that is, having all the relevant facts.
2. Omnipercipient—that is, feeling acutely how all parties will be affected.
3. Dispassionate.
4. Disinterested.
5. Consistent.

In actual practice, no single human being can possibly achieve all these qualifications simultaneously. No single class of individuals can either. That is, scientists may approach omniscience in a limited way, but cannot possibly comprehend how the subject of research may feel. Likewise, the investigator, if he is dedicated to his work, cannot possibly be disinterested or dispassionate. Group decision with widespread representation of both the investigator's as well as the subject's interest is required.

These principles may seem self-evident to those trained in the judicial system, but it is relatively foreign to the field of biomedical research in which scientific data has been almost the sole criterion for action.

With such an approach in mind, it is possible to see the shortcomings of the present approaches to the protection of human subjects. By and large, the scientific community has been the sole or major determiner as to right or wrong behavior in the conduct of research. Again,

let me emphasize that in keeping with the principle of the ideal observer theory, the scientist has an important role to play, but not the only role. Many aspects other than purely scientific must be considered and represented even though the best ethics begins with the best facts.

Even though adequate protection of the physical and mental well-being of subjects has been assured in most instances by scientific self-regulation, when abuses have occurred, they have been monstrous and have seriously damaged the credibility of scientists everywhere. At the moment, for example, enough abuses have been uncovered so that public confidence in the ethics of research is in question.

Even when concern for risk is quite adequate, the scientific community has not been as vigorous in assuring that no discrimination in selection of subjects has occurred. Frequently, low-income populations have been the predominant subjects of biomedical and behavioral research simply because they make up the patient population of many biomedical teaching centers. Yet, due care has not been taken to assure a wider recruitment of subjects. Of particular concern to me as an active worker in the cause of mental retardation and in behalf of children, has been the rather widespread use of institutionalized patients as subjects for research without due concern for consent or advocacy on the behalf of the subject. Just a few days ago, I saw retarded adults being used as subjects for behavioral experiments—not harmed physically or probably psychologically, but being used nevertheless with only the agreement of the administrator of a proprietary custodial institution.

Indeed, the whole matter of informed consent has been regarded rather lightly by many in the scientific community despite the great complexity of the issue. How informed is informed? How free of coercion is any hospitalized or institutionalized subject? Is parental consent always in the best interest of the dependent subject? Such questions are not easily answered, but represent food for thought of considerable importance for a national commission.

To me, the development of principles and guidelines for the Nation as a whole would be of great assistance to scientists and administrators everywhere who are concerned with issues such as nontherapeutic research on the fetus: the newborn, the pregnant mother, the child, the retarded, the incarcerated, the poor.

To me, it is important that there be improvement in public representation and functioning of institutional review boards so that greater excellence in all institutions, not just most institutions, can occur. The greater research accountability of the community for its ethical decisionmaking should not inhibit, but encourage research. The development of mechanisms for compensation should increase rather than decrease public confidence in research in this country.

In considering the specific subsection concerned with psychosurgery I should like to comment briefly. I am not an expert in any way in neurology, psychiatry, or neurosurgery, but as a general principle, I believe great caution should be exercised in developing procedures in which irreversibility is a major concern. Damage to the central nervous system is for all practical purposes irreversible and therefore careful review of the present results seems warranted.

Of equal importance, or possibly even of greater importance because of the larger volume of cases, is the issue of abuses in the delivery of

health services. Recent cases well known to the committee and to the public attest to the fact that informed consent, group decisionmaking, justice as well as utility, the ethical principle of noninjury as well as benefit are important considerations in the care of patients in both public and private service programs.

It is my belief that the establishment of a commission, that the development of guidelines and procedures as a process, will have the valuable additional benefit of improving the climate of ethical decisionmaking everywhere. No monitoring system, no review process is superior to the heightened sensitivity of each and every investigator to the ethical issues in each effort in human experimentation or human care.

The commission provides a highly visible, public forum which can only increase awareness of each scientist and each patient as to the nobility of sacrifice for the benefit of others and for the necessary safeguards required for the protection of such volunteers on behalf of new knowledge for fellow human beings.

In closing, I must point out that the establishment of a commission is a step of major importance. It represents a national commitment to the improvement of the human situation. However, other material commitments must be made in addition if human subjects are to be assured maximum protection. For example, pregnant mothers, the unborn child, the newborn child deserve all the benefits of scientific research—biological and behavioral—just as other members of our society enjoy. Yet many drugs, many procedures, many advances go unused for these groups because adequate research has not been carried out. Many drugs, unquestionably of value in the treatment of infants, bear the label "not for use in infants under 2 years of age because evidence of efficacy or toxicity is not available." Much of this research could be done in immature primates. Indeed, with sufficient dollar support and ingenuity, many of the unsolved medical problems of the fetus and infant could be clarified.

If nontherapeutic, nonbeneficial fetal research is to be prohibited, a far greater financial commitment for primate research must be forthcoming. By far, the vast majority of important fetal problems can be uncovered by animal research even though more costly and more difficult. The therapy of some genetic diseases (such as Tay Sachs) can be studied only by research on human material. However, much of this material can be obtained after death of the fetus without compromising the outcome of the research.

It is my hope that one of the byproducts of the commission and of these and other hearings would be a greater awareness of the failure of our society to commit the resources necessary to solve problems with the least possible use of human subjects. Human experimentation must be a last resort, not the first and least expensive option.

Thank you.

Mr. ROGERS. Dr. Cooke, thank you very much. I think you put in good perspective the balance here that needs to be considered in making these decisions. We are most grateful to you.

Mr. Preyer?

Mr. PREYER. Thank you, Dr. Cooke. In the interest of time, I will ask only one question, although your testimony certainly raises a lot of interesting points.

How widespread today are experiments on children that are based only on parental consent?

Dr. COOKE. I think that is almost the standard operating procedure at the present time, and this involves both nonbeneficial as well as beneficial research, as Dr. Katz pointed out. I don't want to minimize the problems of beneficial research as regards children. The emotional involvement, the quite proper emotional involvement of parent with sick child will make a parent agree to almost any kind of new form of treatment if it will help that child and that may or may not be in the best interest of the child.

I think one of the major tasks that this Commission should tackle would be the whole matter of some advocacy that may be of assistance to the family. I don't want to substitute other people for the family completely at all, but some assistance to the family in trying to make decisions when research on children is involved.

I think older children could definitely be brought into the decision-making much more than they are at the present time.

Mr. PREYER. I think we should look into that. There are some court cases on the subject. As I recall, there is a case holding that parents may be free to become martyrs. It is not so clear that they are free to make martyrs of their children.

Thank you, Dr. Cooke.

Mr. ROGERS. Dr. Carter?

Mr. CARTER. Thank you Dr. Cooke. You have presented quite a good paper here, and I have enjoyed it thoroughly.

To get down to ethics, what is ethics? Could you define ethics for me?

Dr. COOKE. It has been described as considered reflection on the behavior and beliefs of human beings in terms of what ought or ought not be done and what is right or wrong.

Mr. CARTER. What basis is there for ethics?

Dr. COOKE. There are a number of bases. I don't want to pretend that I am a scholar in ethics. I spent only 1 year of study in the field. There are two general, moral systems that seem to be dominant in our thinking at the present time.

One is most easily described as utilitarianism in which the absolute principle which is used as the basis for what is right or wrong in terms of actions or right or wrong in terms of rules, is that action or that rule which produces the most benefit to the largest number. That is the basic, fundamental ethical principle of utilitarianism. This has, as you can imagine, many champions because it grew out of the Bentham and Mill orientation of economics. It has appealed to scientists obviously who attempt to quantitate most things in life.

The other school of ethical reasoning is what has been called formalism in which it is believed that there are other irreducible moral principles than just utility which must be considered in deciding what is right or wrong, what is a good rule or a good act.

Formalism essentially means that in addition to utility, there are other principles which all societies tend to believe in such as justice, the principle of noninjury, the principle of reparation. People may have slightly different lists in terms of what these principles are, but in general, most societies tend to agree there may be a few terribly important, irreducible principles.

An ethical analysis attempts to look at all rules and situations to see what ethical principles are involved and then tries to make a decision on that act or rule as guided by these particular principles.

For example, to give inadequate medical care to a large segment of the population that is poor might be considered from a utilitarian point of view or it might be looked at, is this good from the standpoint of justice? Are you being fair?

One can take different approaches to problems depending upon one's own ethical thinking.

I received some training in the formalism area, and to me I think this is a more appropriate approach to life than simply trying to judge everything on the basis of utility.

Mr. CARTER. You are quite a philosopher, and that is quite an excellent dissertation.

Do you accept the Ten Commandments as the basis for ethical behavior?

Dr. COOKE. I think the Ten Commandments are a statement of rather concrete actions and concrete rules which have been in a sense extracted into a much more abstract approach. When I say, for example, that I believe in the principle of noninjury. I am saying essentially, "Do not kill and do not hurt your neighbor." It is a much broader type of approach than the more concrete rules of the Ten Commandments.

As thinking in the field of ethics has proceeded over the years, it has tended to go from the much more specific and concrete to the much more general that will apply to all sorts of situations.

Thou shalt not kill—one could say—but people then throw in exceptions, such as war, such as capital punishment, and so forth and so on.

In modern thinking, one attempts to go from the more concrete to the more general.

Mr. CARTER. Did you say you accept the Ten Commandments?

Dr. COOKE. The principles of the Ten Commandments, yes. The Golden Rule is probably the one that comes closest to bringing justice, utility, and the principles of formalism together.

Mr. CARTER. Thank you, sir.

Mr. ROGERS. Thank you so much for being here. We are very grateful to you.

Our next witness is Dr. Robert Veatch, Institute of Society, Ethics, and the Life Sciences, Hastings-on-Hudson, N.Y. Thank you for being here and if you would care to highlight the comments in your statement, it will be helpful.

STATEMENT OF ROBERT M. VEATCH, PH. D., ASSOCIATE FOR MEDICAL ETHICS, INSTITUTE OF SOCIETY, ETHICS, AND THE LIFE SCIENCES

Mr. VEATCH. Thank you, Mr. Chairman.

Medical research is in trouble in our country. Those of us who see research as a crucial contribution to advancing mankind's health and happiness, have reason to be disturbed. The daily press is able to report experiments on human subjects which challenge the standards of both the medical profession and the reasonable man. We must find a way

of fulfilling our fundamental obligation to protect individual subjects of research and at the same time keep from destroying the research enterprise which has given our society so much.

In 1966, Dr. Henry Beecher, the eminent Harvard pharmacologist, provided a great service to the medical research community by summarizing in the *New England Journal of Medicine* 22 experiments including the injection of live cancer cells into patients without their knowledge and the purposeful giving of hepatitis to institutionalized mentally ill children. He challenged the profession to develop its own ways of regulating that small proportion of researchers who were conducting ethically questionable experiments on human beings.

Recently newspaper accounts of ethically questioned research have appeared with seemingly ever-increasing frequency. Seven women became pregnant when they unknowingly are given placebos in place of contraceptives; blacks with syphilis are purposely untreated; mentally retarded young women are given experimental contraceptive implants without adequate consent.

In recent testimony before the Senate Health Subcommittee we presented reports of 12 ethically questionable experiments. Researchers inject epinephrine into normal women patients trying to produce an abnormal heart beat in order to test a new drug. Twenty-four subjects who answer an advertisement in a newspaper are given LSD to study long range "personality, attitude, value, interest, and performance change." Ninety patients at a maximum security facility for the criminally insane are given a drug which paralyzes respiratory muscles giving a sensation of drowning in order to test psychological conditioning techniques. Two hundred and sixty mental patients are given unmodified electroconvulsive shocks, a procedure of great trauma, as an incentive to get them to work and support themselves.

One hundred and thirty children with asthma, some of whom received nothing but salt solution injections, are in a study for as long as 14 years. In a study funded by NIMH, 332 mental hospital patients have their urine checked weekly in a study on the use of abusable drugs. Neither they nor their physicians are informed that they were part of an experiment.

Of these 12 experiments we have been able to document at least 5 of these were funded by HEW funds in part. In other cases, we are unable to document the funding. I have detailed this in my Senate testimony¹ which I will not go into further at this time.

I say emphatically my objective is not to call into question these specific pieces of research, but rather to point out that cases such as these are being debated regularly and heatedly within professional circles. There is now reason to be concerned that subjects may find themselves in a research project for which they have not consented or not consented adequately.

There is now a crisis in confidence. It is getting more difficult to find willing volunteers for important research. In at least one State a moratorium has been declared on research in all State prisons jeopardizing not only the advancement of science, but the interests of prisoners as well. At one prison in the State, 96 of the 175 inmates

¹ "Quality of Health Care—Human Experimentation, 1973," hearings before the Subcommittee on Health, Committee on Labor and Public Works, 93d Cong., 1st sess., pt. I, Feb. 22, 1973, pp. 265-275.

have written a letter protesting the moratorium. This comes at a time when subjects—prisoners, patients, and normal volunteers—are indisputably suffering severe harm in a number of cases which may be proportionately small, but in real numbers is intolerable.

We have reached a point occurring only rarely in public policy-making where not only the interest of individual research subjects, but the interest of society as well requires that some action be taken. It is a terribly interesting and important point in the development of the field of experimentation involving human subjects. It is significant that the national debate has reached the stage where Congress is considering taking an historical step. Titles 2 and 3 of H.R. 7724 make a strong and constructive beginning. I feel the bill is in general a good one, worthy of support. I shall try to present reasons why I feel the time has come to do something beyond more studying of the matter. However, I also have some reservations about portions of the bill. I shall also want to mention some areas not covered in the bill which could be and some specific questions concerning the way the bill is now worded.

As a person who spends his days studying the field of medical ethics, I have become convinced that the dream that private researchers can regulate themselves is utopian. It is impossible because some researchers—social scientists and independent medical professionals—are not part of the mainstream medical research network. It is important to realize this bill applies not only to physicians, but a wide range of researchers outside the medical profession itself. It is impossible because some of the small percentage of research projects which are questionable can slip through informal peer of researcher review. It is impossible because the codes themselves are complex and at times contradictory.

One code says informed consent is necessary: another says consent is required unless the researcher thinks the subject will benefit from the experiment. The present peer-of-researcher system does not require consent at all unless the subject is at risk—implying there might be some experiments where researchers could decide that subjects were not at risk, and therefore no review is necessary. It is unfair to researchers and unfair to subjects to leave such crucial public policy choices up to medical research professionals.

AREAS NOT COVERED IN THE BILL

There are a number of things which could be in the present bill which are not. The Commission would, following the current NIH guidelines, for the time being, only have jurisdiction over research funded by HEW. Unfortunately, much of the research which raises serious ethical questions is funded by other Federal agencies. Other studies by drug companies, private research institutes, and individual physicians have no Government funding at all. Soon these studies must receive public attention as well. Hopefully, that would be one of the early projects of the proposed Commission.

Second, the interim informed consent guidelines [sec. 1207. (6)] do not go beyond the present NIH guidelines. As such, they leave out some essential elements necessary for a reasonably informed decision. They could require that the subject be told who, if anyone, will be

responsible for any harm done to the subject in the experiment. They could require as explicitly as FDA regulations do that the patient be told explicitly if there is a control group in the research design. They could require as the Nuremberg code does that the subject be informed of envisioned inconveniences as well as discomforts and risks. I have seen the avoiding of disclosure of inconveniences eliminated from informed consent because that is not specified in HEW guidelines. They could require that the subject be told of someone he could contact such as the chairman of the Institutional Review Board or the national Commission—should he have further questions or doubts.

Third, the act specifies that there shall be two subcommittees in each Institutional Review Board [sec. 1206. (c)], I consider this to be a crucial element of the present proposal and a clear advance over present vague specifications concerning makeup of institutional "peer-of-researcher" review boards. The task of review includes both scientific and social-ethical dimensions and these roles should be clearly identified. But the proposal fails to specify the relationship between the two subcommittees. I would hope that both would include laymen, that is peers of the subject, and that they would be in a substantial majority in the "Subject Advisory Subcommittee"—a name I would prefer to see changed to the "Subject Protection Committee." Further, the proposal does not spell out whether final authority at the level of each Institutional Review Board would rest with the combined Board or whether each subcommittee would have "veto power."

These and other omissions will mean that human subjects of experimentation still will not receive needed protection in many cases. But some of these issues are extremely complex. It would be unfortunate in the extreme to needlessly jeopardize medical and social progress by unnecessarily writing excessively restrictive requirements into the act. A public commission designed to examine these problems with immediate authority to act upon interim provisions while developing carefully researched and thought-out policies will be a reasonable stopgap compromise.

DANGERS WORTH POINTING OUT

In addition to the areas not covered in the act, I also see some dangers at some specific points in the act itself. I shall cite a few and append a written statement for the committees information, raising some more minor and technical questions.

First, if the proposal before us is an act for the protection of human subjects of biomedical and behavioral research, it is crucial to have a clear understanding of what constitutes "behavioral research." I note that in the definitions (sec. 1213) the term is nowhere defined. It may have two meanings. To many social scientists it will have a rather limited meaning—research in behaviorist psychology—while to the layman it may mean more broadly any research designed to study human behavior including all social scientific investigation. It is my hope that the intent of the bill is to use the latter meaning. If not, the act may be considerably less inclusive in application than the present HEW guidelines, which clearly are meant to apply to all social scientific research (in which subjects are "at risk"). To leave such ambiguity would be a tragedy.

Second, I have a great deal of difficulty with the establishment of "exceptional cases" for which informed consent would not be required in the interim period. As presently written, a single physician could decide to experiment upon me without my consent simply by getting written concurring opinions from two of his licensed research colleagues. I feel such exceptions should require rigorous justification and review—such as direct approval by the Commission itself—unless in a life-threatening situation, it is not feasible to obtain such approval.

In the section on the "Duties of the Boards," [sec. 1208. (3)] the act seems to permit the substitution of the consent of the subject's family. Certainly for the adult, legally competent patient, this is unacceptable. Perhaps the wording should be "the patient (or his legal representative)."

In addition, I believe there are technical problems in the wording of the bill which could, among other things, jeopardize the health of a living infant, inadequately protect subject privacy, bias the Commission appointment mechanisms by singling out the National Academy of Sciences as an agency whose nominees should be especially considered. These, however, are minor technical problems the details of which I have appended in my written statement.

The proposed Commission will not resolve all of the serious problems raised by experimentation involving human subjects. We have reached a point, however, where the interests of individual subjects, researchers, and the public at large require action. I fear that unless we begin to counter these developments, medical progress as well as individual subjects will suffer severe harm. We have been "studying the problems" in contemporary society since the Nuremberg trials and historically since the days of Hippocrates. A Commission with power to act immediately to cope with the present crisis and a long-range vision toward a more permanent set of procedures and guidelines is a desperately needed first, responsible step for making public decisions balancing societal and individual interests. It is a step we can ill afford not to take.

[The appendix referred to follows:]

APPENDIX

SPECIFIC COMMENTS ON THE DRAFT OF H.R. 7724 TITLE TWO

While I see Title Two of H.R. 7724 as an important and needed advance in the protection of human subjects of biomedical and behavioral research, I see a number of minor and technical problems in the current draft. These include:

(1) Sect. 1201. (f) While the National Academy of Sciences certainly constitutes one legitimate source of consultation for the Secretary in appointing members of the Commission, its members are uniquely committed to biomedical and behavioral research. If the Commission is to be made up of a majority of members who are not engaged in such research, including those appointed from the general public, I find it dangerous to emphasize this single, specific agency as one from whom nominations should be considered.

(2) Sect. 1205. It is my understanding that the intent of this section is to prohibit research on fetuses who will be or have been candidates for induced abortion. Yet the placement of the phrase "whether before or after induced abortion" so late in the paragraph leaves the meaning ambiguous, implying that all living human fetuses and infants will be or have been candidates for induced abortion. Also limiting acceptable experimentation to that done for the purpose of insuring "survival" would exclude potential beneficial treatments where survival was not at stake, for instance an experimental diet which might prevent mental retardation. The term "survival" should be changed to "health and well being."

(3) Sect. 1206. (c) (2) The term "Subject Advisory Subcommittee" could imply either that the subcommittee's role was simply advisory or that its task was to give subjects advice—both of which I would find unacceptable. I would suggest changing the name to "Subject Protection Subcommittee."

(4) Sect. 1207 (b) (2) I would advocate adding "inconveniences" to the list of things the subject must be told. In some cases the omission of inconveniences from the list, while it is explicitly included in the Nuremberg Code, has been taken by researchers as authorizing the omission of their disclosure to the subject.

(5) Sect. 1207 (b) (end of section) The exclusion of exculpatory language through which the subject is made to waive, or to appear to waive, any of his legal rights is limited to releasing the institution or its agent from liability "for negligence." This implies that other exculpatory language is not excluded such as language which might release the institution from liability for non-negligent harm to the subject.

(6) Sect. 1210 (b) (3) (A) The paragraph authorizes the subject to consent to have his record disclosed to certain individuals. I see no reason why it should not be added to that list "or anyone else specifically authorized by the subject."

(7) Sect. 1210 (b) (3) (B) (ii) This clause authorizes the disclosure of records to those conducting scientific or epidemiological research without the consent of the subject with the restriction that they "may not identify, directly or indirectly, and individual . . ." I see no valid reason why such researchers should have the identity of subjects revealed to them without the subject's permission in the first place. I would like to see "may not identify" changed to "may not have revealed to them."

(8) Sect. 1210 (b) (3) (B) (iii) I see dangers in this paragraph which authorizes disclosure with the consent of the subject if the disclosure is authorized by a court of competent jurisdiction. While I feel it is a valid interest of the state in rare cases to require the disclosure of confidential medical information, but this can seriously jeopardize certain types of research (such as data on illicit drug use) and as well as the individual's right to privacy. I would hope that where risk of future court ordered disclosure is envisioned provision would be made for researchers to obtain legally enforceable protection in advance and, in addition, subjects would be informed of any such risks.

(9) Sect. 1210 (b) (5) This paragraph specifies that, "except as authorized in this subsection, persons may not be compelled to disclose records," but this leaves open the interpretation that they may voluntarily disclose. I would hope the wording would be changed to read "persons * * * shall not disclose and may not be compelled to disclose * * *"

(10) Sect. 1213. The term "behavioral research" needs to be defined.

(11) Sect. 1213 (3) The definition of "health service programs" as "all programs administered by the Secretary except the Social Security Act" is totally unrealistic. This would make an Office of Education program a health service program. Hopefully the Commission would have jurisdiction over all research funded by the Department of HEW as the present guidelines do, but definitions should be clarified.

With these technical problems made explicit and with the recognized need for making use of the Commission's research and experience to meet needs of subjects not mentioned in the present proposal, I consider Title Two of H.R. 7724 a vital step in the direction of adequate protection of human subjects of biomedical and behavioral research.

Mr. ROGERS. Thank you so much, Dr. Veatch. I think you have made some specific suggestions that will be helpful to the committee. I presume you think there should be an appellate procedure?

Mr. VEATCH. I think this is crucial. Certainly appeal from the Institutional Board to the Commission and then beyond that.

Mr. ROGERS. I think it would be helpful if you would let us have specific ideas on that. That would be helpful and then the time element.

[The information requested was not available to the committee at the time of printing—September 1974.]

Mr. ROGERS. I understand you also feel the Commission should get into the business of regulating as well as just studying and making proposals.

Mr. VEATCH. I think working on the interim provisions as specified in the bill is a good move and an important move.

Mr. ROGERS. Mr. Preyer?

Mr. PREYER. Thank you, Dr. Veatch, for some very helpful testimony.

Are you familiar at all with the series of regulations governing the use of psychosurgery in prisons that the State of North Carolina has devised?

Mr. VEATCH. I am not specifically familiar with North Carolina regulations. Our institution has been preparing such guidelines for professional bodies but I am not specifically familiar with North Carolina.

Mr. PREYER. It is a very carefully drawn set of regulations. In fact, it is so carefully drawn, since it has been put into effect, there has been no psychosurgery.

It determines to that extent the prisoner in the presence of his lawyer must make the final decisions as to whether to go forward with the surgery.

Do you think that a procedure carefully worked out such as this one can be used to control psychosurgery at the moment or do you feel that we should have some sort of moratorium on it?

Mr. VEATCH. The debate about regulations in psychosurgery seems to me to be reaching a crescendo. I know that NIH is debating regulations, the professional societies are debating them. I am afraid of declaring a moratorium too precipitously. I think in the bill as drafted, there is a question whether a brain operation to relieve intractable pain might also be caught in the moratorium. I would hate for that to happen.

So I don't think we should rush into a moratorium precipitously. Certainly in the interim period every proposed psychosurgical procedure, at least those on imprisoned and mentally incompetent patients has to be given very careful scrutiny.

Mr. PREYER [presiding]. Thank you very much, Dr. Veatch.

Mr. CARTER. I was very much interested in one of the statements in your presentation about LSD, 24 subjects reading ads in newspapers and then being given LSD by some group. Do you know what group this was?

Mr. VEATCH. I have the published scientific paper that reports this study. I would be happy to provide it after the hearings for you. I want to emphasize that my purpose is not to single out individual researchers for criticism, but to emphasize that there is a great deal going on that is being debated, and we need some sort of systematic way of approaching it.

Mr. CARTER. I feel they are certainly subject to criticism for such things as that.

Those are all the questions I have. Thank you very much.

Mr. PREYER. Thank you, Dr. Veatch.

If I may interject at this time, I would like unanimous consent to place a statement in the record. I would like to do this now in order to avoid interrupting the testimony of the next witness.

Senator Ervin, the senior Senator from North Carolina, has had a special interest in this subject as chairman of the Senate Subcommittee on Constitutional Rights. He has sent a statement and has asked that it be included in the record.

I think the statement will be particularly helpful. It contains an extensive review of the legal cases in this area which will be most use-

ful. I don't know anyone who is more of an authority in the field of protecting the constitutional rights of individuals.

I would like to ask that this statement be made a part of the record at this point.

Mr. CARTER. You have my consent.

[The statement referred to follows:]

STATEMENT OF HON. SAM J. ERVIN, JR., A U.S. SENATOR FROM THE STATE OF NORTH CAROLINA

Mr. Chairman, as you know, Senator Kennedy's Subcommittee on Health conducted hearings last spring on the subject of human experimentation. The importance of these hearings was underscored by a series of events which dramatized some of the kinds of abuses that can take place under the present system of inadequate controlled experiments on human beings. It was in response to these hearings that the Senate Labor and Public Welfare Committee recommended that title II be added to the House-passed H.R. 7724, the subject of your current inquiries.

As chairman of the Senate Subcommittee on Constitutional Rights, I have long been concerned that the constitutional rights of human subjects of behavioral and biomedical experimentation are not fully protected. In a statement I presented to Senator Kennedy's hearings, I expressed this concern and enumerated several instances where the constitutional rights of such subjects need additional protection. Since that time, additional illustrations of this problem have come to light. In recent litigation in Missouri, evidentiary hearings produced over 1,000 pages of testimony detailing abuses that have occurred in Project START, a Federal Bureau of Prisons project studying methods designed to alter the behavior of prisoners by various means.

In Michigan this past July, the Wayne County court handed down the first reported court case having to do with the alteration of human behavior by experimental procedures such as psychosurgery. In *John Doe v. Department of Mental Health*, the court enjoined the performance of an experimental psychosurgical procedure.

The plaintiff was committed to the Ionia State Hospital as a "criminal sexual psychopath." He had been charged with the murder and subsequent rape of a student nurse at the Kalamazoo State Hospital while he was confined there as a mental patient. After his arrival at Ionia, he agreed to participate in a "study for the treatment of uncontrollable aggression." The study had been proposed by Drs. Ernst Rodin and Jacques Gotlieb of the Lafayette Clinic, a facility of the Michigan Department of Mental Health.

John Doe v. Department of Mental Health turned on the issue of whether informed consent can be given by an involuntarily detained mental patient for experimental psychosurgery. The court first noted three elements of informed consent; the person must have the capacity to consent, the consent must be knowing, and it must be voluntary. Because the risks of experimental psychosurgery are so great, the court decided that it is not possible to gain consent from an involuntarily confined mental patient for it could not be competent, knowing, and voluntary.

The court found that the capacity of an individual in the plaintiff's situation is reduced by his mental condition, the deprivation stemming

from involuntary confinement, and from the effects of "institutionalization." A knowledgeable consent, said the court, is "literally impossible," since the facts surrounding any brain surgery are so uncertain. Also, the court stated that the consent of a mental patient confined against his will to experimental psychosurgery cannot be voluntary, for he lives in an environment that is inherently coercive. His privileges, indeed his release from the institution, may depend upon his willingness to cooperate with the authorities; he cannot reason as an equal with doctors and with administrators over whether he should undergo psychosurgery. The court concluded, then, that the three basic elements of informed consent could not be determined with sufficient certainty to warrant resort to such an "invasive procedure."

The opinion states that since adequate consent cannot be obtained in these circumstances, a doctor performing psychosurgery on an involuntarily confined patient would be liable to him in a civil action for battery. Furthermore, according to the court, State action in such a situation violates the 1st and 14th amendments and is an unconstitutional invasion of privacy.

The court said that the freedom to generate ideas is a necessary prerequisite to any freedom to express ideas. Therefore, the former freedom must be constitutionally protected:

To allow an involuntarily-detained mental patient to consent to the type of psychosurgery proposed in the case, and permit the State to perform it, would be to condone State action in violation of basic first amendment rights of such patients, because impairing the power to generate ideas inhibits the full dissemination of ideas.

The court cites several cases as authorities for the right of privacy, including *Olmstead v. United States*, 277 U.S. 438 (1928); *Griswold v. Connecticut*, 381 U.S. 479 (1962); *Stanley v. Georgia*, 395 U.S. 557 (1969); *Rowe v. Wade*, 41 L.W. 4213 (1973). The court asserts that—

[T]here is no privacy more deserving of constitutional protection than that of one's mind. Intrusion into one's intellect, when one is involuntarily detained and subject to the control of institutional authorities, is an intrusion into one's constitutionally-protected right of privacy.

Of course, the decision of a Michigan court is not controlling precedent in other jurisdictions. Even so, the case is the first significant one having to do with experimental psychosurgery on persons institutionally confined. As such, the court's analysis and conclusions will undoubtedly be given serious consideration in subsequent cases, regardless of jurisdiction.

The court's reasoning with regard to the consent issue applies not only to involuntarily confined mental patients, but to all persons involuntarily confined: in particular, our Nation's thousands of prisoners. In my statement to the Health Subcommittee last March, I asked: [C]an an inmate freely volunteer for a program to alter his mind when he is in a prison setting?

At least with regard to experimental psychosurgery, the Michigan court has rendered a negative response to that question.

In California the United States Circuit Court of Appeals for the Ninth Circuit voiced similar concerns. This past April in *Mackey v. Procunier* — F 2d —. No. 71-3062 (9th Cir. Apr. 16, 1973), the Court of Appeals reversed a district court dismissal of a state prisoner's charge that he was administered an experimental drug without his consent. The court stated:

It is asserted in memoranda that the staff at Vacaville is engaged in medical and psychiatric experimentation with "aversive treatment" of criminal offenders, including the use of succinylcholine on fully conscious patients. It is emphasized that plaintiff was subject to experimentation without consent.

Proof of such matters could, in our judgment, raise serious constitutional questions respecting cruel and unusual punishment or impermissible tinkering with mental processes. [The court here cited in a footnote, *Eisenstadt v. Baird*, 405 U.S. 438 (1972); *Stanley v. Georgia*; and *Roe v. Wade*.] In our judgment it was error to dismiss the case without ascertaining, at the least, the extent to which such charges can be substantiated. Slip Opinion at 2.

In view of these legal developments, it becomes imperative that Congress address itself to the serious problem of safeguarding the constitutional rights of the subjects involved in human experimentation.

Federal funding of a wide range of experiments designed to alter permanently the behavior of individuals raises the specter of governmental interference with individual privacy. As I said in my earlier statement, "Our whole constitutional heritage rebels at the thought of giving Government the power to control men's minds." It is for these reasons that all research projects involving human beings should be carefully scrutinized in order to insure that fundamental rights of human subjects are fully protected. I am convinced that safeguards can be established to protect such subjects without limiting unduly the latitude necessary for researchers to continue to make great strides forward against disease and human suffering. At a minimum we must take steps to insure that abuses do not occur within federally-funded human research projects.

I certainly hope that this subcommittee will be persuaded, as the Senate has been, that legislation is needed in this area. I, for one, am convinced that the Congress can move toward the resolution of many of the difficult problems inherent in experimentation on human beings.

To my mind, such a legislative solution should embody at least five essential points:

First, uniform rules should be established by the Federal Government to guide all federally-funded behavioral and biomedical experimentation involving human subjects;

Second, these rules should set forth adequate protection for the rights of human subjects;

Third, before an experiment is funded, it should be reviewed and approved by a national body constituted for the purpose of insuring that the rights of human subjects of experimentation are protected, and that the rules are applied uniformly;

Fourth, certain highly risky procedures, such as psychosurgery, should be subjected to special scrutiny before Federal funding is continued;¹

Finally, and of vital importance if Congress is to be in a position to consider future legislation in this field, a method of regular reporting to appropriate congressional committees of all such experiments involving human subjects must be instituted.

In conclusion, let me emphasize the importance of legislating controls over experimentation which threatens to alter irreversibly the minds and bodies of human subjects. I outlined some of the considera-

¹An example of this type of approach is the decision of Dr. Robert Q. Marston, Acting Director, National Institute of Neurological Diseases and Stroke, National Institutes of Health, to suspend HEW funding for psychosurgery experimentation pending a review of the practice.

tions which originally prompted my concern about human experimentation in the statement which I presented to the Senate Health Subcommittee last winter. I therefore have appended that statement to these remarks for your information.

I urge you to count carefully the costs of future experimentation on human subjects and to weigh scrupulously the constitutional rights and individual liberties of the subject of such experimentation.

[Testimony resumes on p. 252.]

[The attachment referred to follows:]

[From Congressional Record, May 8, 1973]

FEDERAL FUNDING FOR BEHAVIOR MODIFICATION

Mr. ERVIN, Mr. President, recently, the Senate Subcommittee on Health, chaired by Senator Kennedy, conducted hearings on the broad topic of participation of human beings in scientific experiments. These hearings, which covered such diverse subjects as unapproved uses of certain drugs and the philosophical aspects of human experimentation, were of particular interest to me. As chairman of the Subcommittee on Constitutional Rights, I have been concerned for a long time with the protection of individual rights, especially when the private citizen comes face to face with the Federal Government. In light of the growing number of data banks in America, which daily collect more and more information of psychological testing programs, we in the Congress should be aware of the threat these mechanisms pose to individual privacy.

I have submitted a statement for the record of the Subcommittee on Health's hearings. This statement deals with the problem of behavior modification programs funded by the Federal Government. I believe that the protection of individual rights in all scientific programs utilizing Federal appropriations must be paramount to considerations of scientific advancement. The right to privacy and freedom of individual thought must be protected. It is essential that the Congress maintain oversight in regard to programs in which human life is at stake. I ask unanimous consent that the statement be printed in the Record at this point so that the material it contains may be brought to the attention of all the Members of this body and may be available for their consideration.

There being no objection, the statement was ordered to be printed in the Record, as follows:

STATEMENT OF SENATOR SAM J. ERVIN, JR.

I wish to thank the Subcommittee and the chairman, Senator Kennedy, for this opportunity to submit a statement for the record of the Subcommittee on Health's hearings on biomedical research and human experimentation.

The Subcommittee deserves a good deal of praise for the work it is doing in this area and for the large number of important public issues raised in these hearings. The questions surrounding control of the uses of scientific knowledge constitute a most complex and serious problem. We must always make a conscientious effort to avoid curtailing the freedom of scientific inquiry necessary to expand the boundaries of human knowledge. The freedom of science to work and explore by orderly research has long been a boon to our American way of life and we have benefited enormously by that research in technological and medical achievements which have outpaced the rest of the world.

These hearings have come at an opportune time, for after fifty years of scientific research and experimentation in laboratory settings, we have reached a breakthrough in the biological sciences that may promise a more disease-free and health life for all citizens. Experimentation and treatment now have turned their focus from the laboratory to human subjects. In the face of this application of scientific methods, we cannot allow individual rights to be endangered or lost because of a blinding faith in science and medicine. Constitutional safeguards must be assured at the same time that government funding nurtures scientific research and medical treatment.

Many research projects involve experimental therapies which, even in a clinical setting, pose threats to constitutional rights. These therapies may be dangerous when either by their mode of application or by the very nature of the therapy itself, they impinge on individual liberties. If a therapeutic method is to be imposed on a patient without his consent or as a punishment, then the therapy is not necessarily at fault but the method is. On the other hand, if a party consents

to the application of a therapeutic method which either he or his physician does not fully understand or which will unalterably affect his life, then the therapy itself may pose a threat to individual rights.

In light of these problems and the threats to cherished freedoms which may be created by certain scientific experiments or medical treatment, I wish to commend the Health Subcommittee for its foresight in this matter by calling for hearings which allow an airing of the matters involved prior to the funding of further research. We must strengthen the means by which Congress is informed of scientific programs affecting individual rights before federal money is used to support such research. Whatever legislation is recommended by the Subcommittee, I hope it will include a requirement of disclosure and review by Congress before federal financing can be granted.

My experience in this area has taken me through several years of hearings on the various threats to individual liberties posed by governmental invasions of privacy. The Subcommittee on Constitutional Rights has seen psychological tests and other methods used to attempt to develop classification systems for our citizens. We have seen sensitivity training, polygraphs and the growth of federal and private data banks threaten the security of the individual and impose on his dignity. We have seen government monitoring of the activities of Congress and military surveillance of our citizens.

So far there is no national identification system. A citizen may still enter a store, present a credit card, and know that his entire past is not available to a store clerk by the flick of a switch. But the time may soon come when this is no longer true. Already state, federal and private data banks are being created which collect large amounts of data on individuals, data of often dubious accuracy and relevancy, but data which is instantaneously available across the country. Already work is being done on a universal identifier so that every person can be numbered, and then catalogued by that number. Already work is in progress on a single universal identification card to replace the dozens of credit cards, memberships, licenses, and IDs in a citizen's pocket.

As the chairman knows, the problems being studied by the Constitutional Rights Subcommittee are fundamentally the same as those before this subcommittee. That is why I wish to present some of the information we have gathered for your consideration.

I would like first to discuss a problem which I believe has reached the critical stage today in the area of scientific experimentation and treatment—federal funding for behavior modification. The chaos which exists in this field is partly due to a lack of control, a lack of review and a lack of interest on the part of the Congress. I believe there are serious constitutional problems when federal funding is doled out unchecked for behavior modification projects.

Behavior modification involves psychological techniques applied as treatment for behavioral problems.

Behavior modification attempts to alter or change the attitudes and actions of a person; it does not seek to cure the behavioral illness but rather to change the behavior. Behavior modification may involve relatively mild methods such as individual or group therapy as well as more persuasive and more permanent methods as, for example, operant conditioning (reward/punishment concepts). Whatever questions exist with respect to these methods, behavior modification today has an even larger arsenal of methods to draw upon than ever before, and these other techniques present critical issues for individual rights. Drugs can be used to punish and thereby secure a desired behavior (aversive therapy). They can also blunt certain emotions (tranquilizers and psychoactive drugs). Shock therapies can jolt the memory. Finally, the physical brain itself is subject to alteration by surgical or drug means. Behavior modification ranges from rewarding school children with gold stars to punishing prisoners with drugs that simulate Parkinson's Disease or cause convulsions. Naturally, it is not easy to decide which type of behavior modification programs are dangerous to constitutional liberties and which are not. I would like, however, to deal with three separate cases where abuse has occurred or possibly is occurring where the federal government has a responsibility for the preservation of individual rights and the prevention of injury to our citizens.

One of the most flagrant examples of a lack of congressional control and oversight in the area of behavior modification came during the past fiscal year. In 1971 a program was begun at Boston City Hospital by Dr. William Sweet, one of the world's leading neurosurgeons, to explore violent behavior. The project was funded by a \$500,000 grant from NIMH. The project employed various means of studying and treating violent behavior; among these methods

were the implantation of electronic devices in the brain, the use of massive drug doses which can permanently affect behavior, and psychosurgery. The goal of the program was to develop psychological tests to identify violent behavior and develop treatment methods. The project was so controversial that the first hospital approached, Massachusetts General Hospital, refused the grant.

At the same time as this NIMH project was going on, some of the doctors from the project were working on a similar behavior research project funded by the Law Enforcement Assistance Administration. This project was intended to develop a classification system to identify a tendency for violence among prisoners. This project, conducted at a federal male prison and a female multistate prison, was terminated early due to funding abuses arising within the project. Neither project has submitted a completed report, and neither project has submitted a summary of its activities that show any conclusive evidence of success or rationale for further funding. Yet, in hearings before the Senate Appropriations Committee, Dr. Sweet testified that the work had been successful in Boston and at the prisons. Dr. Sweet also stated that one million dollars was desired, under the auspices of NIH, for further work and expansion of the project at Boston City General.

It was only at the last minute that Senator Magnuson addressed a letter to Director Marston of NIH urging caution and care in further funding of violent behavior research. Dr. Marston replied stating that NIH would make the greatest efforts to safeguard individual rights. In response to letters from the Subcommittee on Constitutional Rights, former Secretary of Health, Education and Welfare Elliot Richardson and Secretary Caspar Weinberger have promised that reporting would be made to the Subcommittee on any funding by HEW for behavioral research involving violent behavior studies. Copies of the correspondence dealing with the NIH funding and from HEW are attached to my statement.

Now it should be obvious that programs which aim at typing certain citizens as "violence prone" raise serious problems of individual rights. The issue is no less and no different from a government program of labelling individuals as "radicals," "subversives," or "Communists." Certainly before any such project is funded by Congress, those problems should be exhaustively considered. They never were when these first grants were approved.

The absence of congressional inquiry and of congressional oversight allowed an NIMH project to submit individuals to what many regard as inhuman and degrading abuse by physicians. Projects which involve experimental techniques or techniques which sharply curtail an individual's independence and freedom of thought deserve the utmost concern on the part of the Congress. Reporting of projects such as those funded by LEAA and NIMH would have allowed debate and review by the Congress. No such programs should be funded by NIMH or any government agency unless and until the closest scrutiny is given to them.

Prisons exist as a closed society, eluding the public eye behind high walls and restricted contact. Only recently has there been any interest in assuring prisoners the benefits of those constitutional rights which follow them into the prison or jail. Only in the last decade have court decisions sought to insure the rights to counsel, legal materials, correspondence and of freedom from cruel punishment. Testimony before the Health Subcommittee has revealed that in the coercive atmosphere of a prison, inmates are more than willing to submit to drug experiments and other experimental programs in order to secure money or a change of location and conditions or to please the parole board by a record showing cooperation with the prison authority. The use of behavior modification in such a setting poses serious threats to constitutional liberties. Behavior modification is not simply an experimental concept. It is a treatment to which a prisoner is asked or ordered to submit.

There has been no definitive court case involving behavior modification in the prisons; however, cases are now pending before the courts. One case in California is challenging aversive conditioning therapy which employs a drug known as anectine to produce respiratory convulsions. Cases dealing with medical treatment in prisons have dealt primarily with allegations of malpractice and negligence in treatment or with the administration of drugs-which-produce-injury civil suits. Most courts have rejected complaints alleging unauthorized uses of drugs as punishment.

To understand the Bureau's attitude toward treatment of its mentally disturbed offenders, the following statements by Director Norman Carlson are of note as a preface to the discussion that will follow. Speaking before the Subcommittee on National Penitentiaries [*Future Role of the U.S. Bureau of Prisons* (92nd Cong., 2nd Sess.)] Director Carlson noted the Bureau's attitude to-

ward mentally ill offenders and the need for treatment by the government . . . nearly 20 percent of all offenders committed to our custody suffer from some type of mental disorder, not necessarily psychotic, but certainly present mental illness. It is a fact which we have long been aware of and I think Butner is going to be a facility which will certainly enhance our capabilities to work with this type of population.

In later testimony before the same subcommittee, in June of 1972, the Director indicated what might be the major factors behind this mental disorder in inmates. . . . correctional institutions throughout the country have been plagued with serious problems. These have included work strikes, violent incidents and racial tensions. In the Federal System, we have experienced a number of difficulties, but fortunately none have involved violence. These recent incidents have highlighted the root causes of the problems in our present correctional systems: overcrowded, archaic institutions, inadequate treatment programs, and, in some instances, policies and procedures which serve to dehumanize individuals in confinement.

The Bureau of Prisons cites overcrowding as the major contributing cause of the dehumanization and violence of federal inmates. The Bureau, therefore, creates behavior modification programs to institutionalize the inmate and make him amenable to the best problem of overcrowding.

The Federal Bureau of Prisons has an active program of behavior therapy. In the Springfield, Missouri Medical Facility, Project START attempts "to develop behavioral and attitudinal changes in offenders who have not adjusted satisfactorily to institutional settings." One criterion for transfer to this project is that the inmate should be "from the sending institution's segregation unit." There are no volunteers, only involuntary transfers. (*Operations Memorandum*, 7300.128, Bureau of Prisons, October 25, 1972.) Group therapy and other psychological techniques have been employed in Marion, Illinois, and in Terre Haute, Indiana, as well as elsewhere in the federal system.

An example, which raises the constitutional questions surrounding behavioral modification in the prison setting, comes from my own state. As part of the Bureau of Prisons' ten-year construction plan, a Behavioral Research Center is nearing completion at Butner, North Carolina. The facility, for which plans have been in the making for several years, will house a treatment center for mentally disturbed inmates and a research facility to develop correctional programs for exports to federal and state institutions. To gain more information about the Butner facility, the Subcommittee on Constitutional Rights contacted Director Norman Carlson of the Bureau of Prisons. In response, the Director stated that safeguards will exist at Butner to protect inmates and that all programs will conform to established guidelines for programs involving human subjects. The guidelines employed, the Director explained, were the Nuremberg standards and a directive by the Public Health Service on experiments involving human subjects. Both documents, it should be noted, require that an individual be free from coercion in making his decision to participate in a project and so situated that he is free to refuse. The Bureau hopes that prisoners will volunteer to go to Butner. However, in order to secure certain types of inmates for the research section, involuntary transfers may be required. Director Carlson also assured the Subcommittee that no psychosurgery or massive drug doses will be employed.

The Director's reply leaves a number of problems unresolved.

Behavior modification creates problems for privacy and individual dignity when administered in a custodial setting where coercion is a practical fact. True voluntary participation is difficult if not impossible in a prison. The Supreme Court in *Stanley v. Georgia*, 394 U.S. 557 (1968) stated the problems that governmental invasions of privacy pose for the First Amendment.

Our whole constitutional heritage rebels at the thought of giving government the power to control men's minds. . . . Whatever the power of the state to control public dissemination of ideas inimical to the public morality, it cannot constitutionally premise legislation on the desirability of controlling a person's private thoughts.

This same right of privacy of the individual from governmental invasion was strongly stated in *Griswold v. Connecticut*, 381 U.S. 479 (1965), which was based as well on the Fourth, Fifth and Ninth Amendments.

A prisoner's rights are not infringed by his involuntary transfer to a higher security grade or to a medical facility because he is overtly psychotic. But when he is forced to participate in a treatment or experiment which is not to treat a present illness, but rather to fit a goal set by the Bureau for rehabilitation, and

which involves drugs or coercive measures to change his very personality, due process and equal protection requirements come into play. One must ask, should a prisoner who is not judged mentally ill by the court after psychiatric tests be judged so by the Bureau of Prisons after incarceration and then forced to accept treatment? Indeed, in any place where consent is coerced or not given freely, there seems to be a violation of a basic human right, be it in a prison or conceivably even in a private doctor's office. If treatment is forced without a hearing or inquiry and without true consent, is not the due process assured every citizen—inmate or free—denied?

The programs exemplified by Butner raise some very serious issues:

1. How does a rehabilitation program which involves behavior therapy, be it transactional analysis (game theory) or operant conditioning (reward/punishment theory), fit the Bureau's statutory authorization under Title 18 of the United States Code?

2. The Constitution secures privacy and due process for all Americans. Are these rights violated when an inmate is forced to undergo a psychological therapy because his consent occurred in a coercive setting? Can an inmate freely volunteer for a program to alter his mind when he is in a prison setting? Testimony before the Health Subcommittee indicates that prisoners took part in programs in a prison that they would never consent to in a free world setting.

3. The records of a stay at Butner and any treatment will be integrated with an inmate's files. Is his privacy assured where such records can be disseminated to the parole board or beyond the confines of the Bureau of Prisons? The problem here is similar to that uncovered by the Subcommittee on Constitutional Rights in its continuing investigation of data banks and the dissemination of arrest records and other highly personal information.

4. The Eighth Amendment protection against cruel and unusual punishment may be violated where an inmate is involuntarily sent to a therapy program. Does this not constitute a sentencing beyond that of a judge? Does it not amount to an extra punishment? Therapy programs which employ aversive therapy—inflicting pain to dissuade certain behavior by the use of drugs or prolonged isolation—as part of their treatment could well be violations of the Eighth Amendment.

My concern with Butner is not that its program development concept will develop new programs for managing prisons, but rather that the development will be costly to the rights of inmates and that the developed programs may not resolve the prison system's dehumanizing effect. My concern with the psychiatric treatment center at Butner is not that psychotic patients will be removed from the general prison population, but that there are problems of identification of inmates for treatment; that inmates will undergo treatment in a coercive atmosphere, signing a consent form they may never understand or because they want to appear cooperative to the parole board; and that there are possibilities of abuse in transfers to the unit. Congress has a duty to maintain some form of oversight over prison research and treatment to assure that constitutional liberties are not lost under the rationale of prison experimentation and prison management.

Equally voiceless in our society, because of segregation from the general population, are patients in mental institutions and Veterans' Administration hospitals. Here the problems are somewhat different than in a prison setting. Often the problem for a mental patient is to secure treatment and not just be maintained in a custodial setting. Behavior modification is a part of treatment. In hearings before the Subcommittee on Constitutional Rights in 1970 on the rights of the mentally ill, it was pointed out that 90 percent of all mental hospital inmates were there by judicial commitment. Certainly when the court places a person in a confined hospital setting, as in a prison, there must be maintenance of constitutionally guaranteed liberties. The problems of behavior modification in a mental hospital are not the correctness or appropriateness of treatment but rather problems related to the protection of the rights of an individual undergoing treatment. The recent abuses exposed in the Willowbrook hospital and in mental hospitals in Alabama point to the need for improved oversight of federally funded private and public mental hospitals to insure that patients are given the basic courtesies and dignities afforded other citizens.

The extent to which mental patients or veterans are used for experimentation and development of new methods of therapies has not been investigated. It is appropriate that such an investigation occur and that the Congress consider some form of permanent review of a problem which affects the lives of nearly a million Americans daily and a larger number of our citizens indirectly. The

constitutional problems for the veteran or mentally disturbed person are similar to those of the prisoner—coercion for treatment and experiment, lack of informed consent, where possible, and lack of control over custodial care and medical practices. The involuntary nature of judicial commitment and the subjection to imposed treatments demands the congressional concern for the patient who cannot speak for himself. I will not go into detail about the rights of the mentally ill; the hearings speak for themselves. I want only to express my concern at this point for the possible abuses in hospitals and the need to ensure that basic constitutional guarantees are not denied without due process of law.

I would like to reiterate that I fully understand the difficulties inherent in intervention into the realm of scientific experiment. I commend you on your willingness to venture into this area. Some of the shocking abuses you have exposed as in the Alabama syphilis study and the unapproved uses of approved drugs need to be brought to the attention of the Congress. The constitutional problems are of great consequence. Any citizen may seek mental care assistance at some point in his life and suddenly find himself to be a subject for a doctor conducting an experiment. To assure that all constitutional protections are afforded in medical experimentation and treatment programs is a goal of the utmost importance. Whether that assurance is in the form of congressional control, professional self-restraint or state intervention is secondary to the basic humanitarian and social considerations.

Mr. PREYER. Our next witness is Dr. George Schreiner. It is good to have you with us. Do you have a written statement?

STATEMENT OF DR. GEORGE E. SCHREINER, PROFESSOR OF MEDICINE AND DIRECTOR, DIVISION OF NEPHROLOGY, GEORGETOWN UNIVERSITY MEDICAL SCHOOL

Dr. SCHREINER. I do not. I do have two reprints I would like to leave with the committee. These are previous publications of mine, one entitled "Limbo to Limb—The Moral and Legal Entanglements of the Clinical Investigator" [see p. 255] and "The Ethics of Human Experimentation" [see p. 259].

I am professor of medicine and director of nephrology division, Georgetown University Medical School. I have been a practicing physician for 26 years and did my first clinical investigation 25 years ago. I have published over 200 scientific articles and about 10 or 12 ethical articles relating to human experimentation of which the 2 I gave you are some examples.

I really come as a private citizen, although I am a past president of the American Federation for Clinical Research and am on the Federal Health Committee of the American Society for Clinical Investigation. This committee is concerned with the ethics of experimentation. I have discussed certain things with members of that committee and other things I have not and will speak as a private citizen.

I do think I would like to make remarks that are more philosophical than legalistic. I want to emphasize something I have not heard either yesterday or today: What are the ethics of discouragement or the omission that comes about when we get too contrived, too specific, and too detailed in our regulatory mechanisms. We do have a positive obligation to improve the lot of man. You can satisfy laws by not doing research; but it is just as unethical to cease human research as it is to abuse it—poor committee decisions have been just as frequent as poor research. This is my own experience in serving on a peer review committee and I might state that I do believe in peer review committees.

We had one on a volunteer basis at Georgetown long before there was a requirement in the Food and Drug Administration promulgations and long before there was a requirement for HEW grant requests.

It has been very interesting serving on the committee and watching the evolutions of the various complexities of reviews as the regulations tightened. Dr. Veatch has made some allusions to that.

Something which I think has not been stated is that as one gets distant from real expertise, as you get away from people who have had some familiarity at least with how you do clinical investigation, the votes tend to get more and more negative. I noticed this trend, for example, when the suggestion came out that we should put ethicists, priests, and lawyers on peer review committees, which we did.

For a while there was a considerable difficulty in getting the many projects approved. Where there was a doubt, where there was a gray area, the people who are unfamiliar tend to vote no. This is just a clinical observation of mine. I think we should be very, very careful in appointing Federal regulatory commissions. A broad representation of consumers and ancillary skills is desirable but enough active investigators must be included so that we don't really grind the whole research thing to a halt.

I express this rather concisely in this article in *Clinical Research* in which I said, "the goal of the clinical researcher is not to remain safe, to please lawyers, to satisfy bureaucrats, to abstain from controversy, or even to shun lawsuits. One can do all that simply by not doing research."

The problem is to try to fit this active scientific curiosity and desire to improve the lot of man into a framework that meets some kind of common ethical standard. Certainly the best mechanism for doing that is educating the individual and heightening the ethics of the individual doing the research.

Today's witnesses have cited a few abuses out of tens of thousands of projects supported in recent years.

I think it is important in citing these evils and horrors to mention how many in fact have been reviewed by peers. I would be interested in Dr. Veatch's statement now about many of the studies he mentioned in fact were subjected to peer review or to some kind of protocol analysis. I am certain the one mentioned in the papers so frequently, the Tuskegee experiment was performed many, many years ago by the Public Health Service, an arm of the Government, and was not subject to the type of peer review we have today.

Dr. Chalmers made the statement yesterday he could find only one of the horror stories cited that went through a peer review committee. I think we have to be careful we don't throw the baby out with the bath water. This is a real danger if we continuously restrict the activities of investigators who are already a dwindling breed, perhaps even an endangered species. Are they to be forbidden even the simplest possible statement?

Dr. Veatch claimed that no doctor should be allowed to state that an experiment is without risk.

I frankly violently object to that attitude. Under it the peer review committees would be bogged down forever in trivia. The NIH has stated one can withdraw up to 4,500 cm³ of blood from normal-sized adults without going through the complete formal review committee. Obviously, what is done with the blood is filed in a protocol.

We have found even such simple things as this are subjected to very, very prolonged and ethical and theological discussions when this really does little but obfuscate the basic problem. None of the horror stories

involve those simple experiments with blood or urine. Noninvasive procedures should be expedited and not mixed with the real problems.

None of the citations in the press involve those kinds of experimentation. If we don't get realistic about our review procedures, it seems to me what we are going to have is half the world spending half of its time reviewing what a few people left in research are able to propose.

I think that some kind of balance must be struck in working on a commission which has regulatory capacity. I seriously question whether the Federal Government is sufficiently close to the scene of the action to play such a role. I think the idea of a repository of data, a kind of an appeal-type situation, even a writer of good lines—I think all of those functions are very, very good and very adequate, but when one gets into the regulatory field, you face some very large negatives that must be looked at carefully.

I would like to make a specific statement on section 1202-4 and heartily endorse the concept of no-fault insurance for participants in human research which should get the researcher out of an adversary position where he must admit negligence and become a defendant or aline himself with the insurance company.

I have been speaking on this subject for more than 12 years and I think it is more than high time that we have no-fault insurance to protect these individuals who are doing just as much for the people in our country as those in the Armed Forces. They are obviously courageous if they are willing to be used for their fellow man. They are obviously charitable for giving of themselves, and I think they deserve the protection of society on something other than a negligence basis.

The other point that I would like to speak against is the notion that a committee could commandeer the personal physician-patient record. I think that research is defined so broadly in here that it really would cover millions of people. For example, if one just counted the trial subjects for oral contraceptives of all of the various formulations that have been introduced into the United States, this would cover hundreds of thousands of people. Yet, this act in fact directs the court even without the patient's permission to have all records which includes records, files, papers, processes, controls, and analyses of facilities made available to anybody that the committee delegates.

I think if you do that, about 20 years from now, you will be attending a "Mayo-gate" hearing. If anybody from the White House can call up anybody in HEW and say get those records on this prospective Congressman or this prospective school board member because he was once a part of a research project 20 years ago—this is without statute of limitation—I think you are producing an invasion of privacy which is potentially very, very dangerous and is in direct conflict with the oath of Hippocrates which I and many physicians took, that they will not reveal what they see and hear with regard to the patient.

If you are talking about statistical research or something of this sort then you are a step removed but the way research is designed in here, it would cover any drug trial done in the United States and this is really involving hundreds of thousands if not millions of citizens of the United States, and I think this is a very dangerous type of provision.

[The publications referred to follow:]

Limbo to Limb — The Moral and Legal Entanglements of the Clinical Investigator

By GEORGE E. SCHREINER, M.D.* AND MORTON D. BOGDONOFF, M.D.†

DURING THE past several decades the clinical investigator has enjoyed a great deal of intellectual and operational freedom. This freedom has been both deserved and desirable. However, this tradition evolved when funds were relatively scarce and clinical research facilities were few in number. The years following World War II have been characterized by an abundance of money and an expansion of well-supported facilities and personnel. This growth of clinical investigation has been a boon to academic medicine; more people are working on more clinical problems than ever before.

One of the consequences of such rapid growth, however, has been the increasing awareness of the activity of the clinical researcher by the non-medical portion of our society. Thus the non-medical public has developed an abiding interest in clinical research efforts, and has begun to inquire into the operational details of how clinical research is performed. The fact that the public is eventually paying the bill for the clinical research would appear to provide some justification for its inspection of what clinical researchers do.

This consequence of growth, however, has introduced an unknowledgeable third party to the clinical research activity. Previously, in the relative quiet of the small-scale research efforts of the past half century, the investigator and the patient (and those family and friends close to the patient) were the only parties concerned with the research. Now, however, the public—in certain circumstances represented by the Federal government—wants specific information and has been injected as a third party into clinical research activity.

When someone else begins to inspect, questions are asked and questionnaires beg to be completed.

The clinical investigator must, therefore, reflect and initiate some self-inspection. All must recognize that medicine needs both clinical, basic and therapeutic investigation if it is to advance in knowledge and wisdom. The goal of the clinical researcher is not to remain safe, to please lawyers, to satisfy bureaucrats, to abstain from controversy or even to shun law suits. One can avoid them by not doing clinical investigation. We believe, however, that two major questions merit discussion and examination by the clinical investigator himself: *What are the indications and what are the constraints that should govern clinical research activity?* and . . . *When is it reasonable to reject the inspection and review of the interested third party?*

Though it may appear elementary to begin from the very baseline, our discussion of these questions includes an initial definition of the purpose of clinical investigation—to gather scientifically reliable data within the framework of a well-defined experimental design, concerning one or more specific problems of human biology. This broad statement of purpose clearly presupposes certain conditions—that the investigator understands and knows how to use the scientific method and that those issues which he proposes to study represent areas of interest in which he has already developed a degree of professional competence.

It is apparent, however, that simply fulfilling this statement of purpose (no matter how ingenious the experimental design nor how well established the investigator's competence) in no way provides an unquestioned fiat to begin clinical investigation. In order for the investigation to take place, it must occur in a context in which the investigator pays strict attention to several factors, which include the personal preferences of the patient, the obligations imposed by the common good, the workings of a fundamental moral code, the time and customs of the society in which the study is being conducted and the

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ethics of the medical profession. Justification for a specific protocol is best judged by recognizing human research as a spectrum with a decreasing order of direct and personal good in the research subject. This may vary from studies on therapeutic efficacy at one end, to collections of unrelated statistical, biochemical or physical data at the other end of the spectrum.

The guidelines that the clinical investigator may use to serve as constraints upon his activity may derive from many sources. He may use the teachings of the classic philosophers^{1,2}; he may draw upon natural law as interpreted by religious leaders³; he may refer to the codes of other scientists⁴ or he may use a program proffered by a professional organization such as the code of the American Medical Association.⁵

Whatever frame of reference he elects to use, he surely should fully appreciate the need to keep the guidelines in mind at all times.

The question of constraint is, of course, particularly pertinent to the situation in which the clinical investigator's activity is open for public inspection. The insurer and protector of the public interest in this matter of constraint is the law. It is important that the clinical investigator inspect the role of the law and the judiciary, for in this area he may eventually find himself facing the dilemma of forfeiting some of his enthusiasm and independence in order to fulfill the demands of the third party.

In general, the medical profession has become increasingly alarmed by the growing number of law suits involving practicing physicians. The clinical investigator has not as yet been so burdened. However, the legal precedents covering human experimentation have almost all developed from the allegedly negligent application of experimentation to what was considered by the patient to have been a purely treatment situation: the administration of an as yet unaccepted medication, the performance of an unorthodox operative procedure.⁶

The reflections of the legal profession upon human experimentation many times have stemmed from the concerns and reverberations consequent to the disclosure of the brutalities of the Nazi scientists. From these disclosures and from the extensive discussions that followed has come what is termed the Nuremberg Code.⁶ This code defines the importance of the patient and the many considerations that must always be taken by the

investigator. As a bold reminder to all investigators it merits listing here:

The Nuremberg Code for Human Experimentation

1. The voluntary consent of the human subject is absolutely essential.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problems under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is a prior reason to believe that death or disabling injury will occur; except, perhaps in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that to be taken by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the

exercise of good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability or death of the experimental subject.

The investigator may rightly conclude that if he performs within the context of such accepted guidelines as the Nuremberg Code then he is adequately constraining, in legal terms, his own activity. Such self-assurance and confidence may be unwarranted. Ladimer has indicated that there are no legal decisions and precedents applying to planned medical research on humans: "There is no case directly proscribing such research and there are no regulatory statutes or legal codes."⁹ He further suggests that the Nuremberg tribunals have not created an adequate legal precedent.

The clinical investigator may thus be considered to be in a legal limbo: There are public statements and codes on record regarding clinical investigation, but there are no firm legal decisions in the courts that cover planned investigations. Over the years this hasn't seemed to bother the clinical investigator. His feeling of legal security has been buttressed by the fact that he generally works in the protective environment of a university, research institute or hospital. He has a chance to discuss and submit his experimental designs to his colleagues. In effect this is an advance review by a "jury of his peers." More recently, more institutions have developed devices for sharing responsibilities, such as research committees or committees on new procedures and drugs. Virtually all institutions have administrative echelons which require approval for human research from divisional or departmental directors. Administrators of research institutions, schools and hospitals are particularly cautious about experimentation in such special groups as children and minors, patients with psychiatric diagnoses, investigators, laboratory personnel and medical students, civil prisoners, inmates of orphanages, asylums and corrective homes, and volunteer religious groups, such as conscientious objectors and Mennonites. The considerations regarding these special groups are well summarized in the N.I.H. booklet on the use of "normal" volunteers.¹⁰

The relative security of the clinical investigator has been disrupted of late by three main events:

(1) The establishment of clinical research centers, sponsored by the National Institutes of Health, in a large number of medical institutions. This development has made it economically possible for these institutions to study research volunteers in a manner comparable to the intramural program which has been in effect at the N.I.H. and which has existed at other research institutes. Happily for the investigator, this program has grown to wide acceptability without a clear statement on the part of the N.I.H. as to their legal liability for the natural health consequences, for contestible consequences, for admitted mistakes or for the consequences of negligence in human research. The degree of financial responsibility that the health insurance plans will provide for accidents, mistakes or even intercurrent illnesses during the course of an experimentation has not been clearly established. Moreover, many hospitals and institution insurance carriers have implied a denial of responsibility except in the case of litigated malpractice.

(2) The recent regulations proposed by the Food and Drug Administration which provide for the first time a specific body of technical directions to which the investigator is subject.¹¹ These requirements include written certification by the investigator of "adequate" education and training qualifications, access to accepted research facilities, a general outline of the project, full information on pre-clinical investigation, full records on drug disposition, maintenance of all records for two years, "personal" supervision of the research, responsibility for informed consent and even a divulging of the names of the subjects if "the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual cases studied, or do not represent actual results obtained."

The consent provision has fortunately been modified to permit double-blind studies, investigation of psychic or emotional phenomena and habituation and research on patients whose diagnoses may not be prudently divulged. This loophole was provided in the provision, "The investigator will certify that he will inform any patients or any persons used as controls, or their representatives, that drugs are being used for investigational purposes, and will obtain the consent of the subjects, or their representatives, *except where this is not feasible or, in the investigator's*

professional judgment, is contrary to the best interest of the subjects" (authors' italics). While the exception thus provided is broad, the intent of informed consent is clearly stated. At this point, no investigator can know how the courts will accept the exception.

(3) The Thalidamide debacle and the reams of emotion-filled commentary that have appeared in the public press. For the first time the public has had an opportunity to see some of the details of poor clinical investigation. It has made the public suspicious of drug research. It has also created a wave of angry doubt and will certainly make patients involved in research projects mindful of the possibility of initiating law suits if difficulties ensue. The series of technical requirements contained in the Food and Drug regulations may provide lawyers representing patients who are research subjects with some very tangible guides to use in a potential litigation against the clinical investigator.

The clinical investigator, therefore, once in a legal limbo is now out on a legal limb. Eventually, in actual practice, this new position may not represent any serious problem, but it does throw into bold relief the second of our stock-taking questions, namely, when can the clinical investigator reject the inspection of the interested third party?

We feel this issue is particularly important in the area of protecting the confidential nature of the doctor-patient relationship. Though, as indicated above, the new Food and Drug Administration regulations do permit withholding the names of subjects if certain unusual circumstances occur, the regulation's wording is quite general (" . . . unless the records of particular individuals require a more detailed study . . ."), and just who will eventually decide whether a particular record will require more detailed review is not at all made clear. Patients do have every right to expect that the confidences of their medical histories will be protected by the physician. At present, any third party—insurance company, lawyer, member of the family—must have the signed consent of the patient in order to review the medical data. This mechanism has worked well over the years and it may well be that the clinical investigator, as the subject's physician, will have to insist that third-party review of clinical investigation must not include, without the patient's consent, a knowledge of the

patient as a specific individual. Even consent does not waive certain legal rights to privileged communication.¹² This line of demarcation might represent an important landmark in establishing the province of interest of the so-called interested third party.

Expansion of research has indicated a need for re-examining the ground rules that govern such activity. The clinical investigator has the responsibility to both reaffirm his personal moral code and to clearly mark his path between the demands of the public as a third party and the protection of his subject who, as the second party, is his patient. If moral considerations do not motivate such re-appraisal, legal considerations eventually will. The clinical investigator once in a legal limbo is now distinctly out on a limb.

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Dr. Laurence H. Kyle was kind enough to review successive versions of this essay.

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The Ethics of Human Experimentation

GEORGE E. SCHREINER, M.D.

ETHICS is really morality in action. It is the science devoted to human conduct. It is behavioral and should not be left in terms that are vague, general or even abstract. Medical ethics is the study of human conduct involved in the physician-patient relationship. Although medicine has traditionally dealt only with the prevention, cure, alleviation and investigation of disease, modern medicine has by its own growth and development come to include much more than the physician's own professional conduct in dealing with patients. The nurse has long since been part of the medical team. The dietitian, the social worker, the psychologist, the technician, the therapist and the medical administrator are all sorting out their respective roles. In general, these paramedical personnel are expected to abide by the same rules of conduct as the physician, but their very existence made some of these rules obsolete—most notably the *problem of the medical secret*.

From at least the time of Hippocrates, general moral principles, the inner voice of reason, the experience of history and simple trial and error have all combined to give the physician sound and workable codes of conduct in the prevention, cure and alleviation of disease. Local custom and legal codes such as healing arts practice acts have also served to specifically delineate the limits and the obligations of the paramedical personnel in contributing to these traditional activities.

When it comes to the fourth function, investigation, all members of the medical team are in a "legal limbo" without adequate definition or precedent.

The purpose of clinical investigation and really not only the fundamental purpose—but in some people's eyes the *only* purpose—is to produce scientifically reliable data that will serve to answer specific questions related to human physiology or disease, or in a more basic context that will tend to satisfy the investigator's scientific curiosity. Human research *must*, therefore, be done within the framework of rational experimental design. It is true that honest men will generally produce honest acts. Aristotle said, "Such as a man is, so does a goal or an action appear to them." However, it is quite possible to be honest, kind,

charitable and even religious and *still be an amateur scientist*.

Preparation, training and thoughtful review are essential to good design. Unlike non-clinical research, however, the protocol cannot stand by itself. The clinical investigator has to take into account the personal desires of the patient, the obligations imposed by the common good (especially if this is involved in a justification of his research), the workings of some acceptable moral

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code, the customs of his particular society, the ethics of medical practice and his own personality and integrity.

We have had an explosive increase in research funds. Curiously, we have developed better facilities and more explicit standards for the care of our laboratory animals than we have for our human research subjects. The editors of the *American Journal of Physiology* will not accept a paper based on data obtained from animals in violation of their standard code, but many leading medical journals apply no analogous standard.

Perhaps the problem is too new and the facilities, until recently, too few. The first specialized facility for human research was built in our lifetime, but change is hard upon us. The sudden spread of specialized facilities for human research such as the Clinical Research Centers has brought the quality, diversity, depth and breadth of human research to a point unsurpassed in the history of science. Coupled with technical gains such as atomic reactors, artificial organs, tissue transplants, chronic dialysis, multiple organ biopsies,

electronic physiology, cardiac catheterization, new biochemical techniques and psychopharmacology, the deeper meaning—the ETHICS of human experimentation—must be discussed by the scientists themselves. The problem and its solutions cannot be completely relegated to the moral theologians, to the natural philosophers or to the lawyers. For it is the scientists who are developing the information on which the principles must be applied. It is the scientists themselves who are generating the problems and it is the scientists themselves who should participate in the solutions.

The ethical problem may be dissected on four planes: *Moral*—involving one's individual concept of values; *ethical*—the choice of a practical code of conduct; *legal*—which must be related to the problem involved in a particular legal jurisdiction; and *operational*—that is what the patients (who are the ultimate subjects) expect and accept. Obviously what the patients accept relates to some extent to the first three and how they interact with the patient's own habits and preconceptions. As far as the moral dissection goes, human research may be measured by MORAL VALUES, spelled in the upper case if one views man as *imago Dei*—made to the likeness of God—or moral values may be lower case if the image is a form of democratic humanism stressing the rights inherent in a free individual. Strangely, the logical consequences of such V or values, are little different. They meet on the common ground of the dignity of man, an intact individual who cannot be used as a means by any other man whether his purpose be good, as in science, healing and the building of society; indifferent, as in the accumulation of wealth; or bad, as in greed, crime, lust and ambition for unchecked power.

Whether or not such rights were given by a God and therefore related to Him, any concept of the dignity of man limits the researcher's use of man to those specifically granted by the research subject, such permission being free, proper and surrounded by all the implied safeguards.

In the restricted professional sense of ethics, the researcher must not only resolve his deep moral problems, but must develop his own personal code for his professional conduct. Such personal measuring instruments may need calibration from time to time, and this is provided by deduction from moral values, by the writings of religious leaders, by the peregrinations of natural philosophers, by codes formulated by groups of deliberate men—often with their energies focused by some awful or awesome event (e.g. the Nuremberg Code)—and by the codes of medical and scientific societies that have taken all these factors into consideration.

The most used codes are the Oath of Hippocrates

and the Codes of Claude Bernard, Nuremberg, Helsinki and the British Medical Association.

First of all, the time-honored one is the Oath of Hippocrates. In this most impressive passage of the Hippocratic Collection there is little which can be used by the investigator except that wonderful gem on motivation, "The regimen I adopt shall be for the benefit of my patients according to my ability and judgment, and not for their hurt or any wrong." The Oath also contains a rather fundamental promise, "I will give no deadly drugs to any. . . ."

Many investigators have written practical guides on the problem of experimentation. The one I recommend reading is Claude Bernard's "Introduction to Experimental Medicine," which gives intimate, specific and well-balanced guidelines to the young investigator. Bernard revived the ancient dictum of "Primum non nocere," which means the important thing is not to do any harm, and taught that experiments could be done in man only if proven to be without harm—a test certainly too rigorous for many modern drugs and procedures. He put the proper emphasis on a thorough grounding in other sciences and in the need for animal research. "This help from other sciences is so powerful that without it the development of the science of vital phenomena would be impossible."

The most publicized ethical code is, of course, the code that was formulated in response to a thesis that was done in the name of science by physicians and others as part of the experiment in national socialism under the Nazi regime—the Nuremberg Code. In summary this code contains ten guidelines, which are worth reading:

1. The voluntary consent of the human subject is absolutely essential.
2. The experiment should be such as to yield fruitful results for the good of society, unobtainable by other methods of means of study and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and knowledge of the natural history of the disease or other problems under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is a prior reason to believe that death or disabling injury will occur, except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage if he has probable cause to believe, in the exercise of good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability or death of the experimental subject.

This Code, which attempts to establish both the rights of the human subject used in research and the responsibilities of the investigator, was formulated on the basis of extensive legal discussions of the brutal experiments performed on humans by Nazi scientists; it understandably emphasizes the negative and protective aspects. Even moralists *object to Rule 5*. The investigator has no more right to indulge in self-mutilation than he has to impose this on someone else. This test in the Nuremberg Code is a practical test and was intended to exclude a lot of poor research if the experimenter himself had to put his self-interest to such a rigorous test. The fact is that many experimenters actually lose objective judgment in such situations. They can become so enthusiastic that they might be quite willing to subject themselves to an experiment which is really self-mutilating and which is not a proper test to be done to a research subject. The simple fact that an investigator is willing to go through an experiment is no guarantee that it is ethically proper or morally so. In the terminology of abnormal psychology, Rule No. 5 is a protection against sadism but not against masochism.

There are other problems with the Nuremberg Code. It demands levels of certitude which just aren't available in many practical situations. It is highly unlikely that many of the great advances in medicine would be made if physicians really had to have a prediction of the outcome of their experiments. Many well-designed experiments have been done where it was impossible to predict the particular outcome. Although too rigorous, we have to view the Nuremberg Code in a very understanding fashion. One shouldn't just look at it as words, but rather in the setting in which it

was written, the human reaction that it entailed and the purposes that were behind this rigor. These were purely protective purposes, whereas most investigators would like to see the positive accentuated in some ultimate code to be developed.

The Declaration of Helsinki is the recent code that was developed by the Eighteenth Meeting of the World Health Association. Its basic principles are:

1. Clinical research must conform to the moral and scientific principles that justify medical research and should be based on laboratory and animal experiments or other scientifically established facts.

2. Clinical research should be conducted only by scientifically qualified persons and under the supervision of a qualified medical man.

3. Clinical research cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

4. Every clinical research project should be preceded by careful assessment of inherent risks in comparison to foreseeable benefits to the subject or to others.

5. Special caution should be exercised by the doctor in performing clinical research in which the personality of the subject is liable to be altered by drugs or experimental procedure.

The WHO code divides clinical research into that which is confined to professional care and that which is not confined to professional care. (I believe they should not be separated.)

For clinical research confined to professional care:

1. In the treatment of the sick person the doctor must be free to use a new therapeutic measure if in his judgment it offers hope of saving life, re-establishing health or alleviating suffering. If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely-given consent after the patient has been given a full explanation. In case of legal incapacity, consent should also be procured from the legal guardian. In case of physical incapacity the permission of the legal guardian replaces that of the patient.

2. The doctor can combine clinical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that clinical research is justified by its therapeutic value to the patient.

With respect to non-therapeutic clinical research:

1. In the purely scientific application of clinical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom clinical research is being carried out.

2. The nature, the purpose and the risk of clinical research must be explained to the subject by the doctor.

3a. Clinical research on a human being cannot be undertaken without his free consent after he has been informed; if he is legally incompetent, the consent of the legal guardian should be procured.

3b. The subject of clinical research should be in such a mental, physical and legal state as to be able to exercise fully his power of choice.

3c. Consent should, as a rule, be obtained in writing. However, the responsibility for clinical research always remains with the research worker; it never falls on the subject even after consent is obtained.

4a. The investigator must respect the right of each individual to safeguard his personal integrity, especially if the subject is in a dependent relationship to the investigator.

4b. At any time during the course of clinical research the subject or his guardian should be free to withdraw permission for research to be continued.

The investigator or the investigating team should discontinue the research if in his or their judgment it may, if continued, be harmful to the individual.

The Representative Body of the British Medical Association in 1963 approved the remaining part of this Code:

1. New drugs or other therapy should not be prescribed unless prior investigation as to the possible effects upon the human body has been fully adequate. (Note that the Code avoids the trap of singling out animal investigation as being the only kind of preparation, because it is obvious from recent pharmacologic investigations that perfect animal models in toxicology simply do not exist, e.g., thalidomide.)

2. Before a new drug is used in treatment, the clinician should ensure that the distributors of the drug are *reputable* (how the British determine *that*, I don't know!) and claims made for the products include reference to independent evidence of its effects.

3. No new technique or investigation shall be undertaken on a patient unless it is strictly necessary for the treatment of the patient, or, alternatively, that following a full explanation the doctor has obtained the patient's free and valid consent to his actions, preferably in writing.

4. A doctor wholly engaged in clinical research must be at special pains to remember the responsibility to the individual patient when his experimental work is conducted through the medium

of a consultant who has clinical responsibility for the patient.

5. The patient must never take second place to a research project nor should he be given any such impression. Before embarking upon any research the doctor should ask himself these questions:

a. Does the patient know what it is I propose to do?

b. Have I explained fully and honestly to him the risks I am asking him to run?

c. Am I satisfied that his consent has been freely given and is legally valid?

d. Is this procedure one which I would not hesitate to advise, or in which I would readily acquiesce if it were to be undertaken upon my own wife or children?

These various formulations have generally included in some way the cardinal concepts of full qualification of the scientist, appropriate facilities, informed consent of the subject, good experimental design, full precautions, prior testing on animals or models where feasible, economy of use and minimization of risk.

It is precisely on the *subject of risk*, however, that most codes fail to give guidelines which are useful to the young investigator or research nurse. There is no problem with a clean catch urine specimen because there is no risk, but steroids, immunosuppressive agents, polypeptide antibiotics, cardiac catheterizations, liver biopsy and aortograms have all been introduced with a very tangible risk.

One solution to this apparent conflict between existing codes and actual practice as it is being carried out in medical centers is to develop some sort of a scale for weighing the inherent risk of the procedure against some estimate of the potential benefits to the subject. Such a gradation is attempted here as an example:

Grade 1: The clinical investigation is concerned in whole or in part with determining the relative efficacy of a therapy that may improve the immediate clinical condition of the patient. An example might be a study of a new diuretic agent or of a combination of diuretics or the synergism between acidosis and diuretics in the management of congestive heart failure. An efficacious diuretic regimen clearly would be beneficial and the gravity of the situation determines the limits of acceptable danger and toxicity. One would probably not be justified in testing a highly toxic agent to control edema or, on the other hand, be constrained to test a new agent only in cases in which less toxic ones were ineffective.

Chemotherapy in metastatic carcinoma is an extreme example of another sort, since the gravity of the prognosis makes the testing of highly toxic

agents not only permissible but, at the present time, often desirable.

Grade 2: The investigation is indirectly related to the patient's condition and might produce at least a delayed direct good to the patient. For example, the use of cardiac catheterization to study hemodynamics in the early stages of rheumatic heart disease is justifiable if it may help to elucidate the natural history of rheumatic heart disease which will ultimately be presumably to the direct benefit of this patient. The use of cardiac patients for the bioassay of digitalis preparations would fall into this category. These very patients, although controllable with digitalis, could benefit in the future from improvements in the drug or better understanding of its action.

Grade 3: The investigation involves conditions that the subject may acquire with a high degree of probability. This might include baseline studies of young married women who might be expected to become pregnant. Research on the common cold on people who don't have colds at the present time is obviously quite legitimate, because we all might get colds, with a reasonably high degree of probability. Research on arteriosclerosis is another obvious case in point since we can say that ultimately we are all going to get it. Human experimentation to investigate the mechanism of injury in automobile accidents could be justified on this basis, for the probability is quite high that sometime in our lifetime we could benefit from such knowledge. Nevertheless, such investigations are one degree removed in terms of direct-good to the subject.

Grade 4: The investigation involves conditions that the research subject is not likely to acquire. Justification, therefore, rests not so much on a direct personal benefit, but on some other principle such as charity or a contribution to the common good. Examples include such procedures as the deliberate introduction of nutritional deficiencies or rare diseases in human volunteers. Obviously Walter Reed's experiments fall into this probability for him (but not for the Panamanians!).

Grade 5: The investigation involves conditions which would not conceivably affect the subjects now or later. Studies of this type are designed to produce statistical, biochemical or physical data which might add to the sum total of our basic knowledge. Pure examples are hard to cite because in most research projects currently being done one can find some sort of relationship with a known disease process, but I think we have to face the fact that as certain techniques become available one may be interested in acquiring purely basic biochemical information without necessarily relating it to any disease process.

For example, development of a needle probe to

measure oxygen tension of various organs might include a desire to do this on a human being just to measure the oxygen tension of the organ, without having in mind any disease process.

These grades of human research require us to make careful, philosophic, legal and moral distinctions. Failure to do so can only lead to a great deal of confused thinking when one has to consider such concrete requirements or factors as informed consent, preclinical studies in animals, detailed knowledge of toxicity, ethical rights of domain over our bodies and a host of other factors that are best assessed in relationship of the risk to the potential good.

Among the other items that are operational are the ethical rights of domain over our bodies. If a technique for an amputation, for example, has been developed on an experimental basis, a patient with a crush syndrome might legitimately volunteer as a subject for such an operation since he has the chance that it would also remove a source of infection and reverse a state of catabolism and toxic accumulation of potassium. If our moral code denies a person the right to maim or destroy his body, however, a normal volunteer could not submit to such a deforming operation.

It is easy to define direct good in physical or in what might be called health terms. But we should not overlook, simply because we can't articulate it very well, the intellectual and emotional aspects of man's well-being. This has actually been invoked in court in Massachusetts in the transplant situation.

It may do emotional good and avoid psychiatric harm for a twin to be a graft donor. By the same token, it would be degrading man to a purely material level were we to deny the salutary and noble effects of pure charity, well-motivated. If a donor, sane and well-balanced, is acting out of genuine love for his fellow man, then it may truly be more blessed to give than to receive. This right to use a part for the good of a whole person is the moral principle of totality. To extend the principle of totality to the concept of common good is philosophically dangerous. It opens the door to the use of the individual as a means or an instrument.

Some critical comment on the legal problems may be deserved. Although the law purports to grease the cogwheels of civilization, it often lags behind the scientist and the theologian in considering new applications for old principles. Thus the clinical investigator finds himself and his patient bound down by an anachronistic web of regulations relating often to the excesses of a by-gone era and having as much applicability as a speed limit on a private road in the desert. The British Tissue Act derives, for example, from the 1832 body-snatching excesses of Burke and Hare.

What use is it to discuss the ethics of transplantation if your state forbids autopsy within six hours of death; what use to require prior workout on animals if your community has an anti-vivisection law. If your law forbids surgery except for the patient's physical benefit, all transplants are illegal and you could not have a decision such as that reached by the Massachusetts Supreme Court that a donation of a kidney would contribute to the donor's emotional and mental health (ergo his total being—an exercise of his right to use his totality at the expense of a part).

Finally, what does the patient expect in the operation of human research? Even an atheist, a Nazi or an iconoclast who believes that Science is God and a new piece of information is its own justification cannot ignore the historical codes. Most potential research subjects will expect certain things of the investigator in an operational sense whether he likes it or not.

A marked deviation beckons professional disaster and happy we can be that civilization has reached such momentum in at least one society, but the grim examples afforded by Naziism and

communism should leave us very humble about the long-term efficacy of operational deterrents. Such civilization is a very thin veneer. Modern propaganda techniques can make a people soon forget. Herein lies the worth of our attempting to formalize these thoughts. They should be engraved as deeply as we can engrave them—lest we forget.

While remembering the excesses, one should re-emphasize the positive and constructive aspects of ethical considerations. The clinical investigator seeks to codify in order that he may *do* rather than stop human experimentation. This distinction was beautifully phrased by Pope Pius XII, "The great moral demands force the impetuous flow of human thought and will to flow, like water from the mountains, into certain channels. They contain the flow to increase its efficiency and usefulness. They dam it so that it does not overflow and cause ravages that can never be compensated for by the special good it seeks. In appearance, moral demands are a brake. In fact, they contribute to the best and most beautiful of what man has produced for science, the individual, and the community."

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Mr. PREYER. Thank you very much. I think you have given us some excellent ideas and have made some very serious points. You have given us a very realistic presentation. This invasion of privacy difficulty is one I am sure no one wants to see raised by the bill.

Dr. Carter?

Mr. CARTER. You are professor of surgery?

Dr. SCHREINER. Internal medicine.

Mr. CARTER. I appreciate your statement. I think it explains the position of most physicians quite well. You have great insight into it. I do not believe you made a statement with which I do not agree.

People who are not informed really about medical procedures when they see them, can become amazed and shocked at what we consider routine things which actually don't endanger a patient's life but such actions are made in an effort to save lives.

Still, a layman could not possibly understand all about what is going on.

For instance, if a child was undergoing leukophoresis, a rather new method of examining blood where the blood is taken from a youngster and put through an apparatus which separates it into its component parts and then goes back into the youngster, or into an adult for that matter, a layman might be amazed at such a procedure.

We know that a large percentage of the cancer patients must die. According to all the knowledge we have and using all of it, we know that a large percentage are going to die. Still, in certain cases, X-ray is extremely helpful but it has very serious effects and in some cases chemotherapy can be curative or almost so.

At the time if we have someone looking over our shoulder when we made a decision as to whether a youngster needs this or not, I think that is an invasion of the right of a physician too much so. Do you agree on that?

Dr. SCHREINER. Yes. I don't subscribe to the idea that physicians are sacrosanct and should not be open to analysis and criticism.

I do think, however, that we have had a long, long series now of almost 5 years of steadily tightening peer review. There are obviously some holes in this system. There are some types of research being done outside of academic institutions without perhaps the expertise for consultation available, and I think that studies of that type and the magnitude of that type of research should be done. I think one of the previous witnesses testified that they hope the greatest part of this bill would apply to nonphysicians.

I think we are in a gray area there which deserves a lot of study. I think perhaps in isolated areas where there are no experts, one could come to one or two conclusions—either research should not be done in that area or experts should be made available to them in some positive fashion so that consultation with experts were made, but I have really grave doubts that a committee in Washington can perform that job, and that the direct submission of research problems as was suggested would really serve much in the way of a constructive purpose.

I am sure it would stop bad things from being done. The big problem is would it stop everything from being done which is slightly unpopular at that particular moment in history or does not have the weight of the establishment behind it because all research is done creatively.

The investigator really is a highly creative person. He has a moment of curiosity, he has a moment of intensity. If it is lost, it is lost for a long time to come. I think if you put Picasso in front of a canvas and said, is the paint you are using nontoxic, was the canvas obtained from one of our most-favored-nation trading partners and you started writing all kinds of regulations, chances are the painting would not get done, and no one would ever have a record of paintings not done.

It is easy to get a record of abuses and it is easy to get exceptions to the law. The big problem is finding out what is on the other side. What are omissions? What is created in the negative sense by too specific a restriction.

I think we need to weigh that as well. I am not saying the precautions are not proper. I think they are proper and I think a study committee could do that, but I don't think we are ready to codify that into a regulatory commission that has direct jurisdiction over human research at this time.

Mr. CARTER. In your hospital, if you found some one of your younger physicians on the staff doing some unusual and dangerous procedures, such as using an icpick to sever the corpus callosum or do a pre-frontal lobotomy, how long would he last down there?

Dr. SCHREINER. All human research is submitted in protocol form. Our committee does review them and does reject a fair number. usually in a constructive manner, usually with the kind of suggestions Dr. Cooke made, for example, that perhaps this could be done in primates first. The aim is to try to help the investigator.

I think this is the whole point. If you are sitting in a distant relationship, I can imagine someone sitting on a committee in Seattle, and their easiest solution is to say "don't do it." It is very easy to get into the constructive attitudes that Dr. Cooke mentioned, which is to see whether or not there are alternative systems which may never have occurred to the investigator.

This is the reason for having a sophisticated committee that has some expertise.

For example, I enjoyed Dr. Cooke's testimony or someone's testimony about what is needed to get close to the ideal—the omniscient and so forth. That is fine, but the implication at the end paragraph bothers me.

I have some reservations about the committee and the more distant from specific expertise, I would say, the more problems it is going to have in adopting a constructive point of view.

This has been my own personal experience. It has been an educational process for the nonscientific on the peer committees, really to have to loosen up a little bit because their initial reactions were very, very restrictive and extremely negative.

Mr. CARTER. Certainly in reviewing protocols for certain procedures in your hospital, if you thought they were too dangerous you would not permit them.

Dr. SCHREINER. Of course.

Mr. CARTER. If we had had a group of lay people looking over Von-Roentgen's shoulder, would he have developed X-rays?

Dr. SCHREINER. I think he undoubtedly would not, and I can give you very many other examples. Perhaps one of the greatest diagnostic instruments in our time in terms of our No. 1 killer—heart disease—is the intravenous catheter; the intravenous catheter used on a whole

host of diagnostic techniques. In fact, when the man won the Nobel Prize for that arrived in America with a school appointment, the administration of the particular university where he was going to work forbade him to use it, even though a colleague, Dr. Forsman in Germany had done it on himself.

He had to go to a different university here, happily, an investigator controlled a unit in Bellevue Hospital in New York and was permitted to do the first catheterization there. After it became well known, his first university welcomed him back. Here was a case where work that won a Nobel Prize was blocked by administrators.

Mr. CARTER. I want to thank you for your testimony. You have the insight of one who has been through it.

Mr. PREYER. Thank you, Dr. Schreiner. We have one final witness today, Dr. Richard Behrman, from the Department of Pediatrics, Columbia University.

STATEMENT OF DR. RICHARD BEHRMAN, PROFESSOR AND CHAIRMAN, DEPARTMENT OF PEDIATRICS, COLUMBIA UNIVERSITY, REPRESENTING THE JOINT COUNCIL OF PEDIATRIC SOCIETIES

Dr. BEHRMAN. I don't have a prepared text but I will make remarks directed toward some of the considerations brought up by the people here.

If I could take a moment to identify myself, I am a professor and chairman of the Department of Pediatrics of Columbia University and director of Babies Hospital, the Children's Medical and Surgical Center of New York. My responsibilities are both academic and service. I have also had extensive experience in research with sub-human primates—monkeys, and this research has been devoted principally to studies of the fetus which is directly relevant to some of the comments I am going to make.

I am representing today a number of groups whose principal concern is the health and welfare of children—the Joint Council of National Pediatric Societies which includes the Association of Medical School Chairmen, American Academy of Pediatrics, American Pediatric Society, the Association of Teachers of Maternity and Child Health, and the Society of Pediatric Research.

Obviously, most of my remarks reflect my own views, but my comments on the proposed legislation do represent the consensus of those groups.

First we would like to express our agreement that there is a need to develop a public policy to protect the interests of the subjects involved in human investigation as well as the interest of society, particularly children, to have fetal investigation continued.

We believe that H.R. 10403 in proposing a commission to study these problems and formulate policy is a constructive advance, but at the same time we feel certain aspects of the bill may seriously hamper our progress in treating diseases in children and therefore deserve further study before legislation is enacted. We also would like to state at the start that we support fully the judgment that decisions about policy that involve ethical considerations, certainly decisions about broad policy as well as decision, about policy concerning individual research applications, should reflect a consensus of many peo-

ple in our society and not just the physicians or scientists involved. The mechanism for accomplishing this, we hope, will be carefully studied to develop the proper balance of people.

Specifically I am concerned about combining responsibilities for the Commission to include overall policy development along with the regulatory function for the administration of this policy.

I appreciate, there are a number of areas in which commissions do perform both functions. I believe the major committee of which this committee as a subcommittee has dealt with product safety in this manner. Obviously drug and food standards are another example where commissions have developed and formulated policy and then implemented the regulatory mechanisms for this policy. However, in my own opinion, and I think there would be agreement in substance by the groups I am representing here when we are dealing with moral and ethical problems, some of which have a specific religious basis for the positions of their various advocates, we are dealing with a problem that is different in kind in terms of quantifying the regulations. It will be much more difficult, I believe for the Commission to formulate the best general policies that will both protect our citizens and promote the health of children through research if it is constantly worrying about implementing specific regulations. I would much rather see what was suggested by several other people, either a two-stage function or two separate commissions. The considerations that were raised by the previous witness are quite intimately related to this.

I am also concerned that we not end up throwing the baby out with the bath water as the previous witness pointed out. I would like to add in this regard a comment about nonhuman primate research and give my professional opinion as one who has worked extensively in the field of using primates for fetal investigations. Thirteen years ago, when I entered the field I felt strongly that the need for research was in the nonhuman area, but the situation has changed considerably since then, and one should not carry over attitudes that may have been appropriate at an earlier time under different circumstances. While I think there is still need for nonhuman primate studies involving the fetus, there are a number of serious problems in children that really have to be approached by human investigation.

Returning briefly to the point of the overcentralization of the judgments about research that may possibly be made, if the regulatory function is initially vested in this commission, I would like to refer to a statement Dr. Cooke made earlier in which he said there was research that he participated in 25 years earlier that he would not do now. I think some of the ethical judgments we are dealing with is in an area of ethics in which the changing attitudes of society are most important. There are some underlying principles, but changing social attitudes are probably more important. We should not fix these ethical attitudes in relatively inflexible law.

I am not at all convinced that a commission at considerable distance from the people involved can make judgments about this changing consensus as to what is right. One need only refer to the prohibition and abortion problem to see what a difficult area this is.

Specifically, I would like to turn to several matters of the language of the bill.

It is my judgment that in effect, by singling out fetal research in the way it is singled out in the bill, the bill lends itself to an interpretation that there is a banning of research on the fetus or a moratorium of research which would clearly be to the detriment of children. A substantial number of the problems in young infants start in utero that is the hyaline membrane disease, to mention one, that has national notoriety. The sudden infant death syndrome, about which I believe this committee has always had previous discussions, is another example; some of the leads in development immunology related to infant death syndrome, may come from studying the immunological differences in the fetus.

At a certain point, one has to turn to the human to help humans. I do not think it would have been possible to develop amniocentesis as a diagnostic test which holds forth possibility of substantially reducing, if not eliminating mongolism, under the proposed legislation.

There are estimates for an eightfold decrease in mongolism if this technique were fully employed. Clearly in Tay Sachs's disease, and a number of other genetic disorders might be eliminated or corrected by such tests. I don't agree with the statement of Dr. Cooke that all of this can be done on dead tissue. Unfortunately, it is not true. Specifically hyaline membrane disease, in which a critical ingredient seems to be the immaturity of the lung, might be successfully prevented if we do not now limit total research.

If I could use an example that relates both to amniocentesis and hyaline membrane disease to show the committee what potentially might result from this type of prohibition. There are 55,000 prematures that die each year of a viable age by anybody's criteria when they are born and a substantial number of these die from the hyaline membrane disease.

It looks like the best lead at the moment into this disease is the assay of development based on material that is produced in the fetal lung which flows out of the lung into the amniotic fluid. By sampling it, if it is present, we can make a guess whether that baby is mature enough to breathe with its own lungs after birth.

It seems to me that at this point some of the research in this area has to be done on the human. This may not be therapeutic research, for that individual fetus; and the language in the bill specifically only allows research on the living human fetus or infant whether before or after induced abortion when experimentation is done for the survival of that infant or fetus. Normative data is the basis for a good deal of our ability to deal with disease in infancy. In this instance, we need to know at what time during gestation this critical ingredient appears in the amniotic fluid of normal fetuses in order to identify the infant in utero who is at risk with the disease when we get a sample of his or her amniotic fluid, we have to have something to compare it with to say whether it is normal or abnormal.

It would be like trying to cure growth failure and not knowing what the normal growth pattern is. I am very concerned that the way in which this particular restriction is stated could dramatically decrease our ability to deal with these and a variety of other problems in children.

On the other hand, a case by case, if you will, a common law approach to whether or not a given investigation that is proposed is

appropriate would be much more to the interests of our children and grandchildren in general than this type of a specific exclusion.

I would like to stop at this point.

Mr. PREYER. Dr. Carter?

Mr. CARTER. He certainly knows what he is talking about as I see it, and we certainly don't want to establish a moratorium on investigations of the fetus in utero.

As he so well told us, it would stop research on sudden infant death syndrome and hyaline membrane disease and on the study of mongolism, a determination which can now be made by studying the amniotic fluid and it would prevent more mongoloids from occurring throughout our country, and that is one of the great problems we have today.

He certainly has some points that are meaningful and that we should observe carefully in rewriting this bill which I hope we will do.

Thank you, sir.

Mr. PREYER. Thank you, Dr. Carter. I certainly agree with everything you say, particularly in this area of experiments on live fetuses. The kind of specific information you have given us is extraordinarily helpful because this is a red-hot political issue and the facts are sometimes hard to obtain from emotional discussions.

This kind of testimony will not only be helpful to this committee, but helpful on the floor if it can be more widely disseminated.

I do want to thank you and I am sorry for keeping you so late. At this time, the hearing is adjourned.

[The following statements, letters, and telegrams were received for the record:]

STATEMENT OF C. JOSEPH STETLER, PHARMACEUTICAL MANUFACTURERS
ASSOCIATION

Mr. Chairman and Members of the Committee: The Pharmaceutical Manufacturers Association is a voluntary, nonprofit trade association composed of 110 member companies engaged in the development and production of prescription and ethically promoted over-the-counter drugs. Our members manufacture and distribute 95 percent of such products made and sold in the United States. They also conduct extensive research, including research on human subjects. Accordingly, we have considerable interest in the bill which is the subject of current hearings by your Committee.

H.R. 10403 would establish within the Department of Health, Education, and Welfare a national commission for the protection of human subjects who participate in biomedical and behavioral research programs. The commission's duties would involve: the development of ethical principles and protective measures underlining the conduct of such research; the development of procedures for the certification of institutional review boards to oversee HEW-financed research; and the development of appropriate mechanisms to broaden the scope of the commission's jurisdiction. Other duties would include an investigation of virtually all facets of use of human subjects in biomedical and behavioral research projects.

Prior to the establishment of institutional review boards, authorized by the bill, H.R. 10403 would require each institution engaged in research involving human subjects to assure that: the rights and welfare of such subjects were fully protected; the risks were outweighed by the potential benefits to the subject or by the importance of the knowledge to be gained; and informed consent was obtained by methods that were adequate. The bill defines informed consent and would require that it be obtained in all but exceptional cases. H.R. 10403 would also authorize comprehensive inspections by the Secretary of Health, Education, and Welfare of institutions involved in research and would require records and reports to the commission as set forth in regulations. Provisions governing the confidentiality of information regarding individual subjects are included as well.

Following are our comments on H.R. 10403.

I. IN GENERAL

Although we completely support the goals and purposes of the bill, it appears to us that enactment would result in considerable duplication and overlap with existing law and HEW policies. However, without adopting a position for the Association on the bill per se we would like to suggest a few amendments which we believe will more clearly reflect the bill's purposes and in addition, will assist in restricting application of the bill to situations for which it was intended. Our comments relate to: the interim provisions involving informed consent; jurisdiction of the commission; make-up of the commission; and material that may be published by the commission. It is the interim provisions governing patient consent that concerns us the most.

II. SPECIFIC COMMENTS

A. *Interim Provisions Involving Informed Consent*

Pages 12-14 of the bill require, among other things, that until review boards are established, institutions engaged in human research must assure that, except in exceptional cases, informed consent is obtained by methods that are adequate. The pharmaceutical industry fully supports the concept that informed consent should be obtained except in rare circumstances. Indeed, under the Federal Food, Drug, and Cosmetic Act (21 USC 331 et seq) consent of human subjects is required before drugs can be used for investigational purposes except when the attendant physician deems it not feasible, or in his professional judgment, contrary to the best interests of the subject or patient (21 USC 355(1)). The Food and Drug Administration has published a comprehensive regulation on the subject which includes, among other things, a proviso that the consent in most situations must be in writing. These provisions, in our opinion, are adequate to insure the well-being of human subjects. In any event, we believe the interim provisions should be modified in at least three areas.

First, lines 18-23 on page 12 define as "informed consent", "the consent of a person, . . . so situated as to be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, or other form of constraint or coercion". [emphasis added] We believe that any consent obtained without any element of force, fraud, deceit, or duress is freely given. Therefore, we see no need for the phrase "or other form of constraint or coercion". Further, that phrase gives us concern because under the reasoning of some court decisions defining analogous terms, the phrase might preclude any clinical testing with prisoners, students, institutionalized population and perhaps even the poor. For example, it is established case law that if a potential defendant in a criminal case is held for an undue length of time after arrest before he is arraigned, any confession obtained during that time may not be admitted. The reasoning is that mere detention of the person for an undue length of time would make the confession, as a matter of law, not voluntarily given. We urge that the phrase "or other form of constraint or coercion" be deleted.

Second, in describing the information to be given to the subject in order to obtain consent, the bill, on lines 4-10 on page 13 requires giving to the patient "a description of any attendant discomforts"; "a description of any benefits"; and "a disclosure of any appropriate alternative procedures". We believe the purposes of these clauses can be obtained without use of the word "any". "Any" can be construed to require all minute or theoretical happenings. Therefore, inclusion of the word could result in many frivolous law suits.

Third, lines 4-11 on page 14, defining "exceptional cases" in which informed consent is not required, would require the written concurrence in the attending physician's decision by at least two other licensed physicians not involved in the research project unless a life-threatening situation is involved, and it is not feasible to obtain such concurrence. This would limit the exceptional case situations from that permitted under the decisions of the courts and existing statutes. In the absence of two concurring physicians, if a physician, in his professional judgment, believed it was very much against the best interest of his patient or subject to convey certain information, he would not be permitted to withhold the information unless there was a life-threatening situation.

We suggest that pending the certification of institutional review boards, the term "exceptional cases" be defined to be situations where the attending physician or investigator believes that imparting the information is not feasible, or, in his professional judgment, it would be contrary to the best interests of such subject or patient. This would be consistent with present provisions in the Federal Food, Drug, and Cosmetic Act.

B. Jurisdiction of the Commission

S. 2071 and 2072, virtually identical bills which have passed the Senate, were said by their sponsor to apply commission findings only to research and the delivery of health services in health service programs funded in whole or in part by the Department of Health, Education, and Welfare. In addition, there are provisions in the bill which would indicate that it is intended that the bill apply only in those cases. (See lines 17-22, page 8; lines 20-24, page 10; and lines 15-18, page 14.) However, the limitation is not expressed in several of the bill's sections. Accordingly, we recommend the following amendments.

On page 5, line 3, after the phrase ". . . implement policies and regulations to assure that such research", add the phrase, "and health care in health service programs funded in whole or in part by the Department of Health, Education, and Welfare". On page 11, line 14-24, (involving protocol review subcommittees programs funded in whole or in part by the Department of Health, Education, and Welfare". On page 11, lines 11-24, (involving protocol review subcommittees and subject advisory subcommittees) change as follows: after the word "procedures" on line 19, add "in programs funded in whole or in part by the Department of Health, Education, and Welfare". After the word "research" on line 22, add the words "in programs described in paragraph (1)". Insert the word "the" after the word "that" on line 23.

Lines 8-17 on page 12 would impose interim provisions governing the welfare of subjects pending the certification of institutional review boards. To make it clear that these provisions are only applicable in HEW-funded research, add the following after the word "involved" on line 12; "in programs authorized or funded by Department of Health, Education, and Welfare grants or contracts".

Lines 10-17 on page 15 involve inspection of research facilities by the Secretary. To limit inspection authority to situations intended to be covered by the bill, add the following after the word "subjects" on line 15: "funded in whole or in part by the Department of Health, Education, and Welfare".

C. Make-up of the Commission

Lines 12-16 on page 2 of the bill provide that ". . . members of the Commission shall be appointed from the general public and from among individuals in the fields of medicine, law, ethics, theology, biological science, physical science, social science, philosophy, humanities, health administration, government and public affairs". A large, indeed the major, share of research on human subjects involving drugs and medical devices is sponsored by industry. Industry-supported research is responsible for most of the advances in these fields. It is inconceivable to us that a commission established to review, and recommend procedures for, the entire human research field should not have representation from industry. We urge that the words "pharmaceutical industry" be inserted after the word "government" on line 16.

D. Material That May Be Published by the Commission

Lines 4-10 on page 19 direct the commission to compile a complete list of decisions pertaining to programs under its jurisdiction and to annually publish and distribute reports listing them. Among the cases to be handled by the commission are appeals from decisions of institutional review boards on particular investigation (page 6, lines 11-13) as well as certain protocols (page 7, lines 3-5). Proposed regulations published by the Food and Drug Administration (FR 00-0000) recognize that in most cases the existence of a drug investigational plan is a trade secret and, therefore, should not be divulged. Some investigations under the jurisdiction of H.R. 10403 may well be entitled to such confidentiality. Accordingly, the following should be added after the word "Act" on line 10. "Nothing in this section shall authorize the disclosure of trade secret or other confidential information".

Representatives of the Pharmaceutical and Manufacturers Association would be pleased to discuss our suggested changes to H.R. 10403. It is respectfully requested that this letter be made a part of the printed hearings on this bill.

STATEMENT BY THE AMERICAN ACADEMY OF PEDIATRICS COMMITTEE ON THE FETUS AND NEWBORN

The Committee on Fetus and Newborn enthusiastically endorses the provisions of H.R. 10403 whereby a National Commission is established to undertake a comprehensive investigation and study to identify the basic ethical principles

and develop guidelines which should underlie the conduct of biomedical and behavioral research involving human subjects.

The Committee further agrees with the provisions that the members of the Commission to study and investigate this matter should be drawn not only from the medical community but should also include individuals from the general public and representatives from disciplines such as law, ethics, theology, biological sciences, physical sciences, social sciences, philosophy, humanities, health administration, government, and public affairs.

The information to be generated by provisions of Section 6, wherein further duties of the Commission are outlined, appear to be indispensable prerequisites before definitive regulatory and further legislative measures are adopted. The Study Commission should also be charged with developing alternative recommendations for implementing its findings.

However, until the study of this body is concluded, its recommendations developed, and the mechanism for implementation fully considered by interested parties, the Academy should oppose legislation which establishes a rigid system for implementation of findings with ethical, moral, legal and social implications which may unnecessarily prevent acquisition of new knowledge of benefit in promoting the health of mothers, infants, and children.

EXAMPLES OF NEW METHODS OF DIAGNOSIS AND TREATMENT THAT HAVE BEEN MADE POSSIBLE ONLY THROUGH RESEARCH ON THE HUMAN FETUS AND NEWBORN

A. Amniocentesis—removing fluid from the amniotic cavity

This technique was first used for the measurement of intruterine pressure during labor and could in no way have been considered beneficial to that particular fetus or could the information be obtained from research on animals. During the past decade application of this technique to study amniotic fluid has made possible the detection of over 50 diseases before birth. Many of these diseases result in death during childhood or profound mental retardation.

Familial Disorders of Intraocular Metabolism.—Over 40 such disorders can now be detected. The risk to families of having a child affected with any of these disorders can be as high as 1 out of 4. Many of these disorders have been detected in utero and in a few cases treatment has been started during intrauterine life. In instances in which parents have elected termination of pregnancy, examination of the fetus has provided important insight into the fetal manifestations of the disease and has indicated that if rational postnatal treatment is developed, it may have to be started during intrauterine life to be maximally effective.

Chromosomal Aberrations such as mongolism or Down's syndrome, occur with a frequency of 1 in 600 live born births. These can now be detected early in pregnancy. This information is of immense value to those families who are at high risk of having children with this disorder. The ability to detect chromosomal aberrations provides families with the option of having normal children rather than a child with an untreatable disease in which profound mental deficiency is the hallmark.

Iso-Immune Disease—Rh incompatibility.—The antenatal prediction of those fetuses which would be most severely affected from this condition and at greatest risk of dying in utero was made possible through amniocentesis. Indeed the development of this diagnostic technique for Rh incompatibility could not in the first instance have been considered as benefiting that particular fetus. Through the development of a predictive index for those fetuses at high risk, the intrauterine treatment of these infants was introduced and ultimately preventive treatment of the mother with RhoGAM developed.

B. Drugs

Antibiotics.—Research performed in the last 15 years has permitted more appropriate drug and drug dose selection for infants. This has been most clearly effective in decreasing the mortality from meningitis in newly born infants from 50-60% to 20-30%. These results could not have been obtained in studies performed only in animals.

Antimicrobial Agents.—The study of absorption of hexachlorophene through the skin of infants led to the demonstration of brain lesions in infants bathed with the chemical and demonstrated the potential hazards of such a technique. These findings could not have been obtained in studies performed exclusively in animals.

Vitamin K.—Comparison of three acceptable schedules of Vitamin K dose in human infants (0 to 5 mg) demonstrated that abnormal bleeding occurred in breast fed infants not receiving supplemental Vitamin K. Furthermore, since dose related side effects of Vitamin K were known, the study demonstrated a normal effective and therefore safe dose. Again, these studies could not have been performed in animals.

Relationship between Drugs, Serum Bilirubin and Brain Damage (Kernicterus).—The study of this relationship in premature infant led to definition of factors causing kernicterus and the development of criteria for application of therapy (exchange transfusion). The research subsequently carried out in animals and in the test tube would not have been possible without prior investigation on human infants.

C. Retrolental Fibroplasia—Blindness from Oxygen Toxicity

Control studies in human infants demonstrated that oxygen toxicity was the cause of retrolental fibroplasia; this led to specific animal experiments where the lesions were reproduced. These human observations performed in the early 1950's revealed the role of oxygen in this disease and led to the prevention of blindness in thousands of children. The original control study could not have been considered as beneficial to that particular infant in the light of knowledge available at that time, nor could this initial information have been obtained through animal experiments.

D. Fetal Monitoring During Labor

This important field could not have been developed and advanced to its present state without closely coordinated animal research and observations on the human fetus. The actual application of the techniques to the human fetus could in the initial phases, not have been considered beneficial to that particular fetus.

E. Respiratory Distress Syndrome or Hyaline Membrane Disease

This condition is responsible for more deaths in infancy than any other single cause. In the last 20 years the cause of this condition, its diagnosis, treatment and even prevention, has hence possible primarily through human investigation. This led to the development of animal models from which details of pathogenesis and prevention were derived. Application of this new information to the human would of necessity again require human investigation.

FUTURE RESEARCH WHICH CAN ONLY BE POSSIBLE IN THE HUMAN

A. Perinatal Pharmacology

Because of marked interspecies variation in rate of development and in the degree of maturity at birth, animal experimentation will provide only leads, but not specific answers. The ultimate research will always have to be done on the human fetus or newborn if new therapies are going to be introduced or the toxicity of current modes of therapy are to be evaluated.

Placental Transfer.—Study of the placental transfer of drugs must also in its final analysis be done in the human subject. This is essential if we are to make advances in the area of obstetrical anesthesia; it is vital to increase our knowledge of teratology.

B. Endocrinology

A study of steroid metabolism by the fetoplacental unit has been shown to have an important bearing on the onset of labor. An understanding of the onset of labor is essential if we are going to make any inroads into the perinatal mortality figures—between 18 and 30/1000. Without such knowledge we will not be able to control gestation and prevent prematurity. In the last analysis no animal can be used for this.

Fetal Parathyroid Function.—In the future, a study of this condition is likely to lead to an understanding of tetany and convulsions in the newborn.

C. Immunology

There is now evidence that maternal-fetal cell transfer is a cause of runting (an undergrown or undernourished fetus). Furthermore, there is also evidence that the transfer of cells which are least incompatible to the fetus could be a cause of childhood leukemia. In the last analysis research in this area can only be carried out in the human fetus.

D. Normal Growth and Development

A study of the normal growth and development of both the fetus and newborn infant is essential if departures from normal through various disease and genetic processes are to be appreciated. Information on this area can be derived as a byproduct from much of the fetal and newborn research outlined above. Prohibition of research on the fetus and newborn would prevent the advances necessary for the improvement in the health and wellbeing of the mother and child.

STATEMENT OF EUGENE B. BRODY, M.D., PROFESSOR OF PSYCHOLOGY, UNIVERSITY OF MARYLAND, AND EDITOR IN CHIEF, JOURNAL OF NERVOUS AND MENTAL DISEASE

Summary

There is clear evidence from 37 years of research that selected and applied variants of psychosurgery can offer subjective relief to certain patients.

Prohibition of psychosurgery would interfere with needed new knowledge.

Treatment is currently administered without the necessary scientific controls. A remedy is needed.

Direct governmental control of psychosurgery would involve the legislative and the executive branches in new endeavors heretofore left to the world of medicine. If allowed to expand, the new government effort would demand great legislative attention.

The needed controls should be exercised through existing agencies.

EDITORIAL ON THE LEGAL CONTROL OF PSYCHOSURGERY

There is little argument should the need to study the ethical, social and legal aspects of advancing biomedical research and its results. The question, however, posed by bills impending in the United States Congress, and by recent state court actions, as to whether certain clinical procedures should be controlled through prohibition in federal or other public institutions,¹ or deprivation of governmental support,² is more complex.

Several interrelated issues are involved:

(1) Would such control deprive a less affluent population group, i.e., one which cannot afford private medical care, of a type of needed treatment? This issue requires review of the evidence that the procedure in question offers therapeutic results to patients who, otherwise, would be relegated to continued pain, malfunction or confinement.

(2) Would such control impair the systematic accumulation of data necessary to the continued development of clinically essential knowledge? This issue requires review of the scientific controls exercised during administration of the procedures so as to ensure the validity of the data it yields.

(3) Is the particular organ system involved subject to special risks which might justify a type of control not applied to procedures directed to other organ systems? In the present instance what are the risks peculiar to the brain and its input and output mechanisms?

(4) A special aspect of such control is that it removes the clinical decision from the medical community where it has traditionally rested and transfers it to the community of elected national officials. What are the implications of this transfer?

The question of legal control of psychosurgery involves all of these points. The intensity with which it is raised, however, is clearly a function of the third and this is relevant to the fourth point, the issue of non-medical legal control. The brain is, indeed, the "executive organ" of the individual, and is so perceived by the public. Its integrity is essential to one's capacity to perceive himself as a discrete entity in relation to the inanimate world and others, to experience emotions appropriate to that perception, and to act appropriately as necessary. It has been regarded by many as the source of the qualities essential to being human. This separates it from other aspects of the body and its function. Almost none of these, exposed to risk by any diagnostic or therapeutic procedure, have singled out for federal or local legal attention. Further, no law attempts to eliminate another risk, the application of procedures, e.g. abdominal surgery, to

¹ H.R. 6852, April 11, 1973. To prohibit psychosurgery in federally connected health care facilities.

² S.J. Res. 86, March 29, 1973. To suspend for two years federal support of projects involving psychosurgery.

those who do not need them. Crucial decisions are left to the physician in collaboration with the patient or the patient's relatives.

The major exceptions have been in an area touching both on individual rights and on the definition of being human. These have been in respect to abortion (considered by some as murder) and sterilization (considered by some as infringing on a right to reproduce). In both instances the question of oppression of the socially weak by the socially powerful, who order and carry out the procedures, has been raised.

Similarly, the public is newly sensitized to the possible impairment by therapeutic manipulation of the brain of the subject's capacity to exercise his civil rights. This aspect suggests the possible influence of popular beliefs and attitudes on the rational assessment of medical risks.

But evidently more than brain manipulation alone is at stake here. The method of such manipulation appears important. Why does the public accept the constant attempts to modify the brain by psychological means such as advertising and offering incentives and punishments? It accepts, recognizing the consequent brain hazards, tobacco smoking, coffee and alcohol drinking and the ingestion of more dramatically effective chemicals taken on medical advice or independently to alter states of consciousness. It even accepts as therapy the passage of nonfocused electric currents through the brain although these have demonstrable sequelae in amnesia, and sometimes in emotional blunting.

It is the direct physical invasion of the skull, of the executive system, which seems central to the threat of being rendered less than human, of surrendering one's power of self-determination to the invader. The threat is to one's identity, imposing a change in *who* one is. The directness of the intervention also may heighten the specter of social control by the psychosurgeon. But social control and the fear of infringement of civil rights implies that psychosurgical procedures may be applied to normal persons. Most candidates for such surgery have been ill, confined and effectively disenfranchised for years. The procedure is not applied to a normal, free-living individual who can be considered autonomous and self-determining.

With these considerations in mind let us review the four issues posed above:

(1) Can psychosurgery be considered a type of treatment which federal control would make less available? There is, in fact, an impressive body of evidence, accumulated gradually since 1936, that carefully selected and applied variants of psychosurgery can offer subjective relief to certain patients who would otherwise remain hospitalized, severely constrained in their activities, and plagued by unremitting psychological tension or the threat of unpredictable attacks of violence. The prohibition of psychosurgical treatment in federally supported or other public hospitals or programs may, therefore, make it unavailable for some of these persons.

(2) Would federal or local legal control interfere with the accumulation of new knowledge? The major limiting factor in the successful application of psychosurgical methods, or of other direct approaches to the brain in the search for treatment of major psychiatric disorders, is lack of knowledge. Prohibition of psychosurgical treatment would clearly interfere with the orderly accumulation of such knowledge. There is no doubt, however, that such treatment is currently administered without the necessary scientific controls and this should be remedied.

(3) Do the risks peculiar to brain manipulation justify legal control of therapy through such manipulation? There is a large body of literature documenting these risks. They usually, however, fail to take into sufficient account the pre-operative subjective state and behavior of the person who is a candidate for psychosurgery. Post-psychosurgical comparisons cannot be made with normal individuals. Rather, they must refer to the state of mind of patients who have suffered from serious psychiatric impairment for years. Risks must be weighed against gains, and against the cost of not having the treatment. The literature suggests that when preexisting psychiatric disturbance is taken into account the risk of losing "executive" or "human" qualities—which may have been grossly impaired prior to surgery—is less than it initially appears. In fact some of those not apparent for years may reappear. It also suggests that the loss of such qualities can be minimized as surgical procedures become more refined and, particularly, as individual counselling services for patients and their families become more available.

(4) What are the implications of federal or local judicial or governmental assumption of clinical decision-making power? Should government assume

responsibility for identifying particular medical procedures as hazardous to individuals or society and then attempt to constrain their use by withdrawing funds or outright prohibition? The current regulation of therapeutic chemicals through the FDA may be regarded as a type of analogous control. I believe, however, that a case can be made against comparing a surgical procedure with demonstrated value for a particular category of patients with drugs for which no such value has been established. On the other hand there is unquestioned value in attempting to reach a more precise consensus among those who are professionally responsible for patients. This consensus should include guidelines for patient selection, the use of particular procedures, the presence of scientific controls and evaluative methods, and the provision of adequate counselling and pre- and post-operative supportive services. An important unsolved issue, perhaps the key one in this respect, concerns the problem of informed consent for procedures applied to psychiatrically sick persons.

If it appears that these concerns must be dealt with at the governmental, specifically the federal level, the most constructive initial approaches would seem to be through study commissions or task forces sponsored by the National Institutes of Health or similar bodies rather than through legislation. This kind of approach could be adapted at the state level as well. These study groups could advantageously represent a range of scientific and professional disciplines, as well as the lay community. Certainly this approach would preserve a degree of flexibility which would be lost through the passage of restrictive laws.

STATEMENT OF VERNON MARK, M.D., DIRECTOR OF NEUROSURGICAL SERVICE, BOSTON CITY HOSPITAL, BOSTON, MASS., AND ASSOCIATE PROFESSOR OF SURGERY, HARVARD MEDICAL SCHOOL, BOSTON, MASS.

Summary

Months before the Senate hearings focused legislative scrutiny on neurological surgery as therapy for uncontrollable, individual violence, Dr. Vernon Mark, one main target of psychosurgery critics, spelled out his ethical position on the question. In a report published by the (Hastings) Institute of Society, Ethics and the Life Sciences, he said:

(1) Both environment and man's body must be studied if uncontrollable, individual violence is to be treated.

(2) Neurosurgery should be used as violence therapy only when behavior is abnormal and a result of brain abnormality, and only where personal violence is unwarranted, usually unprovoked, and directly attempts to injure another person.

(3) If those conditions don't prevail, violent behavior should not be dealt with medically.

(4) Violent patients and their families should have impartial, professionally non-involved medical men and informed laymen to monitor "patient consent" procedures in every instance before surgical treatment is given. Dr. Mark has joined with other professionals in exploring ways to implement consumer advocacy in patient consent procedures.

[From the Hastings Center Report, February 1973]

SOCIAL AND ETHICAL ISSUES: BRAIN SURGERY IN AGGRESSIVE EPILEPTICS

(By Vernon H. Mark)

A little over two years ago Frank Ervin, a psychiatrist, and I, a neurosurgeon, wrote a book called *Violence and the Brain*, detailing the application of brain surgery to problems of violent behavior. The public response to that book underscores with great vividness the fact that the medical issues of neurosurgery are no more interesting or vital than the issues of neurosurgery's *social role*. I would like here to offer some reflections about those social issues.

The most important problem to conjure with, from the standpoint of the sciences of human behavior, is the unfortunate dichotomy in basic approaches to behavior. Certain kinds of behavior (for instance, paralysis, blindness and dementia) were put into the province of *organic neurology*. Physicians working in this field have been increasingly reluctant to examine other kinds of abnormal behavior, even when they are associated with obvious brain abnormalities.

On the other hand, social psychiatrists, sociologists, criminologists, and many psychologists tend to view the other behavioral abnormalities, for instance

Intractable depressions and aggressive assaultive behavior, as pure reflections of unusual or abnormal environmental stress. They believe that brain function or dysfunction is not an important determinant as far as abnormal behavior is concerned. To them, all human beings function with the same "normal" brains. Even those few social scientists who admit that brain function might be important in abnormal behavior feel that so little is known about brain function that it is useless to spend time and money investigating it.

Now whatever the sociological reasons for this division of labor in the scientific vineyard, any high school student can see that it results in absurd theoretical suppositions. No human behavior whatever, be it normal or abnormal, can be the consequence of the brain alone without the environment. Nor can any behavior, whatever its environmental determinants, take place without the brain freighting its mechanical impulses with emotion and culture. Therefore any thorough investigation of abnormal, violent behavior should look not only to the environment for causes but also to the brain itself.

Yet when President Lyndon Johnson and Milton Eisenhower convened the Commission on Violence, there were over fifty consultants, representing various fields of sociology, criminology, history, government, law, social psychiatry, and social psychology, but only two representing the brain!

Let me stress that recognition of the brain in behavior does not entail, as some critics might fear, that all behavior should be controlled through the brain. Rather it is precisely because any behavior, normal or abnormal, could be modified through altering the brain, at least in principle, that it is absolutely crucial to make moral decisions about the sort appropriate for neurosurgery and other direct brain manipulations. There are important moral issues at stake, for example, in the very definition of a problem as a medical one, for which medical therapy is appropriate. This problem is pressed further when a behavior problem is defined as a neurological one.

My own position regarding the appropriateness of neurosurgery can be illustrated in terms of three alternatives. The first two of these I unequivocally reject:

The first of these positions holds that medical means should be undertaken to improve any behavior, wherever possible, be the behavior normal or abnormal. Although neurosurgery is not in a position now to improve normal behavior, some people advocate the use of drugs—amphetamines, for instance—for that purpose. The advantage of this position is that it avoids the obvious difficulties in defining normality. The grave disadvantage is that it makes the medical men authorities on improvement and the good life, which they are not, at least under our present social arrangement. Moral values are social concerns, not medical ones in any presently recognized sense.

A second position holds that any abnormal behavior should be treated by whatever medical means are available. Often argued by psychotherapists, this position says that, regardless of any organic abnormality, what is undesirable in abnormal behavior is the behavior, not its organic base. The criteria for alteration should refer to the behavior, irrespective of whether the organic base is normal or abnormal. Should an unusual brain abnormality produce a 50 point I.Q. rise, no one would suggest ablating it: its behavioral product is desirable. (With regard to neurosurgical control of violent behavior, I am against the principle that it could be used to treat abnormal behavior when there is no organic abnormality of the brain.)

A third position, then, is that medical procedures like neurosurgery should be used only when behavior is abnormal, and bad, as the result of an abnormality in the brain. As I shall repeat below, violent behavior not associated with brain disease should be dealt with politically and socially, not medically.

With this brief positioning of what I take to be support for a very circumscribed domain for neurosurgical procedures, I now want to deal with some common criticisms of neurosurgery. Most of the criticisms either construe neurosurgery to be capable of more than it is, or assume that it would be used in areas I believe to be inappropriate. Like any technological power, neurosurgery can be misused, and setting the limits of its use is more than a medical problem.

POLITICAL VERSUS PERSONAL VIOLENCE

Implicit in many of the criticisms of the surgical treatment of violent epileptics is the fear that this treatment will be used against political protestors. This fear is based on a semantic confusion about the word "violence." Many activities in our society are called violent. The "establishment" tends to view as violent any

protest movement against the war, unfair living conditions, or the prison system. Protestors view the reaction of police and the National Guards violent. Minority groups have indicated that social or job discrimination is a form of violence.

The kind of violent behavior for which I might approve neurosurgery, however, has a much narrower definition: personal violent behavior; unwarranted and usually unprovoked acts that directly attempt to, or actually do injure or destroy another person or thing. And, as I have said, I would not approve neurosurgery even in such cases unless the personal violence could be traced to organic brain disease and could not be treated by non-surgical methods.

Some political psychiatrists have argued that social injustice provokes individuals acts of violence which seem "senseless" but which, in reality, are political protests against the social system. As Goebbels showed, political violence of mass proportions can be culled up without counting on people with diseased brains. However, the person whose violence is related to brain disease and is used by a Hitler or Goebbels is a danger to himself and his loved ones, and cannot be counted on to rage only in politically strategic situations. Thus, the morality of preventing such an individual from seeking proper medical diagnosis and cure is certainly in question.

BIOLOGICAL FACTORS IN PERSONAL VIOLENCE

Many sociologists believe that brain dysfunction does not have a role in such behavioral abnormalities as intractable depression, thought disorders, paranoia, or aggressive assaultive behavior of the sort I am concerned with. In the last case, however, there is solid medical evidence to link aggressive behavior to focal brain disease. This behavioral symptom is often present in such clinical disorders as temporal lobe epilepsy, temporal lobe tumors, infections of the brain (such as rabies and post-encephalitic syndromes), and serious brain injuries which affect the under-surfaces of the frontal lobes and the anterior tips of the temporal lobes (usually a transient phenomenon in the last disorder).

The most frequent occurrences of brain dysfunction in violent behavior is in brain poisoning, the most serious and ubiquitous of which is caused by alcohol. Alcohol is a specific brain poison and individuals acutely poisoned with alcohol may have as much dysfunction during the poisoning as would be caused by a brain tumor, infection or injury. The only difference between the former and the latter is that alcohol poisoning is temporary.

The violence in automobile accidents caused by drunk drivers takes a far greater toll than the violence in political protest or repression. A drunk driver suffers from a temporary brain abnormality. Although I certainly do not advocate neurosurgery for the treatment of alcoholism, nor for all kinds of organic brain disease, it is clear that violence is sometimes a function of brain abnormalities, and should be viewed as such.

RACISM

In the most *avant-garde* circles today the favorite critical epithet is "chauvinist." Neurosurgery seems to draw its critics from a somewhat stodgier class: neurosurgical treatment of violent epileptics has been called "racist."

Speaking to a national group of psychiatric investigators about our approach to the problem of violent behavior, a major professor of psychiatry conceded that the biological-social model of violence and the investigation of brain disease associated with violence had some merit. But he classified our project with the proposal of those psychologists who claim that black people have a constitutionally inferior IQ compared to white people. Admitting that the racial idea might have some merit too, he felt that nevertheless funding and research should not be given to such projects until all possible avenues of social and educational rehabilitation have been exhausted.

It seems to me there are really two issues here. The first concerns the political implications of a theory about violence. One of the functions of a theory is that it tells you where to look to find the phenomenon in question. Does the theory that some violence is caused by brain disease lead us to expect it is a characteristic mainly of black people? Certainly not. On the other hand, the theory that personal violence is caused exclusively by social conditions might very well lead us to look at the black ghettos. The environmental cues to personal violence may very well cluster around racially differentiated areas.

The second issue is whether there is any empirical evidence that organically based personal violence is more common among blacks than whites. In my experience there is no special correlation of violence with race. Domestic personal violence occurs in upper- and middle-class homes as well as in the ghettos. When it occurs in the ghetto, however, it may be more visible, spilling out into the streets from the very pressures of overcrowding. It may very well be that violence in ghettos more often gets reported in police records and other data available to the sociologist. But the perspective of the physician is the emergency room and clinic where the products of violence are immediate. From this perspective, class is the predominant color, not black or white.

It is my perception that the biological-social model of violence will not concentrate on one race, ethnic group, or other social segment of our population as do the subculture theories of violence. In fact, I feel it is important in cases of violence related to brain disease to study the violent act primarily and to consider the style of violence, which is socially determined, as a secondary phenomenon.

DANOERS IN A MEDICAL MODEL OF VIOLENCE

All sorts of dire predictions have been made about the outcome of brain research directed toward the understanding and treatment of emotional disorders, and especially those related to violent behavior. Shades of 1984! "The neurosurgeons want to put electrodes in everyone's brain to keep them from protesting!" "They're going to develop a new drug that will completely destroy the will!" "Man's dignity will be shattered and his innate human quality will be destroyed!" These would indeed be serious statements if they were true. But it is important to see just what the issues are.

It is one thing to advocate neurosurgical procedures for certain kinds of violent behavior caused by organic brain disease or dysfunction. It is quite another to advocate them as general methods of behavior control. My own belief is that no form of conditioning, drug therapy, or surgery is necessary or desirable to control normal-brained members of our society, no matter what their political views are or how they express them.

Of course it is true that behavior control techniques developed to be used in a commercial sphere might be adapted to widespread and immoral ends by unscrupulous people. No greater lesson is needed than that provided by Nazi Germany.

But interestingly enough, the control Goebels used were environmental ones, not direct alterations of the brain. No drugs were needed to seduce the German population. The S.S. storm troopers did not have little electrodes implanted in their limbic systems.

Although Joseph Goebels might have reduplicated Skinner's experiments in the best conditioning traditions, he did so before, rather than after, the fact. As a clinician living among the German people for two years after the war, I could find nothing in them that would distinguish them from other human beings.

Can one imagine the most advanced brain electrode technology of the future, or even a new and much more sophisticated group of psychic drugs, that could produce a more perfect form of behavior control than that initiated by environmental "natural" factors in the Third Reich?

One of the important factors to emerge from our own research on the relative influence of deep electrical brain stimulation versus environmental "natural" stimuli is the importance, in terms of effectiveness, of the latter. Of course, effective electrical brain stimulation in target areas can produce pronounced behavioral effects. However, even in susceptible individuals with brain disease, the effect of nonconvulsing doses of electrical stimulation can be remarkably altered and suppressed by giving the subject a demanding and attention-absorbing task during electrical brain stimulation.

My thesis that behavior control through the direct manipulation of the brain is not as dangerous for mass abuse as environmental forms of control should not be taken to imply that it has no dangers whatsoever for mass abuse. But the social limitations on who performs neurosurgery or administers drugs, on whom, and for what reasons, ought to be set through public discussion and social decision. My own claim is that the dangers of mass abuse are not sufficient to warrant preventing the very development of the techniques that might have very great therapeutic value for patients with organic brain disease.

MORAL PROBLEMS IN NEUROSURGERY

If neurosurgery is not much of a danger as a political tool, there still are serious problems with its medical use. I would like to address two of these.

First is the problem of neurological diagnosis. The emphasis I have been placing on the neurological side of the problem of violence ought not be taken out of the context of environmental factors also. Due to the very fundamental problem of specialization in medicine, it is very difficult to maintain a biological-social model of violence in actual practice. The neurologists are in one place and the psychiatrists and social workers are in another.

Yet if the model is worthwhile, treatment of a patient should involve not only his brain but his family, living conditions, job and role in society. It is very important, therefore, to imbed a neurological diagnosis of problems of violence into a larger integrated approach to human behavior. The social forms for this holistic therapy are yet to be worked out, although my own group has tried to include psychiatric and social psychiatric diagnosis along with the neurological.

From my reading of the present situation, however, I believe the greater danger is that the neurological side will be left out. Recently, for example, an airplane hijacker killed one pilot and shot another before he himself was subdued with a blow to the head. Examination of this man afterward revealed he had been a neurological cripple for eleven years, ever since receiving a gunshot wound of the brain. Yet repeated tests, including hours of brainwave examinations, psychological testing, psychiatric and neurological assessment, failed to reveal the tremendous damage that had occurred in this man's emotional center or limbic brain.

The difficulties of diagnosis had their classic but tragic expression in the case of George Gershwin. This talented composer was seen and treated psychiatrically for a long time while a tumor in the limbic system of his brain grew to an unmanageable and untreatable size. The George Gershwin syndrome of the thirties is still being treated in the seventies. Recently eighteen patients were committed to a mental hospital at one of our best university centers who turned out to have tumors of their limbic brains. In some cases, the true nature of this illness was not recognized until the tumor had caused the patient's death.

Second, after the diagnosis of brain disease has been confirmed, what are the problems of proper consent to treatment? Does the patient consent to the treatment? Does he know the dangers of the treatment, and how those dangers compare with letting him pass without treatment? What are the wider factors involved in informed consent when the patient is mentally incompetent?¹

Usually close members of their families are the sources of consent. But in cases of surgery for violence, I believe the patient and his family should have the assistance of an impartial, noninvolved professional group to determine whether surgery or other forms of treatment should be undertaken. In practical terms, this means that a committee of some sort, composed of physicians, or in some cases, physicians and informed laymen, should be present to monitor the medical, psychiatric, and/or surgical treatment.²

In my own practice, I and my group do not accept patients for treatments who do not want therapy, and we do not believe that the public good or public interest should intrude upon the personal medical model in terms of protecting the public against violent individuals.

FREE WILL AND BEHAVIOR CONTROL

Radical critics of the biological-social model of violence often construe human violence to be an expression of free will. In line with this they consider the medical correction of brain disease that would, as a secondary result, stop violent episodes, to have an unnatural and degrading effect on human dignity. As a physician I find this view particularly inappropriate, not because I deny free will, but because I prize the quality of human life.

Many of the patients who come to us with focal brain disease associated with violent behavior are so offended by their own actions they have attempted suicide. They feel their human dignity has been lost precisely because of uncontrollable behavior patterns they find unnatural and repugnant.

Because our work, and that of other physicians, has indicated a clinical relationship between limbic brain disease, such as temporal lobe epilepsy, and aggressive assaultive behavior, I believe the correction of that organic condition gives the patient more rather than less, control over his own behavior. It enhances, and does not diminish, his dignity. It adds to, and does not detract from, his human qualities.

¹ Prison inmates suffering from epilepsy should receive only medical treatment; surgical therapy should not be carried out, because of the difficulty in obtaining truly informed consent.

² In conjunction with Dr. David Allen, we are exploring "consumer advocacy" utilizing a group with religious, legal and community representatives in addition to physicians.

Finally, it is appropriate to return to the specter of a tyrannical government controlling a submissive population through neurosurgery and electrical brain stimulation. Even though this is technically unlikely now, it is a possibility to be conjured with. In the face of this possibility I still have great confidence that the neurological research in behavior control now being done will lead to a better understanding of brain mechanisms, and that when this occurs, it should be possible for brain scientists to devise techniques for making behavior control of one individual by another more difficult or even impossible.

In other words, one of the expected benefits of increased brain research will be the creation of new techniques enabling each individual better to control or govern his or her behavior, without unwarranted or unwanted interference by other individuals or devices.

There is already enough knowledge of environmental and psychopharmacological drugs to control a vast segment of our population, without invoking brain surgery or electrical brain stimulation. The great hope of emotional brain research is that it will free us from our present tyrannies and future dangers of control. To this end brain scientists need the help of philosophers, ethicists, theologians, social scientists and jurists, working in concert.

STATEMENT OF RUSSELL R. MONBOE, M.D., PROFESSOR OF PSYCHIATRY, DIRECTOR, CLINICAL RESEARCH, INSTITUTE OF PSYCHIATRY AND HUMAN BEHAVIOR, UNIVERSITY OF MARYLAND SCHOOL OF MEDICINE

Summary

Concern over psychosurgery is justified. A legislative ban on psychosurgery could deny individuals their rights to this procedure where it is, in fact, the preferred procedure.

Both guidelines and controls over individual cases are needed. Consumers as well as providers of medical care may appropriately take part in the decision making.

A board of review must be established to approve or disapprove psychosurgical procedures. Control board should not be connected with the institutions proposing the procedures. It should include medical men, laymen, at least one lawyer, representatives of appropriate medical specialties. Informed consent review should be part of the board's work. Ideally the board should be *state* or *metropolitan area* in jurisdiction.

Informed consent questions involving possible duress should be settled by a *national board*. Legislation must not discriminate, by restricting use of federal funds, against the poor and others facing difficult access to advanced medical care.

POSITION STATEMENT REGARDING SURGICAL MANIPULATION OF THE BRAIN

The current concern among the laity, legislators and medical profession regarding the social, ethical and medical implications of the surgical manipulation of the brain is certainly justified. The issue is so complex that I will take a primary stand based on 20 years of clinical and research experience in correlating brain mechanisms and behavior. I will exclude consideration of those situations where surgical ablations are deemed medically indicated to remove pathological tissue of a degenerative, neoplastic, vascular or traumatic etiology. I will address myself to modification of symptoms (hence, in the broad sense behavior) through excising an epileptogenic focus—which I will refer to as a neurosurgical procedure—and those instances where there is removal of normal brain tissue to ameliorate symptoms, hence help restore the adaptive balance of the individual. (This I will refer to as psychosurgery.) Although my stand can be debated, I believe both procedures can be justified under well defined clinical circumstances if we wish to provide the best possible medical care for our patients.

To legislate against such procedures or to devise excessively cumbersome bureaucratic restraints might deny an individual his rights to this preferred medical procedure. At the same time, I realize that with our increasing neurophysiologic knowledge that the effectiveness of brain surgery has improved so dramatically that there is the possibility for either uninformed misuse or even planned abuse of such procedures. It is obvious, then, that guidelines for surgery on the brain and the decision as to whether one of these two procedures should be applied to the individual patient must not rest in the hands of a single indi-

vidual or even a small group of individuals, no matter how sound their reputation or impeccable their credentials. Both the neurosurgical and psychosurgical operations often involve complex consideration of informed consent. This may require an appraisal by possible consumers of medical care, as well as the legal profession. As both operations are irreversible, there also should be careful consideration by appropriate experts as to whether non-surgical reversible regimens (e.g. drug therapy) has had an adequate trial and failed. For these reasons, as well as others listed below, a board of review must be established to approve or disapprove such procedures.

Neurosurgical Procedure

These are procedures designed to remove an epileptic focus; that is, an area of excessive neuronal discharge which results in either medical or social incapacitation. I would propose the following criteria for making such a decision recognizing that these criteria are a compromise in the sense that it is conceivable that they might rule out possible candidates who would benefit from the procedure. The compromise seems necessary to differentiate between the indications for a neurosurgical procedure and a psychosurgical procedure. The patient should have at least two of the following clinical findings, which as already mentioned have not responded to any known non-surgical therapeutic regimen.

(1) Clearly defined, well documented seizures;

(2) Other physiologic or behavioral symptoms with such ictal characteristics as: a) precipitous onset, b) abrupt remission, c) frequent recurrence, d) stereotyped quality, and e) relatively short duration;

(3) Scalp electroencephalographic abnormalities recognizing that before EEG abnormalities can be ruled out repeated studies may be necessary utilizing special EEG techniques.

Two of these three criteria are sufficient indications for an exploratory, diagnostic, stereotaxic operation. The final procedure, that is, destruction of abnormal brain tissue, would depend upon identifying via stereotaxic methods the circumscribed focus of abnormal neuronal activity.

To obtain the best clinical results, it should be recognized that careful consideration will have to be given in terms of the risk-benefit ratio to a unilateral versus a bilateral procedure, and a single versus multiple operations.

Psychosurgical Procedure

Psychosurgical techniques should be considered only for those patients demonstrating severely obsessive-compulsive, phobic, anxiety and depressive symptoms, who have not responded to either intensive psychotherapy or protracted psychopharmacologic regimens. The treatment of aggression by psychosurgery, other than those explosive, aggressive, dysecontrol acts, with the ictal characteristics described above, should be considered an experimental procedure demanding a special review (see below).

Sophisticated psychosurgical techniques demand special neurosurgical training and facilities and should be limited to the stereotaxic implantation of electrodes which can be left in place over a sustained period of time so that one can observe behavior outside the operating room. It is feasible now to induce a reversible lesion (e.g., via alcohol or temporary electrical paralysis of the neurons) in order to evaluate the area of the brain where a permanent ablation will give the most satisfactory alleviation of symptoms. The lesional procedure should maximize the permanency of the lesion with the smallest possible destruction of the brain tissue.

Social Control of Neurosurgical and Psychosurgical Procedures

The clinical application of these two possible surgical manipulations of the brain should rest upon the review and approval of a special board. Such a board should not be connected with the institutions proposing the procedure. It should include members of the medical profession with appropriate expertise, as well as laymen, at least one of whom should be a member of the legal profession. This special board should not only review the appropriateness of the surgical procedure, but also the extent of informed consent. Ideally, such a board should be constituted at the local level, that is, the metropolitan area or state.

If there are any particular questions regarding informed consent; for example, the individual is incarcerated in a penal institution, committed to a mental hospital, a minor, or any other suggestion that there might be subtle duress, then the procedure should be reviewed by a national board. This would also pertain to the situation mentioned above (the surgical treatment of aggression) where the brain surgery might in any way be construed as experimental.

Again, I would like to emphasize that these review procedures should not be so cumbersome as to deny the medical benefit or such procedures to any patient regardless of his social and economic status. By-and-large, the procedures here described have in the past been available only to selected individuals with the financial means to purchase expert, private care.

GEORGETOWN UNIVERSITY HOSPITAL,
DEPARTMENT OF OBSTETRICS AND GYNECOLOGY,
Washington, D.C., September 25, 1973.

Representative ROGERS,
Representative NELSEN.

I welcome the opportunity to be able to testify in favor of passage of H.R. 7724. Some years ago, at hearings held by Senator Mondale, I testified in favor of the establishment of a commission to study the implications of medical technology for society and the ethical implications deriving therefrom. I specifically stated that my concern was not just the good of society, but especially the good of science. Since scientific progress depends on the financial and moral support of society as a whole, I foresaw that, if the scientific community operated in isolation and without the informed consent of the society, it might become subject to an anti-scientific "backlash." I think we have seen some such backlash in the past two years. It inevitably leads to the passage of laws, some of which may be initiated in haste and without sufficient insight into all the pertinent considerations.

I now again support the establishment of such a commission. Admittedly, the proposed commission has a more wide-ranging set of duties than that proposed by Senator Mondale some years ago. Yet the reasons for establishing it are similarly persuasive. As the bill clearly implies, the major thrust of the commission's work is to seek mechanisms whereby the health care client, whether patient or research subject, will be made more fully aware of options open to him and thus ensures his full consent to anything which the health professional proposes to do for him. This is fully in accord with present trends towards full disclosure and informed consent in other consumer areas. I similarly welcome those clauses in the bill which seek to maximize freedom for individual physicians and health facilities.

Only when both the health professional and the patient are fully in agreement on the application of medical skills by the former upon the latter can that degree of mutual trust be developed which is at the core of sound medical ethics. I think that H.R. 7724 will help ensure this relationship. As such, I view it as a bill to ensure the civil liberties of patient and doctor alike and I appreciate the opportunity to testify on its behalf.

ANDRÉ E. HELLEGERS, M.D.,
Georgetown University, Washington, D.C.

[Mailgram]

CLEVELAND, OHIO, *September 26, 1973.*

Hon. PAUL ROGERS,
Chairman, House Office Building,
Washington, D.C.:

I urge that decisions on ethical standards for research on children newborn and the fetus be deferred until the recommendations of the National Institutes of Health are available for review and comment.

Respectfully,

ROBERT SCHWARTZ, M.D.,
Professor of Pediatrics, Case Western Reserve University, Director of
Pediatrics, Cleveland Metropolitan General Hospital.

[Telegram]

NEW YORK, N.Y., *September 28, 1973.*

Hon. PAUL G. ROGERS,
Capitol Hill, D.C.:

The Committee on National Medical Policy of the American Society for Clinical Investigation wants to go on record as being in favor of setting up a

study commission, rather than a regulatory commission, to consider ethics of human investigation. We would favor that being done within existing legislation if possible. We are prepared to present our reasons, if you so desire.

NEAL S. BRICKER, M.D.,

*Chairman, Committee on National Medical Policy, American Society for
Clinical Investigation, Bronx, N.Y.*

AMERICAN HEART ASSOCIATION,
New York, N.Y., September 20, 1973.

HON. PAUL G. ROGERS,
*U.S. House of Representatives,
Washington, D.C.*

DEAR CONGRESSMAN ROGERS: The medical volunteers of the American Heart Association have been watching proposed legislation on the ethics of human experimentation with increasing interest. Aside from being a major funder of biomedical research and a professional organization representing 50,000 physicians and medical scientists, the Heart Association is probably the only voluntary health agency with a standing ethics committee. For this and other reasons, the American Heart Association applauds the concern demonstrated in Congress for the dignity and safety of human beings involved in medical research. We are troubled, however, that certain provisions could seriously retard the advance of medical science in this country. In particular, Title II of H.R. 7724, entitled "Protection of Human Subjects," has aroused the most concern since it is potentially the most restrictive. We understand that H.R. 10403 which you have introduced, is substantially similar.

Title II of H.R. 7724 would codify certain propositions independently advanced by the AHA Ethics Committee in its analysis of the "Ethics of Investigation on Seriously and Critically Ill Patients." (A copy of the Committee's report on this subject is enclosed.) These include: the need to insure that the failure of a patient to participate in an investigation would not alienate his physician or prejudice his future care, and the concept that a third party, not directly involved in the planned investigation but concerned primarily for the patient and his relatives, could assist in the explanation of procedures and help assure as full an understanding as possible.

In addition, however, H.R. 7724 calls for the establishment of a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research which would have legislative, executive, and judicial authority. It would be empowered to issue rules and regulations concerning the use of human subjects in research and obtaining their "informed consent." It would also certify institutional review boards and review their performance with respect to announced norms. Finally, it would act as a forum for appeal from decisions of institutional review committees. With its extensive scope and authority, such a Commission could not only control but also stifle clinical research and innovative therapy. We question whether a mechanism so potentially cumbersome and obstructive is necessary to achieve the designated objective.

After reviewing legislative developments, the AHA Central Committee adopted the following resolution at its September 13, 1973 meeting:

Whereas various pieces of legislation have been introduced in Congress reflecting a need to re-evaluate the use of human subjects in clinical research and the legal provisions for the protection of such subjects; and

Whereas the medical volunteers of the American Heart Association in general, and its Committee on Ethics in particular, concur in these concerns; they are, however, apprehensive that hasty and unnecessary restrictions may finally result in the virtual elimination of clinical investigation and its benefits for the betterment of patient care: it is

Resolved that the AHA endorse the proposed establishment of a multidisciplinary advisory national commission for the study of the ethical, social and legal implications of advances in biomedical research and technology but without authority, at the moment, to develop and implement binding policies and regulations.

We understand that you will be holding hearings on H.R. 10403 on September 28th and 29th, 1973, and I regret that the Heart Association was not included among those invited to testify. In view of the short time between the introduction

of H.R. 10403 and these hearings, we would be pleased to provide more specific counsel on legislative alternatives as you may see fit.

Respectfully submitted,

PAUL N. YU, M.D.,
President.

Enclosure.

AMERICAN HEART ASSOCIATION COMMITTEE ON ETHICS, A REPORT TO THE CENTRAL COMMITTEE—DECEMBER 14-15, 1972

The AHA Committee on Ethics held its first in-depth discussion in Spring 1971 on the subject of Ethics of Investigation of Seriously and Critically Ill Patients. This subject was chosen because of its obvious relevance to the affairs of the Association and because such types of investigation had not been specifically considered in codes of ethics and in previous symposia on ethical considerations of investigation.

From the very beginning, the committee has held the firm belief that it could not be judgmental in its decisions. Rather it considers its role as opening up areas for consideration and, as it were, raising the level of consciousness of investigators within and without the Association and hopefully providing guidelines that would help in the planning and conduct of clinical investigation.

Five formal presentations, prepared in advance by committee members, formed the basis for our discussions. These presentations dealt

- (1) With working definitions of serious and critical illness,
- (2) With the types of cardiovascular illnesses that relate to these definitions,
- (3) With responsibilities of physician as healer and/or investigator in design and conduct of investigation of such patients,
- (4) With the role nurses and other members of the health team play in these responsibilities,
- (5) With the legal requirements of informed consent,
- (6) With physicians' view of informed consent in regard to investigations of serious and critical illness,
- (7) With a classification of the types of studies carried out in such illness, and
- (8) With ethical constraints on the scope of clinical investigation in seriously or critically ill children and adults.

The purpose of this report is to provide a distillate of the proceedings and the conclusions arrived at.

Most previous discussions of ethics of clinical investigation have dealt with normal individuals, with patients suffering from terminal malignancies, with the mentally retarded and the elderly. We chose as our subject, patients with life-threatening but potentially recoverable illnesses because with the current investigative efforts in myocardial infarction and stroke such a discussion might prove useful. We have defined *critical illness* as one that is immediately life-threatening and serious *illness* as one that may result in death or permanent disability if its course does not terminate in days or weeks or if its lethal complications are not prevented.

An example of critical illness would be myocardial infarction with shock and of serious illness, acute, uncomplicated myocardial infarction. The difference between the two is either a function of time or whether complications supervene.

Illnesses such as these place a particularly large responsibility, legal and ethical, on physician-investigators in regard to the obtaining of informed consent and in the design and execution of investigation.

Much discussion centered on the problem of informed consent. Probably the most significant development of the session was a clear delineation of the legal requirements of informed consent and the realization how far they fall short of the ethical requirements. Actually, this is because "informed" is an ambiguous word as it is used in our culture. There is nothing intrinsically wrong with the word itself, only in how it is used. To be "informed" implies understanding, while the verb "to inform" is defined as "to impart knowledge of a fact or circumstance, to supply with knowledge of a matter or subject." Thus, to most of us, an informed person is one who comprehends, as opposed to one who has merely been given information; and informed consent, therefore, is to be given by one who truly understands, rather than by one who has simply been given the facts.

In the conduct of clinical investigation the physician/investigator clearly has the responsibility of protecting the rights of the individual and, through his studies, of providing new information for the benefit of the patient and society.

He is legally required to explain the purposes of the study to the patient and gain his consent. However, the legal requirement of a clear description was to the Ethics Committee a far cry from the ethical requirement that the description be understood or, in other words, that the consent be "informed." Patients who are very ill, children—ill or well—and elderly patients are in a position of extreme dependency. Even parents of sick children and relatives of seriously ill adults are also dependent. Very sick people even if seemingly alert, have little or no energy available for understanding explanations of the goals and risks of studies. Their relatives, likewise, have their emotional energies so tied up with concern and worry that they often cannot understand. Parents of sick children are similarly burdened with care. Both groups, also, want most of all to do the best thing for their sick relatives and may have the unrecognized fear that a refusal of participation might alienate the physician/investigator and diminish his potential as physician/healer. As the discussion of these inherent constraints evolved it became apparent that some of the difficulties could be resolved by using a third person, an advocate, who while not directly involved in the planned investigation but concerned primarily for the patient and relatives, could assist in explanations and help assure as full an understanding as possible. Another advantage in having a third person involved is the potential for raising the level of awareness of the physician/investigator in regard to his responsibilities, his interests and motives. This individual can be anybody who feels co-equal with the physician/investigator in regard to an understanding of and concern for the responsibilities involved.

The committee firmly supported the doctrine of informed consent and concurred in this statement concerning it: "The ultimate goal of informed consent is for the patient to understand the treatment or procedure he is to undergo, including all its ramifications, so that his decision to participate will be based on a comprehension of procedure with its dependent risks and advantages. In practice, an on-par understanding cannot be achieved, so that an extra burden is placed on the physician to give the patient any facts and understanding and to act only in a capacity to serve the best interest of the patient. In order to satisfy the legal, scientific and medical requirements of informed consent, it is sufficient to make available the facts necessary to form the basis for intelligent consent. However, this does not satisfy ethical requirements nor those of the professional relationship. In order to assure this, it may be wise to have a third party who can help the patient achieve a better understanding and also assist the physician in reviewing his own interest and motives so that he can be explicit in his own relationship with the proposal."

Our lawyer member emphasized the importance of informed consent by quoting from a recent symposium on sports medicine that "there is no law in the United States that would require an individual to be a participant against his will in any investigational activity involving risks to his health." He also made it very clear that the farther the investigation is from therapeutic research, the greater is the investigators potential legal liability. Thus, legally, non-therapeutic and therapeutic research have different requirements. For the purpose of our discussion we defined therapeutic research as directed toward obtaining information relating to the efficacy of an existing treatment or to the development of a new modality of treatment. Non-therapeutic research, on the other hand, was taken to indicate any studies that did not directly concern the treatment of the patient's illness. One legal authority (Medical Jurisprudence, Waltz and Inbau, MacMillan, 1971) suggests the principle distinguishing feature between the two types rests on the motivation of the investigator whether he is concerned primarily with the welfare of the patient or that of society. Thus, "to the extent that the propriety of an experimenter hinges on the distinction, any close choice—between 'research' and 'therapy'—will be resolved in favor of the former . . . since the presence of some interest other than the welfare of the subject always tends to render the physician's action more difficult to justify legally."

From these considerations evolved a discussion of the types of research, within the framework of therapeutic and nontherapeutic investigation, that are carried out in seriously and critically ill patients and the appropriateness of the types in these two situations. There is *observational* research which, through sequential measurements, follows the course of an illness for the purpose of gaining information concerning the biologic abnormalities that characterize the illness and how they are modified by treatment if such is available. It is two kinds. One involves measurements on blood and other body fluids utilizing no sampling procedure or equipment other than required for the care of the patient. The other

requires specific instrumentation for making the appropriate observations—often this involves an invasive procedure which, if control observations are to be made, can delay the beginning of treatment. Then there are *modification* types of studies. One is therapeutic, which, through use of a new drug or a procedure seeks to ameliorate or cure an illness. The other, through creating some physiologic perturbation, seeks to gain deeper insight into the biologic characteristics of the illness. Inherent in the latter is the postponement of therapy until the necessary observations have been made.

Each of these types carries different risk-benefit ratios and it has its particular relevance for investigation in seriously and critically ill patients. When is research justified in such patients? In answer, the committee has suggested the following:

When it is of potential therapeutic benefit to the patient in his present illness.

When it can be conducted without exposing the patient to additional hazards beyond those occasioned by his illness and the usual care and therapy associated with it.

When it does not modify the circumstances of care or modifies them with anticipated benefit for the patient. (Only when the usual care of the patient is not modified can investigative procedures or research unrelated to the patient's present illness be performed.)

When prospective benefits for other patients are demonstrable.

Only when informed consent is obtained.

It is obvious from the foregoing discussion that the investigator carries a large responsibility for the planning and conduct of investigations of serious and critical illnesses. It requires a particularly sensitive awareness of the extreme dependency that such illnesses impose and of the important time element that, relatively speaking, is not a consideration in studies of normal states or less severe illnesses. These characteristics of serious and critical illness raise the question whether the patient and science are better served by one physician who plays a dual role of healer and investigator or by two persons—one, the physician/healer and the other, physician/investigator. Each clinical scientist and his institution must take the responsibility for this decision.

THE POPULATION COUNCIL,
BIOMEDICAL DIVISION,
THE ROCKEFELLER UNIVERSITY,
New York, N.Y., October 2, 1973.

HON. PAUL G. ROGERS,
Chairman, Subcommittee on Public Health and Environment, House of Representatives, Washington, D.C.

DEAR MR. ROGERS: There is before your committee a bill limiting federal support of research on the fetus, newborn, and perhaps children as well to measures designed to immediately benefit the patient. This would mean, as I understand it, that no observations, however benign (such as blood counts) could be made either on normal infants or on ill infants unless the observation bore directly on therapy.

Two considerations are in order. First: as a result of medical progress, death among children has become a rarity in all age groups except in the perinatal period; this group only recently has begun to benefit from increased attention of clinicians and researchers. It is the last major group where research can lead to major saving of life among infants and children. Current figures show:

Age group:	Deaths per 1,000/year
Birth to 28 days.....	18
1 month to 1 year.....	7
1 year to 14 years.....	0.6

Many of the deaths in the perinatal period have their causes *in utero*; progress here must depend on responsible research during prenatal life, an area of research which there is every reason to encourage.

Second: Obviously research must be both responsible and harmless. I understand that the National Institute of Child Health and Human Development is developing guidelines to help investigators in an area with many ethical problems. These guidelines would be used by those already existing human research committees now functioning in all our medical centers. This, rather than blanket

legislative prohibition, is the direction in which responsible regulation of research in infants and children should be encouraged to move.

Sincerely yours,

JONATHAN T. LANMAN, M.D.,
Associate Director.

FAMILY LIFE BUREAU,
U.S. CATHOLIC CONFERENCE,
Washington, D.C., October 4, 1973.

HON. PAUL G. ROGERS,
Chairman, Subcommittee on Public Health and Environment, Washington, D.C.

DEAR MR. ROGERS: The Subcommittee on Health and Environment has recently conducted hearings on H.R. 10403 and H.R. 1111, and I wish to submit the following comments for the record on behalf of the United States Catholic Conference.

Title II of H.R. 7724, as amended in the Senate, is the Protection of Human Subjects Act. We support this amendment, and urge that the House of Representatives accept it. Biomedical discoveries and scientific research are continually opening the path to greater experimentation and to new medical procedures. However, this raises serious questions as to the ethics of certain procedures. As Leon Kass, former executive secretary of the Committee on the Life Sciences and Social Policy of the National Academy of Sciences has noted, "(W)e must get used to the idea that biomedical technology makes possible many things we should never do" (*Science*, Nov. 19, 1971). Ethicists such as Paul Ramsey of Princeton, Arthur Dyck of Harvard and Charles Curran of the Catholic University of America, agree with Kass as to the need for caution and restraint.

A number of witnesses acknowledged that decisions affecting research procedures must reflect a balancing of social, moral and ethical and medical factors. It is this "balancing process" that is itself most difficult, and when serious problems cannot be resolved, then the law or policy should be restrictive, for to permit the experiments to proceed is to allow the inherent dangers to human life and human dignity to run their course.

Although there are some who believe that the prevailing mechanisms within the Department of Health, Education and Welfare can adequately protect the rights of human subjects, the experience of the past does not sustain this. The Tuskegee syphilis study and the recent sterilization incidents in Alabama and South Carolina are cases in which HEW regulations were ineffective. During recent hearings before the Senate Subcommittee on Health, Dr. Charles Edwards, then director of the Food and Drug Administration, described the policies of FDA in regard to two new chemical contraceptive agents.

The first drug is Depo-Provera, a derivative of progesterone that has been used in the treatment of specific cancers that only affect women. The drug received approval for such use from FDA in 1960 and in 1972. The drug has also been used as a contraceptive agent in other countries, although not approved in the United States for such purpose. The particular contraceptive potential of this drug is that the patient is given an injection effective in preventing conception for about three months. The drug produced tumors in tests on dogs, but not in other animals.

A test of the drug for possible side-effects is being conducted on a group of women in a Tennessee mental institution. The superintendent of the institution maintains that the women have been informed of the possible dangers, and asked to sign the consent forms required by FDA for the investigational use of new drugs in human subjects. According to Dr. Edwards, when the dog studies indicated the development of tumors, an FDA Advisory Committee decided that long-term studies were necessary, and that on-going studies in humans would be allowed to continue only if the subjects were informed again of the dangers, and signed a new consent form. The experimentation in the mental institution is apparently continuing.

However, Marcia Greenberger, a lawyer, also testified before the Senate Health Subcommittee that she had talked with six women at a birth control clinic in Tennessee, five of whom were already taking the drug. None of the six had ever seen the consent form furnished by Upjohn Company, producer of the drug and apparently a collaborator in the testing. All were able to read it and understand it.

In a drug of this type, when serious side-effects are found in animal studies, it is expected that FDA would restrict the experiments on human subjects. FDA explained that the human experimentation was allowed to continue because no

other injectable contraceptive is available or forthcoming. FDA also maintains that the drug is being restricted to women who cannot use other types of contraceptives.

In summary then, FDA is allowing the continued experimentation with a dangerous drug on a group of women in a mental institution, and the use of the drug experimentally among women who sought family planning service from a County Health Department. These women never saw or signed consent forms.

The second drug is Diethylstilbestrol (DES), a synthetic estrogen compound. Formerly used for certain gynecological disorders under proper controls, this drug can also be used after intercourse to inhibit pregnancy. But long-term studies of its use led to the discovery of cancer in the daughters of women who used the drug during their child-bearing years. As a result, FDA issued warnings.

But DES was gaining in popularity as a "morning-after pill," and it had never been submitted to FDA for clearance for this purpose. Studies indicate wide use on college campuses.

Because of its new-found contraceptive potential, researchers worked out a new regimen for its post-coital use. Beginning 72 hours after intercourse, and in a continued low dosage for the next five days, the drug works effectively as a morning-after pill. There isn't likely to be any complications in the next generation, since the effectiveness of the drug precludes offspring. Dr. Edwards noted that one cannot tell what effects it may have on an already developing fetus but "an early abortion by conventional means should be seriously considered" in such cases.

No one seems to know exactly how the drug works, but in the post-coital regimen it is quite clearly abortifacient. No one knows anything of its cancer-inducing properties either, but FDA has allowed its continual use because no one has proven it causes cancer when used post-coitally. Of course, there hasn't been enough time to study this yet, and the widespread use of the drug makes controlled study difficult. Moreover, a cancer specialist expressed opposition to further distribution of the drug.

FDA explains its leniency in these cases because each drug is a promising new contraceptive. FDA apparently assumes that more and newer contraceptive agents must be discovered and marketed. FDA's responsibility is to regulate the sale of drugs and the experimentation for drug development in order to safeguard the health of citizens. In view of FDA's demonstrated leniency in these matters of experimentation with dangerous drugs, there is need for some agency with greater authority and responsibility than is currently evident in HEW.

Although H.R. 7724 establishes this Commission within HEW, it may well be that such a Commission should exist outside of any specific agency with Congressional authorization to scrutinize the activities of all government bodies. In any case, it seems essential to provide a strong political check on those who administer federal funds and federal programs under which experimentation on human beings may be conducted.

In Section 1202(a) (1) the primary duty of the National Commission is carefully stated so as to respect the mutual responsibilities of church and state. Thus, the Commission is "to identify the basic ethical principles and develop guidelines which should underlie the conduct of biomedical and behavioral research involving human subjects. The Commission is "to identify the basic ethical principles" as a consequence of investigation and study, and also as a result of consultation and dialogue with religious bodies, ethicists and scientists. The guidelines or regulations formulated by the Commission should be consistent with the identified principles, and should govern the activity of HEW agencies and HEW funded projects. The wording of this section underwent extensive re-writing in the development of the final draft, and unfortunately, the spokesman for HEW, in his testimony before this Subcommittee, addressed his comments to an early draft of the bill, not to the final version.

Section 1204 provides protection for the individual physician to refuse to perform or assist in the performance of experimental procedures that violate his or her conscience. It also protects any entity receiving HEW funds from being forced to make its facilities available for experiments that are prohibited by the entity on the basis of ethical or moral convictions.

Section 1205 requires the establishment of Institutional Review Boards that will review protocols and will also protect human rights by making sure that human subjects are well-informed prior to giving consent to any experiment. This section could be strengthened by adding a responsibility for continuing review of any project. This is not to impute bad will to the researcher, but to acknowledge that the pursuit of information or of success in an experiment can often blind the research to an increased danger to the subject.

The House version of H.R. 7724 contained a prohibition of experimentation on human fetuses obtained by abortion. A similar prohibition was adopted on the floor of the Senate by a vote of 88-0 after an extensive discussion. The Senate version also prohibited experiments on living infants. This specific prohibition has been opposed by witnesses appearing before this Subcommittee, and one witness explicitly stated that "there should be no prohibition on research activities involving fetuses and infants." The absoluteness and universality of this statement is a telling reason for the need for such legislation.

However, we see this prohibition of experiments on fetuses and infants, prior to or after abortion, as an essential aspect of the bill, and we strongly support it for the following reasons.

First of all, the humanness of the fetus is assumed by all concerned, and the basic reasons for any experiments on fetuses and infants are to gain knowledge about the development of the fetus during pregnancy and to learn more about genetics so as to overcome specific diseases. However, government funding of experiments on aborted fetuses and infants constitutes approval and encouragement of such experiments, placing the fetus or infant in the category of experimental specimen. The issue is not simply the right or wrong of fetal experimentation—an ethical problem that exists regardless of government funding—but rather the responsibility of government to protect human life, even when the child-to-be has been rejected by its parents and/or society. The government must not accede to those who say that since a woman has decided on having an abortion, the fetus is of no value but to be experimented on, or the life of the aborted child is of diminished value and need not be sustained. Granting that some information may be gained by such experiments, the far-reaching implications are too great for government to abandon its responsibility to impose some restrictions.

There are also other supportive reasons for a government policy of restriction rather than of encouragement or permissiveness. First of all, much of the knowledge that is to be gained by experiments on the fetus or infant can also be gained by animal research. It may be more expensive and more demanding, but nonetheless, animals should be used instead of fetuses or infants. For practical purposes, there are virtually no genetic diseases where experimentation on live fetuses is *required* in order to continue research efforts.

Secondly, much of the information needed to study genetic diseases is gained by sampling the amniotic fluid, not from fetal research. Moreover, the basic research data in the efforts to overcome sickle-cell anemia and Tay-Sachs disease was accumulated prior to the recent use of the live fetus as a research specimen. Moreover, the presence of Tay-Sachs disease can be detected by sampling amniotic fluid.

Thirdly, there is serious question among specialists as to whether any serious gains can be achieved by widespread experiments on aborted fetuses. Dr. James Miller, professor of pediatrics at the University of British Columbia, maintains that very little can be gained from general experimentation on therapeutically aborted fetuses. Dr. Kurt Hirshhorn of Mt. Sinai Hospital in New York agreed that therapeutic abortions do not yield much valid information. In April, 1973, Dr. Robert Berliner, NIH Deputy Director for Science, stated that "NIH does not now support research on live aborted human fetuses and does not contemplate approving the support of such research. We know of no circumstances at present or in the foreseeable future which would justify NIH support of research on live aborted human fetuses."

Fourthly, a basic requisite for any experiment is the informed consent of the patient. That is impossible in cases of experiments on the aborted fetus or infant, because the fetus cannot consent and the mother has already decided on the death of the fetus.

The abortion decisions of the United States Supreme Court have created serious problems concerning the value that we attach to the fetus and the infant. Congress should not be made the whipping boy for the Court's opinion, but neither should Congress easily abandon its responsibility to maintain respect for human life, even in its pre-natal stage. Thus, Congress should refrain from encouraging experiments on the fetus by its refusal to provide funds for such research.

Section 1206 contains Interim Provisions, particularly regarding informed consent. These provisions and the consent criteria are worthwhile, and will help protect individuals from a violation of rights.

Once again, we wish to state our general support for this bill, and urge that the provisions of the Senate be accepted by the House of Representatives.

Sincerely yours,

(Rev. Msgr.) JAMES T. McHUOH, *Director*.

U.S. SENATE,
Washington, D.C., October 24, 1973.

HON. HARLEY O. STAGGERS,
House of Representatives,
Washington, D.C.

DEAR HARLEY: It is my understanding that H.R. 10403, the Protection of Human Subjects Act, introduced by Representative Rogers is presently pending before the House Interstate and Foreign Commerce Subcommittee on Public Health and Environment.

I have just received the enclosed letter from one of my constituents supporting this measure and I would appreciate your seeing that her views are incorporated in any hearings which may be held on this legislation.

With best wishes, I am
Sincerely yours,

J. W. FULBRIGHT,
U.S. Senator.

DIOCESE OF LITTLE ROCK,
CATHOLIC SOCIAL SERVICES,
Little Rock, Ark., October 17, 1973.

SENATOR FULBRIGHT: On behalf of the staff working for Catholic Social Services I would urge you to contact Congressmen Harley Staggers and Paul Rogers and add your support to the Protection of Human Subjects Act. It seems vitally important to the moral fiber that we stop wasting infant and potential life, as that we stop wasting young soldiers' lives.

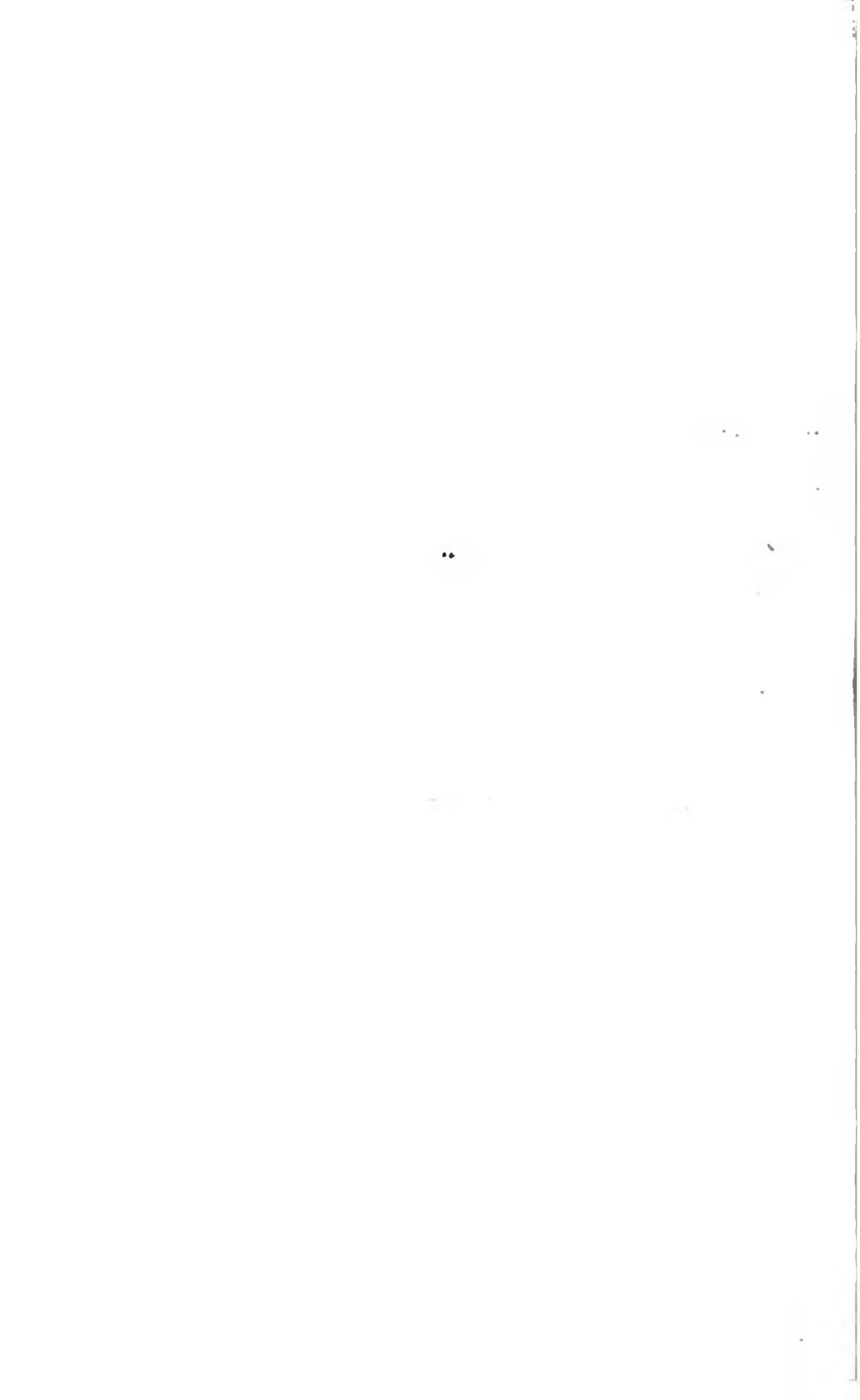
If freedom of life is one of our basic beliefs then we must surely question the termination infant and potential life. Thank you for your time.

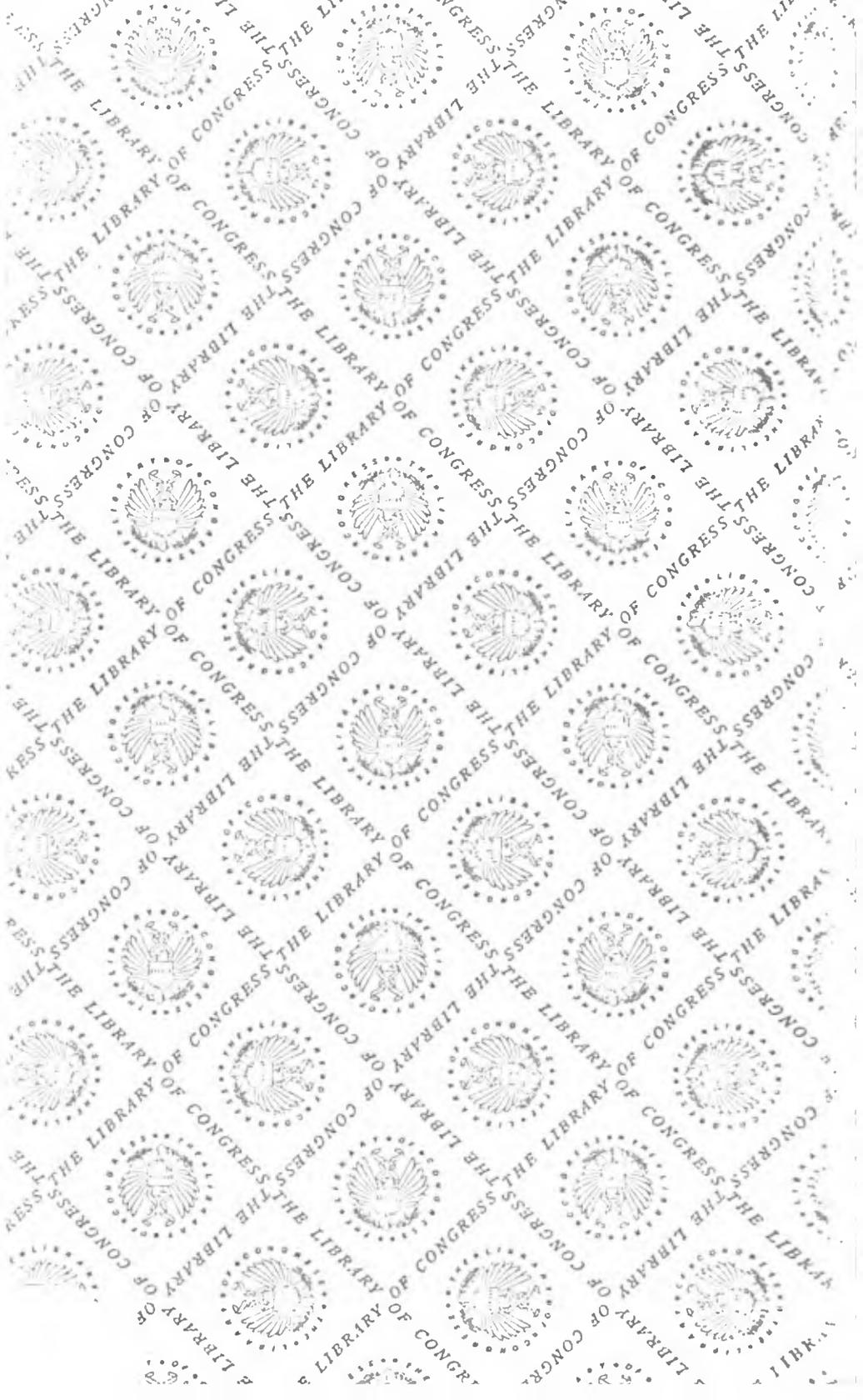
Sincerely,

Sr. LEONA DOELLING.

[Whereupon, at 12:40 p.m., the subcommittee adjourned.]









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