Special Study

Implications of Advances in Biomedical and Behavioral Research

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

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

Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

September 30, 1978

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

On behalf of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, I am pleased to transmit our report on the "Special Study: Implications of Advances in Biomedical and Behavioral Research." This is one of several studies that the Commission was directed to undertake in its mandate under Public Law 93-348, which also directs the Commission to submit its reports to the President, the Congress, and the Secretary of Health, Education, and Welfare.

Of all the topics assigned to the Commission, the Special Study was the most far-ranging; however, because of constraints of time and other responsibilities, the Commission was forced to deal with this topic in great generality. More specific results would have been obtained from a more specific assignment, such as the ethical, social and legal implications of a particular advance in technology. Although we provide only general conclusions in the Special Study, the success of the Comission in other areas of its mandate is evidence of the usefulness of a commission in developing advice in response to a specific assignment.

Thus, the Commission itself is a demonstration of the validity of its conclusion in the Special Study that an advisory commission should be established to anticipate the probable effects of research and technological advances and to stimulate public participation in the decision making. We hope that our report and the accompanying documents that were prepared under contract to the Commission will assist the present debate on the need to establish a successor advisory commission.

We appreciate the opportunity to have worked on this topic of great importance to the nation.

Respectfully,

Kenneth J. Ryan, M.D.
Chairman

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

Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

September 30, 1978

The Honorable Walter F. Mondale
President of the United States Senate
Washington, D.C. 20510

Dear Mr. President:

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Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

September 30, 1978

The Honorable Thomas P. O'Neill, Jr.
Speaker of the House of Representatives
Washington, D.C. 20515

Dear Mr. Speaker:

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Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

September 30, 1978

Honorable Joseph A. Califano, Jr.
Secretary of Health, Education, and Welfare
Washington, D.C. 20201

Dear Mr. Secretary:

On behalf of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, I am pleased to transmit our report on the "Special Study: Implications of Advances in Biomedical and Behavioral Research." This is one of several studies that the Commission was directed to undertake in its mandate under Public Law 93-348, which also directs the Commission to submit its reports to the President, the Congress, and the Secretary of Health, Education, and Welfare.

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Respectfully,

Kenneth J. Ryan, M.D.
Chairman

NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

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APPENDIX B:

Scholarly Adjunct

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 back 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 1970s.

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 the 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 Service 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 determing which intervention mechnisms 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 establishement 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 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 systematically 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 an 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 to 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 questionaire 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 committment 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 technology 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 surrounding 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 agencie 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 that mechanisms 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 participation 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 indicates 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 or 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 membership, 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.

APPENDIX A

A COMPREHENSIVE STUDY OF THE ETHICAL, LEGAL, AND SOCIAL IMPLICATIONS OF ADVANCES IN BIOMEDICAL AND BEHAVIORAL RESEARCH AND TECHNOLOGY

FINAL REPORT

July 1977

Policy Research Incorporated
2500 North Charles Street
Baltimore, Maryland 21218

Center for Technology Assessment
New Jersey Institute of Technology
323 High Street
Newark, New Jersey 07102

Contract No. NO1-HU-6-2105

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PREFACE

This special study was mandated by the U.S. Congress under Section 203 of PL 93-348, The National Research Act. It was conducted under contract N01-HU-6-2105 for the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The study began in September 1975 and was completed in January 1977.

Study Purpose and Methods

The major purpose of the study was to analyze and evaluate:

* the implications of advances in biomedical and behavioral research and technology;
* the implications of policies to deal with such research and the implementation of resultant technologies; and
* public understanding and attitude toward these matters.

The special study consisted of two components: (1) a policy study; and (2) a national opinion survey, an adjunct to the policy study suggested by the study's designers as necessary to meet the Congressional mandate.

Contents, Layout of the Report

This report contains the findings of the policy study and the national opinion survey, and the study conclusions. A complete list of the study products is shown at the end of the Preface.

This report consists of six chapters, and six appendices. A detailed table of contents has been provided to allow readers to find sections of particular interest. All tables, graphs, and other figures have been placed at the end of each chapter to avoid interrupting the text, and to facilitate locating them. Throughout the report titles of subject areas, advances, scen-

arios, and effects of advances have been italicized for the convenience of the reader.

Insofar as possible, a common layout has been adopted for each chapter and each chapter has been divided into several distinct sections. The content of each chapter is summarized below.

Chapter 1, *Introduction, Summary, and Conclusions*, provides a context for the study, describes the mandate, and summarizes the study methods and findings. Conclusions about advances and policies are also presented. This chapter has been circulated widely as a separate document to people who want only an appreciation of the study.

The next two chapters deal with advances in biomedical and behavioral research and technology, and their implications. Chapter 2, *Advances*, outlines the methods used to select the subject areas for the study, develop the advances for each subject area, and identify the implications of advances. Findings are reported, by subject area, according to a common outline: (1) the particular advances that were considered in a subject area are listed; (2) the pertinent findings are described, including the dimensions that underlay panelists' responses; and (3) a brief analysis and evaluation of the findings is presented.

Chapter 3, *Implications of Advances*, addresses the implications of advances more broadly, assessing the manner in which biomedical and behavioral advances will influence individuals and society. This chapter is divided into three sections,

prefaced by a brief methodological note. These sections are: implications for individuals, implications for society, and moral and ethical issues.

Chapters 4 and 5 deal with policies which might be implemented to control or direct biomedical and behavioral research and the implementation of resultant technologies, and the implications of these policies. Chapter 4, *Policies*, reviews the methods used to identify policies for specific advances, general policy statements, and a possible comprehensive national policy, and presents the study findings. As in earlier chapters, the findings are presented in a common outline consisting of a section on findings and a subsequent analysis and evaluation.

Chapter 5, *Implications of Policies*, provides a brief methodological note as an introduction to a general discussion of the implications of possible comprehensive national policy for biomedical and behavioral research and technology. This chapter deals with the implications of policies under five headings: need for controls; the role of government; justice; economic factors; and public participation.

Chapter 6, the final chapter is on *Public Understanding and Attitude*. This chapter reports the findings of the national opinion survey and compares and contrasts panelists' responses to questionnaire items with those of the public. The format for this chapter parallels that for earlier chapters on advances and policies; findings are followed by a brief analysis and evaluation.

Assessment of the Study Method

In an area in which a person's view of "what is" merges subtly with "what should be", the process used to carry out a study to assess technological advancement may be as important as findings that result from that process. At present, there are no standard methods for systematically assessing technologies, the implications of technologies, or the implications of policies designed to regulate the development and implementation of technologies. Consequently, this study itself may be viewed as an innovation. Its novel features included: adversary assessments, two opposed groups arguing the pros and cons of their position; an assessment of the negative consequences that would result from implementing a policy one dislikes; and asking both experts and the general public the same questions, and comparing the results.

The dynamic communication technique developed by Policy Research Incorporated lent itself well to this endeavor. By using a series of three instruments, the study team was able to produce pro and contra arguments which form the basis of various policy alternatives, resource allocation alternatives, outcomes, impacts and effects. The anonymity of the participants was protected, and each panelist was given a chance to modify his or her positions. The method allowed for the presentation of a number of different positions on issues and handled even intense disagreement without polemic.

Based on the results of this study, it would seem fruitful to apply this dynamic communication technique to other complex, ill-structured, and value-laden areas of national policy. In addition, the results of this study would suggest that a national

survey of public opinion is a valuable adjunct to any policy study. By comparing and contrasting the views of experts with those of the general public similarities and differences in opinions and values between experts and public can be identified, providing the policy-maker with more complete information with which to make decisions.

Development of the Study Findings

The policy study which forms the central part of the special study used an iterative approach with a series of three Policy Evaluation Instruments (PEIs). These instruments were used to collect information about specific advances in biomedical and behavioral research and technology and about policies to deal with these advances. Using this method massive amounts of data were generated. The verbatim transcripts of panelists' responses to the PEIs amount to literally millions of words. The summaries of these responses alone total well over 1,000 pages. This report represents a distillation of those responses.

The study findings -- the analyses and evaluations of advances, policies, and their implications -- presented in this report represent the opinions of the 121 consultant panelists who completed PEIs, and the opinions of a probability sample of 1,679 Americans who responded to the national opinion survey. The findings of the study do not necessarily represent the views of the Study Design and Management Group, or of other members of the study team, or those of the Commission. Our purpose has been to report accurately the points of view expressed by the panel and the public. In the design and conduct of the study we

have gone to considerable lengths to insure that what is reported accurately reflects what was said.

Finally, the conclusions presented in this report are based solely on the study findings. We are, of course, responsible for these conclusions.

Cautions to the Reader

We would like to offer two cautions to readers of this report. First, the PEIs were deliberately constructed to provoke debate on issues which are heavily value-laden. This fact is reflected in the diversity of opinions expressed by panelists, and described in this report. Readers of this report, like panelists, may sometimes find themselves caught up in the debate, agreeing with one perspective or disagreeing with another. While we trust that this sense of participation will enliven the report, we also trust that readers will remember that the report describes the diversity of opinions expressed by panelists, and not positions or views advocated or subscribed to by study staff.

The second caution relates to the generalizability of certain results. It is possible to generalize with some confidence the results of the national opinion survey what Americans think about a particular issue, since the survey respondents represented a probability sample of the non-institutionalized adult population of the continental United States. However, much greater caution should be exercised in generalizing from the responses of categories of panelists, such as social scientists, how all members of that category would respond to a particular issue. Panelists were selected for their expertise and interest in the study subject, and each panelist categorized

him/herself as either an ethicist, lawyer, medical scientist, representative of the public interest, or social scientist. The only purpose of comparing the responses of panelists in one category with those in another was to explore fundamental differences of opinion within the panel itself.

Acknowledgements

We would like to thank everyone who particpated in this study: our colleagues on the Study Design and Management Group; its consultants, the other consultants to the study, the study coordinating staff; the study administrative staff; the 121 consultant panelists, particularly those who undertook additional assignments; the 1679 Americans who consented to be interviewed in the national opinion survey, the staff of Louis Harris and Associates, Inc. who administered the survey questionnaire and the staff of Hollander, Cohen Associates, Inc. who pretested it; and the staff of the Commission and the Commissioners themselves.

The following members of the study team deserve special mention. They are: Prakash Grover and John Williamson, who diligently reviewed all study instruments and reports; Bruce Sanders and Ken Dane, who assisted in drafting this report and the summaries of responses to the three PEIs; Kathy Crouch, Skip Locks, and Beverly Randall who typed the study instruments and reports; and Miriam Kelty, the Project Monitor, who provided assistance at every stage of the study.

Study Products

The following ten volumes of material pertinent to this study are available.

Summary of the Final Report. This volume is a concise summary of the study purpose, methods, principal findings, and conclusions. (32 pages)

The Final Report. This volume describes the need for the study, the study purpose, methods, findings, and conclusions. (298 pages)

Policy Evaluation Instrument - 1. The first PEI sent to consultant panelists for completion. (206 pages)

Summary of responses to the first Policy Evaluation Instrument. This volume summarizes: the implications of the 15 advances examined (three in each of the five subject areas), and the appropriate policies to respond to them; the advances added by panelists; the implications underlying resolution of the six scenarios considered; the the policies that would be helpful in resolving issues of the type depicted. (402 pages)

Policy Evaluation Instrument - 2. The second PEI sent to consultant panelists for completion. (250 pages)

Summary of responses to the second Policy Evaluation Instrument. This volume summarizes: the negative consequences of implementing the research and implementation policy least liked by panelists with respect to five advances carried forward from the first PEI, and the ameliorative policies suggested if the least liked policy were implemented; panelists' elaborations of 23 general policy statements listed; and a summary of those urgent policies added by panelists. (272 pages)

Policy Evaluation Instrument - 3. The third PEI sent to consultant panelists for completion. (288 pages)

Summary of responses to the third Policy Evaluation Instrument. This volume summarizes: the positive and negative conseqeunces of implementing the possible national policy described in four policy scenarios, the barriers to implementation and ways of overcoming them, and amendments offered to the particular policies that comprise the scenarios; appropriate resource allocations to health, health R&D, and types of health R&D; and panelists' responses to the national opinion survey questions. (414 pages)

Dateline 1999. This volume provides alternative futures depicted in the form of newspaper stories written by panelists who responded to the third PEI. Panelists were asked to write two brief newspaper stories that might be filed by a science reporter in 1999: (1) if existing policies with respect to biomedical and behavioral research and technology continued to operate unchanged until that time; and (2) if the policies described in the third PEI's four policy scenarios were implemented in the late 1970s. (90 pages)

National Opinion Survey. This volume contains the schedule of questions administered to a probability sample of 1,679 Americans in individual face-to-face interviews -- the national opinion survey. It also contains the report of survey results prepared especially in behalf of those respondents who requested a copy of the survey results. (18 pages)

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Principal Investigator

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President

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Chapter 1: Introduction, Summary, and Conclusions.

THE NEED FOR THIS SPECIAL STUDY

The gap between science fiction and science fact has narrowed steadily during the past several decades. It is, or soon will be within our power to transplant vital organs safely and routinely; to use computers to monitor and control organs or organ replacements; to detect defective fetuses in the womb; to select the sex of our children; and to control the behavior of vast portions of the population by means of drugs.

These are only a few of the more visible advances in the biomedical and behavioral fields. All of these advances, both existing and dreamed of, have been featured in the popular media in the past decade, and all have been brought into the realm of possibility by accelerated progress in technology over the past twenty years.

Progress in Medical Technology

Our present medical technology, of course, is a product of a century or more of steady progress in disease control. Technology available to physicians increased considerably after Koch first demonstrated unequivocally that specific organisms cause certain diseases (1876); after Erhlich made chemotherapy a practical proposition (1909); after Fleming discovered penicillin (1928); and after penicillin and other antibiotics were made available in general medical practice just over 25 years ago.

These scientific developments were achieved against infectious diseases, those caused by specific organisms. Not all of these organisms have yielded, however. Influenza and other varieties of viruses sweep the nation each winter. The common

cold remains something of a medical mystery, despite astonishing advances against other, apparently more complex diseases. And, our progress in preventing, treating or managing the diseases that have emerged as the leading causes of death -- heart disease and cancer -- has not been spectacular. Increasingly, we have recognized that many diseases are related to environmental factors, social patterns, lifestyle, and personal habits.

Effects of Medical Technology

Advances in the biomedical and behavioral sciences can, and often do, have effects other than those related to health. They can alter our concepts about ourselves, our values, and the ways we behave. Many of them, the "pill", for example, have had as much impact on society as they have had on individual health. Others have raised sharp questions of ethics and morals: what is fair and what is not; who shall live and who shall die; and what segments of our society can afford or have access to life-saving technologies. New medical technologies, in general, have sharpened the issues of how health care ought to be provided and how new technologies should be distributed. Crucial questions are posed; questions that, while not always totally answerable, at least require urgent attention by government, the law, the medical industry, and medical and behavioral scientists themselves.

STUDY MANDATE AND METHODS

Legislative Mandate for the Study

In 1974, the U.S. Congress enacted the National Research Act, PL 93-348. Part of this act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the Commission). Section 203 of the Act mandated the special study which is the subject of this report. Section 203 of PL 93-348 states "such Study shall include --

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

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

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

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

(5) 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.

In addition, the Request for Proposals to undertake the study noted that one should be particularly cognizant of the "implications of biomedical and behavioral scientific and technological advances for ethnic, racial, and economic minorities."

Policy Research Incorporated and the Center for Technology Assessment of the New Jersey Institute of Technology were awarded a contract to conduct the special study. The special study consisted of two components, designed to respond to the mandate. They were: a policy study involving a national panel

of 121 experts in the subject of the study; and a national opinion survey, an adjunct to the policy study suggested by the study's designers as necessary to meet the Congressional mandate. The study was designed and managed by an eight member Study Design and Management Group. The study began in September, 1975 and was completed in January, 1977.

Policy Study

The policy study used a dynamic communications technique specifically designed to analyze complex, value-laden, policy related subjects. It was a structured, iterative inquiry carried out through the medium of three Policy Evaluation Instruments (PEIs) mailed to and completed independently by 121 members of a consultant panel between February and August, 1976. Each PEI after the first was developed on the basis of previous responses, and was accompanied by material summarizing responses from the preceding instrument, establishing a dynamic process in which panelists were able to compare and contrast their own views with those of others.

Selection of the Panel

In order to insure the representation of a variety of views, the panel was drawn from the following five broad categories:

* ethicists, philosophers, and religious leaders;
* lawyers and members of the judiciary;
* medical scientists and persons in related fields;
* representatives of the public interest, elected and appointed officials and members of special interest groups; and
* social scientists.

Nominations to the panel were obtained from project staff and consultants, the staff of the Commission, chairpersons and

ranking minority members of seven Congressional Committees and Subcommittees relevant to the subject of the study, and from panelists themselves. Biographical information was gathered for all nominated persons and reviewed independently by four project staff members. Final selection of panelists was made in a number of discrete waves from the pool of nominees felt to be appropriately qualified by reviewers. Qualified persons were selected so as to insure representation on the part of minorities and women and so that panelists were drawn from all regions of the country. The final Consultant Panel represents the 121 panelists who completed one or more of the three Policy Evaluation Instruments.

Selection of Subject Areas and Advances

Five representative areas of technology were chosen for examination in the policy study. These areas were selected from larger lists produced by ten members of the Consultant Panel (two from each panelist category) at an Issues Clarification Meeting held shortly after the inception of the study. Selection of the issues was based on the expection that major advances in these areas would take place within 20 years, and that such advances would collectively generate a broad range of ethical, legal, and social concerns. The five subject areas selected for examination in the study were:

* *Systematic Control of Behavior;*
* *Reproductive Engineering;*
* *Genetic Screening;*
* *Extension of Life;* and
* *Data Banks, Computer Technology.*

Anticipated future advances in these subject areas were provided by expert consultants in each of the five areas. Three advances were selected for inclusion in each subject area, and six scenarios which treated advances as pragmatic problems were also included in the study.

Development of Findings

In the first Policy Evaluation Instrument, panelists identified the most significant advance in each subject area, analyzed and evaluated the implications of this advance, and suggested policies which might be adopted with respect to the advance. In the second PEI, panelists examined the consequences of implementing specific policies with respect to the promotion, or control or limitation of five selected advances, brought forward from the first PEI. In addition, panelists voted on a series of general policy statements to deal with advances, and elaborated on the three policies they considered most urgent to implement.

In the third PEI, panelists were asked to examine the implications of implementing a comprehensive national policy to control and regulate biomedical and behavioral research and technology; identify the barriers to implementing the policy and ways to overcome these barriers; add any additional elements to the policy they felt necessary; and provide any amendments to the policy they considered warranted. The national policy was based on panelists elaborations of the policies selected as most urgent to implement, and was cast in the form of four policy scenarios which specified: (1) the establishment of a new independent agency (entitled the *Permanent National Commission on Biomedical and Behavioral Research and Technology*);

(2) public involvement in policy decision-making; (3) review authority and procedures for biomedical and behavioral research; and (4) implementation of biomedical and behavioral technology. Panelists also reviewed and allocated national expenditures for biomedical and behavioral research, and wrote newspaper articles on the status of bioscience at the turn of the century.

Intrepretation of Findings

Structured responses to PEIs were analyzed statistically. Open-ended items were summarized by study staff, and these summaries, together with copies of the verbatim transcripts of responses, were provided to panelist reviewers who analyzed them to identify the dimensions underlying the responses and to insure the accuracy and completeness of the summaries. Another panelist independently reviewed a set of summaries to identify the dimensions common to all the items summarized, those that cut across several, and those unique to a particular item. The dimensions were analyzed by study staff to identify common themes.

National Opinion Survey

The national opinion survey was designed to elicit public sentiment towards advances in biomedical and behavioral research and technology, and opinions about appropriate policies to handle them. The survey questions were derived in part from the first two Policy Evaluation Instruments completed by panelists.

The questionnaire was administered to a random sample of the non-institutionalized adult population of the continental U.S. A total of 1,679 completed interviews were obtained in the fall of 1976. In order to provide a basis for evaluating public understanding and attitude, a parallel version of the quesion-

naire was included in the third PEI sent to consultant panelists. Survey responses were analyzed statistically and the responses of the public and the panel were compared and contrasted.

The remainder of this chapter of the report presents brief summaries of the major findings of the policy study and the national opinion survey, and the conclusions of the special study.

FINDINGS OF THE POLICY STUDY: ADVANCES

The implications of advances are summarized below by subject area, followed by the implications of advances for individuals and society, and for moral and ethical issues.

Systematic Control of Behavior

Panelists were divided over whether advances in *Systematic Control of Behavior* would enhance or detract from individual freedom. There was particular apprehension about the possibility of government intervention going too far, and though benefits were discussed such as increased productivity, lowered cost of curbing social deviance, and profits for private enterprise, these were balanced against the cost of compromising individual rights and the notion that behavioral treatments might become the only acceptable option for controlling social problems.

The advent of drug therapy for mental illness brought great benefits to sufferers who could lead lives more closely approaching the "normal"; it also may have changed our concepts of mental health and mental illness. Drug therapy for mental illness may have established a climate for acceptance of drugs not only to relieve physical, mental, and emotional pain but also to produce pleasure. Some panelists viewed these developments positively, while others were negative, feeling they would result in an unusual or unhealthy reliance on drugs, or in the subversion of values. Moreover, drug therapy was seen to pose dilemmas for individual freedom versus societal benefits, as do all types of behavior control. Someone (or some group) must eventually decide whose behavior will be controlled and to what extent the mentally ill have rights to accept or refuse drug therapy.

Reproductive Engineering

Reproductive Engineering, which included the imminent commercial availability of *"Select-a-boy, Select-a-girl" kits*, has implications stemming from predicted changes in the sex ratio in society, extending even to the stability of society and to the form and content of marriage and the family. Panelists saw such advances in *Reproductive Engineering* as challenging these basic patterns. Tension between individual rights and freedoms and the "good of society" was pervasive in panelists' examination of these technologies.

Some panelists felt that individuals had the right to use reproductive technologies. People could be free to choose whether or not to have children, to determine family size or composition, and to sever the link between sexuality and reproduction. However, others felt that the absolute exercise of such rights as the ability to select the sex of one's children must be restrained to avoid social disruption — manifested in predictions of changes in the sex ratio -- or to family conflicts where the views of one individual clashed with another.

Equity was also at issue. Some panelists feared that restricted access to scarce and expensive technologies (such as in vitro fertilization) would discriminate against the poor. Others feared that the availability of inexpensive technologies (such as medical sterilization) might result in their differential promotion to selected groups -- such as the poor or minorities.

Genetic Screening

The principal concerns in *Genetic Screening* were the trade-offs between individual rights and the public good and, to a lesser

extent, resolution of problems of long-term genetic change and equity in distributing the technology.

Some panelists thought that individuals had "rights" to the kind of information provided by screening programs, and associated these rights with the exercise of personal responsibility for decision-making. Contrasting with this view, other panelists suggested there should be a right not to seek the information which would be provided by a screening program, and that this personal choice could be perverted or denied by governmental or commerical coercion or through social pressures.

The relationship between screening technologies and abortion as a resulting therapeutic intervention lies at the base of many concerns about the social aspects of screening. Abortion of defective fetuses was viewed favorably by some panelists in that it could decrease the cost of custodial care or treatment. Some argued that it was imperative to avoid these costs, which were generally seen as rebounding onto society when they exceeded a family's ability to sustain them. Other panelists were concerned that the identification of defectives could only bolster a growing notion that abortion is a responsible and acceptable course of action, which would intensify pressures on those morally or religiously opposed to it. These panelists argued society should support options which would allow those not in favor of abortion to avoid it without social stigma.

Concern was also apparent for the existing population of "defectives" and for those who might "slip through the net" of screening technologies. Some panelists feared that the fewer

defectives, the greater the stigma for those who remained. Finally, there was substantial agreement that implementation of screening programs would require equity in the distribution of the technology in order to prevent the development of a differential birth rate of children with defects among particular ethnic or economic minorities.

Extension of Life

Panelists saw issues related to *Extension of Life* more as trade-offs than as pros and cons. The question was not whether there were costs on one side and no costs on the other, but rather which costs should be borne by whom.

Extending life presents problems with respect to the allocation of redistribution of scarce resources. For example, investment in these technologies may force the taxing of the many for the support of those few maintained by expensive life-sustaining equipment. Panelists showed little interest in providing extensive funding for developing these technologies (though they are currently the object of considerable popular attention). Life extending technologies will increase the proportion of older people in the population, raising a potential resource allocation conflict between generations. Advances in life extending technologies may also cause us to choose between support for medical intervention and for prevention.

While the prevention of disease and trauma may lead to improved and longer life, it has many other implications besides. For example, panelists noted tension between the individual's seeking governmental protection in areas beyond his power to control, while at the same time fearing the loss of individual

freedom. Thus, in the minds of many, the government should chastise polluting industries but it should emphasize education rather than prohibitive laws on products when it comes to smoking or other aspects of personal lifestyles that affect health.

Data Banks, Computer Technology

The major implications of *Data Banks, Computer Technology* related to invasion of privacy. Even proponents of the technologies admitted the potential for invasion of privacy and for negative effects on the poor and minorities, many of whom would be unwilling or unable to use the technology. While proponents of computer technology felt the potential benefits outweighed the risk of a slight loss of personal autonomy, opponents feared that even the willingness to accept such a trade-off would erode present values for privacy and confidentiality.

Positive and negative effects were also seen for the quality of health care. Claims by proponents included predictions of reduction in the cost of care, increased accuracy, speed and ease of access to medical records, and improvements in the quality control of health care. Opponents countered these claims with predictions of higher costs for computer equipment and support, loss of intimacy and trust in the physician-patient relationship, and actual harm perpetrated through errors in programming or input. Similar arguments took place over benefits to research and planning as some felt computer technology would lead to great strides in research and planning while others considered these claims at least overblown, if not unfounded.

Implications for Individuals

Implications for individuals and individual rights were noted throughout all subject areas and advances, with both positive and negative effects identified. The panel generally upheld individual rights and values where these conflicted with the needs of society. The central question about individual rights related to whether or not they were freely relinquished. The panel generally objected to aspects of advances or policies which tended to curtail individual rights when individual consent was not solicited or received.

Aspects of advances which tended to enhance individual choice and the exercise of personal responsibility were generally favored by panelists, though not to the same degree. Some panelists were unequivocally in favor of the absolute operation of concepts of individual freedom and autonomy while others viewed this as operating within a social context. While advances themselves tended to be seen as increasing individual choice and responsibility, the interaction of technology was the individual, society, the government, and various agencies was sometimes seen as limiting choice.

Questions of individual health centered largely on the relative risks and benefits of research and technology. Where the potential existed for technologies to result in physical harm, or where there was a possibility that inequities in the distribution of the technology would differentially affect individuals of differing backgrounds or classes, panelists divided over whether the risk of harm or inequity was acceptable.

Implications for Society

Comments on social concerns and issues were frequent, often complex, and indicative of conflict. Social issues were frequently arrayed against individual or ethical issues where social benefits or harms were seen as being traded-off against ethical or individual benefits or harms.

Technological effects such as new knowledge and improvements in health care were often mentioned as social benefits, and a number of panelists appeared to hold the implicit assumption that a freewheeling approach to technological development would produce the greatest good for the greatest number. This viewpoint was challenged by others who felt that all out promotion of technology was likely to prove harmful in the long run. Similarly, economic issues produced disagreement over whether the added costs of bureaucratic supervision, believed necessary to control some technologies, would overwhelm the economic benefits which they might produce. More global economic issues were also addressed, with some panelists noting that advances could lead to major changes in the national or world economic picture -- such as the amelioration of the world population problem, and redistribution of population away from areas of pollution or polluting industries.

Some technologies were seen as promoting changes in social patterns. In particular, some panelists considered developments in *Reproductive Engineering* as capable of producing changes in the sex ratio of the population, patterns of marriage and family life; behavior control technologies could influence the relationship between governing and governed; screening technologies could lead to notions of genetic equality as an obtainable social end.

Finally, some panelists suggested that minorities and the disadvantaged would suffer from the implementation of technologies, while others suggested that minorities and the disadvantaged would suffer from the failure to implement them.

Moral and Ethical Issues

The broad moral and ethical issues identified by the study related to potential changes in human biology and behavior and to the question of equity or social justice. Advances in *Reproductive Engineering* and *Genetic Screening* raised questions about the potential for changing the biology of the human species, but produced substantial disagreement over whether changes would actually occur. Developments in the *Systematic Control of Behavior* might result in certain fundamental Western values of free will and personal responsibility being altered. Panelists tended to accept behavior control technologies if their use were confined to the rehabilitation of individuals, but decry their application to classes of people, or their use to avoid the exercise of personal responsibility.

FINDING OF THE POLICY STUDY: POLICIES

The implications of policies are summarized below in terms of four policy scenarios that collectively described a comprehensive national policy for the control and regulation of biomedical and behavioral research and technology. Findings about resource allocation policy are also summarized briefly. Finally, the implications of a comprehensive national policy are discussed in terms of: the need for controls, the role of government, justice, economic factors, and public participation.

A Permanent National Commission

The first policy scenario described a national agency (termed the *Permanent National Commission on Biomedical and Behavioral Research and Technology*) and specified its scope, authority, accountability, membership, staffing, and evaluation. A majority of panelists supported the concept of such a *Commission*. Panelists particularly approved of those aspects of the policy scenario involving dissemination of information produced by or about such a *Commission*. The most frequently offered amendments to the policy related to the *Commission's* scope and level of authority.

Discussions of the policy scenario revealed three major areas of disagreement about the *Commission*. Economic concerns formed one theme. Some panelists contended that present costs of research and care justified the establishment of a *Commission*, while others contended the *Commission* itself would create staggering bureaucratic costs. A second theme was the quality of research where some contended that a permanent regulatory agency would create efficiency and enhance quality, while others con-

tended that red tape and politicization of research would cause a deterioration in research quality. Finally, some panelists contended that present abuses of power in the health industry justified creation of an independent regulatory agency; others suggested the agency itself would become abusive in its use of power.

Public Involvement

The second policy scenario dealt with *Public Involvement in Policy Decision-making* and contained policies addressing public participation, the gathering of public opinion, dissemination of information, and provisions for the creation of five regional information centers. The panel split nearly equally in support of and opposition to this scenario. Many approved the ends of public participation; the means were less well liked.

The panelists' discussion of the policy scenario highlighted major areas of disagreement. Panelists debated three views of the public -- as interested, informed and helpful; as disinterested and likely to be led by demagogues; and as self-selected individuals and groups whose impact could be either positive or negative. The information centers specified in the policy were opposed by many panelists who feared they would be costly and not conducive to the improvement of research. Supporters of these centers argued that they would supply more detailed and accurate information and increase public confidence in research.

Biomedical and Behavioral Research

The third policy scenario outlined the scope of authority and control over *Biomedical and Behavioral Research*. Specific poli-

cies covered the review of research proposals and projects, the establishment of review boards, and appeal and evaluation procedures. Nearly two-thirds of all panelists supported this policy scenario with the strongest support going for evaluating the risks and benefits of research, enforcement of guidelines and regulations, and the setting of policy with respect to the conduct of research and the protection of human subjects. Two major themes emerged from the discussion of the scenario. One issue was that of the freedom of research and inquiry -- maintained by some as inviolable, but considered by others necessarily secondary to the public need. The other issue was that of the quality of research. Some panelists felt that rationalization of the review process and the development of standards for the conduct of research would improve research quality. Others contended the review process would be encumbered by bureaucratic inefficiency and would result in a decline in the quality of research.

Biomedical and Behavioral Technologies

The fourth policy scenario addressed the *Implementation of Biomedical and Behavioral Technologies* and specific policies related to assessment and evaluation of technologies, promulgation of policies regarding use of technologies, and enforcement of guidelines and regulations. A narrow majority of panelists supported this policy scenario. Opposition to the policy centered around the scope of control. Major areas of support for the policy were in provisions relating to monitoring, evaluating, and assessing technologies.

A principal focus in the discussion of the scenario was

health status. Many felt the policies described would improve the health of individuals and society. However, others were concerned that the policies would result in a limitation of choice of treatment options, contributing to a lowering of the health status of the population. Panelists also foresaw differing impacts of the policy on the marketplace with some suggesting benefits in the reduction of dangerous or useless products while others feared that the review and evaluations would be so expensive and time-consuming that only large companies could provide the capital for development, thus driving individual or small-group development efforts from the field and abetting the growth of monopolies.

Resource Allocation Policy

The majority of panelists favored future resource allocations which would: increase the percentages of the nation's allocation of Gross National Product to health; increase the percentage of the health dollar that goes to health research and development; generally increase total Federal outlays to research and development; and increase the percentage of Federal research and development dollars going to health. Panelists were unanimous in favoring greater allocations to biomedical research than to behavioral research. There was also general agreement that a greater proportion of resources should be allocated to health services and quality assurance research and a lesser proportion to basic research than at present.

Need for Controls

Panelists were split over the need for the control of biomedical and behavioral research and technology. Some panelists were

strongly in support of a comprehensive national policy which would control and regulate all research and implementation, public or private, at all stages. These panelists tended to see the present system as uncontrolled and indifferent to social need. Opposing this view were panelists who favored continuation of a loosely knit system of control, supplemented where necessary by the strenghening of existing agencies, or the use of ad hoc measures. These panelists tended to consider peer controls sufficient to guide research.

Role of Government

Those in favor of regulation tended to see the role of government as beneficial, providing coordinating, planning, and representation. Panelists opposed to the regulatory approach were certain that the attendant bureaucracy itself would be restrictive, unresponsive, and inefficient. Additionally, they feared that research quality would suffer as the bureaucracy favored those who could manipulate red tape over those who were truly creative.

Economic Factors

Panelists favoring a comprehensive national policy for research hoped for economies to result from the coordination of research and the delivery of health care. They suggested that duplication would be avoided, available funds would be equitably distributed, and insurance premiums or malpractice awards might be reduced. Countering these favorable views was the fear that a massive regulatory bureaucracy would drive the costs of research and health care delivery even higher. In addition to costs in Federal dollars, some feared that regulation would create higher

prices to consumers as providers of goods and services passed on the regulatory overhead.

Justice

There was considerable agreement among panelists regarding the desirability of such things as equality of opportunity, the provision of safeguards for special groups, and the need to compensate subjects of research for any harm. The major differences which appeared in this area related to questions of the freedom of individual researchers or the research community to pursue their own course. Some panelists felt that a comprehensive regulatory policy would violate the individual rights of researchers; others saw the curtailment of individual rights as a legitimate subordination of the individual to society, rather than as an infringement on personal liberty.

Public Participation

The active involvement of the public in the biomedical and behavioral research and development enterprise was lauded by some panelists who felt that research could be made more responsive to social need and that a dialogue between producing researcher and consuming public would prove beneficial to research and to society. The restoration of public confidence in research, decreased polarization on important issues, and an anticipatory rather than reactive approach to technological development were seen as likely products of increased public participation by some panelists. These views were directly contradicted by others who felt public confidence in research would be undermined by the emphasis on rules and regulations, dogma would be substituted for dialogue in public debate, and the public would be lulled into a false sense of security -- that "something was being done".

FINDINGS OF THE NATIONAL OPINION SURVEY

The findings of the national opinion survey are summarized below, with the responses of the public compared and contrasted to those of the Consultant Panel. Findings are described under five headings: past and future advances and their effects; use of advances; financial responsibility for treatment; research priorities; and value received.

Past and Future Advances and Their Effects

Seventy-seven percent of Americans could name at least one new test, treatment, or item of new medical knowledge that has come about in the last twenty years. Neither the public (60%) nor the panel (91%) felt that all types of Americans can equally get the new tests and treatments made possible by medical research. Two-thirds of the public, and virtually all panelists, mentioned the poor and disadvantaged as Americans who did not have equal access to new tests and treatments even when they need them. The majority of the public (70%) and panelists (86%) thought that today people who can pay for a new test or treatment or who know an important doctor, were those most likely to get it when it first comes out, and there is limited availability. Most of the public (85%) and the panel (82%) thought that people who apply first for tests or treatments or those who need them most <u>should</u> get a new test or treatment.

Both the panel and public were asked to assess the past as well as to predict future advances. A plurality of both panelists and public agreed that the *Prevention of infectious diseases* has had the greatest good effect on society over the past 20 years. However, other past advances mentioned by the public

were not necessarily the favorites of panelists. Twenty-six percent of the public but only one percent of panelists mentioned *Prevention, treatment of cancer*, while panelists more often mentioned *Improved contraception* and *"The pill"*.

Only about half of the public who could think of a new test, treatment or item of knowledge could mention a specific item with a bad effect on society -- and it was, most often, *Improved contraception*. More than three-quarters of panelists mentioned an advance with a bad effect -- most often *Treatment for mental illness*, specifically *Drug therapies* and *Proliferation of tranquilizers*. In general, health effects predominated as the greatest good effects in the past, while social-ethical effects predominated as the greatest bad effects, in the opinion of both public and panelists.

Projecting the good and the bad in the future -- the next 20 years -- panelists and public again were divided, but again, health advances dominated the good predictions and ethical/individual/political/social effects dominated the bad. The public saw *Treatment for mental illness* (specifically *Proliferation of tranquilizers*) and *Selection of sex of offspring* as the advances most likely to produce bad effects, while panelists predicted *Control of behavior*.

One of the points on which the public and panel agreed was that the most desirable advance in the next 20 years is *Prevention, treatment of cancer*. It was the top priority of 59% of panelists and 73% of the polled population sample. *Prevention, treatment of heart disease, other than surgery* (36% and 26%)

was the second priority, followed by *Treatment for mental illness* (23% and 14%).

Use of Advances

The panel and the public held differing opinions on research to change behavior and to determine which people are likely to commit violent acts. Panelists were much less supportive than the public of such research and of the application of tests predictive of violent acts. For example, 71% of the public (46% of the panel) voted to have tests developed to spot those likely to commit violence. The universal administration of such a test by the government was agreed to by 41% of the public, even though it might be an invasion of privacy (19% of the panel agreed to the same proposition). Finally, a majority of the public (64%) thought that the government should make people who have already committed a violent act take a drug to prevent them from committing further violence compared to 42% of the panel.

There was more agreement between the panel and the public regarding tests for fetal defects. Over 90% of the panel and nearly three-quarters of the public thought that if she wanted it a pregnant woman should have a test to tell if her unborn baby had certain defects -- even if the government had to pay for the test. A majority of both panel and public also said that if a defective fetus were identified a woman should have personal choice about whether or not to seek an abortion. However, 21% of the public (6% of the panel) said a woman should not have an abortion because it is wrong to destroy any life, while 23% of the public (31% of the panel) said it is wrong to bring children with serious defects into the world.

Two-thirds of the public and 60% of panelists said they would not use a self-administered *Select-a-boy, Select-a-girl kit* to choose the sex of their child. Panelists and public agreed that families would more often select boys, particularly for the first child, and that if people could select the sex of their children this would have a bad effect on society. A majority of the panel and the public said that the result would be an imbalance in the sex ratio. However, a majority of both the panel and the public were willing to allow marketing of the kits, although the public was less inclined than panelists to allow marketing of the kits without a prescription.

Financial Responsibility for Treatment

The public and panel were also asked who should shoulder the cost of illnesses caused by environmental factors (such as pollution) and by personal habits (such as smoking). Both agreed that agencies or individuals should be responsible when they are at fault (as with diseases caused by pollution or personal habits) but that social, risk-sharing mechanisms (health insurance) should operate when the diseases are caused by an individual's inherited make-up, or by bacteria or viruses. There was also substantial majority support from both panel and public for individuals' access to information about a doctor's treatment record and to be able to take part in risky experiments, so long as the risks are known and understood beforehand.

Research Priorities

While the panel held clear views about research priorities, the public seemed ambivalent on most questions. Almost all panelists supported research toward healthy life to age 70, rather than

prolonging life past 70. The panel also overwhelmingly supported basic health care rather than research into new tests and treatments, and research into the prevention rather than cure of illness. The public tended to vote in a manner similar to the panel, but frequently volunteered "both equally" as the preferred option. The only area of clear agreement among the research priorities was that panel and public were both overwhelmingly in favor of government support for research to help people take better care of themselves.

Panelists felt the government should do most research on environmentally caused illness, next on illnesses caused by bacteria and viruses, next on inherited illnesses, and finally, illnesses caused by personal habits. The public agreed with the panel in ranking research into diseases caused by personal habits lowest, but the remaining three categories were too close to call.

A majority of both panel and public agreed that researchers, scientists, and doctors should have the greatest say in deciding what problems medical researchers should work on.

Value Received

The panel and the public strongly agreed that we receive good value for medical research paid for by the government. There was also agreement that past advances had changed life for the better, and that future advances would do the same. Almost 90% of the public and the panel thought that they or their families had benefitted from medical research in the past twenty years, and over 90% felt that such research had significantly improved the life of the average person.

CONCLUSIONS ABOUT ADVANCES

During the last century, we have made great strides in our understanding of and ability to influence our health and behavior; seemingly these advances are occurring at an ever increasing rate. The benefits to be derived from new knowledge and new technology to promote health, to prevent ill health, and to treat sickness when it does occur are apparent. No less important, but perhaps less obvious, are the flaws in our knowledge, and the unintended consequences of applying the technologies that result from research.

We have become increasingly aware that new technologies can directly or indirectly affect present and future individuals in society in unsuspected and perhaps deleterious ways. The more technology we apply the more opportunities there are for unintended negative consequences to occur. Technology may also serve to raise new conflicts or sharpen old ones.

This special study analyzed and evaluated the implications of advances in biomedical and behavioral research and technology and of policies to deal with research and the implementation of resultant technologies. Public understanding of and attitude toward these matters was also examined. The general conclusions to be drawn from the policy study and the national opinion survey that comprised the special study are presented below.

Nature of Future Advances and Their Implications

The biomedical and behavioral advances that may most affect society in the next twenty years are extensions of those we know today. Neither the expert consultants who provided information on possible advances which were used as the basis for the study

nor the Consultant Panel identified advances which departed significantly from technologies under development or in existence today. Nor are the foreseen implications of these advances strikingly different from those we have already experienced, although some conflicts will be sharpened and old problems brought to light in a new perspective. There was considerable disagreement among panelists on: the probability that a given effect would occur; the magnitude of that effect; its significance; and the desirability of its occurrence. In part this disagreement stems from assessments based on differential knowledge; in part from differences in worldview, or in values. Individual rights and societal need formed a central concern in this respect.

Ends and Means

When people are asked about desirable advances in biomedical and behavioral research, as the panel and the public were in the national opinion survey, they tend to think of things which have major health implications or effects, e.g., a cure for cancer. In addition, they seem to assume that the means by which these health benefits will be attained are themselves good, or at least do not conflict with other equally important values. However, when advances are focused, and the means of their attainment delineated, as they were in the policy study, issues of value begin to arise. Careful analysis may show that the health benefits may not be as great as once imagined; there may even be the potential for iatrogenic impairment of health. More importantly, the means by which the health benefits are to be attained may come to be seen as harmful or dangerous either to people directly or to their rights. Examined at this level of

detail, advances may no longer look so attractive. For example, if the prevention or treatment of cancer (ranked first in the opinion survey as having the greatest good effect on society in the next twenty years) could only be accomplished through the rigid specification and control of individual behavior, it is doubtful if it would be regarded as the most desirable advance.

Potential Effects of Advances

Advances that might be expected to occur in the next 20 years have the potential to:

* effectively prevent the transmission of a variety of genetic diseases;
* contribute markedly to the solution of the world population growth problem;
* contribute to the general improvement of individual health care for all members of society;
* significantly decrease certain health care costs, particularly the costs of custodial care;
* enhance research and development in epidemiology and preventive medicine; and
* ameliorate the individually debilitating effects of anxiety and depression and the socially debilitating effects of criminal aggression.

However, they also have the potential to:

* substantially alter the present genetic make-up of American society, if not the world;
* substantially alter the sex ratio of American society, if not all the world;
* substantially alter present values regarding life and death, abortion, euthanasia, privacy, human rights, and individual responsibility;
* substantially alter basic American social patterns of marriage and family life;
* create entirely new "minority" or disadvantaged groups based on health status; and

* cause redistribution in the economy through prolonging the average life span.

Thus, advances have the potential both to increase individual freedom and to limit it; to increase societal stability and to reduce it. What balance will be struck depends on one's assessment of the likelihood of an event occurring and the policies one institutes to alter these probabilities in what one considers a desirable direction. For any given advance, some panelists believed that benefits outweighed harms; for others harms outweighed benefits.

Most of the concerns raised by panelists about advances in biomedical and behavioral research and technology, and about policies to respond to them, could be raised in many other areas of life. Yet concerns about justice and equity, individual rights and societal stability, and costs versus benefits seem particularly compelling when viewed juxtaposed with life and death, reproduction, and our genetic future.

Need to Mediate Conflicts Among Values

The need to mediate potential conflicts among values was apparent throughout the study. Some mediation will involve trade-offs between complementary values such as that between individual rights and societal needs. All of the subject areas raised questions about this particular trade-off, and it was very clearly illustrated in *Systematic Control of Behavior*. The application of technologies to control behavior -- particularly violent behavior -- appear extremely attractive to many, particularly among the public in the national opinion survey. Yet the application of behavior control technologies raises questions

about individual rights. Who will decide what behaviors to control? Who will administer the controls? Who will watch the watchers? Will any resultant limitation of rights ultimately affect society more adversely than if the controls were not applied?

Sometimes, apparently good ideas can have counterintuitive consequences that ultimately require trading-off one good with another. For example, providing information about physician performance may allow people to make more informed choices among practitioners -- promoting individual freedom of choice. However, given practitioners of unequal skill, there is likely to be competition for the skills of highly rated physicians -- thus creating potential problems in the equity of health care distribution. Are the highly prized to be highly priced? If not, how are their services to be distributed?

Many of the implications of advances foreseen by panelists will pose considerable problems for society. Many issues will have to be resolved, many trade-offs examined, and many decisions made. Draconian measures are not necessary, and hasty, ill-conceived action may be counter-productive. At least for the present, there is time to improve inadequate systems of control and to construct new ones where necessary. However, panelists did warn against inaction. They expressed a sense of urgency; action is required.

CONCLUSIONS ABOUT POLICIES

Most, but not all, panelists rejected the present piecemeal approach to developing policy with regard to biomedical and behavioral research and technology. Also rejected by the majority of panelists was the notion that enhancing the mandate of existing agencies and institutions would suffice to deal with the problems that are likely to be faced in research and in the implementation of technologies.

Creation of a New National Agency

These panelists believed a new independent national agency was needed. Such an agency could:

* formulate national policy, and facilitate coordination among the agencies that implement policy such as the National Institutes of Health, and the Food and Drug Administration;
* monitor and evaluate agencies charged with implementing policy;
* review and evaluate the implications of research and the implementation of technologies; and
* inform the public and scientific community and facilitate public participation in policy decision-making.

By fulfilling these functions, such an agency would:

* defuse issues, mediate value conflicts, and anticipate problems;
* protect research subjects;
* protect consumers from short- and long-term harms; and
* improve resource allocation.

Many panelists saw a central policy-making agency not simply as a way of avoiding abuse, but also as a means of doing good. For the most part, however, it was recognized that the new national agency would not solve many problems -- because

they cannot be solved. In the end, for every gain there is a loss, and the trade-offs must be made clear to all concerned. Moreover, the purpose of such an agency was not seen simply to prevent all risks to all people on all occasions, but to assess the risks and benefits, and strike the appropriate balance.

While there was considerable disagreement among the panelists about the scope and power which ought to be accorded a national policy-making body, there were some areas of general agreement. Agreement was widespread for policies which involved regulating the conduct of research, including the protection of human subjects and the assessment of risks and benefits of research to both individuals and society. Policies involving the enforcement of appropriate conduct of research and use of technologies, including penalties for abuse or misuse, were also widely supported.

Relationships with Existing Agencies

In establishing a new national agency, cognizance would need to be taken of developing the appropriate linkages with such existing agencies as the National Institutes of Health, the Food and Drug Administration, the White House Office of Science and Technology Policy, and the Congressional Office of Technology Assessment, with a view toward strengthening liaison, preventing duplication of effort (particularly with regard to regulations), preventing interagency rivalry, and establishing clear lines of authority and responsibility. Care should be taken to avoid simply producing an added layer of bureaucracy (resulting in loss of productivity), politicizing research (resulting in unproductive conflict), or overly centralizing control (resulting

in tyranny). It is not sufficient to add or duplicate agencies, or functions; one must subtract or integrate them as well.

The Autonomy of Researchers and Providers

Panelists were deeply divided over the extent to which researchers and providers should be autonomous or operate within a publicly defined context. On the whole, the scales were tipped toward the latter view, and for most panelists the benefits outweighed the costs. Some panelists mistrusted researchers and providers, others mistrusted the governmental bureaucracy which might be erected to deal with researchers and providers, others mistrusted both entities.

Two opposing views regarding the researcher underly many policy choices. To some people the researcher is an individualist pursuing his own intellectual interests, something of a hero contributing to society. They see management structures which tend to direct or control research stultifying the development of new knowledge and harming society in the long run. To other people the same individualistic researcher is an egoist, pursuing his own interests at public expense. They see management structures as necessary to make the development of new knowledge responsive to the public need and to protect research subjects, and benefitting society in the long run. Mediation of these conflicting viewpoints will decide the nature, extent, and productivity of tomorrow's research system.

Resource Allocation

There was substantial agreement for some level of direction of research through a national strategy, though panelists varied on exactly how much direction. There was disagreement about

the extent to which a national strategy would increase research productivity. Medical scientists particularly were inclined to be wary of highly directed research believing instead that essentially non-directed research was the most productive in the long run. There was agreement from all panelists, however, that more resources should be spent on health, particularly health research. A smaller proportion of research funds than at present, however, should be spent on research to develop technology and a larger proportion on health services and quality assurance research.

The equitable distribution of health care, particularly scarce new technologies, will be one of the greatest problems facing society in the next 20 years. There is clear preference for distributing advances according to need. But how is need to be determined? For the most part our knowledge about the efficacy of technology is sadly lacking. If potential health benefit and need is to be a principal consideration in the distribution of technology then we must increase assessment activities. We must also develop improved methods of assessing the consequences of research, and of using the resultant technologies. Finally, we must use these new methods of assessment to provide the information we need for rational decision-making.

Public Participation, Information

The public should be encouraged to participate in policy decision-making to the greatest extent possible. The dissemination of information -- open meetings, publication of evaluations, distribution of policy related materials -- received high marks from the panel, particularly if the dissemination took place through

established channels of communication.

In order that the public be able to make informed decisions it should be provided with valid information. Hence the call for closer monitoring of research, studies of the implications of research, and the evaluation of technologies for safety and efficacy. In addition, the government should encourage (or, if necessary, mandate) that sufficient information be disclosed to the public -- through appropriate product labeling, for example, or through the disclosure of physician performance records. In the same vein, explicitness of policies was seen to be essential. People should know what is being done, how it is being done, who is doing it, etc. To foster this, policies should be written in lay language; implementation of policies should be monitored; evaluations should be conducted by independent third parties to eliminate collusion between regulator and regulated.

Individual Responsibility and Freedom

The panel emphasized policies that enhanced individual responsibility and decision-making, and the dissemination of information.

The individual should be responsible for his own actions, and should be free to decide what is best provided society has no compelling interest in the outcome. Of course, there were substantial differences of opinion as to when society's interests become compelling. Panelists generally tended to support notions of individual freedom, and to dislike excessive governmental intervention in private affairs. There is substantial resistance to extending the hegemony of the Federal government over

the private sector (industry, universities, or individual practitioners), except to control the conduct of research, where society's interest in protecting research subjects and its own integrity was generally seen to be overriding.

There is a positive danger that the concern for social good can overwhelm and erode individual freedom of choice. To some degree, people should be left alone, even if they choose to be unhealthy, in the interests of preventing the development of a health-oriented totalitarianism. In short, individual freedom of choice is more important than research progress or the pursuit of health.

Minorities

Panelists' remarks which addressed the effects of different policies on minority or disadvantaged groups (economic, ethnic, religious, etc.) generally indicated that minority groups would be adversely affected under any set of circumstances. Control of advances was frequently seen as serving to restrict or deny access to minority groups; promotion of technologies was seen as leaving minority groups open to various abuses. It is at least arguable that this finding reflects a tendency to use the disadvantaged as symbols in making a point -- appeals to help the downtrodden carry considerable weight. Biomedical and behavioral research and technology exist in a larger cultural and social context. If a policy has any potential to harm any group, it is likely to harm the disadvantaged to some degree.

Individual Rights Versus Social Need

One value conflict was expressed consistently throughout the findings of the study -- that between a concern for individual rights and responsibility versus social need and responsibility. This conflict was apparent in responses to questions about control of behavior, genetic screening, data banks, and illnesses caused by personal habits such as smoking and excessive drinking. The findings indicate that the notion of responsibility was stressed. Where individual responsibility was involved, as in the relationship between smoking and lung cancer or in the decision to undergo genetic screening, the panel frequently suggested individual solutions. The tendency was to prefer public education to promote informed choice, rather than to enforce regulations to satisfy social need. The public was inclined to allow the operation of individual responsibility in such cases as the decision to participate in a risky experimental treatment, but inclined to enforce conformity to social need where an individual's behavior or choice adversely affects others.

The public's tendency to favor social responsibility was apparent in the area of control of violent behavior. The panel favored individual responsibility in this area, and the public favored social responsibility. Low-income respondents to the national opinion survey -- those most likely to be victims of violent crimes -- tended to favor control. Educated, upper income, professional respondents -- who more closely resemble the panel -- opposed control. This seems to be another example of an increasingly occurring conflict that raises a significant question: Who has a better understanding of the problem, the

public who experience situations that are studied by researchers, or the researchers who study the situations, but are for the most part removed from them?

This conflict suggests the need to provide better public information about the possible implications of advances or courses of action. However, we must recognize that in the end we may face differences in values that cannot be reconciled.

Epilogue

Advances made possible by medical research in the last 20 years have changed life for the better, and both public and panel expect future advances to bring further improvement in the quality of life. The panel agreed, however, that it was time for research and researchers to be evaluated and held to account; time to involve a more representative group of people in research policy decisions; time to set national priorities, goals and strategies; and time to reconcile advances in technology with the economic, health care, and legal systems.

Chapter 2: Advances.

INTRODUCTION

The implications of advances in biomedical and behavioral research and technology were identified using a four-step process:

* Five subject areas in biomedical and behavioral research and technology were selected;
* Three advances were selected and described for each subject area, and six scenarios selected;
* Foreseen implications of the advances and scenarios and appropriate policies to respond to them were identified in the first Policy Evaluation Instrument (PEI) and selected advances from the first PEI were brought forward for elaboration in the second; and
* Panelist responses were summarized and analyzed to produce a compendium of implications for each subject area.

These four steps are outlined below; the results of the process are described in the remainder of this chapter. A detailed description of study methods is provided in Appendix 1.

Selection of Subject Areas

An Issues Clarification Meeting was held to select a limited number of subject areas for consideration in the study. Ten consultant panelists, two from each of the study's five categories of panelist, participated in this meeting. These panelists identified those subject areas in biomedical and behavioral research and technology that had the potential for significant advances within the next 20 years. They also identified the societal concerns (e.g. important values, rights, and processes in society) that would be affected by these advances, making the subject area a significant one. Participants ranked the subject areas and societal concerns identified according to their socio-political importance, and rated the impact of

the most important subject areas on the most important societal concerns.

The results of the meeting were used to determine the minimum number of subject areas, ranked in order of importance, that would impact on the maximum number of important societal concerns. Following several meetings with Commission staff, five subject areas were chosen for study. They were: *Systematic Control of Behavior; Reproductive Engineering; Genetic Screening, Extension of Life;* and *Data Banks, Computer Technology.*

Selection of Advances

Advances in each subject area were identified by asking at least three recognized experts in the subject area to identify and describe from three to five advances that were expected to occur in the next 20 years, and to rank them in order of importance with regard to the impact that the advance would have on society. The three most often mentioned advances in each subject area were those selected for study. Six scenarios selected from 48 scenarios written by members of the SDMG were also considered. Each described a situation brought about by an advance that required resolution (one in each subject area and one that cut across all subject areas). The fifteen advances (three in each of five subject areas) and the six scenarios included in the first PEI are described in Appendix 5.

Identification of Implications

In the first PEI all fifteen of the advances were presented and panelists were asked to select one advance in each subject area as most important, based upon its implications for society. To

insure that no significant advance had been overlooked, panelists were asked to describe any advance in each subject area which they felt to be equal in importance to those listed. Added advances were subsequently compared to those listed in the PEI. Figure 1 shows panelists' selections of most important advance by subject area and the number of advances added. A total of 89 advances were added by panelists; in 59 instances, panelists selected the added advance as the most important advance. There was almost no commonality among the added advances, and their implications did not differ materially from those identified for the advances listed in the PEI.

After selecting the most important advance in each subject area, panelists identified, ranked, and described up to three significant implications of the advance. Implications were structured into seven defined categories. They were: economic, ethical, individual, legal, political, social, and technical. The implications identified for each advance are shown in Figure 2. Panelists were also asked to choose from among specific policy options which could be adopted with regard to research and the implementation of the advance they selected. Panelists' choices of policy options are shown in Figure 3. For each of the six scenarios panelists were asked to select one of two options presented; identify, rank and describe up to three significant implications affecting their choice of option; and describe a policy that would be helpful in resolving the issue (Figures 4 and 5).

The second PEI examined the implications of policies that

might be implemented with respect to five advances (one in each subject area) brought forward from the first PEI for elaboration in the second. These advances were chosen because of the importance panelists attached to them; the wide range of opinions held by panelists regarding research and implementation of the advance; or to ensure that they encompassed the study's five subject areas. They were: *Actions of psychopharmacological agents further understood; Select-a-boy, Select-a-girl marketable kits; Amniocentesis becomes routine; Environmental causes of disease and trauma further controlled;* and *Computerized medical records in use.*

The five advances were presented in the context of opposing policies: (1) promotion of research and implementation; and (2) control or limitation of research and implementation of the advance. For each advance, panelists were asked to identify the policy option they least liked (Figure 6), to indicate up to three negative consequences of adopting that particular policy (Figure 7), and to identify groups that might be particularly affected by these consequences (Figure 8).

Analysis of Responses

Implications and policies identified by panelists were sorted by advance, type, panelist category, and option chosen (where relevant). Responses pertinent to each advance and scenario were summarized by project staff. These summaries were sent to panelist reviewers to identify the dimensions underlying panelists' responses. These dimensions were then analyzed to identify common themes. The analyses, review materials, the original summaries, and individual panelists' responses were

used as resources for writing this and the subsequent chapter of the report.

The remainder of this chapter summarizes, by subject area, the implications of the fifteen advances and six scenarios included in the study. Since the scenario that cut across all subject areas *(Scenario No. 4, Allocation of Health Services Funds)* did not raise any extra implications, it is not summarized separately. Each set of findings is followed by a brief analysis and evaluation. The next chapter elaborates on the implications of advances for individuals and for society, and for moral and ethical issues.

SYSTEMATIC CONTROL OF BEHAVIOR

Three advances and one scenario were analyzed and evaluated in the subject area *Systematic Control of Behavior*. They were:

* *Actions of psychopharmacological agents further understood;*
* *Do-it-yourself anxiety and tension reduction;*
* *More predictable psychosurgical procedures;* and
* *Scenario No. 3, Drug treatments for prisoners.*

Findings

All categories of panelist were in substantial agreement regarding the relative importance to society of the advances. While the majority of panelists selected *Actions of psychopharmacological agents further understood* as the most important advance, lawyers selected this advance and *More predictable psychosurgical procedures* in equal numbers (Figure 1). All panelists who selected the advance *More predictable psychosurgical procedures* wanted it prevented or controlled, both as to research and implementation (Figure 3). Representatives of the public interest voted four-to-three against a policy of offering an anti-aggression drug treatment to prisoners in exchange for parole, while all other panelist categories favored such a policy by about two-to-one (Figure 4).

With respect to research and implementation of psychopharmacological agents, all panelists except medical scientists liked least a policy of promotion -- medical scientists liked least a policy of control. Both panelists who least liked promotion of this advance and those who least liked control, thought that prisoners and residents of health care institutions would be particularly affected (Figure 8).

Four major dimensions were identified in panelists' responses in this subject area. They were:

* The issue of personal feeedom;
* Society and the question of benefits;
* Social and political aspects of diversity; and
* Treatment for symptom or cause.

The issue of personal freedom. Panelists were divided over whether advances in behavior control would enhance or detract from individual freedom. One panelist reviewer identified the basic conflict as that between those who believe in a holistic conception of the human person, with subjectivity and a self-image as a responsible person that should be respected and fostered, and those who believe a person is a collection of "behaviors" that can be manipulated more or less in isolation from each other. One panelist (of the former persuasion) remarked that the very emphasis on the artificial control of behavior in these advances "marks the triumph (but not necessarily the truth) of the behavioristic view of man."

Among the dangers feared, the concept of a person as ready for manipulation was very prominent. This concept might lead others to be callous in manipulating, and might lead the person to think of himself as a passive object appropriate to be manipulated. It was alleged to be difficult to square the concept of manipulability as a common and decent estate of man with the concept of individual responsibility. As one panelist said, in reference to the anti-aggression treatment, "...afterward the person may feel that he is not the real John Jones." There was also

considerable discussion about the ideals appropriate to human life and about how behavioral control advances may trim those ideals unnecessarily. One panelist reviewer underscored an issue central to this dimension:

> ...how to prevent the loss of individuality, responsibility, freedom of choice while providing assistance for those who cannot cope for physical, mental, or social reasons with the rigor of life...

Related to the question of manipulation were twin issues of who would undertake the control of behavior and who would decide what behavior needed controlling. Panelists argued both for freedom of choice in accepting a behavior control technology (e.g., an anti-aggression drug), and for limiting access to such technologies through such means as distribution by prescription. There was also concern that institutional keepers would appropriate the technologies and use them without warrant. The problem of access was considered exceptionally critical for the poor and minorities -- these groups might be denied access to worthwhile advances, yet be the first chosen for experimentation or widespread use to promote docility.

The problem of definition and diagnosis of behavioral deviance was particularly vexing because our understanding of behavior is still primitive. Problems addressed included distinguishing between behavior and motive when only behavior is treated by the technology, the evolution of social homogeneity through behavior control, and the fear that the weak will be those most likely defined as deviant. The prospect of governmental definition of deviance raised the spectre of "1984".

Society and the question of benefits. Panelists cited bene-

fits to society generally in terms of reduced costs for custodial care of criminals and the mentally ill; increased productivity through allowing people to overcome problems keeping them out of the labor force or below their productive potential; and the elimination or curbing of socially costly deviance. However, it was also noted that custodians of deviant people may be more benefitted than the deviants themselves, that benefits could accrue to the pharmacological industry with the potential for commercial exploitation, and that researchers might benefit by the exercise of their right to pursue knowledge at the expense of others. One panelist reviewer noted:

> Panelists warned against the overuse of the advances that would consist in social benefits (e.g., docility) being given more importance than individual rights; if there were an effective anti-aggression drug, for instance, it would be tempting to treat disorders that tend to violence but themselves are not necessarily violent.

Social and political aspects of diversity. The potential for the surrender of personal control and the development of a drug dependent society appeared to many panelists to pose a danger to individuals and society transcending any possible benefits of the technology. Other panelists, less fearful of this eventuality, felt that our society is the kind that can tolerate the introduction of such technologies, and may have real need of them. A panelist reviewer observed that

> ...diversity, including deviance, is a better path to the good society than social management that relies heavily on drugs that can easily be misused or have the potential to control large populations.

Some panelists warned that the development of technologies for systematic control of behavior, which can be applied on a

broad scale, opens the danger for political manipulation or abuse. They foresaw great dangers for the lower classes, institutionalized populations, political dissenters, social deviants, and minority groups, if a dominant elite elected to homogenize society. Finally, they theorized that uniformity of political, social and personal life could ultimately be demanded.

Treatment for symptom or cause. Behavior control drugs in particular, and control technologies in general, were seen as unable to restore "natural" powers of self-control and responsibility. Therefore, to some panelists they did not represent true solutions to problems:

> ...[behavior control technologies] are rather vulgar techniques for dealing with behavior problems which very likely inhere in the social structure in which the individual ... resides.

Another point raised was that some forms of stress may be necessary and their avoidance deleterious. Anxiety, for example, could have its roots in an ethical problem properly responding to the nature of life, and stress could be crucial for maturing or learning. Behavior control technologies which might merely strengthen people's weaknesses were viewed with alarm, with one panelist noting that an artificially induced happiness may be more like the "pig satisfied than Socrates dissatisfied".

Analysis and Evaluation

The debate regarding advances in behavior control technologies seemed to take place on two levels. On one level there was differences of opinion regarding whether behavior control ought to be countenanced at all in our society, or whether the whole

idea of the technology represents "an impiety", in the words of one panelist reviewer. On a more pragmatic level, panelists faced the existence of the technologies and addressed the question of how they ought to be dealt with in the existing political and social climate.

Nearly all panelists placed great weight on notions of informed consent and freedom of choice to accept or reject behavior control technologies, though freedom of choice was not construed to mean free access for everyone. There was concern that informed consent would be difficult to obtain in some settings -- particularly institutional settings -- which might be inherently coercive. Can a person suffering a mental illness truly give informed consent? In some situations (the treatment of criminals), at least some panelists accorded society an overriding interest in the behavior of the individual.

Control of these advances was generally seen as occurring at the Federal level. Some felt the regulatory agencies were already too subject to professional and industrial influence and wanted controls specified in legislation; others looked to the addition of interdisciplinary and lay panels to provide public participation in whatever decision-making process was accorded responsibility. Finally, a number of panelists argued that controls over behavior control technology were impossible, citing as evidence the failure to control abuses of alcohol, heroin, and tranquilizers.

REPRODUCTIVE ENGINEERING

Three advances and one scenario were analyzed and evaluated in the subject area *Reproductive Engineering*. They were:

* *In vitro fertilization available in clinical practice;*
* *Sex selection by sperm separation;*
* *Safe, simple medical sterilization available;* and
* *Scenario No. 1, Select-a-boy, Select-a-girl marketable kits.*

The scenario *Select-a-boy, Select-a-girl marketable kits* was carried forward from the first PEI for further elaboration in the second.

Findings

All categories of panelist were in substantial agreement regarding the relative importance to society of the advances (Figure 1). Lawyers tended to like least a policy of control or limitation of marketing the *Select-a-boy, Select-a-girl kits*, while other categories of panelist liked least a policy of promotion (Figure 6). Panelists selecting either policy option generally agreed on the implications of their chosen option and on the groups which would be particularly affected (Figures 7 and 8). In fact, both those in favor of promotion and those in favor of control of the kits most frequently identified negative social consequences, and mentioned women and young adults among the groups most likely to be affected by the policy option chosen.

Four major dimensions were identified in panelists' responses to this subject area. They were:

* Individual rights and freedom;
* Social and ethical patterns;

* Legal, political, and economic issues; and
* The role of government.

Individual rights and freedom. The principal beneficial effects of reproductive engineering technologies would appear to be in increasing, or sustaining, individual rights and freedom. Women would be more free to choose when -- or if -- to have children, through medical sterilization or surrogate mothering, for example; parents would be free to choose family size and composition, through sex selection technology. People would be free to sever completely the link between sexuality and reproduction. Panelists often mentioned that these freedoms were rights.

There was, however, some ambiguity on the notion of individual rights, as reflected by an apparent conflict between rights viewed as absolute, and rights viewed in a social context. Even among those who tended to see rights as absolute, there was a recognition that the rights of one individual can clash with those of another -- as in family situations where conflicting views over sex selection might be held. The exercise of rights in the context of social structure entailed a certain individual responsibility to avoid undercutting "... basic social structures and patterns that would be self defeating, for then individual rights would have destroyed their own basis in society."

Social and ethical patterns. Many panelists commented on the potential effects of reproductive engineering technologies on basic social patterns such as the sex ratio, relationships

between the sexes, forms of marriage and family patterns, and the effects on population growth and distribution. Some aspects of these technologies were viewed favorably. Sterilization, for instance, could help enhance women's control over their own lives, and both inexpensive sterilization and sex selection technologies could help contribute to the solution of global problems of population growth. However, these favorable aspects were balanced by a number of concerns.

Sex selection technologies were of concern because of their potential for altering the sex ratio of society -- an alteration which might be exacerbated among some subcultures which place a great value on male offspring. Some panelists viewed this potential consequence as a threat to the maintenance of social stability. In vitro fertilization could alter our idea of "mothers" and motherhood. All of the technologies in this subject area were seen as increasing the sense of separation between the procreative and the recreational functions of sex. This separation was viewed neutrally in the case of sterilization, but in the areas of sex selection and in vitro fertilization it was sometimes seen as commodifying and dehumanizing the procreative process.

Some ethical patterns of American society were considered threatened by potential developments in *Reproductive Engineering*. Even the development of such technologies was questioned by some panelists who asked whether it was ethical to publicly fund research which violates the moral and religious beliefs of some, or even many, citizens. The principal ethical questions,

however, centered around equity and economic justice.

Equity was at issue throughout all the advances in this subject area. Panelists expressed concern that access to some scarce technologies (such as *in vitro* fertilization) might be denied some social classes. On the other hand, technologies like sterilization or sex selection could be offered coercively (as a condition of welfare payments, for instance), and might be promoted differently among selected classes. The question of economic justice was raised in connection with *in vitro* fertilization where it was suggested that some economic classes would be exploited if it became possible for the wealthy to buy the services of "surrogate mothers".

Legal, political, and economic issues. The conflict between individual rights and social responsibility gave rise to a number of legal, political, and economic issues. For example, in sex selection technology individual rights might at some time become subject to legal restraint by the state if their exercise resulted in massive changes in the sex ratio. In other advances, entirely new legal situations might arise (e.g., the rights of a surrogate mother to the child, which might entail a legal definition of "motherhood").

Political concern included the potential for intrusion of the government into reproductive freedom without overriding cause. The totalitarian imposition of sterility, production of males for war, and international bargaining with reproductive technologies were all seen as possibilities.

Economic concern tended to center on the potential for commercial exploitation of reproductive technologies. Some

panelists felt the greed of industry could put potentially profitable technologies, such as sex selection kits, on the marketplace before they were fully tested, or sell them at such a price as to deny equal access. On the other hand, a number of panelists felt there was no problem with commercialization of such technologies and that companies should be allowed to pursue reasonable profits. These panelists tended to view the free market system and individual freedom of choice as sufficient for controlling advances.

The role of government. Two views about the role of government emerged from the panelists' responses. Some panelists wanted to minimize the governmental role, restricting it largely to the funding of research and implementation. On the other side, a number of panelists felt that the government (here the Federal government) alone had the power and the resources, and was sufficiently representative to be effective in controlling the development of advances. These panelists tended to see a governmental role in implementing, directing, and controlling the research and application of these advances. There was particular concern for the governmental role in monitoring research and the consequences of advances, determining public opinion about them, and assuming a role in the education of the public about the benefits and harms of technologies and publicizing the results of monitoring.

Analysis and Evaluation

The tension between individual rights and freedom and the good of society was manifest throughout the responses to advances in *Reproductive Engineering*, and the panel seemed divided on which

took precedence. This dilemma was remarkable, in itself, because in other subject areas panelists more frequently preferred to support concepts of individual rights wherever they appeared. Two explanations, either alone or in combination, are offered to account for this finding. First, the potential social disruption foreseen by panelists, should the advances go awry, may have been viewed as so extensive as to override individual concerns. Second, the exercise of certain rights, such as the right to select the sex of a child, may have been viewed as stemming from "trivial" personal values.

Among those panelists who did adhere to a desire for freedom of choice some appeared to do so simply because they felt it was right, while others believed that problems inherent in the technology would be temporary at best and either self-correcting or readily correctable through public policy. Panelists who foresaw social disruption stemming from an unfettered freedom to use reproductive technologies wanted to limit this freedom -- either to preserve the exercise of other freedoms, or to avoid an even greater curtailment of freedom that might be necessary should the social disruption they foresaw come to pass.

GENETIC SCREENING

Three advances and one scenario were analyzed and evaluated in the subject area *Genetic Screening*. They were:

* *Amniocentesis becomes routine;*
* *Widespread screening for inborn errors of metabolism;*
* *Research shows lung cancer, heart disease have genetic basis;* and
* *Scenario No. 5, Marketing of a group insurance plan with genetic screening.*

The advance *Amniocentesis becomes routine* was carried forward from the first PEI for elaboration in the second.

Findings

All categories of panelist were in substantial agreement regarding the relative importance to society of the advance. However, a plurality of ethicists selected *Widespread screening for inborn errors of metabolism* as the most important advance, while a plurality of all other categories of panelist selected *Amniocentesis becomes routine* (Figure 1). Lawyers were slightly in favor of allowing the *Marketing of a group insurance plan with genetic screening*, while all other panelist categories opposed this action by nearly two-to-one (Figure 4).

Panelists split evenly in their choice of a least liked policy for the advance *Amniocentesis becomes routine*. However, regardless of the least favored policy option, either promotion or control, panelists most frequently predicted negative social consequences and tended to agree that women and low income people would be particularly affected (Figures 7 and 8).

Four major dimensions were identified in panelists' responses in this subject area. They were:

* Individual rights and responsibilities;
* Social and ethical aspects of screening;
* Short term health considerations; and
* Long term health considerations.

Individual rights and responsibilities. Individuals were viewed as having "rights" to the kind of information provided by screening which may be necessary to make informed choices about procreation. These rights were often associated with notions of taking personal responsibility for decision-making. However, there was a countervailing thought that the individual's rights included the right not to seek the information and that this personal responsibility could be perverted or denied. Pressures on the individual in the form of direct coercion by government or commercial interests (manipulating subsidies for screening and abortion), or indirect coercion through social pressures or the advice of physicians, were seen as real possibilities. In general, as a panelist reviewer noted,

> ...when confronted with genetic disease (real or imagined), the rights of the mother were considered weightier than the rights of the fetus. In the same confrontation, however, the rights of the fetus were considered weightier than the rights of society.

Thus panelists tended to support strongly concepts of freedom of choice both in the decision to seek -- or not to seek -- screening, and in decisions on what to do about the information found through screening, while condemning social or political pressures which might affect that choice. Physicians were considered as a special class here, with some panelists wondering

about the legal vulnerability of physicians who did not prescribe amniocentesis, in the event of the birth of a child with genetic defects that could have been detected by the test.

Social and ethical aspects of screening. The relationship between screening technologies and abortion as a resulting therapeutic intervention lies at the base of many concerns about the social aspects of screening. Abortion of defective fetuses was viewed favorably in that it could decrease the cost of care (custodial or treatment). Some argued that it was imperative to avoid these costs, which were generally seen as rebounding onto society when they reached the point beyond a family's ability to sustain the costs by itself. Screening and abortion were viewed much less favorably as they related to perceived social pressures.

Panelists were concerned that the identification of defectives could only bolster a growing notion that abortion is a responsible and acceptable course of action, which would intensify pressures on those morally or religiously opposed to it.

> The birth of a significantly defective child is a major emotional tragedy for the parents. The burden would increase if such a child were to be born at a time when a general attitudinal message might say: you could have easily prevented this event.

Increased acceptance of abortion could lead to promoting the idea that it is a community obligation, labelling religious or moral scruples as "selfishness", or stigmatizing people who refused to undergo screening or accept an abortion.

Concern was also apparent for the existing population of "defectives" and for those who might "slip through the net" of

screening technologies. Some panelists feared that society might lose the will (and possibly the incentive) to provide continued support as notions of "preventability" came to the fore, and that the fewer defectives, the greater the stigma for those who remained.

A host of other considerations were offered, ranging from the costs of instituting screening programs and offering them on an equitable basis, to concerns about the disruption of procreative rights, and effects on mate selection. There was even fear that screening could result in the emergence of a class of social outcasts, which could jeopardize the structure of American democracy.

Short term health considerations. Proponents of screening technologies cited favorable short-term health implications in support of their position. The mental health of individuals and families would be aided by positive knowledge of the health of a fetus, and people identified as genetic risks could choose to modify their lifestyles appropriately. Opponents of the technologies cited diagnostic errors (false positives and false negatives), potential iatrogenic damage from invasive techniques such as amniocentesis, and adverse affects on mental health stemming either from being identified as a carrier or from guilt about abortion.

Either way, panelists noted, the burden would be particularly heavy on the poor. The poor would suffer if screening techniques like amniocentesis were routinely done because abortion and other needed services are not equally accessible to everyone;

the poor would suffer if amniocentesis were not routinely available because only the wealthy would be able to make use of it.

Long term health considerations. Long term consequences of screening programs were related to the genetic integrity of future generations. Proponents of screening saw the creation of healthy human progeny as a worthwhile goal unto itself. Some noted that prevention of the transmission of genetic disease would result in overall improvements in the genetic health of the population. They also suggested that widespread comprehensive screening programs would tend to identify everyone as, in some sense, genetically imperfect, which would help allay problems of stigmatization and represent something of a natural check on promoting wholesale eugenics programs.

Opponents were not so certain that only better genetic health was at issue. To this group, the striving toward normality suggested by proponents could easily be turned into a search for perfection. As a panelist reviewer noted, procreation could become "...a yoke, a commodification process in which the perfect are acceptable, but the imperfect are to be regarded as 'factory rejects'." This group seemed to view normality as less a fixed notion than a transient concept affected by changes in social values.

Analysis and Evaluation

The principal issues in genetic screening appear to be the trade-offs which would occur between individual rights and the public good, and, to a lesser extent, the resolution of problems about long-term genetic change and about equity in distributing the technology. For most panelists, the public good tended to

be considered less important than the rights of either the mother or the fetus, and there was also substantial agreement that equity in distributing the technology was necessary to prevent differential birth rates of children with genetic defects among particular ethnic or economic minorities. The problem of long-term genetic change would appear to be ameliorated so long as the freedom to choose could operate untainted by social, governmental, or economic pressures to follow a particular course of action.

While analysis of the responses in the subject area of *Genetic Screening* revealed considerable disagreement on a number of issues, a panelist reviewer identified five ideas common in responses to the advance *Amniocentesis becomes routine* which seemed to transcend individual panelists' positions on policy. First, there should be public education about the benefits and risks, with appropriate identification of high risk categories, and differential promotion in these categories. Second, there should be increased resources for genetic counseling to buttress the education program. Third, there should be assurance of continued funding for the care of defectives to insure that the option to decline screening and abortion was equally as viable as the option to accept. Fourth, there should be freedom of choice and informed consent procedures established in connection with amniocentesis and appropriate government subsidy to insure equitable distribution. Fifth, there should be standards of quality control governing the facilities and personnel administering the screening technology.

EXTENSION OF LIFE

Three advances and one scenario were analyzed and evaluated in the subject area *Extension of Life*. They were:

* *Compact, wearable, artificial kidney developed;*
* *Environmental causes of disease and trauma further controlled;*
* *Gene therapy now available;* and
* *Scenario No. 6, Life and death decisions.*

The advance *Environmental causes of disease and trauma further controlled* was carried forward from the first PEI for elaboration in the second.

Findings

All categories of panelist were in substantial agreement regarding the relative importance to society of the advances (Figure 1). In the scenario, representatives of the public interest were somewhat more inclined than the other groups to allow a panel of persons to decide the fate of a patient on a life support system (Figure 4). Lawyers and medical scientists were about evenly divided over policies of promotion or control of research and implementation regarding *Environmental causes of disease and trauma,* while over 70% of other panelists were against a policy of control (Figure 6).

There were also some differences in the response which did not depend upon panel category but on the policy option chosen. For instance, 24% of panelists who liked least a policy of control of research and implementation of the advance *Environmental causes of disease and trauma further controlled* foresaw negative health consequences arising from such a policy, while none of

the panelists least favoring a policy of promotion noted negative health consequences (Figure 7). The groups particularly affected also differed according to the policy option chosen for this advance, with panelists who least liked a policy of control more frequently mentioning urban populations, workers, and low-income people, while those least liking a policy of promotion tended more to mention private industry and low-income people (Figure 8).

Four major dimensions were identified in panelists' responses in this subject area. They were:

* Allocation or redistribution of resources;
* Equal access to technology;
* Government regulation of development; and
* Education versus regulation.

Allocation or redistribution of resources. Technologies in the subject area *Extension of Life* seemed to raise a variety of questions about resource allocation. Some panelists addressed the problems of "half-way" technologies (e.g., expensive life sustaining machinery), that extend life but do not restore the patient to his previous health status. They noted that investment in these developments required taxing the many for the support of the few. Allocation was also cited as a problem when it related to the assignment of scarce resources to those in need -- either the assignment of life saving equipment, or the allocation of funds to clean up particular environmental problems. Deciding on resource allocations between prevention and cure was underscored with respect to *Environmental causes*

greed on which would be the more costly approach. One view had it that "...pure air and water may be too much to be affordable," while the other felt the cost of comprehensive programs for prevention of environmental harms would be cheaper than paying on a piecemeal basis.

Redistribution of resources was noted with respect to changes in population composition and location, and with respect to the distribution of funds for particular technological enterprises. Technologies which extended life at the later end of its span have the potential for increasing the proportion of older people. This may require redistribution of either money or jobs, and could accentuate conflict between generations. Technologies associated with environmental problems may have the effect of relocating people either away from high risk areas or out of dangerous industries. Allocative decisions between crisis intervention modes of medical treatment and preventive measures, such as education, also represent redistributive questions.

Equal access to technology. Panelists were concerned that investments in expensive life-saving technologies may produce advantages only for the wealthy few. At the same time, there seemed to be little interest in providing extensive funding for development of these technologies. Benefits were only foreseen under the circumstances that a large number of people could be "normalized". However, this would involve large-scale public funding. With respect to environmental manipulation, problems of equal access related to availability of information and

funds for improving the environment. The basic concern was for equity in deciding how, where, and when changes would be made.

Government regulation of development. The question of government involvement ran throughout the advances in *Extension of Life*. In general it appeared that panelists ceded decision-making authority to the government either because it was the only likely source of funding, because it alone had the necessary authority, or becuase of a distrust of industry. In the case of the artificial kidney, the government was the source of funds, hence the source of the allocation decision. In the case of environmental causes of disease, only the government (generally the Federal government) could exercise power at a level sufficient to accomplish change. In gene therapy, the potential harms appeared so great that the government was called upon for protection. The distrust of industry manifested in environmental areas, and to a lesser extent in gene therapy, was not universally held. Some panelists feared that business could become "...a whipping boy and enemy of good environment", which would jeopardize the free enterprise system and encourage greater public control.

The problem foreseen in extending government regulation was the concomitant loss of individual freedom. This was held as particularly true in *Environmental causes of disease and trauma further controlled*, where panelists cited examples of air bags for cars and restrictions on smoking as intrusions on individual freedom. Conflict seemed to exist in this area between seeking government protection in areas beyond the indivi-

dual's power to control, while at the same time fearing the loss of individual freedom. Thus, government protection was sought against polluting industries but avoided if it had to do with enforcement of an altered personal lifestyle; the zeal to improve overall health should not seriously infringe on individual rights.

Education versus regulation. Although there was widespread appeal to the government as a source of regulation, not all government activity was seen as regulatory. Particularly, with respect to policy approaches for further controlling *Environmental causes of disease and trauma*, panelists recommended a strong role for the government in providing education about life styles and their consequences. The concern for education itself seemed a response to the concern over increasing Federal encroachment on individual freedom. In general, the notion of education was tied to policies for promoting research that would lead to a new and better knowledge about environmental processes and effects.

Analysis and Evaluation

Throughout this subject area, panelists tended to see issues more as trade-offs than as pros and cons. Some of the trade-offs noted were: investing in life-saving equipment versus preventive medicine; preventing technological development versus developing expensive technologies, then providing them universally, and stopping pollution versus the cost of industrial (and economic) dislocation.

Perhaps out of this sense of multiple trade-offs and the problems of making allocations of one kind or another, the panel frequently looked to appropriate sources of authority. In the

scenario which depicted a life and death decision they debated whether a physician or a representative panel was the appropriate source of authority. With respect to the advances themselves there was more agreement. Panelists suggested the government would have to mediate many of the questions, or, by educating the public, help individuals to regulate themselves, e.g., as regards smoking.

Sometimes the questions became so complex that the nature of the trade-offs became obscured. The pursuit of research into environmental causes of disease would mean an added tax burden, both on wage-earners and on industry, which could undercut economic growth. Failure to pursue such research would mean continuation of double costs -- payment for products of industry and payment for medical costs caused by environmental deterioration. As one panelist observed, "...it is not whether there are costs on one side and no costs on the other. The issue is, which cost will be borne by whom?"

DATA BANKS, COMPUTER TECHNOLOGY

Three advances and one scenario were analyzed and evaluated in the subject area *Data Banks, Computer Technology*. They were:

* *Computerized medical records in use;*
* *Computer simulates metabolic processes, aids patients;*
* *Computer screens patients, provides check-ups;* and
* *Scenario No. 2, Hospital responsibility for physician performance data.*

The advance *Computerized medical records in use* was carried forward from the first PEI for elaboration in the second.

Findings

All categories of panelist were in substantial agreement regarding the relative importance of the advances (Figure 1). In the scenario, a majority of medical scientists (57%) thought that hospitals should not be responsible for informing prospective patients about data on physician performance, while 80% or more of each of the other four categories of panelist favored such responsibility (Figure 4).

Ethicists and social scientists most often liked least a policy of promotion of *Computerized medical records in use*, while the other three categories of panelist most often liked least a policy of control or limitation. In the case of the ethicists the vote was over two-to-one against their use (Figure 6). There was also a very apparent difference in the negative consequences foreseen for *Computerized medical records in use*, depending upon the policy option chosen. Panelists who liked least a policy of promotion of this technology more frequently foresaw negative ethical consequences. Panelists who

liked least control of the technology overwhelmingly identified negative technical consequences (Figure 7). Low income people, chronically ill people, and physicians were the groups panelists mentioned most often as those likely to be particularly affected by the negative consequences of the technology -- whether it was promoted, or limited or controlled (Figure 8).

Five major dimensions were identified in panelists' responses to advances in this subject area. They were

* Privacy and personal control;
* Quality and cost of health care;
* Broad health coverage and equitable distribution;
* Changes in the physician-patient relationship; and
* Long range planning and research.

Privacy and personal control. Comments about privacy, as it relates to developments in computer technology, were universally negative. Even proponents of the technologies admitted the potential existed for invasion of privacy and that this would particularly affect the poor and minorities. Proponents tended to view the potential benefits, both for individuals and for society as a whole, as overriding any slight loss of personal privacy or autonomy. Countervailing this was a sense among opponents that developments in computer technology could erode the value for privacy and confidentiality by fostering notions of the acceptability of trade-offs between these rights and some presumed set of benefits.

Some panelists expressed a concern for privacy so strong that with respect to computerized medical records they suggested

patients be the ultimate "owners" of the record, controlling access to it and making changes in it themselves. Violation of confidentiality was seen as resulting in a host of problems. For example, the labelling of groups by health status could be used to classify workers, or even to develop new principles of social stratification.

The extent of opposition to computer technologies involving data gathering and storage was underscored by a panelist reviewer who observed:

> The potential for governmental, medical (research), and commercial (employment and insurance) intrusion and exploitation of individuals and groups was considered so great by so many panelists, and [the] ameliorative policies so overwhelming, that virtually all possible benefits to society and individuals would be eradicated.

While panelists seemed to be of one mind regarding the dangers of invasion of privacy (though divided over whether the potential harms were greater or less than the benefits), they viewed the relationship between developments in computer technology and its effects on personal control more equivocally. Computer technologies could lead to increased patient responsibility, improved patient self-image, the demystification of medicine, and increased patient independence. On the other hand, a system could develop where patients had to submit to computerized screening prior to receiving care, and patient care could be come increasingly impersonal and mechanistic.

Quality and cost of health care. Both positive and negative effects on the quality and cost of health care were foreseen with respect to advances in this subject area. Positive bene-

fits were claimed for those aspects of computer technology which might reduce the cost of care, insure completeness in the medical record, increase the speed and ease of access to records, decentralize facilities, improve quality control of health care providers, educate patients, and establish continuity of care. The efficiency of computerized record systems and computer conducted check-ups were also viewed as helping to release physician time for more personal patient care by avoiding duplication of tests or the handling of routine visits. Patient populations considered to be particularly benefited by these developments included the elderly, poor or itinerant patients (particularly the peripatetic middle class), and patients with complex, multisystemic diseases.

Negative aspects of computer technology noted by the panelists included those that would arise through higher costs occasioned by the use of capital intensive equipment, and enhancement of a mechanistic view of patients as machines to be repaired, a loss of intimacy and trust in the physician-patient relationship, and outright harm perpetrated through errors in programming or input to medical records. More subtle effects might occur through the tendency to some patients to avoid use of the technologies. The poor, minorities, and the less educated were seen as particularly likely to either avoid using the technology, or be incapable of using it to its potential.

Broad health coverage and equitable distribution. Panelists noted that hard policy choices would have to be made between emphasizing care for the greatest number versus directing

attention to long-term, life-saving research. A panelist reviewer asked, "...will our efforts to improve quality truncate the distribution [of advances], or will our emphasis on equity impair overall health services?" Computer technologies could help broaden the base of health care by allowing more people to be served and served better, but they could also lead to inequities. At the worst, the technology was seen as harboring the potential for developing a two-class system. Such stratification might be based on wealth where one class would be able to seek and pay for high quality, personalized health care; it might be based on sophistication where the less sophisticated would avoid the mechanistic technology; or it might be based on fear of exposure where patients with potentially stigmatizing diseases would avoid seeking treatment.

According to some panelists, the publication of physician performance records could lead to the stratification of practitioners with those highly rated charging high fees to those able to afford them, leaving lower-rated physicians to serve the poor and posing problems for the equitable distribution of health care. As a panelist reviewer noted:

> Everyone wants the best: not everyone can have the best: not everyone is the best. These are the facts. Any suggested information about a physician's performance would naturally divert people away from some and towards others merely on the basis that some perform better but not because any are unqualified. The resultant heavier load on the select few leaves many unused and underused, a situation we can ill afford.

Changes in the physician-patient relationship. Both the advances and the scenario raised questions about the nature and

direction of changes in the physician-patient relationship. Computerized check-up and screening systems, computerized medical records, and hospital release of physician performance information raised issues of the depersonalization of the physician-patient relationship, the development of a climate of mistrust, and the addition of a third entity into the traditional two-party relationship. Panelists held differing views on whether such changes would be for the better or the worse.

Some panelists noted that these advances would help to demystify medicine and promote individual responsibility for health by providing patients with better information and more direct control over their own health care. Others in favor of the advances suggested that physicians would have more time to devote to personal relationships with their patients if computer technology were able to handle some routine aspects of practice.

The view of those in opposition to the technologies was that the introduction of mechanistic technologies into day-to-day medical practice would separate the patient further from the physician. Depersonalization, and mistrust created by such things as concern over leakage of medical records or knowledge about the physician's performance record, would be accompanied by a lower quality of health care, according to these panelists.

Long range planning and research. The discussion of advances in computer technology generally emphasized the long term preventive approach to medicine rather than the short

term therapeutic approach -- though this was not an exclusive focus. Panelists singled out preventive medicine, public health planning, and epidemiology as areas which might be particularly benefited by advances in computer technology. Continuity of care would promote preventive medicine and together with an increased climate of personal responsibility for health care, could help lower the total costs of care. The aggregated data in computerized systems would also be valuable for epidemiological research, and ultimately for preventive medicine. The study of rare diseases would be aided, and new insights gained into the etiology of diseases. Public health planners would have aggregated data for performing cost-benefit analyses, and for effecting a better distribution of personnel and facilities. Caveats mentioned in this area related to the "Achilles heel" of computer technology -- input accuracy -- and some panelists considered claims for these planning and research benefits overblown, if not unfounded. Such uses of computer technology as auditing the performance of practitioners, developing profiles of physicians, and building a data base on medical practices and their outcomes were viewed with mixed emotions. Some saw benefits from these practices (e.g., improved quality control) others saw harms (e.g., violation of the privacy of physicians).

Analysis and Evaluation

The implications of advances in this subject area seemed to hinge on panelists' views of equity and the values held about technological progress and social concern. The issue of equity was quite clear when panelists were concerned about a high cost

technology that appeared to be especially prone to distributional inequities, such as computerized aids to organ function.

Less clear was the question of technological progress and social concern and the interaction of these issues with questions of equity, which appears to characterize advances involving more widespread applications of computer technology. Proponents of technologies such as computerized medical records generally alluded to such technological benefits as improved planning, research, and patient care. Social concerns, such as the invasion of privacy, were either muted by the assumption that safeguards could be provided, or accepted as an intrinsic cost of the advance. Equity in distribution seemed to be assumed. Opponents of these technologies were unwilling to accept the trade-off of privacy for progress, and some considered the technology inherently inequitable because many people would be either unwilling or unable to use it. The policy problem raised was one of maintaining a balance between technological benefits and social harms while simultaneously insuring equitable distribution.

The advance *Computerized medical records in use* illustrated a degree of mistrust of established institutions on the part of panelists. Opposition to record systems was frequently based on a distrust of government or commerical interests that might abuse individual privacy. Proponents of the record systems often seemed to favor them for their potential to monitor physician performance, reflecting "...an intrinsic mistrust of the medical profession," according to one panelist reviewer.

Figure 1

MOST IMPORTANT ADVANCE IN EACH SUBJECT AREA BY PANELIST, FIRST PEI (1)

Subject Area/Advance Selected (3)	Category of Panelist (2): Ethicists	Lawyers	Medical Scientists	Reps. of Pub. Int.	Social Scientists	Total Panel	Percent Total
Systematic Control of Behavior							
Actions of psychopharmacological agents further understood	11	5	11	10	11	48	50%
Do-it-yourself anxiety and tension reduction	6	2	3	3	2	16	17%
More predictable psychosurgical procedures	1	5	4	5	3	18	19%
Added advances	4	2	2	2	4	14	15%
Total	22	14	20	20	20	96	100%
Reproductive Engineering							
In-vitro fertilization available in clinical practice	5	2	2	1	3	13	14%
Sex selection by sperm separation	4	1	4	6	5	20	21%
Safe, simple medical sterilization available	11	9	13	12	9	54	56%
Added advance	2	2	1	1	3	9	9%
Total	22	14	20	20	20	96	100%
Genetic Screening							
Amniocentesis becomes routine	9	8	10	8	9	44	46%
Widespread screening for inborn errors of metabolism	10	3	7	3	6	29	30%
Research shows lung cancer, heart disease have genetic basis	3	3	3	6	4	19	20%
Added advance	0	0	1	2	1	4	4%
Total	22	14	21	19	20	96	100%
Extension of Life							
Compact, wearable, artificial kidney developed	2	2	1	0	0	5	5%
Environmental causes of disease and trauma further controlled	13	9	10	15	10	57	58%
Gene therapy now available	3	2	6	4	2	17	17%
Added advance	4	1	4	2	8	19	19%
Total	22	14	21	21	20	98	100%
Data Banks, Computer Technology							
Computerized medical records in use	13	9	13	15	9	59	61%
Computer simulates metabolic processes; aids patients	2	2	2	0	0	6	6%
Computer screens patients, provides check-ups	5	2	3	3	6	19	20%
Added advance	2	1	3	2	5	13	13%
Total	22	14	21	20	20	97	100%

(1) 98 of 129 panelists (76%) completed the first PEI.

(2) Self-assigned categorization.

(3) See Appendix 5 for the full description of each advance.

Figure 2

SIGNIFICANT IMPLICATIONS OF ADVANCES BY SUBJECT AREA, FIRST PEI

Percentage of panelists mentioning this type of implication: (1)							
Subject Area/Advance (2) (3)	Economic	Ethical	Individual	Legal	Political	Social	Technical
Systematic Control of Behavior							
Actions of psychopharmacological agents further understood (N=48)	27	38	75	25	23	65	29
Do-it-yourself anxiety and tension reduction (N=16)	31	25	63	63	13	100	19
More predictable psychosurgical procedures (N=18)	0	72	72	61	28	28	11
Reproductive Engineering							
In-vitro fertilization available in clinical practice (N=13)	39	69	31	31	0	37	0
Sex selection by sperm separation (N=20)	30	50	45	5	8	95	15
Safe, simple medical sterilization available (N=54)	37	56	70	26	24	72	7
Genetic Screening							
Amniocentesis becomes routine (N=44)	30	86	57	39	2	43	7
Widespread screening for inborn errors of metabolism (N=29)	21	62	86	35	14	59	35
Research shows lung cancer, heart disease have genetic basis (N=19)	42	16	68	5	16	68	26
Extension of Life							
Compact, wearable, artificial kidney developed (N=5)	100	60	0	20	40	40	20
Environmental causes of disease and trauma further controlled (N=57)	84	18	25	21	54	61	18
Gene therapy now available (N=17)	35	59	71	18	18	53	24
Data Banks, Computer Technology							
Computerized medical records in use (N=59)	39	20	54	29	17	68	63
Computer simulates metabolic process; aids patients (N=6)	83	83	50	17	17	33	17
Computer screens patients, provides check-ups (N=19)	68	21	58	5	0	58	63

(1) Percentage of panelists selecting an advance who indicate the type of implications among the three most significant implications of the advance for society.

(2) "N" indicates the number of panelists who selected the advance as the most important one in a subject area.

(3) See Appendix 5 for a full description of each advance.

Figure 3

POLICY APPROACH FOR EACH ADVANCE BY SUBJECT AREA, FIRST PEI (1)

Percentage of panelists selecting this policy (2)							
Subject Area/Advance (3) (4)	Prevent or Control Research & Implementation	Promote Research & Implementation	Control or Allow Research Evaluate or Allow Implementation	Allow Research & Implementation	Promote Research Control or Evaluate Implementation	Allow Research Promote Implementation	Other Policy
Systematic Control of Behavior							
Actions of psychopharmacological agents further understood (N=48)	40	15	29	2	8	6	0
Do-it-yourself anxiety and tension reduction (N=16)	13	38	13	13	6	19	0
More predictable psychosurgical procedures (N=18)	100	0	0	0	0	0	0
Reproductive Engineering							
In-vitro fertilization available in clinical clinical practice (N=12)	67	8	8	0	0	16	0
Sex selection by sperm separation (N=20)	55	0	20	15	5	0	5
Safe, simple medical sterilization available (N=54)	17	35	20	2	9	17	0
Genetic Screening							
Amniocentesis becomes routine (N=42)	12	24	31	2	10	21	0
Widespread screening for inborn errors of metabolism (N=26)	35	8	35	8	12	4	0
Research shows lung cancer, heart disease have genetic basis (N=17)	6	59	18	6	6	6	0
Extension of Life							
Compact, wearable, artificial kidney developed (N=5)	20	40	20	0	0	0	20
Environmental causes of disease and trauma further controlled (N=57)	5	46	12	0	32	5	0
Gene therapy now available (N=17)	59	12	24	0	6	0	0
Data Banks, Computer Technology							
Computerized medical records in use (N=57)	19	11	28	5	33	4	0
Computer simulates metabolic process; aids patients (N=6)	33	33	0	0	33	0	0
Computer screens patients, provides check-ups (N=19)	11	21	26	11	26	5	0

(1) Policy approaches were discerned by analyzing panelists' separate votes on (1) policy with respect to research, and (2) policy with respect to implementation. Research policy options were: prevent; control; allow; promote. Implementation policy options were: prevent; control; evaluate; allow; promote use by people who need it; promote for use by people who want it.

(2) Percentage of panelists selecting the policy approach for each advance. Rows sum to 100%.

(3) See Appendix 5 for a full description of each advance.

(4) "N" indicates the number of panelists who selected the advance as the most important one in a subject area, and a prefered research and implementation policy.

Figure 4

SCENARIO OPTION SELECTED BY CATEGORY OF PANELIST, FIRST PEI

Scenario No./Scenario Option (2)	Ethicists	Lawyers	Medical Scientists	Reps. of Publ. Int.	Social Scientists	Total Panel	Percent Total
	Category of Panelist (1)						
Scenario No. 1: Select-a-Boy, Select-a-Girl Marketable Kits							
Allow marketing of kits	11	7	8	10	11	47	49%
Do not allow marketing of kits	11	7	13	10	8	49	51%
Total	22	14	21	20	19	96	100%
Scenario No. 2: Hospital Responsibility for Physician Performance Data							
Hospitals should be responsible	17	12	9	17	16	71	74%
Hospitals should not be responsible	4	1	12	4	4	25	26%
Total	21	13	21	21	20	96	100%
Scenario No. 3: Drug Treatment for Prisoners							
Treatment should be allowed	15	10	14	8	12	59	62%
Treatment should not be allowed	7	4	7	12	7	37	39%
Total	22	14	21	20	19	96	100%
Scenario No. 4: Allocation of Health Services Funds							
University Hospital receives funds .	4	6	6	4	8	28	33%
Neighborhood health clinic receives funds	17	8	10	13	9	57	67%
Total	21	14	16	17	17	85	100%
Scenario No. 5: Marketing of a Group Insurance Plan with Genetic Screening							
Insurance commissioner should approve marketing	7	8	8	6	7	36	38%
Insurance commissioner should not approve marketing	14	6	13	14	12	59	62%
Total	21	14	21	20	19	95	100%
Scenario No. 6: Life or Death Decisions							
ICU physician should decide	11	5	8	4	7	35	40%
Panel of persons should decide	11	6	11	13	11	52	60%
Total		11	19	17	18	87	100%

(1) Self-assigned categorization

(2) See Appendix 5 for a full description of each scenario.

Figure 5

SIGNIFICANT IMPLICATIONS OF SCENARIOS, BY OPTION CHOSEN, FIRST PEI

Percentage of panelists mentioning this type of implication: (1)							
Scenario(2)/Option Chosen (3)	Economic	Ethical	Individual	Legal	Political	Social	Technical
Scenario No. 1: Select-A-Boy, Select-A-Girl Marketable Kits							
Allow marketing of kits (N=47)	19	43	75	17	11	62	13
Do not allow marketing of kits (N=49)	16	61	45	4	18	94	20
Scenario No. 2: Hospital Responsibility for Physician Performance Data							
Hospitals should be responsible (N=71)	14	52	51	70	9	54	13
Hospitals should not be responsible (N=25)	12	52	44	80	8	40	20
Scenario No. 3: Drug Treatment for Prisoners							
Treatment should be allowed (N=59) .	34	51	76	36	7	68	9
Treatment should not be allowed (N=37)	8	46	76	57	30	60	14
Scenario No. 4: Allocation of Health Services Funds							
University Hospital receives funds (N=28)	75	21	21	0	21	50	68
Neighborhood health clinic receives funds (N=57)	74	40	9	2	39	67	9
Scenario No. 5: Marketing of a Group Insurance Plan with Genetic Screening							
Insurance commissioner should approve marketing (N=36)	64	44	50	14	14	44	11
Insurance commissioner should not approve marketing (N=59)	31	75	75	36	9	44	2
Scenario No. 6: Life or Death Decisions							
ICU physician should decide (N=35) .	20	63	40	34	6	54	6
Panel of persons should decide (N=52)	25	73	50	48	2	54	4

(1) Percentage of panelists indicating the type of implications as among the three that most significantly influenced the option chosen.

(2) See Appendix 5 for a full description of the scenario.

(3) "N" indicates the number of panelists who selected the option for a scenario.

Figure 6

POLICY OPTION PANELISTS WOULD LEAST LIKE TO SEE IMPLEMENTED FOR THE FIVE ADVANCES CONSIDERED IN THE SECOND PEI, BY SUBJECT AND CATEGORY OF PANELIST (1)

	Category of Panelist (2)						
Advances (3)/Policy Option	Ethicists	Lawyers	Medical Scientists	Reps. of Pub. Int.	Social Scientists	Total Panel	Percent Total
Actions of Psychopharmacological Agents Further Understood							
Promotion of research and implementation	16	12	11	12	11	62	59%
Control or limitation of research and implementation	8	7	14	7	7	43	41%
Total	24	19	25	19	18	105	100%
Select-A-Boy, Select-A-Girl Marketable Kits							
Promotion of research and implementation	18	8	15	11	11	63	60%
Control or limitation of research and implementation	7	11	10	9	7	44	40%
Total	25	19	25	20	18	107	100%
Amniocentesis Becomes Routine							
Promotion of research and implementation	13	11	12	8	10	54	51%
Control or limitation of research and implementation	11	8	12	12	9	52	49%
Total	24	19	24	20	19	106	100%
Environmental Causes of Disease and Trauma Further Controlled							
Promotion of research and implementation	7	9	11	2	4	33	30%
Control or limitation of research and implementation	17	10	14	18	17	76	70%
Total	24	19	25	20	21	109	100%
Computerized Medical Records in Use							
Promotion of research and implementation	17	8	11	9	12	57	53%
Control or limitation of research and implementation	7	11	12	11	9	50	47%
Total	24	19	23	20	21	107	100%

(1) 110 of 128 panelists (86%) completed the second PEI.

(2) Self-assigned categorization.

(3) See Appendix 5 for a full description of each advance.

(4) Percentage of panelists who responded to the item selecting the stated policy option.

Figure 7

NEGATIVE CONSEQUENCES OF ADVANCES CONSIDERED IN THE SECOND PEI, BY LEAST LIKED POLICY OPTION

Percentage of responses mentioning this type of negative consequence: (1)									
Advance (2)/Least liked Policy Option (3)	Economic	Ethical	Health	Individual	Legal	Political	Social	Technical	Environment and Other
Actions of psychopharmacological agents further understood									
Promotion of research and implementation (N=61)	3	25	11	21	16	51	66	30	0
Control or limitation of research and implementation (N=43)	16	9	4	5	2	19	49	63	0
Select-a-boy, Select-a-girl marketable kits									
Promotion of research and implementation (N=62)	6	27	8	13	5	15	84	13	2
Control or limitation of research and implementation (N=44)	25	52	5	14	16	11	52	16	2
Amniocentesis becomes routine									
Promotion of research and implementation (N=53)	47	47	13	15	6	17	98	15	0
Control or limitation of research and implementation (N=52)	48	15	13	23	0	2	65	40	0
Environmental causes of disease and trauma further controlled									
Promotion of research and implementation (N=33)	49	12	3	21	3	42	42	49	12
Control or limitation of research and implementation (N=76)	34	3	45	5	1	12	25	46	24
Computerized medical records in use									
Promotion of research and implementation (N=57)	11	70	11	14	4	11	42	56	2
Control or limitation of research and implementation (N=50)	22	14	10	12	4	6	12	88	2

(1) Percentage of panelists selecting a policy option as that least liked who indicated the type of negative consequence among the three most significant negative consequences that would occur if the policy were implemented.

(2) See Appendix 5 for a full description of each advance

(3) "N" indicates the number of panelists who selected the policy option as that least liked.

Figure 8

GROUPS PARTICULARLY AFFECTED BY THE NEGATIVE CONSEQUENCES OF ADOPTING THE LEAST LIKED POLICY OPTION, PROMOTION OR LIMITATION OR CONTROL OF ADVANCES CONSIDERED IN THE SECOND PEI (1)

Advance (2)	Actions of psychopharmacological agents further understood		Select-a-boy, Select-a-girl marketable kits		Amniocentesis becomes routine		Environmental causes of disease and trauma further controlled		Computerized medical records in use	
Least liked policy (3) / Group Particularly Affected	Promote (N=62)	Control (N=43)	Promote (N=63)	Control (N=44)	Promote (N=54)	Control (N=52)	Promote (N=33)	Control (N=76)	Promote (N=57)	Control (N=50)
Men	10	7	30	25	9	10	0	8	0	10
Women	13	7	65	34	59	40	0	8	12	16
Low-income people	34	19	19	32	46	48	33	40	46	32
Children	16	7	32	9	19	27	6	17	12	8
Young adults	11	9	27	52	13	25	12	9	7	2
Urban population	8	5	0	2	0	4	27	43	0	0
Workers	5	7	0	0	15	6	12	42	9	12
Acutely ill people	2	19	0	0	0	0	6	4	19	30
Chronically ill people	16	40	3	2	11	4	12	22	39	38
Residents of health care institutions	48	40	0	2	9	8	6	1	21	16
Persons in prisons	65	30	0	0	6	0	3	0	12	2
Physicians	8	12	6	9	9	14	3	4	37	44
Biomedical scientists	8	21	0	5	2	10	0	13	9	46
Private industry	6	2	5	9	0	2	33	13	4	6

(1) Only groups mentioned by at least 25% of panelists for at least one policy option of at least one advance have been included in this figure.

(2) See Appendix 5 for a full description of each advance.

(3) Research and implementation policy panelists would least like to see implemented. "N" indicates the number of panelists who selected the policy.

Chapter 3:
Implications of Advances.

INTRODUCTION

The preceding chapter presented summaries of the implications of advances by subject areas. This chapter addresses the implications of advances more broadly, assessing the manner in which biomedical and behavioral advances in general will influence individuals and society. These implications of advances were derived from two sources. They were:

* reports on panelists' responses to each advance and each scenario considered in the first PEI and each advance and scenario elaborated on in the second, provided by panelist reviewers; and

* reports on the dimensions underlying the responses to all advances and all scenarios in the first PEI, and all advances in the second, provided by panelist reviewers.

The implications of advances are discussed under three major headings:

* Implications for individuals;

* Implications for society; and

* Moral and ethical issues.

Individual implications relate to the potential impact of advances on individual responsibility and choice, individual rights, and individual health. Social implications relate to economic effects, technological effects, social change, and minorities. Moral and ethical issues include the impact of advances on biological change, behavioral change, and equity.

IMPLICATIONS FOR INDIVIDUALS

The panel's concern for the individual was manifest throughout the implications of advances and policies. Responses focused on problems of individual health, effects on the individual's economic position, protection against stigmatization, the improvement or protection of individual choice, the protection of individual rights, and other more specific issues. Both positive and negative effects on individuals were identified.

In some advances the panelist's view of the individual appeared to be a critical factor in determining attitudes toward the advance, or toward policies designed to deal with the advance. What appeared to be critical was not so much the effect of advances on individual health or economics, but the potential effects on individual values or the relationship between individual actions and social consequences. Thus, there was a tendency for individual effects to be confounded with either ethical or social considerations.

The panel tended to favor the individual to the extent that it generally upheld individualistic values and supported the rights of individuals when these conflicted with the needs of society. However, there was a great range of opinion among panelists regarding where social concerns legitimately overrode individual concerns and where the exercise of individual rights might become detrimental to the social good.

Individual Responsibility and Choice

Panelists frequently looked at advances in terms of the way they would either increase or decrease personal responsibility,

particularly as this was manifest in the ability to exercise choice. As a panelist reviewer noted:

> It is an ideal for human life, accepted almost universally in our society, that a person take responsibility for his or her actions, develop the capacities required to act responsibly, and be held responsible by others.

Advances in all of the areas had some qualities which could tend to enhance personal choice and responsibility, and they were almost always viewed favorably by panelists regardless of their overall position with respect to an advance. One panelist reviewer suggested that the panel was divided into two groups holding quite different notions of personal choice and responsibility:

> One group appears to ground all aspects of the ethical dimension in a concept of freedom. Absolute freedom of choice is the most important ethical-moral source and norm, and any violation of it undercuts all ethical-moral aspects of life; therefore, freedom of choice is maximized over against all other values.
>
> The other point of view is grounded in the belief that freedom of choice is indeed one of the most important ethical moral dimensions of life, but it is never in isolation and must always be exercised in relation to consequences. It is not an absolute value which stands of and by itself but only as a part of a complex of values from which it cannot be abstracted. The exercise of one's own freedom can only be done in relationship to the freedom of others, and one cannot assume that the pursuit of one's own freedom will automatically in the long run bring the greatest good for oneself and others.

Personal responsibility and choice are enhanced in two ways, either by the provision of information to an individual or by the creation of a new option. Sometimes both conditions were met in an advance. The exercise of personal responsibility and choice was seen as taking place within a social and political environment which has distinct and varying effects. While the

technologies themselves might have an inherent potential for increasing personal responsibility and choice, the interaction of these technologies with the individual, society, the government, or various agencies could lead to decrements rather than increments in personal responsibility and choice.

Panelists regarded advances in information technology as opening the possibility for diminishing the information received. Computers could be programmed incorrectly or misinformation entered leading to false information on which an individual might act. Physicians, particularly those who might themselves be opposed to procedures like abortion, could withhold information, or testing could produce false positive or false negative results. Some panelists believed that the nature of the technology itself would deter some people from its use. Due to a lack of sophistication, poor and minority groups, for instance, were considered by some panelists unlikely to be able to deal with mechanistic advances, such as computer technology. There were also concerns about differential applications of technology. This was usually characterized as taking place along economic, racial, or ethnic lines. Thus, the poor may not have access to amniocentesis and the information it provides. Alternatively, the poor could be offered an "excess" of information about sterilization procedures.

Individuals can also receive information they do not want, a particular danger in widespread screening programs. A person opposed to abortion or unsure about abortion could be inadvertently included in a screening program and provided information

about fetal defects. Under these circumstances individual choice or responsibility would not be enhanced, but conflict and guilt might arise instead.

If options are foreclosed, or made less viable in some way, personal responsibility is derogated. There was particular concern about the possibility of government intervention in the subject areas *Systematic Control of Behavior*, *Reproductive Engineering*, and *Genetic Screening*. The government could force the population (or selected parts of it) to take behavior control drugs, manipulate the sex ratio through sex selection technology, or affect the genetic future by mandating screening and selection procedures. Intervention could be insidious, rather than direct. Welfare payments might be made contingent upon sterilization, payment for amniocentesis might be made contingent upon aborting any fetus identified as defective, or amniocentesis itself might be promoted through the expedient of refusing public support to defective children.

Social values could develop which would tend to foreclose individual options. This seemed a particularly strongly held view in the subject areas *Reproductive Engineering* and *Genetic Screening*. There was some concern that the freedom of choice to undergo amniocentesis would be abrogated by social pressures to prevent the birth of "defectives". Some panelists also saw social attitudes as having an effect on the acceptance of behavior modifying drugs as a way of coping with pressures.

Agents and institutions of various kinds were considered to exert a coercive effect on individuals. The institutional set-

ting itself (prisons or hospitals) may be intrinsically coercive since cooperation with a suggested option (particular therapy) is rewarded. Schools or teachers could exert a coercive effect on children in the imposition of such advances as anti-anxiety tapes since children may not be able to exercise a truly informed choice. Similarly, patients suffering a mental problem of some kind may not be able to exercise a responsible choice in decisions about the administration of drugs or surgery.

It was not only patients, or those to whom the advances would be administered who might suffer coercion. Physicians were sometimes seen as having their options foreclosed by pressures to conform. The use of life extending technologies was viewed as mandated by threats of malpractice, as was the use of screening technologies.

Individual Rights

The rights of individuals were proclaimed throughout the responses in all of the subject areas. Among these rights were noted: the right to life, the right to procreate, the right to privacy, the right to psychological and physical health, the rights of women, the rights of minorities, the right to treatment, the right to freedom of choice, and the right to avoid coercion. For the most part, "rights" were simply asserted, their existence apparently considered self-evident, and only a few were accorded an evidentiary basis in law or the Constitution.

Some of the rights asserted were manifestly affected by the technological advances forwarded in the study, or reflected

in an understanding of the present state of technology. The right to die, for instance, has been asserted largely as a function of relatively recent developments in life saving medical technologies. The right to procreate was seen as being given new meaning by potential advances in reproductive engineering; sometimes that meaning was unfavorable, as in surrogate mothering. The right to select the sex of one's offspring was advanced as a function of developments in sex selection technology.

Individual rights appeared almost sacrosanct to a number of panelists, but for most there was an apparent willingness to trade off rights in some areas, or to forego putting them into effect in others. For instance, there was some sentiment for trading off individual rights to refuse behavior control in the interest of social stability, though many panelists strongly upheld individual rights in this regard. There was also a sense that some individual rights would be foregone in deference to the overall health needs of society, particularly in matters of environmental health and safety. However, there was a distinct sense here that things could go too far in the derogation of individual rights. Seat belts and motorcycle helmet laws were offered by several panelists as examples of unwarranted governmental intervention in private lives. Some rights might not be exercised in the interest of social welfare or family harmony. Exercise of an individual right to select the sex of children might affect the sex ratio, to the detriment of society, or create a clash between family members over the

sex to be selected.

The loss of individual rights was a primary concern to some panelists. In general, technologies which could be applied on a widespread basis were seen as potentially threatening to individual rights. In one area, *Computerized Medical Records In Use*, the threat to individual rights formed the central theme of panelists opposed to the technology. The critical question about the loss of individual rights seemed to center on whether they were freely given or expropriated by another individual, an agency, or the government. Panelists countenanced the individual's relinquishing of rights in situations of informed consent and objected strongly to curtailment of rights by external agents or agencies when consent was not solicited or received.

Individual Health

Panelists seemed in general agreement that advances would have an overall beneficial effect on individual health. They also seemed to agree on the possibility of some risks to individual health arising from the advances. They differed considerably on the degree of risk foreseen or acceptable. Few panelists adopted either a "damn the torpedoes" outlook or called for a ban on technology based on the risks. Almost all panelists were willing to accept some level of risk.

For some types of advances the individual health issue centered on the possibility of iatrogenic disease -- through such things as errors in the medical record, errors in testing procedures producing false positives or false negatives, and errors in surgical procedures. Where these possibilities existed, panelists were divided over the relative benefits

and harms with some preferring to avoid the potential risk, while others appeared to consider such a risk acceptable. Advances may also affect the health of individuals of different social classes differently, because of something inherent either in the technology (requiring technical sophistication) or in an aspect of society itself (race or class attitudes). In these cases some panelists were either willing to accept some risk of inequity or contended that the same classes would be differentially affected by the absence of technology. Other panelists seemed unwilling to accept the risk, particularly when inequity seemed inherent in the technology, rather than as a function of social attitudes.

Several advances raised the fear of unknown effects on individual health. A lack of longitudinal data concerned those who feared that obvious short-run benefits would prove seductive when too little was known about long-term consequences.

IMPLICATIONS FOR SOCIETY

Social concerns and issues were more frequently commented on than any other type of implications. Where social effects were seen they were frequently complex and productive of considerable conflict. In *Systematic Control of Behavior*, for example, benefits such as increased productivity, lowered costs of curbing social deviance, and profits for private enterprise were ranged against such costs as the curtailment of individual rights, and the notion that behavioral treatments might become the only acceptable means for controlling social problems. Similar problems were suggested for *Genetic Screening* where the fear expressed was that society's desire to decrease the number of defectives born (for cost and other reasons) might lead to a social climate in which pressures would be exerted to force screening. A concomitant loss of social willingness to provide support for defectives who slipped through the screening process was also feared.

Panelists foresaw dangers in implementing advances that might lead to the abuse of minority groups, or the undermining of traditional social values, in such areas as: the family, freedom, political order, religious groups, professions, equality under the law, the sacredness of human life, and protection of the weak (including fetuses).

Panelists' responses to the implications of the advances revealed four major areas of concern: technological effects, economic effects, social change, and effects on minorities.

Technological Effects

Technological benefits expected from advances included such things as increased knowledge, improved health care, and contributions to future research. In general it appeared that new knowledge was of greatest importance to panelists as a benefit, and was frequently cited by those in favor of promoting research and implementation of advances. Not all technological effects were considered beneficial, however, and some panelists thought there were inherent dangers in technology which could operate to reduce or even negate the benefits.

Panelists who saw technological benefits argued that research is cumulative and that blocking technological development harms those for whom the technology is being developed, creates a climate inimical to research in general as an attitude of control spreads to other areas, and stalls progress in the accumulation of human knowledge. Panelists who saw dangers in technological advance did not necessarily disagree that benefits would be forthcoming but felt that the benefits would not be achieved without careful control. These panelists suggested that technology was being pushed faster than controls could be devised to handle it and that this resulted in the application of technologies which were flawed in one way or another. There was also a notion that technological development could be misdirected — a technology once developed and applied tends to block off other, perhaps better technologies (e.g., improving cures for cancer might lessen efforts to find ways of preventing cancer).

A panelist reviewer concluded from this dichotomy:

> One group seems to have an implicit faith in the inherent power of a freewheeling approach to produce the greatest good for the greatest number at the least cost for the whole of society through the automatic working of its search for freedom.
>
> The other group works much more out of a checks and balance point of view which argues that the largely unchecked and all out promotion of advances could prove to be more expensive, more dangerous, less equitable, and in the long run more destructive to the total values, economic, political, and legal structures of our society.

General improvements in health care were expected from a number of advances. The discussion of computerized medical records exemplified some of the beneficial attributes foreseen. According to a panelist reviewer, panelists suggested the technology would result in:

> Stemming the rapid rise of cost of medical care; increased opportunity for preventive health care by identifying and/or treating high risk individuals or groups; standardization of health care; easier ascertainment of substandard care and elimination of incompetents (quality control)...

But there could be problems in attempting to improve health care without some "checks and balances" as panelists contended in discussing amniocentesis. Here there was concern that development of a widespread program would result in increased demand for competent personnel to undertake the procedure. In the absence of a means to fulfill this demand it was considered likely that there would be a greater use of personnel with a lower level of training, thus increasing the potential for iatrogenic disease.

The production of new knowledge and contributions to future research were generally considered beneficial, but some drawbacks were identified. Advances in *Systematic Control of Behav-*

ior, Genetic Screening, and *Data Banks, Computer Technology* were all noted for the potential to produce new knowledge fundamental for future research. Computerized medical records, in particular, were regarded for their potential to usher in a new era of epidemiological research and discovery. Genetic screening would provide data for genetic research. Psychopharmacological agents and psychosurgical procedures were seen as contributing to an understanding of the human mind.

These benefits were countered by a variety of concerns. Errors in the record might negate the benefits of computer technology. The risks entailed in gathering knowledge about genetic engineering might not be worth the benefits. Advances in knowledge about the relationships between health and environment could result in severe industrial or geographical dislocations as people moved from dangerous industries or areas to less dangerous ones.

Economic Effects

The economic concerns which stood out in panelists' responses included the relationship between the costs and benefits of research, and the costs of bureaucratic supervision. Some advances seemed to generate agreement among panelists regarding the relationship between costs and benefits. This occurred mainly in areas where high cost technologies were associated with limited distribution, as in the case of the *Compact, Wearable, Artificial Kidney*. Panelists generally did not favor advances of this nature. The line between where a technology became cost-effective seemed very thin, however, and panelists disagreed extensively over whether costs of development or the

costs of the attendant bureaucracy would overwhelm the benefits.

Advances involving widespread application or availability most frequently raised concerns about the costs of bureaucratic supervision. Costly maintenance systems were foreseen for screening programs, environmental health and safety initiatives, and medical records systems, and there was no agreement over whether these costs would be greater or less than the expected benefits. This problem was exacerbated by the perceived lack of any kind of accounting procedures which might consider social costs and benefits as well as financial profit and loss.

A variety of other economic effects were touched on in the discussions. Life extending technologies could increase the costs to society of sustaining life, and environmental regulations could cause major population shifts. The relationship between economics and social values was also explored by some panelists who were concerned that wholesale use of behavior control methods might have an undesirable effect on economic productivity by affecting the work ethic (but not all panelists viewed this eventuality as a societal harm).

On the positive side, a number of advances were seen as reducing the costs of health care for both the individual and society. Screening technologies and behavior control were considered likely to reduce the costs of custodial care in institutions, and computer technology was considered likely to reduce the costs of individual health care. Benefits were even noted for the world economic picture stemming from developments in reproductive control which would help the world population

problem.

Societal Change

Though society was viewed by the Consultant Panel as open to change, certain social patterns were related to values so fundamental as to warrant overriding protection. The sex ratio (viewed in some contexts as a fundamental social pattern, but in others as a "natural order") and monogamous marriage were considered such patterns. The technology of sex selection was commonly agreed to have a potential for changing this social pattern. The majority of panelists thought (and the public concurred) that the direction of this potential change would be for a predominance of male children -- particularly among first borns.

Some panelists felt that no significant change would take place, or, if it did, countervailing forces, inherent in society or deliberately set into motion, would tend to smooth out differences over time. A larger number felt that a preference for male children would be persistent and that a great imbalance in the sex ratio would lead to other social changes like increased homosexuality or polygamous marriage.

Other changes in fundamental social patterns were noted but not stated so unequivocally. Behavior control technology could influence the relationship between governing and governed; screening technologies could lead to notions of genetic equality as an obtainable social end. All of the technologies noted were seen by at least some panelists as having an impact on religious or moral beliefs widely held in western society.

Minorities

Concern for minorities cut across most of the advances and subject areas. This concern tended to take two forms: either minority groups could have an advance forced on them to their detriment, or they could be denied access to the advance on a par with the more advantaged.

Generally, the panel did not point to particular ethnic or racial groups but aggregated these groups as, simply, "minorities". The issue arose in the context of those advances where some sort of discrimination, labeling, or manipulation could be applied by a relatively powerful force, e.g., the government, the wealthy, or society at large, to the disadvantage of others, e.g., the poor, the institutionalized, or the uneducated. Panelists least liking promotion of an advance frequently highlighted possible dangers of social control over minorities and the poor as an outcome of its promition. Amniocentesis, for instance, was considered an area where social policy could operate against those resisting the procedure. Roman Catholics were used as an example of a group which might refuse amniocentesis on religious grounds, and suffer subsequently from pressures exerted by those in the majority. However, panelists opposed to control were apt to foresee another kind of discrimination. Some feared that only the sophisticated and the wealthy would be able to avail themselves of amniocentesis if it were not widely distributed, thus discriminating against the poor and less well educated.

It seemed implicit in panelists' arguments that trade-offs might have to be considered among various minority groups. By

promoting an advance, the rights of one group might be threatened; by controlling or prohibiting the advance, another group, or even the same group, could be negatively affected in some other way.

MORAL AND ETHICAL ISSUES

Panelists addressed moral and ethical issues extensively. In many cases these issues were entwined with individual and social questions -- as in the discussions of individual rights or the treatment of minorities -- and these have already been presented. The broad moral and ethical issues considered by the panel related to the potential for fundamental changes in human biology and behavior, and the question of equity or social justice.

Biological Change

Advances in gene therapy, amniocentesis, screening for inborn errors of metabolism, and sex selection all raised similar issues with respect to altering basic human biology. Gene therapy could become an instrument for introducing completely new germ plasm to the gene pool of the species, or the manipulation of genes at some locus could have the unanticipated side effect of altering genes at other loci. The result in either event would be alterations in human biology of a completely unknown type and direction. Gene therapy was nearly universally feared because of the uncertainties involved in assessing the long term outcomes, though there was some support for promoting its development for short-term gains.

Amniocentesis and screening techniques in general were seen as allowing a directive effect over human biological characteristics. The direction would come about through a process of negative eugenics as "defectives" were identified and therapeutic abortion took place. Screening techniques in particular could have a sort of genetic "leveling" effect, bringing a

rather new and different meaning to the notion that "all men are created equal".

Many panelists also tended to see screening technologies as part of a general social effort to produce healthy children, arguing that "screening will enable us to create a new generation of biologically less imperfect children." Those opposed to screening, or at least suspicious of it, feared that the process of selection would transcend a search for normality and become a striving for perfection.

Sex selection technologies could have a limited impact on biological change if the technology was used for genetic reasons -- the avoidance of sex-linked diseases. The magnitude of the impact was somewhat obscured since the technology, it was recognized, would allow expression of characteristics to be avoided, while at the same time allowing continuation of the genes in the gene pool. Panelists were also concerned that once a sex selection capability had been introduced, demand for the ability to select other characteristics would follow.

The potential for biological change noted above was widely agreed upon by the panelists. However, there was substantial disagreement about whether or not changes would be beneficial or harmful, or in the case of undeniably harmful changes whether or not they would come about at all. Panelists were very much divided -- either on ethical grounds, or on the grounds of individual rights versus social responsibility -- on whether there was a human right or duty to engage in willful manipulation of the genetic heritage of the species.

Behavioral Change

There was no doubt among panelists that human behaviors could be changed. A panelist reviewer identified a division between a "holistic" view of humanity and a mechanistic view. Panelists adopting a holistic perspective were concerned about advances in *Systematic Control of Behavior* because of a perceived potential for very fundamental changes in a Western, humanistic view of man as a creature of free will and personal responsibility. The use of drugs, psychosurgery, and even techniques such as tension reduction, was viewed as promoting a dulling effect on society as people became homogenized in accordance with some central set of approved behaviors. As a panelist reviewer noted:

> Among the dangers feared, the conception of a person as ready for manipulation was very prominent.... It was alleged to be difficult to square the conception of manipulability with the conception of responsibility.... There was also considerable discussion about the ideals appropriate to human life and how behavior control advances may trim those ideals unnecessarily.

Panelists' views on these changes were mixed. In general it appeared that so long as the effects were confined to the rehabilitation of individuals needing assistance to cope with life or to return to society as productive members, they were generally viewed favorably. The advances were viewed much less favorably in connection with their application to classes of individuals, or if they were deliberately sought as a means of avoiding personal responsibility.

Equity

The concern for equity, or social justice, was expressed throughout the discussion of advances and was particularly prominent in discussions of scenarios. The notion that policies should be fair to various interest and identity groups encompassed

fair treatment for the poor, prisoners, patients, physicians, women, and virtually any other group identified in the discussions. Underlying the discussion of equity was the implicit sense that a pluralistic society could only be maintained in a climate amenable to a plurality of values. This point was explicitly made in connection with behavior control technologies, and was prominent in the discussion of amniocentesis.

One aspect of the question of equity was the notion of equal access to health care. Concern over equal access was reflected in a number of advances and related to the fair distribution of the benefits of technology (or sometimes the equitable distribution of risks). Panelists were very concerned about equal access to high cost technologies even to the extent of questioning whether it was appropriate to spend public funds on technologies which might have limited distribution. A particular concern in limiting access to scarce technological resources was the avoidance of "factoring of social standing or social worth into the decision [about who should benefit from the technology]", according to one panelist reviewer. With regard to technologies of wide application, panelists voiced concern about either social attitudes, personal values, or even the technological nature of an advance itself and the role these factors might play in equal access.

Chapter 4:
Policies.

INTRODUCTION

The implications of policies to control and regulate biomedical and behavioral research and the implementation of resultant technologies were identified using a four step process:

* Policies to deal with specific advances in biomedical and behavioral research and technology were identified in the First Policy Evaluation Instrument (PEI), and used to construct a series of general policy statements for consideration in the second;

* Policy approaches were identified from panelists' evaluations of the general policy statements and from panelists' elaborations on those policy statements considered most urgent, and used to construct four policy scenarios for evaluation in the third PEI;

* Consequences of and barriers to implementing the national policy described in the four policy scenarios contained in the third PEI were identified, and amendments and additions to the policies that comprised the scenarios described; and

* Panelist responses to the third PEI were summarized and analyzed to produce a compendium of implications for each of the policy scenarios.

These four steps are outlined below; the results of the process are described in the remainder of this chapter. A detailed description of study methods is provided in Appendix 1.

Policies for Specific Advances

In the first PEI, panelists were asked to select and describe the research and implementation policies most appropriate to deal with the advance they considered most important for each of the five subject areas considered. In addition, panelists were asked to suggest the kinds of policies which would help in the resolution of the issues raised in the six scenarios described.

Panelists' responses to each advance and scenario were

analyzed and summarized by project staff. A list of general policy statements was compiled from these results; a review of the legislative intent in setting up the Commission, the mandate for the study; and from various documents produced by the Commission itself. The initial list of statements was reviewed by the Study Design and Management Group (SDMG), and the final list of policy statements selected.

General Policy Statements

In the second PEI panelists were presented with 23 general policy statements (and their associated sets of subsidiary statements) and asked to decide whether or not they agreed with the statement and whether or not it was urgent to implement the policy. They were then asked to choose the five most urgent policies, to rank them in order of urgency, and finally, to elaborate on the three policies selected as most urgent to implement.

Panelists' responses to each general policy statement, and their elaborations on those policies considered to be most urgent, were analyzed and summarized by project staff. These summaries were sent to panelist reviewers to identify and summarize the dimensions underlying panelists' responses.

Panelists' elaborations on those general policies viewed favorably were used to construct four policy scenarios. Each scenario dealt with a separate aspect of a possible national policy; collectively they described a comprehensive national policy. Elaborations on the general policy statements formed elements of the policy scenarios; where necessary, elements were added to round out the policy. The addition of elements was made in line with the general direction suggested by panelists'

elaborations on the general policy statements.

The policy scenarios were reviewed by members of the SDMG and the same panelist reviewers who had reviewed the summaries of the general policy statements, and revised in line with their suggestions. The revised policy scenarios were then carried forward into the third PEI.

Policy Scenarios

In the third PEI, panelists were asked to examine the four policy scenarios that collectively described a possible national policy with respect to biomedical and behavioral research and technology. Each scenario consisted of a number of particular policy statements, elements of the national policy. The four policy scenarios were: *Permanent National Commission; Public involvement in policy decision-making; Biomedical and behavioral research;* and *Implementation of biomedical and behavioral technologies.* A synopsis of the four policy scenarios is shown in Figure 9. They are described fully in Appendix 6.

For each scenario, panelists were asked to:

* identify and elaborate on positive and negative consequences they anticipated would result if the policy were implemented;

* identify and describe barriers to implementation of the policy and the ways in which these barriers might be overcome;

* indicate their degree of support for, or opposition to, each of the particular policies that comprised the scenario;

* offer specific amendments to particular policies that would enhance positive consequences or ameliorate negative ones; and

* add additional policies they thought necessary to complete or augment the national policy described.

Panelists were also asked to indicate their preferred allocations for health and health research and development (R&D) vis-a-vis other activities, and the relative priorities that should be afforded to the different types of R&D activities described.

Identification of Implications

For analytic purposes, panelists were classified on the basis of their mean scores as supporters or opposers of a policy scenario. Responses to each policy scenario were sorted by this mean score and summarized by project staff. These summaries were sent to panelist reviewers to identify the dimensions underlying panelists' responses. These dimensions were then analyzed to identify common themes. Resource allocation items were analyzed statistically. The statistical analyses, materials provided by panelist reviewers, the original summaries, and individual panelists' responses were used as resources for writing this and the subsequent chapter of the report.

Figure 10 presents the degree of support for implementing each of the four policy scenarios based on a mean score of responses to the particular policies. Figures 11 to 14 present panelists' votes on each particular policy contained in the policy scenarios. The remainder of this chapter summarizes the findings for each of the four policy scenarios and for the resource allocation questions. Each set of findings is followed by a brief analysis and evaluation. The next chapter examines the implications of these policies with respect to: the need for controls; the role of government; justice; economic facotrs; and public participation.

PERMANENT NATIONAL COMMISSION

The first policy scenario described a *Permanent National Commission on Biomedical and Behavioral Research and Technology*, established by an Act of Congress. Particular policies addressed organization of the *Commission*, membership, staffing, level of authority, scope, accountability, and evaluation of the *Commission's* performance. The *Commission* was described as having a national level of authority which included promulgation of policies and guidelines, the establishment of a national strategy for public funding of research, and the auditing of research projects.

Findings

Support for the concept of the *Commission* was relatively high. Supporters of the policy represented 54% of the panel, and only 17% were opposed -- the smallest number opposed to any of the policy scenarios in the study (Figure 10). Consistent support was received across all categories of panelist except medical scientists. Ethicists offered support in the greatest measure (64%); medical scientists least (33%). The first policy statement in the scenario, essentially a vote on the establishment of the *Commission* itself, received the strong support of 51% of the panel and an additional 26% offered approval if the policy were amended in some way. Only 11% of the panel either opposed the policy statement in any form or found it unnecessary (Figure 11, policy no. 1).

Panelists were generally in favor of those aspects of the policy scenario which involved the *Commission* in a public communications process. Policies involving dissemination of information about the *Commission's* policies, evaluations of its efforts, re-

sults of the audits of research, or interface with the public and interest groups in the development of policy were strongly supported by as many as 82% of the panelists (Figure 11, policy nos. 9, 13, 14, 18, and 19). Policies which related to the *Commission's* jurisdiction and authority did not fare so well. The purpose of the *Commission* drew strong support from only 32% of the panel and qualified support from an additional 29% (Figure 11, policy no. 2). A majority of the panel opposed the way in which the *Commission* allocated research funds (Figure 11, policy no. 11).

In general the policy amendments offered were directed toward either administrative arrangements (modifications of specific points such as number of *Commissioners*, term of service, etc.), or toward changes in the scope or level of authority of the *Commission*. In the latter case the predominant direction of change was to reduce the *Commission's* scope.

Three major dimensions were identified in panelists' responses. They were:

* Economic concerns;
* Quality of research; and
* Use or abuse of power.

<u>Economic concerns</u>. Economics formed a central theme in the responses of a number of panelists whether for or against the *Commission*. To some, the current costs of research and medical care served as justification for the establishment of a *Commission* which might serve to ensure a just distribution of funds appropriate to a national system of priorities and goals. To others, the *Commission* represented the intrusion of a stag-

gering bureaucracy which would enormously increase the costs of biomedical and behavioral research.

Quality of research. The quality of research was extensively addressed. Favorable aspects of the scenario *Commission* included benefits for research quality, efficiency, and effectiveness. Duplication of effort would be avoided; wasteful, harmful, or dangerous research would be weeded out; and a

> haphazard approach to the awarding of research endeavors would be supplanted by a goal-directed effort which, as commerce has shown, would inevitably lead to a more rapid resolution of pressing health needs of our people.

Moreover, researchers would become accountable -- finally

> -- to a series of overseers, who would ensure that all research was performed in an ethical fashion, scientifically sound, and pursued in a manner in accord with the original protocol, and that some demonstrable benefit might be expected; for if these criteria were not met, the already funded project would be swiftly discontinued.

Ill effects of the *Commission* were also described. Some panelists viewed the composition of the *Commission* as politically motivated and lacking scientific vision. The short term of office for *Commissioners* (three years) would preclude attracting truly outstanding candidates. The massive increase in red tape and paperwork, and uncertainties of finding grant support were thought to be so intolerable that it would repel our finest scientific minds. All of this would lead to a significant deterioration in the quality of biomedical research. Finally, as one panelist reviewer observed:

> ...Opponents of the Commission saw the allocation of 90% of the funds to priority projects [stated in the scenario] as catastrophic, and they based their view on the fact that most clinically significant advances have been the result of serendipitous discoveries emanating from the basic sciences.

Use or abuse of power. The use or abuse of power was extensively addressed, with some panelists alluding to the power of the pharmaceutical companies, medical researchers and the medical establishment in general as justification for establishing a *Commission*. Opponents of the *Commission* protested against the politicization of research, the usurpation of Congressional powers, and the loss of checks and balances in the democratic system, seeing the *Commission* itself as an abuse of power. In terms of its scope, some questioned its legality under the Constitution.

Analysis and Evaluation

A majority of panelists supported the concept of a *Permanent National Commission* as a means of dealing with the problem of directing and regulating biomedical and behavioral research and technology. Opposition to the concept arose over questions of cost and the possible harm to the research effort growing out of an increased bureaucratization of research. The underlying question of whether the individual freedom of researchers "to pursue their interests in a climate of freedom", in the words of one panelist reviewer, should be "subservient to the public will and needs", was resolved by most panelists in favor of the public need.

PUBLIC INVOLVEMENT IN POLICY DECISION-MAKING

The second policy scenario dealt with public involvement in policy decision-making. The scenario described provisions of the Act designed to encourage public involvement and the dissemination of information to the public. Particular policies addressed the *Commission's* responsibilities with respect to public participation, the gathering of public opinion, and the means and standards for dissemination of information. The policies also specified the creation of five federally funded regional information centers to support the involvement and dissemination efforts.

Findings

Overall this was the least supported of any of the policy scenarios. Some 44% of the panel generally supported the policy, but 40% were opposed (Figure 10). The greatest level of support was found among representatives of the public interest (65% supported) and the heaviest opposition among medical scientists (58% opposed). The first policy statement in the scenario -- another measure of the panel's overall view -- was supported as written by 44% of the panelists and approved if amended by another 26% (Figure 12, policy no. 1).

The panel appeared to be generally in favor of the ends of the scenario, but unhappy with some of the means. The particular policies which stated the ends of public participation in policy formation, public education, and dissemination were generally well received, sometimes by over 75% of the panel (Figure 12, policy nos. 2, 3, and 4). Some means were also approved -- such as public meetings and information dissemination through

established media. However, any aspect of the policy scenario which touched upon the existence of the five regional information centers was strongly opposed, and no policy which mentioned the centers was supported by a majority of the panelists. The particular policy establishing the five centers was approved as written by only 19% of the panelists and the policy on appropriations by 26% (Figure 12, policy nos. 7 and 10). Opposition centered on the exclusion of existing agencies (such as universities) from consideration as centers, and the cost involved. The amendments, therefore, buttressed the view that costs and the opposition of established institutions would be major negative consequences of the policy.

Two major dimensions were identified in the panelists' responses to this scenario. They were:

* Views of the public; and
* The value of information centers.

Views of the public. Whatever the context under discussion -- the anticipated effects on the quality of research, the social dimensions of public participation in policy formation, public education and the dissemination of information being the main points -- outcomes, as noted by a panelist reviewer, seemed to be based on one of three views of the public:

* A public interested in [biomedical and behavioral technology], seeking information, and with a reservoir of ideas for technological problem-solving and with well-grounded reservations about present technological solutions.
* A public primarily interested in other things, and largely disinterested and uninformed about the details and issues involved in [biomedical and behavioral technology].

* A public consisting of self-selected individuals and interest groups which might have either a positive or negative impact.

Supporters of increased public involvement occasionally went beyond accountability and consumer protection to a populist sense of participation as the public's natural right (as the eventual owners of all social institutions). Those opposed sometimes adopted an elitist tone.

Positive consequences were anticipated when an intelligent and informed public is involved. The public enters into a productive and valuable partnership with the scientific community; diversity is encouraged without reducing productivity; more support is obtained for research activities and for the application of the developed technologies; research becomes more comprehensive; and other specialists (via the mechanism described for public participation) participate in the research process. Research is also likely to be improved by open, intelligent debate (involving the public) leading to priority setting and policy making, and there may be increased scholarly attention to research policy as a field of study.

Negative consequences were anticipated from a disinterested public. Rather than open debate, panelists feared acrimony and the possibility that demagogic attacks would stir public fears about research. In these circumstances direct participation could lead to the curtailment of research, or encouragement of only the most pedestrian of projects.

The value of information centers. While the concept of public participation seemed reasonably palatable to most panelists,

though a cause for uneasiness to some, the provisions for the information centers were less well liked. Mention of these centers was infrequent in the positive consequences. They were considered potentially valuable as a public resource supplying more detailed and accurate information on biomedical and behavioral research and technology and the investment of public funds than might be available through the media. They were also valued for the potential to increase public confidence in research and researchers, for their use as a forum, and as a decentralized counterweight to the *Commission*.

Among the negative consequences, the centers were prominently mentioned in connection with economic and technical factors. Panelists expressed concern over costs and the ability of the centers to carry out neutral studies on sophisticated projects. Cost of the centers was a frequently mentioned barrier to implementing the policy scenario and there was a strong feeling that established institutions would oppose their development. There was also a fear that the centers could become a "boondoggle" providing only the illusion of public participation.

Analysis and Evaluation

The sum of the responses to this policy scenario seem to approve, in principle, the notion of public participation and public education. However, the positive benefits expected from improved public participation and education were intangible, having to do with an improved climate for research and decision-making rather than providing direct contribution to the outcome of research. Under these circumstances, panelists seemed loath to approve extensive funding, or new departures which ran the risk of challenging existing institutions or agencies.

BIOMEDICAL AND BEHAVIORAL RESEARCH

The third scenario described the *Commission's* jurisdiction over biomedical and behavioral research. Particular policies outlined the scope of *Commission* authority, specified policies with respect to the review of research proposals, and described the establishment and organization of Regional Review Boards and Institutional Review Boards, and described the creation of a compensation fund for subjects of research. Policies dealing with the review boards described responsibilities, membership, staffing, appeals processes, and evaluation.

Findings

This policy scenario received more support than any other. On the whole, 63% of all panelists supported the policy while only 22% were opposed (Figure 10). Representatives of the public interest and ethicists were most frequently in support (83% and 79% respectively) while medical scientists and social scientists supported the scenario less frequently (46% and 50% respectively). The first policy statement in the scenario which established the *Commission's* jurisdiction over biomedical and behavioral research was supported as written by 46% of the panelists and approved if amended by another 19% (Figure 13, policy no. 1).

The level of support on the panel for some type of regulation of research was impressive. The particular policies having to do with the *Commission's* setting of policies for research, evaluating risks and benefits of research, and enforcement of guidelines and regulations received the support of as much as 75% of the panel (Figure 13, policy nos. 2, 12, and 15). Lower

levels of support were indicated for procedures accomplished by the various review boards, and the lowest level was indicated for the boards themselves. Only 39% of the panelists supported the particular policy describing Institutional Review Boards and 42% approved the particular policy establishing Regional Review Boards (Figure 13, policy nos. 6 and 7). This distribution of responses seems to confirm the impression that the panelists objected to the establishment of additional layers of bureaucracy.

The provision for a compensation fund for research subjects was supported as written by 56% of the panelists with an additional 22% offering support if the policy were amended (Figure 13, policy no. 16). Many of the amendments offered were in the direction of strengthening this aspect of the scenario.

There were a considerable number of amendments addressed to limiting the scope of control accorded the *Commission* in the policy scenario (Figure 13, policy nos. 1 and 9). This may have reflected a concern over the constitutionality of certain aspects of the scenario.

Two major dimensions were identified in the panelists' responses to this policy scenario. They were:

* Freedom of inquiry; and
* Research productivity and quality.

Freedom of inquiry. The most fundamental question implicit in panelists' responses was characterized by a panelist reviewer as follows:

> Does the scientific and research community have an absolute, inviolable autonomy which holds primacy over its

> social responsibilities, or do the rights, freedom and protection of the subjects of human research hold an inviolable primacy over the advance of biomedical research?

Expression of this question was manifest in the panel's focus on the legality and constitutionality of a national level of control of research in view of the "traditional freedom of science and research to set its own goals and priorities". On one side was a feeling that the level of control described in the scenario represented a serious infringement on the freedom of inquiry, while on another was the sense that the establishment of national priorities and goals, together with means of protecting individuals and society, had advantages which outweighed the restrictions placed on the research community. Opposition of scientists to extensive governmental and political control was also foreseen and the fight for freedom of inquiry was considered likely to be waged on constitutional grounds.

Research productivity and quality. Negative effects of the policy were generally related to research productivity and quality. Concern over the bureaucratic implementation of the policy -- red tape, layers of bureaucracy, and administration by incompetents -- was central to the notion that research would be harmed if the policy scenario were implemented. The scientific community, universities, private industry, and even Congress were seen as opposing the policy for reasons of cost or because the system would be constraining.

The review boards provisions also drew attention. Some contended that support for such a bureaucracy would cut heavily into funds available for research; others noted that the poli-

cies described would be discriminatory to non-profit organizations, particularly universities.

However, panelists did see some positive effects stemming from the policy. Some of these included improvements in the quality of research through the review process, protection of human subjects of research and compensation for those harmed, and protection of the general public. Standardization of review procedures and formal standards for the treatment of human subjects were also considered beneficial since they would facilitate research and ease some burdens on researchers.

Analysis and Evaluations

Both the amendments and the discussions of the policy scenario indicate substantial support for policies which would help to rationalize and make explicit the review of research proposals and the monitoring and review of the actual conduct of research to insure safety and to evaluate risks and benefits. However, there was opposition to development of these policies in the context of a complex bureaucratic system both because of the costs involved and because of the possible effects on research productivity. Panelists also feared that the particular policies described in the scenario were potentially discriminatory to non-profit institutions, particularly private universities.

IMPLEMENTATION OF BIOMEDICAL AND BEHAVIORAL TECHNOLOGIES

The fourth policy scenario described the *Commission's* jurisdiction over the implementation of biomedical and behavioral technologies. Particular policies established a classification of technologies and addressed the authority and responsibility of the *Commission* with respect to technologies in each classification. *Commission* responsibility related to assessment and evaluation of technologies. *Commission* authority extended over all biomedical and behavioral technologies and included the ability to prescribe sanctions for failure to observe guidelines and regulations.

Findings

A narrow majority of panelists supported this policy scenario. Overall, 52% of the panel supported the policy, while 33% were opposed (Figure 10). Social scientists were most frequently in support of the policy (65%), while medical scientists supported it least frequently (33%). The first policy statement in the scenario -- describing the scope of the *Commission's* jurisdiction over technologies -- was supported by 46% of the panel, but opposed or found unnecessary by 26%. Opposition centered on the broad jurisdiction allowed the *Commission* in the scenario.

The distribution of the panelists' votes on the particular policies and the amendments offered support the contention that concern over the scope of jurisdiction was central to the panelists' view of the scenario. Particular policies having to do only with the *Commission's* jurisdiction were not well supported (Figure 14, policy nos. 1, 2, and 5). Support was

also not forthcoming when jurisdiction entailed constraints on providers (Figure 14, policy nos. 4, 10, and 14), except when this was clearly directed at the protection of individual patients (Figure 14, policy no. 9).

Greater levels of support were offered for particular policies which had to do with monitoring, evaluating, and assessing technologies (Figure 14, policy nos. 7, 8, 11, and 12). Apparently the concept of a comprehensive review and assessment of technologies was palatable to a majority of panelists. A majority was even willing to strongly support provisions for enforcement of penalties for failure to observe policies and guidelines (Figure 14, policy no. 13).

Three major dimensions were identified in panelists' responses to this policy scenario. They were:

* Impacts on health;
* Impacts on the marketplace; and
* Jurisdictional conflicts.

Impacts on health. A primary focus of this scenario was health, expressed either in terms of improvement in the health of individuals and society, or the prevention of harmful effects through the correct use of medical services and technology.

Among the anticipated benefits of the *Commission* were: better public use of health information; decreased mortality; decreased morbidity from social-medical problems (e.g. drug addiction); heightened emphasis on the need for improved drugs, procedures and devices; quality control of medical and health technology with assurance of safety and efficacy; prevention of

misleading advertising; movement from subjective diagnostic and treatment procedures towards those more scientifically based; greater provider effort to improve products and services; and reduced consumer dependence on providers (physicians in particular and the medical industry in general).

The problems foreseen were generally ascribed to the level of control described. These included: the tendency to develop products aimed at large consumer markets with a commensurate decrease in effort on behalf of those with rare disorders; a decreased range of technologies that would be developed; denial of a patient's free choice of new innovative technologies; a lower level of health and medical care resulting from interference in the patient-physician relationship; and the demotion of psychiatry and placebos in medicine (paralleling increased use of psychotherapeutic drugs).

Impacts on the marketplace. Another issue raised in this scenario was the impact of the proposed regulatory system on the marketplace. The majority of panelists foresaw a two-pronged attack whereby dangerous or questionable products and services would be abolished, leaving a much more limited range of choice for a public made more discriminating by the same system.

However, certain costs in the form of latent consequences were also foreseen. Some panelists felt testing and evaluating drugs and other technologies would be so expensive and time-consuming that only large companies could provide the capital for development, thus driving individual or small-group efforts from the field. In turn the government would be open to a

variety of charges, including restraint of trade, abetting the growth of monopolies, inflating prices, retarding the development of needed drugs and procedures, and interfering with the free choice of individuals. An additional point made in this context was that many scientists and technicians would be diverted from conducting their own scientific work to assessing, testing, and evaluating the work of others.

Jurisdictional conflicts. Some panelists felt that the policy described in the scenario would create considerable conflict with existing Federal agencies. The role of the *Commission* was seen as overlapping agencies, such as the Food and Drug Administration, and some panelists suggested revision of the scenario to provide policy-making powers to the *Commission* but leaving implementation with existing regulatory agencies whose functions would be clearly spelled out.

Analysis and Evaluation

Panelists expressed concern over the workability of this scenario. While attracted by anticipated benefits relating to consumer protection and health, they foresaw problems in implementing a policy with so wide a scope -- both from a constitutional viewpoint and from the practical perspective of whether the bureaucratic structure described could operate effectively in the context of American society (particularly whether or not vested interest groups would co-opt or oppose the *Commission*).

RESOURCE ALLOCATION POLICY

In 1975, the U.S. spent $118.5 billion on health, up from $71.6 billion (1975 prices) in 1955. This amount represented 8.3% of the nation's Gross National Product (GNP) -- the total market value of all goods and services -- in 1975, compared to 4.6% in 1955.

Total health research and development (R&D) expenditures have also increased over the years -- from $541 million (1975 prices) in 1955 to $4,610 million in 1975. But as a percentage of all health expenditures they have decreased from a peak of 4.9% in 1965 to 4.0% in 1975.

Over the past ten years, Federal health R&D obligations have remained relatively constant as a proportion of total health R&D (62% in 1965, 61% in 1975) and as a proportion of all nonindustry (principally drug companies) health R&D (82% in 1965; 85% in 1975). The proportion of all Federal R&D obligations going to health R&D, however, increased from 8.0% in 1969 to 13.3% in 1974, but dropped to 13.1% in 1975. During this same period total Federal R&D obligations declined steadily from 8.5% to 5.8% of Federal government outlays. The National Institutes of Health, which spent $1.9 billion in 1975, account for the majority of Federal health R&D expenditures (66% of the total of $2.8 billion). See Figure 15.

Findings

The majority of panelists thought that in the future we should allocate: (1) a greater percentage of the nation's Gross National Product to health (85% said this); (2) a larger percentage of the health dollar to health R&D (86%); (3) a greater

percentage of total Federal outlays to R&D (66%); and (4) a greater percentage of total Federal R&D funds to health R&D (88%). See Figure 16. There were no differences among panelist categories regarding preferred future allocations for health and health R&D.

Based on 1975's level of Federal health R&D expenditures ($2.8 billion), panelists' allocations among the different types of health R&D were essentially the same for 1975 and 1985. All panelists favored biomedical research over behavioral research, with the median panelist allocating $750 of every $1,000 to biomedical research (compared to $250 for behavioral research). Panelists' division of the health R&D dollar within these two areas of research was basically identical. Preferred allocations for each type of health R&D are shown in Figure 17.

There were few differences among panelist categories with respect to allocating the health R&D dollar among types of research. Basic research was funded most heavily ($235 of every $1,000), particularly by medical scientists ($258 of every $1,000). Representatives of the public interest wanted health services research funded more heavily than basic research, allocating $175 of every $1,000 to the latter and $256 of every $1,000 to the former.

Analysis and Evaluation

Panelists agreed almost unanimously that a greater proportion of the nation's resources should be devoted to health activities, and that a greater proportion of the health dollar should be spent on R&D. In general, panelists also agreed that greater emphasis should be placed on health services and quality assur-

ance research and less emphasis on basic research than is the case at present. Since no data on the level of Federal funding for each type of research are available, comparisons are difficult to make. Nevertheless, in 1975 the National Institutes of Health accounted for 66% of all Federal health R&D, yet, according to the median panelist, only $550 of every $1,000 (including management monies) should go for technology development research (basic and applied research). Moreover, in 1974 2.9% of Federal health R&D funds were spent on delivery of health care R&D, yet the median panelist thought that $160 of every $1,000 (including management monies) should go for health service delivery research, not counting quality assurance and education research.

Figure 9

A SYNOPSIS OF THE FOUR POLICY SCENARIOS (1)

No. 1: Permanent National Commission

The first policy scenario described a Permanent National Commission on Biomedical and Behavioral Research and Technology established by an Act of Congress. Particular policies addressed organization of the Commission, membership, staffing, level of authority, scope, accountability, and evaluation of the Commission's performance. The Commission was described as having a national level of authority which included promulgation of policies and guidelines, the establishment of a national strategy for public funding of research, and the auditing of research projects.

No. 2: Public Involvement in Policy Decision-Making

The second policy scenario described provisions of the Act designed to encourage public involvement in decision-making and the dissemination of information to the public. Particular policies addressed the Commission's responsibilities with respect to public participation, the gathering of public opinion, and the means and standards for dissemination of information. The policies also specified the creation of five federally funded regional information centers to support the involvement and dissemination efforts.

No. 3: Biomedical and Behavioral Research

The third policy scenario described the Commission's jurisdiction over biomedical and behavioral research. Particular policies indicated the scope of Commission authority, specified policies with respect to the review of research proposals, described the establishment and organization of Regional Review Boards and Institutional Review Boards, and described the creation of a compensation fund for subjects of research. Policies dealing with the review boards described responsibilities, membership, staffing appeals processes, and evaluation.

No. 4: Implementation of Biomedical and Behavioral Technology

The fourth policy scenario described the Commission's jurisdiction over the implementation of biomedical and behavioral technologies. Particular policies established a classification of technologies and addressed the authority and responsibility of the Commission with respect to technologies in each classification. Commission responsibility related to assessment and evaluation of technologies. Commission authority extended over all biomedical and behavioral technologies and included the ability to prescribe sanctions for failure to observe guidelines and regulations.

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(1) See Appendix 6 for a full description of each policy scenario.

Figure 10

DEGREE OF SUPPORT (OR OPPOSITION) FOR IMPLEMENTING THE POSSIBLE NATIONAL POLICY DESCRIBED IN THE FOUR POLICY SCENARIOS DESCRIBED IN THE THIRD PEI, BY CATEGORY OF PANELIST (1)

Category of Panelist (2)							
Policy Scenario (3)/Degree of Support (or Opposition) (4)	Ethicists	Lawyers	Medical Scientists	Reps. of Publ. Int.	Social Scientists	Total Panel	Percent Total
Scenario No. 1: Permanent National Commission							
Generally support, as written	16	12	8	12	11	59	54%
Support, with amendments	7	5	9	6	5	32	29%
Generally oppose	2	3	7	2	4	18	17%
Total	25	20	24	20	20	109	100%
Scenario No. 2: Public Involvement in Policy Decision-Making							
Generally support, as written	10	9	7	13	9	48	44%
Support, with amendments	6	4	3	2	2	17	16%
Generally oppose	8	7	14	5	9	43	40%
Total	24	20	24	20	20	108	100%
Scenario No. 3: Biomedical and Behavioral Research							
Generally support, as written	19	12	11	15	10	67	63%
Support, with amendments	1	4	5	1	5	16	15%
Generally oppose	4	4	8	2	5	23	22%
Total	24	20	24	18	20	106	100%
Scenario No. 4: Implementation of Biomedical and Behavioral Technology							
Generally support, as written	14	10	8	11	13	56	52%
Support, with amendments	4	4	4	3	1	16	15%
Generally oppose	6	6	12	5	6	35	33%
Total	24	20	24	19	20	107	100%

(1) 110 of 125 panelists (88%) completed the third PEI.

(2) Self-assigned categorization.

(3) See Appendix 6 for a full description of each policy scenario.

(4) Panelists were classified according the mean score of their responses to each of the particular policies contained in the policy scenario. Scale point 5 (unnecessary) was equated with scale point 4 (oppose in any form). Panelists with a mean score of 1.000 to 1.750 were classified as "generally support as written"; those with a mean score of 1.751 to 2.499 as "support, with amendments"; and those with a mean score of 2.500 or greater as "oppose the policy".

Figure 11

PANELISTS' VOTES OF THE PARTICULAR POLICIES THAT COMPRISED POLICY SCENARIO NO. 1, *PERMANENT NATIONAL COMMISSION*, THIRD PEI

Particular Policy (1)	Strongly Support	Support with Amendments	Oppose unless Amended	Oppose in Any Form	Find Unnecessary
1. A National Commission (N=109)	51	26	13	6	5
2. Purpose of the Commission (N=108)	32	29	25	12	2
3. Composition of the Commission (N=107)	30	33	24	10	3
4. Terms of Appointment of the Commissioners (N=108)	44	35	12	7	2
5. Commission Staff (N=108)	74	12	1	6	7
6. Commission Policies, Guidelines, and Regulations (N=107)	44	23	19	11	3
7. Commission Approval of Policies (N=107) ..	59	15	13	9	4
8. Appeals to Commission (N=107)	48	20	15	13	5
9. Commission Audits Research (N=107)	53	21	7	14	6
10. A National Strategy for Research (N=108) .	50	16	15	15	5
11. Allocation of Research Funds (N=106)	22	26	25	24	5
12. Commission Meetings (N=107)	49	28	8	7	8
13. Procedure for Establishment of Policy by Commission (N=106)	57	22	10	7	5
14. Public Dissemination of Commission Policies (N=107)	82	8	3	5	3
15. Application of Commission Policies (N=106)	43	9	20	25	4
16. Penalties (N=108)	45	17	16	19	4
17. Self-Evaluation by the Commission (N=106)	60	17	8	9	6
18. Congressional Evaluation of the Commission (N=106)	65	18	4	7	7
19. Annual Report to Congress (N=107)	83	4	2	5	7

(1) See Appendix 6 for a full description of each particular policy.

Figure 12

PANELISTS' VOTES OF THE PARTICULAR POLICIES THAT COMPRISED POLICY SCENARIO NO. 2, *PUBLIC INVOLVEMENT IN POLICY DECISION-MAKING*, THIRD PEI

Particular Policy (1)	Strongly Support	Support with Amendments	Oppose unless Amended	Oppose in Any Form	Find Unnecessary
1. Public Involvement in Policy Decision-Making (N=106)	44	26	16	9	5
2. Public Access to Meetings and Materials (N=106)	66	22	9	1	3
3. Responsibility to Inform the Public (N=107)	63	16	7	8	7
4. Commission Conducts Studies of Implications (N=107)	79	8	3	4	7
5. Commission Sets Standards of Consumer Education (N=106)	49	28	8	13	9
6. Commission Undertakes National Opinion Surveys (N=107)	51	14	14	12	9
7. Five Information Centers (N=107)	19	28	15	24	14
8. Selection of Centers (N=106)	39	18	7	25	11
9. Governance of Centers (N=104)	39	14	6	27	14
10. Center Appropriations (N=106)	26	18	15	31	9
11. Purposes of the Centers (N=107)	50	9	9	22	10
12. Review and Evaluation of the Centers (N=105)	41	15	8	22	14

(1) See Appendix 6 for a full description of each particular policy.

Figure 13

PANELISTS' VOTES OF THE PARTICULAR POLICIES THAT COMPRISED POLICY SCENARIO NO. 3, *BIOMEDICAL AND BEHAVIORAL RESEARCH*, THIRD PEI

Particular Policy (1)	Strongly Support	Support with Amendments	Oppose unless Amended	Oppose in Any Form	Find Unnecessary
1. Commission Jurisdiction over Biomedical and Behavioral Research (N=106)	46	19	18	16	1
2. Commission Policies, Guidelines, and Regulations (N=104)	65	14	14	4	3
3. Commission Review of Research Projects (N=105)	51	16	14	16	3
4. Researchers Interpret Commission Policy (N=106)	59	15	6	17	4
5. Institutional and Regional Review Boards (N=106)	52	24	10	11	3
6. Institutional Review Boards (N=106)	39	29	14	13	5
7. Regional Review Boards (N=106)	42	29	9	15	5
8. Submission of Research Proposals (N=105)	50	27	9	11	4
9. Categories of Researchers Covered (N=104)	61	14	6	16	3
10. Decisions on Funding Research Proposals (N=106)	58	16	9	13	4
11. Board Review for Adherence to Guidelines (N=106)	55	22	5	15	4
12. Enforcement Authority of the Commission (N=106)	60	15	8	14	3
13. Appeals to the Commission (N=106)	60	14	9	12	5
14. Monitoring of IRB, by RRBs (N=104)	49	17	11	16	7
15. Annual Review of Research (N=104)	75	12	2	9	3
16. Compensation Fund for Research Subjects (N=105)	56	22	11	7	4

(1) See Appendix 6 for a full description of each particular policy.

Figure 14

PANELISTS' VOTES OF THE PARTICULAR POLICIES THAT COMPRISED POLICY SCENARIO NO. 4, *IMPLEMENTATION OF BIOMEDICAL AND BEHAVIORAL TECHNOLOGIES*, THIRD PEI

Particular Policy (1)	Strongly Support	Support with Amendments	Oppose unless Amended	Oppose in Any Form	Find Unnecessary
1. Commission Jurisdiction over Technologies (N=105)	46	13	14	23	4
2. Classification of Tangible and Intangible Technologies (N=107)	37	22	17	22	2
3. Classification by Use and Safety (N=105)	61	13	6	16	4
4. Commission Sets Policies for Application of Technology (N=106)	41	18	16	25	1
5. Assessment of Technologies by DHEW Agencies (N=104)	44	17	16	19	3
6. Assessment Prior to Application or Use in Practice (N=105)	64	14	4	13	5
7. Independent Assessment of Technologies (N=104)	50	23	12	14	1
8. Action on Assessments (N=104)	53	18	7	18	4
9. Descriptions of Intangible Technologies (N=103)	51	15	9	24	2
10. Application for Approval as Standard Medical Practice (N=105)	41	20	11	25	3
11. Evaluation of Existing Technologies (N=105)	59	14	8	16	3
12. Procedures for Monitoring Approved Technologies (N=105)	54	22	6	15	3
13. Penalties for Failure to Observe Policies and Guidelines (N=104)	53	18	8	18	3
14. Licensing of Providers (N=103)	46	14	13	23	5

(1) See Appendix 6 for a full description of each particular policy.

Figure 15

TRENDS IN HEALTH RESOURCE ALLOCATION. PERCENTAGE OF: (1) FEDERAL R&D OBLIGATIONS FOR HEALTH R&D; (2) GNP FOR HEALTH; (3) FEDERAL OUTLAYS FOR R&D; AND (4) HEALTH EXPENDITURES FOR R&D

Figure 16

MEDIAN PANELIST'S RESOURCE ALLOCATIONS, 1980 AND 1985, THIRD PEI

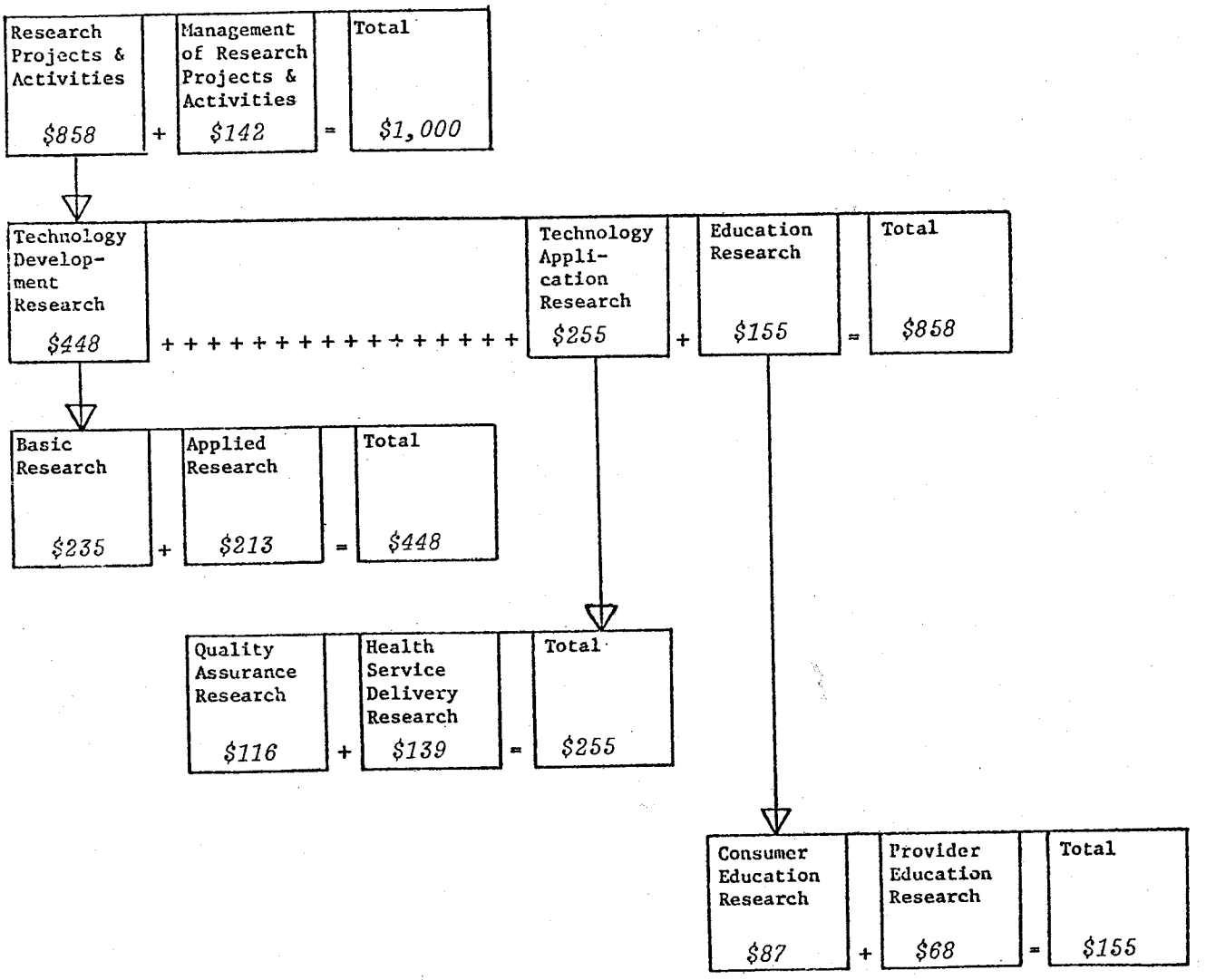
Resource Allocation (1)	1975 (2)	1980	1985
Percentage of Gross National Product that the U.S. should spend on health (all personal and other health services, health R&D, etc.) *N=97*	8.3	10.0	10.5
Percentage of total U.S. health expenditures that should be spent on health R&D (basic and applied research, quality assurance and health services research, and consumer and provider education research, etc.) *N=97*	4.0	6.0	7.0
Percentage of federal government outlays that should go for R&D (defense R&D, space R&D, health R&D, etc.) *N=95*	5.8	6.1	7.0
Percentage of total federal R&D funds that should be spent on health R&D (basic and applied research, quality assurance and health services research, and consumer and provider education research, etc.) *N=95*	13.1	15.0	16.0

(1) "N" indicates the number of panelists who completed this item.

(2) Actual figure.

Figure 17

MEDIAN PROPORTION OF FUNDS THAT SHOULD BE ALLOCATED TO EACH TYPE OF MEDICAL RESEARCH IN 1975, ACCORDING TO PANELISTS (1)



(1) Proportions based on $1,000. Where necessary, median values normalized to equal totals indicated (N=83).

Chapter 5:
Implications of Policies.

INTRODUCTION

The implications of the policy scenarios were derived from three sources. They were:

* Reports on the salient dimensions of each policy scenario, provided by panelist reviewers;

* Reports on the salient dimensions underlying the responses to all policy scenarios, provided by two panelist reviewers, one who supported the *Commission* and one who opposed it; and

* Two position papers, one written by a panelist who supported the *Commission*, the other by a panelist who opposed it.

The implications of the policy scenarios highlight those major issues which appeared to shape panelists' views on the *Commission* and its policy and regulatory functions. The dimensions identified are those which cut across the four policy scenarios, and on which consistent ideas and opinions were found. Each dimension raised divergent views and there was a variety of opinions on just what factors underlay those diverging views.

The position paper writers articulated their viewpoints from perspectives in political philosophy. The position paper author in favor of the *Commission* observed:

> Government should be involved in restoring equilibrium between the rights of the individual and the needs of society in biomedical and behavioral research.

The opposite viewpoint contended that the *Commission* and its attendant functions was

> ...inconsistent with basic values concerning autonomy/freedom, understood either as embodying intrinsic justice/fairness values, or as an efficient decentralized spontaneous ordering system for a complex production/distribution system -- including biomedical research.

However, not all panelist reviewers saw the diverging viewpoints

as grounded in political philosophy. One panelist reviewer thought the issues were more pragmatically based in relation to political power.

> Biomedical/behavioral research has acquired, or it may acquire the abilities to cause, prevent, and cure disease; the abilities to alter and direct the nature and structure of man and other living things; and through these accomplishments it is conceivable that science might acquire the power to control individuals, peoples, nations, indeed mankind. "Brave New World" in its most diabolical aspects is a new reality, at least in the minds of the current politically powerful. History has shown us that existing power yields most unwillingly to emerging power. At issue is power, and at play is fear, fear of the loss of power.

Whatever the ideological or philosophical basis underlying panelists' views, they wanted to achieve the same ideals. All panelists wanted to save money, or use money more productively. They wanted to cut red tape and to provide some kind of structure which would allow good projects to come to the fore while the bad would be weeded out. The panelists wanted any *Commission,* or Commission-like structure, to be both responsive to the public and immune from political influence. Finally, the panelists seemed to agree that more and better public education is either desirable or necessary (differing on whether the public really wants such education or if it can absorb it).

Agreeing on these ends as desirable, the panel disagreed over the means of achieving them, and they reflected that disagreement throughout their responses. Five dimensions were identified in panelists' responses. They were:

* The need for controls;
* The role of government;
* Justice;

* Economic factors; and
* Public participation.

In the remainder of this chapter, the implications of the policies are discussed in relation to these five themes.

THE NEED FOR CONTROLS

One of the fundamental issues brought to light in the study was a clash of values over the need, the extent, and the means of control over biomedical and behavioral research and technology. At one extreme were those favoring the continuance of the present loosely-knit system of controls and regulations for normative conditions, with ad hoc measures for emergencies, perhaps to include an ombudsman service rather like the present Commission. At the other end were those enthusiastically in support of the *Commission* described in the policy scenarios, one which would have the power to regulate all research and implementation, at all stages, whether publicly or privately financed in order to eliminate present abuses and prevent future ones.

The sentiments expressed ranged from the desirability of controls only when necessary to protect individuals and the collective good, to the desirability of organizing and directing individual behavior (e.g., the researcher's behavior and the selection of his research project) in line with social consensus.

The regulatory view held that society should establish the priorities for research, select the research project and monitor the results closely. The researcher was seen, ideally, as the agent of society. Panelists holding this view considered the present research system as laissez-faire, uncontrolled and indifferent to social needs. Today's researchers were sometimes viewed with suspicion, distrust and hostility. One panelist reviewer characterized this view as follows:

> Accountable to no one but their consciences, medical researchers have squandered millions of dollars of taxpayer funds for no demonstrable purpose or gain, and, in the process, have abuse countless research subjects. When asked for a public accounting, researchers balk, and justify all their efforts on the benefits accrued to mankind by research efforts, generally efforts produced by someone else.

Implicit contradictions about the role of researchers and their relationship with industry, usually represented by the pharmaceutical companies -- "everyone's favorite whipping boys" -- were also to be found. As some panelists pointed out, policies such as those described in the scenarios would give continuous, visible publicity to the fact that the biomedical/biotechnical market is glutted with highly advertised, largely unassessed diagnostic and therapeutic procedures and products which may at best be ineffectual and at worst dangerous. Research and industry were frequently seen as one and the same by those favoring greater regulation, and the researcher was depicted in two negative roles, entrepreneur of applied technologies, and independent pursuer of basic knowledge.

> Many panelists, particularly those among the group opposed to [the scenario *Commission*], seemed to view the researcher as a lonely, individual hero, pregnant with contributions to mankind but harassed by a bureaucracy staffed with mediocrities or czars.

These panelists tended to rely on professional controls exerted by the individual and his peer group, and with the usual interchange of direct and indirect pressures from society at large.

THE ROLE OF GOVERNMENT

A great range in attitudes was displayed towards bureaucracy, from the position that it is

> ...an opprobrious term applied by dissenters as a general critism of the slow but careful working of government machinery in a democratic society, to a distaste and distrust for what was seen as the ineffective and inefficient bureaucracy and the bureaucratic mode.

The View of Those Supporting the Commission

The panelists who favored regulation emphasized the expected beneficial results. The *Commission* was regarded by these panelists as an effective coordinating and planning mechanism, apolitical, responsive to the commonweal and capable of rational planning with elimination of waste and duplication. Supporters depicted the *Commission* as an essential vehicle for providing representation and balance in government commensurate with the growth of science and the social importance of technology in the contemporary world -- a "biomedical Supreme Court".

Further, the *Commission* would provide a background consensus which would serve as the basis for legal determinations, thus strenghtening and clarifying law in the areas of research, science, and medicine. Particularly crucial was the determination of nationally uniform definitions of life and death to clarify legal ambiguities now surrounding euthanasia, abortion, organ donorship, malpractice, and so forth. Coalescence of now widely disparate agencies, such as the Food and Drug Administration and the National Institutes of Health, was favored by supporters of the policies described as an effective method to reduce costs, duplications, and gaps in services, and thereby better coordinate the conduct of research and the delivery of care.

The fear on the part of some in support of the *Commission* was that powerful and antagonistic interests would reduce it to a shadow agency, perhaps worse than no agency at all. Present regulatory agencies, jealous of domain, could contest every function, or submit to the letter but not the spirit, while other internal political pressures could tend to compromise or discredit the *Commission's* integrity. External interests such as medical and behavioral scientists (organized medicine and researchers), and industry (the pharmaceutical companies) could cause similar problems.

The View of Those Opposing the Commission

Those generally opposed to the *Commission*, or who wished to amend it, regarded the increased bureaucracy as formidable and an insurmountable problem in itself. Among the negative consequences predicted was that an over-large, over-centralized *Commission* would stifle research with red-tape and conflicting regulations. Centralization, itself, was seen as a step toward effecting a more restrictive control over researchers, industry, and providers. Those panelists opposed to the *Commission* also believed that it would be remote from Congressional direction, and unresponsive to those within its hegemony. Some felt the lay majority on the *Commission* would be a serious obstacle to progress. The conflict between expert and lay expositions of biomedical and behavioral issues might well make *Commission* deliberations vulnerable to hearsay evidence and ignorant polemics. There was also the concern that the growth of a research bureaucracy would either favor entrepreneurial researchers who could manipulate red-tape requirements over truly creative indi-

viduals, or freeze out all but the most pedestrian and safe types of research. The review system could be abused to delay or kill research which did not have an established proponent somewhere on the *Commission* staff.

Some panelists viewed the aims of the *Commission* as good, but did not think that such a national policy could accomplish all the things set forth in the scenarios. These panelists doubted that a new governmental agency could function differently from present agencies or avoid being subject to the same ills. As part of the system it would be potentially dangerous -- the "scientific gestapo" and "science czars" -- because of the extensive powers granted to it.

Those panelists who opposed the *Commission* completely argued with conviction that the very worst was sure to occur. For those panelists, chiefly scientists and researchers, the fear that an essentially "lay" superstructure would be all administration and no substance was quite clearly expressed.

ECONOMIC FACTORS

The distribution of economic resources was a concern for most panelists in at least one of three contexts: the cost of medical research; the cost of health care delivery; and the cost of operating the *Commission* and its attendant bureaucracies.

Potential Economy

For many, the high cost of current research, exacerbated by duplicatory efforts, lack of goal-directiveness, the high fees and salaries of providers and researchers, etc., justified the creation of a *Permanent National Commission*. There was a hope that the review and coordination of biomedical and behavioral research and the delivery of care would result in a just distribution of available funds, commensurate with a national policy defining goals and priorities.

It was noted repeatedly that the national system of health care research and delivery is the most expensive in the world, though probably not the best. The *Commission* could provide the means to slow the trend of the past several years toward an ever-higher proportion of the nation's resources being expended on the national health budget. For example, by adopting uniform national definitions, e.g., "standard medical practice", money will be saved in insurance premiums and malpractice awards. In fact, some expected that lawyers as middle-men would be eliminated on this front because of the compensatory fund the *Commission* would oversee for those harmed iatrogenically or in the course of participating in research projects.

Potential Burden

But even for the many supporters of the concept, there was a

concern that the *Commission* would present a massive bureaucracy that could dramatically escalate the cost of research and delivery while not saving anything near what its operational expenditures might be. The cost of staffing and operating the *Commission*, generating public involvement, etc., could prove astronomical. Additionally, the practice of financing each of these components might well nurture public naiveté and the belief that money can buy almost any result. The information centers were singled out, particularly, as likely to produce a plethora of rhetoric at an enormous expense.

Besides the direct costs in tax dollars for operating the *Commission*, the public, in the role of consumer, would pay additionally in the marketplace. Costs borne by producers of biomedical goods and services for testing and reviewing their products, and disseminating educational information about them, would be passed on to the consumer in the form of higher prices. However, non-profit organizations, such as universities, would have to absorb such costs in lieu of parallel constituencies to pass them on to. Such economic factors were viewed as so important as to be one of the most-cited barriers to implementing the *Commission:*

> Perhaps these financial considerations should be part of the public decision as to whether the best thing we can do now is a narrow effort directed at curbing the real abuses we know (or suspect) exist, or a more wide-ranging effort to do good unilaterally.

JUSTICE

Justice was a pervasive moral principle expressed throughout the policy scenarios. This was addressed in terms of rights of the individual; equality of opportunity (even for researchers to get trants); the need for appeals processes; the provision of standards (so that persons are treated fairly and equally); harmful effects when politicization of a procedure and a regulatory system occurs; the need for safeguards for special groups -- e.g., children, prisoners, the poor, and minority groups; dangers of over-centralization; dangers through excessive homogeneity of a society; and the need for compensation for all effects from research.

Panelists differed in their perceptions of justice. One of the continuing conflict areas among them was rights of the individual versus rights of society or social groups, or rights of social groups or institutions (e.g., universities, academic groups, businesses, privately funded research) versus those of society. Hope was expressed that a *Commission* such as that described might provide the means by which society could resolve some of these conflicts among rights and thus establish the foundation for law in this area.

Protection of Human Subjects

Panelists supporting the *Commission* cited the protection of human subjects as an important gain. Opponents made little mention of this matter and so it was difficult to know if they regarded it as a major problem requiring new methods of solution, or if the *Commission* was considered to be a solution in itself.

Numerous positive consequences were expected. Better super-

vision of the conduct of research involving human subjects would be an improvement over the auditing and reviewing done by institutional boards, and over existing procedures for informed consent. National minimal standards would be assured and would result in well-established guidelines that might become the basis for articulated international ethical codes. The new standards would ensure more protection for persons who are participating in research projects and increase the researchers' awareness of their responsibilities. A need was seen for this system where there are no institutional review boards.

Commission as Watchdog

Sometimes the *Commission* was seen as a watchdog that polices the scientific world for evidence of abuse. Certain practices would become specifically proscribed and penalties levied. These watchdog and police functions were regarded as punitive in tone by some, however, and rejected on this ground.

Medical scientists inveighed against the restriction of the rights of biomedical and behavioral researchers to pursue their interests in a climate of freedom. Some of the policies described in the scenarios were viewed by them, and by some other panelists, as a violation of their individual liberties, albeit in the name of the public good.

Most panelists did not connote the regulation and direction of research with infringement of researchers' civil liberties, however. Rather, the nature of research was seen as legitimately being subordinated to the dictates of society, this being the best way to achieve equity all around.

PUBLIC PARTICIPATION

Many panelists seemed to find a value in public participation even beyond the reciprocity of ideas and influences between (and among) sectors of the public and those directly involved in either research and development or the regulation of biomedical and behavioral technologies. They perceived this aspect of the national policy described as providing a general stabilizing influence on society. Some of the anticipated effects seen by this group were: less polarization on important issues; shifting of responsibilities for public policy onto a broader base; strengthening and clarifying the law by providing background consensus; providing a buffer between politics and research; demonstrating the responsiveness of government; informing the public that they have a voice that is heard; restoring confidence in science; giving the public a feeling of participating in scientific matters; establishing order out of chaos; anticipating new problems and situations so that the public can be informed before the new problems suddenly appear; and assisting the public to become less dependent on physicians.

On the other hand, some panelists were concerned that not all of the results of public participation would be beneficial. There was a distinct fear that dogma could be substituted for dialogue in confrontations between the public and the *Commission*. The *Commission* itself could lead to a false sense of security -- that "something was being done". Furthermore, the emphasis on rules and regulations might itself generate a public loss of faith in researchers.

Chapter 6:
Public Understanding and Attitude.

INTRODUCTION

The Study Design and Management Group recommended, and the Commission agreed, that a national survey of public opinion be conducted as an adjunct to the policy study in order to address that item of the study mandate which called for "an analysis and evaluation of public understanding" of the implications of advances in biomedical and behavioral research.

The national opinion survey was closely integrated with the policy study, and the questionnaire was partially based on material generated by the first and second Policy Evaluation Instruments (PEIs). The questionnaire was administered to a probability sample of 1,679 Americans in individual face-to-face interviews in the fall of 1976. In order to provide a basis for evaluating public understanding and attitude, a parallel version of the questionnaire was included in the third PEI sent to consultant panelists.

In this chapter, the findings of the national opinion survey are reported and the responses of the general public are compared and contrasted to those of the consultant panelists. Survey findings are described under five headings. They are:

* Advances and their effects;
* Application of selected advances;
* Rules about research, safety and efficacy of tests and treatments, financial responsibility for treatment;
* Research priorities; and
* Value received for dollars spent, future outlook.

A brief analysis and evaluation is provided at the end of each set of findings.

ADVANCES AND THEIR EFFECTS

Findings

Knowledge of advances. Seventy-seven percent of Americans could name at least one new test, treatment, or item of new medical knowledge that has come about in the last twenty years. Knowledge of advances was found to be related to education, occupation, and income. For example, 92% of college graduates and 86% of high school graduates could name at least one new test, treatment, or item of knowledge, while only 61% of those who did not graduate from high school could do so.

Four classes of tests, treatments, and knowledge made possible in the last 20 years were mentioned by at least ten percent of respondents. *Prevention, cure of cancer* was mentioned most often -- by 56% of those interviewed who could think of at least one new item (Figure 18).

Access to advances. Neither the public nor the panel felt that all types of Americans can equally get the new tests and treatments made possible by medical research (Figure 19). Responses to this question, like those on general knowledge of advances, appeared to be related to education. The panel was overwhelmingly of the opinion that there was not equality of access (91%), while the public in general was less certain (60%). However, 73% of college graduates among the public held this opinion, compared to 41% of those who did not graduate from high school. Two-thirds of the public, and virtually all panelists, mentioned the poor and disadvantaged as Americans who did not have equal access to new tests and treatments even when they need them. Rural people were also mentioned frequently by the panel,

but not by the public — not even by those living in rural areas. There was little agreement (21% of the public and 7% of the panel) that if new tests and treatments cannot be made available to all who need the, it is better not to develop them at all.

Who gets a new test, treatment? The majority of the public (70%) and panelists (86%) thought that today people who can pay for a new test or treatment, or who know an important doctor were those most likely to get it when it first comes out, and there is limited availability (Figure 19). This view was particularly prevalent among those who thought that not all types of Americans have equal access to new tests and treatments. Most of the public and the panel thought that people who apply first for tests or treatments or those who need them most should get a new test or treatment. Seventy percent of the public who thought new tests and treatments should be distributed on the basis of need thought rules should be set up to decide which people most need them, and the majority of these respondents (66%) thought that researchers, scientists, and doctors should have the final say about such rules.

Best advances and their effects. A plurality of both the public and the panel agreed that the *Prevention of infectious diseases* has had the greatest good effect on society; 24% of the public (18% of panelists) specifically mentioned *Prevention of polio* (Figure 20). However, the public and the panel showed little similarity in their choices of "best advance" after this initial agreement. Twenty-six percent of the public (but only

1% of panelists) mentioned *Prevention, treatment of cancer;* 12% of the public mentioned *Organ transplantation, by-pass surgery, radical surgery* (but only 4% of panelists). Only 4% of the public mentioned *Improved contraception* (2% mentioned *The pill*), compared to 16% of panelists (11% of all panelists mentioned *The pill*).

Health effects were predominantly mentioned as outcomes of the new test, treatment, or knowledge that has had the greatest good effect on society (Figure 20). The most frequently mentioned among these were *decreased morbidity, increased longevity,* and *decreased stigma and fear.* Technical effects, predominantly the generation of new knowledge, and ethical effects were prominent among panel mentions, but were of minor significance among public responses.

The effects mentioned by the public in relation to the new test, treatment, or knowledge of the last 20 years having the greatest good effect on society are shown in Figure 21.

Worst advances and their effects. Only 52% of the public who could think of a new test or treatment, or item of knowledge made possible in the last 20 years mentioned a specific item as having had a bad effect on society; 77% of panelists did so (Figure 22). Among those who mentioned a "worst advance" *Improved contraception* was mentioned most often by the public (23%), and *Treatment for mental illness* most often by panelists. *Drug therapies* and *Proliferation of tranquilizers* were mentioned specifically by 21% of panelists and 17% of the public. Social and ethical effects were among those most often mentioned in

connection with the new test, treatment, or knowledge that has had the worst effect on society (Figure 22). Health effects were not as prominent as they were in advances that have had the greatest good effect on society. The effects mentioned by the public for each advance are shown in Figure 23.

Best future advances and their effects. The most desirable future advance identified by both the panel and the public was *Prevention, treatment of cancer*. Of those responding, 73% of the public mentioned this advance and 59% of the panel (Figure 24). *Prevention, treatment of cancer* was also the first choice of both public and panel as the advance most likely to have a good effect on society in the next twenty years, though not by as wide a margin. Slightly over half of the public responding to the question (52%) selected this advance, but only 15% of the panel (Figure 25).

The most notable differences between the panelists' choices of best advances and those of the public were: *Improved health services, access, availability* (mentioned by 9% of panelists but only 2% of the public); and *Health education, knowledge* (mentioned by 11% of panelists but only 3% of the public).

Health effects, such as *decreased morbidity, increased longevity* and *decreased stigma and fear* predominated in the advance that will have the greatest good effect on society in the next 20 years, as they did in the case of the advance that has had the greatest good effect on society in the last 20 years (Figure 25). The effects foreseen for the various advances mentioned by the public are shown in Figure 26.

Worst future advances and their effects. Seventy-four percent of panelists named a new item which would have the worst effect on society in the next 20 years, but only 36% of the public did so. There were striking differences between panelists and public as to what the worst new development will be (Figure 27). The public most frequently named *Treatment for mental illness* (14% of those among the public mentioning an item; 9% of panelists) and *Selection of sex of offspring* (13% vs. 4%). Panelists mentioned *Control of behavior* most often (23% of panelists; 3% of the public). The fact that the opinion survey questionnaire included specific items on the selection of sex of offspring may have triggered this response. However, there were more items in the questionnaire related to the control of behavior than there were on the selection of sex of offspring.

Other noticeable differences between panel and public over the worst future advances were: *Improved contraception* (not mentioned by any panelist but by 8% of the public); and *Life-extending equipment; artificial life support organs* (mentioned by 15% of panelists but only 4% of the public). The most frequently mentioned effects of the worst future advances were not health effects, but political, environmental, ethical, individual and social effects (Figure 27). The effects for each advance mentioned by the public are shown in Figure 28.

Analysis and Evaluation

The public is generally well informed about advances in medical research over the past twenty years. However, the public's view of these advances differs somewhat from the view of the panel.

The difference appears to be related to either a degree of scepticism on the part of the panel, or a tendency of the public to view advances in medical research as inevitably good.

A smaller proportion of the public than the panel could name past or future advances as having a bad effect on society. Where bad effects of advances were mentioned, they were generally social in nature (as opposed to effects on health), but the public had a greater tendency to believe that the advances affected morals unfavorably or were against God or nature. Conversely, the public had a greater tendency to ascribe beneficial health effects -- particularly increased longevity -- to past and future advances.

There was widespread agreement (amounting to near unanimity among panelists) that poor and disadvantaged Americans do not have equal access to medical advances. The sentiment for developing equitable access to advances was strong as indicated by the proportions of panelists and public calling for distribution of advances according to need or on a first-come-first-served basis. Reinforcing this sense, one-fifth of the public felt it was better not to develop advances at all, if they cannot be distributed equitably.

The public's lack of faith in the way advances were distributed did not appear to stem from actions of the medical community. Two-thirds of those advocating the establishment of rules to govern who should get a new test or treatment were willing to allow the medical community to establish those rules.

APPLICATION OF SELECTED ADVANCES

Findings

Testing for and prevention of violence. The public and the panel held differing opinions on research on behavior, and the application of tests for and the control of violent behavior. The majority of the panel (61%) voted for research into new ways to change behavior, while the public was less interested in this area (43%). However, while the public expressed less interest in research into behavior control, they displayed much greater interest than the panel in research on tests to determine which people are likely to commit violent acts and on the applications of such tests and also of technologies to eliminate violent crime (Figure 29).

Overall, 71% of the public favored research into the development of tests to predict violent behavior, compared to 46% of the panel. The universal administration of such a test by the government was acreed to by 41% of the public, even though it might be an invasion of privacy (19% of the panel agreed to the same proposition). One-third of the public (but only 7% of the panel) were in agreement that the government should make everyone likely to commit a violent act take a behavior control drug, even if they haven't committed the act yet.

A majority of the public (64%) thought that the government should make people who have already committed a violent act take a drug to prevent them from committing any more, compared to 42% of the panel. Ten percent of the public (26% of the panel) thought while such people should not be forced to take the drug, it should be offered as an alternative to prison; 18%

of the public (32% of the panel) thought that people who had committed violent acts should neither be forced to take a drug nor offered such a drug as an alternative to a prison sentence; and 8% of the public were not sure on one or both issues.

A substantial proportion of the public (29%) agreed to research on tests which would predict violent acts, mandatory testing, and government administration of a behavior control drug to prevent the occurrence of a predicted violent act. Few panelists (7%) agreed to such a course of action.

Tests for certain defects. A majority of both the public and the panel were in agreement regarding the administration of tests for certain defects. There was widespread agreement (72% of the public; 93% of the panel) that if a pregnant woman wanted a test to tell if her unborn baby had certain defects she should have the test even if the government has to pay for it (Figure 30).

On the subject of abortion, if a defective fetus were identified, both public and panel were in majority agreement that an abortion should be a matter of personal choice (50% of the public; 63% of the panel). Nearly one-third of the panel (31%) felt a woman should have an abortion, either because taxpayers would have to support the child, or because it is wrong to bring defective children into the world, compared to 23% of the public. However, the public was more inclined than the panel to suggest that a woman should not have an abortion at all because it is wrong to destroy any life (21% of the public; 6% of the panel).

A majority of the public (67%) also agreed with the proposition that individuals be required to have tests to show if they are likely to have children with certain defects prior to being given a marriage license. Only a slight majority (51%) of panelists agreed with this proposition. Eighty-four percent of the public (and 85% of panelists) who agreed to violence predictive tests also agreed to required premarital tests. On the other hand, while almost all panelists (94%) who disagreed with mandatory testing for a tendency to commit violent acts also disagreed with required pre-marital testing; only 39% of the public did so.

Select-a-boy, Select-a-girl kits. Only 19% of the public (38% of panelists) said they would use a self-administered *Select-a-boy, Select-a-girl kit* to select the sex of a child, were such kits available; 67% of the public (60% of panelists) would not do so (Figure 31).

Panelists almost universally believed that if *Select-a-boy, Select-a-girl kits* were available, people would use them to select boys most often (91% said this), and a boy as the first child (94% said this). The public was less certain on this score: 48% thought boys would be selected more often, and 73% thought boys would be selected as the first child.

If people could select the sex of their children this would have a bad effect on society, according to 52% of the public (61% of panelists); a good effect according to 12% of the public (22% of panelists); and no effect according to 20% of the public (14% of panelists). Sixteen percent of the public and 3% of pan-

elists were not sure what effect it might have. The most important effect the ability to select the sex of one's child would have on society was creation of an imbalance in the sex-ratio (Figure 32). Effects mentioned often by those who thought the ability to select the sex of children would have a good effect on society were: affect the sex ratio (31% of the public; 14% of the panelists); limitation of family size (25% of the public; but no panelists).

The majority of the public (55%) and of panelists (62%) thought that people should be able to get the *Select-a-boy, Select-a-girl kits* (Figure 31). The public, however, was less inclined than panelists to allow marketing of the kits without a prescription (25% of those favoring availability, compared to 56% of panelists of similar persuasion). All of the panelists (91% of the public) who thought the ability to select the sex of one's children would have a good effect on society thought people should be able to get the kits (Figure 33). In contrast, 57% of panelists (66% of the public) who thought the ability to select the sex of one's children would have a very bad effect on society also thought the kits should not be available.

Life and death decisions. A majority of the public (67%) and of panelists (88%) thought specific rules should be drawn up to decide at what point a person is dead. Of the public and panelists who favored such rules, 75% of the public but only 37% of panelists thought that researchers, scientists, and doctors should have the final say about such rules (Figure 34). Medical scientists favored

allowing researchers, scientists, and doctors to have final say on the rules more than did other panelists (45% vs. 34%). Thirty-eight percent of panelists thought the government should decide such rules, but only 6% of the public thought so.

In the particular example cited in the questionnaire, the majority of panelists (57%) felt a special hospital panel consisting of people such as a doctor, lawyers, and a member of the clergy should decide the life and death decision on hand. Only a small fraction of the public (12%) chose this option. A plurality of the public (40%) left the decision to the patient's family and personal physician (compared to 12% of the panel). Thirteen percent of the panel (5% of the public) felt that no one should decide.

Analysis and Evaluation

The public was considerably more willing than the panel to sacrifice some individual rights in the interest of social benefits. In cases where the welfare of society seemed at issue (the prevention of violent behavior and avoidance of costs of support for defective children), the public seemed particularly willing to allow suspension of individual rights to privacy or choice. However, this principle did not extend to the abortion of a defective child, where both the public and the panel favored individual freedom of choice.

Both the public and the panel also favored freedom of choice in areas where the welfare of others was not so directly at issue (voluntary testing for fetal defects, availability of sex selection kits). Still, the panel was generally more inclined than the public to allow freedom of choice or access.

The public also displayed a greater tendency than the panel to allow physicians to control access to advances. The public wanted to allow researchers, scientists, and doctors to have the final say in establishing rules about life and death, and physicians to control access to sex selection technology through prescriptions.

RULES ABOUT RESEARCH, SAFETY AND EFFICACY OF TESTS AND TREATMENTS, FINANCIAL RESPONSIBILITY FOR TREATMENT

Findings

Rules about research, tests, and treatments. According to the majority of panelists (72%), at present, there are too few rules about the way medical research is done on people, although the majority of medical scientists (52%) thought there were too many rules (compared to only 16% of other panelists who held this opinion). The public did not agree on whether there are too many or too few rules. Some said there were too many rules (15%), some said too few (34%), some thought the number was about right (20%), and some were just not sure (30%).

The public and the panel were divided over whether or not companies do enough tests to see that a drug is safe and that it really works (Figure 35).

The panel was divided over who should decide when a new test or treatment is ready to be used routinely by doctors: 47% thought it should be researchers, scientists, and doctors; 37% the government. Medical scientists favored researchers, scientists, and doctors more than other four categories of panelists (71% to 40%), and not the government (17% to 43%). Most of the public (72%), however, favored researchers, scientists, and doctors. Also, most of the public (87%) and panelists (82%), thought the government should not prevent anyone from having a risky experimental treatment if he/she wants it and knows about the risks.

The majority of the public (68%) and panelists (69%) agreed that hospitals should have to tell patients about the

past treatment record of any doctor who will be treating them. A majority of medical scientists (63%), however, disagreed that this should be done (compared to only 22% of other panelists; 27% of the public).

Financial responsibility for treatment. A majority of the public (57%) and of panelists (63%) thought that the industry causing pollution should be most responsible for the cost of illnesses attributed to environmental factors such as pollution (Figure 40). Panelists were divided with respect to financial responsibility for treating illnesses caused mostly by personal habits: 36% of panelists held the person to be mostly responsible; 34% of the person's health insurance plan. A majority of the public (62%), however, thought that the person with the illness should be responsible, with 19% mentioning the insurance plan. Public and panelists were also divided on who should be most responsible for the cost of treating illnesses caused mostly by a person's inherited make-up; 48% of the public (47% of panelists) said the person's health insurance plan, and 30% (39% of panelists) the Federal government. A similar division obtained regarding responsibility for the cost of treating illnesses caused mostly by bacteria or viruses. Forty-five percent of the public (54% of panelists) thought a person's health insurance plan should be mostly responsible, while 30% of the public (33% of panelists) mentioned the Federal government, although medical scientists favored the person's insurance plan by a wide margin (78% vs. 48% for other panelists).

A majority of the public (54%) and of panelists (79%)

agreed that people whose personal habits make them more likely to get sick should pay more for health insurance. People who had never smoked were more likely to agree with the proposition than those who smoked regularly (65% vs. 40%).

Analysis and Evaluation

The willingness on the part of public and panel to allow those who know about the risks to participate in experimental treatments reinforces the sense that freedom of choice was an important principle when it did not directly conflict with the interests of society. In addition, it was apparent that both panel and public favored the release of information on physician performance, perhaps as a basis for making informed choices.

The public's faith in researchers, scientists, and doctors was underscored again in the willingness to allow them to decide when a new test or treatment is ready to be used routinely by doctors. Again, this viewpoint was in decided contrast to the panel in general.

There was substantial agreement on the distribution of financial responsibility for illness. When agencies or individuals were at fault, as in diseases caused by pollution or personal habits, responsibility was more frequently assigned to that agency or individual. In other cases (diseases caused by bacteria, viruses, or inherited diseases) social risk sharing mechanisms such as insurance or the government tended to be selected.

RESEARCH PRIORITIES

Findings

What research should be done. A large majority of the public (77%) and panelists (93%) were in favor of government support of research to help people take better care of themselves. However, the panel and the public were both divided over whether more money should be spent to discover new knowledge, or to use existing knowledge more completely. Beyond these questions there was little correspondence between the panelists' view of research priorities and the public's.

Panelists voted in large majorities for: research toward healthy life to age 70, rather than prolonging life past 70 (95%); basic health care, rather than medical research for new tests and treatments (85%); prevention of illness, rather than treatment for people when they get sick (81%); and curing those who have a chance of becoming healthy, rather than spending on care for those who are sick and will never get any better (85%). The public's votes on the same questions tended to follow the panel's votes, but to give only pluralities or narrow majorities where the panel's choices had been overwhelming. In addition, the public frequently volunteered "both equally" as the preferred option (Figure 37).

The panel also displayed a clear ranking of research priorities according to particular types of illness. Panelists felt the government should do most research on environmentally caused illness, next on illnesses caused by bacteria and viruses, next on inherited illnesses, and finally, illnesses caused by personal habits (Figure 37). The public agreed with the panel in ranking

research into diseases caused by personal habits lowest, but the remaining three categories were too close to call.

Who decides what problems to work on. At present researchers, scientists, and doctors are the groups with the greatest influence in deciding what problems medical researchers work on, according to 55% of the panelists; 29% thought the government had the greatest influence. More medical scientists than other categories of panelist thought the government had the biggest say (54% vs. 21%). The public was less certain on this score. About one-third thought the government had the biggest say; another third thought it was largely decided by researchers, scientists, and doctors (Figure 38). A majority of the public (64%) and of the panelists as a whole (54%) thought that researchers, scientists, and doctors should have the greatest say in deciding what problems medical researchers work on. Medical scientists were much more in support of this position than other panelists (71% vs. 49%). Finally, 54% of panelists and 49% of the public felt medical scientists and researchers were more concerned with following their own research interests than with doing research that will help the public.

Analysis and Evaluation

The public does not appear to have a clear sense of desired priorities for medical research, although there is strong interest in self-assistance technologies, such as do-it-yourself tests. The panel, on the other hand, has a very clear sense of priorities. This difference is probably attributable to the fact that the panel had considerably more information on which to base its judgment.

Even though a majority of the panel and a plurality of the public felt that medical scientists were principally concerned with their own research interests, the majority would allow medical scientists and researchers to have the biggest say in deciding what problems to work on. This is consistent with both the public's confidence in medical scientists and the public and panel's views of individual rights.

VALUE RECEIVED FOR DOLLARS SPENT; FUTURE OUTLOOK

Findings

Value received for dollars spent. In the last 20 years the United States has invested $60 billion (in 1975 prices) in medical research, $36 billion, coming from the Federal government. Has the public received value for dollars spent?

According to public and panelists, not only do we get good value from medical research paid for by the government (70% of the public and 78% of panelists said this), but the new knowledge, tests and treatments made possible by medical research have changed life for the better (94% of the public, 91% of panelists said this, Figure 39). Panelists who classified themselves as medical scientists agreed more strongly than their colleagues that the public gets good value from medical research paid for by the government (92% vs. 75%), and that the fruits of medical research have changed life for the better. The vast majority of panelists (87%) and of the public (87%) thought that they or their families have benefited from medical research in the last 20 years and that they have significantly improved the life of the average person (91% of panelists and 94% of the public agreed this was so).

The public and the panel were divided over whether new tests and treatments increase the cost of medical care more than they actually benefit people. Forty-seven percent of the public felt this was the case; however, the majority of panelists (63%) disagreed with the statement.

Future outlook. Almost everyone (93% of both panel and public) thought that, overall, the new knowledge, tests, and

treatments that medical research is likely to come up with in the next 20 years will change life for the better, with 49% of the public and 19% of panelists believing very much for the better.

Analysis and Evaluation

The public and the panel agreed that medical research has been beneficial and that it will continue to be in the future. The public particularly was optimistic about the benefits. However, the public tended to be slightly more skeptical than the panel about the benefits of new tests and treatments in relationship to their costs.

Figure 18

NEW TESTS, TREATMENTS, OR NEW KNOWLEDGE MADE POSSIBLE IN THE LAST 20 YEARS MENTIONED BY THE GENERAL PUBLIC (1)

New test, treatment, knowledge	General Public (%) (2)
Prevention, treatment of cancer	56
Prevention of infectious diseases	43
Organ transplantation, by-pass surgery, radical surgery	27
Prevention, treatment of heart disease, other than surgery	11
Life-extending equipment, artificial life support organs	7
Treatment for mental illness	7
Improved contraception	6
Treatment for infectious diseases	6
Prevention of birth defects, screening for genetic disease	5
Diagnostic equipment, CAT-scanner, autoanalyzer, etc.	5

(1) Classes mentioned by at least 5% of those mentioning an item. 77% of the general public could think of at least one new test or treatment or item of new knowledge; the remainder (23%) answered "not sure", "none, nothing", or did not respond to the question (wN=1,307).

(2) Since up to three mentions were possible, the column does not sum to 100%.

Figure 19

ACCESS TO NEW TESTS AND TREATMENTS

Question	Response	Consultant Panel (%)	General Public (%)
Do you think all types of Americans can equally get the new tests and treatments made possible by medical research, or not?	Yes	9	32
	No	91	60
	Not sure *	0	8
What types of Americans can get less of the new tests and treatments, even when they need them?	Poor, disadvantages (1)	99	67
	Rural population	31	3
	Ethnic, racial minorities	16	3
	Middle class people	10	13
When a new test or treatment first comes out, there is sometimes not enough for everyone who needs it. Today, who is most likely to get a new test or treatment? Is it:	People who can pay for it?	60	56
	People who know an important doctor or other person?	26	14
	People who apply for it first?	5	15
	Those who need it the most *	6	8
	Other classes of people *	0	3
	Combinations of the above *	1	1
	Not sure *	3	3
Today, do you think any rules have been set up to decide which people most need a new test or treatment?	Yes (2)	(3)	47
	No		25
	Not sure *		28
Today, who do you think has the final say when it comes to setting up these rules?	The government (4)	(3)	28
	Researchers, scientists, and doctors		58
	The company that developed the new test or treatment		3
	Citizens' groups, someone else		4
	Combinations of the above *		2
	Not sure *		5
Who do you think <u>should</u> get a new test or treatment, if there is not enough for everyone who needs it? Should it be:	People who can pay for it?	2	5
	Or people who know an important doctor or other person?	1	2
	Or people who apply for it first?	20	38
	Those who need it the most *	62	47
	Other classes of people *	10	5
	Combinations of the above *	2	1
	Not sure *	4	2
Do you think rules should be set up to decide which people most need a new test or treatment?	Yes (2)	(3)	70
	No		20
	Not sure *		11
Who do you think should have the final say when it comes to setting up these rules?	The government (4)	(3)	9
	Researchers, scientists and doctors		66
	The company that developed the new test or treatment		5
	Citizens' groups, someone else		12
	Combinations of the above *		4
	Not sure *		4
If new tests and treatments cannot be made available to all who need them, it is better not to develop them at all.	Agree	7	21
	Disagree	93	78
	Not sure *	0	1

* Volunteered response

(1) Percentage of respondents who answered "no" to preceding question. Because multiple responses were possible answers do not sum to 100%. Responses were open-ended.

(2) Percentage of respondents who answered "those who need it" in preceding question.

(3) Because the trigger response was volunteered it was not possible to include this question in the self-administered version of the questionnaire sent to panelists.

(4) Percentage of respondents who answered "yes" in preceding question.

Figure 20

NEW TEST OR TREATMENT OR NEW KNOWLEDGE MADE POSSIBLE IN THE LAST 20 YEARS THAT HAD THE GREATEST GOOD EFFECT ON SOCIETY (1), AND THEIR EFFECTS (2)

New Test, Treatment, Knowledge	Consultant Panel (%)	General Public (%)
Prevention of infectious diseases	26	31
Polio	*18*	*24*
Improved contraception	16	4
The pill	*11*	*2*
Treatment of infectious diseases	9	4
Antibiotics	*9*	*3*
Health education, knowledge	8	2
The relationship between smoking and cancer	*4*	*1*
Treatment for mental illness	8	3
Drug therapies	*7*	*1*
Knowledge of genetics	5	--
The discovery of DNA, genetic code	*3*	--
Prevention, treatment of cancer	1	26
Knowledge about cancer	*0*	*9*
Detection of, screening for cancer	*1*	*5*
Nonspecific treatment of cancer	*0*	*8*
Organ transplantation, by-pass surgery, radical surgery	4	12
Heart transplants	*1*	*3*
Prevention, treatment of heart disease, other than surgery	2	6
All other classes (each mentioned by less than 2% of panelists, 2% or less of the general public)	21	12
Total	100	100

Effect	Consultant Panel (%) (3)	General Public (%) (3)
Decreased morbidity, physical and mental	47	62
Technical effects	22	4
Ethical effects	15	--
Control, limit population, family size	14	3
Other effects on individuals	13	1
Increased quality of life	12	16
Other social effects	9	1
Environmental effects	8	3
Other health effects	8	13
Increased longevity	5	34
Decreased stigma, fear, anxiety, labelling	5	8
Economic effects	2	6

-- less than 1%.

(1) Classes mentioned by at least 5% of those mentioning an item. 100 of the 107 panelists who completed this part of the PEI (93%) mentioned a specific item; 3% answered "not sure"; 4% did not respond to the question (N=100). Of the 77% of the general public who could think of a new test or treatment or item of new knowledge, 92% mentioned a specific item; the remainder (8%) answered "not sure", "none, nothing"; or did not respond to the question (wN=1,204).

(2) Effects of all tests, treatments, or new knowledge mentioned as having had the greatest good effect on society in the last 20 years.

(3) Since up to three mentions were possible, columns do not sum to 100%.

Figure 21

EFFECT MENTIONED FOR EACH CLASS OF NEW TEST, TREATMENT, OR KNOWLEDGE THAT HAD THE GREATEST GOOD EFFECT ON SOCIETY IN THE LAST 20 YEARS. (Percentage of the general public mentioning the effect)

New test, treatment, or knowledge (1) / Effect (2) (3)	Prevention of infectious diseases	Prevention, treatment of cancer	Organ transplantation, by-pass surgery, radical surgery	Prevention, treatment of heart disease, other than surgery	Improved contraception	Treatment of infectious diseases	Treatment for mental illness
N=	*373*	*314*	*139*	*75*	*46*	*45*	*33*
Economic effects	3	2	9	7	4	2	12
Ethical effects	0	0	0	0	6	0	0
Decreased morbidity, physical and mental	87	60	29	47	4	77	32
Increased morbidity, physical and mental	1	0	1	4	0	0	12
Increased longevity	17	43	80	51	2	34	0
Decreased stigma, fear, anxiety, labelling	15	8	6	3	0	2	6
Increased utilization	1	0	0	0	5	0	0
Other health effects	2	20	1	21	2	0	33
Increased quality of life	9	21	20	23	2	14	15
Other effects on individuals	1	1	1	1	4	0	10
Legal effects	0	0	0	1	0	0	0
Controlled, limited population, family size	0	0	0	0	88	0	0
Other social effects	0	0	0	0	7	0	6
Technical effects	1	6	1	4	0	5	14
Environmental and other effects .	1	3	0	3	0	0	0

(1) Classes mentioned by at least 3% of the public mentioning an item. Of the 77% of the general public who could think of a new test or treatment or item of new knowledge, 92% mentioned a specific item; the remainder, 8%, answered "not sure", "none, nothing", or did not respond to the question (wN=1,204). "N" indicates the number of respondents who mentioned the particular advance.

(2) Classes and subclasses of effects mentioned by at least 5% of the public naming a specific item as having had the worst effect on society.

(3) Since up to three mentions were possible, columns do not sum to 100%.

Figure 22

NEW TESTS, TREATMENTS, OR NEW KNOWLEDGE MADE POSSIBLE IN THE LAST 20 YEARS THAT HAS HAD THE WORST EFFECT ON SOCIETY (1), AND THEIR EFFECTS (2)

New Test, Treatment, Knowledge	Consultant Panel (%)	General Public (%)
Treatment for mental illness	28	19
Drug therapies	*13*	*5*
Proliferation of tranquilizers ..	*8*	*12*
Psychosurgery, lobotomy	*4*	—
Life-extending equipment, artificial life support organs	12	7
Control of behavior	9	1
Insufficient testing of drugs ...	7	12
Thalidomide	*5*	*6*
Improved contraception	7	23
The pill	*6*	*16*
High cost of care, poor health care	6	3
Organ transplantation; by-pass surgery; radical surgery	6	4
Prevention, treatment of cancer .	0	8
Pollution environmental hazards .	5	5
All other classes (each mentioned by 2% or less of panelists, 3% or less of the general public)	20	18
Total	100	100

Effect	Consultant Panel (%) (3)	General Public (%) (3)
Increased drug, alcohol addiction .	18	10
Environmental effects	18	5
Increased utilization of drugs, services	15	42
Technical effects	15	9
Other effects on individuals	15	9
Created false hopes, expectations .	11	1
Other social effects	11	7
Other ethical effects	9	10
Increased morbidity, physical and mental	7	13
Decreased quality of life	7	5
Other health effects	6	11
Morals unfavorably affected	4	11
Economic effects	1	9
Increased stigma, fear, anxiety, labelling	0	6

— less than 1%.

(1) Classes of new tests, treatments, or new knowledge mentioned by at least 5% of those mentioning an item. 82 of the 107 panelists who completed this part of the PEI (77%) mentioned a specific item; 10% answered "none, nothing", "don't know"; 13% did not respond to the question (N=82). Of the 77% of the general public who could think of a new test or treatment or item of new knowledge, 48% mentioned a specific item; the remainder (52%) answered "not sure", "none, nothing", or did not respond to the question (wN=653).

(2) Effects of all tests, treatments, or new knowledge mentioned as having had the worst effect on society in the last 20 years.

(3) Since up to three mentions were possible, columns do not sum to 100%.

Figure 23

EFFECTS MENTIONED FOR EACH CLASS OF NEW TEST, TREATMENT, OR KNOWLEDGE THAT HAD THE WORST EFFECT ON SOCIETY IN THE LAST 20 YEARS (Percentage of the general public mentioning the effect)

New test, treatment, knowledge (1) / Effect (2) (3)	Improved contraception	Treatment for mental illness	Insufficient testing of drugs	Prevention, treatment of cancer	Life-extending equipment	Pollution, environmental hazards	Organ transplantation; bypass surgery; radical surgery	Prevention of infectious diseases	High cost of care, poor health care
N=	*150*	*120*	*80*	*54*	*45*	*34*	*24*	*23*	*20*
Increased economic hardship, poverty	0	1	0	1	27	0	0	0	0
Increased health care costs	0	1	7	7	2	0	0	4	58
Other economic effects	0	1	4	4	2	2	0	0	16
Morals unfavorably affected	41	2	0	0	0	0	0	0	0
Against God, nature	1	0	0	0	10	0	13	0	6
Other ethical effects	13	4	0	2	18	2	12	0	0
Decreased morbidity, physical and mental	1	1	2	6	0	3	0	0	0
Increased morbidity, physical and mental	14	8	42	7	0	31	0	4	0
Decreased longevity	0	2	1	1	2	3	8	4	5
Increased stigma, fear, anxiety, labelling	0	2	5	24	3	8	8	14	6
Increased utilization	61	38	46	43	13	19	29	59	11
Other health effects	2	5	6	14	3	6	36	15	5
Decreased quality of life	0	1	4	3	40	3	7	0	7
Created false hopes, expectations	0	0	1	4	2	0	8	0	0
Other effects on individuals	2	24	5	7	4	7	4	0	0
Legal effects	0	1	1	0	0	5	0	4	0
Increased crime, deviance, violence	1	17	0	0	0	0	0	0	0
Increased drug, alcohol addiction	3	41	1	0	2	3	0	0	0
Other social effects	8	2	2	0	8	0	0	0	0
Technical effects	1	5	20	24	2	3	12	17	27
Environmental and other effects	2	1	1	7	0	45	3	0	0

(1) Classes mentioned by at least 3% of the public mentioning an item. Of the 77% of the general public who could think of a new test or treatment or item of new knowledge, 48% mentioned a specific item; the remainder, 52%, answered "not sure", "none, nothing", or did not respond to the question (wN=653). "N" indicates the number of respondents who mentioned the particular advance.

(2) Classes and subclasses of effects mentioned by at least 5% of the public naming a specific item as having had the worst effect on society.

(3) Since up to three mentions were possible, columns do not sum to 100%.

Figure 24

NEW THINGS CONSULTANT PANELISTS AND THE GENERAL PUBLIC WANTED MEDICAL SCIENCE TO COME UP WITH IN THE NEXT 20 YEARS (1)

New test, treatment, knowledge	Consultant Panel (%) (2)	General Public (%) (2)
Prevention, treatment of cancer	59	73
Prevention, treatment of heart disease, other than surgery	36	26
Treatment for mental illness	23	14
Control of pollution, environmental hazards; prevention of environmentally caused disease	20	8
Improved health services, availability, accessibility	13	3
Control of violent behavior; aggression	13	2
Prevention of aging, senility; prolongation of healthy life	13	3
Health education, knowledge	10	4
Improved contraception	9	3
Prevention of birth defects, screening for genetic disease	9	7
Treatment of infectious diseases	5	7
National health policy, various aspects	5	2
Prevention, treatment of arthritis	1	8
Prevention, treatment of muscular dystrophy	1	6
Prevention, treatment of diabetes	0	10

(1) Class mentioned by at least 5% of those mentioning an item. 104 of the 107 panelists who completed this item (97%) mentioned a specific item; the remainder (3%) did not respond to the question (N=104). 90% of the general public mentioned a new test or treatment or item of new knowledge; the remainder (10%) answered "not sure", "none, nothing", or did not respond to the question (wN=1,526).

(2) Since up to three mentions were possible, columns do not sum to 100%.

Figure 25

NEW THING THAT WILL HAVE GREATEST GOOD EFFECT ON SOCIETY, IN THE NEXT 20 YEARS (1), AND THEIR EFFECTS (2)

New Test, Treatment, Knowledge	Consultant Panel (%)	General Public (%)
Prevention, treatment of cancer	15	52
Nonspecific treatment of cancer	*11*	*48*
Health education, knowledge	11	3
Education of the public about diet	*4*	*3*
Improved health services, access, availability	9	2
Control of pollution, environmental hazards; prevention of environmentally caused disease	9	6
Improved contraception	9	1
Prevention, treatment of heart disease, other than surgery	8	5
Treatment for mental illness	6	7
Prevention of birth defects, screening for genetic disease	3	2
Treatment of infectious diseases	3	2
All other classes (each mentioned by 3% or less of panelists; 2% or less of the general public	27	20
Total	100	100

Effect	Consultant Panel (%)(3)	General Public (%)(3)
Decrease morbidity, physical and mental	39	40
Increase quality of life	15	21
Increase longevity	14	31
Other economic effects	10	8
Decrease stigma, fear, anxiety, labelling	10	17
Other health effects	10	4
Technical effects	8	3
Control, limit population, family size	8	1
Other social effects	8	4
Other effects on individuals	5	7
Political effects	5	--
Environmental and other effects	1	6
Decrease health care costs	0	6

-- less than 1%.

(1) Classes mentioned by at least 5% of those mentioning an item. 98 of the 107 panelists who completed this part of the PEI (92%) mentioned a specific item; 1% answered "none, nothing", 7% did not respond to the question (N=98). Of the 90% of the general public who could think of a new test or treatment or item of new knowledge they wanted medical science to come up with, 88% mentioned a specific item; the remainder (12%) answered "not sure", "none, nothing", or did not respond to the question (wN=1,340).

(2) Effects of all new tests, treatments, or new knowledge mentioned that will have the greatest good effect on society.

(3) Since up to three mentions were possible, columns do not sum to 100%.

Figure 26

EFFECTS MENTIONED FOR EACH CLASS OF NEW TEST, TREATMENT, OR KNOWLEDGE THAT WILL HAVE THE GREATEST GOOD EFFECT ON SOCIETY IN THE NEXT 20 YEARS
(Percentage of the general public mentioning the effect)

	New test, treatment, knowledge (1)				
Effect (2) (3)	Prevention, treatment of cancer	Treatment for mental illness	Control of pollution, environmental hazards	Prevention, treatment of heart disease, other than surgery	Health education, knowledge
N=	*699*	*91*	*79*	*69*	*40*
Decrease health care costs	6	3	5	1	5
Other economic effects	3	13	2	7	10
Decrease morbidity, physical and mental	36	19	64	42	54
Increase longevity	45	7	17	45	9
Decrease stigma, fear, anxiety, labelling	28	5	0	11	0
Other health effects	3	6	4	4	13
Increase quality of life	15	31	13	31	22
Other effects on individuals	6	20	4	5	10
Decrease crime, deviance, violence	—	35	2	0	8
Other social effects	—	2	0	0	0
Environmental and other effects .	5	9	28	4	9

— less than 1%

(1) Classes mentioned by at least 3% of the public mentioning an item. One of 90% of the general public who could think of a new test or treatment or item of new knowledge they wanted medical science to come up with, 88% mentioned a specific item; the remainder, 12%, answered "not sure", "none, nothing", or did not respond to the question (wN=1,340). "N" indicates the number of respondents who mentioned the particular advance.

(2) Classes and subclasses of effects mentioned by at least 5% of the public naming a specific item as having had the worst effect on society.

(3) Since up to three mentions were possible, columns do not sum to 100%.

Figure 27

NEW THINGS THAT WILL HAVE WORST EFFECT ON SOCIETY IN NEXT 20 YEARS (1), AND THEIR EFFECTS (2)

New Test, Treatment, Knowledge	Consultant Panel (%)	General Public (%)
Control of behavior	23	3
Nonspecific control of behavior	*16*	--
Life-extending equipment; artificial life support organs	15	4
Knowledge of genetics, gene manipulation	13	11
Manipulation of genes, genetic engineering	*8*	--
Pollution, environmental hazards	9	9
War, biological weapons	*5*	*1*
Pollution	*4*	*4*
Treatment for mental illness	9	14
Proliferation of tranquilizers	*9*	*11*
High cost of care, poor health care	8	4
Selection of sex of offspring	4	13
Improved contraception	0	8
Insufficient testing of drugs	0	4
National health policy, various aspects	3	4
All other classes (each mentioned by 2% or less of panelists, 3% or less of the general public)	16	26
Total	100	100

Effect	Consultant Panel (%)(3)	General Public (%)(3)
Domination by the state, special interests	16	11
Environmental effects	16	11
Other ethical effects	15	6
Increase morbidity, physical and mental	13	14
Increase dependency, lower self-esteem	11	--
Other social effects	10	12
Decrease quality of life	9	3
Technical effects	9	3
Other health effects	9	10
Other effects on individuals	8	7
Increase genetic regulation	6	5
Increase utilization of drugs, services	5	15
Create false hopes, expectations	5	0
Other economic effects	1	11
Against God, nature	0	7
Affect the sex ratio	1	6
Increase health care costs	0	5

-- less than 1%.

(1) Classes mentioned by at least 5% of those mentioning an item. 79 of the 107 panelists who completed this part of the PEI (74%) mentioned a specific item; 8% answered "none, nothing" or "don't know"; 18% did not respond to the question (N=79). Of the 90% of the general public who could think of a new test or treatment or item of new knowledge they wanted medical science to come up with, 40% mentioned a specific item, the remainder (60%) answered "not sure", "none, nothing", or did not respond to the question (wN=604).

(2) Effects of all new tests, treatments, or new knowledge mentioned that will have the worst effect on society.

(3) Since up to three mentions were possible, columns do not sum to 100%.

Figure 28

EFFECTS MENTIONED FOR EACH CLASS OF NEW TEST, TREATMENT, OR KNOWLEDGE THAT WILL HAVE THE WORST EFFECT ON SOCIETY IN THE NEXT 20 YEARS (Percentage of the general public mentioning the effect)

New test, treatment, knowledge (1) / Effect (2) (3)	Treatment for mental illness	Selection of sex of offspring	Knowledge of genetics, gene manipulation	Pollution, environmental hazards	Improved contraception	High cost of care, poor health care	Insufficient testing of drugs	National health policy	Life-extending equipment
N=	*87*	*81*	*66*	*52*	*48*	*27*	*26*	*25*	*24*
Increase economic hardship, poverty	0	0	0	0	2	12	4	0	0
Increase health care costs	1	1	2	0	2	30	0	9	0
Other economic effects	0	2	0	0	4	15	4	19	0
Morals unfavorably affected	1	2	4	2	12	0	0	0	4
Against God, nature	0	31	14	0	4	0	4	0	8
Increase genetic regulation	1	8	30	0	0	0	0	0	0
Other ethical effects	4	6	4	0	0	4	0	13	0
Increase morbidity, physical and mental	16	0	3	45	22	15	14	4	4
Decrease longevity	3	0	0	8	3	0	4	0	0
Increase stigma, fear, anxeity, labelling	0	1	0	2	2	4	6	12	8
Increase utilization	23	3	14	0	24	7	73	3	4
Other health effects	5	0	0	5	0	16	4	8	25
Effects on individuals	15	1	6	4	12	4	4	10	17
Domination by the state, special interests	16	4	33	2	0	0	0	36	0
All other political effects	0	0	2	0	0	0	0	0	0
Increase crime, deviance, violence	15	2	0	1	5	0	0	4	0
Affect the sex-ratio	0	41	3	0	0	0	0	0	0
Other social effects	2	5	12	2	8	0	0	0	17
Technical effects	0	0	0	0	3	6	0	15	8
Environmental and other effects	2	6	1	34	12	4	3	8	17

(1) Classes mentioned by at least 3% of the public mentioning an item. Of the 90% of the general public who could think of a new test or treatment or item of new knowledge they wanted medical science to come up with, 40% mentioned a specific item; the remainder, 60%, answered "not sure", "none, nothing", or did not respond to the question (wN=604). "N" indicates the number of respondents who mentioned the particular advance.

(2) Classes and subclasses of effects mentioned by at least 5% of the public naming a specific item as having had the worst effect on society.

(3) Since up to three mentions were possible, columns do not sum to 100%.

Figure 29

TESTS FOR VIOLENT ACTS: USE OF DRUGS TO PREVENT VIOLENT ACTS

Question	Response	Consultant Panel (%)	General Public (%)
Research should be done to develop new ways to change a person's behavior, that is, the way he or she acts.	Agree	61	43
	Disagree	39	47
	Not sure *	0	11
Research should be done to develop tests to find out which people are likely to commit violent acts such as murder or rape.	Agree	46	71
	Disagree	54	22
	Not sure *	0	8
Suppose a test existed that could tell if a person is likely to commit a violent act, such as murder or rape. Even though it might be an invasion of privacy to make everyone take such a test, the government should make everyone take it in order to protect people from violent acts.	Agree	19	41
	Disagree	81	57
	Not sure *	0	8
If a drug to control violent behavior existed, the government should make everyone who has committed a violent act, such as murder or rape, take the drug to prevent them from committing any more violent acts.	Agree	41	66
	Disagree	59	28
	Not sure *	0	7
The government should make everyone who is likely to commit a violent act, such as murder or rape, take such a drug, even if they haven't committed the act yet, to make sure that they don't.	Agree	7	33
	Disagree	93	56
	Not sure *	0	10
The government should offer such a drug to a person who has committed a violent act, such as murder or rape, as an alternative to a prison sentence.	Agree	59	39
	Disagree	42	50
	Not sure *	0	11

* Volunteered response

Figure 30

TESTS FOR CERTAIN DEFECTS

Question	Response	Consultant Panel (%)	General Public (%)
As you may know, there are tests which show if people are likely to have children with certain defects. Before being given a marriage license, individuals should be required to have these tests.	Agree	51	67
	Disagree	49	27
	Not sure *	0	6
As you may know, there is a test that a doctor can do to tell if an unborn baby has certain defects. If a pregnant woman wants such a test, when should she have it, if at all?	Only if she can pay for it herself.	4	12
	Even if she can't pay for it herself and the government has to pay for it	93	72
	Or, shouldn't she have it at all ..	4	9
	Not sure *	0	7
Jane Doe has had this test. It showed that if the baby were born it would have serious defects that would require life-long care. Since Jane Doe could not pay for this life-long care herself, the government would have to pay for it. What should be done?	She should have an abortion, because taxpayers would have to support the child	8	6
	She should have an abortion no matter who would pay for the care of the child, because it is wrong to bring children with serious defects into the world	23	17
	She should have an abortion only if she wants one, because it is a matter of personal choice	63	50
	She should not have an abortion at all, because it is wrong to destroy any life	6	21
	Not sure *	1	5

* Volunteered response

Figure 31

SELECT-A-BOY, SELECT-A-GIRL MARKETABLE KITS

Question	Response	Consultant Panel (%)	General Public (%)
Suppose a company has developed a safe medical product which people can use when they want to select a boy or a girl baby. These "select-a-boy" and "select-a-girl" kits would be used before the woman gets pregnant. The kits would be sold through drug stores.			
If you wanted to have a child and these kits were available, would you use one?	Yes	38	19
	No	60	67
	Not going to have any children (1)	0	6
	Not sure *	2	8
If these kits were available, do you think people would use them to select boys more often or to select girls?	Boys	91	48
	Girls	1	5
	Both equally *	5	19
	People wouldn't use them *	0	5
	Not sure *	3	23
If these kits were available, do you think people would select a boy or a girl for their first child?	Boys	94	73
	Girls	2	3
	Both equally *	3	7
	People wouldn't use them *	0	3
	Not sure *	1	14
If people could select the sex of their children, what effect do you think this would have on society, i.e. people in general, and not just the people who would use the kits? Would it have:	A good effect?	22	12
	A somewhat bad effect?	35	25
	A very bad effect?	26	27
	Or, would it have no effect at all?	14	20
	Not sure *	3	16
Now, do you think people should be able to get these kits?	Without a prescription	38	14
	Only if prescribed by a doctor	30	41
	Or, not at all	32	38
	Not sure *	0	6

* Volunteered response

(1) This response almost exclusively confined to people aged 45 years and older

Figure 32

MOST IMPORTANT EFFECT THAT ABILITY TO SELECT THE SEX OF CHILDREN WOULD HAVE ON SOCIETY, ACCORDING TO VIEW OF EFFECT (1) (2)

Effects mentioned by those who thought that ability to select the sex of children would have -- a good effect on society	Consultant Panel (%) (3)	General Public (%) (3)	Effects mentioned by those who thought that ability to select the sex of children would have -- a bad effect on society	Consultant Panel (%) (3)	General Public (%) (3)
Control, limit population, family size	50	25	Affect the sex ratio	62	64
Affect the sex-ratio	14	31	Other social effects	15	10
Other individual effects	14	10	Against God, nature	11	22
Other social effects	14	6	Other effects on individuals	2	7
Increase quality of life	0	25	All other effects (each mentioned by only 1 panelist; 3% or less of the general public)	3	10
All other effects (each mentioned by only 1 panelist; 1% or less of the general public)	9	7			

(1) 22% of panelists responded "a good effect"; 61% "a bad effect"; and 14% "no effect"; 3% responded "don't know".

(2) 12% of the general public responded "a good effect"; 51% "a bad effect"; 20% "no effect"; 17% responded "don't know", or did not respond to the question.

(3) Since more than one mention was possible columns do not sum to 100%.

Figure 33

APPROPRIATE DISTRIBUTION OF SELECT-A-BOY, SELECT-A-GIRL KITS, BY EFFECT OF THE KITS ON SOCIETY

Distribution (1)	Consultant Panel, Percent Effect of kits on society					General Public, Percent Effect of kits on society				
	Good	Somewhat Bad	Very Bad	None	Total	Good	Somewhat Bad	Very Bad	None	Total
Without a prescription	74	24	11	57	36	27	10	4	26	14
Only if prescribed by a doctor	26	30	32	36	30	64	41	30	50	43
Not at all	0	46	57	7	33	9	48	66	23	42
Total	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
N=	*23*	*37*	*28*	*14*	*102*	*192*	*404*	*438*	*326*	*1,360*

(1) "N" indicates the number of panelists or public who mentioned this effect.

Figure 34

LIFE AND DEATH DECISIONS

Question	Response	Consultant Panel (%)	General Public (%)
A person, John Doe, is being kept alive by a machine. He is unconscious, in a coma. Doctors think that he is close to death and that he has no chance of recovery. Another person, David Smith, will die if not put on the machine. Doctors think that if David Smith is put on the machine he has an excellent chance of recovery.			
The problem is that the hospital has only the one machine and there isn't time to get another one.			
Who, if anyone, should decide if John Doe should be taken off the machine in order to give it to David Smith?	No-one, John Doe should stay on the machine until he dies	13	5
	John Doe's personal doctor	1	6
	John Doe's family only	0	13
	John Doe's family and his personal doctor	12	40
	The hospital doctor in charge of the machine	3	3
	A special hospital panel consisting only of doctors	7	9
	A special hospital panel consisting of people, such as a doctor, lawyer, and member of the clergy	57	12
	The local courts	2	2
	Someone else *	7	3
	Not sure *	2	6
As you may know, in a few cases when someone is being kept alive by medical equipment, it is difficult to determine if the person is alive or dead. Do you think specific rules should be drawn up to decide at what point a person is dead?	Yes	88	67
	No	12	18
	Not sure *	0	14
Who do you think should have the final say as to what the rules should be? Should it be:	The government? (1)	38	6
	Researchers, scientists, and doctors?	37	75
	Citizens' groups, someone else? ...	5	11
	Combinations of the above *	19	5
	Not sure *	1	3

* Volunteered response

(1) Percentage of respondents who answered "yes" to the preceding question.

Figure 35

RULES ABOUT RESEARCH, APPLICATION OF TECHNOLOGIES

Question	Response	Consultant Panel (%)	General Public (%)
At present, do you think there are too many rules, or too few rules about the way medical research is done on people.	Too many rules	24	15
	Too few rules	72	34
	Just about the right number *	2	20
	Wrong rules *	2	0
	Not sure *	0	30
Before a drug is used routinely, companies do enough tests to see that the drug is safe and that it really works.	Agree	52	58
	Disagree	48	35
	Not sure *	0	6
The government shouldn't prevent anyone from having a risky experimental treatment if they want it, know about the risks.	Agree	82	87
	Disagree	18	8
	Not sure *	0	5
Hospitals should have to tell patients about the past treatment record of any doctor who will be treating them.	Agree	69	68
	Disagree	31	27
	Not sure *	0	5
Who do you think should decide when a new test or treatment is ready to be used routinely by doctors? Should it be:	The government?	37	13
	Researchers, scientists, and doctors?	47	72
	The company that developed the new test or treatment?	0	7
	Citizens' groups, someone else?	7	4
	Combinations of the above *	9	2
	Not sure *	1	2

* Volunteered response

Figure 36

FINANCIAL RESPONSIBILITY FOR TREATMENT

Question	Response	Consultant Panel (%)	General Public (%)
Some illnesses seem to be caused mostly by environmental factors such as pollution. Who should be mostly responsible for paying the cost of treating such illnesses?	The person with the illness?	2	4
	Or the person's health insurance plan?	11	11
	Or the government?	16	22
	Or the industry causing the pollution?	63	57
	Someone else *	8	--
	Combinations of the above *	0	3
	Not sure *	0	3
Some illnesses seem to be caused mostly by personal habits such as smoking or drinking. Who should be mostly responsible for paying the cost of treating such illnesses?	The person with the illness?	36	62
	Or the person's health insurance plan?	34	19
	Or the government?	10	7
	Or the company making the product, such as cigarettes or alcoholic drinks?	16	8
	Someone else *	4	--
	Combinations of the above *	1	1
	Not sure *	0	3
Some illnesses such as diabetes, sickle cell anemia, and hemophilia, seem to be caused by a person's inherited make-up. Who should be mostly responsible for paying the cost of treating such illnesses?	The person with the illness?	3	14
	Or the person's health insurance plan?	47	48
	Or the government?	39	30
	Someone else *	7	2
	Combinations of the above *	4	2
	Not sure *	0	4
Some illnesses such as measles, influenza, and tuberculosis seem to be caused mostly by bacteria and viruses. Who should be mostly responsible for payint the cost of treating such illnesses?	The person with the illness?	5	19
	Or the person's health insurance plan?	54	45
	Or the government?	35	30
	Someone else *	3	1
	Combinations of the above *	2	2
	Not sure *	1	3
People whose personal habits (such as smoking or drinking) make them more likely to get sick should pay more for health insurance.	Agree	79	54
	Disagree	22	40
	Not sure *	0	6

-- less than 1%

* Volunteered response

Figure 37

RESEARCH PRIORITIES

Question	Response	Consultant Panel (%)	General Public (%)
The government should support research to help people take better care of themselves, such as developing do-it-yourself tests to see if they have certain illnesses.	Agree	93	77
	Disagree	8	19
	Not sure *	0	4
On which should the government spend more money: to make sure everyone can lead a more healthy life until the age of 70, or to prolong life past the age of 70?	Healthy life to 70	95	57
	Prolong life past 70	5	21
	Both equally *	0	18
	Not sure *	0	4
On which should the government spend more money: to discover new knowledge, tests, and treatments, or to use the knowledge, tests, and treatments we already have more completely?	To discover new knowledge	51	40
	To use what we have	49	33
	Both equally *	1	23
	Not sure *	0	4
On which should the government spend more money: to spend money so that everyone can get basic health care or to spend money on medical research so that new and better tests and treatments can be found for serious illnesses that do not affect everyone?	Basic health care	85	41
	Support medical research	14	30
	Both equally *	1	25
	Not sure *	0	4
On which should the government spend more money: to try and keep everyone healthy and prevent them from becoming ill or to treat people when they get sick?	Keep healthy, prevent illness	81	58
	Treat those who get sick	18	18
	Both equally *	1	22
	Not sure *	0	2
On which should the government spend more money: to cure sick people with some chance of being healthy again or to care for people who are sick and will never get any better?	Cure sick people with a chance	85	60
	Care for sick who will not get better	12	4
	Both equally *	2	31
	Don't know *	2	5

In order to improve the health of the average person, the government can emphasize any of four types of medical research:

1. *research on illnesses that are mostly caused by personal habits (such as smoking and lung cancer; and heavy drinking and liver disease);*
2. *research on illnesses that are mostly caused by an individual's inherited make-up (such as diabetes, sickle-cell anemia, and hemophilia);*
3. *research on illnesses that are mostly caused by bacteria or viruses (such as measles and tuberculosis); and*
4. *research on illnesses that are mostly caused by things in the environment (such as air pollution and lung disease).*

Question		Mean Rank Score (1)	
Which type of medical research do you think the government should do most?	1. Personal habits	3.3	3.1
	2. Inherited make-up	2.9	2.1
	3. Bacteria and viruses	2.1	2.3
	4. Environment	1.7	2.4

* Volunteered response

(1) Product of the sum of the ranks divides by number of responses: 1 is highest priority.

Figure 38

DECISION-MAKING WITH RESPECT TO RESEARCH

Question	Response	Consultant Panel (%)	General Public (%)
In deciding what research to do, most medical scientists and researchers are more concerned with following their own research interests than with doing research that will help the public.	Agree	54	49
	Disagree	46	35
	Not sure *	0	15
At present, what group do you think has the biggest say in deciding what problems medical researchers work on. Is it:	The government?	29	34
	Researchers, scientists, and doctors?	55	32
	Private industry, such as drug companies?	12	18
	Citizens' groups, someone else?	0	3
	Combinations of the above *	5	1
	Not sure *	0	12
What group do you think should have the biggest say in deciding what problems medical researchers work on? Should it be:	The government?	21	12
	Researchers, scientists, and doctors?	54	64
	Private industry, such as drug companies?	0	2
	Citizens' groups, someone else?	8	14
	Combinations of the above *	16	3
	Not sure *	2	5

* Volunteered response

Figure 39

VALUE RECEIVED FOR DOLLARS SPENT; FUTURE OUTLOOK

Question	Response	Consultant Panel (%)	General Public (%)
Overall, do you think that the new knowledge, tests, and treatments made possible by medical research have changed life very much for the better, somewhat for the better, somewhat for the worse, or very much for the worse?	Very much for the better	33	59
	Somewhat for the better	64	34
	For the worse	2	2
	Both for the better and for the worse *	0	3
	Had no effect *	0	1
	Not sure *	1	1
Do you think you or your family have benefitted from the new knowledge, tests, and treatments made possible by medical research in the last 20 years?	Yes	87	87
	No	13	13
New knowledge, tests, and treatments made possible by medical research have significantly improved the life of the average person.	Agree	91	94
	Disagree	9	4
	Not sure *	0	2
In general, the public gets good value from medical research paid for by the government.	Agree	78	70
	Disagree	21	19
	Not sure *	1	11
New tests and treatments made possible by medical research increase the cost of medical care much more than they actually benefit the people who get them.	Agree	38	47
	Disagree	63	38
	Not sure *	0	16
Overall, do you think that the new knowledge, tests, and treatments that medical research is likely to come up with in the next 20 years will change life very much for the better, somewhat for the better, somewhat for the worse, or very much for the worse?	Very much for the better	19	49
	Somewhat for the better	74	44
	For the worse	6	2
	Both for the better and for the worse	0	3
	Will have no effect	0	0
	Not sure *	1	2

* Volunteered response

Appendix 1:
Methods

INTRODUCTION

This special study was mandated by the U.S. Congress under Section 203 of PL 93-348, The National Research Act. It was conducted under contract N01-HU-6-2105 for the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

Study Objectives

The objectives of the study were:

* to identify a limited number of subject areas and advances in biomedical and behavioral research and services within each subject area that will probably take place in the next 20 years, quintessential examples, to act as foci of inquiry;

* to identify foreseen implications of these quintessential advances in biomedical and behavioral research and services, and appropriate policies to respond to them;

* to examine the implications of policies that might be implemented with respect to selected, quintessential, technological advances in biomedical and behavioral research;

* to evaluate certain general policies that may be used to control or direct certain aspects of biomedical and behavioral research and the implementation of resultant technologies;

* to examine the consequences of a possible national policy that might be adopted with respect to biomedical and behavioral research and the implementation of resultant technologies; and

* to analyze and evaluate public understanding of and attitude toward advances in biomedical and behavioral research, technology, and services and their effects, the use of technology in medical practice, and policies pertinent to the entire subject of study.

Study Methods

In order to accomplish the special study objectives two integrated inquiries were designed and implemented. They were: (1) a policy study; and (2) a national opinion survey, an adjunct

to the policy study suggested by the study's designers as necessary to meet the Congressional mandate. The study began in September 1975 and was completed in January 1977.

The policy study was a structured, iterative inquiry involving 121 eminent individuals drawn from five broad categories: ethicists, lawyers, medical scientists, representatives of the public interest, and social scientists. It was carried out through the medium of three Policy Evaluation Instruments (PEIs) mailed to and completed independently by panelists. After the first PEI, each subsequent PEI built upon panelists' responses to previous iterations.

The national opinion survey questionnaire was based, in part, on material generated by the first and second PEIs. It was administered to a probability sample of 1,679 Americans in individual face-to-face interviews. In order to provide a basis for evaluating public understanding and attitude a parallel version of the questionnaire was included in the third PEI sent to consultant panelists.

The methods used to conduct the special study are described in this appendix to the report. They are presented in the following order: study management; policy study; national opinion survey; and preparation of the final report.

STUDY MANAGEMENT

This study was a fully integrated effort undertaken jointly by Policy Research Incorporated and the Center for Technology Assessment of the New Jersey Institute of Technology. The study was headquartered in the offices of Policy Research Incorporated, Baltimore, Maryland.

Study Design and Management Group (SDMG)

The study was designed and implemented by an eight member Study Design and Management Group (SDMG). This group, which represented a balance of expertise in the medical, legal, ethical and social areas: formulated the initial design; monitored its implementation; revised the design and guided the development of the project to meet the objectives of the study; and reviewed all reports issued. Implementation of the study design flowed from the SDMG through a Project Coordinator to the other members of the Study Coordinating Staff, who were full-time employees of Policy Research Incorporated.

Study Coordinating Staff (SCS)

The Study Coordinating Staff (SCS) was responsible for the operational functions of the study, including processing, reviewing, synthesizing, and summarizing the results of the PEIs; preparing drafts of the final report, and maintaining contact with members of the Consultant Panel.

Consultants to the SDMG

Five consultants were retained to aid the Study Design and Management Group in carrying out their activities. The Consultants to the SDMG functioned as independent reviewers of the various instruments and reports produced by the SDMG. They were chosen for their diverse expertise and different viewpoints to add scope to

the project management, and to enhance the quality of the study products.

Consultants to the Study

A number of additional consultants participated in the study. The roles of these consultants included pretesting instruments, and supplying specific technical assistance to the study.

Appendix 2 lists members of the Study Design and Management Group, Consultants to the SDMG, the Study Coordinating Staff, and other study staff members; Appendix 3 consultants to the study.

Meetings, Presentations, Communications with the Commission

The SDMG met fourteen times throughout the conduct of the study to monitor and guide its progress. The commission's Project Monitor attended these meetings on a regular basis in order to maintain communication between the project and the Commission staff and the Commission itself. All materials related to the study were forwarded to the Commission staff and members of the Commission as they were produced. In addition, four presentations were made to the Commission during the course of the study.

The first presentation related to the design of the study and initial progress, including development of the issues for inclusion in the study, the selection of panelists, and the first Policy Evaluation Instrument. This presentation was made in October, 1975. (Separate meetings were held with Commission staff on the subject of issues selection.) Interim reports were presented to the Commission in April, 1976, and September, 1976. These reports constituted interim products of the study. A final presentation to the Commission was made in 1977 after submission of the final report of the study.

INTRODUCTION TO THE POLICY STUDY

Inherent in the policies which people recommend is an implicit view of the future which is predicated on their view of the past and of the present. Consequently, the most fruitful way of understanding the ethical, legal, and social implications of advances in biomedical and behavioral technology is to engage in a realistic discussion of the policy alternatives available to influence these advances, and the problems inherent in the means by which these advances are produced. The study approach began with the assumption that normative plans for the future are idealized plans for extending what is known in the present. The approach based the implications of advances and policies on the projections of as many diverse disciplines, professions, and types of personalities as feasible. Moreover, it encompassed ethical as well as technical considerations, and therefore followed a system of inquiry suggested by Churchman in the Design of Inquiring Systems (Basic Books, NY, 1971).

The methodology elaborated to conduct this study represents a new method of systematically analyzing complex, value-laden, policy-related subjects. Essentially, it is a dynamic communications process in which information generated by a group at one point in time is elaborated on in the next. This dynamic communications process incorporated a dialectic between contrasting views, designed to produce the best underlying pro and contra arguments which form the basis of various policy alternatives, resource allocation alternatives, or outcomes, impacts and effects. Through this process as many considerations

as possible are brought into the discussion.

Organization of the Policy Study

The study involved the discussion of the implications of advances, and policy alternatives available to control and regulate the conduct of research and the distribution of technology. This discussion focused on five quintessential subject areas in research and technology which currently confront the various facets of the health system. The persons who participated in the discussion were 121 eminent individuals, collectively known as the Consultant Panel, representing different perspectives on the problem.

In order to provide a variety of views and perspectives pertinent to the subject of the study, the Consultant Panel consisted of persons drawn from the following five broad categories, with about 25 in each category: ethicists; lawyers; medical scientists; representatives of the public interest; and social scientists.

The discussion was carried out through three Policy Evaluation Instruments (PEIs) mailed to the Consultant Panel on February 6, May 12, and August 14, 1976. Each PEI subsequent to the first built upon panelists' responses to previous PEIs. During the course of filling out these PEIs panelists were able to make known their views, arguments, and assumptions about advances in biomedical and behavioral research and technology and about policies which might be implemented to deal with those advances. The discussion of advances and policies unfolded from the flow of information from one PEI to the next. The progress of the discussion was from the general to the

specific; from general implications of a number of quintessential advances, to specific implications of stated policies with respect to advances, to specific positions with respect to selected advances; and from general policies to address biomedical and behavioral research and the implementation of the resultant technology, to specific policies governing many aspects of research and the implementation of resultant technology. Each PEI was designed to allow a dialectic between competing views.

Individual respondents remained anonymous throughout the dialectic process so that points of view could be expressed without the obligation to adhere to past positions, or to be fixed in one's positions. Moreover, since panelists could independently and freely assess the material presented, interpersonal considerations and group dynamics were minimized.

SELECTION OF THE CONSULTANT PANEL

In order to provide a variety of views and perspectives pertinent to the subject of the study, the Consultant Panel consisted of persons drawn from the following five broad categories:

* ethicists, philosophers, and religious leaders;
* lawyers and members of the judiciary;
* medical scientists and persons in related fields -- including medical doctors from various specialized areas; biochemists; biophysicists and biologists; experimental psychologists; pharmacologists; and representatives of the drug, health appliance, research apparatus, and hospital industries;
* representatives of the public interest -- including members of the Congress and other legislative bodies; members of the Executive Branch of the Government; and members of special interest groups including minority groups, consumer interest groups, and organizations who maintain a particular moral/ethical position vis-a-vis the practice of medicine; and
* social scientists -- including sociologists; psychologists; economists; urbanologists; planners in various disciplines; and managers and administrators.

The Consultant Panel was selected in a number of discrete waves to insure that a balanced panel resulted from the selection process.

At the time the proposal for the study was submitted, approximately one-half the number of persons required to make up the panel had been selected and confirmed. After the contract was signed, work was begun on compiling lists of potential members for the Consultant Panel and assembling biographic data on each candidate. Nominations were generated from project staff and consultants, the staff of the Commission, the chairpersons and ranking minority members of seven Congressional Committees and Subcommittees relevant to the study, and from con-

firmed panelists themselves.

Biographical data on each nominated potential panelist were collected from various published sources. A total of 30 different reference works were consulted in an attempt to provide sufficient biographical information to reviewers. The data were transcribed onto Panelist Nominee Forms which were distributed to a Panel Selection Task Force for evaluation.

The Panel Selection Task Force consisted of four persons drawn from the Study Design and Management Group (SDMG) and Study Coordinating Staff (SCS). Each reviewer made an independent assessment of the appropriateness of a nominee to be a panelist. The major criteria for selection to the Consultant Panel were qualifications and experience relevant to the study. Final selection of panelists was made from the pool of those nominees felt to be appropriately qualified by the reviewers. Qualified persons were selected to the panel so as to ensure that minorities, including women, were represented and that panelists were drawn from all regions of the country.

Letters of invitation to selected potential panelists were mailed at various times during the study. Each person approached received a letter inviting him/her to join the Consultant Panel, a copy of the technical proposal, some other materials pertinent to the study, and a Consultant Panelist Information Survey. The Consultant Panelist Information Survey form was developed to allow accepting panelists to provide the study team with certain administrative data, and to allow a panelist to place himself or herself in the most appropriate category.

Returned Consultant Panelist Information Survey forms were reviewed and the information was transferred to Panelist Control Cards. Analysis of returned survey forms produced the data necessary to balance the panel to the greatest extent possible. Persons selected in later waves of the selection process were no less qualified than those selected earlier.

The panel selection process resulted in the nomination and review of 680 people. Of this number, 281 were invited to serve as panelists at some point in the study, and 149 people consented to serve (Figure 1.1). Panelists who were unable to continue with the study at any time were replaced from the pool of qualified persons within their own category so as to maintain an appropriately balanced panel. At each mailing of a Policy Evaluation Instrument, the Consultant Panel consisted of at least 125 people. The final Consultant Panel represents the 121 people who completed one or more Policy Evaluation Instruments.

Appendix 4 lists the names and affiliations of members of the Consultant Panel.

SELECTION OF ISSUES

An Issues Clarification Meeting (ICM) was planned in September, 1975 and held in Baltimore on October 25 and 26, 1975. The purpose of this meeting was the development of: (1) a limited number of quintessential subject areas in which advances in biomedical and behavioral research and technology might be expected to take place; (2) the important societal concerns that these advances would challenge; and (3) some of the potential problems that might be produced through the impact of particular subjects on specific concerns. Two panelists from each of the five panelist categories (ethicists, lawyers, medical scientists, representatives of the public interest, and social scientists) were participants in the ICM.

Prior to the meeting, each participant completed a pre-meeting assignment that formed the starting point for the meeting itself. This assignment included recommending subject areas for inclusion in the study, and indicating relevant concerns related to each subject area. At the opening of the meeting, participants were divided into two groups of five persons (one from each panelist category).

Each group was provided with a copy of the subject areas and societal concerns identified by members of that group in the pre-meeting assignment. Participants added to the subject areas and social concerns listed. Separate votes on the importance of the subject areas and societal concerns identified were then taken. Subject areas were ranked according to socio-political importance, and the potential for revealing differences of opin-

ion among the five panelist categories. Additionally, the eight top-ranked subject areas were rated for their impact on the societal concerns considered most important.

Subsequently, the two groups met in plenary session to compare and discuss the items that had been identified. A final vote on the socio-political importance and potential for revealing differences of opinion among panelist categories was taken on a combined list of subject areas produced from the eight most important subject areas identified by each small group.

The output of the Issues Clarification Meeting was reviewed by the SDMG. The SDMG analyzed the ratings of the subject areas, and the relative importance of the societal concerns. In the final analysis, the subject areas that were selected represented the minimum number of subject areas that would reflect the maximum number of important societal concerns. Following several meetings with the staff of the Commission, the final list of subject areas was selected as foci of inquiry for the study. The five subject areas chosen were: *Systematic Control of Behavior, Reproductive Engineering; Genetic Screening; Extension of Life;* and *Data Banks, Computer Technology.*

THE FIRST POLICY EVALUATION INSTRUMENT

The first Policy Evaluation Instrument (PEI) was designed to identify foreseen implications of technological advances in biomedical and behavioral research and technology, and to suggest policies to respond to these implications.

Design of First PEI Evaluation Workbook

Two members of the SDMG independently developed design skeletons for the Evaluation Workbook section of the first PEI. One design skeleton emphasized the development of policies based on the implications of specified advances in biomedical and behavioral research and technology. The other emphasized the elaboration of general policies related to scenarios which were based on advances in biomedical and behavioral research. The SDMG decided to incorporate aspects of both design skeletons in the elaboration of the final design of the Evaluation Workbook.

In order to obtain three advances in each subject area, the author of a Background Paper and at least two other recognized experts in the particular subject area were asked to suggest and describe from three to five advances in the subject area that were expected to occur in the next 20 years, and to rank them in order of importance with regard to the impact that the advance would have on society. Descriptions of advances in a subject area were reviewed by the Principal Investigator and other members of the study staff, and common advances identified. The three most often mentioned advances in each subject area were selected for inclusion in the first PEI, yielding a total of 15 quintessential advances for the five subject areas.

Forty-eight scenarios were written by members of the SDMG

and reviewed by the SDMG and the consultants to the SDMG. The six scenarios receiving the most votes in a poll of the SDMG and consultants to the SDMG were included in the first PEI. A scenario pertinent to each subject area was included, and one scenario cut across all subject areas.

Pretest

Ten pretesters, two from each of the study's five categories of panelists, were asked to complete the first pretest version of the first PEI, and to complete the Pretesters Evaluation Workbook that accompanied the instrument. Pretesters were selected to be representative of panelists insofar as possible, except that all resided in the Baltimore-Washington area. Two students of the New Jersey Institute of Technology also acted as pretesters of the first PEI. Nine of the twelve pretesters completed the task. On the basis of these pretests and reviews, the subsequent discussions, and the votes of the SDMG and the Consultants to the SDMG with respect to what items were essential to the study, a second pretest version of the first PEI was prepared.

Two additional consultants pretested this version of the first PEI and completed the Pretesters Evaluation Workbook. The major concerns at this juncture were: (1) the time it would take for a panelist to complete the PEI and; (2) the comprehensibility of items. Subsequent to the second pretest of the first PEI, a meeting, attended by members of the SDMG, Consultants to the SDMG, and project staff, was held to discuss pretest results and further refine the first PEI. The final version

of the PEI was mailed to the Consultant Panel on February 6, 1976; it consisted of three sections: background papers, introductory materials, and an Evaluation Workbook.

Background Papers

A background paper was written for each of the five subject areas. They were written by members of the Consultant Panel who had expressed an interest in writing such a paper and who had demonstrated expertise in the particular subject area. Background paper writers were provided with a standard outline, so that the papers would include a comparable degree of information. Papers received from authors were reviewed by members of the SDMG, supplemented when appropriate by members of the SDMG or consultants to the SDMG who were experts in a particular subject area, and edited by project staff.

Introductory Material

The introductory materials consisted of three documents: Introduction, Definitions, and Completed Example. The Completed Example was prepared after the contents of the Evaluation Workbook had been finalized. Responses given in the Completed Example were based on those obtained in pretests of the instrument for an advance and scenario not included in the final version of the PEI. Certain terms were identified for which standard definitions were provided. The terms were defined from a variety of sources: dictionaries and other reference works, the SDMG, its consultants, and members of the Consultant Panel. The final version of the Introduction was written after the contents of the first PEI had been finalized. The purpose of this booklet was to acquaint panelists with the study process.

Evaluation Workbook

The Evaluation Workbook was arranged by subject area. For each subject area under consideration, panelists were asked to review the three selected advances and to choose from the advances listed (or from the one they were allowed to add) the one advance that was most important, that is, the one having the most significant implications for society. For this most important advance, panelists were asked to identify and rank up to three significant types of implications of the advance, and to elaborate on these implications. Finally, panelists were asked to choose among separate policies with respect to (1) research that gave rise to the advance, and (2) the implementation of the advance itself, and, if appropriate, to elaborate on these policies.

The six scenarios followed the five subject areas. In the scenarios, panelists were provided with two options, asked to decide which they favored, and then asked to elaborate on the basis for their decision. Finally, they were asked to select which groups and agencies should participate in the resolution of the issue, and to describe a policy that would be helpful in resolving issues of the type depicted in the scenario.

THE SECOND POLICY EVALUATION INSTRUMENT

The second Policy Evaluation Instrument was designed to examine the implications of policies that might be implemented with respect to selected technological advances in biomedical and behavioral research, and to evaluate policies pertinent to the subject of the study, taken as a whole.

Of the 15 advances and 6 scenarios included in the first PEI, five were brought forward to the second PEI to serve as models in this respect. They were: *Actions of psychopharmacological agents further understood; Select-a-boy, Select-a-girl makretable kits; Amniocentesis becomes routine; Environmental causes of disease and trauma further controlled;* and *Computerized medical records in use.* These five items were chosen because of the importance panelists attached to them; the wide range of opinions held by panelists regarding research and implementation of the advance; or to ensure that they encompassed the study's five subject areas.

Pretest

A draft version of the second PEI was pretested by six people, at least one from each of the study's five panelist categories. As with the first PEI, each pretester completed a draft version of the instrument and a Pretester's Evaluation Workbook. The comments made by pretesters were reviewed and discussed by members of the SDMG. On the basis of these reviews, the subsequent discussions and the votes of the SDMG and the Consultants to the SDMG with respect to what items were essential to the study, the final version of the second PEI was prepared. The second Policy Evaluation Instrument was mailed to panelists on May 12,

1976; it consisted of three sections: synthesis papers, introductory materials, and an Evaluation Workbook.

Synthesis Papers

Panelists were provided with a synthesis paper for each advance or scenario brought forward from the first PEI. Each synthesis paper consisted of three parts: a pro position statement advocating the promotion of research and implementation of the advance; a contra position statement advocating control or limitation of research and implementation of the advance; and general summaries of the policies and implications. Each position statement was written by a panelist who selected the particular policy for the advance in the first PEI.

Position statement writers were provided with and drew on the anonymous responses of all panelists who also selected the same overall policy to respond to the advance. The authors of position statements were allowed considerable latitude in presenting the best possible argument for the policy they advocated, and in developing the implications of the advance. The general summaries of policies and implications, the results of the first PEI, were developed by project staff. In addition, all position statements were reviewed and edited by project staff.

Introductory Materials

Introductory materials included with the second PEI consisted of an Introduction and a Completed Example. The Introduction contained a brief statistical summary of the results of the first PEI, a discussion of the development and intent of the second PEI, and instructions for completing the PEI. The Completed Example presented examples of both implications of policies

material and general policy statement material. The implications of policies examples were drawn from material contained in the first PEI which had not been carried over. The general policy statement examples were drawn from policy statements which had not been selected by the SDMG for inclusion in the second PEI. As in the first PEI, final drafts of these documents were prepared after the Evaluation Workbook had been finished.

Evaluation Workbook

In the second PEI, as in the first, there were two major parts in the Evaluation Workbook -- a section on implications of policies, and a section on general policy statements.

The implications of policies part of the workbook built upon the synthesis papers, and particularly on the position statements advocating either promotion of research and implementation or control of research and implementation.

In this part of the PEI, panelists were asked to identify which of the two opposite policies they would least like to see implemented. After selecting the policy least liked, panelists were asked to think about the implications of this (antithetical) policy not only in terms of benefits or harms intrinsic to the technology, but also the additional harms or benefits that might stem from implementing the policy itself.

Panelists were asked to identify and describe briefly the three most significant negative consequences (undesirable effects, disbenefits) that would occur if the policy they least liked were to be implemented. They were also asked to identify what group or groups, if any, would be particularly affected by these negative consequences. Finally, panelists were asked to describe

what specific policy could be adopted, or what other steps could be taken to ameliorate the most significant negative consequence of implementing the policy least liked, thereby making it more tolerable. Such policies could be aimed at preventing or minimizing the occurrence of the negative consequence or at compensating for it were it to occur.

The general policy statements part of the workbook contained 23 major policy statements and their associated sets of subsidiary statements. A list of general policy statements was compiled from the results of the first PEI; a review of the legislative intent in setting up the Commission, the mandate for the study; and from various documents produced by the Commission itself. The initial list of policy statements was submitted to the SDMG for review and the final list of items was selected on the basis of the recommendation of the SDMG.

In the general policy statements part of the Evaluation Workbook, panelists were asked to vote on a number of policies relevant to the study. Each policy was presented in the form of a statement and panelists were asked to decide whether or not they agreed with the statement and whether or not it was urgent to implement the policy. Other general policies that panelists considered should be implemented urgently could be added in space provided for that purpose. Panelists were then asked to choose the five most urgent policies, and to rank them in order of urgency. Finally, they were asked to elaborate on the three policies selected as most urgent to implement.

THE THIRD POLICY EVALUATION INSTRUMENT

The purpose of the third and final PEI was to examine the consequences of a possible national policy that might be adopted with respect to biomedical and behavioral research and the implementation of the technologies that result from such research. The material brought forward from the second PEI consisted of the results of the responses to the general policy statements and the panelists' own descriptions of the most urgent policies.

Pretest

Five persons completed copies of a draft version of the third PEI and a Pretester's Evaluation Workbook which accompanied the instrument. As in earlier iterations of the study, reviewers' comments were reviewed and discussed by members of the SDMG. The final version of the third PEI was based on these discussions and on the votes of the SDMG and the Consultants to the SDMG with respect to what items were essential to the study. This version of the third PEI was mailed to the panel on August 14, 1976; it consisted of three sections: a synthesis paper, introductory materials, and an Evaluation Workbook.

Synthesis Paper

The synthesis paper contained an overview of responses to the general policy statements from the second PEI, and a general summary of panelists' responses to each separate policy statement, prepared by project staff. The overview identified, interpreted, and summarized the salient dimensions underlying panelists' responses to the general policy statements. Each general summary of a policy statement followed a common outline, reporting as faithfully as possible panelists' elaborations of

the policy.

In order to insure that the general summaries prepared by the project staff accurately reported what panelists had said, the general summaries and verbatim transcripts of panelists' responses were sent to two members of the Consultant Panel for review. The two panelists, each reviewing one-half of the general summaries, were asked to examine each general summary in conjunction with the verbatim transcripts to identify and correct any significant biases or deficiencies in the summary. Reviewers' comments were taken into account in preparing the final synthesis paper.

Reviewers were also asked to identify, interpret, and summarize the salient dimensions underlying panelists' responses for those general policy statements reviewed, and to provide an overview as a summary of their findings. The separate overviews were combined and edited by the project staff. This composite review was sent to each reviewer for comment to insure that it met the intent of the original review.

Finally, these two panelists were asked to review four policy scenarios which were developed by the SDMG on the basis of the results of the general policy statements part of the second PEI to serve as the principal focus of the third PEI. The purpose of this review was to ensure that the policy scenarios reflected the content of panelists' elaborations to the general policy statements.

Introductory Materials

The introductory materials for the third PEI included an Introduction and a Completed Example. The Introduction contained a summary of the statistical results from the second PEI, some background on the intent of the instrument, and instructions for completing the instrument. The Completed Example used material on health care delivery as the basis for policy questions and resource allocation decisions. Examples of general opinion questions were drawn from questions deleted from earlier versions of the national opinion survey.

Evaluation Workbook

The focus of the third PEI was on general policies with respect to research and implementation rather than on specific research projects or the implementation of specific technologies. It was not judged possible to identify all the advances that might result from biomedical and behavioral research and technology; consequently, aggregate panel and advisor comments clearly indicated that the most meaningful purpose would be to identify and discuss mechanisms to continually evaluate, regulate, control, and direct research and implementation. In this way it would be feasible to examine the likely impact of the policies on society, and on the research and implementation process itself.

The third and final PEI drew together the policies previously described by panelists to deal with biomedical and behavioral research advances, the resultant technologies, and the implications of implementing the policies themselves.

In the third PEI panelists were asked:

* to examine four policy scenarios that collectively described a possible national policy with respect to biomedical and behavioral research and technology, each scenario dealing with one aspect of the national policy. The four policy scenarios were:

  -- *Permanent National Commission;*

  -- *Public involvement in policy decision-making;*

  -- *Biomedical and behavioral research;* and

  -- *Implementation of biomedical and behavioral technologies.*

* to review past trends in expenditures for health related research, and to establish priorities.

* to respond to a number of general opinion questions.

* to describe what they thought might occur if the national policy described in the four scenarios <u>was</u> implemented, and what might occur if the policy <u>was not</u> implemented.

For each policy scenario panelists were asked to consider the implications of the national policy the scenario described. First they were asked to identify and describe up to two positive consequences (desirable effects, benefits) and up to two negative consequences (undesirable effects, disbenefits) anticipated if the policy described in the scenario were implemented. Next, panelists were asked to identify and describe up to two barriers to implementing the policy described in the scenario, and the ways in which these barriers might be overcome. Finally, panelists were asked to indicate the degree to which they supported or opposed the particular policies that comprised the national policy described in the scenario, and to offer any specific amendments.

In the resource allocation part of the Evaluation Workbook panelists were provided with a brief overview of national re-

sources devoted to health and health research. They were asked to indicate their preferred allocations for health and health research vis-a-vis other activities, and the relative priorities that should be afforded to the different types of health research activities described.

In the general opinion questions part of the Evaluation Workbook, panelists were asked to respond to the same series of questions that were asked of the general public in the national opinion survey adjunct to the policy study.

Finally, panelists were asked to write two brief newspaper stories that might be filed by a science reporter in 1999: (1) if existing policies with respect to biomedical and behavioral research and technology continued to operate unchanged until that time; and (2) if the policies described in the third PEI's four policy scenarios were implemented in the late 1970s.

ANALYSIS AND SUMMARIZATION OF PEI DATA

At each mailing of a Policy Evaluation Instrument, the Consultant Panel consisted of at least 125 people. The response rates for the three PEIs were 76%, 86%, and 88%, respectively (Figure 1.2). A total of 121 panelists completed at least one Policy Evaluation Instrument and 87 panelists (72% of those completing PEIs) completed all three instruments; 20% completed two PEIs. Each PEI took approximately six to eight hours to complete. The intake period for each PEI was 40 days from the date following mailing.

Each step of the analysis process was carried out systematically and every effort made to insure panelists' views were reported accurately. Each Policy Evaluation Instrument contained both structured and open-ended questions; the analytic techniques applied to each PEI were the same. Structured questions were analyzed statistically, and responses among self-assigned categories of panelists were compared.

For open-ended questions, all verbatim responses were transcribed and then stored, sorted, and retrieved by computer. A summary of responses to each PEI item was prepared by project staff from the resultant printouts. Each summary represented, as completely as possible, the ideas expressed by panelists who responded to an item. Where appropriate, overviews of the responses were also prepared.

Each of the staff summaries were then submitted for critical review to a consultant panelist. The objectives of this review were to: (1) evaluate the summaries for accuracy in

reporting panelists' responses (and to correct any biases or deficiencies identified), and (2) identify, interpret, and summarize the salient dimensions in panelists' responses. In order to accomplish these objectives, panelist reviewers were provided with printouts of the verbatim responses, as well as with the staff summaries and overviews, and a set of instructions.

Another panelist was asked to review independently staff summaries pertaining to an entire part of a PEI. The objective of this review was to identify, interpret, and summarize the salient dimensions common to all the items summarized, those that cut across several, and those unique to a particular item. The findings of these independent reviews were then compared and synthesized; they formed the basis for drafting the study report.

INTRODUCTION TO THE NATIONAL OPINION SURVEY

In order to address that item of the study mandate which called for "an analysis and evaluation of public understanding" of the implications of advances in biomedical and behavioral research, the SDMG recommended that a national survey of public opinion be conducted as part of the special study. The Commission approved of this adjunct to the special study in April; the necessary amendment to the contract was subsequently signed, and work begun in May 1976.

The national opinion survey was closely integrated with the policy study. The items for the survey questionnaire were drawn from, or based on, those contained in the first two PEIs. In order to provide a basis for evaluating public understanding and attitude a parallel version of the national opinion survey questionnaire was included in the third PEI as a set of general opinion questions.

The administration of the survey questionnaire and subsequent data tabulations was subcontracted to Louis Harris and Associates Inc., the result of a competitive procurement. Responsibility for development of the survey instrument, specification of the analytic framework, and evaluation of the results remained with the SDMG.

In addition to the survey, a comprehensive review of the literature on public attitudes toward research and technology, particularly biomedical and behavioral research and technology, was also undertaken to broaden the perspective of the inquiry.

DESIGN OF THE SURVEY QUESTIONNAIRE

The national opinion survey was designed to elicit public sentiment towards advances in biomedical and behavioral research and technology, and opinions about appropriate policies to deal with them. The questionnaire itself was designed to be administered by an interviewer in a face-to-face interview of less than one hour.

Questionnaire Development and Pretest

Starting in late May, an intital draft of the questionnaire was developed by the SDMG based upon material from the first and second PEIs. The initial draft was completed on June 11, 1976, and forwarded to the SDMG, Consultants to the SDMG, and Project Monitor for review. Additional copies of this draft were provided to the Project Monitor for review by the Commission and for initiating Office of Management and Budget clearance procedures. The initial draft was revised on the basis of reviewer comments, reviewed again, and revised again for the first pretest version.

The pretests were conducted by Hollander, Cohen Associates, Inc., an opinion research organization located in Baltimore. The first pretest consisted of ten interviews; persons were selected to provide responses from men and women of a variety of ages, but not a wide geographic dispersion. Two interviewers, one of them black, conducted this pretest. The pretest version was also reviewed by the SDMG, selected Consultants to the SDMG, Louis Harris and Associates, and the Project Monitor and other Commission staff. Review and evaluation of the first pretest draft, and the results of the pretest itself led to the develop-

ment of the second pretest version.

The second pretest consisted of three series of ten interviews. These interviews were obtained from men and women of different ages, and sufficiently dispersed through the Baltimore metropolitan area to provide some representation by race and socio-economic status. Three interviewers, one of them black, were used for this series of pretests. The second pretest version was reviewed by the same individuals who reviewed the first, and, as in the case of the first pretest, a debriefing meeting was held with the interviewers following the pretest.

A draft of the proposed final instrument was prepared following the second pretest, reviewed by the groups noted above, and forwarded to the Commission for its review. The final instrument resulted from this review. The instrument was finalized on August 9, 1976; Office of Management and Budget clearance was received on September 10, 1976. Following reproduction of the instrument, administration began in late September 1976, and was completed in early November 1976.

ADMINISTRATION OF THE QUESTIONNAIRE AND TABULATION OF RESULTS

Sample Selection

The national opinion survey questionnaire was administered to a stratified national sample of the noninstitutionalized civilian population of the 48 continental United States. The sample was based on the latest census information available for the population of each state in the country, as well as on the population living in standard metropolitan areas and in the rest of the country. These figures were updated by intercensal estimates produced annually by the Bureau of the Census, and sample locations revised biennially to reflect changes in the country's demographic profile.

A random sample of the population was drawn using multistage cluster sampling, a method which assures every household a statistically equal chance of being drawn into a given survey. The national sample was first stratified in two dimensions: by geographic region (east, midwest, south, and west), and by size of place within each region (city, suburb, town, and rural area). This stratification insured that the ultimate selection of interviews reflected within one percentage point the actual proportions of U.S. residents living in different regions and community types.

Within each stratum the selection of the ultimate sampling unit (a cluster of adjacent households) was achieved by a series of steps. The cities, suburbs, towns, and rural areas were listed according to population size from biggest to smallest within a region and then a precise location was selected by a random pattern which guarantees a probability proportional to

census estimates of the given location's respective household populations. The next step was to construct a detailed map of the selected locations, which contain approximately 30 households each. This process was carried out in the New York offices of Louis Harris and Associates.

Using the randomly selected starting point, and the routing pattern provided, interviewers contacted 19 households in each cluster. At each household the interviewer listed by age and sex, all adults who lived in that household. Then, using a predetermined procedure to ensure that the proper number of respondents of each sex and age were sampled, the interviewer selected which member of that household was to be interviewed. If the person was not at home or not available, the interviewer made an appointment to conduct the interview. If no one was at home at the initial call, the interviewer made three callbacks, on different days and at different times of the day. If, after the initial contact and three call-backs, no one was at home, the potential respondent was dropped and not replaced.

When a sampled person refused to be interviewed, the interviewer contacted the next household in the pattern and substitued the appropriate adult at that household for the sampled person who refused to be interviewed.

Following the procedures outlined above 2,503 households were contacted and 1,679 interviews were conducted, achieving a completion rate of 67%. In 19% of the households contacted, the respondent refused to be interviewed; in 14% of the sampled

households no interview was completed because no one was home on the intital contact or on the three subsequent callbacks. The response rate falls within the usual range of response rates for this type of survey.

Informed Consent, Confidentiality of Responses

Prior to commencing the interview potential respondents were read a statement of purpose that described: the purpose of the study; the content of the questionnaire; the processing, analysis and presentation of responses to insure that the confidentiality of responses would be maintained; a respondent's right to refuse to answer any question; and the anticipated average length of an interview.

Respondents who consented to be interviewed were given a copy of this statement to keep, and a postage paid card to mail to Policy Research Incorporated, if they wanted to receive the results of the survey. Twenty-four percent of the respondents requested the results of the survey.

No individual respondent will ever be identified. Face (control) sheets were removed and destroyed as soon as processing was completed. No identifying information appears on the data tape. All responses are reported in aggregate form to protect the anonymity of respondents.

Validation

Before the completed questionnaires were processed, they were turned over to an independent validating service within Louis Harris and Associates. This service rechecked approximately 20% of each interviewer's respondents to guarantee that the work was properly conducted and completed according to all specified procedures.

Data Processing

Once validation was completed and editing checks were made, open-ended (unstructured) questions were coded to permit computer processing. Coding schemes were developed by two members of the SDMG who read approximately one fifth of the questionnaires and all of the completed PEI general opinion questions prior to finalizing the coding schemes. The coding schemes permitted respondents' actual statements to be recorded as completely as possible. Following a review of the frequencies of each code, responses were also aggregated into sets and supersets, as appropriate, for purposes of analysis.

The coded questionnaire was key punched, 100% key verified, and put onto magnetic tape. The data were computer edited to eliminate such errors as multiple-punches to closed-ended questions and inaccuracies in skip instructions.

Analysis

An analytic framework for the questionnaire was developed by members of the SDMG and reviewed by the entire SDMG, consultants to the SDMG, Commission staff, and staff of Louis Harris and Associates. In designing the analytic framework emphasis was given to answering those questions directly related to the study mandate as quickly as possible. For this reason the analysis was limited to cross-tabulations. The final analysis specifications were given to Louis Harris and Associates who were responsible for producing frequency distribution, cross-tabulations and other specified analysis.

The coding schemes and analytic framework used for the questionnaire were also applied to the PEI general opinion questions to ensure comparability of results. The data produced by these analysis were used in writing the final report.

REVIEW OF THE LITERATURE

Because the number of questions that could be included in the opinion survey questionnaire was limited, a review of the literature was carried out in order to broaden the perspective of the inquiry. A comprehensive review of the literature on public attitudes toward research and technology, particularly biomedical and behavioral research and technology, was undertaken. In addition, knowledgeable individuals were contacted in an effort to make the review of the literature as exhaustive as possible, and to identify any unpublished data.

Three computerized bibliographic searches of the literature were conducted. In addition, a number of institutions and individuals were identified as potential information sources. Letters soliciting information were mailed to 244 individuals and organizations in the United States and overseas. Responses were received from approximately one-third.

No surveys of public opinion regarding the subject of this study were found. However, three surveys of the general public on related topics were identified, as were a number of surveys of specific populations (e.g. physicians) on specific issues (e.g. abortion). A few articles <u>about</u> public participation in policy decision-making related to scientific or technological matters (including the biomedical and behavioral areas) were also revealed by the literature search. In general, the majority of articles identified dealt with "ethical issues" in biomedical and behavioral research and technology or their effects on society, individual freedom of choice, and other concerns --

even though the search was focused on public understanding of and attitude toward the subject. Such articles were written from an individual or small group perspective.

In summary, there was a dearth of primary data pertinent to the subject of inquiry, and a large amount of opinion and speculation, much of it philosophical in nature.

PREPARATION OF THE FINAL REPORT

Findings from the three PEIs that comprised the policy study and the national opinion survey were combined in the final report of the study.

The first draft of the final report was reviewed by members of the SDMG, consultants to the SDMG, and Commission staff. Based on the findings presented in the report, each reviewer identified what he/she considered to be the principal study conclusions. In addition, in order to ensure that study findings were reported accurately, the Principal Investigator and another member of the SDMG independently compared reported findings to those identified by panelist reviewers and contained in the national opinion survey tabulations. Based on their findings and reviewers' comments a second draft of the report was prepared. The second draft of the final report contained the conclusions identified by reviewers after reading the findings reported in the first draft.

The second draft of the report was subsequently submitted for review to the same groups who reviewed the first draft. In addition, the Principal Investigator and another member of the SDMG independently compared the conclusions to the findings to ensure their supportability. Based on their findings and reviewers' comments a final draft of the report was prepared. The final draft report was subsequently edited for publication.

Figure 1.1

SELECTION OF THE CONSULTANT PANEL: PERSONS NOMINATED, INVITED, ACCEPTING, AND COMPLETING PEIs; BY CATEGORY OF PANELIST

Selection Step	Ethicists	Lawyers	Medical Scientists	Reps. of Publ. Int. (2)	Social Scientists	Total Panel
Nominated to Consultant Panel	83	96	204	131	166	680
Invited to join Consultant Panel	35	68	61	61	56	281
Accepting invitation	28	34	29	26	32	149
Completing at least one PEI	25	23	26	22	25	121

(1) Self-assigned categorizations for accepting panelists; a priori categorization for all others.

(2) Includes relevant organizations.

Figure 1.2

PANELISTS COMPLETING PEIs, BY CATEGORY

	Ethicists	Lawyers	Medical Scientists	Reps. of Publ. Int.	Social Scientists	Total Panel
First Policy Evaluation Instrument						
Number of panelists at time of PEI mailing	26	23	26	26	28	129
Number completing PEI	22	14	21	21	20	98
Percent completing PEI	85%	61%	81%	81%	71%	76%
Second Policy Evaluation Instrument						
Number of panelists at time of PEI mailing	25	25	27	25	26	128
Number completing PEI	25	19	25	20	21	110
Percent completing PEI	100%	76%	93%	80%	81%	86%
Third Policy Evaluation Instrument						
Number of panelists at time of PEI mailing	25	25	26	23	26	125
Number completing PEI	25	20	24	21	20	110
Percent completing PEI	100%	80%	92%	91%	77%	88%

(1) Self-assigned categorization

Appendix 2:
Members of the Study Design and Management Group, Consultants to the SDMG, Study Coordinating Staff, and Study Administrative Staff.

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Appendix 5:
Descriptions of the Fifteen Advances and Six Scenarios included in the First Policy Evaluation Instrument.

ADVANCES IN SYSTEMATIC CONTROL OF BEHAVIOR

Advance No. 1: *Actions of Psychopharmacological Agents Further Understood*

Laboratory and clinical psychopharmacological research will generate new knowledge about how psychopharmacologic drugs affect mental activity and produce behavioral changes. More detailed and complete understanding of the mode of action of such drugs on neuromuscular and neurophysiological functions will facilitate the development of new drugs that produce desired mind-altering or behavioral effects specifically and predictably. For example, the mode of action of opiates may be understood sufficiently to allow a drug to be developed that has powerful analgesic properties but with its consciousness-altering and addictive properties eliminated or reduced.

Advance No. 2: *Do-it-yourself Anxiety and Tension Reduction*

A preprogrammed, automated technique for teaching deep muscle relaxation as a means of anxiety and tension reduction will be developed as a result of parametric research. The result of such research will be the specification of the type of materials to be presented, their order or presentation, and the number required to reduce anxiety and tension in a given population.

The automated package will consist of a tape recorder and seven tapes, containing step-by-step instructions to the listener. In three one-half hour segments the listener would be taught, in a doctor's office, classroom, or in the privacy of his/her home, how to achieve a state of deep relaxation and emotional calm by systematically tensing and relaxing major body muscle groups and areas, i.e., arms and hands, feet and legs, facial muscles, breathing. Following these first three sessions -- heard on three consecutive days -- the listener would then follow the directions on the four remaining tapes -- each of which would be listened to on succeeding days also. The last four tapes would enable the listener to achieve a state of deep relaxation in an increasingly shorter time. Separate packages might be developed for different population groups; e.g., adults, children.

While the technique might be prescribed by health professionals, it would be self-administered and cost about $100 to purchase. It could be applied on a wide scale not only by persons under constant stress (physicians, lawyers, executives, etc.) but could also be applied as part of a mental hygiene program in schools to teach children healthy means of dealing with tension.

Advance No. 3: More Predictable Psychosurgical Procedures

Advancing knowledge from animal and clinical studies about brain structure and functions, and the definition of psychosurgery as an experimental treatment, subject to rigorous design and evaluation requirements, will lead to the development of more predictable and precise psychosurgical procedures capable of effecting specific behavioral changes.

The use of more precise psychosurgical procedures for defined types of behavioral alterations will probably take place on a small scale, in relatively few clinical centers. This behavior change technology will be administered by neurosurgeons, with psychiatrists, neurologists, and related specialists involved in evaluative studies. As an investigative procedure, the uncertainty factor, including physical risk, will be high.

ADVANCES IN REPRODUCTIVE ENGINEERING

Advance No. 1: *In-vitro Fertilization Available in Clinical Practice*

Infertility due to various common disorders causing bilateral Fallopian tube occlusion will remain a problem, one that will be treated by in-vitro fertilization.

In-vitro fertilization consists of fertilizing an egg with a sperm outside the human body, with the resultant embryo (fertilized egg) implanted in a recipient uterus where it grows and develops normally.

Eggs are obtained using a simple surgical procedure, and placed in culture; sperm are then added. A few days later, using a syringe introduced through the vagina, the resultant embryo is implanted into the recipient uterus. Proper hormonal balance in the lining of the uterus is required for implantation.

The several steps involved in in-vitro fertilization will take place in hospitals and will be carried out by physicians supported by specially trained technicians. The cost of in-vitro fertilization will be relatively high, about $1,000.

Advance No. 2: *Sex Selection by Sperm Separation*

The X-sperm (female producing) and Y-sperm (male producing) present in semen can be separated in the laboratory using a filtration process.

Semen is allowed to pass through a special filter. The smaller and more round-headed Y-sperm pass more readily through the filter than do the larger more elongate-headed X-sperm. The spearated sperm are collected and the appropriate fraction (X-sperm or Y-sperm) used for artificial insemination. Filtration does not completely separate sperm, rather it greatly increases the concentration of one type of sperm to 93%. Moreover, recovery of Y-sperm is easier than X-sperm, and therefore conception results more often after artificial insemination of enriched Y-sperm semen than of enriched X-sperm semen.

Sex selection by sperm filtration is carried out by trained technicians under the guidance of a physician and requires attendance at a hospital or clinic. The specific procedure costs about $350.

Advance No. 3: *Safe, Simple Medical Sterilization Available*

A safe and effective medication for sterilizing women will be developed. The medication permanently prevents reproduction

after one injection, would be administered by para-medical personnel with limited training, and will cost about $10.00 per shot. Physical risk from the medication is less than that from routine abortion. Moreover, women receiving the medication show no changes in appearance and sexuality is unimpaired.

ADVANCES IN GENETIC SCREENING

Advance No. 1: *Amniocentesis Becomes Routine*

Amniocentesis, which allows the physician to detect chromosome anomolies in an unborn child, will become a routine part of prenatal evaluation, particularly in women over 35 for whom the risk of bearing an affected child increases markedly.

Amniocentesis involves withdrawing a small quantity of the fluid that surrounds the fetus by introducing a hollow needle into the uterus through the pregnant woman's abdomen. Fetal cells contained in the fluid are cultured in a central laboratory and a chromosomal assessment made.

A fetus with a chromosome anomaly, as would be the case in Down's Syndrome (Mongolism), for example, could be selectively aborted, thus preventing the condition. The technique can also be used to determine the sex of an unborn child.

Testing, which is technically simple, will be done by physicians or trained technicians. The risk of physical harm to the mother is minimized, and to the fetus is virtually nonexistent. Reliability is high; there are few false diagnoses.

Amniocentesis will be relatively inexpensive, costing between $50 and $100 per test.

Advance No. 2: *Widespread Screening for Inborn Errors of Metabolism*

The development of automated methods of biochemical analysis will make it possible to identify the carriers of genes that determine autosomal recessive traits. There will be simultaneous testing for many, 50 or more, metabolic errors that are commonly carried (1 in 61 persons) but that rarely manifest themselves (1 in 15,000 persons) because a child born to two persons with the trait has only a 1 in 4 chance of being affected.

These analyses, which will be performed on blood serum and red cells, urine, and other body fluids, will allow the entire population to be screened and allow carriers to be given genetic counseling.

Testing will cost $5.00 to $15.00 per person, depending on the number of tests performed, and carries minimal physical risks. It will be applied or supervised by physicians.

Advance No. 3: *Research Shows Lung Cancer, Heart Disease have Genetic Basis*

The genetic basis will be discovered for variations in the

susceptibility of individuals to common conditions, such as lung cancer and heart disease. Such discoveries will go a long way to explaining why not all cigarette smokers, for example, succumb to lung cancer. Simple biochemical tests such as those for certain configurations of tissue antigens, will allow the assessment of an individual's susceptability to certain diseases in which behavioral or environmental factors play an important etiological part -- lung cancer in cigarette smokers, for example.

Tests to assess an individual's susceptibility to such conditions will cost about $25.00 each and be performed by a technician in a doctor's office or clinic. Testing will involve no physical risk.

ADVANCES IN EXTENSION OF LIFE

Advance No. 1: *Compact, Wearable, Artificial Kidney Developed*

On-going research will result in the development of an artificial kidney small enough to be worn in back-pack style. Moreover, problems of using dialysis machines, such as the maintenance of the site at which the tubes that circulate the patients' blood through the machine enter the body, will be solved, making an artificial kidney a practical replacement device.

The development of an artificial kidney will greatly improve the treatment of chronic renal failure and provide a viable alternative to kidney transplantation. However, initial investment costs will be relatively high. Although treatment with an artificial kidney will remain relatively expensive, it will probably cost less than present techniques like chronic renal dialysis which currently costs between $20,000 and $40,000 per patient per year.

Advance No. 2: *Environmental Causes of Disease and Trauma Further Controlled*

Epidemiological and clinical research will increase our understanding of the causative factors associated with specific diseases and with life threatening accidents and trauma. Removal of certain substances from the environment, such as chemicals known to cause cancer, can reasonably be expected to extend life. Knowledge about the causes of accidents may allow us to redesign products so that they become less of a life-threatening hazard.

In certain instances we may find adding substances to the environment beneficial. The addition of fluoride to water and iodine to salt, are aimed at reducing or preventing certain diseases (dental cavities and goiter, respectively). Future possibilities include, for example, antioxidants which could be added to food to retard the aging process, and the addition of vitamins to alcoholic beverages to reduce the incidence of alcoholic neuropathies.

The cost of altering or adding specific factors to the environment or removing them from it will vary greatly. The cost of removing a substance widespread in the environment would obviously be high, while the cost of redesigning products would depend on the particular circumstance. Inconvenience and restricted use might also occur. The cost of adding substances to the environment would again vary with the degree of use. Additional costs would be incurred if the substance was universally incorporated into a food, for example, even though only a small proportion of the population would benefit as a result.

Advance No. 3: Gene Therapy Now Available

There are a number of genetic diseases, labeled collectively "inborn errors of metabolism," which result from the absence or severe reduction in the patient of a particular enzyme. Disease is caused in these cases either through the accumulation of the substance which the enzyme is supposed to destroy or convert, or by reducing the availability of the product of the enzyme's reaction.

The deficiency of particular enzymes will be overcome through gene therapy. Microbiologists working with viruses that bear the deficient enzyme will literally replace the missing genetic information in a human cell simply by giving the patient a viral infection. The virus will then transmit to the human the genetic information necessary to make the enzyme. The long term effects of adding genetic material to the patient's cells may only be learned as a result of life-long follow-up, and possibly only after life-long follow-up of his or her descendents. Possible consequences include the development of cancer in later life and the alteration of germ cells which could affect subsequent generations in unknown ways.

The cost of gene therapy, once developed, would be less than current methods of patient management, such as endocrine replacement therapy. Such treatments would be delivered by specialized physicians and scientists working in major hospitals.

ADVANCES IN DATA BANKS, COMPUTER TECHNOLOGY

Advance No. 1: *Computerized Medical Records in Use*

The advent of large data storage devices, inexpensive data retrieval devices, and sophisticated programming will result in the computerization of the medical record. Application of this technology within the next 20 years will mean that at the end of this period approximately 80% of the U.S. population will have medical records that are computerized.

Although separate computerized medical records will still be maintained on individuals by each service provider (hospital or physician, for example) this data could be accessed remotely if required. Moreover, records on related individuals could be linked together so that the provision of family care, for example, could be facilitated.

Additionally, each person could be given a copy of his or her medical record on a small computer tape cassette that could be transferred from institution to institution.

The use of such computer technology will increase the completeness of each individual's medical record. Adoption of a standard record format would facilitate the process of building a complete medical record.

Apart from any improvement in medical practice brought about by more complete medical records, such records can be used for medical care quality assurance programs and also for research purposes. Data from the records of patients treated by the same physician could be aggregated and used to assess his or her performance. The analysis of very large bodies of data are often required for disentangling the genetic, environmental and other factors influencing the etiology of disease processes and conditions. Also to be considered is the variation in the response of individuals to different treatments. A person's life-long computerized medical records would doubtless be a rich source of data for such research.

The cost of maintaining an electronic, computerized, patient record will be less than maintaining the traditional paper file.

Advance No. 2: *Computer simulates metabolic processes; aids patients*

Increased understanding of the physiological and pathological processes of organ systems will be embodied in computer models that will be able to simulate them. The successful simulation of such processes will enable computer controlled management of organs or organ replacements. Computer controlled patient management will first be applied in intensive care. Miniaturization and improved electronics will allow certain organs or organ replacements (kidney, limbs, etc.) to be managed by

computer in the ambulatory patient, virtually maintenance free. Physicians and other specially trained technicians will be required for fitting and monitoring such devices, and for computer controlled patient management. The cost of such devices, or of simply managing an organ by computer, will remain relatively high as they will not be mass produced.

Advance No. 3: Computer screens patients, provides check-ups

Regular health check-up will be provided by paramedical personnel using computers. Individuals going to a local doctor's office, clinic, or screening center will interact with a computer via a video-terminal. The computer will take a medical history or ask pertinent questions. Based on an analysis of patients' responses to these questions and on data about body functions provided by special sensors and tests, the computer will warn of impending illness or state changes, offer preliminary diagnoses, or suggest certain treatments or actions. Such computer-aided screening, diagnosis, and testing will cost about $20.00 per application, and could provide the physician with a valuable adjunct for diagnosing, treating, and managing the health of his/her patients.

SCENARIOS

Scenario No. 1: Select-A-Boy, Select-A-Girl Marketable Kits

The XYZ company has developed a safe and effective method for preselecting the sex of one's children. The method consists of a vaginal douche and foam used prior to intercourse. The separate preparations, douche and foam, have been extensively tested and are without significant side-effects. The use of the method does reduce fertility -- on the average, couples would have to try three times as long to conceive as they would without the use of the preparations. If the woman does conceive, however, 97 of every 100 pregnancies will produce a child of the desired sex. The incidence of congenital malformations in babies born to mothers using the method is no higher than those born normally. The XYZ drug company has decided to market the foam and douche under the brand names Select-a-Boy" and "Select-a-Girl". These moderately priced kits will be marketed through drugstores, and will contain: a detailed book of instructions about using the preparations and timing sexual intercourse to maximally ensure conception; reasons for infertility; an educational packet on family planning, added after intense lobbying by a group dedicated to zero population growth. Should XYZ company be allowed to market the kit?

Option 1: The XYZ Company should be allowed to market the kit.

Option 2: The XYZ Company should not be allowed to market the kit.

Scenario No. 2: Hospital Responsibility for Physician Performance Data

Dr. de Best, a respected surgeon nearing retirement age and Chairman of the University Hospital's Department of Surgery, performs an established surgical procedure on John Doe. Mr. Doe's operation is uneventful and he is discharged from the hospital. Some short time later he develops great abdominal pain and is rushed to the hospital where he dies. An autopsy shows Mr. Doe died as a result of an unquestionably poor surgical technique by Dr. de Best. Mrs. Doe blames the hospital for his death and seeks help from a public interest law firm. Ms. Good, the lawyer to whom she is referred, learns that the research unit of the University Hospital conducts periodic studies of physicians' performance. Ms. Good secures a copy of the most recent report (which was conducted sometime prior to Mr. Doe's operation). The data shows that over a two year period, ten patients on whom Dr. de Best performed the same surgical procedure probably died as a result of negligence on his part. On further investigation, Ms. Good finds that these results were known to the hospital administration and board. Dr. de Best has died since the surgery was performed,

so legal suits are brought on Mrs. Doe's behalf by Ms. Good against the hospital for not informing Dr. de Best's prospective patients of Dr. de Best's record.

Should hospitals be held responsible for informing prospective patients about data on physician performance?

Option 1: Hospitals should be responsible for informing prospective patients about data on physician performance.

Option 2: Hospitals should not be responsible for informing prospective patients about data on physician performance.

Scenario No. 3: *Drug Treatment for Prisoners*

A highly successful drug is available that provides the reduction of aggressive and assertive behavior on the part of individuals taking it. No significant side effects have been established after clinical trials of 3-5 years duration. Users of the drug become conditioned to a nonassertive behavior pattern and can terminate use after a year of treatment but retain the behavior brought about by the drug. The drug is given in doses which allow for sufficient aggression to be maintained for coping with stressful societal conditions.

A state prison system wishes to offer this treatment on a voluntary basis to prisoners who crimes involved aggressive behavior, as judged by a medical review board on an individual case basis. The treatment costs approximately $1.00 per patient day. Prisoners accepting the treatment could be granted a parole if they are successfully treated by the drug while the sentences of those choosing not to participate will be unaffected. Should such a program be allowed?

Option 1: The treatment of prisoners with the drug should be allowed.

Option 2: The treatment of prisoners with the drug should not be allowed.

Scenario No. 4: *Allocation of Health Services Funds*

A mid-sized city has received funds to expand its health services, with the proviso that the funds be used for capital improvements or equipment only. Two groups are in competition for the use of these funds. The first is the local teaching and

university hospital which is lobbying for a sophisticated, computerized, diagnostic machine. Previous research and application have demonstrated that this equipment can serve to improve the acute diagnosis of intracranial lesions, reduce side effects of current procedures, and possibly reduce mortality by early diagnosis. It would also provide urgently required data for research into certain illnesses (brain damage, cancer, etc.). The equipment would be the only set-up of its kind in the region and would be used in the diagnosis of approximately 10,000 persons per year. Without this equipment approximately 1,000 persons would die each year because their conditions would not be diagnosed in time for life-saving surgery to be performed. The number of persons benefiting from the research data provided is difficult to determine, although a study to estimate this is planned.

On the other hand, there is a second group which insists that the funds be used to construct a neighborhood health clinic in the densely populated and lower-income section of the city that currently has no such facility. This clinic would provide acute care services for approximately 30,000 persons each year. This additional care would result in reducing the infant mortality rate and aid in early detection of treatable diseases.

The construction costs for both projects are equivalent. Should the funds be awarded to the university hospital, or the neighborhood health clinic?

Option 1: The University Hospital receives the funds.

Option 2: The Neighborhood Health Clinic receives the funds.

Scenario No. 5: Marketing of a Group Insurance Plan with Genetic Screening

An insurance company has developed a new family plan that offers exceptionally wide coverage at a substantially reduced rate. The plan, however, is only able to provide such coverage because enrollees must meet certain criteria, one of which is to undergo genetic screening. It also requires that any fetus of enrollees undergo genetic screening and prenatal diagnostic checks. Additionally, if the screening or tests indicate that the fetus is afflicted with any disorder likely to require extensive, life-long care, it is to be aborted. Non-compliance will mean ineligibility for further prenatal or postnatal care for either mother or child.

The company applies to an insurance commissioner for permission to offer this plan in his state. The insurance commissioner denies the application, contending that it discriminates against those with genetic defects and those who object to

genetic screening. He also asserts that individuals cannot be obligated to undergo genetic screening as might be the case if employers select the option as a group plan. A public interest group protests this decision on the grounds that it interferes with fair marketing practices, and that otherwise qualified individuals who choose to undergo the genetic screening in order to be eligible for reduced rates should be allowed to do so. Should the company be allowed to market the plan?

Option 1: The Insurance Commissioner should approve marketing of the plan.

Option 2: The Insurance Commissioner should not approve marketing of the plan.

Scenario No. 6: *Life or Death Decision*

Mr. Smith, a 26 year old social worker, has been in a coma for 3 weeks in the local hospital where he is being treated for severe trauma. The doctors think that there is only about 30% chance of his coming out of the coma and his health being largely restored; he would perhaps have to be sustained on the life saving equipment for two to three months. The issue is brought to a head with admission of an accident victim, a 52 year old university professor who needs the same equipment and who has a better than 50% probability of survival. He must use the equipment at this hospital, for if he is transported to another one, he would almost surely die.

Mr. Smith's family insists that the question of removing the equipment be decided by the physician in charge of the Intensive Care Unit (ICU) after he consults with each patient's family physician. The family of the university professor asserts that the only just resolution is to have a panel, perhaps consisting of the ICU physician, both family physicians, and three persons appointed by the hospital (a physician, an attorney, and one other person) make the decision. They contend it is more than a personal, "first come first served" question; that it is a community question.

Everyone realizes that this decision will set a precedent for this hospital, and for other hospitals in the area. Who should decide?

Option 1: The ICU physician should decide.

Option 2: The panel of persons should decide.

Appendix 6:
Descriptions of the Four Policy Scenarios included in the Third Policy Evaluation Instrument.

POLICY SCENARIO NO 1: PERMANENT NATIONAL COMMISSION

01 A permanent National Commission on Biomedical and Behavioral Research and Technology (the Commission) was established under the Biomedical and Behavioral Research and Technology Act (the Act). The Commission is an independent organization funded by and reporting to the U.S. Congress. The Act authorized the operation of the Commission for a period of 20 years. At the end of this period, the Commission would be abolished and its functions cease unless authorized by a new act.

02 The purpose of the Commission is to optimize the benefits and costs to society of biomedical and behavioral research and technology. The Act gave the Commission jurisdiction over all aspects of biomedical and behavioral research and the implementation of resultant technologies, plus the duty to recommend priorities to Congress for approval and for funding. The Commission acts at the national policy level, promulgating guidelines, regulations, and definitions. These guidelines, etc., are enforced through various incentives and penalties prescribed by the Act. In all cases, the Commission's rulings are final, unless amended by an Act of Congress, or by the courts. Its rulings are implemented by the Executive Branch of the federal government (specifically, DHEW).

03 The Commission has 15 full-time salaried members: 7 scientists and researchers, 7 nonscientists and nonresearchers, and a chairperson who must be a nonscientist/nonresearcher. Nominations to the Commission are made by the President; however, Congress actually appoints the commissioners and selects the chairperson. The President provides the names and qualifications of twice as many persons as are required. The appropriate committees in the House and in the Senate then select from that list. Differences about appointments are resolved by the chairpersons of the committees. All nominations may be rejected; the President must then submit a new list of qualified individuals.

04 Commissioners serve three year, nonrenewable terms. At the beginning, five members were appointed for one year, five for two years, and five for three years. Scientists/researchers are replaced by other scientists/researchers, and the same holds true for nonscientists/nonresearchers. There are no special restrictions on commissioners except direct or indirect conflicts of interest. Similarly, there are no special quotas of representation for commissioners (e.g., behavioral scientists, lawyers, ethicists, etc.), although the Act specified that membership must be as representative as possible. A resume, Statement of Qualifications, and Conflict of Interest Statement for each commissioner are available to the public, either free by inspection, or on payment of a reproduction fee if a copy is requested.

05 The Commission employs a staff divided into departments, to support its functions, prepare materials for review, etc.

06 The Commission formulates and promulgates policies, guidelines, and regulations pertaining to biomedical and behavioral research and technology, and it is also responsible for promulgating pertinent definitions (such as the point at which life ceases in a human being). The Commission concerns itself only with major policies, guidelines, regulations, and definitions. Federal agencies, review boards, and other agencies are responsible for interpreting them and providing detailed directives.

07 Although the Commission must approve (i.e., promulgate) all policies, guidelines, definitions, etc., federal agencies (such as FDA, FTC, etc.), professional societies, or other groups with expertise in specific areas may draw-up guidelines, regulations, definitions, etc., and submit them to the Commission for approval. In some cases, the Commission may conduct special studies prior to promulgating guidelines, etc.

08 The Commission decides on cases submitted to it for appeal, such as those submitted by researchers whose proposals received an adverse ruling from review boards. In order to determine if a case should be considered by the Commission, it is first reviewed by a panel consisting of three Commissioners, at least one of whom is a scientist/researcher, and one a nonscientist/nonresearcher. Only those cases considered to be precedent-setting are sent to the Commission.

09 The Commission annually audits a random sample of biomedical and behavioral research projects conducted with public funds, and reports on such factors as: the extent to which the project was conducted in accordance with the proposed work, including protection of human subjects; the scientific soundness of the methodology with which the project was conducted; the validity of "knowledge" gained as a result of the project. The results of these audits are available to the general public in a report written in lay language.

10 The Commission is responsible for formulating a national strategy on public funding of biomedical and behavioral research and the implementation of resultant technologies, including the proposal of priorities. This national strategy is reviewed every two years. As part of this review, the Commission will consider the work of federal agencies charged with dispensing funds, in order to determine the extent to which national strategy directions were followed. The Commission is also responsible for collecting data regarding expenditures for biomedical and behavioral research (public and private). The appropriate categories to be used by federal agencies for reporting such expenditures are de-

termined by the Commission to facilitate the collection of meaningful data. Every two years, the Commission recommends this national strategy, including priorities, to the Congress for approval and funding.

11 Ninety percent of federal funds for biomedical and behavioral research projects are allocated to those projects expressly related to the national strategy. In order to encourage innovative and creative research not necessarily related to present-day priorities, the remaining ten percent is placed in a special fund. Researchers may submit proposals to obtain these funds in designated categories of research (e.g., technology development, technology application). There is a ceiling on the amount of funds that can be requested for a research project under this category. The categories and ceilings are determined by the Commission in a biennial review. Proposals are screened for scientific merit (to rule out truly unworkable projects) by a peer-review panel. Acceptable proposals are given a serial number. Every three months serial numbers are drawn randomly until the amount in that research category for the quarter has been allocated. Proposals selected for funding must observe all Commission guidelines pertaining to research projects. Unsuccessful proposals are included in the next three drawings, and then withdrawn. Researchers may not submit more than one proposal per quarter in each category. A researcher whose proposal is turned down for inclusion in the drawing may appeal the decision to a panel operated by the Commission.

12 The Commission meets as often as necessary to accomplish its functions. However, it must meet at least weekly to discuss or adopt policies, reports, etc. Although the Commission is based in Washington, D.C., at least once each month it meets in a different location. These meetings are usually held in DHEW regional offices or at the Centers. All meetings are open to the public. A transcript is made of each meeting, and the proceedings are summarized. Summaries and transcripts are available to the public on a subscription basis or may be inspected at the Commission's office, or at various repositories such as DHEW and other federal government offices.

13 The Commission is required to take a roll call vote to adopt policies, guidelines, definitions, reports, etc. A simple majority is needed for adoption. Minority views on an issue are reported after the vote has been taken. Votes of the Commission and minority views are published in the proceedings and in the report on the subject to which the vote pertains. Issues to be addressed by the Commission, such as the revision of a definition (e.g., the point at which life ceases in a human being), are announced in the Federal Register 30 days prior to the start of the Commission's deliberations on the subject. The period of deliberations is 60 days. During this time, testimony may be heard or sent in.

Staff papers on the subject and those requested from or submitted by professional organizations, contractors, etc. are also reviewed by the Commission during this period. Within the next 30 days, the Commission publishes its first report. This report contains its recommendations on the issue (e.g., a definition), along with any testimony, papers, etc. Interested gorups or individuals are then given 60 days to comment on the report. Within 30 days following this period, the Commission must publish its final report. This report contains its ruling on the issue and any comments received in response to the first report. The final report, therefore, establishes policy.

14 The Commission maintains a repository of its policies, guidelines, and regulations pertaining to biomedical and behavioral research and technology. These policies, etc., which are open for public inspection, are written in a form understandable by lay persons. Key aspects of the policies, etc., are actively disseminated to the general public through the media. Organizations, scientists, and researchers can receive a copy of these policies, etc., simply by asking to be placed on a mailing list. They are automatically sent to review boards and panels.

15 All policies, guidelines, regulations, and definitions apply to individuals, private (for-profit and non-profit) and public organizations, whether or not they use public funds for their research.

16 The Act provided penalties for persons or organizations who infringe Commission policies, guidelines, regulations, etc. Depending on the severity of the infringement, or if it was willful or criminally negligent, the Commission can censure the person involved; prevent him/her from receiving federal funds for research or for the treatment of patients; refer the case to the appropriate professional licensing authority; or refer the case to the Justice Department for prosecution. Such penalties apply to those regulated (e.g., researchers, practitioners, etc.), and to the regulators (e.g., federal employees or private organizations that perform reviews, assessments, evaluations, etc., on behalf of the Commission).

17 Every four years the Commission evaluates the effectiveness of its own policies, regulations, guidelines, etc., or those of subordinate agencies, to ensure that such policies serve the purposes for which they were designed and that the purposes themselves are still appropriate. An outside organization is selected by the Commission to carry out this evaluation. The organization's report is published. The Commission debates the report, and issues a report on problems which have been revealed, and what should be done about them.

18 The work of the Commission is evaluated by the Congress every two years. The basis for this evaluation includes, but is not limited to, the following: written reports available to the public; open hearings held by Congressional committees; and special studies requested by Congress.

19 The Commission publishes an annual report to Congress, summarizing the year's activities, and the findings of the reports it issued during that year.

POLICY SCENARIO NO 2: PUBLIC INVOLVEMENT IN POLICY DECISION-MAKING

01 Several provisions of the Act setting up the Commission were written to encourage and facilitate public involvement in policy decision-making with respect to biomedical and behavioral research and technology, and to inform the public on these subjects. Public involvement was achieved through the structure and operation of the Commission itself, review boards (see Scenario No. 3), and through the creation of five public information centers.

02 All meetings of the Commission are open to the public. Individuals and groups are encouraged to comment on proposed policies, guidelines, regulations, etc., at every stage of their formulation. They are able to participate in debates of the Commission on issues being addressed by it, presenting either oral or written testimony. A repository of all policies, etc., in effect is maintained by the Commission and copies may be inspected or obtained by the public (see Scenario No.1). An approved research proposal may also be inspected or obtained by the public (see Scenario No. 3). All assessments of technologies are published (see Scenario No. 4). Reports on the Commission's activities are published annually.

03 The Commission is responsible for informing the public generally about the implications of biomedical and behavioral research and the implementation of the resultant technologies. To this end, it supervises a number of information services, and conducts media campaigns. Through these mechanisms the Commission disseminates its findings and those of the reports it issues, prepared by itself or others on its behalf.

04 The Commission conducts studies of the implication of advances in biomedical and behavioral research and technology, and makes its findings known to the public through reports on the studies, its information service, and the media, if appropriate.

05 The Commission sets standards detailing the nature and extent of information which marketers of biomedical and behavioral products and services must provide to consumers about the bad (as well as the good) effects of these products and services, and how this information is to be presented, e.g. on the product packaging, at place of sale, or through the media (with advertisements). The Commission can also specify that a certain proportion of a marketer's revenues be used to give such information to the public.

06 On matters the Commission holds to be especially important, a survey of national opinion may be undertaken and the results published prior to the Commission voting on the issue.

The Commission also conducts surveys of national opinion to evaluate its own activities and decisions and to see how its effectiveness is perceived by the public. The results of these surveys are also published.

07 The Act created five independent Biomedical and Behavioral Research and Implementation Information Centers (the Centers). These five Centers were selected by the National Commission on the basis of competition and geographical representation. In order to encourage creativity and diversity, only new not-for-profit organizations were eligible. (Universities and other existing public and private organizations were ineligible, although they could join in a coalition that resulted in a new, legally separate entity.)

08 An entity wishing to become a Center had to prepare a proposal adhering to an outline provided by the Commission. Each proposal was published and subjected to public debate. Finally, the Commission designated five organizations as Centers.

09 Each Center is a legal entity with a Board of Trustees and an Executive Staff. Composition of the board and selection of members is the responsibility of each organization. The Board of each Center is responsible for determining the Center policy, selecting staff, etc.

10 Each Center receives $6 million annually from the Congressional appropriation that supports the Commission. Although the Centers file an annual work plan with the Commission, each Center is free to develop the programs and projects aimed at public participation that it deems appropriate. Also, Centers are free to solicit contributions from the general public. Contributions, however, are limited to a maximum of $1,000 per person per year. Only persons aged 18 years and older may contribute; organizations may not.

11 Centers have the following purposes: to monitor research and technology directions in their region; to foster the implementation of policies and regulations; to assess public opinion and understanding; to disseminate information to the public; and to engage in other public participation activities (such as forums, debates, question-answer services, etc.).

12 Every two years the work of each Center is reviewed by the Commission in open public hearings. Citizens groups and individuals are invited to comment on the Centers. Each Center may comment on the activities of the others. New applications from groups who want to form a Center are also reviewed, and the Commission is free to replace an established Center with a new one if this would diversify the constituencies represented or if an old Center is found to be deficient. (The total number of Centers, however, remains at five.)

POLICY SCENARIO No 3: BIOMEDICAL AND BEHAVIORAL RESEARCH

01 The Act gave the Commission jurisdiction over all biomedical and behavioral research. The Commission is responsible for defining what constitutes biomedical and behavioral research and therefore what falls within its purview under the Act; any research involving people as subjects was do designated, as was any biomedical and behavioral research that technically could be done on people (but is not done for ethical or other reasons, such as research using animal models), and any biomedical and behavioral research that has implications for individuals or for society.

02 The Commission sets policies, guidelines, and regulations, with respect to: the protection of human subjects of research; the evaluation of risks and benefits to subjects and to society of research, including technologies that could reasonably be expected to emerge from the results of the research; and establishes specific precautions for conducting research.

03 The most important distinction made by the Commission is to divide research projects into those that must be reviewed prior to implementation and those that need not be reviewed. Certain policies, established by the Commission, must be followed about research which does not require review prior to implementation. The Commission established a system of International Review Boards (IRBs) and Regional Review Boards (RRBs) to review all other research proposals.

04 The responsibility for interpreting Commission policy about which research proposals must be reviewed rests with the prospective researcher. However, a researcher is able to obtain a ruling from either an IRB or RRB as to whether or not his/her project must be reviewed prior to implementation.

05 Organizations that conduct biomedical and behavioral research can either establish their own institutional review boards (IRB) to evaluate each protocol and RIS, or rely on a Regional Review Board (RRB) for this purpose. All scientists and researchers not employed by an organization must apply to the RRB for approval of research proposals.

06 Institutional Review Boards (IRBs). Each IRB must comprise Seven persons: Three scientists or researchers; three non-scientists or non-researchers from outside the organization (such as lawyers, ethicists, and representatives of the public), and a chairperson who must not be a scientist or researcher, or in the employ of the organization. All members are recruited and serve their terms according to procedures determined by the organization. A resume, Statement of Qualifications, and Conflict of Interest Statement for all IRB members must be filed with the local RRB and with the

Commission, and be available for public inspection. Detailed minutes must be maintained, including records of votes and Statements of dissent. An annual report of IRB activities must be filed with the RRB. The IRB is responsible for seeing that researchers actually carry out work as stated in their proposal (the protocol and Research Impact Statement) through a system established by the IRB. Due process safeguards such as hearings and appeals to the RRB (and finally to the Commission) are provided for the protection of researchers. The cost of operating the IRB is borne entirely by the organization.

07 Regional Review Board (RRB). There are ten RRBs, one for each DHEW Region. All RRB members are full-time employees paid from the same appropriations that meet the cost of the Commission. Each RRB comprises nine members: four scientists and researchers, four nonscientists and researchers, and a chairperson who is also a nonscientist-nonresearcher. Each board member serves a three year term; memberships are staggered to ensure continuity. While board members can serve more than one term, they cannot serve two consecutively. Nominations to RRBs may come from professional societies, citizens and other groups and from self-nomination. A resume, Statement of Qualifications, and Statement of Conflict of Interest must accompany each nomination. These documents are available for public scrutiny and comment. All selections are made by a majority vote of the Commission, after the public has had the opportunity to offer testimony on nominees or applicants.

08 Researchers wanting to conduct a biomedical or behavioral reseacher project that requires review must submit a research proposal (application) to an IRB or to a RRB for approval, prior to commencing work. The proposal must consist of a protocol (outlining the experimental design, analytic methods, etc.), and a Research Impact Statement (RIS). The latter must include a discussion in lay terms of: the purpose of the research; a summary of the methodology; a discussion of the use of human subjects if any; and the risks and benefits involved both to the subjects, if any; and to society of the research and of any technologies that might emerge from the research. A research proposal (protocol and RIS) turned down by one IRB cannot be filed with another IRB or RRB, unless this fact is stated. Additionally, the IRB or RRB turning down the original application must be identified as well as the reasons for refusal. Any amendments to the original proposal must be clearly indicated.

09 Review of research proposals (protocol and RIS) prior to implementation applies equally to individuals, private for-profit, private non-profit, and public organizations.

10 The decision to fund a particular research project is made by the agency or organization granting the funds, using what-

ever criteria it considers appropriate. However, agencies or organizations (public or private) granting funds must draw the attention of grantees to IRB/RRB approval requirements. Although a researcher may secure funding for a research project, he or she cannot commence operations without approval by an IRB or a RRB. (The fact that a proposal is approved by an IRB does not mean anyone will fund it, however.)

11 The IRB or RRB, as appropriate, must review each research proposal received to see that it meets all guidelines set for such research by the National Commission. The IRB or RRB can approve the research, call for modifications in methods, or prohibit it. On approval the research can begin. A copy of the RIS for each approved project must be filed with the appropriate RRB and with the Commission withing 30 days of commencement of the work.

12 While the Commission does not approve research projects (RISs) prior to work commencing, it has the authority to halt research if any violations of guidelines are found in a RIS or if, in the opinion of Commission staff, serious risks to any individual or to society may result from the research. In the event that a project is halted, a hearing is held by the Commission. After receiving testimony from the researcher and other interested parties, the Commission can: allow the work to proceed as planned, or with modification; allow the work to proceed for a limited period with subsequent review for final determination; or prohibit the research.

13 A researcher or a scientist who feels his research proposal was unfairly disapproved (by an IRB or RRB) may appeal to the Commission. Similarly, an IRB or a RRB member who felt a project was wrongfully approved could ask the Commission to halt it. However, only cases judged to have significant merit by the appropriate Commission panel (e.g., those that would be precedent setting or would require interpretation of guidelines) are actually considered by the Commission for resolution.

14 Apart from reviewing research proposals (protocols and RISs) the RRB is responsible for monitoring the work of the IRBs within its jurisdiction to see that they adhere to Commission guidelines, and that they employ appropriate procedures to monitor the work of researchers within their organization. Monitoring takes the form of reviewing the minutes of IRB meetings, talking with IRB members, individual researchers, subjects, or interested citizens, as appropriate. A RRB may caution an IRB found to be deficient and review it again in six months, disband it for a specified period, or abolish it entirely, as appropriate. In addition, the organization or an individual member of the IRB may be prosecuted if considered to be negligent in carrying out IRB functions. These sanctions and penalties may be appealed to the Commission.

Each year the RRB must submit a report on the status and activities of IRBs within its region to the Commission. This report is available to the public.

15 Each year, Commission Staff review a random sample of RISs to determine research directions, steps being taken to protect human subjects, and evaluations of risks and benefits to both individuals and to society. A report of findings is published annually by the Commission. In addition, all RISs are available for public inspections at the offices of the Commission and RRB.

16 The federal government operates a fund to compensate research subjects for harms suffered as a result of participating in research. The fund is supported from general tax revenues, and is administered by the Secretary of DHEW, although guidelines for compensation are laid down by the Commission. Claims must be filed with the Secretary of DHEW, who after investigating the case, is responsible for determining, according to the Commission's guidelines, if a claimant is to be paid and the amount. The amount of compensation must be repaid to the bund by the organization (or individual) conducting the research if the Seeretary's investigation finds they were negligent or otherwide did not observe Commission guidelines. In such cases, the Secretary may also rule that the organization (or individual) be prohibited from receiving public funds for a specified period. A person denied compensation, or an organization held negligent, may appeal the case to the Commission. While DHEW is responsible for processing claims and making compensation, all cases in which compensation was paid are reviewed each year by Commission staff and a report published documenting awards made, liability, and other pertinent findings. These reports are also used to revise or strengthen Commission research policies, guidelines, and regulations.

POLICY SCENARIO NO 4: IMPLEMENTATION OF BIOMEDICAL AND BEHAVIORAL TECHNOLOGIES

01 The Act gave the Commission jurisdiction over the implementation of all biomedical and behavioral technologies, both those existing at the time it was set-up and those those that might be developed subsequently. Initially, the Commission concentrated on policies for new technologies, later turning its attention to policies for technologies being developed or tested or in use at the time it first became operative.

02 The Commission is responsible for defining what constitutes a biomedical or behavioral technology and, therefore, what falls within its purview under the Act. Anything designed to test, monitor, improve, maintain, or treat human biomedical or behavioral functioning was determined to be a biomedical or behavioral technology. The Commission adopted the following classification of technologies:

* Tangible technologies: All technologies which consist of a recognizable product. This would include all drugs, devices, or instruments, and equipment or facilities such as ambulances or coronary care units.

* Intangible technologies: All technologies that depend upon information or services. These are further classed into provider-activated and self-activated categories.

  -- Provider-activated: Those intangible technologies that involve the services of a provider such as psychiatrists, surgeons or counselors. These are further classed as specific or nonspecific.

    - Specific: surgical procedures, treatment regimens, etc.

    - Nonspecific: counselling, etc.

  -- Self-activated: Those intangible technologies which do not require the services of a provider such as books on child rearing, transcendental meditation, diet, exercise, etc.

The Commission determined that all biomedical and behavioral technologies except those that are intangible self-activated are subject to specific policies.

03 A technology is first classified according to the stage of its development: application (first, limited use); and use in general practice (routine, more wide-spread use). Next it is classified according to its safety and efficacy to the individual and its risks and benefits to society. Separate

policies pertain to each stage of development, and to each safety-efficacy/risk-benefit classification.

04 The Commission sets policy with respect to the application of a technology, its use in general practice, and the assessment of a technology to determine if application or use in practice should be permitted and under what circumstances. Policies that pertain to application (given application is authorized) are directed toward: who may receive the technology and who determines if particular patients meet the specified criteria; what patients must be told about the technology; who may provide it; under what conditions; etc. Policies that pertain to use in practice (given use is authorized) include: identification of who may use the technology (e.g. if it can be sold over the counter, only prescribed by doctors, etc.); what information must be given to prospective users; etc. Policies that pertain to assessments include identifying those authorized to conduct them, how they are to be done, what data are to be collected, etc.

05 While the Commission formulates policies with respect to what is to be assessed, how it is to be assessed, etc., the assessments of technologies are conducted by appropriate agencies in DHEW, such as FDA. The Commission evaluates the assessments made by the responsible agencies through the reports they issue. In addition, the Commission audits a random sample of assessments each year to ensure that they are carried out adequately and properly. A report of the functioning of the agency is then prepared and made public. Bureaucrats found to be deficient in properly carrying out their duties in accordance with Commission policies may be censured, dismissed, or the case referred to the Justice Department for prosecution, depending on the nature of the irregularities discovered. Bureaucrats may appeal any such action to the Civil Service Commission, except an indictment which is, of course, disposed of by the courts.

06 All new tangible technologies, including drugs, etc. must be assessed prior to application (i.e. first, limited use) and again prior to use in practice. The purpose of these assessments is to determine the safety and efficacy of technologies for individuals and their impact on society.

07 Assessments must be made by an organization or agency other than those that developed the technology. Moreover, persons who worked in its development cannot be employed to assess the technology (even if they now work for a different organization). The cost of this independent assessment is borne by the organization that wants to market or use the technology. The organization that developed the technology can perform its own assessment, however, results of the assessments are submitted to the federal agency monitoring the assessment. The supervising federal agency can order

a second independent assessment if the results of the first and those of the developing organizations differ markedly. The cost of this additional assessment is also borne by the organization that wants to market or use that technology.

08 The results of the assessments are considered by the supervising federal agency, which then designates whether or not the technology can be used, the conditions of use, etc., in accordance with the policies formulated by the Commission. An unfavorable ruling can be appealed to the National Commission. The Commission, however, only reviews those cases judged to be precedent-setting, or those that would clarify or call for modification to existing policies.

09 A new intangible, provider-activated, specific technology must be precisely described and the description filed with the federal agency designated by the Commission to supervise these technologies. Patients (clients) may be offered this new technology, but the provider must inform them that the technology is experimental. The person or organization employing the technology must keep records in accordance with Commission guidelines and file annual status reports on the safety and efficacy of the procedure.

10 Application may be made to the supervising federal agency to designate an intangible, specific, provider-activated technology as "accepted medical practice". The supervising agency can also initiate a review of the procedure, usually after sufficient time has elapsed for the data to be in, or if available evidence justified this. The evidence submitted in support of the application is then reviewed by an independent group of experts and the results of the review considered by the supervising agency. Responsibility for identifying experts rests with the federal agency, although an expert is randomly assigned to a particular case. The agency takes appropriate action in accordance with Commission guidelines. Such action may be to prohibit the procedure; to make persons inelibible to receive it if it is paid for by federal funds; to keep it as experimental technology; or to permit its use under specified circumstances. Rulings may be appealed to the National Commission, which usually only agrees to review precedent-setting cases.

11 Under the Act, the Commission was mandated to evaluate the safety and efficacy of existing technologies that had not been evaluated to its satisfaction prior to use. First, the Commission undertook a review of the numbers of persons affected (i.e. using a technology each year) and the total annual cost of its use. Specific data were also assembled about the safety and efficacy of those technologies affecting the most people and those that were most costly. This latter task was assigned to the appropriate DHEW agency, which also had to report on each of the technologies assessed. After review of the agency report, the Commission issued

its own report and recommendations for comment. Interest groups or individuals were then able to offer additional evidence or otherwise comment on the report. After the prescribed period, the Commission issued a final report and statement of policy.

12 The Commission also established policies for monitoring the safety, efficacy, and impacts of technologies approved for use in practice. As new information becomes available, restrictions imposed by the federal supervisory agency may be lessened or tightened, as appropriate. Technologies may even be redisgnated as experimental or their use prohibited if new evidence warrants this. Again, the marketer or user of the technology may appeal to the National Commission, although the Commission only agrees to hear precedent-setting cases.

13 Failure by researchers, practitioners, marketers, or other users of technologies to observe Commission policies and guidelines may result in: an adverse report to the appropriate professional regulatory board or society; loss of grants or contracts; prohibition from obtaining grants or contracts for a specified period; or loss of accreditation (e.g. a practitioner cannot treat patients whose care is paid for in whole or in part from federal funds). If failure to observe guidelines appears willful or to involve criminal negligence the case can be referred to the Justice Department for prosecution. This may result in fines or even a jail term, as specified in the Act.

14 Insofar as intangible, provider-activated, nonspecific technologies are concerned, the Commission can require providers to be licensed or registered, undergo special training or be accredited, or to provide specific information to the public, such as "the patients receiving the services I offer for your condition report no greater improvement than those not receiving such services." Responsibility for implementing these policies is vested in the appropriate federal agencies.

APPENDIX B

SCHOLARLY ADJUNCT

Report to:

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

December 1976

The National Research Act (P.L. 93-348) which established the National Commission for the Protection of Human Subjects instructed the Commission, among other things, to undertake a "special study" of the implications for public policy of advances in biomedical and behavioral research and technology. This mandate was described in section 203 of the Act in the following terms:

> The Commission shall undertake a comprehensive study of the ethical, social, and legal implications of advances in biomedical and behavioral research and technology. Such a study shall include -
> (1) An analysis and evaluation of scientific and technological advances in past, present and projected biomedical and behavioral research and services;
> (2) An analysis and evaluation of the implications of such advances, both for individuals and society;
> (3) An analysis and evaluation of laws and moral and ethical principles governing the use of technology in medical practice;
> (4) An analysis and evaluation of public understanding of and attitudes toward such implications and laws and principles; and
> (5) 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.

This section derived ultimately from a resolution (S J Res 71) introduced into the Senate on March 6, 1973, by Senator Walter Mondale, which called for the establishment of a National Advisory Commission on Health Science and Society. In the course of the hearings which led up to the passage of P.L. 93-348, the Senate Committee on Labor and Public Welfare made the following statement with respect to the mandate:

> The Committee is impressed with the vast explosion of knowledge and progress in the field of biomedical and behavioral research and technology. The Committee

> believes that these advances have far outstripped man's capacity to understand them and to maximally benefit from them . . . many of these advances will have the potential to alter the nature of our society. These changes in society are brought about in an orderly and constructive manner. Therefore, the Committee believes that the National Commission should undertake a comprehensive investigation and study of these matters and should therefore incorporate the provisions of S J Res 71 in this title.

In addressing itself to section 203, the Commission issued a Request for Proposals to organizations interested in conducting this "special study" on behalf of the Commission. A Technical Review Committee evaluated a number of proposals, and selected one employing the Delphi methodology with a panel of 125 persons. However, the Review Committee suggested that this study should be supplemented in two ways: (1) by a public opinion poll, and (2) by developing some way of drawing on the experience of a more limited number of leading scholars and scientists to focus on the issues raised in the special study mandate. This latter task was referred to as the "scholarly adjunct" to the special study.

The present report is the outcome of that second phase of the special study operation. It has been prepared by a "core group" of 6 scientists and scholars from Harvard University and Boston University, in collaboration with the staff of the Commission; and it incorporates the results of a larger discussion meeting with some 25 participants, held at Bishops Lodge, Santa Fe, New Mexico, in late June of 1976.

At the Santa Fe colloquium, members of the "core group" took the chair at meetings of four working groups which concentrated on different sections

of the special study mandate, and in the preparation of this report they have accepted primary responsibility for corresponding sections of the document. Other participants in the Santa Fe meeting have also made substantial contributions to the report: notably, to the three case studies included here as appendices.

Given the broad scope of this report, it was not to be expected that all 25 participants should have viewed the problems of health science and health care in terms of the same priorities. Still, there was broad agreement over the manner in which we have characterized the interrelations between biomedical and behavioral science and technology and the wider social context, and over the general policy goals that are enumerated in the final chapter of the report. As to the detailed ways in which those goals may best be achieved in practice, there were -- and remain -- a variety of opinions, depending both on the relative priorities one attaches to the different public interests involved, and on legitimate differences of judgment about the likely effects of alternative possible changes in the institutions and procedures of government, health, science and health care delivery.

As an advisory group, we have limited our own analysis and evaluation to the diagnosis of current problems, and the description of various policy options and goals. We have not felt that it was our proper task to choose between these options, or between alternative routes to the goals. The Commission itself will, presumably, be having to arrive at more formal "recommendations" to the Congress in the course of its own deliberations on the entire special study.

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Chapter 1

The Social Context of Policy for Biobehavioral Technology and Research

1.1: The General Background to the Issues. The ethical, social, and legal implications of recent and prospective advances in biomedical and behavioral research and technology, with which the mandate of this special study is concerned, need to be analysed and evaluated in their proper social and historical context. Biomedical and behavioral research or technology -- "biobehavioral technology" for short -- enters into the pattern of human life within the industrialized societies of the late 20th century in complex and pervasive ways. On the one hand, it is a significant agent of social change: so, many recent public discussions have emphasized the active roles of science and technology, as affecting the length, nature and quality of human life, both on the individual and on the social level. On the other hand, biomedical and behavioral scientists and technologists are themselves continually reacting to changes in other features of modern society: in this respect, innovations in biobehavioral technology represent responses to other, larger scale changes in the patterns of social policy, individual behavior, and ethical belief.

The two-way character of this interaction is often overlooked. For instance, the report of the Senate Committee on Labor and Public Welfare, quoted in our Preface, expresses anxiety that current advances in biomedical and behavioral research and technology may be "outstripping man's capacity to understand them," and "having the potential to alter the nature of our society." But the problems and processes in which biobehavioral technology is involved are more complex than this view suggests. The effects of Science on Society -- e.g., the influences which move from biomedical or behavioral science and technology toward the larger society -- are inextricably bound

up with the effects of Society on Science -- e.g., those other, equally significant influences which move from the broader contemporary human situation toward the innovative activities of biomedical or behavioral research and technological development. Furthermore, both of these contrary sets of interactions need to be analysed and evaluated within a larger frame: notably, as they relate to the overall sequence of contemporary historical and social changes, many of which have nothing directly to do with health, or with the activities of health professionals.

In its essentials, the character of life in the liberal democracies of the Western world during the late 20th century has been shaped by two fundamentally non-technological factors: the experience of large-scale industrialization beginning around A.D. 1800, and the urbanization which followed upon it in Western Europe and Northern America. That dual process of industrialization and urbanization was, no doubt, the occasion for a striking wave of technological innovation; but it would be a grave oversimplification to assume that the resulting technological advances had themselves been the primary historical cause of the Industrial Revolutions with which they were associated. If anything, the reverse is the case. The beginnings of this industrial reorganization long preceded the technological innovations which it eventually exploited. Beginning with modifications in the medieval system of landholding and agriculture in Western Europe, a succession of profound social, economic and organizational changes was necessary before it would become practicable -- during the years around 1800 -- to support, encourage, and take advantage of technological discoveries and inventions in the new "industrial arts"; and, apart from that social context, those innovations would have been without any major effect on human welfare.

Considering the scope of recent improvements in individual and public health in the United States, we may thus be inclined to assume that the single most significant influence on the length and quality of human life during the last 150 years has been the development of scientific medicine, and to expect further, comparable improvements from the same source. Yet the actual facts reveal a more complex picture. The development of sulfonamides and other antibiotics has certainly given us a remarkable new power to control and cure many infectious diseases, especially the diseases of childhood; yet, over the last century and a half, the overall death rates after the age of 15 have changed to a surprisingly small extent.

The real battle for health and against disease, indeed, has never been one for the medical profession alone. Even where adult death rates have changed substantially, it is not easy to disentangle the contributions of medicine and biomedical science from the consequences of other -- perhaps more basic -- changes in social structure, administrative procedure and human attitudes. Taking all things together, it seems likely that changes in housing codes, standards of employment and occupational safety, as well as in public attitudes toward sanitation, water purity and pollution, work practices and racial discrimination, diet and exercise -- which have taken place independently of, and alongside, recent changes in medicine itself -- have had more effect on many aspects of human health than the better practice of professional medicine. The contributions of the medical profession to the overall state of the nation's health are important, in some cases even crucial; so that problems in the economics of medical care, and in the provision of medical education, are legitimate matters of public concern. But, in the entire

pattern of health care and health policy, the role of the professional physician -- especially, the professional physician in private practice -- is a limited one. In the overall improvement of the nation's health, the work of medical professionals and their scientific colleagues thus forms only one component within a much larger network of social and professional activities.

These same more basic changes in social structure and public attitudes are relevant also to the "frame" within which priorities for medical research are determined, and the resulting biobehavioral technologies applied. On the one hand, the recent successes of scientific medicine have helped to forge a powerful new alliance between biomedical scientists and professional physicians. In turn, the strength of this alliance has tended to impose on policy makers and the wider public one particular, somewhat narrow definition of the "problems" of biobehavioral science and technology: a definition that focusses on the scientific study of somatic processes, and aims at the development of "technological fixes" for all health problems -- so distracting attention from the social determinants of the issues involved. (As we shall see later, the attractions of this limited definition for research scientists and practicing physicians, respectively, are connected but not identical.) On the other hand, where innovations in biomedical or behavioral technology have been developed without regard to specific social needs or demands, and have been then introduced into society "out of the blue," their broader effects have been correspondingly limited. The consequences of such innovations have been most far-reaching, in cases where the innovations were themselves developed as responses to <u>preexisting</u> social demands or needs.

It is instructive, for instance, to see how the 20th century development of new birth control techniques was related, in point of history, to contemporaneous changes in public attitudes toward sex and reproduction, family life and the ethics of pleasure. In this case, too, it is often supposed that a technological innovation was the primary cause, the social change the effect: viz. that the invention of the contraceptive "pill" has been the prime agency initiating an epidemic of sexual "permissiveness." Yet, once again, there is at least as strong an argument for seeing the actual causal relationship as going in the opposite direction. Considering the timing of the relevant changes in contraceptive techniques and in public attitudes, we may well conclude that it became practicable to develop and market oral contraceptives on a large scale in the years following World War II, only as a result of previous widespread changes in public attitudes toward sexual morality. Historically speaking, some workable methods of birth control have been known at more times, and in more cultures, than is generally assumed. If these techniques are "in demand" in industrialized countries at the present time, that is not because they are the products of brand new technologies: rather, it is because novel social factors -- e.g., the availability of social security for the aged, and the threat of over population -- have undermined older arguments against limiting family size and encouraged a general reappraisal of traditional attitudes toward sexuality. In this case as in many others (it seems) we are too easily tempted to view technology as the primary cause of changes on the individual and social human levels; even where the basic direction of influence has been, rather, the reverse.

Throughout this report, accordingly, we shall be discussing the implications of advances in biomedical and behavioral research and technology for

ethics and society, law and public policy, as elements in a two-way interaction: alongside, and in conjunction with, the implications of changes in the ethical and social, legal and political areas for the activities of biobehavioral scientists and technologists themselves. Only in this way can one form a clear picture of current problems, or recognize in what ways the current institutions of health science and health care are ill-adapted to tackle those problems.

Certainly, the roles of "biomedical and behavioral research and services" in social and individual life have become increasingly complex and hard to grasp in recent decades; while, at the same time, the problems of public policy arising from the social involvement of biobehavioral technology have seemingly become more intractable. In our view, however, the reasons for this intractability do not lie solely -- or even very substantially -- in the sophistication of the technological innovations themselves. First and foremost, they spring from the fact that biomedical and behavioral research and services nowadays touch on, and interact with, the broader patterns of individual, social and political life at so many more points, and in so many more ways than before. And, given the democratic traditions of American life, one inevitable consequence of this increasing scope has been a greater expectation by the public at large that they will have a chance to participate in critical decisions about the uses to which new biobehavioral technologies are to be put.

Instead of narrowing our attention on to the detailed content of particular socially influential innovations in biobehavioral technology, therefore, we shall attempt in this present report to focus:

(1) on the <u>processes</u> by which biomedical and behavioral research and technology interact with the larger patterns of social and individual life;

(2) more particularly, on the decision points at which it is possible, practicable and useful to intervene in those processes, so as to channel them in desired directions;

(3) specifically, on the various mechanisms -- ethical and judicial, administrative and political -- by which such channeling can best be offered.

The resulting discussion will certainly not be narrowly "factual" or "value free"; nor could it have been, given the Congressional mandate to "analyse and evaluate" the policy implications of biobehavioral technology. But we have done our best to state our ethical and social values and preferences explicitly; and we have deliberately rested the argument on social values forwhich there is broad acceptance in principle, even though their political consequences are not always recognized in practice.

At first sight, the crucial policy problem in the biobehavioral field might seem to be that of bringing the Juggernaut of Technology under responsible public control. Instead, the most fundamental and taxing problem turns out to be the preliminary one: of mapping, in comprehensive and discriminating detail, the growing network of interrelations within which biobehavioral innovations reinforce and contribute to, modify and react to social changes and vice versa. This introductory chapter provides a first rough sketch-map of this network, which will be filled out in more detail later in the report.

1.2: The Widening Scope of "Health" and "Health Services." The last 75 years have seen striking changes, both in the general conception of "health"

current among professionals and lay people alike, and in the resulting hopes and expectations for the provision of "health services." A century ago, it was still the general practice to regard good health as consisting in a simple freedom from illnesses, which were seen as afflictions or visitations of body or spirit, to be endured with patience and treated with wise care. Since then, a very different conception of health has arisen to challenge that earlier one: this selfconsciously "positive" definition, as adopted by the World Health Organization, presents health as "a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity," to be fostered and promoted by deliberate social policy and active professional intervention. This newer conception has (it is true) been widely criticized for its extraordinary breadth and vagueness; yet it captures a view that has become widely influential -- even if as an expression of aspirations rather than of actualities -- and the consequences are particularly evident in public expectations about the promise and potentialities of health care. This can be recognized clearly enough, both in the scope alloted to somatic medicine at different stages during the last 75 years, and in changing public attitudes and expectations toward the psychological problems of human individuals and groups.

(A) The Changing Function of "Medicine." At the beginning of the 20th century, most medical practice still consisted in the care and management of the sick, and the physician rarely found himself in a position to cure his patients' diseases. At that stage, accordingly, the prime function of medical practice was pastoral. Since then, the practice of medicine has expanded into three new areas, and each fresh enlargement of scope has given rise to fresh public attitudes and expectations, so calling for new decisions about social policy.

(1) The most striking change since the year 1900 has been the great increase in the range of conditions that can simply be "put right": partly, as a result of improvements in our physiological understanding, but largely through the development of "antibiotic" agents, beginning with the sulfanomides in the 1930's. As a result, one prime function of medicine has become curative. This change has not only given new powers to much professional practice in medicine but, even more, has transformed lay attitudes toward the medical profession. (Instead of devoted attention, the public has come to expect "magic bullets" and "miracle cures" for all identifiable diseases.) Indeed, many of the policies, practices and relationships to which we are most accustomed in the mid 1970's became securely established only as a result of this change: notably, the current tendency of much medical practice and biomedical research to focus on somatic or physiological factors and processes, and to downplay the social and environmental conditions of "disease."

(2) Meanwhile, the practical scope of medicine has expanded further, going far beyond the provision of after-the-event "cures." Through the development of more discriminating indicators and diagnostic techniques, it has become possible, much more often than before, to recognize far in advance when a particular patient is susceptible to a particular disease, or liable to develop some pathological condition, and take measures to prevent that outcome. In a word, one essential function of current medicine is now preventive. Similarly, through new developments in public health and social medicine, it has become possible to cut off the spread of many illnesses before they affect individual patients: whether through programs of innoculations, or through improvements in water supply or sanitation, or through social policies of other kinds.

(3) At the present time, furthermore, the scope of medicine is enlarging in two other respects, and as a consequence medical practice is becoming also corrective and augmentive. On the one hand, it is becoming possible to remedy directly certain physiological "defects" or "malfunctions," which would otherwise be liable to cause sickness, pain or mental anguish. One representative example of this new trend, at a superficial level, is cosmetic surgery: at a more basic level, the biomedical goals of "genetic engineering" would be of the same kind. On the other hand, it is becoming possible, also, to enhance and improve the quality and level of normal functioning; and this kind of "augmentive" task will very likely play an increasing part in medical practice. Such enhancement of functioning is already familiar in the area of sex therapy, but other comparable techniques are certainly on their way. For instance, we may expect to see the development of pharmacological agents and other treatments capable of enhancing an individual's intellectual or physical performance.

This expansion of scope, by which the scope of pastoral and curative medicine has widened, to embrace preventive, corrective and augmentive functions, brings with it corresponding changes in the social implications, costs and organization of medical practice. Physicians whose armamentarium of remedies was confined to those available in the 1890's evidently had far less power to affect our lives (whether individual or collective) than those who can now cure serious infections in a couple of days, correct an ugly nose, improve our intellectual performances, and/or iron out our matrimonial problems. Even more: as the scope of medicine has widened, its practice has become more highly institutionalized. Instead of looking to an individual physician for pastoral care, the patient nowadays deals with a complex

institutional system, and this fact significantly affects both the attitudes of attending physicians to those in their care, and also the impact on individual patients of the health services so provided. To say this is not to imply that particular physicians have less personal concern for their patients than did their predecessors. It is merely to recognize that, as the medical profession has become aggregated and the delivery of health services has been organized into larger institutional units, different sets of interests have become activated from those that embodied in the traditional "doctor-patient relationship."

The loss of this old personal touch, together with the sense of control that it gave to the individual patient, is even more evident where health care is a matter for preventive public health measures on a collective basis, rather than for the delivery of after-the-event treatment to individuals. In the field of public health, individual citizens can achieve understanding and control over practices having a significant effect on their health and welfare (e.g., fluoridation) only by participating in the formation and implementation of the corresponding social and political policies. And what makes the task of developing an adequate public response to the resulting problems so very complex is -- quite simply -- the sheer multiplicity of functions undertaken by contemporary medicine, and the correspondingly wide range of relationships, both individual and institutional, through which medical practitioners interact with the larger public.

(B) The Development of Psychological Sciences. The changes taking place during the present century in attitudes and expectations about the treatment of mental, psychological or spiritual afflictions are equally striking, if not

entirely parallel. In somatic medicine, the function of pastoral care always lay with the physician: the newer responsibilities -- curative, preventive, corrective and augmentive -- have simply been added to that primary concern. By contrast, responsibility for pastoral care in psychological matters was, by long tradition, vested in quite a different profession: viz., the clergy. Until recently, it was the duty and prerogative of ministers, rather than of physicians or psychotherapists, to console the bereaved, to give meaning to tragedy, to provide counsel to the emotionally confused, principles for parents in the education of their children, moral and sexual guidance to the community in general. If at the present time psychiatrists, psychotherapists and other "mental health" professionals play a large part in the provision of such counselling, the reason does not lie in some drastic 20th century epidemic of "mental disease": rather, it results from a new differentiation and allocation of professional responsibilities that were previously combined and centralized in the churches.

Over the last 100 years -- for good or ill -- the pastoral role of the clergy has thus been gradually diminishing. Many of its functions have been taken over by secular agencies and professions: e.g., by lay schoolteachers, clinical psychologists, and social workers. In certain fields, notably psychiatry and public education, professional bureaucratic institutions have even developed, which compare in their scale and complexity to the churches themselves. In some other formerly clerical fields, this has not yet happened: in the delivery of social services, psychological counseling, aptitude testing and the like, people of many different kinds are involved, and the moves toward professional monopoly and public licensure have made far less progress. During

the last 10 or 20 years, however, the provision of "psychological health services" has at last begun to put into practical application discoveries and techniques originally developed within the behavioral sciences, in the same systematic way that 20th century medicine has done with discoveries in physiology, biochemistry and allied sciences.

We may speak here of the "behavioral sciences" in a broad sense: including not just psychology, but also sociology, anthropology, economics, history and all those disciplines which seek to apply scientific principles to the understanding of human behavior -- past, present and future. In some of these fields, research follows the general patterns of basic science, e.g., using experimental methods to study learning in animals. In others, the methods are those more typical of applied science, e.g., employing psychotherapeutic techniques to correct learning disabilities in children, or using anthropological understanding to assist culture change in subliterate societies.

While the scientific standing of research in these behavioral fields has not been recognized for as long as it has in the biological and medical (to say nothing of the physical) sciences, philosophical speculation about "human nature" -- aimed at an understanding of behavior, as related to its social and historical context -- has been continuous since classical times. The modern movement, aimed at developing more strictly "scientific" analyses of human behavior, developed in Western Europe and the United States during the late 19th century; and the new methods were first applied to practical problems in the educational field, with the development of <u>intelligence testing</u> in France. The resultive testing methods -- which came to have a broad application to personnel selection and other kinds of aptitude testing -- were based on elaborate and sophisticated

experimental studies of learning, both in animals and in humans, as well as on research in applied statistics. They first caught public attention during World War I, when they were extensively used in assigning military personnel to different tasks. Meanwhile, parallel development were taking place in the field of psychotherapy. The earlier forms of psychotherapy were concerned primarily with hysteria and certain neurological pathologies, and were developed in the United States, France and Austria around the turn of the century. They, too, achieved public prominence during the first World War, in treating the psychological consequences of brain injuries, battle fatigue and "shell shock." Thus, practical application and social utility provided, from the beginning, a significant locus for the development of the behavioral sciences.

During the years since World War II, the behavioral sciences have expanded rapidly, and three trends are particularly worth noting. Firstly, the methods employed in these fields of studies are increasingly technical and precise. Basic research in the behavioral sciences makes increasing use of mathematical models and statistical methods; and a similar emphasis has extended into such practical applications as psychotherapy, with the development of behavior modification techniques, biofeedback, sexual therapies, and group techniques. Secondly, the distinction between the behavioral and biological sciences is increasingly blurred. The techniques of biofeedback indicate how useful physiological methods can be in dealing with problems of learning and psychotherapy; and experience with psychoactive drugs has shown the value of handling significant emotional and psychological problems by drug treatment, or -- more effectively -- by judiciously combining drug treatment and counseling. Thus, physiology has come to the aid of psychological medicine. Conversely,

the behavioral sciences have begun to add important new insights to somatic medicine. For instance, epidemiological research is teaching us how far any individual's mode of life and personality, patterns of exercise and ways of coping with stress can affect his liability to coronary artery disease and similar physiological malformations. In this way, applied psychology will put us in a position to develop preventive and corrective health measures for dealing with significant physiological pathologies.

Finally, in the psychological as in the medical field, the provision of "health services" is increasingly concerned with enhancing personal life by augmenting normal functions. As the techniques of social psychology, physiological psychology and psychotherapy expand into the areas of learning and group relations, family dynamics, sexual functioning and child development, the pursuit of "health" is moving away from the narrower, traditional sense of "freedom from disease," and is approximating the promotion of "complete physical, mental, and social well-being," as covered in the newer WHO definition. So, the last 30 years have at the same time seen the behavioral sciences becoming more "scientific," by adopting more precise and sophisticated techniques from psychophysiology and psychometrics, and also more "socially oriented" and "technological," through finding practical application to problems of education and nutrition, public policy and personal satisfaction.

These progressive expansions in our conception of "health," and in the public's expectations about the delivery of "health services," may be used in passing to throw light on one topical controversy about medicine and the medical profession. It is sometimes claimed today that the current professional proce-

dures of medicine are themselves "iatrogenic," or "disease producing" -- i.e., that the procedures, rather than the patient's actual "complaints," define and even generate the conditions with which the physician deals. At one level, the number of tonsilectomies and hysterectomies performed in any given county is determined (on this view) primarily by the number of surgeons who have to be kept busy, only secondarily by any clearly indicative symptoms of organic pathology. At another level, the widespread condition known as "hypertension" commonly gives rise to no specific complaints, and warrants "treatment" only if we accept one particular interpretation, about the likelihood of the affected individuals developing serious circulatory problems at a later stage. The conclusion which some critics draw from these and other examples is that the medical profession is incorrigibly committed to somatic or physiological conceptions of "disease" and "treatment"; and that the general public can hope to free itself from iatrogenic illnesses only by destroying all medical monopolies, deprofessionalizing the provision of health service, and developing lay systems of "self treatment" and mutual aid.

The standpoint adopted in this present report is a different one. A narrowly somatic or physiological conception of disease does, in our view, have real and serious defects. Yet we do not believe that these shortcomings are insuperable, or that current medical practice is irredeemably committed to any such view. Rather, all those concerned with the pursuit of health and the provisions of health care services -- whether as professionals, or as shapers of public policies, or as concerned members of the lay public -- need to understand how the scope of the health sciences and biobehavioral technology have changed during the current century, and become more responsive to the social, behavioral

and ethical dimensions of the resulting problems. Heart disease may appear a purely somatic condition, in a way that (say) anxiety or industrial injuries are not. But our current understanding of the antecedents of even the most clearly somatic illnesses brings with it the plain lesson that no such sharp distinction can safely be drawn. Pathological conditions of all kinds have social or psychological, as well as organic or physiological determinants. In the long run, therefore, the most effective way to deal even with somatic problems may well be to devise social or behavioral, rather than purely somatic solutions.

1.3: Health and Social Policy: The Blurring of Responsibilities. If the boundaries to such terms as "health" and "medicine" have changed so strikingly during the 20th century, so too -- in consequence -- have (1) the social locus of professional medicine and psychotherapy, (2) the ways in which biobehavioral research and practice pose social or political problems, and (3) the resulting needs to subject these enterprises, along with their attendent monetary and social costs, to public scrutiny and/or governmental intervention. More particularly: it is increasingly difficult to draw any hard and fast lines between "medical" or "health" services, and human or social services of other kinds. As the goal of the health professions shifts away from managing diseases and postponing death, toward improving the quality of human life and functioning -- both individual and collective -- the practical decisions facing physicians and psychotherapists are moving away from strictly "technical" matters, toward the patient's work habits and plan of life, his social relations and even his basic ethical attitudes. Correspondingly, the problems of "health" now facing governmental and other policy makers -- in the new WHO sense, of "health" as physical, mental,

and social well-being -- make it increasingly hard to mark "health problems" and "health services" off from other kinds of social problems and social services.

Health problems, in consequence, nowadays overlap with problems of nutrition, and environmental protection, employment policy and education, social welfare and even recreation. (1) To begin with nutrition: at one extreme, there are still many Americans whose health is at risk from nutritional deficiencies -- including many young children, who can be permanently damaged by under-nutrition. Lacking coordinated policies for tackling the problems of health and nutrition together, physicians may find themselves unable to treat the resulting "ill health" in the only effective way. The one "medicine" truly specific for starvation -- viz., food -- is not a prescription drug, and the provision of food stamps is not administratively recognized as a "medical" matter. At the other extreme, many Americans are exposed to the diseases of over-nutrition and, with the shift of attention from infections to (e.g.) heart disease and stroke, the significance of dietary habits is becoming clearer every year. On the level of national politics, however, public policies toward eating, drinking and other forms of "consumption" have, hitherto, been almost exclusively concerned with restrictions and prohibitions, designed to limit or control the use of alcohol and narcotics, or at best to banish the last marginally carcinogenic additive from commercial food products. The political imagination of the country has not yet been captured by the truly massive health problems generated by sheerly excessive calorie intake, and by over-consumption of fats, refined sugars and cholesterol -- which result in far more disabling illness and premature death than are ever likely to be caused by commercial food coloring agents.

(2) Similar obstacles exist also where health policy runs up against policies for employment. There is growing evidence today that hypertension and similar states spring largely from unsatisfactory conditions of life, notably from bad working conditions and similar forms of stress; yet professional physicians and policy makers alike still tend to assume that such circulatory conditions are best treated in pharmaceutical ways, even though an effective national program for tackling such conditions would have to attend also to the social practices involved. In this and other areas, issues of medical policy cannot be set apart from issues about employment standards and occupational safety, industrial organization and similar broad social issues. Indeed, the long term side effects of ignoring these social factors and continuing to "medicalize" such problems -- that is, defining them in terms amenable to purely somatic therapy -- may in many cases be even worse than the original conditions themselves.

(3) In the area of environmental protection likewise: there are clear associations between current levels of air pollution and the widespread occurence of respiratory disease, in several parts of the U.S.A. the public water supply is also in an unsatisfactory condition, while the spread of carcinogens may evidently result as much from atmospheric pollution as from food coloring agents or the like. Yet long-established political and administrative habits still hamper the development of effective policies for tackling problems of environmental health. The sheer political "clout" of the industries generating much of this air and water pollution has stood in the way of the reforms needed to prevent it; and the political debates about ecology and environmental protection still too often treat the subject as concerned only with esthetics and amenities -- "the professor's petunias are wilting" -- while ignoring the grave and widespread public health problems arising from inadequate

(4) Such overlaps between health problems and other social problems occur in the behavioral, quite as much as in the biomedical field. Public education and private psychotherapy (as we noted) are both specialized descendants of the general psychological services traditionally provided by the clergy; and their differentiation is still not yet complete. So, problems of definition and jurisdiction still arise along the boundaries between health policy and education policy. Some psychologists would claim that the best school and college teaching has always relied on techniques of "behavior modification"; and argue that discoveries of contemporary psychology can contribute significantly to raising the standards of education, by making possible still more effective methods of instruction. Yet any model of education as aimed at "psychic health" has only a restricted part to play in debates about educational methods and policies. The professedly "value free" character of psychological inquiries and techniques -- whether in intelligence testing, learning theory or behavior modification -- limits their value when it comes to dealing with the "value laden" problems of educational policy and administration; and the long history of institutional separation between medicine and education only accentuates these limitations in practice. As a result, though the problems of education and mental health are becoming increasingly close, important and difficult issues of social policy and public values will continue to arise at the boundary between them.

(5) Similarly, with welfare and social services: in the field of family welfare, for instance, better psychological understanding of normal child development, and its vicissitudes, have led to the development of "family therapies" and other procedures. These and similar innovations are helping to take much of psychiatric medicine out of the asylum or state hospital, and into new areas of

public service, which involve broadly social and ethical values as well as more strictly medical techniques. This "deinstitutionalization" of mental treatment, and the associated development of community mental health services has some undoubted virtues; yet it is not clear that the resulting social and policy overlaps between health and general welfare services are truly understood. In other directions, too, the expansion of behavioral technology is inevitably leading many health professionals across the thin line separating matters of "health" from broader issues of "welfare." The physician who advises an obese client to change his diet and working habits rather than taking (say) hormone pills -- like the public health official who seeks to drum up support for improving his community's water supply -- is thus inescapably led into moral counseling as well as orthodox medical therapy, political lobbying as well as administrative planning. Finally, with the spread of the health services into "augmentive" medicine and psychotherapy, physicians and psychotherapists are offering people the chance not merely to escape actual disease, but also to live fuller and richer lives; and this change is blurring not merely the distinction between health and education, but even that between health and recreation. (At what point do "occupational therapy" and "recuperation" blend over into "recreation," or "encounter groups" become a new kind of social club?)

This progressive erosion of the lines that formerly separated health matters from other matters of social and political concern faces us with practical problems, most particularly, because our institutions respond very slowly to such changes. So long as the main therapeutic tools of medical practice were certain straightforward prescription drugs and surgical procedures, one could delineate "medicine" from its neighbors rather sharply, and it was a comparatively simple matter, as a result, to administer a "medical" insurance scheme or insure the

safety of new "medical" agents. As the health field broadens, by contrast, we are compelled to pay more attention to social, environmental and similar issues; and existing patterns of policy making and administration place correspondingly more constraints upon us, thus exposing the overall public welfare to arbitrary bureaucratic distortions.

Since the practical problems with which the average citizen needs professional help are less and less easily classified into neat categories -- legal as contrasted with medical, physiological as contrasted with psychological, welfare problems as contrasted with spiritual problems -- existing institutions and practices are thus liable to become correspondingly obsolescent. Administrative structures or insurance schemes designed to tackle the problems of one decade place obstacles in the way of developing social services (including health services) matched to the actual needs of a later decade. As we shall see, therefore, some of the most urgent problems raised by innovations in "biobehavioral technology" are, precisely, those concerned with monitoring the functioning of our institutions and administrative structures, so as to anticipate and guard against this kind of institutional obsolescence.

1.4: Perspectives on the Analysis of Health Policy. In considering the social context within which innovations in biobehavioral technology are developed and utilized, we have been led to pick out three connected sets of themes for special emphasis:

(1) the two-way nature of the interaction by which technological changes (in medicine and psychotherapy, as elsewhere) influence, and are in

influenced by, changes in the broader social, economic and political situation.

(2) the one-sided ways in which the actual complex determinants of health (environmental, social and behavioral, as well as somatic) are currently reflected, alike in the accepted priorities for biobehavioral research, and in the general patterns and modes of medical and psychological treatment.

(3) the need to redefine the different responsibilities in the provision and utilization of health services -- firstly, between the medical and scientific communities, on the one hand, and individual patients on the other; secondly, between the government, on the one hand, and private individuals or institutions on the other; and, finally, between all the different public agencies concerned with social problems and social services of one kind or another.

These themes will be picked up again at the end of this report, when we turn to discuss the policy goals suggested by our analysis.

In the chapters that follow, we shall deal in turn with three topics specifically raised in the Congressional mandate for this special study. Chapter 2 will consider the role of scientific research, particularly government sponsored research, as a factor in the generation of new biomedical and behavioral technology, with special reference to the broader context within which research is undertaken, and the special conditions required in order to provide for the fruitful pursuit of scientific discovery. Chapter 3 is concerned with public attitudes towards biobehavioral research and services,

notably with changes in the nature of public knowledge about, and concern with, biobehavioral science and technology. Chapter 4 describes the existing means available for the ethical and legal channeling of biobehavioral technology, and draws attention to some of the points at which the available mechanisms appear to fall short of current needs. Finally, in Chapter 5, we shall present a number of general policy goals, and indicate some of the options for moving toward these goals that were identified and discussed in the course of our discussions at Santa Fe and elsewhere.

In addition, three case studies are included as appendices, at the end of the report. Their aim is to give some more "body" to our analyses and proposals, by illustrating how they apply to some representative examples in more detail. The first of these studies deals with the problem of "hypertension," as an issue in preventive medicine, having complex social, environmental and political, as well as technical implications. The second study surveys recent changes in the field of mental health, with particular reference to the use of psychoactive drugs and "behavior control" techniques. The last study reports on, and discusses, the political issues raised in the current controversy about "Recombinant DNA" research, as illustrating the new ways in which research scientists are having to become "accountable" for the social implications and effects of their work.

Let us touch briefly, here, on just a few of the issues that will be discussed at greater length below. (1) At the scientific end of the biobehavioral spectrum, there is a significant lag in dealing with the problem of <u>research priorities</u>. Whereas the wider public is increasingly aware of the relevance to health of social and environmental factors, with all their

practical overtones and implications, the biomedical research community -- when left to run its own affairs -- is still inclined to overemphasize the somatic (or physiological) aspects of disease, which lend themselves better to straightforward, uncontroversial investigation within the monastic calm of the scientific laboratory. This divergence of interests is liable to enhance the strains currently affecting the "social contract" between the United States scientific community and the American public at large: the contract that has survived, at least, since the establishment of the National Science Foundation under the Truman administration, following the "concordat" outlined in Vannevar Bush's report, Science, The Endless Frontier.

At the present time, some serious rethinking is called for, both about the need to protect and promote the vital interests of basic science itself -- for all those reasons which Vannevar Bush rightly underscored -- and about the need to enlarge the range of options taken into account in determining the priorities of applied research. As to that: biobehavioral scientists sometimes dismiss all suggestions that the lay public must play some part in this rethinking, on the ground that non-scientists are unqualified to appreciate such inescapably technical issues. Yet it must be replied, with equal justice, that many professional scientists and physicians are also handicapped in such discussions, since they do not always understand the public values and interests involved. Whatever may be the case within the field of pure science, accordingly, public priorities for applied research in our view require discussion by joint lay/professional groups; and active participation by lay representatives in this kind of decision making is, almost certainly, the best way of rebuilding an informed and sympathetic public constituency for biobehavioral research.

(2) Meanwhile, at the practical end of the spectrum, we shall be echoing the general concern with the problems of cost control, while noting that the pursuit of "technological fixes" for problems of a complex social character can often increase the apparent need for expenditure, without producing any commensurable results. (Having too much money or expensive apparatus can block effective problem solving, as surely as having too little: those who have to work with "sealing wax and string" are obliged to tackle their problems with more ingenuity and imagination than those who are enslaved to elaborate technological machinery.) Nor is this simply a matter of the quantitative economics of health care: the current emphasis on sophisticated technology has also affected the character of health care services in the United States, in qualitative ways, not all of them desirable.

For example: there has been a growing centralization of medical facilities in large capital intensive hospitals equiped with costly and wonderful apparatus, whose operations are nonetheless remote from the actual lives and problems of the people to whom they provide care. The technical arguments in favor of this centralization are clear enough; but the social arguments against this tendency also need be considered with equal seriousness. In the field of education, the principles of lay participation have never been abandoned and the corresponding tendency toward centralization has been successfully resisted -- particularly, in the area of primary education: in that field, the price to be paid for centralization, in the way of depersonalization and the loss of democratic accountability, has been judged unacceptable. The field of biomedical and behavioral services is faced with essentially the same policy choices. If we chose to resist depersonalization and loss of democratic accountability, we could do so; just as those tendencies have been resisted in the pro-

vision of education. And the experience of other countries -- Israel, say, quite as much as China -- encourages a belief that community health centers and family planning services (like primary schools) could be made generally available if we pleased, if not on every block, at least within ~~each~~ easy walking distance of every city home.

If we are ever to reach that point, however, it will be necessary to set aside the current preoccupation with the technology of health care, and to recognize that technological issues are currently masking other, underlying social and economic issues. To provide general health care by setting up a network of neighborhood "health centers," for instance, would certainly have the effect of reducing, both the technological component in health care delivery, and the scale of capital investment required in costly apparatus. Yet the improvement in the national health brought about by such a program would probably be greater than anything that could result from further massive investment in technologically sophisticated equipment. Similarly, the diehard opposition of the American medical profession to any general replacement of "fee" payment by a system of "salaried services" (such as has long been instituted in the field of education, and even in the armed forces' medical services) probably does more to drive up health costs than any technological innovations. At any rate, these social and economic choices need to be faced explicitly; and we need to recognize, in particular, that policy choices taken on this level are prior to -- and largely preempt -- all subsequent technical decisions about the utilization and control of innovations in biobehavioral technology.

To sum up: the biomedical scientists and research psychologists, physicians and psychotherapists who create and utilize biobehavioral technology

carry on their professional work at the present time within a rapidly changing social context. During the last few years, the activities of biobehavioral science and technology, medicine and psychotherapy, have moved away in a dozen directions from a simple concern with "bodily defects," to embrace social, environmental and other "problems of living." This expansion in the scope of the health and health related professions is a primary fact underlying all subsequent, narrower questions about the implications of technology with the general health field; and it has helped to set up a basic tension, which affects all decisions about policy for health and health services.

On the one hand, there is a continued momentum toward "medicalizing" all fresh types of problems ~~even~~ as they emerge, even in fields not hitherto regarded as the concern of the physicians or psychiatrists (including some that are fundamentally social, ethical or political rather than technical), and so to make over an even larger range of autonomy to the professional communities of science and medicine. On the other hand, there is a new but growing counter pressure toward "demedicalizing" the health services, and reclaiming the lay public's right to a say in policy and administration throughout the health field, even in medicine itself. In the short term, of course, the former direction of development is the more "comfortable" one, since it allows us to leave the present institutional arrangements just as they are; and, not surprisingly, powerful voices have recently been raised in its support. Yet, in the longer run, there is reason to believe that continuing to move in this direction alone will only aggravate the risk of polarization between the lay public and the biomedical professions, through failing to provide proper representation for the public's legitimate interest in the ethical and social aspects of contemporary health

science and health care. Moving in the opposite direction, by contrast, will mean accepting the need for some structural changes in the institutions by which biobehavioral research is currently undertaken, and health services provided, in the United States. Yet the question must be faced, whether it will be possible to deal effectively either with the political tensions between the biomedical professions and the public, or with the social and ethical problems raised by current biobehavioral technology, unless we are prepared to reanalyse the place of those institutions within the larger community, and devise changes designed to adapt to the new situation.

In the years ahead, this tension between "medicalization" and "demedicalization" will remain a basic element in all policy discussions about health and health related issues. Our current problems cannot be dealt with in any simple minded way, by choosing to move comprehensively in one of the two directions, rather than the other. We live in a situation in which, at certain times and in certain respects, it will be necessary for us to move in either or both of these directions; and we must take all our resulting decisions in ways that acknowledge, and balance off, the legitimate claims of both the professions and the lay public. For the biomedical research community of course has its own proper concern, to ensure that the intellectual and practical conditions for fruitful scientific work are not disrupted by the reckless and uninformed criticism of politically motivated "outsiders." Yet science and medicine may expose themselves to even more serious dangers if their professional communities adopt a purely defensive posture, and seek to preserve the existing institutional arrangements at all cost.

Throughout the present report, therefore, we have found it insufficient to consider "the ethical, legal, social and public policy implications" of contemporary biobehavioral science and technology with an eye to the pattern of institutions and administrative mechanisms currently in place: in addition, we have felt bound to ask ourselves also what alternative institutional arrangements are possible, and what new policy options would be created by adopting such alternative arrangements. Rather than confining ourselves to the content of possible policies for particular biobehavioral technologies, considered in isolation from their institutional context, we have accordingly interpreted the Congressional instruction to consider "policy implications" as including, also, implications for the institutional machinery through which policies for the health services and health service delivery are formed and implemented.

One final caution needs to be added at this point. Just because we have chosen to analyse and evaluate the development and influence of biobehavioral technology against a very broad social background, we have scarcely been able to suggest ways in which all the current difficulties in this area can be corrected by straightforward Congressional action. As will be apparent, indeed, many of these difficulties are simply particular aspects or consequences of certain much larger social processes, which are themselves too vast to be effectively controlled or directed by simple legislative or administrative measures The policy goals to which we direct attention in the final chapter of this report should accordingly be read, not as proposed "solutions" to specific "problems," but rather as possible ways of responding adaptively to -- and so lessening the severity of -- social conflicts and transitions that, in themselves, are probably unavoidable.

Chapter 2

Biobehavioral Research and Its Social Applications

2.1: The Multiple Pathways of Research and Innovation. Discussions about the implications of biobehavioral research, and about the policies that guide (or ought to guide) both the conduct of that research and the application of its results in health care, necessarily rest on assumptions about the nature of scientific innovation and its relations to the social context. For example: one particular view, which treats health care as "applied biomedical science" -- the view sometimes known as the Bench to Bedside view -- has played an influential part in the development of the existing institutions of health care and health research in the United States, and is presupposed in many current policy discussions about science, medicine and health care. (It can even be detected at work in Senator Mondale's Resolution, S.J. 71, from which the present "special study" takes its origin; since that resolution speaks throughout of the effects of biobehavioral technology on society, rather than of the responsiveness of that technology to society.)

Given their relevance to questions about policy for health care and biobehavioral technology, these assumptions need to be examined here with some care. In this chapter, accordingly, we shall explain our views on the nature and social context of biobehavioral research, indicating some of the ways in which such considerations bear on the decisions that affect the applications of biobehavioral research and technology in health care.

In criticizing many of the traditional views about the nature of research and how it impinges on society, we shall at the same time be arguing

that the scientific community has real and substantial needs. But our discussion will also suggest that the reactions of many contemporary scientists against calls for public accountability and for greater public participation in decisions about research policy, are based on oversimplified views -- not confined to scientists -- about the nature of the scientific enterprise itself.

Scientific discovery and therapeutic innovation are, in fact, complex processes, and relatively little reliable knowledge exists about their course and determinants, particularly in the case of twentieth century developments. The importance of gaining a better understanding about the nature of research, including the ways in which "practical applications" may be generated, is underscored by current pressures on biomedical scientists and the government funding agencies to concentrate on "applied," "mission-oriented," "targeted," or "categorical" research: intended to find solutions to specific health care problems as rapidly as possible. For the past decade, as a result, debates about the relations between "basic" and "applied" research have been often strident though, as Alvin Weinberg pointed out in 1967, "The argument about the relationship between applied and basic research -- the confrontation of the Baconian and Newtonian views -- has been raging since the 1700's." And, Weinberg cautioned,

> because the question [about the basic-applied relationship] is once more asked in sharp and urgent terms, particularly with respect to biomedical research, [that] by no means implies that new or particularly cogent insights have been attained.

To begin with, then, we would argue that stereotyped accounts of how research is done, in terms of "the scientific method" -- as found in the intro-

ductory pages of scientific textbooks -- bear little resemblance to what researchers actually do in their laboratories or clinics. The received wisdom about science tells us that research, new knowledge, and its applications progress incrementally, by adding each fresh "discovery," like a new "brick," to previously laid bricks in the slowly rising edifice of "truth." In traditional formulations, science is also held to be an autonomous, "objective" endeavor, in which scientists eschew dogma, are value-free, and rely entirely on experimentation and hypothetico-deductive thought. Another more recent element in the received view of scientific research and discovery concerns the role of "serendipity." Because serendipity is misunderstood as a kind of totally fortuitous, chance discovery, it has been elevated into a general explanation of the fact that basic research often yields unforeseeable new findings and applications.

Views of science contravening this traditional image have long been proferred by philosophers, historians, and by some scientists themselves. In 1975, for example, Sir John Eccles, a Nobel Laureate neurophysiologist, wrote:

> I experienced a great liberation in escaping from the rigid conventions that are generally held with respect to scientific research. Until 1944 I held the following conventional ideas . . .: First, that hypotheses grow out of the careful and methodical collection of experimental data. . . . Second, that the excellence of a scientist can be judged by the reliability of his developed hypotheses. . . . Finally . . . that it is in the highest degree regrettable and a sign of failure if a scientist espouses an hypothesis that is falsified by new data so that it has to be scrapped altogether. When one is liberated from these restrictive dogmas, scientific investigation becomes an exciting adventure opening up new visions.

Traditional views about the "essential nature" of scientific research impinge upon real-life decisions about the management of research in a number of ways. It is often assumed, for example, that although Science makes valuable contributions to the public good through practical application, the actual processes and needs of the research itself are "craft mysteries," which can be truly understood and estimated only by those actively involved in the research. The autonomy of Science is, as a result, not just an historical accident or operating strategy, but a precondition for serious research: any outside intervention in the real work of science by those not "in the know" can only have the effect of disrupting that work. A second assumption is that the requirements which scientists themselves perceive as necessary for their research have to be presented to prospective patrons -- including governmental agencies -- in the form of "non-negotiable demands." If the Federal Government decides to lend its financial support to Science, well and good; but, given the complex, selfdirected, and fragile nature of the scientific research enterprise, this support must be given (if at all) on Science's own terms.

About these basic assumptions, two initial comments need to be made. First: so far as concerns of choice of specific topics in very basic areas of scientific research, they contain a real kernel of truth. The question, which of several alternative lines of investigation shows most promise of improving our fundamental ideas about some given aspect of Nature, can certainly be approached only by people who are at home in the science concerned; and any temptation for governmental authorities to patronize one group of pure scientists rather than another, for reasons external to the needs of

the particular scientific discipline, should be resisted. (The Lysenko affair in Russian genetics illustrates the damage that flows from disregarding this maxim.) Secondly, however, any extension of this maxim to all the broader issues of "science policy" would be fallacious. The decision to give public financial support to scientific research at all is an essentially political decision; and decisions about what kinds of applied research to select for support involves not only technical considerations from within the discipline, but also considerations of social policy and priorities. As such, policy needs to be determined in ways that allow for adequate public "input."

Traditional accounts of the nature of research and innovation also tend to present a simplistic, unidimensional picture of how useful results, or applications, come about. In the biomedical or biobehavioral arena, this process is seen as progressing unilaterally "from the lab to the clinic" -- from unfettered basic science inquiries to an eventual useful application in the practice of medicine.

To challenge this lab to clinic (or bench to bedside) view of biomedical research is not to play down the importance of "basic" research, both as an endeavor in its own right and as an essential element in the acquisition of new medical knowledge and technique. It is simply to recognize the fact that has begun to be well documented in recent sociological and historical studies; namely, that biomedical research involves complex, two-way interactions between "categorical" (disease-oriented) investigations and more "fundamental" (discipline-oriented) research avenues, in addition to the critical social determinants already discussed in our first chapter.

To the extent that we acknowledge the complexity of biomedical research, we must correspondingly recognize that much of this work can be labeled as strictly "basic" (or "fundamental") on the one hand, or as "applied" or ("categorical") on the other hand, only with difficulty. As such, the different kinds of biomedical research fall along a continuing spectrum, directed toward the phenomena of health and illness. At one end of this spectrum, we are clearly in the area of "applied technology"; but, at the other end, it is hard to find any area of "basic" research so remote from practice that does not involve any prospective "practical use," at a sufficiently distant time. In most instances, characterizing research as "basic" or "applied" is further complicated by the need to specify whether this distinction is being applied to (1) the particular problem being investigated -- whether disciplinary or technical -- (2) the personal motivation of the researcher -- whether scientist or physician -- (3) the source of funding -- whether science-oriented or mission-oriented -- (4) the locus of the research activity -- university or hospital, say. Considering these four factors separately, we may be led to give very different characterizations to one and the same piece of research, which may qualify as "basic" by one standard, "applied" by another.

In sum, the "basic"/"applied" distinction is often used in a superficial way; and the labelling of research activities as basic, fundamental, applied, categorical, etc. is largely a heuristic device, having little reference to the actual course and determinants of biobehavioral research and innovation. If we study the actual course of biomedical research projects, we may be struck by these comments of Paul A. Weiss, whose own investigations into morphogenesis -- ranging from submicroscopic cellular biology

to surgical methods for nerve regeneration -- illustrate well the continuity between "basic" and "applied" research:

> Unbroken lines of development changes [in science] are apt to go unnoticed by those most closely and continuously involved in them, and it usually is left to the historians later to trace them and package them artificially into separate epochs, stages and phases.
>
> A similar artifact is the customary categorical distinction between "basic" and "applied" research. No more realistic is the conceptual separation between "theory" and "practice". . . . All such distinctions are a matter of degrees of interest and focus and varying proportions in the mixtures of methodologies applied, but certainly are not properties of the subjects under study. As nature knows no pigeonholes, so knowledge, and the research leading up to it, constitute unbroken continua. That is to say, no borders, fence posts, or other signs of discontinuity are met along the roads from the most fundamental principles of physics to the most sophisticated devices of technology. . . . from the most elementary discoveries in the cellular and developmental biology of animals to the prevention and cure of human disease. Pigeonholing is plainly a managerial device for the convenience, expedience and efficiency in handling practical affairs in the infinitely graded diversity of the real world, however, there is no counterpart for the labels that designate the various pigeonholes.
>
> . . . Of course, curious and purposeful investigators and practitioners alike ignore straightjackets to their thoughts and searchings imposed by extraneous formalisms. They shuttle freely between the "basic" and "applied" directions of the research continuum.

2.2: The Influence of Social Context on Biobehavioral Research. Contrary to the implications of the standard view, then, research and technological developments do not only, or even usually, flow unidirectionally, from the scientist's laboratory bench to the patient's bedside or society generally. Rather, the directions of scientific and technological research are strongly responsive to societal inputs.

There are, once again, historical reasons for our too-ready acceptance of the standard view. In terms of recent history, we have been strongly affected by greatly increased effectiveness of curative medicine, during and after World War II. This improvement was the practical consequence of applying new discoveries in biochemistry and pharmacology, and soon spread throughout the whole world of tertiary, or hospital medicine. It drew Federal funds on a large scale, into the support not only of the NIH, but also of basic research conducted within industry and by academic scientists. For a time, indeed, it seemed that biochemistry, molecular genetics and related sciences held the crucial "keys" to the relief of human suffering of all kinds. The faith in the power of medical science to bring Utopia (expressed in Sinclair Lewis's Arrowsmith with special reference to microbiology) was easily extended to "the biomedical sciences" at large. So, Society was advised to support basic biomedical research generously and uncritically, in the certainty that a better grasp of the inner secrets of Nature was the surest way of developing effective cures for human suffering. Knowledge would move from the esoteric domain of scientific understanding, where it could be pursued only on its own elusive terms, to the practical domain, where it would take the form of a cure for any ailment.

Hence have arisen the widespread expectation, still widely current among the general public, that science would bring us a continuing stream of dramatic, and dramatically effective, improvements in curative somatic medicine. Given the exaggerated character of these expectations, however, any prolonged failure for the Conquest of Polio to be followed by an equally spectacular Conquest of Cancer, Heart Disease, etc. has been bound to generate

some disappointment about the underlying programs of biomedical research. Along with this disappointment, there has grown up also a concern about the social risks and responsibilities involved in the new powers of biomedical science, and about the dangers of authoritarianism implicit in the exercise of esoteric knowledge.

Some of the recent disenchantment with biomedical research and the institutions that sponsor it also seems to stem from the illusion that all problems of health and illness can be solved by a "research blitzkrieg" -- an illusion that Rene Dubos addressed so eloquently in his book, The Mirage of Health. Alternatives to the standard, received models of the research process have begun to appear in the past 10 to 15 years, largely through the development of the "new" historical sociology (or social history) of science, which treats the enterprise of science not merely as an exercise of pure reason -- governed by its own procedures and progressing in isolation from its historical context -- but as an activity carried on by human inquirers -- partly as individuals, but largely within collective societies and institutions that interact with, influence, and respond to the larger society within which they function. The more complex and subtle analysis that is possible, given this newer perspective, avoids any suggestion that Science proceeds quite independently, and merely hands over its discoveries to Society as and when they occur: it focuses just as much on the interactions that take place at the interface between the activity of scientific inquiry itself and the goals, policies and activities of the larger Society.

In order to put this new understanding fully to work, in support of policy making in the area of biobehavioral technology, one would need many more detailed

sociohistorical case-studies than yet exist, of representative episodes in which biological science, medical technology and the like have generated (or developed in response to) social changes. Here, we can proceed only on the basis of the material currently at our disposal. In the Appendices to the present report, we have sketched fuller analyses of three sample episodes; but we suggest that -- as a basis for future discussion and policy-making -- the Congress would do well either to undertake, or to commission, a fuller and more detailed series of such studies. (Dr. Comroe's study of cardiovascular therapies for the President's Biomedical Research Panel, and the "Traces" study of contraceptive techniques for N.S.F., are two instances of what needs to be done in this respect.)

Topics for this kind of analysis might well include the following. (1) The development of microbiology and its relationship to the public health movement. As to this first example: it is clear, on the one hand, that the creation of bacteriology and related sciences during the second half of the nineteenth century had dramatic effects on Society, by way of urban sanitation, the control of waterborne infections and the like, with remarkable consequences for life expectancy in the general population. But it is equally clear that the social needs and demands that were met in this way antedated these scientific discoveries. (The squalor of the new industrial cities of the late 18th and 19th centuries was a topic for comment and satire at least from the time of Hogarth, and preoccupied many of the Utilitarian social reformers.)

What is not yet clear is how far, and by what channels, the urgency of these social needs communicated itself to the microbiologists, and so stimulated the questioning that led to the scientific developments in question.

Significantly perhaps, much of the pioneer scientific work in this field was done in France, where -- as Joseph Ben-David has emphasized -- biomedical research was generally carried on under the wing of hospitals, rather than, as in Germany, at universities. Given the overall impact of modern microbiology on human health, indeed, it is surprising how little is yet understood even in this prototypical case, about the manner in which the science grew up and about the steps by which its discoveries were put to actual practical use.

(2) The biomedical and behavioral influence of 20th century bacteriology. Historically speaking, there is only one other case in which the social influences of biobehavioral science have been demonstrated as clearly as in our first example: viz. the manner in which 20th century innovations in bacteriology, biochemistry and pharmacology have, firstly, led to the development of cures for -- in some cases, even to the virtual elimination of -- many of the infectious diseases that had been scourges of humankind throughout history; and secondly, have given human beings the prospect of modifying and controlling their own psychological states. Once again, there was demonstrably a reciprocal interaction between science and society in this field. Though the first sulfonamides were available before 1940, the main head of steam behind the development of penicillin and its successor antibiotics developed during World War II, in response to wartime needs.

However, the larger pattern of social processes, influences and interactions in which these antibiotics have played a significant part remains to be analysed. Among other things, of course, it includes the wide problem of world population. As many commentators have pointed out, population pressures are most directly the consequences, not of an absence of birth control, but rather of "death

control." (As for the current and prospective effects of psychotropic pharmaceuticals on individual and social welfare: certain of these are discussed below, in the Appendix on Behavior Modification techniques.) Here too, then, we are concerned with a complex and subtle network of interactions between, on the one hand, the changing patterns of 20th century life and public expectations and, on the other hand, the priorities of biobehavioral research and development, both in the academic and public sectors and in industrial laboratories.

(3) The polio vaccine. It would be worth studying the development of vaccines for poliomyelitis in more detail than has been done, just because it seems at first sight to be a prime illustration of the "Bench to Bedside" process. Evidently, the actual discovery of the Salk and Sabin vaccines could scarcely have been accelerated by the mere injection of more public money into vaccine research: yet, it is necessary, even in such cases as this, to bear in mind the complexities of the research process and of the research community, as these affect the distribution of effort and attention between different problems and lines of investigation, and the receptivity of the scientific community to novel ideas of different kinds.

(4) The social context and influence of oral contraceptives. The development of the contraceptive pill not only illustrates the inability of scientific competence, by itself, to generate a socially useful technology. It makes clear, also, the value to basic science of the opportunities created by social needs and technological investment. For the pressure to develop new varieties of oral contraceptives came from the social side: from the concerns

of a few individuals who saw clearly the real human needs of millions of women. And the resulting emphasis on biochemical technology and clinical research gave a strong impetus to the development of steroid chemistry itself, leading to the pursuit of new lines of basic research, and to the discovery of many new hormones and biochemical mechanisms hitherto unknown.

Given what we already understand in outline about the interactions of Science and Society, such examples as these illustrate a number of significant points. To begin with: a certain tension must be recognized, between the "analytical" or "reductionist" methods proper to much scientific research, and the more "synthetic" or "holistic" approaches needed for a well balanced system of health service delivery. To cite E.H. Starling: writing in 1921, he warned of the intellectual dangers involved in carrying over reductionist habits of mind into clinical practice, in terms that call to mind Goethe's earlier attacks on reductionist Newtonian science.

> The danger arose out of the fact that the method of physiology was, of course, largely analytical; the functions of the body were split up into their several parts and the conditions of each of these were studied, while the synthesis, which was much more difficult, was often forgotten. The physiologist in medicine played only with his pawn or his knight or his queen, whereas the clinician had got all the pieces in his hands. It was necessary for the physician to complete the work of the physiologist. While it was true that any advance of medicine on other than physiological lines would be chimerical, it must not be imagined that because they knew physiology they were aware of all the moves along all the files and ranks and diagonals of the chequered board.

The strong concentration on a mastery of the "basic" or "preclinical" sciences, characteristic of medical education in the United States since the time of Flexner, thus exposes medical practice to dangers as well as to benefits. And

the recent shift of attention in the Congress and elsewhere, away from the mere promotion of the biomedical sciences and toward a greater concern with "health care delivery," can be seen as an attempt to redress this balance: an attempt to modify old institutions and create new ones, that will promote the public interest in "synthesis" as well as "analysis," in distributive justice as well as scientific truth.

Again, we have to accustom ourselves to analysing the interaction of science and society in terms, not of oneway influences, but rather of reciprocally acting "feedback loops." Clinical and social experience, and the concepts developed to understand it, have a utility to basic science, as well as vice versa; and new methods are needed to take advantage of these connections. It has been suggested, even since the Johnson Administration, for instance, that all sorts of desirable biobehavioral innovations may currently remain "locked up" in the nation's scientific laboratories, instead of being developed and put into practical use. If there is any truth in this suggestion, the reason is not that the scientists concerned are indifferent to the possible significance of their work for clinical practice. Rather, it is that so few well established channels exist by which an understanding of clinical needs and problems can be "fed back" to the laboratory scientists, who as a result often remain unwittingly ignorant about the clinical potential of their discoveries.

In this respect, acceptance of the Bench to Bedside model is self-reinforcing, in ways that have unintended and undesirable social effects. To the extent that people underestimate the extent to which an understanding of social needs and demands can stimulate work in even the most basic of sciences, they

neglect the channels of communication through which biomedical and behavioral scientists might have the opportunity to learn more about the possible applications of their work. In this way, they are led to ignore the need for new institutional connections, which could facilitate a "transfer" of new knowledge into practice.

Finally: in making the proposals we do in Chapter 5 below, about novel institutional arrangements for the management of biobehavioral science and practice, we see these also as ways of making available to the public at large the information that needs to be taken into account, if the current aspirations toward democratic participation are to have any fruitful result. Only in this way can we hope to create a situation within which politicians, scientists and the larger public will share a common perception of the opportunities (as well as the dangers) implicit in new biobehavioral science and technology; and so help to dissipate the fears and suspicions that at present cloud the attitudes of the public toward the scientific and medical professions, and *vice versa*.

Chapter 3

Public Interests and Attitudes

3.1: Nineteenth Century Background. Public interest in scientific research and science-based technology is, of course, partly generated by expectations about the benefits to come than the growth of scientific knowledge, and those expectations are founded both on immediate experience and on more broadly based longer term assumptions about nature, human life and society. The peculiar course and circumstances of American history -- the establishment of this nation on a relatively unexplored and unsettled continent, as well as the intellectual traditions and urban-industrial social order it shares with Britain and Europe -- have done much to shape those assumptions. As a result, attitudes and institutions born early in the history of the Republic have had a persistent influence on American thinking, and are still at work, in seemingly paradoxical ways, is the arguments and apprehensions about science and technology being voiced today.

One powerful foundation for public support of scientific and medical activity in America has been the widely held view that natural and social resources are effectively boundless, waiting only to be tapped and utilized by human ingenuity. The ready availability of public land and the scarcity of labor (particularly skilled labor) encouraged this image of unbounded opportunity for much of the 19th century. In medicine, for instance, the absence of an educated elite meant that access to both professional education and professional care could at first be free of restrictions through licensing or formal institutional arrangements. Whether this was advantageous or damaging to health is not the present question: what concerns us here is that medical and scientific enterprise made claims on popular loyalty and support.

To the extent that scientific education and research needed sustained support, a mixture of state and private patronage was generally seen as the appropriate means. And although these needs were modest by present-day scales, and even by the standards of the time, the low level of public funding is not an adequate indication of attitudes and expectations toward science and medicine. Patronage was concentrated on the development of libraries, scientific collections and learned societies, which in turn nurtured learning, while the responsibility for the protection of public health was also a matter of general concern. Often, the threats to health were perceived as having external origins: diseases such as cholera, imported from foreign shores, was particularly liable to evoke organized responses. At the same time, the promise of improvement evoked measures to insure full utilization of resources, without needlessly restricting inventiveness.

On the whole, as science came to be identified with growing material prosperity based on useful knowledge, the middle decades of the nineteenth century were characterized by increased public commitment to the practical application of science. The establishment of the Patent Office, and the funding of agricultural research through the Morrill Act and the land-grant colleges, exemplify this confidence. Meanwhile, quarantine laws, and regulations to protect the public health, sought adequate control that would not exert undue restriction of commerce.

By the turn of the century, both applied science and medicine had registered striking achievements; and these successes gave substance to the reformed curriculum for both undergraduate and professional education. Engineers who had earlier learned their art in the field could now be educated in specialized

institutions, and medical training came to rely less on apprenticeship and more on laboratory and classroom instruction. While graduate degrees in pure science were still relatively rare, applied science and medicine increasingly led to productive and rewarding careers and social roles. By 1915 Charles William Eliot, former president of Harvard University, could propose "that this method of preventive medicine is the one which should be universally applied for the defense of society against the evils which afflict it -- such, for example, as alcoholism, prostitution and war."

While, in the arena of social policy, anxiety about possible conflicts between public good and private enterprise sparked debates about the regulation of business and commerce, it still seemed almost ludicrous to suggest that the scientific and medical enterprises could pose similar threats. On the contrary, science was most often pictured as the guardian of public welfare, and philanthropic activity which had formerly been promoted in charitable and moral terms now sought legitimacy through identification with medicine and science. The fear that science might be hobbled or corrupted by political intrusion seemed far more serious than the suggestion that science and technology could endanger health and welfare. Both the growing community of science-trained experts and the lay public argued that physicians and applied scientists should be allowed to pursue truth freely, in the interest of their clients. While this sentiment of support did not generally lead to substantial public funding, here too there were indications of a shift in the pattern of support to science.

The newly professional image of science and medicine was visible in the establishment, and growing authority, of professional societies; private fortunes

amassed through business and industry found ways of linking private enterprise to the support of science and medicine, sharing the opportunity for "doing well by doing good"; and the federal government moved beyond the limits of its earlier commitment to the health care of merchant seamen and the armed services, to protect the health of the civilian population at large. The establishment of the Children's Bureau (1912), the support to states for venereal disease control through the Chamberlain-Kahn Act (1917), and the Sheppard-Towner Act of 1921 providing "matching funds" for the protection of maternal and child health, were indications of a modest yet novel investment by government in medicine. Yet at no level was the public support of scientific and medical research primarily vested in the government and, particularly in the health area, private institutions and foundations remained the most important resource, as illustrated by lay leadership of the National Tuberculosis Association (1904) and the American Society for the Control of Cancer (1913).

This diversity in the sources of support for science should not, however, be read as public hesitation to endorse science. Rather, the evidence suggests that scientists themselves were not yet fully prepared to accept the burden imposed by heightened public hopes and expectations. The early decades of the twentieth century, in fact, found the public unambiguously enthusiastic about the achievements and promises of scientific and medical research. Where problems remained, it appeared that the solutions would lie in the spread of scientific knowledge and practical know-how.

3.2: The Contemporary Situation. It was the economic depression of the 1930s and the destructive effects of World War II (particularly the Atomic Bomb) that first aroused active and widespread fears that science had unleashed powers

beyond human control. While ever larger commitment of public resources brought undeniable achievements, the magic of science and medicine was not only inspiring but also terrifying. The economic costs of big science and big medicine spiraled, but the social costs were more difficult to evaluate: indeed, the highly technical character of much scientific research often led Americans to despair about fashioning adequate safeguards for the application of this knowledge. In some important areas public policy seemed to rely on specialized knowledge that limited the participation of laymen in the process of decisions. Atomic power both manifested and symbolized the close connection between the good and evil forces at science's command -- abundant energy could mean either a richer life or the destruction of life -- and this was only one of the many possible areas of conflict.

Even where there had at first seemed no room for "unintended consequences" (as with penicillin) unexpected dilemmas appeared. While syphilis could be treated simply and effectively for the first time, for instance, freedom from the fear of the disease might encourage sexual contacts on a scale that challenged traditional professional and personal values. Meanwhile, as medical prowess increased, the relationship between physician and patient altered. Whether individual care or community health was the focus of attention, there emerged problems of relative cost and benefit, contradictions between social gains and personal values, and the contesting claims of differential needs and expectations.

As a consequence of these dilemmas and ambiguities, public perceptions of science and medicine are in a state of some uncertainty. To begin with, it is no longer clear that, in regard to the value of scientific knowledge, there is any longer a unified "public opinion:" different sections of the lay public

now seem to take very different points of view. On some levels, the older enthusiasm for know-how still preserves its force: on others, a new skepticism and distrust seem to have taken hold, though it is hard to tell how deeply it is rooted in the public mind. Any discussion of public policy for biobehavioral technology needs, accordingly, to acknowledge the new complexities both in the actual tasks of technology and in public expectations and attitudes toward its practical application.

What do we know about the current state of these attitudes and expectations? There have been several studies of public opinion about science and technology in general, but little study specifically of biobehavioral technology or lay understanding of it. Before reviewing the major themes emerging from available studies, we need to consider some general issues about opinion research, in particular as it concerns public views about science and technology.

Four issues are worth touching on here. First: most opinion research has been conducted without any specific information about the respondent's "knowledge base." This can be important since, by using respondents who have no relevant information, it is possible to solicit opinions in ways that in fact create them. For preference, one should first assess the state of knowledge of a given population, and then look at its opinions, in light of that knowledge. Instead, the closest that opinion research comes is to give respondents the option of answering that they don't know, or have no response. In the available studies of public opinions about science and technology, the proportion of the population reporting a "do not know" or "no opinion" response is above average, compared to most public opinion surveys; and those responses

differ significantly with the income and education of the respondents. In 1974, the National Science Board, for instance, conducted a survey of public attitudes about science and technology. Asked a question about the general harm or good resulting from science and technology, 20 percent of those with less than a high school education had no opinion, while only 4 percent of those with some college experience had no opinion: likewise, 21 percent of those with family incomes under $5,000 per year report no opinion, while only 6 percent of those with an income in excess of $15,000 reported no opinion. So, where definite opinions were reported, they were apt to reflect the views of the more highly educated and wealthier segments of society. In future studies, it would be helpful to analyse better both why the poorer and less educated segments in society more often report no response or no opinion: whether this is because they are less informed, less interested, less certain of their opinions, or whatever.

A second problem is that most opinion studies about science and technology have tended to lump together all different sciences as "science" and all types of technologies as "technology" -- to say nothing of blurring the distinctions one might make between science and technology -- instead of soliciting opinions about specific scientific or technological issues. Yet behavioral science research strongly suggests that, as a predictor of behavior, the utility of a response is directly related to the specificity of the opinion solicited. The more that opinion studies ask in quite general terms about "science" or "scientists" or "technology," rather than about specific sciences or specific technological developments, the less likely is it that the opinions solicited will be significantly related to behavior.

A third, related issue is the problem that, where public opinions have been solicited about "science," these have drawn principally on a public image of the "hard" (or physical) sciences, rather than on ideas about the biological or social-behavioral sciences. (There seem to have been no studies of public knowledge, and opinions, about specific aspects of biological, behavioral or social science, or their associated technologies.)

Finally, while it may be informative to know what "the public" thinks and feels about science and technology, we must eventually face the question, how public knowledge and attitudes toward science and technology bear on the determination of public policy. The public has a variety of mechanisms for participation -- some formal, others informal -- and it does not represent a single coherent, homogeneous group: indeed, so far as we can yet tell, lay participation in science and technology involves many of the same processes and mechanisms that determine lay participation in other aspects of American society, such as voluntary associations and political parties. If this is the case, the opinions of some members or groups will be much more important for the development of science and technology policy than those of other societal groups.

3.3: The Public and Science. To begin by looking at public attitudes toward science: the 1974 opinion survey for the National Science Board investigated public preferences about tax expenditures for different types of science and technology. As shown in Table 1, science and technology leading to improved health care was most highly favored, while scientific and technological activities leading to improved weapons for national defense received least support. As the National Science Board report noted, these data must be interpreted with

TABLE 1

In Which of the Areas Listed Would You Most Like to Have Your Taxes Spent for Science and Technology?

	Percent Choosing Area* 1974
Improving health care	69
Reducing and controlling pollution	50
Reducing crime	58
Finding new methods for preventing and treating drug addiction	48
Improving education	48
Improving the safety of automobiles	29
Developing faster and safer public transporation for travel within and between cities	26
Discovering new basic knowledge about man and nature	21
Finding better birth control methods	18
Weather control and prediction	14
Space exploration	11
Developing or improving weapons for national defense	11
No response	3

(Adapted from Table, p. 148 in Science Indicators, 974, National Science Foundation, 1974.)

* Multiple responses were accepted.

care. They may reflect merely "areas of general concern to the public" rather than "the possible specific role of science and technology in dealing with" these issues.

There is another problem which exists with these data also. For example: while the public may support research to "reduce crime" in general, if this involved placing a special detention facility in a given community, there would probably be much less support for this measure in that community. This general principle, that private interests sharply modify general opinion support, probably holds for most of the issues listed in Table 1, and suggests that opinion studies of this kind would be more informative if they paid more attention to contextual considerations of kinds that affect the personal significance of the issues.

We may turn now to the recent survey by Etzioni and Nunn of the public opinion literature about science. They begin by noting that, within the intellectual and scientific community, current views about how the public sees science, scientists, and the role of science in society are mixed but predominantly negative. (They cite, for instance, Jerome Wiesner's concern about the "deep distrust of science and technology expressed by many in our society.") In sharp contrast, a number of actual studies suggest that, while there has been some "erosion" of the earlier faith in science, a significant part of the public still views science as a worthwhile and socially valuable enterprise, and the public image of scientists generally remains one of respect and trust. True: opinion has been shifting somewhat in directions unfavorable to science. In 1957, for instance, 43 percent of the public felt that science changes our way of life too fast and 23 percent saw it as a threat to people's ideas about right and wrong; but by 1964 the percentages agreeing to these positions had increased

to 57 and 42 percent respectively. But, taken overall, the national survey results compiled by Etzioni and Nunn continue to show general public confidence from 1966 to 1973, in a number of "institutional areas," including science. (See Table 2.) In all the institutional sectors listed, there has been some loss of public confidence, but the 19 point loss for science, from 1966 through 1973, is comparatively moderate.

So while there has been some increase in public concern about the impact of science, scientists as an occupational group have fared comparatively well in terms of public "prestige." According to the NSB study, in 1947 the public ranked scientists second in prestige, behind physicians alone, and they obtained the same ranking in 1974, also.

Again, while the public may have expressed greater concern about the impact of science on beliefs about right and wrong and rates of social change, a substantial majority still consider the net effect of science as good. Taking science and technology together, some 75 percent felt that science and technology had changed life for the better in 1974, as compared to 70 percent in 1972. Only 5 percent saw a overall change for the worse. Correspondingly, 56 percent described their general reaction to science and technology as one of satisfaction or hope in 1974, while 5 percent described it as one of fear or alarm. In assessing the benefits of science and technology, the public saw improvements in medical care as the most significant: their largest worries about the impact of science and technology had to do with its environmental impact. And while in 1974 fewer people than in 1972 felt that science and technology could solve most of society's problems (such as pollution, disease, drug abuse, and crime) nearly 25 percent still held such faith in science and technology, as compared

TABLE 2

Percentage of the Public Indicating "A Great Deal" of Confidence in 16 Institutional Areas: 1966 vs 1973

	Year of Poll		Change
Institution	1966	1973	1966-1973
Medicine	72%	54%	-18%
Science	56	37	-19
Education	61	37	-24
Finance	67	--	--
Religion	41	35	-6
Psychiatry	51	--	--
U.S. Supreme Court	51	32	-19
Military	62	32	-30
Retail business	48	--	--
Federal executive branch	41	29	-12
U.S. Major companies	55	29	-26
Congress	42	23	-19
The Press	29	23	-6
Television	25	19	-6
Labor	22	15	-7
Advertising	21	--	--

(Adapted from Table 3, p. 194 in A. Etzioni & C. Nunn "Public Appreciation of Science in Contemporary American," Daedalus, vol. 103 (1974), pp. 191-206.)

with 30 percent in 1972. Finally, even though in general the public is somewhat more worried about science and technology today, there still does not seem to be much support for imposing stronger controls on them. For example, of the public sampled in the 1974 study, 28 percent felt "that the degree of control that society has over science and technology should be increased," while 46 percent felt less control would be desirable.

While the larger public has maintained its support for science in recent years, there nonetheless exist segments of the public that are significantly disaffected toward science. Who are these people, and what is the source of their disaffection?

The 1974 NSB study found that, in terms of age, significant disaffection occurred chiefly among the elderly (60 plus); but the major differences in opinion about science were related to levels of education and income. For example: in 1974, while 71 percent of those with some college education felt that science and technology do more good than harm, only 54 percent of those with less than a high school education expressed this opinion. Likewise, 70 percent of those with an income in excess of $10,000 were positively disposed, but only 58 percent of those with lower incomes. Etzioni and Nunn reached similar conclusions. While science has lost some public support, they noted the largest disaffection "among politically weaker, less informed, less educated groups."

In passing, it is worth noting a concern voiced by Etzioni and Nunn. As we remarked, little is known to indicate how well informed the public is about science; but it appears that the public is in need of much more information. In commenting on the level of public knowledge, Etzioni and Nunn wrote:

> The percentage of respondents who did not know how they felt about a given institution provides a rough estimate of its remoteness from the public's mind. Compared to all other institutions in 1973, science received the highest percentage of "don't know's" (10 percent of all respondents and from 15-20 percent of low-status respondents) . . . This suggests that science might stand to gain respect by explaining to the public more fully what it is and what it does. Indeed, this would seem to present an important educational challenge to science, since those for whom science is most remote have similar social backgrounds to those least confident in science.

While it may be important that policy makers and scientists learn as much as possible about public views of science, there is thus a considerable need, also, for the public to learn more about science.

3.4: The Public and Technology. Let us now turn to review studies of public opinion about technology. As we remarked earlier, these have in general failed to separate out different types of technology, or even to consider how far the general public even views science and technology as separable. The National Science Board studies of 1972 and 1974 phrased all their questions in terms of "science and technology." Etzioni and Nunn claim that the "overwhelming majority of the public seems to confuse science and technology and sees science in a very technological, instrumental light." But La Porte and Metlay believe that "the public makes a distinction in their evaluations of the outcomes of scientific work and technological work." The work of La Porte and Metlay is based on a random sample of California adults largely similar to a national sample, and seems to provide some data for attempting to disentangle public opinions about science and technology respectively.

They note, for instance, the concern expressed by leading scholars and scientists (such as Edward Shils and Robert Morrison) about dwindling public

confidence in, and respect for technology and technologies. In relation to such issues as supersonic airplanes and the environment, there seems to be a "growing uneasiness about technological matters among a generally acquiescent public." Yet their own public opinion survey has less clear results. Thus, they found that, while there was strong support for pure science, the public felt more concern about the applications of science or technology. When asked if they agreed with the idea that basically science was good, but the uses of science were problematic, 75 percent agreed. Further, when asked to comment on the view that attempts to control inventions available for public consumption would lead to a worsening of life, only 37 percent agreed. Apparently, while their respondents considered that science should be permitted considerable latitude, some control over technological developments were necessary.

Certainly, the public seems to have priorities for determining what constitute more or less desirable technological developments. About 61 percent of La Porte and Metlay's respondents, for instance, regarded technological developments leading to an increase in employment as "extremely important."

TABLE 3

What Are the Important Values to be Considered in the Implementation of Technology?

Goal	Ranking
To increase employment	1
reduce pollution	2
make life enjoyable	3
reduce taxes	4
improve lot of poor	5
improve U.S. image abroad	6
increase leisure time	7

(Adapted from Table 3, p. 124 in T. La Porte and D. Metlay, "Technology Observed: Attitudes of a Wary Public," Science, vol. 188, April 11, 1975, pp. 121-127.)

In this respect, the La Porte and Metlay study of public attitudes toward technological development mirrors the findings outlined above concerning publicly acceptable rationales for science. In addition, it turned up a number of general conclusions regarding the public image of technology. For example:

(a) Expertise of a technical nature is highly regarded, and is seen as legitimately "exercising . . . a great deal of influence . . . in selected technological areas."

(b) Governmental leaders are given considerable less support than technological experts, and are seen by the public as exercising influence in too many technological areas.

(c) Business leaders "received little or no confidence, and were perceived as influential in four of six developing technological areas."

(d) While viewing itself as the least involved in six major developing technological areas, the public viewed "itself as the 'actor' most entitled to be involved."

Given the observation that the public generally is more supportive of science than of technology, we might ask what are the sources of concern about technology, and in what segments of the population is it most pronounced? A number of factors evidently feed into this concern. Of particular import have been the increasing impact of various technologies on our way of life generally, and on our environment in particular. Within the domain of medical care, the press has given much attention to the economic and ethical problems posed by a variety of health technologies. At the same time, the view of technology presented in the mass media has been disjointed and confused. Early life extending procedures, such as heart transplantations, were first hailed in the media as major triumphs; only later were the legal, economic, and sociopsychological issues examined by the press, and only then did the public begin to appreciate

the limitations of such technological developments.

Finally, the rise of interest and advocacy groups is providing the public with more information about significant technological developments. Such groups insure that, when scientists or experts speak up on both sides of a complex issue, both points of view can reach the wider public; and, in this way, the public may get a better sense of the political nature of science and technology, and so acquire more sophistication about the issues, and recognize that scientific and technological changes are amenable to some means of control.

We remarked earlier that major dissatisfaction with science and technology, taken together, occurs primarily among the poorer, the less educated, and the elder segments of society. The study by La Porte and Metlay suggests that, with respect to technology alone, the greatest alienation -- and the largest support for political control of technology -- are to be found among younger respondents, and those who define themselves as politically "liberal." As they note,

> The particular distribution of age and political identification suggests that those who are young and who identify themselves as "liberal" form the core of potential opposition to technological development and that such opposition is at least in part a function of different value preferences. The associations between political identification and attitudes about technology, distrust of decision-making, and concern for environmental impacts all make this point.

So, it seems that opposition to science on the one hand, and to technology on the other, may be based to some extent in different parts of the population. In addition, the disaffection with science -- being found most often among

economically poorer, less educated and older people -- may not provide a base for sustained political intervention. Opposition to technology, on the other hand, appears to be commoner among groups having potential political significance.

3.5: Conclusion. The studies surveyed in this report suggest some provisional conclusions about public views on science and technology. The public does seem to entertain somewhat different views on science and technology, when asked questions which emphasize the difference. In general science is viewed in a more favorable light than technology.

The public appears to be concerned about both the direct and indirect impact of science on society, and more so about the impact of technology. At the same time, it is aware of the benefits that have resulted from scientific and technological activities. And, the public appeals to definite but mixed values in legitimating the social worth of science and technology. In the absence of major changes the public will probably continue to support science strongly, although there may be increasing calls for action to regulate or control technology. Certainly, the public now feels it is one of the most disenfranchised groups in relation to policy decisions about science and technology, while seeing itself as having a strong right to influence such decisions.

To the extent that the public views biobehavioral science and technology in the same way as science and technology generally, these general conclusions presumably hold equally for them, too. However, since biobehavioral technology

is directly or indirectly related to the improvement of medicine, public anxiety may be less than in areas like environmental pollution or supersonic aircraft. The public has much interest in, and gives great support to, health related or medical science and technology: there may be concern about the costs of health care, but the public still strongly supports research aimed at solving problems that threaten life or health.

However, it is apparent that we need further studies which focus specifically on biobehavioral science and technology. Not only ought public opinion be solicited in this area, but the level of public awareness about such issues as behavior modification and genetic engineering needs to be surveyed. Finally, it would be useful to assess not only the nature of public knowledge and views about biobehavioral science and technology, but also their views about how they might participate in the regulation of biobehavioral applications.

Chapter 4

The Ethical and Legal Channeling of Biobehavioral Technology

Biomedical and behavioral research and practice are currently matters of intensive professional review, public discussion, and policy debate in the United States. Ideally, a social policy for channeling research on biobehavioral technology, as it moves through the spectrum from laboratory and human experimentation to regular use, ought to meet two separate requirements. It should provide rewards for developing new therapeutic practices based on scientific knowledge, and it should also create controls sufficient to protect the public at large from ineffective or unsafe procedures, while securing the personal rights of individuals, both as experimental subjects and as patients.

Historically, the scientific and medical professions have operated with considerable autonomy: this autonomy has been part of an implicit "social contract" between the professions and the larger society. In the field of therapeutics, this "contract" has included an understanding that biomedical and behavioral scientists will monitor the introduction of new therapeutic methods and regulate the use of experimental procedures on human subjects, especially patients. But, in recent years, this professional autonomy has been increasingly limited by the imposition of extra-professional controls and channeling mechanisms at the national, local, or institutional level.

The controls that channel the course of biobehavioral technology, whether facilitative and constraining, are numerous in their nature and sources. While we shall here deal particularly with ethical and legal controls, it is necessary to bear in mind that the character and operation of such controls significantly

reflect the social milieu in which biobehavioral research and practice are conducted at a given historical juncture. Prevailing social values and public attitudes strongly affect the types of channeling mechanisms generated within the professions at any time, or imposed on them by external sources. Thus, in recent years, public policy -- as promulgated by legislation, regulatory agencies, legal rulings, and guidelines -- has tended to emphasize the "constraining" aspects of channeling mechanisms, to the neglect of their "facilitative" aspects.

This current emphasis upon constraints reflects a complex interaction between several features of the current public milieu. In recent decades, science and medicine have been increasingly "demystified" and "secularized," and researchers have been increasingly portrayed as competitive, political human beings engaged in work that is largely routine and often boring. In this connection, it is illuminating to contrast the image of research conveyed to the layman in Sinclair Lewis' classic, Arrowsmith, with that conveyed by more recent works such as James Watson's The Double Helix and Joseph Hixon's The Patchwork Mouse. Science and medicine have also come to be perceived as "big business": as a complex, technologically sophisticated, and highly expensive enterprise, and one senses the revival of a populism that is in part expressed as a conflict of interests between the "little" citizen and "big" science or medicine. These populist concerns about individual autonomy, about our ability to control the future, and about the social consequences of science and technology, have helped to shape the types of control mechanisms imposed upon biobehavioral research and technology.

While Americans still seem confident of our general ability to control the future, and thereby avert many types of potential risks -- particularly in

health-related areas -- they seem to have declining expectations about major "breakthroughs" in the biomedical and behavioral areas. As a result, individuals are less willing to place themselves significantly at risk, for what they perceive as relatively small potential research benefits. This "risk-aversiveness" is encountered in many other areas of contemporary life also. But people's perception of risk is related to what they see as the source of that risk, and there is evidence (from the popularity of Frankenstein to current fears about recombinant DNA and behavior control) that such risks are perceived as particularly threatening when they originate in "science."

Finally, both the perception of risk and willingness to accept risks are affected by the level of the problem being addressed. When a major benefit has yet to be attained, there is greater willingness to assume often unknown risks: once that benefit is realized, relatively smaller known risks often arouse anxiety. Thus, the great desire for effective anti-schizophrenic drugs legitimated the testing and licensing of the powerful phenothiazine, chlorpromazine (Thorazine), despite adverse side-effects; but, now that an established armamentarium of major tranquilizers is available, there is greater concern to protect recipients against such side-effects as tardive dyskinesia. (Comparably, the potential risks from oral contraceptives were initially outweighed by the greater risks of unwanted pregnancies; but now that effective oral contraceptives are available, there is greater concern about the relatively smaller risks from such side-effects as endometrial carcinoma.)

Such public attitudes and expectations, though discussed only briefly here, can strongly affect the types of social control mechanisms that do,

and will, direct the course of biobehavioral science and technology, and so determine whether there is an equitable balance between facilitation and constraint.

4.2: Ethical and Legal Channeling Mechanisms. At the outset, then, ethical and legal controls cannot be adequately assessed unless one considers them in their social context; thus, the preliminary classification set out in Table 1, below, includes various types of societal influences (such as inputs from the public) that fall only marginally within the "ethical" and "legal" categories. Evidently, all of these types of channeling mechanisms do not and could not conform to a single, monolithic model; and different types of mechanisms have quite different merits and defects for different purposes.

Starting from a consideration of the drug and surgery models: one can classify channeling mechanisms according to their source or locus -- individual, professional or extra-professional. Individual controls, or ethical norms, clearly affect the conduct of biobehavioral research and practice; professional controls range from the scientist's or physician's own professional training and socialization to mechanisms utilized by groups of professionals within institutions; while what one may term extra-professional controls or channeling mechanisms may derive their authority from administrative, legal or legislative sources.

We can classify and analyze these channeling mechanisms further, in terms of their varied interactions and effects on various facets of biobehavioral science. Controls may operate formally or informally. Informal controls are those that operate primarily through interpersonal contact, and the con-

sequences that the professional sees as flowing from the approval or disapproval generated in that contact. Formal control mechanisms operate in a more structured and codified manner, through more clearly defined institutions or channels. As a glance at Table 1 indicates, many controls have both formal and informal components. Thus, for example, an investigator's decision about when to initiate research involving human subjects will be influenced by his own professional contacts and personal judgments, and by collaborative peer relationships, as well as by formal processes involving the funding agencies, regulatory bodies, or institutional review boards.

Another useful distinction is that between channeling mechanisms that operate "before the fact" and "after the fact." (In human experimentation, for instance, both informal and formal ethical controls are instances of "before the fact" controls.) When formal approval is required before initiation of a research project -- as with FDA permission for clinical trials of a new drug -- persons or groups other than the investigator are also responsible for assessing benefits and risks. When only subsequent review is expected, as in the review of a new surgical procedure by a hospital mortality or tissue review committee, the investigator is in jeopardy only if a risk eventuates and harm occurs. Malpractice law is a good example of "after-the-fact" controls: these operate most commonly and effectively in the medical, rather than the behavioral area, probably because it is harder to prove risk-related injury in the behavior area. For basic science the analogue to malpractice is the law of torts, which imposes on persons an obligation to provide redress if they negligently damage another person or his property; but, because basic scientific research creates immediate risk to far fewer

people than biomedical research or practice, the tort laws serve as a much less powerful constraint than malpractice law.

The United States legal tradition is on the whole weighted in favor of promoting innovative procedures. At most, the innovator personally, or users of a product, may have to pay damages for legally compensable harm; but this constraint is often weakened by limitations on the kinds of harm that are compensable, by the difficulty of establishing causation, and by the problem of assessing relevant damage. In medical research, the burden has been somewhat shifted by an increased use of regulatory mechanisms requiring prior approval, to a point at which the regulatory agencies, instead of balancing facilitation against constraint, have in some cases a predominantly constraining function.

While legal and legislatively-based regulatory controls are formal and extra-professional in nature, ethical controls are predominantly informal, and derive from the individually and professionally instilled values and attitudes of those engaged in biobehavioral studies. Normative ethical codes, stating what ought to be done in research involving human subjects, have been promulgated by many professional groups since the drafting of the Nuremberg Code in 1947, and have gained regulatory stature since 1966 in the Public Health Service's Policies and Procedures for the Protection of Human Subjects. These PHS regulations, coupled with the increasing public and professional attention to ethical issues, have greatly increased awareness of and sensitivity to ethical channeling mechanisms. However, there is a documented variability in the exercise of formal ethical controls by peer review mechanisms, and many areas -- particularly basic research areas, and

many spheres of behavioral work -- do not fall under the purview of formal ethical controls. Thus, the exercise of both facilitative and constraining ethical controls rests predominantly with the individual researcher.

In his book Reason and Conduct, philosopher H.D. Aiken analyzed four levels of moral discourse, an analysis that illuminates consideration of the sources and effects of ethical controls in the biobehavioral field. At Aiken's first level, called by others a "gut level response," we respond emotionally to whether or not we like what is going on. This level is often seen in mass media coverage of ethical issues in biobehavioral technology; and, all too frequently, in discourse among professionals as well. Aiken terms the second level the "moral" level, where discourse speaks, in a here and now, to the question, "What should we do in a particular situation?" Level three is Aiken's "ethical" level, moving beyond the existential concerns of level two to a concern with the general principles by which we justify our actions in particular situations. Finally, Aiken writes of the "post-ethical" level, at which we address the question of why we should be moral at all, why we should care about our fellow humans and what is done to them.

The issues arising on this fourth, "post-ethical" level are difficult to articulate, but it is these broader human concerns that ultimately generated the establishment of such bodies as the National Commission, as well as the current bioethics movement more generally. We can discuss principles at Aiken's third, or "ethical" level with greater care and familiarity: such principles as individual autonomy, personhood, accountability and truth-telling, or the value of knowledge. These principles we attempt to apply as level-two "moral"

or normative guides to action in particular situations, in which we have to assess risks and benefits, obtain informal voluntary consent, be accountable for the short and longer-term consequences of our work, or whatever.

4.3: Discussion. The preliminary classification of channeling mechanisms presented in Table 1 is intended principally to illustrate their complexity, and the need for a clearer definition and deeper assessment of professional practices and social policy in biobehavioral technology; and it raises more questions than it answers. We need to understand more fully, for example, how each type of control applies, and with what effects, to specific areas. Thus, one could use our classification to analyze how the exercise of any given control will affect different types of research or practice, ranging across the spectrum from basic research (e.g., recombinant DNA) to such applied, nontherapeutic behavioral procedures as those of sex therapy. That is, one can categorize the various goals of biobehavioral science and technology; and, having made policy decisions about the desirability of their pursuit, systematically assess which combination of channeling mechanisms will most effectively facilitate, or check, the goal's attainment.

As noted earlier, the differences between the various mechanisms that channel innovations in drug therapy and surgery illustrate the diverse ways in which biobehavioral technology is controlled, and the factors that should be evaluated in proposing new controls. Innovations in drug therapy are subject to a system of formal control mechanisms, principally exerted from without the profession through the procedures and regulations promulgated and legally enforced by the Food and Drug Administration (FDA). To move a new drug from laboratory study to clinical trials, and then to non-investigational use,

involves a long and complex process from animal toxicity studies through post-marketing requirements. Although directed primarily at the pharmaceutical industry, as the usual "sponsors" of a new drug, these requirements obviously act too as powerful control mechanisms on the activities of the clinical investigator. (In addition to FDA regulations, two other formal control mechanisms affecting drug development are the PHS policies for research with human subjects, and the regional and national systems for monitoring adverse drug reactions.)

The processes by which the efficacy and safety of new surgical procedures are evaluated are not, by and large, subject to the same formal controls. Innovative surgery does not fall under the purview of any public agency. Again, the chief source of surgical innovations is the individual physician, rather than an industrial research organization, and this fact has an important bearing on the economics of regulatory procedures. Whereas the direct costs of developing and evaluating innovative drug therapies fall directly on the drug industry, and indirectly on the consumer, the formal evaluation of new surgical procedures would have to be financed in ways that have yet to be determined.

Furthermore, except in the case of long-term expensive programs like organ transplantation, most new surgical procedures are not developed using federal research funds, and the application of institutional peer review mechanisms to innovative surgery is highly variable: it relies chiefly on ad hoc procedures established by local hospitals and medical groups, and their mode of operation depends very much on how the surgeon himself defines the "experimental" character of the procedure -- particularly on whether he

treats it as "research" or not. Again, with few exceptions (such as the international transplantation registry maintained by the American College of Surgeons and the National Institutes of Health) procedures have not up to now been developed for systematically collecting, analysing, and reporting data on the effectiveness and safety of given surgical procedures, old or new.

In principle, however, the scientific issues raised by innovative surgery are no different from those raised by clinical research on any new treatment: whether drugs or radiation therapy, psychosurgery or acupuncture. To the extent that a procedure is new and the evidence of its value inconclusive, the practice will not yet have been accepted within the profession. This being so, it should arguably be clarified or made the object of research designed to evaluate its effectiveness and safety by scientific standards.

In the past twenty years, the general methodology for evaluating therapeutic procedures has advanced greatly, and the controlled clinical trial has gradually evolved, using techniques such as random assignment, control groups, quantitative measures of change and advanced statistical methodology. But these procedures have rarely been applied to novel surgical procedures.

There are a number of historical and practical reasons for this difference. Some have to do with the training and "role-definition" of the surgeon, in contrast to other types of physicians; others have to do with the problems involved in using surgicals patient as "control." Again, to the extent that surgical interventions are often more "dramatic" than drug interventions -- more apt to be used in desperate or emergency situations, where all other treatments have failed -- there are certain differences inherent to the application of surgical

and drug therapies. So, except for "after-the-fact" litigation, existing formal controls seem to be not as well adapted to the "each-case-on-its-own-merits" approach of surgery as they are to the drug-therapeutics approach. Nonetheless, such long-standing controversies as that over the efficacy of various procedures in the treatment of breast cancer -- particularly, the radical vs. simple mastectomy dispute -- underscores the importance of developing better systems of controlled therapeutic trials in the surgical field also.

The formal controls governing drug research in the United States are, of course, the subject of current dispute, debate, and legislative proposals. Some analysts argue that the FDA's restrictive controls have created a medically-serious drug lag in the United States. A recent GAO report, by contrast, urges stricter controls in the area of new drug testing and charges that the FDA is not adequately protecting human subjects or the consuming public, by failing to enforce compliance with its own testing requirements. Similar debates have arisen equally about both old and new surgical procedures: from hysterectomy and coronary bypass procedures to psychiatric neurosurgery. The high costs of technologically complex surgical care, together with the absence of rigorous data about the efficacy and safety of many procedures, have generated what many see as the central ethical -- and economic -- issue in surgery today: that of "unnecessary" surgery. The need to resolve this issue is one factor that may impel more systematic clinical trials, for determining the efficacy of both innovative surgical procedures, and of those which are established but poorly evaluated.

4.4: Conclusion. The tasks of identifying the different channeling mechanisms at present influencing different types of biobehavioral science and technology, defining their components, and understanding of how and why they

take the form they do, are of more than academic interest: they bear directly on many aspects of research and practice that are matters of concern and policy decision both within and outside the professions. So, it is unproductive to debate the question of whether there are "too few" or "too many" controls in entirely general terms. Rather, we need to deal with more specific issues: e.g., how to define "innovative therapies," what criteria to use in determining the experimental-therapeutic status of new procedures, etc. And, in all such studies, we have to bear in mind the fact that "channeling" mechanisms can act, in different ways, either as facilitators or as constraints. Furthermore, we need to consider all the different parties affected by any new policy. Professional organizations, hospitals, medical schools, universities and research institutions, individual physicians, patients and their families, those financing research and practice, and the public at large, all have their own stakes in such a review.

As we scan the spectrum of biobehavioral activities, and the diverse channeling mechanisms that do, or might, affect those activities, it is clear that no single set of control processes can apply to the whole field. At present, formal controls most strongly affect areas of research and practice that place recipients at some definable "risk." They are weakest, or entirely absent, in basic research areas and in what we have called "augmentive" behavioral areas, where non-professionals play a greater role than elsewhere. In general, however, there is no comprehensive statement to be made about how well, or poorly, existing ethical and legal channeling mechanisms are succeeding in constraining or facilitating given areas of work; nor are we ready to propose specific new controls, given our judgment that the nature and effects of existing controls is not yet adequately understood.

Indeed, any proposed new channeling mechanism -- particularly a formal one -- should itself be regarded as an innovation, and evaluated against objective standards, just as much as a biomedical or behavioral innovation. We should ask, for example, how any new control will interact with existing controls; what its unintended side-effects may be; how it will affect the desired balance between advancing research and treatment and protecting the welfare of research subjects and patients -- not to mention the economic effects of instituting and implementing a new control.

With these considerations in mind, we reviewed the various controls now governing biomedical and behavioral research and practice, and discussed -- in rather speculative terms -- the idea of a National Therapeutics Review Board, with sections for various areas of biobehavioral technology. Our discussion ranged over the need for and possible functions of such a board, its possible composition, status and authority, ways of avoiding a complex, unidimensional regulatory agency, and the nature of "appeals" processes. Rather than proposing any specific new control mechanism of this kind, we would recommend at this juncture that various groups, within and outside the government, initiate and/or continue systematic and detailed case studies on the effects, and effectiveness of controls in various areas. To help systematize and coordinate research and policy deliberations, some kind of "national clearinghouse" is desirable, to coordinate and disseminate research results, legislative proposals, etc. dealing with channeling mechanisms for biobehavioral science and technology.

TABLE 1. Summary of Channeling Mechanisms for Biobehavioral Science and Technology

I. Individual.

A person's value and belief system, as shaped by his or her culture, society, family, education, religion, etc. Major source of ethical precepts.

II. Professional.

A. Scientist's/physician's professional training and socialization, including his role definition and professional values and beliefs.

1. Are personal and professional values and beliefs congruent?
2. Are there conflicts between research goals and societally-defined needs and values?
3. Are there conflicts between research and treatment goals in clinical areas?

B. Scientist's/physician's decisions about aspects of his work such as:

- when to initiate basic research
- when to initiate non-therapeutic research with human subjects
- when to initiate therapeutic research with human subjects
- where work falls on research to application spectrum.

1. These decisions involve informal and formal criteria for evaluating need, short and long term risks and benefits to individuals and groups, and efficacy; all judgments that do or should invoke ethical parameters. Particularly when human subjects may be at risks, we need to ask, what are the criteria for safety and efficacy, and who determines the adequacy of the criteria and the evidence?

C. Peer Mechanisms. Examples of these controls, which operate both informally and formally, include the following. Other types of peer controls are listed under II.E.

1. Professional Certification Processes
2. Participation in collaborative research groups
3. Relationships in informal professional networks ("invisible colleges")
4. Membership in professional organizations
5. Codes of ethics established by professional groups
6. Scientific and ethical criteria established by conferences and journals for presentation and publication of papers
7. Professional recognition and award; such as the Nobel Prize
8. Groups systematically collecting, evaluating, and disseminating research/treatment data (such as the organ transplantation and dialysis registries)

D. Ethically-based relationships between researchers and research-subjects in nontherapeutic and therapeutic research.

There is a need to define the relationships that ought to and can obtain in basic research areas, such as recombinant DNA, where there is not a readily definable "subject at risk."

E. Institutional Mechanisms. Professionals working within the various institutional settings where biobehavioral inquiries are conducted, such as hospitals, university laboratories, and industry, exercise various types of controls over their peers' work. Examples of these institutionally-based, professionally-exercised controls include:

1. Staff meetings and clinical rounds

2. Peer review committees for research with human subjects (following the PHS guidelines for such research)
3. Peer review committees for clinical practice, such as tissue, mortality, and utilization review committees
4. Ethical/Legal Research and Advisory Bodies. A number of professional groups in both the private and public/governmental sectors, have come into being in response to the ethical, legal, and social issues posed by biobehavioral technology. Representatives of these professional groups are the Institute for Society, Ethics and Life Sciences, the Kennedy Center for Bioethics, and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

III. Extra-Professional Controls.

A. Institutional. Examples:

1. Setting credentials, policies, for hiring and promotion
2. Administrative decisions on lines of research to engage in
3. Budgetary allocations

B. Legal. Examples:

1. Professional licensure
   No such control for Ph.D. basic research and for many types of behavioral researchers/therapists
2. Licensure of research facilities
3. Malpractice decisions, statutes
4. Decisions, statutes on questions such as consent, proxy consent, right to refuse treatment, definition of death, privacy rights, occupational health standards, etc.

5. Tort law

C. State and Federal Legislative Acts.

Establish regulatory agencies and their authority

D. Private and Governmental Funding Mechanisms, including:

1. Universities and foundations
2. Third-party payers: definitions of what is reimbursable re experimental/therapeutic status and re behavioral interventions
3. Agency (e.g. NIH, ADAMHA, NSFP, executive, and legislative policy decisions on appropriations for biobehavioral areas)
4. Peer review processes for awarding funds
5. Agency regulations, guidelines on conduct of research
   (a) with human subjects
   (b) basic research: recombinant DNA guidelines

E. Agencies to Assess Appropriate Use, Assess Efficacy and Safety. Examples:

1. Regulatory agencies
2. PSROs, HSAs
3. GAO

F. "The Public." Examples:

1. Mass media
2. Religious groups
3. Special interest groups (e.g. voluntary health organizations)
4. Public interest groups

Chapter 5

Public Policies and Policy Mechanisms

5.1: Introduction.

Science and the Public

> The conflict between academic research and public safety that has rocked Cambridge for the past three weeks marks a real and historically justified divergence. It is a conflict that has been intensified by the emergence, since the 1960s, of public participation as a functional tenet of democracy. And it took a major and, we think, good turn last Wednesday when the Cambridge City Council became the first local government in the country to intervene to limit scientific endeavors and showed it could balance the considerations fairly.

As the Boston Globe editorial writer for July 10, 1976, points out, current public concerns about the needs and implications of biomedical and behavioral science and technology have two complementary aspects. On the one hand, each of the problems in question arises within a particular context, raises quite specific issues, and has an individual "bite": on the other hand, each of them is made more acute by the contemporary demand that there should be greater lay participation in all decisions materially affecting the public interest. As a result, even the most technical and technological looking problems often turn out to raise, also, important issues of social justice, public accountability, and political representation.

In this report, we have set out to map some of the complex connections linking the biomedical and behavioral scientists' research laboratories to the social context within which health care is actually delivered. As we have seen, the lives and attitudes, health and sickness of the American population at large are affected by, and in turn affect the professional activities of

biobehavioral scientists and technologists in many varied ways. Scientific discoveries may have striking consequences for medical practice and the broader public welfare; but, just as often, changes in the broader pattern of social relations and expectations may create new opportunities for innovation in biobehavioral science and technology. When we address questions of public policy in the biobehavioral field, therefore the complexity of these interrelations is a prime consideration.

In analysing and evaluating "the ethical, social, legal and public policy implications of biomedical and behavioral science, technology and services," we have been impressed by the multiplicity of decision points along the road between the research laboratory and the locus of health care delivery: i.e., the multiplicity of points at which policy options arise that can affect the country's "health system." At the scientific end of the spectrum, for instance, policy choices between alternative lines of biomedical and behavioral research can serve either to encourage or to counteract the current emphasis on the somatic determinants of health or ill-health, as contrasted with the environmental or social determinants, with all the practical consequences that flow from such an emphasis. At the consumer's end of the spectrum, other policy options can largely shape the manner in which, and the terms on which, the American public has genuine access to the great variety of health services theoretically available to them; and the varied patterns of health service delivery in other countries today clearly indicate that alternative policies could have resulted, and might yet result in this country too, in the development of a quite different pattern of relations between professional health care practitioners and their clients. (If Americans insisted on having locally

controlled health centers as urgently as they insist on having locally controlled primary schools, the problems of creating such centers would be a matter not of technological ingenuity, but rather of political will.)

Given the complexity of these interactions, it is a subtle and delicate task to establish and maintain a fruitful adaptation of Science to Society -- particularly, of biobehavioral technology to the nation's state of health. New problems are created in this area, not merely by changes in the content of biobehavioral technology, but also by changes in the context of health care, in the life habits of the public at large, and even in the basic structure of social relations; since changes on any of these levels can significantly modify the legitimate needs or demands of the different agents involved -- whether scientists or technologists, physicians or administrators, politicians or lay people.

In developing this present report, we have become especially conscious of eight general policy goals which seem most closely related to the "ethical, legal and social" problems of biobehavioral technology, and which are therefore in urgent need of attention. Three of these goals have to do with the roles of science and scientists in the process of biobehavioral innovation:

(1) Reconsidering the priorities for scientific research in relation to biobehavioral technology;

(2) Enlarging the scope for public accountability by the scientific community; and

(3) Developing new methods for assessing the social costs and benefits of biobehavioral technology.

Three of them have to do with the roles of biobehavioral technology in health care, and its relations to the administration and monitoring of health service delivery:

(4) Developing mechanisms for the evaluation of biomedical and behavioral therapies;

(5) Improving social control over health costs and health service priorities; and

(6) Increasing public participation in the local administration of health care.

The two final goals are more general in their scope:

(7) Redefining the scope of "expertise" in the areas of science, technology and health service; and

(8) Developing mechanisms for the continued monitoring and evaluation of policy making in the biobehavioral field.

All of these policy goals are directed toward what we see as Congress's continuing concern in this area, from the time of Senator Mondale's hearings until now. All of them (that is to say) are directed toward increasing the role of the larger community, of democratic procedures, and of broader public interests, in channeling the application of biobehavioral technology to serve the social and political ends of our society, without in the process stifling the professional enterprise of biobehavioral science itself. As a result, all of them are presented within the essentially pluralistic context of American society: with an eye to representing and harmonizing the distinct but legitimate interests of all the parties involved -- including the scientific research community, the professional providers of health care, and the citizen-

taxpayers who are also the final recipients (or "consumers") of health care services.

We shall be discussing these eight sets of policy goals here in broad terms, and seeking to clarify the goals toward which they are directed. It does not seem to us that, in this field, one can formulate any general or universal "allocation principles," or develop any simple "algorithms" for deciding our policy problems; so we have concentrated rather on questions about the policy process, hoping to indicate some of the alternative means, or options, by which the goals might be achieved. Nor have we taken sides between the different options, or made any very specific proposals for reform, since these would call, in each case, for more elaborate and sharply focused studies than we could embark on here. (The Commission may wish to sponsor sample studies of this kind at a later stage in its deliberations on the special study.)

5.2: Policy Goals for Biobehavioral Science and Technology.

(1) Reconsidering the policy mechanisms and priorities for scientific research in relation to biobehavioral technology. The current debate about the place of science and technology in contemporary society, and about the proper roles of the medical and scientific professions, has reawakened questions about the politics of scientific research -- notably, about the policy mechanisms by which research priorities are set -- that go back to the arguments about the social control of nuclear physics, and about the place of "basic science" on the national science, in the years immediately following World War II. This debate has once again called in question the standing of scientific research (including biomedical and behavioral research) as a

recipient of public support and finance; and it provides the occasion for a thorough reappraisal, not merely of the public administration of science, but above all of the manner in which research priorities are currently determined and decided.

The encouragement of responsible and wisely directed scientific research in the biobehavioral area is, of course, strongly in the public interest. If needless obstacles are placed in its way, the chief long-term victims will be, not the scientists themselves, but the entire community. In this respect, the implication of some current rhetoric about science -- that the public interest lies in protection from the activities of scientific researchers, rather than in the promotion of their work -- must be heavily discounted. The central goal of policy for biobehavioral research should therefore be, not to hamper the progress of scientific research in general, but to insure that it is directed and conducted in fruitful, responsible and discriminating ways.

While seeking to counteract any public "alienation" from the scientific enterprise, however, we equally need to ask ourselves whether, in the determinations of research policy and priorities, scientists can hope to retain, undiminished, the degree of autonomy to which they have become accustomed over the last 20 years. In this respect, it is important to see where the line must be drawn, between those narrowly technical choices which are most appropriately and efficiently made by the established process of professional "peer review," and those other broader questions about research priorities that inescapably raise social and political issues. Once a particular budget line has been established to support research on (say) the molecular biochemistry of cell division, the further subdivision of those funds between the available "research projects" can

no doubt, in normal cases, be left to the professional judgment of the molecular biochemists and cell biologists themselves. Away from this purely technical level, quite different issues are involved. Decisions about the allocation of funds between work on different branches of science or types of diseases, or on disparate aspects of health and ill-health, take us into the realm of ethical, social and political considerations; and the full confidence of the public in the relevant processes of policy decision depends on its being clearly seen that the ethical, social and political interests of the wider community, in all their variety, are being adequately represented in those processes.

Taken in its entirety, the problem of insuring that legitimate public interests are fully, broadly and fairly represented in the process of setting priorities for the public support of biobehavioral research, raises complex and varied issues. Different kinds of research involve different values; and, in each case, the most effective mechanism needs to be found for dealing with the resulting questions. As to the internal values of science: the questions that arise about the funding of the "purest" branches of basic science clearly differ from those about the funding of basic research that has evident prospect of practical relevance -- to say nothing about directly "applied" research in clinical medicine or elsewhere. (Research on physical cosmology, for instance, perhaps should compete for public support with symphony orchestras and art galleries, rather than with medical research.) As to the mechanisms of policy decision: the issues look quite different, depending on whether we see the central problem as that of insuring proper representation for <u>the public</u>, or rather for <u>public interests</u>. In the determination of socially fruitful research priorities for applied science, the inclusion of "public representatives" on the

responsible committees and councils is only one -- and not necessarily the most effective -- possible means of getting "public interests" taken into account; and it needs to be considered just how the involvement of lay persons in the public direction of scientific research can contribute toward insuring that the "output mix" of biobehavioral research serves the relevant lay interests in the most balanced manner.

Two distinct sets of considerations are relevant at this point. On the one hand, there are grounds for putting a good deal of trust in the spontaneous decisions of the scientific research community, when those decisions are adequately informed about the actual needs of the larger society. In radar and medicine alike, for instance, the fruitfulness of wartime research during the early 1940s resulted less from any direct public participation in research decisions than from the scientists' own heightened awareness of the country's practical needs. (Often enough, indeed, the scientists' grasp of what was technically feasible made it possible for them to propose brand new lines of research, e.g., on microwave radar, that neither the public nor the military planners were in a position to foresee.) On the other hand, there are reasons for thinking that, at the present time, the decisions at which the scientific research community tends to arrive, when left to itself, are not adequately informed about broader social needs. The division of the overall NIH budget as between the different Institutes is determined by negotiations within the NIH, and between NIH and the Congress, in which different groups of research scientists press the technical claims of their various programs in the competition for appropriations. But it is not clear that, in the process, the scientists concerned either have, or seek out, any

real opportunity to assess the social significance of their work, or to measure the relative importance of their different programs against the evidence of well-documented public interests. (If it turned out -- to give just one example -- that malnutrition in our inner cities is responsible for serious neurological damage in the general population, are there any existing channels by which this knowledge would immediately influence -- or, better still, be sought out by -- the scientists at NIH working on neurological disease?)

In thinking about the policy processes for determining research priorities in the biobehavioral sciences, accordingly, the Commission will need to discuss both how suitable individuals can be identified and recruited to serve as "public representatives" on the various public bodies involved, and also what other means exist of seeing that all relevant social needs and public interests are taken into account in shaping the research programs of NIH and other agencies responsible for directing and conducting biobehavioral research. These questions touch on the current structure and operations of NIH at more points and in more ways than we can discuss in detail here. In this respect, significant changes are in fact already under way within NIH, which -- if carried through -- would be useful steps in the directions we are proposing. For instance, there has been a first partial reorganization of the Director's advisory committee; there has been a broadening in the responsibilities of Study Sections, to embrace certain ethical issues (particularly, in the realm of "human subject protection") as well as technical matters; there has been a tentative move toward setting up new Study Sections for "sociomedical studies" and related fields, though this project apparently remains blocked within the upper reaches of the DHEW bureaucracy; and there is a real prospect that creation of the proposed National Ethical

Advisory Board will make it possible for the NIH to move into the discussion of social, as well as more narrowly "ethical" issues.

At some other levels, however, much could still be done. Though the Advisory Councils of the different National Institutes of Health could, in theory, serve as forums for the fruitful representation of public interests and needs, they are currently encouraged to do so only to a very limited extent, and the present methods of selecting "lay representatives" are open to question. (The public interest is not adequately served by the political appointment of busy celebrities like Mr. Frank Sinatra, however well intentioned they may be.) If the Commission wishes to pursue the problem of "public representation" further, indeed, one thing it may be helpful to evaluate is, just how representative and effective these Advisory Councils currently are, and how their operation can be improved. Meanwhile, some other major Federal agencies for the support of scientific research (e.g., the National Science Foundation) do not even have the full range of Study Sections and Advisory Councils existing at NIH; and, once again, the Commission may find it desirable to evaluate the workings of those other agencies, before proposing the creation of any new institutions.

Finally, there is the question of "community action" and "community representation" on a broader scale. The response of the Cambridge City Council to the problem of possible biohazards in Harvard's "Recombinant DNA" program is only one illustration of a more general issue. The task of promoting and channeling the vigorous and responsible development of scientific research, as an element in the national life, has to be dealt with at many levels and in many different places: not just in Washington or Bethesda but in states and local

communities across the country, not just on the central budgetary level but at other more peripheral points, wherever significant decisions about science are taken.

This need carries with it, also, an opportunity. If the political situation of America's scientists has weakened and eroded over the last 20 years, one reason for this has been their unwillingness to spend time and energy seeking out and developing a sufficient constituency of sympathizers and supporters in the larger community. Nothing could do more toward overcoming this weakness than a readiness on the part of the scientific community in the United States to "open up" the argument about their own priorities and policy preferences to public view, and to draw in to the discussion a fresh population of informed and interested laymen, who could develop into the sympathetic political constituency the American scientific community at present sorely lacks.

(2) Enlarging the scope for public accountability by the scientific community. To carry these issues one step further: the historical development of the natural sciences has reached a stage at which research scientists are having to accept a substantially higher degree of "public accountability" than they have been accustomed to up to now. In this respect, the recent move toward better protection of human research subjects is only one of several moves toward reintegrating the natural sciences into the wider community. For instance: whatever constitutional protection scientists might be able to establish for their "freedom of inquiry" under the First Amendment -- an issue which has never been adjudicated in the Courts -- it is now, for the first time, an active and lively question whether the very pursuit of certain lines of research

may not expose the public at large to "clear and present dangers" whether in the form of radioactive contaminants or of "rogue" viruses.

In this respect, without questioning the good will and hard work that went into the development of the NIH guidelines for recombinant DNA research, it is a real question whether enough was done to insure that the interests of the communities affected by the research were fully represented in the process: so, however adequate the actual content of the resulting guidelines may in fact be, there is no way in which, as matters stand, they can be generally perceived as being adequate. However exaggerated some of its rhetoric, the counterattack by the Cambridge City Council is a reminder that other considerations and parties are involved: neither on the national level, nor locally, do adequate forums apparently exist in which ethical, social and legal issues such as those raised by recombinant DNA research -- issues of kinds that are bound to arise again in the future in other cases, quite unpredictably -- can be argued out and resolved in ways that meet all legitimate concerns.

The question of "public accountability" is, however, a broader one than this first glance at the DNA problem suggests. In considering how biobehavioral technology may affect their welfare or interests, the public at large are entitled to assurances of at least three different kinds. (1) They are entitled to protection against direct harm or injury from the acts of biobehavioral scientists and technologists, whether in the form of "biohazards" or otherwise; (2) they are entitled to be told, as early as possible, about any new technologies that are coming onto the scene which may have major effects on their modes of life and/or on the structure of society; and (3) they are entitled to have their views taken into account, both about what things are currently going

amiss in the health care area, and also about what things they themselves see as constituting "good health," and so as the proper goals of health policy.

Clearly enough, these three classes of "public interests" in the implications of biobehavioral science and technology raise issues of quite different kinds, and cannot all be dealt with by the same institutional mechanisms. Even the case of recombinant DNA is a complex one, and raises issues of all three sorts. For, quite aside from (1) the potential biohazards of the basic research itself, the longer term possibilities opened up by the developing techniques of "genetic engineering" both (2) stand to affect human life and society in some very profound ways, and in addition (3) would give us the means to perform all kinds of novel "corrective" and "augmentive" procedures, with major implications for our conceptions of "health" and/or "normality."

The biohazards problem (1) is, of course, already being tackled by several government agencies, while the whole judicial system stands ready to intervene in case questions of tort liability arise about DNA research. Meanwhile, the questions raised by recombinant DNA research about (3) the nature of "health," and the development of new criteria of health, are just those that should be dealt with by the procedures discussed earlier, in connection with our first set of policy goals. There remains (2) the problem of developing a public "early warning" system: for drawing attention to radical new technologies, and provoking a public debate about their likely consequences for the general welfare and for the future of society. Here, the effective discussion is only beginning: the short term problem of biohazards has up to now largely distracted attention from longer term questions about the practical applications that may flow from recombinant DNA research.

This, indeed, is one of the chief kinds of questions posed in the original Mondale Resolution, and we shall have more to say about it later on. For the moment, it is important simply to put on record the debt that is owed to the research scientists involved for taking the initiative, and opening up the issues of recombinant DNA research at a time when the wider public had no reason to know what was on the way. The question is, how institutional arrangements can be developed, by which this individual initiative will become a matter of course, rather than a novelty or an exception: institutional arrangements (that is) by which scientific research workers will automatically accept and respect the need for public accountability, as a normal exercise in professional responsibility.

In pursuing this policy goal, too, it is important that scientists should not see themselves as under attack, and so adopt a defensive posture. Since contemporary research involves possible hazards of quite novel kinds, scientists need to cooperate in working out procedures and mechanisms which fully satisfy all legitimate demands for public accountability, wherever there are genuine grounds for bringing scientific research under review. This need is not confined to individual scientific researchers. It applies, with still greater force, to the professional societies and institutions by which the interests of the scientific community are promoted and pursued.

So, it does no good for such crucial organizations as the National Academy of Sciences to behave in ways that give the impression of "holding the public at bay." Nor does it help matters, either, for leading scientific agencies of the national government to define their functions in too narrowly technical a way, and shut their eyes to the social implications of their activities. Al-

though "scientific autonomy" may be an effective organizing principle in the determination of research priorities, it is not in itself a value that can any longer be pursued without qualifications or exceptions. Rather than continuing to defend Science from outside criticism or regulation of any kind, the public spokesmen for Science would do better to help in devising methods of accountability that will leave the actual enterprise of Science as unhampered by regulatory processes as legitimate public needs permit.

(3) Developing new methods for assessing the social "costs" and "benefits" of biobehavioral technology. Any proposal to introduce broader social considerations into the determination of public priorities -- whether for biobehavioral research or for the delivery of health care services -- presupposes that we have sufficiently precise ways of assessing "social costs" and "social benefits" in this area. At the present time, this is not the case, and we need to develop better "measures" or "indicators" for all the key variables, if we are to deal with the relevant social considerations in a subtle and discriminating way. Otherwise, there is a real danger that our political decisions will continue to be distorted by overreliance on excessively narrow economic definitions of the key terms involved.

This general problem is familiar to those who have studied the problems of environmental protection: there the task of reanalyzing the "social costs" incurred through industry's uncontrolled and untaxed use of "the commons" -- air, surface water and the like -- has recently been receiving some overdue attention. But the same problems arise, with equal urgency, in the areas of health science and health care delivery. How are we best to interpret terms like cost and benefit, effectiveness and impact, assessment and accounting, as

they apply to innovations in biobehavioral science and technology, or to health service delivery systems? In such contexts, our "indicators" or "measures" will need to reflect the actual values, needs and preferences of the people affected in ways for which no clear "dollar cost" at present exists.

In the industrial sphere, inadequately costed use of "the commons," resulting from reliance on misleading economic indicators for "business efficiency" and the like, played a substantial part in encouraging the inefficient and polluting use of natural resources. In a similar way, a concentration on limited, technical aspects of biobehavioral science and health service delivery, without any adequate costing of their other unintended prices and consequences, can have an equally misleading and distorting effect on health investment. In both cases, the problem is to make sure that our reliance on current economic concepts and indicators does not distort the perception of our political aims: still more, that it does not guide us in directions which will actually frustrate the fulfillment of those aims.

5.2: Policy Goals for Health Care.

(4) Developing mechanisms for the evaluation of therapies. There is one other major area in which the public interest is at present particularly ill-served: viz., in the evaluation of medical, surgical and psychotherapeutic procedures, therapies and treatments. A full scale administrative mechanism exists, of course, for monitoring and regulating the development and introduction of new pharmaceutical preparations and devices, before they are put into general medical practice; and we have been very conscious, in our discussions, both of the positive services provided by such agencies as the Food and

Drug Administration, and of the criticisms to which their current structure and operations have recently been exposed. If we consider rather the broader field of medical, surgical and psychotherapeutic procedures, by contrast, the general public has at present no way of satisfying itself about the efficacy and merit of the treatments or therapies recommended to them by their professional advisors. And since, even in the pharmaceutical field, the effective distance between the FDA and the actual recipients of health care is so vast, the lay public is too often confronted with a straight choice between following "expert" advice on trust, or walking out.

Meanwhile, it is a commonplace in the world of professional medicine that the efficacy of many "routine and accepted practices" of long standing has never been subjected to full and detailed scientific evaluation by acceptable modern standards; to say nothing of some recent, fashionable surgical procedures, such as coronary bypass surgery. And, if this is true within the most narrowly technical of medical fields, it is certainly no less true in the burgeoning field of psychotherapy, "behavior therapies" and the like.

In our meetings at Santa Fe and elsewhere, the possibility was much discussed of developing some kind of Therapeutics Evaluation Board, responsible for promoting and accrediting evaluations of medical and psychotherapeutic procedures of kinds that the public is currently compelled to accept on trust. The precise specifics of any such proposal would need very close examination. Some very different patterns are clearly available: these could range from a publicly sponsored advisory agency for "medical consumers," by way of a clinical research agency empowered to issue non-mandatory "certificates of efficacy," to a full scale regulatory agency similar to the FDA, with elaborate mandatory powers. At the very

least, all authenticated information about the general efficacy, limitations and/or side effects of medical, surgical, psychotherapeutic and other health related procedures, should be readily available to "consumers" of health services, or their organizations. Since the aim of this proposal would be to bridge the gap between "experts" and the lay public, this kind of evaluation could not be left to an expert panel alone. Rather, what is needed is a "consumer oriented" agency, having not only the power to assess "efficacy" and "social costs," but also the prestige to influence the direction of research on new types of therapy and treatment modalities. This being so, the further problem arises of recognizing how research on new therapies and treatments (and the associated decisions about research priorities) are to be best related to biobehavioral research generally: particularly, that for which NIH is responsible.

In this connection, the President's Biomedical Research Panel has urged that the research tasks and functions of the National Institutes of Health should be delimited narrowly: they have argued, for instance, that NIH should not be required to concern itself <u>either</u> with problems relating to health care delivery, <u>or</u> with questions about the efficacy of new therapeutic agents, treatment modalities, or programs of preventive medicine. Serious doubts have, however, been raised about these proposals. For it is not clear that the Panel's recommendations really confront the complexities of the choices involved, or do anything more than demand that the traditional autonomy of the biomedical research community be preserved in a rapidly changing situation.

Nor is there any obvious ground for consensus on the central issues of the Panel report. By now, both the Congress and the wider public are evidently coming to perceive the efficacy of medical and other health procedures as a matter of national responsibility: the kinds of programs of evaluation that are currently sponsored and/or mandated by the Food and Drug Administration in the case of pharmaceutical agents, and are being recommended by the Commission itself in the case of psychosurgery, will surely be extended, as a result, to other types of medical and surgical procedures, and to health care delivery systems also. So, the question that needs asking is, not so much how NIH can be spared from involvement in these further responsibilities, as how these new tasks are to be most effectively related to NIH's central responsibilities for basic science.

If the problem is restated in this way, the choice it calls for is not easy. Whether the duties of NIH are enlarged to include therapy evaluation, or whether some other research agency is created for that purpose, difficulties will be created for the biomedical research community in either case. On the one hand, it is the received wisdom -- as expressed in "Shannon's Law" -- that any involvement of NIH in matters of health care and health service delivery only dilutes the quality of its scientific work. On the other hand, while NIH at present has the capacity to attract the best scientific manpower in the biomedical field, any policy that resulted in a diversion of public funds into a competing research agency for clinical evaluation and research might, in the longer run, pose a more serious danger to the scientific supremacy of NIH.

(5) Increasing social control of health costs and priorities. The development of biobehavioral technology has social and political implications for health

care in the area of health service costs and priorities also. For the most part, we have avoided concentrating on the specifically economic aspects of health care delivery and related services in our discussions. We have done so, not because we consider economic issues unimportant, but rather because most of the technical questions about health care costs, resource allocation and the like, seemed to us to be properly statable and answerable only when viewed against the background of larger social and political issues and policies.

In studying the changing scope of biomedical and behavioral practice, for instance, we repeatedly noticed how prior commitment to a particular pattern of health care services can influence the professional values of the practitioners involved -- whether physicians, medical administrators, or whatever; and this commitment may, as a result, dictate a particular kind of reliance on new (and often very costly) technological apparatus. To cite one extreme example: the determination to keep terminally ill human beings alive at any cost, even in a vegetative state -- whether that decision rested finally on the most admirable ethical principles, or the fear of litigation -- would involve the health service system in a vast investment in expensive machinery for "preserving life" (or "prolonging dying") to the detriment of other kinds of health care. In less obvious ways, likewise, any preoccupation with the somatic determinants of health and ill-health, or neglect of the social and environmental determinants also encourages physicians and administrators to invest in "technological fixes" which may, by epidemiological standards, be more expensive than they are effective.

In the long run, it is hard to see how the problem of health service costs and priorities can be dealt with, without bringing them under more direct social control. At earlier stages in the development of modern medicine, it may have been legitimate to regard the practical problems of health care as "technical" problems for the medical profession and its immediate associates. In the future, this view will surely be less and less acceptable: both, because the actual content of health care problems increasingly involves ethical and social, as well as technical issues, and also because so large a fraction of the costs of the health care system are being paid out of tax money. From now on, it will be necessary (as Lewis Thomas argued) to justify all elaborate investments in "high technology" equipment in terms of a broader system of social values and priorities; and policies which encourage such investments will have to be decided on quite deliberately, and defended, in relation to that broader scheme of social priorities -- in competition with (e.g.) anti-pollution measures, new employment policies, policies for nutrition, and the rest. That being so, it should be clear that all such decisions finally rest on a political basis, and that the entire American electorate has a legitimate stake both in the procedures by which the decisions are made, and in the steps that are taken to monitor and control their consequences.

(6) Increasing public involvement in the local administration of health care. The changes outlined in the first chapter of this report, in the social context of health care and in the very concept of "health" itself, have significant implications for the control of health care administration at the point of delivery. As matters stand, health care professionals -- physicians, psychiatrists, surgeons, etc. -- retain a substantial monopolistic control over

the actual provision of services to the client or consumer. As a result, patients often find it hard to be confident that the services actually provided take sufficient account of their own social situations, ethical beliefs and patterns of life. Rather, the professional inclination to "tunnel vision" caricatured many years ago in Bernard Shaw's play, The Doctor's Dilemma, is growing stronger not weaker: being reinforced by (for instance) the need to select technical procedures of kinds that are "reimbursable" from medical insurance.

This "over technicization" of health care delivery can probably be overcome, only if the recipients of health care are involved to a much greater extent in its organization and administration, and if those services are oriented towards the specific needs and problems of particular communities, work places, etc. Such an orientation would naturally help the health professionals involved to focus on those elements of the social context that may be as essential for the delivery of full health care as the more narrowly technical factors. And, further, such a reorientation might well make it possible to provide health services that were not only more relevant to the patients' actual situation, but are also more economical.

In our discussion, we heard reports about "health service units" or "group practices" in which the organization and administration are run jointly by the professionals and the lay public involved; and these reports suggested that an open collaboration can be of immediate benefit not only to the public, but also to the professionals themselves. So long as the providers of health care are tempted to set themselves apart from (even, above) their clients and patients, they only encourage exaggerated expectations on the part of the lay

public, which subsequently give way to disillusion at the lack of success, and may eventually result in litigation. When they approach their patients, instead, as colleagues rather than expensive benefactors -- not to say, miracle workers -- they can reasonably hope to develop a better understanding about the actual needs of these patients, and so win back some of the confidence and respect that has been eroded over the last 10 or 20 years.

In this respect, the professional providers of health care -- like the scientific community -- can well afford not just to "mend their fences" with the larger public, but to encourage the development among the lay public of the capacity for knowledgeable involvement in health related matters.

In this respect, the new "health systems agencies" provided for in P.L. 93-641 could create a fresh opportunity for involving the lay public in the monitoring and administration of health service delivery at the regional and local level. If experience with the recently established PSROs provides any guide, one cannot be wholly sanguine that this will in fact happen. Although the PSROs too are supposed to operate "in the public interest," it is already apparent that they can easily be "taken over" and run by the professional guild of health service providers in their own interests; and there is a danger that citizen participation in both PSROs and HSAs will -- aside from a little populist rhetoric -- be neutralized, if not toally frustrated. The secrecy with which some PSROs have begun to operate can serve only to protect the interests of the professional guild <u>from</u> public scrutiny not to promote the delivery of better service <u>to</u> the public. (Why should the public not be allowed to find out how different hospitals and/or physicians are evaluated by their colleagues? Why should not PSRO assessments, either of individuals or of institutions, be

public documents?) The institutions of government in a democracy are properly directed, not to entrenching monopolistic practices still further, but to defending the larger interests of the consumer against the abuses of monopoly power, whether by industrial corporations or by "learned professions." Indeed: one very helpful task the Commission might choose to undertake is that of evaluating the operation of PSROs and other novel institutions for monitoring the quality of health care.

5.4: Other More General Policy Goals.

(7) Redefining the scope of "expertise." The general thrust of our present argument is not to call in question the need for professional expertise in the fields of health science and health service delivery. On the contrary: there is clearly a need to develop and maintain technical facilities and skills of the highest quality, as one important resource within the entire health service system. Instead of denying the claims of professionalism, we would argue that the benefits of expertise should be more widely shared, and that institutional obstacles to the fruitful collaboration of professionals and the lay public should be further lowered. It should be one goal of policy, accordingly, to scrutinize and redefine the scope of expertise in the biobehavioral field and to modify the legal and institutional framework of health care so as to meet the actual needs of a rapidly changing situation.

So long as the actual content of medical and psychiatric knowledge remained intrinsically scientific and technical, as it was during the post-Flexner era, the technical concerns of health care professionals were -- understandably, even if never wholly justifiably -- rather sharply separated from the human concerns of the lay public. Given the current broadening in the scope of health needs

and health services, by contrast, there are strong arguments for allowing broader access to the specialized knowledge which has, during recent decades, become the private preserve of the medical and health related professions. Just as, within future health care systems, the values determining the "appropriate" use of new biobehavioral technologies will have to be public values, rather than technical or professional ones, so too the skills and knowledge mobilized in the course of health care could with advantage be spread more widely.

In certain respects, the technicalities of physiology or psychiatry will no doubt remain matters for specialists; yet that is no reason for making the entire body of medical understanding an arcane mystery, or for preserving rigid professional boundaries in the face of broader social needs and priorities. On the contrary: one practical step toward "defusing" current problems in the health service system would be to give better statutory protection to the work of (e.g.) paramedical personnel, "self-help groups," community referral centers, and similar joint lay professional initiatives. For complex reasons of history and law, the provision of psychotherapy and other behavioral services has never become so restrictively organized as is the case in medicine proper. Rightly or wrongly, it has been assumed that patients are less gravely "at risk" in their dealings with psychological counsellors than with physicians and surgeons. Within the behavioral or psychological field, in consequence, there is at present much more scope for "therapy groups" and the like, than there is for (say) giving real medical responsibilities to nurse practitioners, or paramedical personnel.

Without questioning the need for responsible supervision by fully qualified practitioners, one may still see strong arguments for the often-expressed view

that many medical practitioners are currently "over-qualified" for their actual work; so that the delivery of health care to those in need could be organized more economically, as well as more effectively, and in ways more directed toward their actual situations and values, if a much larger segment of the population had access to medical and other health related knowledge. In both the health sciences and the health care delivery system, a lowering of the barriers between health professionals and the larger public would encourage a broader understanding, both of the proper requirements of "technical expertise," and of the necessary social goals and priorities of an effective health service.

(8) Monitoring and evaluating policy making institutions and mechanisms in the health field. In conclusion, let us draw attention to one special problem, which arises directly from the complexity of the interactions between modern biobehavioral technology and the larger activities of American society. As matters stand, it is almost impossible for any one person to recognize all the different "decision points" along the road linking health science research to the actual provision of health services: still less, to obtain a proper overview of the effects of the decisions taken at all these different loci, or put forward a rationally based policy for coordinating the decisions taken at all these different points. So, quite apart from all questions about reforming existing institutions or creating new ones (e.g. for therapy evaluation), it should be a central goal of policy to improve our means for monitoring and evaluating the whole range of policy making institutions and mechanisms in the health field.

At this point, the Commission might well consider undertaking, or sponsoring, some further studies, aimed at spelling out the nature, functions and techniques

of "evaluation" and "monitoring" in this field. Over the last 35 years and more, a powerful methodology has evolved for evaluating drugs, therapies, etc. by the use of "double blinds," placebos and the rest; while some kind of a beginning has been made with techniques of "program evaluation" in connection with Head Start and similar OEO programs. But, hitherto, we have had no general technique for evaluating the operation of entire social agencies or institutions. In this respect, indeed, the Commission's own investigations into the operation of Institutional Review Boards represent a significant innovation in the techniques of social evaluation. If the aims of the present special study are to be carried through further, one way of proceeding may thus be to identify some of the key social mechanisms involved in the health science and health care systems, and to extend to them also the kinds of scrutiny already given to IRBs. The first step toward an effective policy for the social application of biobehavioral technology must, after all, be to develop better methods for identifying and monitoring the operations of the different aspects and agencies involved in the development and utilization of that technology.

We recognize that some important steps have already been taken in this general direction, in recent months and years. An Office of Science and Technology Policy is being reinstated in the White House, under a President's Science Advisor; the Office of Technology Assessment has been established in the Congress; while the Institute of Medicine of the National Academy of Sciences undertakes important studies on the economic and social aspects of health science and health care; not to mention the creation of the National Commission for the Protection of Human Subjects itself. In addition, the General Accounting Office

retains its own power to step in and conduct detailed evaluations of public programs, as occasion requires, in the health sector as in any other. All the same: it is not clear, as things stand, that the operations of these agencies will have the continuity needed if the operations of the policy mechanisms intervening along the way between the scientific laboratory and the point of health care delivery are to be adequately monitored. So, there still seem to be strong arguments in favor of establishing just the kind of "National Advisory Commission on Health Science and Society" contemplated in Senator Mondale's original resolution of March, 1973. As we see it, such a National Advisory Commission would need the same kind of broadly representative membership as the existing National Commission for the Protection of Human Subjects. It should include people with a wide range of humanistic or social qualifications, as well as health professionals; and it would require substantial autonomy and independence from the Executive departments. Whether it might operate alongside, or under the wing of the present Commission, or in conjunction with the OTA or some other Congressional agency, is a matter for subsequent debate on which we shall give no opinion here.

One last point we do have to add, by way of conclusion. The ethical, social, legal and public policy problems connected with biobehavioral technology have arisen, and will continue to arise, in largely <u>unpredictable</u> ways. Although Section 203 of its establishing Act instructed the National Commission to undertake a "comprehensive study" of these implications, that task cannot be tackled and completed exhaustively, and once for all. Instead, the problems arising in this area need to be kept under continuing scrutiny and review; and, whatever else comes out of the present special study, we particularly hope that Congress will recognize the desirability of such continuing evaluation. For the tasks

laid out in Section 203 will have to be tackled afresh, repeatedly and in new contexts, in the light of future technological innovations whose nature and social implications cannot at present be foreseen; and also with an eye to future changes in the broader economic and social, political and cultural situations.

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APPENDIX 1

The Case of Hypertension

by Eric J. Cassell, M.D.

The case of hypertension is useful in a discussion about the protection of human subjects because of the many ways in which the disease can be seen and the changes in the meaning of "human subject" that occur with these different frames of reference.

Hypertension is a disease in the most classic sense. This is to say that, even before the existence of practical devices to measure blood pressure, the disease was (or could have been) known by characteristic changes in the heart, kidneys, and other organs. The heart, seen simply as a mechanical pump, changes size and configuration as a result of prolonged pumping against an increased load. Persisting long enough, this extra work leads to failure of the heart to meet the load and congestive heart failure results. Characteristic changes in the small blood vessels results in renal disease and ultimately renal failure. Other blood vessel effects are seen in the heart and brain. These alterations are associated with the stigmata of long term hypertension - heart failure, myocardial infarction, renal failure and stroke. As I noted earlier, this pathology, particularly the heart and renal failure, can be identified without reference to a measure of blood pressure and meets classical structural criteria for the definition of a disease. This one view of the human subject with hypertension falls within the framework of the classical medical model - the person with abnormal organs whom we term diseased. We are not used to calling such people human subjects but rather prefer to call them "patients." They are the object of our care because they are sick by any

definition (and probably in any culture). Their protection involves protection from their illness - the agent of damage is their disease. They and our society believe their protectors to be physicians.

It came to be known, however, that the damaged organs of such people was associated with elevated arterial blood pressure - the state called hypertension. Hypertension is now defined as a blood pressure of greater than 140 mm of mercury systolic and 90 mm of mercury diastolic. It should be recognized that the definition is somewhat arbitrary. Normal blood pressure ranges from over 200/100 (with vigorous activity) to very low pressures during sleep. But physicians have defined hypertension as a blood pressure of over 140/90 whenever taken at rest in a medical setting. Physicians are primarily interested in fixed hypertension - when the blood pressure is always greater than 140/90 taken at rest. (Blood pressure varying from high to low in that setting is called labile hypertension and is presently of lesser interest.) It is of some interest that recent studies have shown that the blood pressure taken in the doctor's office is an accurate reflection of the blood pressure throughout the day.

There are a few known causes of hypertension. Certain tumors of the adrenal gland and a type of alteration in blood flow to the kidney, for example, are causes, but in the vast majority with high blood pressure, no cause can be found. These individuals are said to have essential hypertension. Lack of demonstrable cause has allowed theories of cause to proliferate - and indeed, they have. Excess dietary salt, repressed rage, urbanization and other possibilities have all been offered with, unfortunately, a dearth of supportive evidence.

What is of greater importance is that the state of hypertension has come to stand for the disease hypertension. By that I mean that, in the minds of laymen and even many physicians, the state of having elevated blood pressure has come to be equated with the disease characterized by alterations in blood vessels and the heart that I discussed above. In the simplest terms, many people with high blood pressure feel themselves to be in imminent danger of having a stroke even when their hypertension is first diagnosed. In fact, sustained elevation of blood pressure is a risk factor causally related to the disease but the relationship is not one-to-one. That is, not everybody with high blood pressure develops the disease and at this time, there is no way of predicting who will and who will not develop heart failure, heart attacks, renal disease or stroke. Further, the condition of having fixed elevation of blood pressure (over 140/90) has no symptoms, despite the fact that patients often attribute their headaches or their lack of feeling fit to their elevated blood pressure. Recent studies have shown that hypertension is an extremely common condition in the United States. Somewhere between 10% and 20% of the population has elevated blood pressure. Ethnic differences in the prevalence of hypertension have been known for many years. Recent studies show that 71% of black women over 65 years of age have hypertension as compared to 49% of white women of the same age. In the same age group, hypertension occurs in 66% of black males but only 27% of white males. For people over age 18 (hypertension is rare below that age), the prevalence among blacks is 28% and among whites 15%.

Effective measures for lowering blood pressure have been available for many years, but until relatively recently, most such drugs had serious or very

unpleasant side effects. That may have been one of the reasons that controversy over the utility of lowering blood pressure to prevent the effects of hypertension has also raged for years. But, more recently, carefully controlled large scale clinical studies have demonstrated clearly that sustained lowering of blood pressure is both possible and beneficial. This is to say that a population of hypertensive people whose blood pressure is maintained by medication at normal or near normal levels does not develop heart disease, stroke or renal disease with anywhere near the same frequency as a population whose pressure remains elevated. Furthermore, blood pressure can be lowered in 85% of hypertensives by the use of one drug from the class of thiazide diuretics. These agents contract the body's fluid volume by depleting sodium (many patients call them "water pills"). Thiazide diuretics have a low (though not negligible) incidence of side effects and often one pill daily is sufficient. The blood pressure of most of the other 15% can also be lowered although the use of other drugs increases the complexity of treatment and the incidence of side effects.

I can summarize at this point by saying that hypertension has now become, in the minds of the public and many physicians, not the disease of heart blood vessels I described originally, but rather a disease characterized solely by the numbers that come from a blood pressure instrument and the threat of heart disease, renal disease and stroke. Further, hypertension is extremely common and shows ethnic differences in prevalence which have political overtones. Finally, the disease is easy to treat and treatment is effective in reducing risk.

One might say, as many have, that hypertension represents the ideal case for preventive medicine. By the application of relatively simple therapy to

large populations at risk, the risk is abated. Indeed, the argument has been extended by the demonstration that the children of hypertensive parents have higher blood pressures (although within the normal range) than the children of non-hypertensives and that therefore treatment should or at least could be started in childhood.

It will be apparent on a few moments reflection that it is not practical (or perhaps even possible) in doctors' offices or hospitals to find and treat the between 20 million and 40 million people in the United States who have high blood pressure.

Popular expression of the need to find hypertension are the high blood pressure booths that can be found in churches, supermarkets, health fairs and so forth. Recent excellent research has shown the practicality of diagnosing and treating hypertension on the job site using paramedical personnel trained specifically for this. The ubiquitous blood pressure instrument and the simplicity of treatment make these massive efforts possible. It has also been demonstrated that job site non-doctor treatment may be more effective in maintaining lowered blood pressure than therapy given by physicians in their offices.

Who is now the human subject? It is no longer someone with damaged organs who must be protected or saved from that damage. Rather, the human subject is a person with elevated blood pressure and no evidence of disease but a subject merely because he has a risk for a disease. And we do not know how great the risk is! In the enthusiasm for widespread treatment (on the job, in the community but not necessarily in the doctor's office), two important facts have dropped from sight. The first is that of a group of individuals found

to have elevated blood pressure about one third will be shown to have normal blood pressure on repeated measurements. The second commonly overlooked fact is that the Veterans Administration's study which demonstrated the utility of lowering blood pressure to prevent heart disease and strokes only included patients whose diastolic blood pressure was over 105!

Therefore, it is not at all clear what overall benefit will come from treating huge numbers of people with elevated blood pressure. Some individuals will be prevented from developing hypertensive disease but no one knows who those individuals are. While hypertension is very common, death from hypertension (or associated diseases) is vastly less common. At present, it is impossible to predict which person with elevated blood pressure will go on to develop hypertensive disease. Thus, the benefit of mass treatment is unclear. What, aside from money and manpower, are the costs?

Although the thiazide diuretics presently used to treat hypertension appear to be relatively safe, they do have side effects. What will be the effect of treating a huge number of people with a drug that depletes the body of sodium and potassium, that produces varying degrees of impotence in as many as 25% of males, and that occasionally produces depression or other psychic symptoms?

The answer is not known because the drugs have not been used long enough, but it would be extremely unusual if this was the first drug not to have unintended long term problems.

Other things need to be considered. What will be the effect of convincing millions of people that they have a disease (and they must be convinced or they

will not take the medication) when, in fact, they may not? The treatment of hypertension in churches and on the job does not demedicalize hypertension, rather it increasingly medicalizes a large population that may already be too medically minded.

In other words, the worst unintended side effect of the mass treatment of hypertension may not be the production of deleterious drug effects but rather the solidification of a wrong framework of reference. The reason mass therapy of hypertension seems so reasonable is the exclusive focus on the possibility of heart disease or stroke. Another example may make the point. A patient had a lump in her thyroid which was thought at first to be an unimportant cyst. A new diagnostic method was used which raised the question of solid tumor and, by inference, of cancer. Immediate operation was advised. It was not a big operation, but she was in considerable discomfort for about two weeks. The scar will be on her throat forever, and she will dress differently because of it for years. The tumor was benign. Discussions of tumors of the thyroid always focus on the question of malignancy and outcomes are measured in those terms. We do not discuss outcomes in terms of peoples' lives but only in terms of the tumor. Was the tumor cancer and what happened to the tumor? That may seem reasonable at first thought; after all, if someone has lung cancer, the tumor's fate is their fate. But it is not so reasonable even when death is the inevitable result because, as we have come to learn, there is more than one path to death. And when death is not the inevitable issue, such a focus or framework of reference is even less reasonable. While cancer of the thyroid is not rare, death from cancer of the thyroid is very rare. Should we not ask other questions apart from whether or not somebody is going to die? It seems

to me that it is reasonable to widen the framework of reference. Do people who are operated versus those who are not have more divorces, poorer work histories, less or more children, more frequent other illnesses or operations and so forth? Is not the fact that families of leukemic children have very high breakdown and divorce rates part of the outcome of leukemia?

If these wider frames of reference are important in considering malignancies and their treatment, they should be of even greater importance in considering the protection of human subjects who are found to have an elevated blood pressure.

In looking for unintended side effects of the mass treatment of hypertension, we must look beyond the side effects of the drugs. What happens to the lives of people involved in treatment programs and to their other health related behavior?

It is difficult to focus on these other questions precisely because we have always seen our job to be epitomized by the protection of hypertensives from stroke. It is reasonable to ask what the price will be for the whole population if mass treatment programs for hypertension continue to hold us to such a narrow view of human existence.

APPENDIX 2

Mental Health and Behavior Control

By Gerald L. Klerman and Perry London

I. Introduction: Overview of Future Trends

Psychoactive drugs and diverse forms of behavior modification and psychotherapy are the two major technologies developing in the mental health field. The use of both of these technologies is increasing enormously, and will likely continue to increase in the foreseeable future. This paper will describe the background of these events and examine some of their social impact. Our general forecast is that the future belongs to mental health (or to mental illness, depending on how one looks at it). Within this general forecast statement, we will discuss four topics:

(1) The increase in use, now and in the future, of drug and behavioral technologies in mental health services.

(2) Their impact on the organization of the mental health care system and therapeutic practices.

(3) Areas of public policy concern, particularly:

  (a) behavior control as a possible political danger, and,

  (b) the boundaries of health and problems of living and of values.

(4) Possible public policy mechanisms to enhance or constrain control or development of these trends.

II. The Two Technologies

There are two technologies in mental health now developing very rapidly -

psychoactive drugs and behavior modification and psychotherapies. In various forms, they have been with us for many decades, if not centuries. What is new is the growth in their complexity, technical sophistication and scientific foundations in experimental psychology, neurochemistry and pharmacology. Like all technologies, the degree of benefit or harm attendant to their use depends not so much on their intrinsic scientific basis or empirical technique, but upon the social values and public institutions brought to bear to channel, encourage, regulate or control their development and application.

Because of the potential of this technology, the title of this paper incorporates two of the alternative uses of drugs and psychotherapy. The two technologies to be discussed - psychoactive drugs and behavior modification and psychotherapy - can be utilized for therapeutic purposes in mental health, or for behavior control. To what extent they will be so utilized in the future will depend upon our society's values, and the public policy mechanisms implemented.

New Drug Technologies

In the past two decades, there has been an explosion of interest and knowledge and use of drugs for behavior. The psychoactive drugs are of increasing number and kinds. The history of the development of these drugs is well described (Swazey, 1974) (Ayd, 1972) (Caldwell, 1970). (Swazey's book provides an excellent history of chlorpromazine, the first phenothiazine).

In Brave New World Revisited, Huxley cites with horror the fact that, in the U.S. alone, 48 million prescriptions a year were being written for tranquilizers. That was in 1958. Six years later, over 45 million prescriptions

were written for the three major tranquilizers alone, and another 104 million prescriptions for other psychotropic drugs. This phenomenal increase in the number of such drugs around and the extent to which they are being used has been continuous over the past two decades, with the total number of prescriptions for them, by now, on the order of 270 million annually, which is perhaps 25% of all the prescriptions being filled in American drugstores. Also, new drugs, such as the antianxiety and antidepressant drugs, tend continually to replace older ones, such as the barbiturates, but not to replace them completely - so the whole armory grows in variety as well as size.

Concern over psychotropic drugs is among the oldest and newest of civilization's preoccupations. At the dawn of civilization, in the Ancient Middle East, alcoholic ferments were widely utilized, having been developed at about the same time as the domestication of animals, the discovery of agriculture, and the creation of the first cities. Almost every society since has developed various potents, brews, and remedies aimed at changing mood and behavior, be it disturbed or normal. The ancient Greek Homeric legends contain discussions of various drugs which today we would consider psychotropic. In western society, scientific interest in psychotropic drugs emerged in the middle of the nineteenth century when pharmacology and psychology developed as distinctive scientific disciplines. In France, Austria, England, and the U.S.A., interest grew in the opiates, in hashish, and in other derivatives of cannabis, and in cocaine, as Western European scientific and intellectual circles became increasingly aware of drugs used for psychotropic purposes in the cultures of South America, the Middle East, and the Orient.

Psychopharmacology did not emerge as a distinct science, however, until the decade after World War II. The term psychopharmacology had been used in the 1940s and 1950s in a few scientific articles, but it was not until the discovery of LSD by Hoffman in 1943 and the synthesis and clinical introduction of chlorpromazine by French pharmacologists that a systematic, scientific investigation of drugs which affect the mind reached self-conscious and organized proportions. Thereafter, the pace quickened rapidly. Dozens of new compounds were developed for therapeutic investigational use, various national and international societies were formed, and federal and other support emerged.

In large part, the rapid growth and wide impact are consequences of the recent development of pharmacologic compounds which alter mental functioning and of the reevaluation of previously used substances such as alcohol and cannabis in the light of advanced psychopharmacologic techniques. The findings from neurobiology, neurochemistry, and neurophysiology have also made it increasingly possible to relate the psychological effects of psychotropic drugs with normal biological mechanisms of action upon the brain.

Today, the science of psychopharmacology encompasses the study of a wide range of compounds, only some of which are being used for therapeutic purposes. Psychopharmacology refers to the scientific field which studies drugs that affect the mind, behavior, intellectual functions, and mood. Psychotropic drugs are those compounds which influence the psychic functions and behavior. Not all psychotropic drugs are therapeutic. For example, heroin, LSD and alcohol are psychotropic drugs with considerable social and research interest, but currently they have no demonstrated therapeutic value in the treatment of established mental illness. Reevaluating previously used compounds in light of

new discoveries of the relationship between the brain and behavior, it is possible to regard psychotropic drugs as falling into three main groups depending on the purpose for which the drug is used. These groups are:

1. Therapeutic agents. Those psychotropic drugs such as antipsychotic, antidepressant, antianxiety agents used for treatment of psychiatric disorders. The success of these compounds has contributed greatly to the changes in the therapy of mental illness and to man's greater awareness of the potentialities of psychopharmacology.

2. Drugs used for nontherapeutic purposes - recreation or personal enjoyment. It is indicative of the ambivalence of our society towards these compounds that no generally agreed upon term exists for this use of psychotropic drugs. Included in this group are alcohol, hashish, marijuana, and other derivatives of cannabis, the various hallucinogens (also called psychomimetics) and psychedelics, including LSD, psilocybin, and mescaline, and the various opiates including morphine and heroin. These drugs have in common the capacity to alter the normal mood state in a way that subjects find pleasurable and seek repeated experience without being directly involved in treatment of defined mental illness or psychological disturbances.

3. Drugs to enhance performance and capabilities. Although, at the present time, there are relatively few drugs which have the demonstrated capacity to enhance performance, this area probably represents the future scope of psychotropic drugs. Currently, drugs such as caffeine, and at times amphetamines, are used to counter fatigue and to alter the decrement

of performance by improving memory, learning, sexual ability, and intellectual functioning. Use of these drugs generates controversy and conflict in society, since we have not yet determined the modes by which individuals and groups should regulate and control consciousness, emotional states, or behavior by use of psychotropic drugs.

Psychoactive Drugs Used as Therapeutic Agents

The treatment of mental illness has been dramatically changed, if not revolutionized, since the mid-1950s, when pharmacotherapeutic agents had their first impact. During a brief period, four new types of drugs were introduced into therapeutic practice: chlorpromazine, rauwolfia, meprobamate, and imipramine. The dramatic effects of these drugs on a wide variety of mental and other illnesses not only has influenced therapeutic practice, but also has led to increasing sophistication in the evaluation of these compounds. Because of initial skepticism about their efficacy, considerable effort was expended to develop new research techniques, and new methods evolved such as the double blind and placebo-controlled trials, advanced descriptive techniques, psychometric evaluation, and multivariate statistical techniques dependent upon computer technologies in the evaluations. As a further consequence, the demonstrations of the therapeutic efficacy of these compounds generated questions about their modes of action on the brain and precipitated a vigorous interchange between clinical investigators in neurochemistry and neurophysiology.

It is conventional to divide the main classes of drugs used as therapeutic agents into three groups: antipsychotic drugs (those used in the treatment of major mental illnesses, including schizophrenia and related syndromes such as paranoia and catatonia); antidepressant drugs, and antianxiety drugs. While the

three classes of drugs described represent the main classes used as therapeutic agents in mental illness, mention should be made of two other clinical states in which drug therapy has produced highly valuable results. Lithium has been successful in the treatment of mania and recurrent affective disorders, and psychomotor stimulants have had good results for hyperkinetic children with learning and attitudinal problems.

We are at the end of the first wave of the drugs which include at least three main classes of drugs:

1. The antipsychotic drugs include chlorpromazine, the prototypic drug, for the drugs used for psychoses, like schizophrenia, major paranoia; including thorazine and phenothiazines, etc. They have had major impact on the treatment of the serious mental illnesses.
2. The second group are the antidepressants, the MAO inhibitors and the tricyclics. There is evidence that their proper use will reduce the suicide rate and contribute to a reduction in use of hospitalization and to shorten periods of hospitalization.
3. The third group, which accounts for the largest number of prescriptions, are the antianxiety drugs. Librium and valium are two of the three most widely prescribed drugs in the world.

There are some semantic problems to be clarified. Although there is imprecision about the use of the term antipsychotic for this category of drugs, it has a considerable advantage over the initially advocated term, "tranquilizer," which unfortunately, since 1950, the lay press has tended to emphasize. The word tranquilizer is now seen as a misnomer since it

implies utility only in patients who are excited and requiring calming. Experience has shown that these drugs have significant effects upon disturbed thinking as occurs in schizophrenic psychoses, but that they are unlikely to influence significantly any excitation and overactivity without the presence of disturbed thinking.

Widespread usage distinguishes major tranquilizers, such as the phenothiazines, from the minor tranquilizers, such as the meprobamate series and the diazepoxide derivatives. This latter group is related more closely to the sedative-hypnotics than to antipsychotics such as the barbiturates. The major tranquilizer minor tranquilizer distinction is inadequate and inaccurate. It implies that the meprobamate-barbiturate group is basically similar to the phenothiazine group, but contains weaker pharmacologic compounds. This is not accurate and it is far better to see these two classes of compounds as qualitatively different.

The most rapid increase in drug use has been in antianxiety drugs, such as valium, librium and miltown. From 1964 to 1974, their popularity jumped from 45 million to over 110 million (generally refillable) prescriptions yearly. The use of antidepressant drugs such as elavil, antipsychotics such as stelazine and thorazine, and hypnotics such as the barbiturates, has increased a little, but not much. Valium, darvon (actually a pain drug, not a tranquilizer) and librium are now the three most prescribed drugs in the entire world and valium the single most prescribed compound in the U.S. In any given year, twenty-two percent of the adult population of this country uses some prescriptive psychoactive drug, 9% use at least some over the counter psychoactive drug, and 14% admittedly increase their alcohol consumption

as a means of coping with distress. Most of the prescriptions are written by general practitioners, not by psychiatrists, but they are mostly prescribed for psychological problems. Even considering the overlap, 30 to 40% of the adult population, over 20 million adults, and up to 25% of the total population of the United States uses some chemical compound to ease psychological distress in any one year. And there is little doubt, in terms of statistical projections, that it will increase for the foreseeable future: the more so if, as pharmacologists predict, today's drugs will be rendered obsolete by more potent and specific ones tomorrow. This has not happened because physicians are too ready to prescribe pills. The evidence is that physicians are not always happy about dispensing these drugs, or, for that matter, about treating these patients, but often they do not know what else to do with them. People want relief from their distress, expect the physician to help them find it, and leave the physician, therefore, feeling that there is little else they can do than prescribe, like it or not.

It is not just physicians who are anxious about these drugs. A vocal group of social critics views their increasing use, with moral alarm, as "the over-medication of our society." The over-prescription of these drugs, they contend, tends to undermine the moral fiber of the nation by the "mystification of personal problems and interpersonal difficulties," so that people are encouraged to evade their problems by happy pills, instead of coping with their problems by confronting them.

Non-therapeutic Uses

If there is a case for alarm over the statistics on drugs as medication, then there ought to be a red alert, if not a downright panic, over mood changing

drugs in general, because so far, we have been talking only of medical psychotropic drugs. The statistics report less data about use of coffee, tea, alcohol or marijuana - that is, the pleasure drugs. Not only is it clear that the pleasure drugs are being used at one time or another by up to half the adult population - but that their use is rapidly becoming decriminalized. One reason for this trend is that there is increasing knowledge and admission that the harmful effect of these drugs is overrated. Huxley noted that a medical commission appointed by New York's Mayor LaGuardia report, in 1944, that marijuana was not a menace, but just a nuisance. The same conclusion, it seems, was reached by a British commission as early as 1894, by British, American, and Canadian commissions in 1968, 1970 and 1972, respectively, and by the Consumers Union in 1972.

More important that the facts reported by these commissions, for our purposes, is the fact of the swell of reports themselves, reflecting the personal experience of millions of people who have used the drugs and not felt that the effects were bad ones. These events will produce the legalization of marijuana for the same reason, finally, that social events produced the lifting of Prohibition. The Talmud warned, almost two thousand years ago, against making a law that the community cannot live with. The prohibition of alcohol was such a law; the civil disorder that resulted from it was so great, relative to whatever gains may have accrued from it, that the law had to be repealed. Alcohol is a poison and, by comparison with marijuana, a menace not just a nuisance. But people would not accept its prohibition; and the same thing is probably true of marijuana. The fact that many people want these drugs means that they are likely to get them,

sooner or later, which means in turn, for drugs that are legal and acceptable to begin with, that the market is likely to go on expanding. And in these facts lie the biggest coming policy issues of mental health technology: people want what they value and try to get what they want. In a society whose economy develops products and distribution facilities in approximate response to people's apparent values, the direction of the drug industry seems highly predictable.

In a work-oriented society, people use stimulant drugs more than pleasure drugs. So coffee and tea and tobacco have long dominated the West, and hashish and opium have been more prevalent in the Orient. And people use anxiety reducing drugs in societies where stress produces anxiety, which is everywhere, but even more so in societies which create conflict within people's internal value systems. In our society, the expansion of all kinds of drug use may be a response to a growing transitional value conflict between puritanical and hedonistic ethics, reflected in evaluations of drug usage as the clash between what Harvard Psychiatrist Gerald Klerman calls "psychotropic hedonism versus pharmacological Calvinism." That may also be why the statistics of drug use across age groups, at least in California, are such that younger men use more stimulants, middle-age ones use more tranquilizers, and old people use more sedatives. The younger men want to keep up or get ahead, old people want to turn off and go to sleep, and the rest of us would like some peace and quiet.

The ultimate issue here, in any case, is not the value of drugs, but the value of virtues. The same questions are addressed the same way, if less dramatically, by all the self-administered, self enhancing, non-chemical devices of behavior control technology. The most important of these are psychotherapy and behavior modification.

Psychotherapy and Behavior Modification*

Huxley did not name psychotherapy among ominous behavior control methods, and people tended not to think of it as a form of behavior control until around 1960, when behavior modification started getting known. They are doing so now, quite appropriately, as behavior modification is rapidly becoming the dominant speciality within the psychotherapy industry. There is every reason to think that it will continue to grow, especially in the areas of self-help and self-control. Within the mental health establishment, Transcendental Meditation, Sex Therapy, Assertiveness Training and Biofeedback have become very popular. Outside the establishment, Erhard Seminar Training (EST) has become a mass marketing operation for conveying similar messages. The EST statement may be the most global: "Transform your ability to experience living." But each of the methods implies the same goal: "By mastering this technology, you will be a happier person," whether being happier means better able to satisfy a work ethic, or to perform better at something specific, or to feel better, in general, on whatever grounds. The dominant psychological technology in mental health is in what is called "behavior modification" or "behavior therapy." This is now the case, and it will be much more the case in the future. In this paper, we are not making any case in favor of behavior modification. What we are describing is that behavior modification presents a new technology, and like any new technology, is able to make advances because it can produce specificity of analysis which the previous psychological therapies had not been able to do easily, efficiently, and effectively.

* This section does not elaborate upon the various forms of psychotherapy, and other behavioral techniques, since these have been discussed in detail in a previous paper by P. London and G. Klerman "Boundaries Between Research and Therapy Especially in Mental Health" prepared for the National Commission in January, 1976.

The trend toward behavior modification is extremely pronounced. A student of London's reviewed issues of 75 English language journals specializing in psychotherapy between 1973-1975: the primary action was clearly in the field of behavior therapy. O'Leary and Wilson in 1974 published a book summarizing behavior therapy, now called behavior modification, and they said this about the literature. In 1951, two major psychology and two major psychiatry journals between them carried four articles: in 1970, the same journals carried 70 articles. Since 1963, six journals which are devoted to behavior therapy have come into existence, and two more are being opened in Europe this year. There now is at least one annual review volume on behavior modification and behavior therapy.

Increasingly, behavioral methods are coming to dominate the professional field of psychological therapy, but they are part of what we consider to be a general trend for the expansion of the psychotherapies. We foresee an increasing market of consumers; a larger and larger set of followers, to whom unconventional therapies are increasingly acceptable, and personnel who are not professionals in the formerly established sense of the word. Some of these unconventional therapies are the direct outgrowth of professional psychological activities, such as hypnosis, gestalt methods, bioenergetics, transactional analysis, and biofeedback. Many of these therapies are also susceptible to application by non-professionals, and many of them have given rise to different therapeutic devices that are being actively conducted by nonprofessionals. Bioenergetics, for example, has had spin offs in rolfing, in the Feldfries method, and in what you might call "touching-feeling-nude" encounters.

There are a number of other therapies that are very specific. These include sex therapy, assertiveness training, meditation, weight control, and EST, transactional analysis, biofeedback. They are very important because they are spin offs of the psychotherapy technology, but have great specificity. People can use these therapies for specific kinds of problems without committing themselves to the total psychotherapeutic encounter that was traditionally necessary with psychoanalysis.

All these methods are, on any reasonable definition, "technologies": they are systematic ways of doing something specific. Their claim to specificity is what promises to transform psychotherapy into a more or less effective technology, for the precise application of specific treatments to specific conditions is what has long been most missing (and most lamented) in much of psychotherapy. Behavior modification, or action therapy, is the one new area of psychotherapy where specific new methods are being reported in the professional literature.

The most popular techniques, however, are not necessarily ones which fit the traditional notion of psychotherapy as a means of repairing functional disabilities, that is, as a means of healing. Like drugs, they can often be seen even more as a means of enhancing performance, or self-satisfaction, than of repairing dysfunctions.

Also, like drugs, behavior modification not only provides technologies for "hedonic treatments," but ones that are cheap enough and specific enough - like sex therapy and assertiveness training and biofeedback - to be marketable in a depressed economy. If therapy is cheap, people can afford to buy it in

a depression; if it is specific, they may be willing to spend money on it anyway, because it holds so much promise of helping them. Assertiveness training is cheap and specific; sex therapy is expensive but specific; biofeedback varies in both respects. (It is the least popular of the three.)

Sex therapy and assertiveness training were both described in 1958 in Joseph Wolpe's early work, Psychotherapy by Reciprocal Inhibition, which provided much of the professional impetus from which behavior modification was soon to grow popular. But neither treatment became very popular until a decade or more later and, as both proliferated (generally without Wolpe getting much credit), they seem to have evolved growth rates which compare favorably to those of drug use. There may be over four thousand sex therapy clinics in the United States now, not counting therapists who do not advertise it as their specialty, and assertiveness training, in schools and churches as well as clinics, is too popular, to count its teachers or its minors.

It is not surprising, then, that psychotherapy and psychotropic drugs increasingly reflect the same contemporary value. They are both technologies that you can take or do, not only to make yourself stop feeling bad, but also to make yourself start feeling good - a quantum term, which always means "better than you felt before." The aim of these therapies is to reduce the discomforts and to increase the pleasures of a society.

III. Impact on Mental Health Care System

A number of changes in the mental health care system have come about in large part as the consequence of these new drugs and behavioral technology.

There have been some significant changes in the health care system that provide mental health services. There is very good documentation that there has been a significant shift from an emphasis on mental health as an inpatient to outpatient services. That the utilization of inpatient services for 100,000 has remained fairly constant over the past 20 years, but outpatient services have gone up, both proportionally and in absolute numbers.

NIMH maintained data for over 20 years on the utilization of clinics and mental hospitals: VA, private, county, psychiatric units in general hospitals, and clinics. These data indicates that there is an overall increase in utilization. Adjusted for population increase, there has been a doubling of the proportion of the population using public mental health services from 1954-1974 from 0.8% of the population to over 2% in 1974.

Interestingly, the importance of inpatient facilities has decreased relative to the growth in the total system. Inpatient episodes have remained fairly constant, at about 800 inpatient admissions per 100,000 of the population. Within the inpatient sector, there has been a steady decline in the relative importance of the public sector, the state and county hospitals and VA hospitals, a slight increase in the admissions to private hospitals and a marked increase in use of psychiatric services in general hospitals. Mental health services has become more pluralistic. The governmental "monopoly" on mental hospitalization has ended. To a great extent this has happened because of the considerable expansion in coverage for mental hospitalization by health insurance policies. The health consumer now has a choice of where to go for mental hospitalization, previously public mental hospital services were all that were available, except to the very wealthy.

The greatest increases in mental health services, both absolutely and relatively, have been in the use of outpatient facilities; child guidance clinics, after-care clinics, day centers, community clinics. A new type of facility - the community mental health center - has been created. These clinics service many patients and employ a lot of professionals. In 1972, over 1% of the population - 2 million people - were treated in these clinics, averaging between 5 and 10 visits per year per person. Most of these clinics are supported by tax funds at the federal, state or local level. To a large extent, they have been successful in meeting the goals of the federal program by providing services to the urban poor, rural residents, and to Black, Puerto Rican and other disadvantaged segments of the population who, in the era studied by Hollingshead and Redlich, were not receiving mental health care except in the large public hospitals.

In addition to these changes in utilization and structure of the health care system, there have been significant changes in manpower. Now and in the foreseeable future, utilization of services is increasing faster than the growth of the professions. Consequently, there is a shift in the balance between services provided by professions, and those provided by para-professionals and non-professionals. The non-professionals are increasing, both absolutely in number, and relatively in proportion to the professionals. How long these trends will continue, and at what point there will be a leveling off of the growth of the mental health manpower fields, is not certain.

Within the mental health professions, there will probably continue to be tension between the two dominant doctoral level professions, psychiatry and psychology, and we may well foresee public pressure to force a combination

or unification between these two professions. Mental health services are increasingly being incorporated into other service systems, including the educational system, prisons and other correctional institutions, military, and other organizations which are not primarily part of the health system, but which are increasingly making use of mental health services.

IV. Areas of Public Concern

Anticipating the continued growth of the use of these technologies, six areas of public concern can be identified. These are:

1. The fear that these technologies which will be used for behavior control for political ends. More will be said about this below.
2. Defining the scope of mental health services and the boundaries between health and religion, law, education and personal value choice.
3. Ethical aspects of human experimentation in mental health research.
4. Demonstration of relative efficacy and safety for these technologies when used for treatment.
5. Cost effectiveness, and
6. Developing a manpower policy, particularly for the relations between professionals and non-professionals, and, within the professionals, the relationship between psychiatry and the other medical specialties, as well as between psychiatry and clinical psychology, and between clinical psychology and the other branches of psychology.

Having identified these six areas, we will elaborate upon the first two in some detail, since they have the most far-reaching ethical and social implications.

Behavioral Control and Public Policy

The concern that these technologies will lead to political consequences was, of course, prototypically expressed by Aldous Huxley, in Brave New World. Drugs and behavior modification have not been used for the political manipulations Huxley feared. Even so, his concerns were reasonable ones, because the technologies involved do make it possible for some people to invade the liberties of others, controlling how they act, and also maybe, at some point, even how they feel. Most contemporary critics of these technologies are worried chiefly about how to resist incursions on personal liberty by controllers. This concern is part of the Western political tradition, namely, the resistance to tyranny. Most of the controversies, legal actions, and public policy debates and decisions over the past decade about drugs and other possible behavior control technologies have been offshoots of that preoccupation. Congress, the courts, consumer protection organizations, public interest lawyers, professional guilds, and thoughtful private citizens have all addressed aspects of the technology by which some persons control others. The main misuse to which they have been alert is that in which apparently benign uses of behavior control, as in medicine, infringe on civil liberties. That such misuse is often unintentional makes it more insidious, not less dangerous.

Public policy problems of defining and preventing the misuse of behavior control have arisen with every major kind of control technology, from psychotherapy through drugs and implantations, and with every kind of captive or

catchable audience - children, the mentally retarded, prisoners, hospital patients, and research subjects. Some of the specific issues have been gross infringements, such as giving school children drugs to make them more manageable in class, or forcing prison inmates into operant conditioning or psychotherapeutic programs. Others have involved subtle questions, such as defining the difference between experimental treatments and established ones, so that the former can be surrounded with restraints that protect patients. The common problem is that of protecting the weak from the strong, so that they are not victimized by their inferior state.

What Huxley and other social critics did not anticipate is that the biggest social changes engendered by drugs and behavior modification technologies do not arise from what people can do to <u>each other</u>, though those political dangers are potentially real enough, but from what people will want to do to themselves. The social consequences of greatest potential concern in a benevolent, free, society, are not the impositions of malicious intentions and hostile restraints, but of benign intentions and amicable enhancements. It is amicable enhancement, so common in daily life that we take them for granted, that constitute the most important kinds of consequences of these technologies. They are matters of how people want to treat themselves because they are things which individuals want to do, or want done to them. The social and ethical problems which result are those of the incursions these treatments make on society's values, for they challenge the tradition of Puritan ethics and move us further and further, faster and faster, towards a hedonic, or pleasure-oriented ethic. This trend is resulting, as we believe, from the interactions of an improving technology for the self control

of mood and behavior with an abundant economy and a political tradition of relatively great individual liberty. The continuation of this trend will occur as long as those forces are operating. In that event, these technologies need badly to be understood, monitored, and regulated, because their further scientific development is not likely to be halted or undone.

The Boundaries of Health and Mental Health

If, as we indicate, the main issues raised by these technologies are not so much the political spectre of "behavior control," but rather the increasing capability for technology to enhance personal functioning, the resultant concern for society in the future will be to define the boundaries for health and mental health, particularly as drugs and psychotherapies encroach upon areas previously regarded as in the province of religion, education, law and personal value choice. These issues have already become the subject of debate for medication. Our society is in the midst of a debate as to whether or not we are an overmedicated society. Articles in newspapers and popular magazines, multiple discussion panels on television and at least three Congressional committee hearings have been devoted to public discussion of this topic. These public discussions have their counterparts within the mental health professions where there are continuing debates as to the proper role of medication in the treatment of psychiatric disorders in general and the specific role of antianxiety agents in therapy states of anxiety and depression.

The critics argue that we are being an overmedicated society. (See, for instance, C. Muller's article in Science, "The Overmedicated Society: Forces in the Marketplace for Medical Care." Muller discusses the forces that might have led to such overmedication, and notes that many of the relevant issues

are exaggerated in the prescription of psychoactive drugs. Similarly, Lennard et al. noted that:

> As more and more facets of ordinary human conduct, interactions, and conflicts are considered to be medical problems, physicians, and, subsequently patients become convinced that intervention through the medium of psychoactive drugs is desirable or required.

They further state that:

> The pharmaceutical industry is redefining the relabeling as medical problems calling for drug intervention a wide range of human behaviors which, in the past, have been viewed as falling within the bounds of normal trials and tribulations of human existence.

This issue has gained prominence, in large part, because of the misuse of prescriptions, and the use of psychoactive drugs, as described above. The issues raised by psychoactive drugs have their counterpart in the general concern for the expanding use of all mental health services, and the possible need to better define the limits of mental health itself.

Our reponses to this concern is that the definition of "illness" is itself a value, and is determined by social conventions. There is no fixed quantity of illness, particularly of mental illness, at any one time, at any one society. The definitions of illness and the extent of legitimate medical intervention, are variable and determined by at least three factors including:

1. the general social economic level of the society, as reflected in the wealth of the individual patients and clients,
2. the available biomedical technology, in this case, medications and psychotherapy, and

3. the general societal expectations and values around health and illness as they are perceived, defined and acted upon by the individual patient.

In the modern era, particularly in industrial urban nations, these three factors all combine so as to constantly extend the definition of illness to include not only conditions which might produce death, severe disability, or even pain, but also distress, including psychological and emotional distress. Extending the duration of life is no longer the major task of the health care system, but improving the quality of life.

Our conclusion, therefore, is that the definition of illness is a social definition, and that the limits to "illness behavior" are likely to expand with rising expectations. "Life, liberty and the pursuit of happiness" were promised to us by the Declaration of Independence, and it is fitting in this Bicentennial year to consider that the American public has come to regard this promise as now including the absence of anxiety, guilt, and insomnia. Not only is the health care system being called upon to assist in the removal of distressing symptoms, but increasingly to enhance our capacity for performance and happiness, as is evident when we consider the role of the health care system in the sexual revolution with regard to contraception, abortion, and the sexual psychotherapies.

This situation we have described above, the expanding use of the health care system in a modern industrial urban society, is not without its critics. If these critics prevail, rather than these matters being dealt with as part of the health care system, alternative institutions, such as law, religion,

or education, would be the proper focus for resolution of personal behavior conflict and reduction of emotional tension and psychic distress.

Nevertheless, our prediction is that the health care system will continue to be the locus for technology development and service delivery in this area. The conventional institutional supports that societies have relied upon since the Neolithic revolution are: the family and extended kinship, the church, and the residential neighborhood. Modern urban and industrial society, with its high geographic mobility and secular orientations to the meaning of life, utilizes these traditional institutions less and less for social support, for provision of meaning to life, and for consolation for death, pain, disability, and loneliness. Given the prevalence of distress in human experience, where will people turn? The extended family ties are less available. Religion is less valued. The church has fewer resources as an institution. Geographic mobility means fewer friendships and neighborhood supports. But the health care system is there. It is scientific. It is secular. It has financial base for support - namely, the insurance system. It is effective. It has technology.

V. Public Policy Mechanisms

Public policy mechanisms can either enhance and facilitate these trends, or they can restrict, regulate or control the development and application of these technologies. The society as a whole can exercise many options, particularly through its various agencies, most notably, Congress and other legislatures, but also through various executive agencies and budgetary allocations.

We have identified three major areas where public policy decisions are likely to be made within the next few decades. In identifying these areas, we have assumed that the trend to include drugs and behavioral technologies within the overall health system will continue. It is, of course, possible that this basic pattern will be reversed, and that "health" will no longer be the umbrella within which drug treatment and behavioral treatment for emotional problems are legitimized. Nevertheless, assuming the continued use of the health system, the following mechanisms are likely to emerge:

1. Most important is the likely inclusion of mental health services within national health insurance. The major determinant of the extent to which the boundary of mental health services enlarges will be the extent of coverage under health insurance. This will include the nature of services covered, both drugs and psychological services, and the type of practitioners, medical and non-medical, who are eligible for reimbursement. The rate at which national health insurance expands over the next few decades to include what are now considered to be "minor disorders" of neurotic distress and emotional problems, will probably be the main consideration in determing the rate at which health encroaches upon areas now regarded as legal, educational or religious.

2. Next there is the development of a long term manpower policy. It is likely that there will be licensing of various kinds of psychotherapeutic professionals, comparable to that now provided for M.D.'s. The continued separation of psychology from medicine may result in pressure from the public at large for a combining of clinical psychology and

psychiatry into a new profession. This is a major policy decision, comparable to the efforts of the 19th century to combine the various medical practitioners. Another area of manpower mechanism will evolve around the extent to which financial and other support is provided for the further development of paraprofessional and non-professional types of mental health personnel.

3. Finally, there is the possible development of a national therapeutic board, as has been discussed elsewhere in the body of this Report. The extension of the powers of such a board to review the evidence for the efficacy and safety of behavior therapy, psychotherapy and other forms of behavior modification, along with psychoactive drugs, would provide a powerful impetus to quality research in this field, and to increase scientific basis for methods of behavioral therapy.

VI. Conclusions

Our analysis of mental health technologies had led us to conclude that these policy decisions about the mental health services can provide a quasi-experimental approach to testing the hypotheses that: (1) health and illness are essentially social conventions, and (2) the health care system is increasingly called upon to deal with the quality of life rather than its prolongation.

Our forecast is that, as our society becomes more urban, more industrial, more mobile, more secular, and more individualistic, the health care system in general - and the mental health care system in particular - will be called upon more and more to deal with problems which were previously regarded as

social, legal, or even moral. In this expansion of the health care system, medication, psychotherapy and other behavioral technologies will be ever more widely used as means of coping with distress, enhancing performance, and improving the quality of life. The goals of the health care system traditionally emphasized reduction of death and disability, and also relief of distress. It is the extension of the definition of "distress" that leads to the moral criticism. In the past, distress involved intense pain, as in broken limbs and abdominal catastrophies, etc. However, in the current era, the definition of distress has been broadened to include emotional complaints and psychic misfortunes, including anxiety, tension, insomnia, etc. In addition to the relief of distress, there is greater concern with the enhancement of performance, and the improvement of the quality of life, not only in mental health, but throughout health in general.

All members of the population are potential consumers of mental health services. Given the definition of illness under the WHO criterion, most children could use help with furthering his/her personal, physical, psychological, cognitive, and emotional development. Most adults would like to be relieved of tension, guilt, insomnia. We would all like the health care system to make us more sexually potent, more beautiful, more intelligent, live longer, and happier. The major scientific question is: do the health and psychological professions have the biomedical and behavioral technology to achieve these goals?

The future probably will produce drugs and behavioral technologies which will promote memory, improve learning, increase sexual activity, decrease rate of memory loss, and enhance performance. The social question then will be not

"what is morally right?" but, "is it effective?" "at what cost?" "is it safe?" "what are the social consequences?"

APPENDIX 3

Recombinant DNA -- Science as a Social Problem

By Everett Mendelsohn, James Sorenson and Judith Swazey

On July 15, 1976 The Cambridge (Mass.) Chronicle carried a banner headline across all six columns of its first page: "Three Month Ban on DNA Research O'Kayed by Council." To the local citizen of Cambridge and to the scientific practitioner who read this headline, the meaning seemed clear. A City council made up entirely of lay persons had voted to ban one form of basic biological research for a limited period of time. One city councilor commented at the time that had a public vote been taken among the lay citizens of Cambridge, it would have been 99 to 1 in favor of the ban. To scientific observers there was the chilling specter of scantly educated public bodies directly tampering with the conduct of basic research. It is hard to imagine a more starkly constructed confrontation between what science has considered its prerogatives and freedoms in designing research, and what worried citizens consider as their right to protection against hazard. That this dispute should be played out in the chambers of a local city council gives clear evidence of how far we are from having satisfactory procedures for discussing, assessing, and deciding on the proper modes of interaction between scientific research communities and the various groups that make up the public.

The case of recombinant DNA is a particularly interesting one, since there are very few examples in the history of science in which a moratorium has been declared in an area of basic research. (See below for discussion of the source of the initial moratorium and further discussion of the Cambridge

actions.) As witnessed in the recent history of cardiac transplantation, the calling of a clinical moratorium by physician-researchers themselves, or the imposition of a moratorium on their work by others, has occured with some frequency in the history of medical research, particularly when human subjects are involved. In the history of basic sciences, one of the few other examples that bear any similarity to the case of recombinant DNA was the attempt of some atomic scientists in 1939 to keep tight secrecy around all work pertaining to nuclear chain reactions. The effects of such secrecy would, of course, have been a dramatic slowing of progress in this area of basic research. The scientists recognized then that such secrecy and implied moratorium ran counter to the deepest traditions of science, and the plan failed to secure wide acceptance and was fairly quickly abandoned. These traditions include the largely unstated assumptions that the goals and guidelines of basic research are developed almost wholly within the scientific community, and that the ability to carry out basic research in an unrestricted manner is closely linked to the very bases of successful science and the fundamentals of academic freedom.

Just as the concern for the implications of a sustained chain reaction were first voiced from deep within the scientific community -- indeed, it was only those with substantial knowledge who could raise question -- so, too, concern about the hazards of experimentation with recombinant DNA came initially from those very scientists who were most directly connected with the potential research.

The issue arose through the development of techniques permitting the isolation and rejoining of segments of DNA, which would then allow for the

construction of biologically active recombinant DNA in living cells. The fact that the major host for such experiments involved E. coli, a bacterium which resides in the human intestine, added to scientific concern. The several groups of scientists who were conducting the research believed that their breakthrough would lead to an ability to create recombinant DNA molecules from a variety of animal, bacterial, and viral sources. They were aware that the outcome of such research could well lead to very important theoretical and practical advances. But they realized too that they might breach the long processes of evolution, creating novel types of DNA that could be highly infectious and/or have biological properties that could not be fully predicted in advance.

During the summer of 1973, a group of scientists attending the Gordon Research Conference on Nucleic Acids expressed concern about the scientific advances that they were witnessing and requested that the National Academy of Sciences undertake exploration of the issues. A copy of the letter to the Academy by M. Singer and D. Soll was published in Science (Vol. 181, p. 114, 1973), and was thus first brought to the attention of the larger scientific community. The Academy established a committee that was chaired by Paul Berg, Chairman of the Department of Biochemistry at Stanford University, and included ten other scientists close to research in the field.

After a good deal of internal give and take, as well as personal "research soul searching," the Berg Committee made a series of important recommendations. First, they urged "scientists throughout the world" to "join with the members of this committee in voluntarily deferring" a series of experiments. In the

interim, they wished to examine "the potential hazards of such recombinant DNA molecules" and to develop adequate methods "for preventing their spread." Secondly, they called for a very careful weighing of any "plans to link fragments of animal DNA's to bacterial plasma DNA or bacterial phage DNA." For, they warned, experiments which joined a foreign DNA to a DNA replication system would "create new recombinant DNA molecules whose biological properties cannot be predicted with certainty."

The Committee, thirdly, requested the Director of the National Institutes of Health to consider the establishment of an advisory committee whose tasks would be to oversee "an experimental program to evaluate the potential biological and ecological hazards" of the experiments noted above; to develop procedures to "minimize the spread of such molecules within human and other populations"; and to establish "guidelines to be followed by investigators working with potential hazardous recombinant DNA molecules." Finally, the Berg Committee called for an international meeting of relevant scientists from all over the world, to be convened early in 1975 to review scientific progress in this area and to further discuss appropriate ways to deal with the potential biohazards of recombinant DNA molecules.

The Report of the Committee on Recombinant DNA Molecules was a cautious one, which attempted to strike a note of realism and moderation. The Committee explicitly noted "that adherence to our major recommendations will entail postponement or possibly abandonment of certain types of scientifically worthwhile experiments." They also noted the difficulty of the evaluative tasks that they were suggesting.

It is worth making explicit what the Berg Committee did and did not deal with. Their interest was limited specifically to certain selected types of recombinant DNA experimentation, and their call was for a temporary halt in certain types of research and a careful review before other types were undertaken. Their interest did not extend to broader questions about the potential applications of these and other types of genetic experiments, for purposes such as biological warfare or genetic engineering. Instead, they addressed the very specific and limited area of hazards to public health which might be created by genetically altered bacteria developed with their new technique.

The discussions to date had taken place wholly within the context of the scientific community, and, indeed, the proposals of the National Academy of Sciences Committee on recombinant DNA molecules asked only for further considerations and guidelines to be developed within the scientific community.

The international meeting called for in the report from Berg's Committee met at Pacific Grove, California in March 1975, gathering at a Conference site called Asilomar. The outcome of this international conference on recombinant DNA molecules met with mixed response. One prominent dissident DNA specialist, Erwin Chargaff, referred derisively to the "Council of Asilomar" where "there congregated the molecular bishops and church fathers from all over the world in order to condemn the heresies of which they themselves had been the first and principal perpetrators." Judging the outcome in extremely negative terms, he went on to say this was probably the first time in history that the "incendiaries formed their own fire brigade." Others within the community of experimenters breathed something like a sigh of relief, thinking that they had come through a difficult period in which they had shown high responsibility and public concern.

At the opening session of the Asilomar Conference, Nobel Laureate David Baltimore - a member of the NAS committee chaired by Paul Berg - reminded the more than 100 conferees from 17 countries why they had assembled. In so doing, Baltimore, like other researchers before and after, sought to segregate the scientific issues sharply from the ethical and moral issues. The Asilomar meeting, he said, was not being held to discuss such "peripheral" ethical and moral questions as whether genetic engineering should be done at all, and its possible applications for chemical and biological warfare. Rather, the Asilomar scientists were to find a strategy for recombinant DNA research that would "maximize the benefits and minimize the hazards of the future," and offer this strategy as guidance to governments, scientists, and "private individuals" around the world.

The Asilomar Conference report was written by Paul Berg and four co-authors, and a summary was reported by the Executive Committee of the Assembly of Life Sciences of the National Academy of Sciences on May 20, 1975. The overall conclusions of the report were: the moratorium on research could be lifted; an assessment of potential risks could be made; and with proper precautions, facilities with varying degrees of physical and biological containment could be constructed within which the experimentation could be safely conducted. The only set of experiments to be deferred were those dealing with recombinant DNA derived from highly pathogenic organisms, DNA which contained toxinogens and, finally, large scale experiments using recombinant DNA's that are able to make products potentially harmful to humans, animals, or plants. The Conference also noted the possibility of developing a safer group of host organisms and vectors, or carrying organisms, and felt that continuous work in this area

would improve vector-host systems which might reduce the biohazards of research. Several additional areas of research not currently being conducted, which would be helpful to understanding problems of survival of laboratory strains of bacteriophages, were to be encouraged, as well as the work of monitoring various elements of experimentation. The Committee of Asilomar scientists, in sum, issued a report which opened by giving recognition to what they felt would be the "revolutionary" impact of recombinant DNA research techniques, and closed by proposing procedures for physical and biological containment which would permit research to proceed with appropriate safeguards.

In one sense, the guidelines promulgated by the Asilomar Conference could be viewed as public policy, because they were accepted on a temporary basis as the guides which would govern the granting of research funds by the National Institutes of Health and the National Science Foundation. The next formal steps within the scientific community were to be taken by an NIH advisory committee on recombinant DNA molecules, that had been appointed in response to the recommendations made by the original Berg Committee. Indeed, it was this NIH committee which had recommended that the Asilomar guidelines be used as the basis against which to evaluate the funding of research. During the summer of 1975 the NIH committee, meeting in Woods Hole, Massachusetts, assessed, argued about and ultimately weakened the experimental guidelines. Responding to criticisms that the Woods Hole draft was too lax, the head of the NIH committee, DeWitt Stetten, appointed a second subcommittee to reevaluate and propose alternative guidelines. In February 1976, the Director of NIH held hearings on the proposed guidelines, which had been revised by the second subcommittee in December. These hearings

represented the first, limited, public input into the NIH deliberations on recombinant DNA research. Despite some criticism that the guidelines were not strict enough in their containment requirements, and questions about how they would be generally enforceable beyond researchers receiving NIH funds, they were promulgated on June 23, 1976 (see the Federal Register, July 7, 1976, Pt. 2, Vol. 41, No. 1, p. 31).

In the months between the Asilomar Conference, the Woods Hole subcomittee meeting, and publication of the final revision of the guidelines, the character of the discussions altered markedly. Beginning with what seemed like the contained considerations of those directly involved in recombinant DNA research, arguments broadened to include sharp criticisms from such inside-outsiders as Erwin Chargaff and the "Genetics in Society" group of Scientists and Engineers for Social and Political Action (SESPA). There was also a foretaste of the public interest that was to come when the Senate Health Subcommittee chaired by Edward M. Kennedy of Massachusetts held hearings on public policy for recombinant DNA techniques in Washington, D.C. on April 22, 1975. The discussion begun within the scientific community was further joined by the public or its representatives on at least two university campuses, the University of Michigan and Harvard University, during the spring of 1976, when recombinant DNA research and facilities to house it became the focus of attention of University committees on research safety and policy. Then, the most striking break in the internally contained discussions occurred when the issue of recombinant DNA research became the focal point for several meetings of the Cambridge (Mass.) city council in late spring and early summer 1976.

Thus, even as the scientific community attempted through a series of internal subcommittee hearings of the NIH to define policy and guidelines for research, dissident groups within that research community and lay public groups moved the issues to a far larger forum than that envisaged by that first group of DNA researchers who had called for a research pause or moratorium in 1973. Prior to the issuance of the NIH guidelines, formal public involvement was minimal at best, being limited only to the public members of the advisory committee to the director of the NIH and to those members of the public who could make their way to a brief advisory committee meeting (February 10, 1976) and testify as witnesses.

What, then, are the issues raised by recombinant DNA research, and what are the proper bodies to evaluate and to resolve those issues? Members of the DNA research community and others among their scientific supporters at first seem shocked that an issue which seemed to rest on careful consideration of highly technical matters should break out of the scientific arena and become part of public and even political discourse. As the scientists focused on the issue, many of them wanted to draw the lines of consideration as tightly as possible, dealing principally or solely with the problem of "biohazards." Some, we have seen, wished to rule out discussion of what they saw as the "peripheral" considerations of ethics and morality -- e.g., whether recombinant DNA research should be conducted at all, because of the implications of these techniques for genetic engineering and biological warfare. Others in the scientific community expressed concern over whether the public could ever gain enough understanding about recombinant DNA research to make appropriate decisions. Still others saw a basic issue of intellectual and academic freedom, an issue of rights that

they felt scientists would lose if the public, whether informed or not, became involved in making decisions about the regulation of basic research.

As discussion of recombinant DNA research has moved beyond the confines of the scientific community that both initiated that research and first surfaced concerns about its possible hazards, it has become evident that a broad and complex range of issues demand scrutiny. That is, the task of assessing this research, and of deciding who should do the assessment, involves a benefit-risk calculus that involves far more than technical matters of research methods and biohazard containment procedures. One fundamental matter, of import not just to the scientific community, already has been alluded to: Do "we" -- contemporary society -- still want to grant scientists their long held "rights" of autonomy, to develop and pursue basic research areas according to the dictates of their professional judgment? If the answer is no, as may be the case with recombinant DNA research, then who ought to determine which avenues of research are pursued, under what conditions, and what are the implications of this new governance for science? Answers to these questions rest on value judgments. And value judgments are invoked because, despite the belief of some scientists that one can separate questions about science from questions about ethics and values, science is not and never has been "value-free."

Decisions about the pursuit of recombinant DNA research, by whomever they have been or will be made, involve assessments of various types of short-term and long-term benefits and risks. While it was the involved research community who first "went public" with this calculus, it is important to remember that they called only for a moratorium -- a temporary cessation of certain types

of recombinant DNA research. That is, as the Asilomar Conference report made clear, these scientists' deliberations were premised on the conviction that they were engaged in work of revolutionary importance. Recombinant DNA research, they affirmed, ought to go forward; the questions were ones of pace and suitable precautions. It was only as the debate moved into more public forums, partly in response to criticisms about the nature of the Asilomar proceedings, that the question began to be voiced, "Should recombinant DNA research be done at all?"

Both proponents and opponents of recombinant DNA research have articulated, with various degrees of clarity, the following types of questions about benefits and risks. (But, we would add, there has emerged no consensus among the factions as to satisfactory answers.) First, there are questions about benefits. Working with a fundamental research methodology such as the techniques developed for recombinant DNA, how accurately are we able to forecast the types of useful results, in terms both of fundamental knowledge and applications, that might be gained? Can we predict with certainty new research pathways that might be developed for the work? And can we tell the lengths of time that will be required for the work to yield given results? In brief, how good are we at assessing present and prospective benefits for a given area of basic research? Secondly, there are risks of a near and long term nature that may arise "from tinkering with evolution" or breaching natural genetic barriers. Who is competent to define and estimate present biohazard risks, and how accurately can they do so? Thirdly, in a situation where there are short and long term recognized and potential risks and benefits, how shall we decide what types of experiments should be conducted and should not be conducted? How shall we decide what

physical and biological safeguards are necessary for experiments, and how shall we monitor the procedures of the ongoing experiments? And further, how shall we establish a calculus for projecting future implications, as contrasted with retrospective judgments on past and present problems?

Fourthly, when it comes to ethical, social, and legal issues presented by fields such as recombinant DNA research and by the potential applications of that research, how shall we establish guidelines that transcend the narrow issue of protection against biohazards, and instead focus on the broader responsibilities of science and scientists. Is post hoc adjustment or rehabilitation enough, or is there a necessity for developing careful, predictive processes?

Fifthly, should and can we establish enforceable guidelines, at local or national levels, to regulate any or all recombinant DNA research, when conducted by researchers receiving public funds, by the private sector, such as pharmaceutical companies, or by a biology instructor? And, if there are potentially grave hazards, what good is regulation in one country alone? What are the modes for discourse and possible regulation at an international level?

The formal and informal groups and agencies that have become involved in the recombinant DNA discussion to date reflect the tangled web of interactions within and between science, government, and elements of the lay public. On the scientific side, the semi-formal Berg Committee and the Asilomar Conference group were joined by the statutory authority of the National Institutes of Health and its advisory panels and subcommittees, the

advisory groups on research safety and policy committees on University campuses, and various individual scientists voicing deep concerns about the research and about the ways it was being dealt with by the "science establishment."

On the public side, the debate has been joined by such diverse agencies as the Board of Regents of the University of Michigan, the Dean of the Faculty of Arts and Sciences at Harvard University, the city council of Cambridge, Massachusetts (and the lay subcommittee on research hazards that they appointed), several congressional subcommittees, and semi-public and semi-private political action groups within the scientific community. That no resolution of the issues of near and long term risks and benefits have been achieved is apparent. And equally apparent is the current lack of any mechanism, or procedure, for encompassing the obviously conflicting interests of the numerous involved parties.

In a headline on June 16, 1976, the Washington Star caught the picturesque view of the Cambridge scene: "Is Harvard the proper place for Frankenstein tinkering?" In many ways the Cambridge situation has been a perfect one in which to see all the elements of the enlarged debate acted out in public, in contrast to the University of Michigan, where the debate was confined largely to the academic community. There was the flamboyant mayor who has made a career of "defending the little people against Harvard"; there was a city council long known for lively public debates that often involved the City's two major educational institutions, MIT and Harvard; and there was the all star cast of scientists on both sides of the issues. That cast included several Nobel Prize winners, who split on this issue, and a very active chapter of Science for the People, which included among its members, geneticists and microbiologists of some standing. The controversy arose in the most conventional of

manners, when researchers in the Department of Biochemistry and Molecular Biology proposed that a new facility be constructed which would conform to the guidelines developed at Asilomar and further polished in the NIH. They planned to construct the laboratories in the already existing biological laboratories, a sprawling red brick building, guarded by two rhinoceroses. Perhaps it is symbolic, with respect to this controversy, that the laboratories face out to Divinity Avenue and the old building of Harvard Divinity School, and back on to Andover Hall, the new quarters of the Divinity School.

With the notable exception of Nobel Prize winner, George Wald, the molecular biologists favored the proposed research facility, and gave strong backing to the conduct of research on recombinant DNA. When the discussion came to the biology department where the facilities were to be located, the situation became more difficult. Although the proposal had passed a biohazards subcommittee, composed of scientists, some vigorous opposition developed among biologists at both the senior and junior level. A fairly stormy meeting of the Department was held, and although a vote would probably have favored moving ahead with the research, there was certainly no clear consensus.

The next step was consideration by the University's committee on research policy. This committee held an open hearing to which all members of the University were invited and at which the proponents and opponents of recombinant DNA research rehearsed their views. The perspectives expressed covered the full range, from those praising the research and its important potentials to those sharply critical of the biohazards which might be encountered, to others who raised the long term issue of involvement in research on genetic engineering.

Most of the discussants were from within the scientific community, including members from groups at MIT, Brandeis, Boston University, and the several hospitals in the area. The dramatic high point of the meeting foreshadowed what was to come, when a member of the Cambridge City Council arose, introduced herself, and indicated that the Council was keeping a watchful eye on the activities at the University. As had been predicted, the University's Committee on Research Policy (made up almost entirely of natural scientists) submitted a positive recommendation to the Dean, who then authorized construction of a high safety level (P3 level) containment facility.

Enter the City Council, which in early June put Harvard and MIT on notice that it was conducting a public hearing on June 23rd, to which scientists and the lay public were invited to present their views. On June 23, the Council opened its hearings in packed chambers; in attendance were representatives of the major research facilities, as well as visiting officials from the NIH and the other agencies. The hearings, which were filled with vigorous argument and a good deal of humor, lasted until one a.m. and were then adjourned to meet again on July 7. One councillor commented that the two weeks between those sessions saw more intense citizen contact with council members than had occurred on any other single issue facing the city of Cambridge. The Council strategy clearly was to arrive at a compromise. It recognized its public responsibility and its role as representatives of the local citizenry. It realized its responsibilities under the public health and safety laws, which require it to pass on the safety of all manner of facilities, from gasoline filling stations to complex industrial plants. The Council also recognized that, by and large, it and the citizenry it represented were not yet knowledgeable enough about recombinant

DNA work to make a fully informed decision; but, on the other hand, they noticed that decision there must be.

What emerged was a combination of political compromise and plans for greater public involvement in science. The compromise took the form of a Council's decision to ask for only a three months' moratorium on recombinant DNA research, a request that was readily agreed to by the scientists involved. (A three month extension was later voted by the council as they awaited a committee report.) A committee of scientists and lay people was established, the Cambridge Laboratory Experimentation Review Board, which was to hold hearing and present a recommendation to the Council for further action. At the other end of the spectrum, the Mayor, who envisages himself as the protector of the "little people" of Cambridge, invited the proponents and opponents of recombinant DNA work to take their palces in adjacent booths at the Saturday market in Kendall Square, Cambridge. The sight of the eminent scientists with shirt sleeves rolled up, digging in for a long session of public education with all comers, was a fascinating one, and added a new dimension to modes of handling disputes between scientists and the public.

While the Cambridge situation might be seen as the microcosm of a much broader problem, one thing seemed clear to all the participants: in the final analysis, resolution of the issues raised by recombinant DNA research would not be solved in the context of a small group of universities and a relatively small city's elected council. For, the problem transcends those narrow boundaries, albeit the community focus provided one of the more interesting scenes for debate and interaction between experts and lay people.

In the course of the debates in Cambridge and those held in such other localities as Ann Arbor, Michigan and the New York Academy of Sciences, a variety of proposals were brought forward, each seeming to reflect to some degree the interests of one group or another. The City Council in Cambridge, for example, listened to a proposal that it recommend to the Nobel Prize Committee that they explicitly exempt work on recombinant DNA from Nobel Prize consideration, thereby lowering one pressure for intensive and speedy work at this time. The Nobel Prize winning biochemist, George Wald, pleaded for a general slow down in research, pointing out that, if the problem is an important one today, it will be equally important at some future time when greater precautions might be taken. Others suggested that the research be taken out of populated areas and conducted instead in remote facilities operated under conditions of extreme caution. In response to the complaint that having to go long distances to conduct their research would be a great inconvenience to the scientists, one commentator noted that, given the scientists' claim of great benefits to humanity from the research, such a trip should not make that much difference.

Another proposal was that there be a period of intensive research to find an alternate host or series of host organisms other than E. coli, which would be much less likely to infect humans or those plants and animals on which they depend, and would thereby lower the probability of producing human harm. The estimate for developing the amount of knowledge needed to replace E. coli bacterium as the host organism ranged from two years down to six months. Another suggestion was that certain areas of research be ruled out at least for the present, so that the issue of hazard might be examined in

greater detail and under less pressure.

The Cambridge City Council heard recommendations for moratoria ranging from the three months that were agreed upon to a period of two years, and some kept insisting on the need for putting off the research until some later date. The position of the organized research community at Harvard and MIT was that research should proceed within the guidelines established by the NIH, and thus taking place in containment facilities appropriate to the risks envisaged. There were some among the scientists who saw the whole discussion as downright interference in their work, and they just asked to be left alone. It was clear that none of these proposals by itself would make everyone happy, nor was it clear that any mix of them would leave any one of the participants happy. The outstanding question thus is, through what procedures could a decision be arrived at which would give real scope for public participation, while at the same time providing real care for the needs of science and experimentation?

To the observer of the debates that have swirled around recombinant DNA research since 1973, one persistent tendency has emerged. In the course of the discussions, even those at the Cambridge City Council, the issue seemed to focus time and time again on the specific question of immediate biohazards, with some participants in the debates pointing to broader matters, such as whether the research should be done at all, and, if so, its longer term evolutionary and societal implications. The scientists have pointed either to the nature of the hazards and the difficulties of resolving them, or to the operational steps that could be taken to lower the risk of hazard and of potential harm. To the public participants in the debate, the issue was

brought back continually to what harm might be done to the community, the family, or the individual.

On only one or two occasions, and generally within a political context that sharply questioned contemporary scientific activity, was the issue of genetic engineering ever raised. The concept that there might be some form of "forbidden knowledge," which neither the scientific community nor public bodies are yet able to deal with, never received careful attention. Thus, while we find from many sides a plea to establish modes for developing science, medicine, and technology in such form that its current actions do not lead to future harm, we seem not to have even an appropriate framework within which to discuss the issues involved. To the scientist, genetic engineering seems little more than an extension of existing techniques for altering natural genetic patterns, while to the lay person genetic engineering seems so far from comprehension as to fall more nearly within the realm of science fiction.

As the case of recombinant DNA makes apparent, areas of science generally thought to be within basic research, now and with some probability in the future, will raise questions of short term and long term public hazard. That the scientific community has the ability to spot issues of this sort has once more been demonstrated by the fact that some recombinant DNA researchers themselves noted the danger, signaled it, and attempted to find the mode for remedial and preventive actions. It is also apparent that, particularly in those areas where science may have consequences for the public, some members of the public are no longer docile or willing to remain outside the framework or critical decision making. But equally apparent is the fact that there are at this point few procedures by which the public and the participating researchers

can join in the important discussions, evaluations, and forecastings that are part of the decisions of why, how, and when to proceed. The design of such procedures seems to demand high priority.

Since the summer of 1973, as we have indicated in this brief chronicle, the range of issues perceived in recombinant DNA research, and the numbers and types of people dealing with those issues, have broadened considerably beyond the concerns voiced by the small groups of scientists at the Gordon Research Conferences. At this writing (November 1973), the subject of recombinant DNA research and how to deal with the issues it poses has generated a diverse array of scientific, political, public policy, and legal responses, at local, state, and federal levels. Among the scientific community, the rapidly expanding pace of recombinant DNA research is indicated by the establishment of a new journal, Gene, "an international journal devoted to gene cloning and recombinant nucleic acids," to begin appearing in 1977.

The NIH guidelines have been followed by a second document, one, to our knowledge, unique for a basic research activity: a draft Environmental Impact Statement on recombinant DNA research, developed in accordance with the National Policy Act of 1969 (see the Federal Register, Sept. 9, 1976, p. 38425). In the Executive Branch of government, biologist Donald Kennedy has been appointed as a consultant to the White House Office of Science and Technology Policy: one of his assignments is policies concerning guidelines for recombinant DNA research. And, in Congress, Senator Kennedy's Health Subcommittee again held hearings (in September) on the implications of recombinant DNA work, focusing particularly on the plans of private industry and government research agencies to conform to the NIH guidelines.

State governments and private groups, too, are becoming involved in the question of how widely applicable and enforceable the NIH guidelines are. The New York State Attorney General, for example, presently is considering how to control recombinant experiments in his state, whether by somehow requiring all researchers to comply with the NIH guidelines, or by imposing stricter regulations. And two of the country's largest environment law firms, the Environmental Defense Fund and the Natural Resources Defense Council, have petitioned the Department of Health, Education, and Welfare, asking the government to extend the NIH regulations to cover all laboratories doing recombinant DNA work, including private industry.

As these instances of federal, state, local, and private initiative make clear, questions about whether recombinant DNA research should be pursued -- and if so, how, -- are far from settled, the expectation of the Asilomar conferees notwithstanding. And, complex as the situation is within the United States, it is evident that public policy, ethical, legal, and scientific "channeling mechanisms" must be developed not only within this country, but internationally as well. For, recombinant DNA molecules, and also the potential benefits and risks they carry with them, do not recognize geographic boundaries.

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In addition to these and many other individual references on the recombinant DNA debate, those interested in this subject should be aware of the Recombinant DNA Project underway in MIT's Oral History Program. Under the direction of Professor Charles Weiner, the Project thus far has collected over 1,000 documents and taped oral history interviews with 45 individuals, dealing with recombinant DNA research.

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