Friday
May 25, 1979

Part X

Department of Health, Education, and Welfare

Office of the Secretary

Protection of Human Subjects of Biomedical and Behavioral Research

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary

Protection of Human Subjects of Biomedical and Behavioral Research

AGENCY: Department of Health, Education, and Welfare.

ACTION: Notice of Report and Recommendations for Public Comments.

SUMMARY: On July 12, 1974, the National Research Act (Pub. L. 93–348) was signed into law, thereby creating the National Commission for the Protection of human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to conduct a "special study" of the ethical, social and legal implications of advances in biomedical and behavioral research and technology. In discharging its duties under this mandate, the Commission: contracted for the conduct of an iterative policy study involving a national panel of consultants; contracted for a national opinion survey to serve as an adjunct to the policy study; and sponsored a four-day colloquium of 25 scientists and scholars. The Special Study addresses the implications of advances in biomedical and behavioral research and recommends the establishment of an advisory commission to anticipate the probable effects of research and technological advances for individuals and society, and to stimulate public participation in decisionmaking. The published copy of the report which includes the supporting documents assembled by the Commission is available as DHEW Publication No. (OS) 78–0015, for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

DATES: The Secretary invites comment on the Special study. The Comment period will close August 23, 1979.

ADDRESS: Please send comments or requests for additional information to: F. William Dommel, Jr., J.D., Assistant Director for Regulations, Office for Protection from Research Risks, National Institutes of Health, 5333 Westbard Avenue, Room 303, Bethesda, Maryland 20205, Telephone: (301) 496–7005, where all comments received will be available for inspection weekdays (Federal holidays excepted) between the hours of 9 a.m. and 4:30 p.m.

Dated: March 30, l979,

Charles Miller,

Acting Assistant Secretary for Health.

Approved: May 17, 1979.

Hale Champion,

Acting Secretary.

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

Members of the Commission

Kenneth John Ryan, M.D., Chairman, Chief of Staff, Boston Hospital for Women.
Joseph V. Brady, Ph.D., professor of behavioral biology, Johns Hopkins University.
Robert E. Cooke, M.D., president, Medical College of Pennsylvania.
Dorothy I. Height, president, National Council of Negro Women, Inc.
Albert R. Jonsen, Ph.D., associate professor of bioethics, University of California at San Francisco.
Patricia King, J.D., associate professor of law, Georgetown University Law Center.
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National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Commission Staff

Professional Staff.—Michael S. Yesley, J.D., staff director: Barbara Mishkin, M.A., assistant staff director; Duane Alexander, M.D., pediatrics; Tom L. Beauchamp, Ph.D., philosophy; Bradford H. Grey, Ph.D., sociology; Miriam Kelty, Ph.D., psychology; Betsy Singer, public information officer; Dorle Vawter, research assistant.
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Table of Contents

Special Study

Implications of Advances in Biomedical and Behavioral Research

I. The Mandate

The National Commission for the Protection of Human Subjects was directed under section 203 of Public Law 93–348 to conduct a "special study" of the ethical, social and legal implications of advances in biomedical and behavioral research and technology. The issues reflected in the special study go beck at least to 1945 (the year of Hiroshima) and have continued to develop in significant ways since Public Law 93–348 was enacted in July 1974. Since the last century, but most markedly from the time of World War II, advances in science and technology have been influencing the character of social and individual life. Such advances have created problems not only on account of their immediate consequences, but also because of their side effects. Questions have been raised regarding issues that range from "tampering with nature" to invasion of privacy. In addition, the complexity of scientific and technological issues has placed a strain on governmental machinery, most notably in democratic societies and nations where public participation and understanding have important roles to play in the formation of policy. In addressing section 203, accordingly, the immediate problems of biomedical and behavioral research and technology must be considered in relation to broader aspects of social change and public policy.

The recognition by then Senator Walter Mondale that the impact of biomedical and behavioral science and technology was more widespread and had given rise to more public disquiet than had been properly appreciated led him to sponsor S.J. Res. 145 in 1968 and S.J. Res. 75 in 1971, resolutions from which section 203 of Public Law 93–348 was derived. Similar considerations were responsible for a series of additional steps and inquiries in the government and elsewhere during the 1970's.

In the Congress, the Office of Technology Assessment, established in 1972, has conducted inquiries into the impact of certain innovations in medical technology and services. Related areas have been studied by other divisions of Congress, including the staffs of the relevant House and Senate subcommittees, the General Accounting Office, and the Congressional Clearinghouse on the Future in the Legislative Reference of the Library of Congress.

At the National Academy of Sciences, the Academy of Engineering and the Institute of Medicine have studied the medical and nonmedical impacts of some innovations. Within DHEW, an Office of Health Technology has recently been established to coordinate

analysis and testing by agencies of efficacy and safety, cost effectiveness, and standards of development for new and existing technologies, and to assist in determining which intervention mechanisms should be used to promote, inhibit or control the development and use of technologies. The National Institutes of Health has established an Office for the Medical Applications of Technology and has also been seeking to extend the roles of the National Advisory Councils to enlarge the contribution of public representatives to the development of research policies and priorities. The establishment of local Professional Standards Review Organizations and Health Systems Agencies provides new mechanisms for involving members of the professional community and lay public in monitoring the health care delivery system, including such new technologies as computerized tomography. The Bureau of Health Planning and Resources Development is sponsoring a study, mandated by Public Law 93–641, on technological advances in health and planning.

Similarly the reintroduction of science policy advisers into the Executive Office of the President, through the creation of the Office for Science and Technology Policy in 1976, could play a part in the development of public policies in the area of section 203.

Each of these assessment activities has its own goal, and none of them attends exclusively and explicitly to the ethical, social and legal implications of advances in technology. While the various mechanisms have been performing in their own spheres, there has been a demonstrable increase in interest in careful review of the implications of new technologies.

The most striking episode to take place in the area of the Special Study since the enactment of Public Law 93–348 has been controversy over recombinant DNA research. The broad concern over such research was almost totally unforeseen, even by the scientists most closely involved. This controversy demonstrated the range and depth of public disquiet and political feeling that can be aroused by the prospect of seemingly drastic new biomedical or behavioral influences on society originating in branches of science too technical for the public to understand. Whether or not, in fact, recombinant DNA research involves so grave a threat to the public health as some participants have maintained, the debate has made it clear that a better system of early warning and monitoring is required. Novel developments likely to result from projected biomedical and behavioral research should be identified and assessed systemically before they arouse public alarm and political passions.

II. Activities Sponsored by the Commission

A request for proposals, which reiterated the language of section 203, was published in the *Commerce Business Daily* in February 1975. Proposals received were evaluated by a technical review panel which recommended that a contract be awarded jointly to Policy Research Incorporated and the New Jersey Institute of Technology (PRI/NJIT) to conduct and iterative policy study involving a national panel of consultants. Two other projects were implemented simultaneously. One was a national opinion survey to serve as an adjunct to the policy study. The other, recommended by the technical review panel as an alternative approach to the mandate, was a four-day colloquium of twenty-five scientists and scholars. A core group of the participants prepared a report of the colloquium.

The reports to the Commission that resulted from these different projects (reprinted in the Appendix of this statement) involved very different approaches to the special study. The PRI/NJIT policy study used a dynamic communication technique designed to analyze value-laden policy-related content. It consisted of a structured, iterative inquiry mailed to and completed by 121 consultant panelists between February and August 1976. Each successive inquiry instrument was based on responses to the preceding one. Panelists were thus provided feedback and were able to compare and contrast their own views with those of others. The study design relied heavily on a policy Delphi technique that sought to synthesize divergent positions advocated by respondents. Anonymity was protected, panelists had the opportunity to modify their positions, and different positions on issues were presented. Five subject areas were selected with the expectation that advances in those areas would generate a broad range of ethical, legal and social concerns during the next twenty years.

The national opinion survey was designed to elicit public attitudes toward advances in biomedical and behavioral research technology and alternative policies to deal with them. A structured questionnaire was administered to a random sample of 1,679 noninstitutionalized adults in the continental U.S. A parallel version of the questionnaire was administered to the Delphi panelists, and the responses of the public and the panel were compared and contrasted.

The colloquium developed an historical and sociological perspective on recent advances in biomedical and behavioral research and services using a case study method. The social impact of advances was explored, as were existing legal and institutional constraints and incentives governing the introduction of new technologies into medical practice. In addition, current knowledge about the public's understanding of and attitudes toward advances and their implications was reviewed.

In general, these different approaches yielded similar results. The immediate consequences of the scientific and technological advances in biomedical and behavioral research and services since World War II are perceived, for the most part, as beneficial by professionals and the lay public. Neither group fears that the scale and character of the advances to be expected over the next few decades will change so drastically as to invalidate this optimistic assessment. Some of the anxieties expressed in the legislative hearings on the original Mondale resolution, and more recently in the recombinant DNA debate, appeared to both groups of the Commission's respondents to have been exaggerated; If immediate action is called for at the present time, both groups agreed, it will chiefly be to create new institutions to monitor the development and introduction of new technologies in the biomedical and behavioral fields, and to draw the attention of legislatures and the public to social problems arising from the use of these new technologies.

Some of these resulting social problems are already apparent, and the kinds of measures required to deal with them are discussed below. But it is probably worth underlining that, among all of the Commission's respondents, no significant body of opinion emerged that was opposed to continuation of the scientific and technological research that has led to so many innovations since 1945. Still less was there significant support for anything resembling a moritorium on biomedical and behavioral research. On the contrary, there was widespread consensus that, for the foreseeable future as for the past, the advantages flowing from such research will continue to outweigh the incidental problems resulting from them.

III. Findings with Implications for Public Policy

Several broad findings may be derived From the policy study, public opinion survey and the report of the colloquium sponsored by the Commission that are generally consistent with other literature addressing similar problem areas.

1. Today most Americans view scientific advances and technological innovations positively. However, there is growing recognition among the public, the scientific community and government officials that societal problems are increasingly complex and that the application of advances and innovations in biomedical and behavioral research and technology should take into account not only scientific and technological factors, but also their social context and the extent to which society can accommodate these advances.

2. Value conflicts are an inevitable consequence of the tensions in a pluralistic society between competing commitment to personal freedom and social responsibility, privacy and the public need for information, and the degree to which citizens should be protected by government. Behind these diverse concerns lie quite different views of the human image, of the nature of state authority, and of the form of the public welfare. The ethical concerns raised by advances in biomedical and behavioral techology reflect not only the novelty of these advances, but the deeper uncertainty and diversity of social values. Any public policy about these advances must respect the plurality of social values. Solutions which are reached in a democratic manner must genuinely protect the welfare of individuals and communities.

3. Situations in which the introduction of new technology could be of considerable benefit to some individuals, but only at the expense of others, create problems of equity. Often technological innovations are initially available only at high cost due to the expense of development and the apparatus involved. If public funds are used to make these new technologies available, decisions must be made regarding which individuals should benefit, and how to allocate benefits when resources are limited. There is a need to address the problem of equity of access to the benefits of innovations and the problems suurounding the allocation of limited resources.

4. The lack of understanding of the details of scientific developments and the feeling that decisions are made by depersonalized government agencies lead to an erosion of trust by the public. Research activities, including funding mechanisms, should be accessible to the public to enhance general understanding of developing knowledge. Mechanisms should be developed both to educate the general public and to encourage its participation in making value decisions. Scientists should be sensitive to concerns of the general public.

5. There is a recognition that the introduction of new technologies may have unanticipated and unwanted side effects detrimental to the health of individuals, and the mechanism need to be developed to protect against such hazards. There should be an early warning system in which there is an assessment of potential secondary impacts prior to the dissemination of new technologies. The results of such technological assessments should be widely available to the public to provide a knowledge base for decision-making and to enhance public pariticipation in the development of policy.

IV. Recommendations

The Commission's findings that have implications for public policy cluster in two areas: one set of findings indicate a perceived need for a program to assess the social impact of technology. The second suggests a need to facilitate public information and public participation in research and technological innovations and the policy decisions that result. These findings suggest that a mechanism should be established to monitor and evaluate innovations and to provide an early warning system in which the probable effects of innovations in biomedical and behavioral research and technology can be assessed publicly, prior to development of widespread dissemination. The existing entities referred to previously serve narrower constituencies and goals, and the independence and broader mandate of a new body are needed.

The establishment of a mechanism to encourage public participation in policy formulation was of special concern to Mr. Mondale who, during legislative hearings on the resolution to establish a Commission on Health Science and Society in 1971, said that studies of advances and their implications should be incorporated into a public process by which society might express its right to say something about its own future: "The public's stake is too great. And the need for consensus as to how society should deal with these profound problems is too clear. . . I think we need something far more official and far more public if we are to reach agreement on the ways in which society is to organize itself to handle these unprecedented problems."

The National Commission for the Protection of Human Subjects recommends, as have Mr. Mondale and Senator Kennedy, that an advisory commission be employed to anticipate the probable effects of research and technological advances for individuals and society, and to stimulate public participation in decision making. A commission with diverse memebership, independent of control by any government agency or private institution, would be able to examine issues without the customary institutional and political constraints. The commission should not be dominated by health professionals, for its main purpose would be to facilitate widespread debate involving all segments of society in the ethical and policy issues that affect all people and about which diverse views should be heard. The commission would be able to clarify many issues and foster better understanding by the public and by those directly involved in decision making. It would not itself decide issues but rather help society to decide who should decide them and to explore the implications of various decisions that may ensue.

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