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ABSTRACT

This Senate bill includes a discussion of the need for legislation protecting human subjects of biomedical and behavioral research and provides synopses of public hearings on this subject conducted by the Committee on Labor and Public Welfare. The legislation providing for the establishment of the Commission for the Protection of Human Subjects of Biomedical and Behavioral Research is set forth and includes the Commission's duties, specific areas to be studied by the Commission, and other administrative details. (MH)

Calendar No. 841

94TH CONGRESS, 2d Session } SENATE { REPORT No. 94-885

PRESIDENT'S COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH ACT OF 1976

MAY 14, 1976.—Ordered to be printed

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Mr. KENNEDY, from the Committee on Labor and Public Welfare, submitted the following

REPORT

[To accompany S. 2515]

The Committee on Labor and Public Welfare, to which was referred the bill (S. 2515) to amend the Public Health Service Act to establish the President's Commission for the protection of human subjects involved in biomedical and behavioral research, and for other purposes, having considered the same, reports favorably thereon with an amendment in the nature of a substitute, and recommends that the bill as amended do pass.

I. HISTORY AND NEED FOR THE LEGISLATION

The United States has long been recognized, throughout the world, as the leader in biomedical and behavioral research. Unfortunately, the time and attention which has been given to the development of our biomedical and behavioral research program has not been matched by the development of policy adequately to protect human subjects of that research.

Since 1973, the committee has held more than 15 days of hearings on the adequacy of existing policies for the protection of human subjects of biomedical and behavioral research. These hearings have been very disturbing. It became clear to the committee that in many cases the human subjects of research were inadequately protected and placed subjects at grave risk.

The Senate report on H.R. 7724, the National Research Service Award Act, which was filed on August 3, 1973, summarized the need for legislative action as follows:

The hearings examined a wide variety of abuses in the field of human experimentation: Drugs are commonly used for unapproved purposes without informed consent and without proper medical follow-up; experimental surgery has been performed at the discretion of an individual physician without submitting his work for prior review by a group of peers; and medical devices can be developed by an individual physician on the basis of his own judgment and used in human beings without adequate prior testing. Dr. Robert Veatch of the Hastings Center of the Institute of Society, Ethics and the Life Sciences recounted numerous examples of university-based biomedical and behavioral studies involving human subjects which raised profound ethical questions that had been inadequately addressed by the investigators prior to beginning the study.

Some of the most startling testimony was presented by Dr. Bernard Barber, Chairman of the Department of Sociology at Barnard College. In his prepared statement he said:

"When we asked our 350 physician-researchers who were all together involved in 424 different studies using human subjects, to estimate how much benefit their studies had for the subjects, how much risk, how much possible benefit for future patients, and how much scientific value, what they themselves told us showed that 18% of the studies involved more risk than benefit for present subjects. Some of these less favorable studies were said to promise benefits to future patients, but even when these future benefits were thrown into the balance, there were still 8% of the studies that involved more risk than benefit. Since these are the researchers' own estimates, remember, it is not unlikely that at least some small underestimation of risks, some small overestimation of benefits is involved.

But this 8% of the studies, what we call the least favorable studies, were not carried out at random on types of patient subjects. We also had asked our researchers to tell us the relative proportions of private and ward or clinic patients used on each study. Using this information, we found that studies where the risks are relatively high in proportion to therapeutic benefits for subjects, are almost twice as likely to be done using subjects more than ¾ of whom are ward or clinic patients.

Even when we put the benefits to future patients and possible benefits to medical knowledge into the balance, we still found that the least favorable studies were almost twice as likely to be done on ward or clinic patients."

Dr. Barber, whose results have been published in a book entitled *Research on Human Subjects: Problems of Social Control on Medical Experimentation*, went on to say:

"In our intensive interview study of 350 medical researchers who are in two institutions that supposedly review all research, 9% of the respondents volunteered the information that they were doing research that had not been peer reviewed. And even where peer review had been carried out, our studies show some of it is not being done under mandated

or what we roughly define as the most efficacious of conditions. For example, there is a lack of mandated continuing review in many institutions; there is a lack of face-to-face discussion and moral confrontation among the reviewers; and there is an absence of appeal procedures.

"The Committees in the several separate institutions are not in touch with one another and are therefore without benefit of pooled experience and, I should add, benefit of pooled moral indignation.

"With regard to efficacy, moreover our data show that medical school peer review committees, where one would expect excellence, are no better than committees, in other types of research institutions."

Dr. Jay Katz, one of the leading experts in the country on this subject, testified:

"Though the United States Public Health Service and DHEW policies has provided some significant controls over research practices, I submit that they are inadequte and that the problems remain unsolved. Let me note briefly that neither the United States Public Health Service nor HEW have addressed themselves with sufficient seriousness of purpose to the implementation of the primary intent of their primary intent of their policies for the protection of human subjects."

Dr. Katz further testified that HEW policies do not address the questions such as 1) the use of prisoners for research purposes, 2) the participation of children in research 3) the jurisdiction of the institutional review committees, and 4) the need for supervision of research in related disciplines.

Time and time again in the course of the hearings the Committee heard testimony about abuses in the field of human experimentation. Whether the hearings focused on DepoProvera, DES, supercoil, experimental surgery, prison research, university-centered research abuses, the Tuskegee Syphilis Study, genetic manipulation, behavioral control; or the Goldzieher contraceptive study, it would appear that the common theme was, "Let the patient beware."

The testimony, particularly the Relf family with respect to the Montgomery, Alabama, sterilization case, and the testimony of Ann Burgess with regard to the use of DepoProvera in Tennessee, in addition to numerous press reports and other information reviewed by the Committee, convinced the Committee that it was essential that any legislation be extended to provide similarly adequate protection for the recipients of health services to the maximum extent feasible from those health service programs that fell within the Committee's jurisdiction, as for participants in biomedical and behavioral research projects. The Administration witnesses, although opposed to the enactment of S. 2072, which in substantial measure is similar to the protection of human subjects titles of the bill reported by the Committee, did not take issue with the intent of the legislation. Their concern was "Before our review is completed, however, enactment of legislation on this subject would deter the progress we have al-

ready made." All other witnesses supported the legislation, Dr. Albert Sabin, world renowned research scientist, summing up the consensus of all witnesses by saying, "This legislation is needed, with no 'ifs', and 'ands', or 'buts'."

Subsequently, the Congress passed the National Research Act which established a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This Commission was not only to review the policies for the protection of subjects of biomedical and behavioral research and to make recommendations to improve those policies, but was also to consider the ethical, social, and legal implications of advances in biomedical research and its accompanying technology.

The committee believes that the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research has been functioning very successfully. At the same time, as oversight hearings in this area continued, it became increasingly clear to the committee that the jurisdiction of the National Commission was too limited and that human subjects were at risk in those biomedical research programs which were outside the Commission's jurisdiction.

The need to expand the scope and jurisdiction of the National Commission was made evident by the hearings of April 22, September 10 and 12, and November 7, 1975. In those hearings, the committee learned that both the CIA and the Defense Department had been involved in the widespread testing of hallucinogenic drugs on unsuspecting citizens, servicemen, and employees of the agencies. These experiments, which were perceived to be necessary to meet the needs of national security, violated the basic principles of biomedical and behavioral research with human subjects and their rights. The subjects were not informed of the risks and benefits associated with participation in experiments. No medical followup was attempted, and serious harm resulted from the experiments.

Some of the research involved thousands of Army volunteers at a handful of bases around the country. In these cases medical supervision was inadequate, medical backup was deficient, and long-term followup virtually nonexistent.

Perhaps most disturbing of all was the revelation that unsuspecting American citizens from all social classes were administered hallucinogenic drugs without their knowledge, in normal daily social situations. No medical supervision of these experiments had ever been contemplated, nor was follow-up medical care ever carried out.

The committee was also disturbed to learn that narcotic addicts were bribed with narcotics in return for their participation in hallucinogenic drug testing experiments.

The committee wants to take special note of the fact that there was a memorandum of understanding implemented between the Department of Defense and the Food and Drug Administration. That memorandum exempted the Department of Defense from the requirements of the investigational new drug process, whenever those drugs being tested were classified for national security. That memorandum abrogated the responsibility of the Food and Drug Administration and substituted for it an internal Department of Defense peer review system. However, the hearings disclosed that the peer review within the Department of Defense was not carried out, and the required meetings between the Department of Defense and the Food and Drug Administration never materialized.

In considering the testimony at these and subsequent hearings, the committee became convinced that all human subjects who participate in Federally-funded biomedical or behavioral research programs deserve comparable protection. The committee could no longer justify the limitation of the Commission's authority to those research programs conducted with the Department of Health, Education, and Welfare funds in light of the significant abuses of other departments and agencies.

The committee notes that, when expansion of the National Commission's jurisdiction was discussed with the Veterans' Administration, the leadership of that organization was receiptive to the concept that a uniform code of protection be established for all subjects of Federally funded biomedical and behavioral research. The committee notes that the Veterans' Administration has for years had its own rules to protect research subjects. The committee believes that there is a compelling need to have all subjects of research accorded a uniform, consistent and comprehensive level of protection.

For all these reasons, the committee became convinced that the jurisdiction of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research should be expanded to cover all subjects of biomedical and behavioral research regardless of Federal funding source and that the Commission itself should be upgraded and made a Presidential Commission in order to reflect this important and expanded mandate.

During the course of committee hearings on these subjects, a segment of the Nation's scientific community took an historic step. A group of researchers involved in a particular kind of genetics research, i.e. recombinant DNA research, decided voluntarily to suspend the continuation of their work for a period of time. This self-imposed moratorium was observed around the world. It had never before been done in the history of science. The action was prompted by the ethical, legal, social and safety implications of the research that was in progress. After a period of time, this self-imposed moratorium was lifted and the scientists agreed to resume their work under a carefully developed set of guidelines. This whole episode, which was the subject of an April 9th, 1975, hearing before the committee, illustrated the importance of the Commission's additional function—the studying of the ethical, legal, social and safety considerations of all new biomedical and behaviorial research involving human subjects. The committee is convinced that, as technology develops and as science becomes more sophisticated, additional serious questions, similar to those faced by the scientists involved in recombinant DNA research, will be raised. The committee believes that it is important that a body with the wide-ranging expertise of the Commission consider these kinds of issues. The committee believes that the consideration of ethical, moral, legal and social implications of biomedical and behaviorial research are not the exclusive province of science alone, and the makeup of the National Commission reflects that view. Accordingly, the committee believes the need has been demonstrated to expand this area of the Commission's responsibilities and it has done so in two ways. First, by specifically requiring that the Commission study the ethical, social and legal implications of recombinant DNA research as well as the safety questions of that research. Second, by specifically requiring that the Commission continually review and

analyze the ethical, social and legal implications of *all* biomedical and behavioral research on human subjects conducted by and through any Department or Agency, and by requiring that the Commission make appropriate recommendations for the protection of human subjects of that research.

II. Hearings

The committee has conducted extensive public hearings on the issues with which S. 2515 is concerned, dating back to February, 1973.

February 21, 1973

Witnesses included Charles C. Edwards, who was at that time the Commissioner of the Food and Drug Administration (hereafter referred to as FDA), Henry Simmons, the Director of the Bureau of Drugs, Peter Hutt, the Assistant General Counsel, Gerald F. Meyers, Director of the Office of Legislative Services for the Food and Drug Administration, and John Zapp, Deputy Assistant Secretary for Legislation of the Department of Health, Education, and Welfare (hereafter referred to as HEW or DHEW). Other witnesses included Marsha Greenberger of the Center for Law and Social Policy in Washington, D.C., Nathan Kase, chairman of the Department of Obstetrics and Gynecology, Yale University School of Medicine, Leonard Brooks of the New Woman's Clinic in Washington, D.C., Robert Hutcheson of the Tennessee Department of Health, Family Planning Division, Anna Burgess of Monterey, Tenn., James Brown, superintendent of the Arlington Hospital and School for the Mentally Retarded in Arlington, Tenn., and Dr. William Hubbard, executive vice president of the Upjohn Co. The hearing focused on the use of Food and Drug Administration approved drugs for any unapproved purpose. The problem was illustrated by a detailed case history of the use of DepoProvera in the maternal health family planning program throughout the State of Tennessee. Although approved for use in the treatment of endometrial cancer and in endometriosis, DepoProvera is considered to be experimental by the FDA for use as a 3-month injectable contraceptive. In spite of this, the hearing testimony established that more than 1,500 women received the drug in the maternal health family planning program throughout the State of Tennessee as an injectable contraceptive. Anna Burgess, one of the women who received it, testified that she was never informed of the potential side effects, never signed a consent form, and experienced a significant degree of discomfort after taking the drug. Dr. Kase and Ms. Greenberger reported on the results of a field investigation in which six women in Cumberland County, Tenn. including Miss Burgess, were interviewed about the use of DepoProvera. Dr. Kase concluded that informed consent was not obtained in any of the six cases, no attempt was made to achieve patient awareness, and the potential short and long term hazards of the drug were not discussed. He testified: the routine safeguards consistent with good medical practice which should be applied prior to initiating any therapy were not offered to these patients; adequate overall care prior to, during or subsequent to usage was not regularly, predictably or responsibly available or achieved; and at least one patient felt that she was coerced by her welfare agency to accept a birth control medication.

In spite of the fact that the FDA had developed a complete and detailed informed consent procedure and form in collaboration with the

Upjohn Co., none of the 1,500 women receiving DepoProvera regularly in Tennessee was given the necessary information provided for by such informed consent. Furthermore, consent forms used by the State family planning department and by the school and hospitals for the mentally retarded in Arlington, Tenn. were clearly not in accord with such informed consent requirements.

Dr. W. N. Hubbard, Jr., the executive vice president of Upjohn, testified that subsequent to the hearing, shipment of the drug to the Arlington school and hospital would be stopped, informing the committee that the Upjohn Co. did not approve of the unapproved use of DepoProvera in Tennessee.

February 22, 1973

Dr. Robert Veatch of the Hastings Institute, Hastings-on-Hudson, N.Y. testified and recounted a series of university-sponsored research projects which violated established ethical principles or which raised profound ethical questions. The major points of his testimony were: that most patients of medical research were not adequately protected; that ethical considerations were not given enough weight and that a system must be developed whereby these issues could be discussed before such experiments are approved.

February 23, 1973

Witnesses included Dr. Bertram Brown, the Director of the National Institute of Mental Health (who was accompanied by Dr. John Sherman, the Acting Director of the National Institutes of Health, Dr. Murray Goldstein, the Associate Director of the Extramural Programs of the National Institute of Neurological Diseases and Stroke, Dr. David Keefauver, Assistant Director for Extramural Programs of NIMH, and Dr. Lyle Bivens, Chief, Neurophysiology Section of Behaviorial Sciences, Research Branch, NIMH), Dr. Orlando J. Andy, Department of Neurosurgery, University of Mississippi, Dr. Peter Breggin, a psychiatrist from Washington, D.C., Dr. Robert Heath, professor and chairman of the Department of Psychiatry-Neurology at Tulane University School of Medicine, Professor B. F. Skinner of Harvard University, and Dr. Willard Gaylin, president of the Hastings Institute. This hearing focused on psychosurgery and other techniques for behavioral control currently being developed in research centers across the nation. Dr. Brown's testimony defined psychosurgery as "a surgical removal or destruction of brain tissue or the cutting of brain tissue to disconnect one part of the brain from another, with the intent of altering behavior, even though there may be no direct evidence of structural disease or damage in the brain."

Dr. Brown said that in this country each surgeon is free to perform such surgery on the basis of his individual judgment, except when surgeon is participating in an HEW supported project, he is required to follow certain guidelines. Dr. Brown testified that he considered it to be an experimental procedure which if done, should be done under the most well-controlled circumstances. He testified on the need for peer review to be sure that the quality of medicine practiced was consistent with the highest possible standards. Dr. Andy testified that psychosurgery was not an experimental procedure, and that he felt comfortable using it for treating aggressive, uncontrollable, violent and hyperactive behavior which does not respond to other therapy. He said that his work was not submitted to formal peer review and

that the decision to operate was one that should be made by the individual doctor in consultation with the family and the patient, Dr. Peter Breggin testified that psychosurgery could not be justified in any way and that it should be banned outright. Dr. Heath described his research which centered around the technique of implanting small electrodes and canulas into precise predetermined brain regions. Dr. Heath testified that all of his research was subject to the review of the medical school human research committee, which is composed of medical scientists, attorneys and clergymen. He stressed the importance of the peer review procedure, especially when medicine goes into uncharted territory. Dr. Heath stressed the importance of having doctors not actively involved in the project review its merits. Dr. B. F. Skinner described his research into the modification of behavior by the use of positive and negative rewards and conditioning.

Dr. Willard Gaylin testified that behavior control was an enormously serious problem that had not been attended to adequately and "it needs a kind of regulation that is not at present available, that some of these are legislative and some of these are not legislative." Dr. Gaylin's testimony expressed concern about the degree of freedom physicians had both to prescribe drugs for any purposes and to perform experimental surgey on the basis of individual judgment. He said that medicine has adopted "a kind of paternalistic or authoritarian role." He felt that strong peer review and a system of protection of human subjects of research ought to be developed.

March 6, 1973

Witnesses Mitford, Cowan, Lawson, Jones, Schoefer and Diamond and the Life Sciences, John Sherman, the Acting Director of the National Institutes of Health, who was accompanied by Robert W. Brolan, Deputy Director of Science of NIH, Lewis Thomas, the dean of the Yale School of Medicine, Michael E. DeBakey, president of the Baylor College of Medicine, and James D. Watson, Nobel laureate and professor of Molecular Biology at Harvard University. This hearing focused on the past accomplishments of biomedical research, the potential future developments in biomedical research, and the need for continued support and expansion of the nation's biomedical research activities.

All witnesses, including Dr. Sherman, advocated a continued high level of Federal funding support and commitment in regard to biomedical research.

March 7, 1973

Witnesses included author Jessica Mitford, Geoffrey and Eileen Cowan of the UCLA Law School, Sidney Wolfe of the Health Research Group, David J. Sencer, the Acting Administrator of the Health Services and Mental Health Administration, John Jennings, the Associate Commissioner for Medical Affairs of the Food and Drug Administration; Alan Lawson of the Prisoners' Rights Council in Philadelphia, Pa., (accompanied by Charles J. Shoefer of the Philadelphia People's Bail Fund and Leodus Jones, Community Assistance for Prisoners, Philadelphia, Pa.), Bernard L. Diamond, of the School of Criminology at the University of California, Alexander Capron, assistant professor of law at the University of Pennsylvania, and Joseph C. Stetler, the president of the Pharmaceutical Manufacturers Association.

Dr. Wolfe testified about the use of an experimental intrauterine device called "supercoil" which was developed by a non-physician, and was experimentally used on 15 of the 20 women who had been transported from Chicago to Philadelphia for treatment. Many of them were in their second trimester of pregnancy. Dr. Wolfe described the severe consequences suffered by several of these women.

Dr. Seaver condemned the use of the supercoil in the context presented. The testimony of other administration witnesses pointed out that in the absence of any categorical medical device legislation, there were serious difficulties confronting HEW in its attempt to regulate the development and use of devices. As with drugs and with experimental surgery, physicians were free to develop and use devices on the basis of their own individual judgment with no requirement that their work be submitted to peer review or quality controls.

Witnesses Mitford, Cowan, Lawson, Jones, Schoefer and Diamond all described the nature of biomedical research in prison systems and the effect of a biomedical research testing program on the rest of the prison social structure. Dr. Capron's testimony suggested a total moratorium on prison research until the special ethical questions surrounding it could be discussed in greater detail. Mr. Stetler testified that prison research had made a significant contribution to the development of new drugs and that the nature of the population—a well-controlled and regulated one—made them an ideal group for research. He also testified that in his opinion the use of approved drugs for unapproved purposes was not as widespread as it appeared to be "in the minds of the committee."

March 8, 1973

Witnesses included Fred Gray, attorney and legislator from the State of Alabama, and Lester Scott and Charles Pollard, two participants in the Tuskegee Syphilis Study, Professor Bernard Barber, chairman of the Department of Sociology at Barnard College, Jay Katz of the Yale University Law School, Henry Beecher of the Harvard Medical School, William Barclay of the American Medical Association.

The testimony of Witnesses Gray, Scott and Pollard described events surrounding the Tuskegee Syphilis Study. Scott and Pollard, as two of the participants, described through their testimony how they got involved, how they learned they were members of an experiment, and what they thought had been happening to them during all those years. Professors Barber and Katz spoke of the need for the Government to become more actively involved in the protection of human subjects of biomedical research and behavioral. Each, in his testimony, independently suggested the establishment of a commission to deal with the ethical questions that had been raised in the previous hearings, and the need to establish a governmental focus for the protection of subjects of biomedical research. Dr. Katz, when asked by Senator Mondale if a study commission should be established, responded that it was important to go beyond study commissions and begin to develop a mechanism to implement the recommendations that would be made. Dr. Beecher testified that the past 8 or 9 years had seen considerable improvement in the situation regarding ethics and clinical research, but he pointed out that there was still a long way to go. He cited examples of recent research that had raised profound ethical questions. Dr.

Barclay, testifying on behalf of the American Medical Association, said that the final responsibility for the treatment of patients rests with the individual physician, and that it was proper for him to have the right to use an unapproved drug or to perform experimental surgery if that was, in his, the physician's opinion, in the best interest of the patient.

April 30, 1973

Witnesses included Dr. Henry Simmons, Deputy Assistant Secretary for Health, Fred Gray, attorney and legislator of the State of Alabama, Carter Howard and Herman Shaw, two participants in the Tuskegee Syphilis Study, Peter Buxton, law student in Sn Francisco, Calif. and Dr. Vernal Cave. director of the Bureau of Venereal Disease Control in New York City Department of Health. This hearing focused on the Tuskegee Syphilis Study and the HEW investigation of the circumstances surrounding it, including why the HEW Ad Hoc Advisory Committee was disbanded prior to issuing its final report. Two former subjects of the study described their understanding of it and testified there had been no adequate informed consent. Dr. Buxtun's testimony described his attempts to bring the study to the attention of HEW officials long before the story was first reported by the Associated Press, and the difficulties he encountered in that undertaking. Dr. Vernal Cave, a member of the Commission, testified as to the obstacles that HEW had put in the Commission's way. He gave his personal views on what the study meant, why it had happened, what course of action should now be taken.

June 18, 1973

This was a joint hearing with the Veterans' Committee. The witness was Donald Johnson, the Administrator of Veterans' Affairs. This hearing focused on the extent of psychosurgery in Veterans' Administration (hereafter referred to as VA) hospitals. The hearing explored the conditions under which psychosurgery has been performed and the past and present systems in VA hospitals for monitoring the performance of such procedures. Differences between the NIH guidelines and the VA guidelines for the protection of human subjects were discussed and explained.

June 28, 1973

Witnesses included Lloyd Melmon of the American Federation of Clinical Research; Bernard Barber, chairman, Department of Sociology at Barnard College; Clayton Rich, the dean of the Stanford University Medical Center; Albert Sabin of the Fogarty International Center of the National Institutes of Health; James Bennett, Lawrence Beck and Sherman Levine, three students currently receiving NIH research training and fellowship support.

This hearing focused in part on the Protection of Human Subjects Act which was introduced on June 26, 1973, and responded in great measure to the issues raised in the previous hearings. Doctors Melman, Barber, Sabin, and Rich endorsed the Protection of Human Subjects Act.

June 29, 1973

Witnesses included Charles Edwards, Assistant Secretary for Health; Eugene Braynwald, chairman of medicine at the Peter Bent Brigham Hospital, representing the Association of American Medical

Colleges; Jay Katz, Yale University School of Law; Ivan Bennet, dean of the NYU School of Medicine; Ephraim Friedman, dean of the Boston University School of Medicine; and Daniel X. Freedman, chairman of the Department of Psychiatry, University of Chicago.

Dr. Edwards requested and was granted postponement of his testimony until July 10th. Dr. Bravnwald, in his testimony on behalf of the Association of American Medical Colleges, and Jay Katz, both strongly endorsed the Protection of Human Subjects Act.

July 10, 1973

Witnesses included Henry Simmons, Deputy Assistant Secretary for Health and Scientific Affairs, Joseph Levin, general counsel of the Southern Poverty Law Center, Mr. and Mrs. Relf of Montgomery, Ala., Dr. Warren Hern of Denver, Colo., and Howard Phillips, former Acting Director of Office of Economic Opportunity (hereafter referred to as OEO).

Dr. Simmons, on behalf of the Department of Health, Education and Welfare, testified in opposition to the Protection of Human Subjects Act. He said that although he agreed with the intent of the act, he felt the Department had the authority to handle the matter by regulation and urged, in view of an HEW study, due April 1974, that no action be taken. The hearing then focused on the sterilization of Minnie and Mary Alice Relf by the Montgomery, Ala., family planning clinic.

Testimony indicated that the sterilization was performed without informed consent by the parents. Testimony further revealed that the guidelines on sterilization which were originally developed and approved by OEO for their community action projects were never disseminated. Dr. Hern testified as to his understanding of why they were not sent out. Howard Phillips, the former Acting Director of OEO, testified that he did not approve the use of Government funds for sterilization; that he did not know sterilization was taking place at the time he was Acting Director; and that he believed the decision not to issue sterilization guidelines was influenced at least to some degree by Presidential opposition to the use of Government funds for such purposes.

April 22, 1975

This hearing focused on the ethical, legal, social and safety questions of recombinant DNA research, and the process by which those kinds of questions are resolved in our society at the present time. The hearing was not intended to single out a particular kind of research, but rather to raise broader issues that our country will be called upon to face over and over again in the years ahead.

Witnesses included Dr. Stanley Cohen and Dr. Halstead Holman of the Stanford University School of Medicine, Dr. Donald Brown of the Carnegie Institute of Washington, and Dr. Willard Gaylin of the Institute for Bioethics and Life Sciences.

September 10, 1975

Witnesses included Dr. Alexander M. Schmidt, Commissioner, Food and Drug Administration; Col. William R. Jordan, U.S.A., Retired; Ms. Elizabeth Barnett; Mrs. Mary Ray; Mr. and Mrs. William Chaffin; Mr. Vincent Ruwet; Mrs. Alice Olsen and her children, Lisa, Eric, and Nils; Lt. Gen. R. R. Taylor, Surgeon General of the Army;

Gen. Kenneth R. Dirks, Assistant Surgeon General for Research and Development of the Army and Mr. Charles D. Ablard, general counsel.

The hearing focused on the use of experimental drugs in human subjects on the part of the Department of Defense and the Central Intelligence Agency.

Commissioner Schmidt testified that a Memorandum of Agreement had been entered into by the Department of Defense and the Food and Drug Administration in April 1964, which exempted the Department of Defense from the normal procedure for the review of investigational drug use in classified tests, providing that such use was reviewed by an internal departmental review board and that periodic meetings would be held between Department of Defense representatives and representatives of the Food and Drug Administration who had security clearances, so that the Food and Drug Administration would be kept appraised of the nature and results of such tests. This Memorandum of Understanding was renewed in 1974. Commissioner Schmidt stated that there had, in fact, only been two such meetings of any substance during the 11-year period the agreement was in effect and that relative to such classified research "we have known essentially nothing about how it was conducted."

Colonel Jordan testified that he was one of a group of 34 Army officers who volunteered for an LSD test at Fort Benning, Georgia in 1960. He said that he signed a consent form and was told that there might be some transitory bizarre side effects lasting from 12-14 hours but would then return to a normal state. He said he was not told of any further possible adverse effects. He said that although he did apparently return to a normal state after the transitory effects, he subsequently experienced periods of confusion and vertigo and in December 1961 had an epileptic seizure. Colonel Jordan said that his epileptic seizure continued periodically thereafter and in 1972 he began an effort to persuade the Army to conduct followup examinations on the other men who had been on the test to determine whether any of them had experienced any long-range adverse effects. He said that after 2 years of fruitless effort culminating in a letter to the Chief of the Army, and the intervention of Senator Chiles of Florida, he finally received assurances from the Army that the followup would be conducted.

Mrs. Ray testified that she had been employed as a research assistant at the University of Minnesota Phychiatric Hospital in the early 1960's, and had assisted in LSD experiments being conducted under a grant from the Air Force. She said that she had also volunteered as a subject for an LSD test which was conducted on a Saturday without medical supervision. She said the experience was terrifying and that she contemplated suicide. Mrs. Ray said that she had experienced chronic anxiety ever since the LSD experiment.

Mr. Chaffin testified that he had volunteered for a drug test at the Edgewood Arsenal in 1958 while a member of the Air Force. He said he did not find out that he had been given LSD until the testing at Edgewood Arsenal was publicized in the summer of 1975. Both Mr. Chaffin and his wife described an incident which occurred 13 years after the test when he attempted to commit suicide but had no recollection of the event thereafter. He said that he had also experienced periods of extreme depression.

Ms. Barnett testified that her father had died in the New York Psychiatric Hospital in 1953 and that his family was told only that he had died following an overdose of a drug being given for diagnostic and/or therapeutic purposes. She said that she was not told until July 1975 that he father died as a result of a drug administered in an experimental test sponsored by the Army. She said that there was no record that her father had consented to the administration of the drug and that to the contrary, the records indicated that the drug was apparently forced upon him.

Mr. Ruwet and the Olsen family testified about the suicide of Dr. Frank Olsen in 1953 following the unwitting administration of LSD by representatives of the Central Intelligence Agency. Mrs. Olsen said that she did not learn until June 1975 that her husband had been given LSD 1 week prior to his death.

General Taylor testified that all testing of experimental drugs had been suspended by the Secretary of the Army in July 1975 pending an investigation by the Inspector General. He said that prior to the suspension, various drug studies had been ongoing at Edgewood Arsenal, as well as contracts for tests at universities and at one prison. General Dirks acknowledged that only three protocols for experimental drug research at Edgewood Arsenal were submitted for internal review in the 11-year period since the 1964 Memorandum of Agreement with the Food and Drug Administration which provided that all such protocols should be submitted.

September 12, 1975

Dr. Van Sims, chief of the medical research division of the Biomedical Laboratories at Edgewood Arsenal, Md., was the witness. He testified that experimental drug testing involving 300–400 servicemen volunteers per year had been conducted at the Edgewood Arsenal up to the suspension of testing in July 1975. He acknowledged that the consent form being used in 1975 was identical with the one signed by Colonel Jordan in 1960 that mentioned only that "certain transitory discomforts may occur," and that the form was signed only once at the beginning of the volunteers' tour of duty, rather than for each experiment.

November 7, 1975

The witnesses included Dr. Harris Isbell, formerly associated with the Narcotics Rehabilitation Center at Lexington, Ky.; James H. Childs of Washington, D.C., and Edward M. Flowers of Seabrook, Md., former inmates at Lexington; Dr. Frederick Sidell of the Edgewood Arsenal in Maryland; Dr. Edward M. Gunn, a former employee of the Central Intelligence Agency; Central Intelligence Agency officials—Carl E. Duchett, Deputy Director, Science and Technology; Dr. Sayne Stevens, Associate Deputy Director, Science and Technology; George L. Carey, Legislative Counsel and Robert Chin, Associate Legislative Counsel; and from the Department of Defense—Lt. Col. William G. Wisecup, Assistant Surgeon General for Research and Development, U.S. Army; Captain C. E. Brodine, Office of Scientific Research, U.S. Navy; Major Leo F. Jarozewski of the Air Force Surgeon General's Office.

The hearing was a continuation of the September 1975 hearing covering experimental drug testing on human subjects by the Department of Defense and the Central Intelligence Agency.

Mr. Childs and Mr. Flowers testified that while they were inmates at the Federal Narcotics Rehabilitation Center at Lexington, Ky., they were given narcotics as an incentive to participate in experimental drug testing. Dr. Isbell testified that the drug testing at Lexington had originally been sponsored by the U.S. Navy, but that the testing was subsequently, in 1953, taken over by the Central Intelligence Agency through the Navy and the National Institute of Mental Health. He acknowledged that narcotics were given to inmates as an incentive for participation in the drug experiments.

Dr. Gunn testified that he was employed in the medical office of the Central Intelligence Agency from 1955 to 1971, and that continual offers of assistance in the protection of human subjects from the medical office to the Central Intelligence Agency group performing experimental drug tests were rebuffed.

Mr. Duchett testified that the Central Intelligence Agency had "absolutely no objection whatsoever to subjecting agency activities in this field" to S. 2515. He said, "It does not interfere in any way with our current method of doing business, and therefore, we have no objection to it."

Mr. Duchett acknowledged that the Central Intelligence Agency has sponsored the drug testing at the Narcotics Rehabilitation Center at Lexington, Ky. and that the Central Intelligence Agency conducted testing of hallucenogenic drugs on unwitting subjects such as Dr. Olsen and other subjects in social situations and that there was no follow-up for adverse effects. Dr. Duchett acknowledged that such testing was wrong.

General Dirks testified that he had recommended support of S. 2515, but that the Office of Management and Budget had decided that he and the other representatives of the Department of Defense should testify in opposition to the bill.

III. Committee Views

A. Establishment of Commission

The committee has carefully reviewed and been impressed by the performance of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. It is particularly pleased that the Commission has been successful in gaining the confidence and respect of the biomedical research community.

The committee believes that the current Commission performs a vital function, one that had heretofore been inadequately performed by the Department of Health, Education, and Welfare. Furthermore, the committee is convinced that the work of the Commission is applicable to all federally funded biomedical and behavioral research programs involving human subjects. The source of research funding is not important to the subject of biomedical and behavioral research. The protection of subjects' rights, the ethics and implications of research projects are quite independent of funding source.

The committee believes there is a demonstrated need to expand the jurisdiction of the current DHEW Commission to afford equal protection for all human subjects of biomedical and behavioral research in federally-funded programs. Since this expansion would involve other departments and agencies of the executive branch, the commit-

tee believes the National Commission must be made a Presidential Commission and be removed from within the DHEW. Accordingly, the committee believes the President should appoint the members of the Commission with the advice and consent of the Senate.

It is the intent of the committee that the membership of the new Commission reflect the same diversity of expertise and background as is currently represented on the present national Commission.

Because some of the research previously conducted by Departments and agencies of the Federal Government relate to national security, the committee believes that members of the Commission should receive, prior to their appointment, security clearances from the appropriate agencies. It is the committee's intent that all federally-funded research, regardless of its level of security classification, be made available for review by the members. The committee intends that no classified information be made available until members have been cleared. Furthermore, the Committee intends that security clearances be granted before final appointment of any member.

The committee understands the importance of the development of a close working relationship between the Commission and the agencies and departments whose research it reviews. Therefore the committee has provided that representatives of the Departments of HEW and DOD, the CIA, the Science Advisor to the President, and the Veterans Administration be made ex officio, nonvoting advisors to the Commission. It is not the intent of the committee for these representatives to be active participants in the ongoing work of the Commission, but rather to act as advisors on particular subject areas and to function as liaisons between the Commission and their respective department or agency.

The committee reaffirms its belief in the importance of constantly infusing new expertise into the Commission. Thus it limits the terms of each member and staggers the expiration of those terms. The committee does not believe that service on the DHEW National Commission should in any way disqualify an individual for service on the President's ommission. Furthermore, the committee intends that the prohibition against successive terms not preclude an individual from repeated service on the Commission.

The Committee intends that the Commission be given access upon request to any and all information regarding research involving human subjects carried out with Federal funds.

B. Commission duties

It is the intent of the committee that all of the functions, powers, and duties of the current National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research be assumed and carried out by the President's Commission, and that those functions, powers, and duties be applied to all departments and agencies conducting biomedical or behavioral research on human subjects, and not just to DHEW.

In those cases where mandated activities for the DHEW Commission have already been completed, the committee does not intend for them to be repeated. It does intend that policy recommendations made to DHEW as a result of those activities be furnished to the other agencies and departments, as appropriate.

The committee believes that the requirements for publication of DHEW Commission recommendations and HEW responses to those recommendations has worked well. Accordingly, those same requirements are imposed on all agencies and departments receiving recommendations from the President's Commission.

The committee believes that the President's Commission is in a unique position to look to the future and analyze the ethical, social, and legal implications of all biomedical and behavioral research involving human subjects. The committee feels that human research subjects will benefit from the anticipation of potential problems which might result from future technological advances. The committee intends that the Commission make recommendations when appropriate to help departments or agencies to prepare for these advances and for research in these areas.

The committee is aware of the controversy surrounding past and present research involving the use of recombinant DNA. The committee believes there are profound ethical, social, legal and safety considerations involved in such research. Thus, the committee intends that the President's Commission study these issues. The committee does not imply that such research should be restricted in its current status. It does intend, however, that the members determine whether any guidelines are necessary for research in this area in order adequately to protect the human subjects of the research.

C. Special study

Sec. 479

The committee intends that the Presidential Commission carry out those aspects of section 479 which have not been completed by the current DHEW Commission.

D. Authority to publish

The committee believes that the publication of Commission reports is one of the most effective ways to generate widespread public understanding of these complex legal, social, and ethical issues. The committee believes that these reports will, in some cases, be preludes to significant policy decisions. Therefore, the committee has provided the Commission its own authority to publish reports and other materials as it deems necessary.

IV. Tabulation of Votes Cast in Committee

Pursuant to section 133(b) of the Legislative Reorganization Act of 1949, as amended, the following is a tabulation of votes in committee:

There were no rollcall votes cast in the Committee. The motion to favorably report the bill to the Senate carried unanimously by voice vote.

V. Cost Estimates Pursuant to Section 252 of the Legislative Reorganization Act of 1970

In accordance with section 252(a) of the Legislative Reorganization Act of 1970 (Public Law 91-510, 91st Congress) the committee expects that although no additional authorization is involved, supplemental appropriations may be requested as follows:

	Estimated cost		
	Millions		*Millions*
Fiscal year 1977	85	Fiscal year 1980	5
Fiscal year 1978	5	Fiscal year 1981	5
Fiscal year 1979	5		

VI. Section-by-Section Analysis

The purpose of S. 2515, as reported by the Senate Committee on Labor and Public Welfare, is to amend the Public Health Service Act to establish the President's Commission for the protection of human subjects involved in biomedical and behavioral research. (The bill re-establishes the present National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research as a Presidential Commission, and also broadens the jurisdiction and membership of that Commission.)

Short Title

Section 1 of S. 2515, as reported provides that the act may be cited as the "President's Commission for the Protection of Human Subjects of Biomedical and Behavioral Research Act of 1976".

Amendment to the Public Health Service Act

Section 2. Amends title IV of the Public Health Service Act to include a new "Part J—Protection of Human Subjects", with provisions for additional sections 477–483, summarized as follows:

Establishment of Commission

New Section 477 of the Public Health Service Act establishes a commission to be known as the President's Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (referred to as the "Commission"), and outlines the composition, qualifications, and powers of its membership. Eleven members are to be appointed by the President of the United States, selected from individuals in the fields of medicine, law, ethics, theology, the biological, physical, behavioral and social sciences, philosophy, humanities, health administration, government, and public affairs, with five members to be specifically engaged in biomedical research involving human subjects. All security clearances must be obtained for all members. Until the President makes such appointments, the members of the present National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research who are serving when this Act becomes law shall be members of the (new) Commission (provided that certain security restrictions with regard to classified information shall apply until security clearances are obtained). Terms of office for members are designated as four years, except for members filling vacancies in the middle of a term, and except for the original members, whose terms are to be staggered to allow for continuity. A Chairman and a Vice Chairman will be designated by the President of the United States. Seven members will constitute a quorum, but a lesser number may conduct hearings. Members of the Commission who are Members of Congress or other U.S. Government employees will be reimbursed for travel and expenses, without further salary compensation. Other Commission members will receive compensation in an amount not to exceed the

daily equivalent of a GS–18 pay schedule rate, as well as reimbursement for travel and expenses. Representatives of the Department of Health, Education, and Welfare, the Department of Defense, the Central Intelligence Agency, the President's Science Advisor, and the Veterans' Administration will serve as nonvoting, ex officio advisors to the Commission. Powers of the Commission include the authority to appoint and fix compensation for additional personnel as it deems advisable, to procure additional temporary or intermittent services of experts or consultants (with appropriate compensation, not to exceed the GS–18 daily equivalent salary rate), and to secure information (including classified information) directly from any department or agency to enable it to carry out its duties.

COMMISSION DUTIES

New section 478(a) of the Public Health Service Act outlines the duties of the Commission as follows:

(1)(A)(i) to conduct a comprehensive investigation and study to identify the basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human subjects:

(ii) to develop guidelines which should be followed in such research to assure that it is conducted in accordance with these principles;

(iii) to advise, consult with, and make recommendations to the appropriate agency or department responsible for such research in order to administratively apply these guidelines;

(B) The Commission is directed to consider the following in carrying out the above duties:

(i) the boundaries between biomedical or behavioral research involving human subjects and the accepted and routine practice of medicine;

(ii) the role of assessment of risk-benefit criteria in determining the appropriateness of research involving human subjects;

(iii) appropriate guidelines for the selection of human subjects to participate in the research;

(iv) the nature and definition of informed consent in various research settings; and

(v) mechanisms for evaluating and monitoring the performance of Institutional Review Boards, which are required under section 474 of the Public Health Service Act to be set up to review biomedical and behavioral research involving human subjects to protect the rights of these subjects.

(C) The commission is also directed to look at the possibility of applying its principles and guidelines to the delivery of health services to patients under department or agency programs.

(D) In accordance with its previously outlined duties under subsection (a)(1)(A) of new section 478 of the Public Health Service Act, the Commission is directed to continually review and analyze the implications described and make appropriate recommendations as necessary.

(2) The Commission is directed to identify the requirements for informed consent and to investigate the nature of the consent obtained from, and type of research performed with children, prisoners, mili-

tary personnel, and the institutionalized mentally infirm. After looking at the way such consent is obtained, the adequacy of the information given to the subjects, and the competence and freedom of the subjects to make their choice for or against involvement in the research, the Commission will make any recommendations it deems necessary to the appropriate department or agency conducting the research. This paragraph of the legislation defines the terms:

"Children" as individuals who have not attained the legal age of consent to participate in research as governed by law in the locality where the research is to be conducted;

"Prisoners" as individuals who are involuntarily confined in correctional institutions or facilities as defined in section 601 of the Omnibus Crime Control and Safe Streets Act of 1968 (43 U.S.C. 3781);

"Institutionalized mentally infirm" as individuals who are mentally ill, mentally retarded, emotionally disturbed, psychotic, or senile, or who have other impairments of a similar nature and who reside as patients in an institution; and

"Military personnel" as individuals who are active and inactive members of the United States Armed Forces and employees and agents of the Central Intelligence Agency.

(3) The Commission is directed to conduct an investigation and study of past, present, and projected research involving the modification of any living organism or virus by the insertion of recombinant DNA molecules. They are to look at the ethical, social, and legal implications of this type of research, and evaluate the potential hazards posed to research personnel, to human subjects, and to the public at large. If appropriate, the Commission is empowered by this section to develop guidelines on how such research should be conducted in order to protect human health.

Special Study

New section 479 of the Public Health Service Act directs the Commission to undertake a comprehensive study of the ethical, social, and legal implications of advances in biomedical research and technology, which is to include an analysis and evaluation of each of the following—

(*a*) scientific and technological advances in past, present, and projected biomedical and behavioral research and services;

(*b*) the implications of these advances, both for individuals and for society;

(*c*) laws and moral and ethical principles governing the use of technology in medical practice;

(*d*) public understanding of and attitudes toward these implications and laws and principles; and

(*e*) implications for public policy of such findings that are made by the Commission with respect to the above.

Administrative Provisions

New section 480 of the Public Health Service Act outlines the following administrative provisions for the Commission—

(*a*) to hold hearings, sit and act whenever and wherever necessary, take testimony, and receive evidence as it deems advisable;

(*b*) to require any department or agency to which recommendations for action have been made, to publish such recommendations in the Federal Register within sixty days of receipt, and to provide an opportunity for public response with respect to the recommendations. The department or agency shall (1) determine the appropriateness of the Commission's recommended action, and (2) if it does not feel the action to be appropriate, publish in the Federal Register this determination, together with an adequate statement in defense of the department or agency's position. If it agrees with the recommendation of the Commission, it must comply with the action as expeditiously as is feasible.

(*c*) for purposes of this new Part J of Title IV of the Public Health Service Act, "department or agency" means any department, agency, instrumentality, grantee, or contractor of the Federal Government.

Authority to Contract

New section 481 of the Public Health Service Act authorizes the Commission to contract for the study and design of mechanisms to be included in its recommendations.

Authority to Publish

New section 482 of the Public Health Service Act authorize the Commission to publish reports and other materials which it deems necessary.

Transfer of Functions

New section 483 of the Public Health Service Act transfers the functions, powers, and duties of the present National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and those of the National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research (88 Stat. 348–354) to the new President's Commission. Excepted are those duties regarding studies required under section 202 of the National Research Act (which established the original National Commission), which have already been completed and published.

Miscellaneous

Section 3. (a) Repeals part A of title II of the National Research Act (42 U.S.C. 2891).

(b) Repeals sections 211 and 213 of the National Research Act.

VII. Changes in Existing Law

In compliance with subsection (4) of rule XXIX of the Standing Rules of the Senate, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets; new matter printed in italic):

PUBLIC HEALTH SERVICE ACT, AS AMENDED

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TITLE IV—NATIONAL RESEARCH INSTITUTES

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Part J.—PROTECTION OF HUMAN SUBJECTS ESTABLISHMENT OF COMMISSION

SEC. 477 (a). There is established a Commission to be known as the President's Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (hereinafter in this title referred to as the "Commission"). The Commission shall be composed of eleven members appointed by the President of the United States with the advice and consent of the Senate. The President shall select members of the Commission from individuals distinguished in the fields of medicine, law, ethics, theology, the biological, physical, behavioral and social sciences, philosophy, humanities, health administration, government, and public affairs; but five (and not more than five) of the members of the Commission shall be individuals who are or who have been engaged in biomedical or behavioral research involving human subjects. All members shall, prior to appointment, have received all security clearances from the appropriate departments or agencies. Until such time as the President acts to appoint members of the Commission, those members of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, who are serving upon the date of enactment of this Act, are deemed members of the Commission: Provided, That no classified information be made available through a request of the Commission until appropriate security clearances be obtained by such members.

(b) The term of office of each member of the Board shall be four years; except that (1) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term; (2) the terms of office of members first taking office shall begin on the date of appointment and shall expire, as designated at the time of their appointment, four at the end of one year, four at the end of two years, and three at the end of four years; and (3) a member whose term has expired may serve until his successor has qualified.

(c) The President shall designate one of the members of the Commission as Chairman, and one as Vice Chairman. Seven members of the Commission shall constitute a quorum, but a lesser number may conduct hearings.

(d) Members of the Commission who are Members of Congress or full-time officers or employees of the United States shall serve without additional compensation but shall be reimbursed for travel, subsistence, and other necessary expenses incurred in the performance of the duties vested in the Commission. All other members of the Commission shall receive compensation at a rate to be fixed by the Commission, but not exceeding for any day (including travel time) the daily equivalent of the effective rate for Grade GS–18 of the General

Schedule while engaged in the actual performance of the duties vested in the Commission, plus reimbursement for travel subsistence and other necessary expenses incurred in the performance of such duties.

(e) The Commission shall meet at the call of the Chairman or at the call of a majority of the members thereof.

(f) Representatives of the Department of Health, Education, and Welfare, the Department of Defense, the Central Intelligence Agency, the Science Advisor to the President, and the Veterans' Administration shall serve as non-voting, ex officio advisors to the Commission.

(g)(1) The Commission shall have the power to appoint and fix the compensation of such personnel as it deems advisable, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and the provisions of chapter 51 and subchapter III of chapter 53 of such title, relating to classification and General Schedule pay rates.

(2) The Commission may procure, in accordance with the provisions of section 3109 of title 5, United States Code, the temporary or intermittent services of experts or consultants. Persons so employed shall receive compensation at a rate to be fixed by the Commission, but not exceeding for any day (including travel-time) the daily equivalent of the effective rate for Grade GS–18 of the General Schedule. While away from his home or regular place of business in the performance of services for the Commission, any such person may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703(b) of title 5, United States Code, for persons in the government service employed intermittently.

(h) The Commission may secure directly from any department or agency information necessary to enable it to carry out its duties. Upon request of the Chairman of the Commission, each department or agency shall furnish all information requested by the Commission which is necessary to enable the Commission to carry out its duties. For purposes of this part, the term "information" includes any information which is deemed to be classified for any purpose (including national security) by such agency or department.

Commission Duties

Sec. 478. (a) The Commission shall carry out the following:

(1)(A) The Commission shall (i) conduct a comprehensive investigation and study to identify the basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human subjects, (ii) develop guidelines which should be followed in such research to assure that it is conducted in accordance with such principles, and (iii) advise, consult with, and make recommendations to the appropriate agency or department for such administrative action as may be appropriate to apply such guidelines to biomedical and behavioral research conducted or supported under programs administered by the appropriate agency or department, and concerning any other matter pertaining to the protection of human subjects of biomedical and behavioral research.

(B) In carrying out subparagraph (A), the Commission shall consider at least the following:

(i) The boundaries between biomedical or behavioral research involving human subjects and the accepted and routine practice of medicine.

(ii) The role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects.

(iii) Appropriate guidelines for the selection of human subjects for participation in biomedical and behavioral research.

(iv) The nature and definition of informed consent in various research settings.

(v) Mechanisms for evaluating and monitoring the performance of Institutional Review Boards established in accordance with section 474 of this Act and appropriate enforcement mechanisms for carrying out their decisions.

(C) The Commission shall consider the appropriateness of applying the principles and guidelines identified and developed under subparagraph (A) to the delivery of health services to patients under programs conducted or supported by any department or agency.

(D) The Commission shall continually review and analyze the ethical, social, and legal implications of all biomedical and behavioral research on human subjects conducted by and through any department or agency, and shall make appropriate recommendations for the protection of human subjects of biomedical and behavioral research to such department or agency.

(2) The Commission shall identify the requirements for informed consent to participation in biomedical and behavioral research by children, prisoners, military personnel and the institutionalized mentally infirm. The Commission shall investigate and study biomedical and behavioral research conducted or supported under programs of any department or agency and involving children, prisoners, military personnel, and the institutionalized mentally infirm to determine the nature of the consent obtained from such persons or their legal representatives before such persons were involved in such research; the adequacy of the information given them respecting the nature and purpose of the research, procedures to be used, risks and discomforts, anticipated benefits from the research, and other matters necessary for informed consent; and the competence and the freedom of the persons to make a choice for or against involvement in such research. On the basis of such investigation and study, the Commission shall make such recommendations to any department or agency as it determines appropriate to assure that biomedical and behavioral research conducted by or supported under the appropriate department or agency meets the requirements respecting informed consent identified by the Commission. For purposes of this paragraph, the term "children" means individuals who have not attained the legal age of consent to participate in research as determined under the applicable law of the jurisdiction in which the research is to be conducted; the term "prisoner" means individuals involuntarily confined in correctional institutions or facilities as defined in section 601 of the Omnibus Crime Control and Safe Streets Act of 1968 (43 U.S.C. 3781); and the term "institutionalized mentally infirm" includes individuals who are mentally ill, mentally retarded, emotionally disturbed, psychotic, or senile, or who have other impairments of a similar nature and who reside as patients in an institution; the term "military personnel" means individuals who are active and in-

active members of the United States Armed Forces and employees and agents of the Central Intelligence Agency.

(3) The Commission shall conduct an investigation and study of past, present and projected research in the modification of any living organism or virus by the insertion of recombinant DNA molecules. The Commission shall consider the ethical, social, and legal implications of such research, and evaluate the potential hazards posed by such research both to research personnel, the human subjects of such research, and to the public at large. The Commission shall, if appropriate, develop guidelines on how such research should be carried out in order to protect human health.

SPECIAL STUDY

SEC. 479. The Commission shall undertake a comprehensive study of the ethical, social, and legal implications of advances in biomedical and behavioral research and technology. Such study shall include—

(a) an analysis and evaluation of scientific and technological advances in past, present, and projected biomedical and behavioral research and services;

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

(c) an analysis and evaluation of laws and moral and ethical principles governing the use of technology in medical practice;

(d) an analysis and evaluation of public understanding of and attitudes toward such implications and laws and principles; and

(e) an analysis and evaluation of implications for public policy of such findings as are made by the Commission with respect to advances in biomedical and behavioral research and technology and public attitudes toward such advances.

ADMINISTRATIVE PROVISIONS

SEC. 480 (a). The Commission may for the purpose of carrying out its duties hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Commission deems advisable.

(b) Within sixty days of the receipt of any recommendation made by the Commission under this Part, the appropriate department or agency shall publish it in the Federal Register and provide opportunity for interested persons to submit written data, views, and arguments with respect to such recommendation. The appropriate department or agency shall (1) determine whether the administrative action proposed by such recommendation is appropriate to assure the protection of human subjects of biomedical and behavioral research conducted or supported under programs administered by it, and (2) if it determines that such action is not so appropriate, publish in the Federal Register such determination together with an adequate statement of the reasons for its determination. If the appropriate department or agency determines that administrative action recommended by the Commission should be undertaken by it, it shall undertake such action as expeditiously as is feasible.

(c) For purposes of sections 477, 478, and 480 of this Act, the term "department or agency" means any department, agency, instrumentality, grantee, or contractor of the Federal Government.

AUTHORITY TO CONTRACT

SEC. 481. The Commission may contract for the study and design of mechanisms to be included in such recommendations.

AUTHORITY TO PUBLISH

SEC. 482. The Commission shall have the authority to publish reports and other material which it deems necessary.

TRANSFER OF FUNCTIONS

SEC. 483. The functions, powers, and duties of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and those of the National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research (88 Stat. 348–354) are transferred (except those duties regarding studies required under section 202 of the National Research Act which have been completed and published) to the Commission.

MISCELLANEOUS

SEC. 3 (a) Part A of title II of the National Research Act (42 U.S.C. 2891) is repealed.

(b) Sections 211 and 213 of the National Research Act are repealed.

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