Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

Varmus – Human Subject Protection

Divider Title: _____

REVISED

Testimony of
Harold E. Varmus, M.D.
Director, National Institutes of Health

Before the
Subcommittee on Human Resources and Intergovernmental Relations
Committee on Government Reform and Oversight
United States House of Representatives

Thursday, May 8, 1997
Rayburn House Office Building, Room 2247
10:00 a.m.

FOR RELEASE UPON DELIVERY

Mr. Chairman and Members of the Subcommittee:

I am Harold Varmus, Director of the National Institutes of Health. I am pleased to appear before the Subcommittee to describe our system of protection of human research subjects, a responsibility of enormous weight. While the collection of scientific data to expand our knowledge of the causes of human ills is the ultimate aim of medical research, of importance is the protection of the individuals who assist us through their participation in research studies. Without these individuals, it would have been impossible for us to have made such remarkable progress in the development of effective treatment and prevention strategies for a host of human diseases and conditions.

History of Human Subjects Protection

May 30 marks the 22nd anniversary of the formal promulgation of the Department of Health and Human Services' (DHHS) regulations for Protection of Human Subjects in research (Title 45 Code of Federal Regulations Part 46). This vigorous system of protections, designed to preclude the very problems we will discuss today, is guided by a set of principles--respect for persons, beneficence, and justice--which are the three quintessential requirements for the ethical conduct of research involving human subjects. It is based on a succession of judgments made by a variety of individuals in the context of DHHS regulations. Scientists, ethicists, lawyers, advocacy group members, and, most importantly, public citizens look at research protocols and weigh risks and potential benefits.

Let me take a moment to give you some background on the development of human subjects protections. Our modern-day system began with the Nuremberg Code, which was developed for the Nuremberg Military Tribunal to provide standards by which to judge the human experimentation conducted by the Nazis. Many of the Code's principles regarding the ethical conduct of research involving human subjects still are followed today. It was followed in 1964 by the World Medical Association's *Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects*; and in 1966, NIH issued "Policies for the Protection of Human Subjects, which established the institutional review board (IRB) as one mechanism through which human subjects would be protected.

As I have mentioned, it was in May 1974 that the DHHS regulations were issued, elevating to regulatory status NIH's "Policies." Then in July 1974, the National Research Act was enacted, which established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The activities of the National Commission, which was active from 1974 to 1978, culminated in the development of the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* The Report set forth the three basic ethical principles underlying the acceptable conduct of research involving human subjects, mentioned above, which continue to guide us today. Over the years, the DHHS regulations have been revised six times, adding additional protections for vulnerable populations.

Whose Responsibility Is The Protection of Human Subjects of Research?

Who is involved in protecting human subjects? The architecture of the current system involves at least half a dozen levels of protection. Ultimately, protection depends on several principles. First, the clinical investigator must be scientifically well-trained and also aware of his or her ethical responsibilities as a researcher committed to both the advancement of knowledge and the welfare of research participants. The initial planning of the research protocol is a vital part of the protection of human subjects, during which time the researchers perform a thorough review of the literature in order to develop a research plan and also to identify any potential risks associated with the research. The investigators address both benefits and risks associated with the research, and formulate an appropriate process to inform potential participants, to obtain informed consent for participation, and to document the consent.

Second, there is review and approval of the research protocol by a local IRB, a requirement of the DHHS regulations for Federally-supported research. Although non-Federal research is not covered by these regulations, you should be aware that the DHHS regulations are in general use by others as well. Following IRB review, additional review responsibilities rest with 1) the executive official of the research site; 2) the scientific review group at the NIH (generally, within the Division of Research Grants, or within an NIH Institute or Center [IC]); 3) the Advisory Council or Board of the funding IC; and 4) the executive official of the funding entity. Each has the authority to raise concerns about human subjects issues and to request further evaluation and correction of any problems found.

Once multiple review of the proposed study design and informed consent documents has been accomplished, and the proposal is funded, there is the crucial interaction between the research volunteer and the research investigator. It is at this point that the informed consent process begins -- when the research volunteer is apprised of what will be required for his/her participation in the study, including known associated risks. The informed consent document is only one component--the written component--of the informed consent process. I will describe the particulars of informed consent later. There also may be several individuals involved with the research volunteer during the process of obtaining informed consent, and throughout the course of the study, such as the nursing and scientific staff, as well as a physician. There also may be a consent auditor or monitor, or an advocate for the research subject to ensure that research subjects understand and are kept informed of any proposed changes or risks.

IRB Review

As I mentioned earlier, IRB review is required by DHHS regulations. The IRB must be established at the local level and have a minimum of five people, including at least one scientist, one nonscientist, and one person not otherwise affiliated with the institution conducting the research study. Having the IRB at the research site is the cornerstone of our system of protection of human subjects. IRB review is a prospective and continuing review of the research by a group of individuals with no formal interest in the particular research study, who are in the best position

to know the resources of the institution, the capabilities and reputations of the investigators and staff, and the prevailing values and ethics of the community and, thus, the likely subject population. No human subjects research may be initiated, and no ongoing research may continue, in the absence of an IRB approval. The NIH cannot provide funds for human subjects research unless an IRB approves the protocol for such studies.

Once research is initiated that involves human subjects, IRBs have continuing responsibilities. These include the conduct of continuing review at intervals appropriate to the degree of risk, but not less than once per year; the authority to observe or have a third party observe the consent process and the research; prompt reporting of any unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance with the IRB's requirements or determination, or with the regulations; and authority to suspend or terminate IRB approval of research that is not being conducted in accord with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

Data Safety Monitoring Boards

An additional layer of review that is sometimes employed is an independent Data and Safety Monitoring Board, or "DSMB," appointed to oversee and to evaluate the research investigation. Size and make-up of DSMBs vary; however, most include physicians with expertise in the disease under study, gained either through patient care or in the conduct of research, statisticians, and experts in scientific specialities. A patient advocate also may be included among the members of a DSMB. At periodic intervals during the course of a research study, the Data and Safety Monitoring Board reviews the accumulated data and makes recommendations on the continuation, or modification, of the study. When a study is stopped prematurely because of a toxic effect or because a strong positive effect was seen, and it would be unethical to continue with some subjects not receiving the test article that has demonstrated benefit, it is likely due to the intervention of a Data and Safety Monitoring Board.

Institutional Officials

The final responsible party at the applicant/grantee institution is the institutional official, who signs-off on the research project when the application is submitted to the funding agency and assumes responsibility for the research project on behalf of the institution when the award is accepted.

Those directly involved with the protection of human subjects on behalf of the NIH are the members of peer review groups, the Director and other staff of the funding institute or center, and the Office of Protection from Research Risks (OPRR). Located administratively and logistically at the NIH, OPRR exerts extensive oversight of the entire process of human subjects protection for HHS-supported research. Among its many responsibilities, the OPRR develops and monitors, as well as exercises compliance oversight relative to, DHHS regulations; establishes criteria and negotiates for Assurances of Compliance with institutions engaged in

DHHS-supported research involving human subjects; conducts programs of clarification and guidance for both the Federal and non-Federal sectors with respect to the involvement of humans; and evaluates the effectiveness of DHHS policies and programs for the protection of human subjects. OPRR plays a major role in ensuring that human subjects of research are informed and protected and that thorough investigations of human subjects concerns are conducted. OPRR also investigates complaints from research subjects and others concerned with their welfare, and conducts a national program to educate the research community about human subjects protections.

Members of NIH scientific review groups and advisory councils evaluate the proposed involvement of human subjects in the research and identify comments or concerns regarding protections for human subjects. NIH program staff work with the principal investigator and the institution to resolve any human subject comments or concerns prior to award. Grants management staff confirm that an applicable Assurance of Compliance and IRB approval have been obtained prior to award. Once these steps are completed, the Institute or Center Director makes the decision whether or not to fund the research project.

A Perfect System?

While I have emphasized the multiple layers of protection inherent in this system, I know you are most concerned about the possibility that this system can somehow fail. We acknowledge that despite our best efforts, there are occasions when the systems for protection are not perfect or the individuals charged with ensuring adequacy of these protections are unable to foresee potential problems. What is the possibility of a failure in human judgment running through six or more layers of review? Certainly, the successes far outweigh the failures. Nevertheless, there have been research studies that have required further evaluation for human subjects concerns. To give you a sense of the kinds of problems we have encountered, I will relate brief accounts of selected research studies involving human subjects concerns and highlight actions taken to address them.

In one well-publicized instance, concern was raised about the proper explanation of risks in the informed consent process for a study involving research subjects with schizophrenia at the University of California at Los Angeles (UCLA). After extensive review of concerns voiced, and of the institution's informed consent practices in general, it was determined that the IRB did not exercise sufficient oversight of the informed consent process. The institution was directed to revise the informed consent process. In addition, OPRR instituted close monitoring of the institution's human subjects activities, and issued a report on the investigation of UCLA activities relative to this protocol. As a result of this occurrence, the Acting Director of the National Institute of Mental Health (NIMH), the funding entity for the study, sent correspondence to more than 200 clinical investigators to provide each with a copy of the OPRR report and to request that they carefully scrutinize all informed consent documents for full compliance with the OPRR recommendations. In 1995, the Institute released a program announcement--Informed Consent in Clinical Mental Health Research--to expand upon previously funded research on informed

consent. NIMH also has sponsored, and co-sponsored with advocacy groups, a number of workshops and conferences aimed at addressing issues specific to mental illness in clinical research.

In a second instance, concern was expressed about the misuse of an expedited IRB review process. OPRR identified failure of leadership within the IRB as the root of the problem, resulting in resignation of the IRB chairman. Sometimes, an OPRR review leads to a finding that the concerns were unfounded as in the case of another institution. OPRR followed up on concerns that were raised about whether a particular IRB was properly conducting the required annual review of continuing research. The institution demonstrated to OPRR that some 2,000 research protocols involving human subjects had, indeed, received continuing review by the IRB in accord with DHHS regulations.

Protection of Vulnerable Populations

Let me return briefly to the specific responsibilities of the IRB and the concerns IRBs must address. IRB review assures that risks are minimized; risks are reasonable in relation to anticipated benefits; selection of subjects is equitable; there is proper informed consent; and the rights and welfare of subjects are maintained in other ways, as well. This is particularly important when subjects are likely to be vulnerable to coercion or undue influence.

What populations are judged to be vulnerable? IRBs pay careful attention to research involving children, prisoners, pregnant women, individuals with mental disabilities, individuals who are economically disadvantaged, and individuals who are educationally disadvantaged.

The DHHS regulations provide extra protection for vulnerable subjects in several ways. If an IRB regularly reviews research that involves a vulnerable category of subjects, consideration must be given to including as IRB members one or more individuals who are knowledgeable about and experienced in working with the vulnerable population. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, IRBs must see that additional safeguards are included in the study protocol. Specific, detailed protections are actually written into DHHS regulations pertaining to pregnant women, fetuses, human ova fertilized in vitro, prisoners, and children. I would like to highlight a few additional protections in place for several of these vulnerable groups.

Children

Recognizing the need for special attention to pediatric subjects of research, it is assumed that children are incapable of providing informed consent. As such, special protections are mandated for this vulnerable population. As required by regulation, parents or legal guardians must give proxy consent for their children to participate in research protocols. In protocols involving only minimal risk or those involving greater than minimal risk but which have the prospect of direct benefit to the child, only one parent must give consent. In protocols involving

a minor increase above minimal risk or more than a minor increase above minimal risk in which the child stands not to benefit, both parents must sign a consent form.

As an additional protection, within the intramural program of the NIH--with specific, rare exceptions--children between the ages of 7 and 18 who are capable of understanding that they are involved in a research project are required to sign an "assent" form, which acknowledges their affirmative agreement to participate in a research protocol. Much care is given to writing assent forms in readily understandable language that is age-appropriate and to providing simple oral explanations, sometimes accompanied by visual demonstrations with dolls or by role-playing. Research investigators and nursing staff are often assisted in the "assent" process by patient advocates and assent auditors who are not involved in the research project in order to avoid any possibility of coercing the child into participating in the protocol.

Persons with Mental Illness or Dementia

Although there are no DHHS regulations providing specific protections for persons with mental illness or dementia, special attention is being given to informed consent issues related to their involvement in research studies. Recognizing the many issues surrounding patients with mental illness, the NIMH co-sponsored with the National Alliance for the Mentally Ill (NAMI) a series of meetings, including a symposium at the NAMI annual meeting, to discuss ethical issues concerning human subjects with mental illness in biomedical research. The NIMH and NAMI now are planning co-sponsorship of a meeting with a broader group of participants to develop a series of principles to guide informed consent with potentially cognitively impaired subjects. NIMH also sponsored a conference, *Ethical and Human Subjects Issues in Mental Health Research with Children and Adolescents*, to discuss the specific ethical challenges involved in this research. In addition, the NIMH and OPRR co-sponsor regional workshops to focus on issues specific to patients with mental illness in clinical research. These workshops, held throughout the country, are attended regularly by approximately 1,000 IRB members and researchers.

Issues of informed consent are of particular concern for the elderly population, particularly with regard to Alzheimer's disease patients and others with diminished cognitive capacities. The National Institute on Aging (NIA) is participating in a Request for Application on informed consent in research involving human subjects, which I will discuss later. NIA is particularly interested in the role of cognitive function in aging, and the ability of the elderly to understand and remember so that information related to the consent process is meaningful.

In addition, the NIA issued an announcement in the NIH Guide to Grants and Contracts, in October 1996 on "Implementation of Policies for Human Intervention Studies." This notice codifies additional oversight on the part of NIA Program Administrators to ensure the safety of participants in NIA-supported intervention studies.

Beyond these guidelines and the general NIH-wide guidelines on protection of human subjects, the NIA has no formal written guidelines for informed consent for research with Alzheimer's disease patients. However, efforts are being made to maintain consistent practices across large multi-site clinical studies. For the Alzheimer's Disease Cooperative Studies Program, the Principal Investigator reviews the consent forms from each site for consistency and appropriateness.

In addition, the NIH Warren Grant Magnuson Clinical Center--together with the NIMH, the NIA, the National Institute of Neurological Diseases and Stroke, and other NIH institutes--has pioneered the concept of the durable power of attorney applied to research participation, whereby individuals, while competent, could identify someone to represent their best interest and provide informed consent should they later become cognitively impaired. The classic example of when this would be used is with participants in a study of progressive dementias.

Drug Users

The National Institute on Drug Abuse recognizes the importance of drug users to drug abuse research and the special attention that must be given to ensuring informed consent in this special population. In addition to the roles that the IRB and OPRR play in ensuring the protection of participants in NIDA research studies, the Institute adheres to the basic principle and provides guidance that the investigator has the primary responsibility for the protection of vulnerable subjects. The investigator must give adequate consideration to the mental and physical conditions and motives of the individuals in terms of their ability to fully understand the context of the informed consent. If there is a question about a potential subject's ability to give meaningful and informed consent, an independent clinician, ethical consultant, or uninvolved third party with appropriate qualifications should be asked to evaluate this ability if the subject is to be entered or continued in the study.

Those most necessary to drug abuse research are drug abusers. Recidivism is a key issue in drug abuse treatment research, and relapse cannot be studied without the use of individuals who have taken drugs. Research that requires administration of drugs to individuals who are addicted to drugs warrant special attention, however. There are a number of extremely important principles which need to be addressed by anyone considering or evaluating requests to conduct research using drug-addicted individuals. Medical and mental examinations and screenings must be made to ensure the absence of any medical or mental condition for which further drug exposure would be contraindicated. A thorough assessment of the risks entailed if the participant is to be exposed to a higher dose, rate of administration, and/or new route of administration than they would normally encounter by their own choice in their usual circumstance must be made. Finally and most importantly, investigators must make a serious and concerted effort to link these individuals to drug abuse treatment

The effects of drug use on adolescents is a major issue in drug abuse research and children are often involved in drug abuse prevention research. If the hypothesis being tested

requires the involvement of individuals under age 18 and the risk/benefit assessment is favorable, the investigator must: (1) obtain the individual's consent and/or assent to participate in the study; (2) obtain permission from the parent(s) or guardian for the individual to participate in the study; and (3) comply with any applicable local laws governing such research.

Assurance of Compliance With Human Subjects Regulations

The DHHS regulations for Protection of Human Subjects are not a set of rules that can be applied rigidly to make determinations of whether a proposed research activity is ethically "right" or "wrong." Rather, they are a framework in which investigators, IRB members, and others can ensure that serious efforts have been made to protect the rights and welfare of research subjects.

OPRR oversees implementation of the regulations in all DHHS facilities as well as domestic and foreign institutions or sites receiving DHHS funds. OPRR requires that each DHHS agency and extramural research institution that conducts research involving human subjects set forth the procedures it will use to protect human subjects in a policy statement called an "Assurance of Compliance." An Assurance statement is a formal, written commitment to: 1) widely-held ethical principles; 2) the DHHS regulations for Protection of Human Subjects; and 3) institutional procedures adequate to safeguard the rights and welfare of human subjects. The terms of the institution's Assurance are negotiated with OPRR. The detailed, written Assurance statement becomes the instrument that OPRR uses to gauge an institution's compliance with human subject protections if there is a problem.

At OPRR's discretion, institutions with large research portfolios and demonstrated expertise in human subjects protection may be granted a Multiple Project Assurance (MPA). An MPA, as the term implies, is an institution's pledge of full human subject protections for multiple projects at the institution. More than 450 institutions currently hold an MPA. As an agency regulated by OPRR, the NIH Intramural Research Program, with 14 Institutional Review Boards overseeing research conducted at the NIH itself, has earned a Multiple Project Assurance from OPRR.

Informed Consent

All present today know how integral, and how crucial, the process of informed consent is to the protection of human subjects, whether in research or in other situations where medical assistance is necessary. Many have a general picture of informed consent, and it is useful to add higher resolution to that picture. DHHS regulations specify 14 elements of informed consent. Of these, eight are required and are designed to ensure that research subjects are fully informed

about the studies in which they are to enroll, the risks and benefits, if any, as well as their rights with regard to participation in DHHS-sponsored research. These are highlighted below.

1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental.

2) A description of any reasonably foreseeable risks or discomforts to the subject.

3) A description of any benefits to the subject or to others that may reasonably be expected from the research.

4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

6) For research involving more than minimal risk, an explanation as to whether any compensation will be paid, whether any medical treatments are available if injury occurs, and, if so, what they consist of, or where further information may be obtained.

7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

A researcher who seeks to recruit an individual for research without conveying these elements of information in language understandable to the potential subject is not obtaining *informed* consent.

Implementing informed consent is a dynamic endeavor, and we are always seeking new perspectives. For example, a June 2, 1997, conference co-sponsored by the National Cancer Institute, the NIH Office of Research on Women's Health, the National Action Plan on Breast Cancer, and others, will seek to identify principles and models for prospectively obtaining, storing, and utilizing stored tissue specimens for research. Also, the National Bioethics Advisory Commission (NBAC), which is charged with providing guidance to Federal agencies on the ethical conduct of current and future human biological and behavioral research, is reviewing all

of the human subjects protections for their adequacy and appropriateness today. You will hear more about this from my HHS colleague, Dr. William Raub.

Special Considerations in Informed Consent

With any set of regulations, situations arise that require special consideration. DHHS regulations for Protection of Human Subjects do provide avenues for such occurrences, recognizing that certain consent procedures with IRB approval may not include or may alter some or all the elements of informed consent, or that a waiver of the informed consent requirement may be made. These avenues may only be used in certain narrow circumstances. The DHHS regulations (45 CFR 46.116(d)) provide for waiver of the requirements to obtain informed consent when all four of the following circumstances pertain:

- the research involves no more than minimal risk to the subjects;
  ("Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.102(I)].)

- the waiver, or alteration, of consent will not adversely affect the rights and welfare of the subjects;

- the research could not practicably be carried out without the waiver or alteration; and

- whenever appropriate, the subjects will be provided with additional pertinent information after participation.

IRBs are required to make and document these judgments.

You will hear about waivers and informed consent in emergency situations from Mary Pendergast, Deputy Commissioner, Food and Drug Administration..

Research on Informed Consent

Despite the specificity of Federal regulatory language on informed consent, its endurance through many years, and the enthusiasm with which we all adhere to it, there is little empirical work in existence to document the degree of understanding achieved by research participants. There is a scarcity of data that bear upon, for example: 1) research subjects' comprehension of a study's methods and procedures; 2) subjects' understanding of relative risks and benefits of participation; 3) subjects' understanding of confidentiality and any exceptions to confidentiality; and 4) subjects' understanding of the implications of withdrawal from a study. Such data are needed to aid in designing informed consent procedures that are readily comprehended by prospective participants and, at the same time, impart all critical information.

In this vein, the NIH has joined with the Department of Energy and the Department of Veterans' Affairs in a Request for Applications (RFA) for original research proposals in the area of "Informed Consent in Research Involving Human Participants." The sponsoring organizations are jointly issuing this RFA because voluntary informed consent is the defining aspect of interactions between researchers and participants, and is integral to the conduct of the scientific research funded by all of these organizations. One of the goals of this RFA is to bring together perspectives of these different agencies, since their different research foci reflect a diversity of issues relating to informed consent. Of course, many facets of understanding the informed consent process are shared, and hence a combined effort is efficient for the agencies and scientists alike. Such data should be useful in designing informed consent procedures that are readily comprehended by prospective participants and impart all critical information. The goal of the present initiative is to develop and test alternative strategies for obtaining informed consent in diverse populations and determine optimal ways to obtain informed consent for research participation.

The three agencies have set aside funds in FY 1997 to support projects in response to this RFA. More than 80 proposals were submitted by the March 11, 1997, closing date for receipt of applications. These three agencies are igniting the engine of research in an area that has for too long been under explored.

Conclusion

In the final analysis, Mr. Chairman and Members of the Subcommittee, research investigators, institutions, NIH, and DHHS are stewards of a trust agreement with the people who volunteer to be research subjects. We have a system in place that to the greatest degree possible 1) minimizes the potential for harm; 2) enables and protects individual, autonomous choice; and 3) promotes the pursuit of new knowledge. By doing so, we protect the rights and welfare of our fellow citizens who make a remarkable contribution to the common good by electing to volunteer for research studies. We owe them our best effort.

Thank you, Mr. Chairman. I will be pleased to answer any questions you may have.

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

Satcher – Human Subject Protection

Divider Title: _____

DRAFT

TESTIMONY OF

DAVID SATCHER, M.D., PH.D.

CENTERS FOR DISEASE CONTROL AND PREVENTION

PUBLIC HEALTH SERVICE

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT

SUBCOMMITTEE ON HUMAN RESOURCES

U.S. HOUSE OF REPRESENTATIVES

MAY 8, 1997

INTRODUCTION

Good morning, I am Dr. David Satcher, Director of the Centers for Disease Control and Prevention (CDC).

I am pleased to have the opportunity to testify before the Subcommittee on Human Resources on the very important topic of informed consent in government-sponsored research.

CDC is one of the Federal agencies in the Department of Health and Human Services that is actively engaged in conducting research involving human subjects. CDC conducts public health research which includes, but is not limited to, clinical trials, epidemiologic studies, health status surveys, laboratory studies, and intervention studies. We, therefore, are particularly concerned with protecting human research subjects and in assuring that an informed consent process is used that allows individuals to decide freely whether to participate in a research study.

In thinking about the mission of CDC and the role that research plays in achieving that mission, two points need to be made that relate to this hearing. The first is that we must maintain clear and unwavering respect for the dignity and worth of all individuals. The second is that there is no substitute for good, rigorous science. Our ethics that ensure the rights and welfare of study participants must be as sound as our science.

CDC is committed to protecting all persons who agree to participate in research studies. We

believe strongly in the ethical principles that underlie the conduct of research delineated by The National Commission for the Protection of Human Subjects of Medical and Behavioral Research in The Belmont Report - that individuals are autonomous and are capable of making decisions about their lives, that individuals should be protected from harm, that benefits should be maximized to individuals, and that there is fairness among individuals in the distribution of risks and benefits. We also make every effort to comply fully with Title 45, Code of Federal Regulations, Part 46 for Protection of Human Subjects, known as the Common Rule. We are, however, aware of incidents indicative of lapses in our efforts to protect individuals who have participated in research we have conducted. I am confident that the corrective actions we have taken are working to protect research subjects.

PROTECTION OF HUMAN RESEARCH SUBJECTS

Excellence in science requires a mastery of the ethical principles that address the protection of human subjects and a mastery of the scientific method. We strive for excellence although we have sometimes failed to achieve it. For example, the Department of Health and Human Services continues to deal with the aftermath of the Tuskegee Syphilis Study. This study was conducted by the U.S. Public Health Service in 1932 to 1972 to learn more about untreated syphilis. In so doing, treatment was withheld from a group of poor black men infected with the disease. In addition, the participants were not informed about the study and their voluntary consent to participate was not obtained.

Recognition of the ethical violations committed in this study led the Federal government to

delineate ethical principles for guiding research and to develop Federal regulations outlining policies and procedures for protecting human subjects. We are doing a better job of protecting persons who participate in research. However, the legacy left from the Tuskegee Syphilis Study continues to affect negatively the willingness of minorities to participate in research. We must learn from this study and move beyond it so that we restore trust in the research process.

I would like to describe to the Subcommittee what CDC does to protect human research subjects. In addition, I will discuss human subject protection issues related to a measles vaccine study we conducted in Los Angeles and two hepatitis A vaccine studies we conducted in North and South Dakota.

There are six institutional review boards (IRBs) that review research protocols that are developed in the various components of CDC and ATSDR. Some of the IRBs are headquartered outside of Atlanta, such as at the National Center for Health Statistics (NCHS) in Hyattsville, Maryland and at the National Institute for Occupational Safety and Health (NIOSH) in Cincinnati, Ohio. The work of the IRBs is coordinated by the Deputy Associate Director for Science to facilitate consistency in protocol review across the IRBs.

When the IRBs review research protocols, they examine the risks associated with the study, the potential benefits, if any, that the study participants may receive, and whether the risks are justified in light of the potential benefits to be gained from the study. They pay careful attention to the selection of subjects, particularly the inclusion of traditionally under-represented

sociodemographic groups, such as women and minorities. How participants are enrolled and how informed consent is obtained are areas of particular concern.

Informed Consent Process

Because informed consent is essential to conducting ethical research, I would like to review the informed consent process and how CDC assures that an effective consent process is used in each research study. Informed consent is a process of interaction between the researcher and the participant that begins when the participant is initially approached to participate in the study. The researcher explains the study and may provide written information about the study. During this phase of the process, the researcher fully discloses information about the study to the potential participant. This is done in a way that the potential participant can understand the information. Often, the potential participant asks questions and seeks out information about the study which may not be included in any written material about the study; research staff then provide that information to the participants. At the point where potential participants believe they understand the study and the researcher believes the potential participants understand the study, the researcher asks the potential participants whether they wish to participate in the study. A written consent form is signed by the participants, unless explicitly waived by the IRB.

The informed consent process does not end at this point, but continues with the researcher providing information to the subject throughout the life of the study. New information is provided as it becomes available and any questions are answered that the subject may have. In this manner, the consent process is an ongoing exchange of information during the duration of the

study.

CDC's IRBs review studies to make certain that an adequate consent process is in place. Although our IRBs focus heavily on the written consent document, they also review all information that accompanies the consent document, including scripts used by researchers to present information verbally about the study. Our IRBs require that certain key elements are included in all consent forms, as specified in the Common Rule. In addition, we require that consent forms be written at a reading level appropriate to the study population, generally at the 8th grade reading level. In studies involving vulnerable populations such as children or incarcerated persons, we take extra precautions such as requiring assent to participate from children 7 years and older as well as parental consent, and we make every effort to ensure that, if incarcerated persons are to be included in a study, they are not coerced to participate.

Improvement in Human Subjects Protection Efforts

In recent years, we have taken several major steps to improve our human subjects protection efforts, some of which pertain directly to obtaining informed consent. Three of the most important steps are as follows. First, we have developed clear and consistent policies and guidelines about protecting human subjects. For example, there is a policy for including women and minorities in research, guidelines for defining research and non-research activities in public health, a policy describing the roles of management for making decisions about human subjects review, and a policy describing what types of research must be reviewed by an IRB. These policies communicate a clear message about CDC's determination to protect human subjects and

the role that investigators, managers and IRB members have in assuring that sound, ethical research is conducted. The policies reinforce the Common Rule and the Belmont Report by stating the rights of individuals to have full disclosure of information related to the study in order to decide whether to participate in the research.

Second, we have increased training on conducting ethical research and protecting human subjects for CDC staff. We have sponsored workshops, and we will be introducing a multimedia, computer-assisted training program. Our training is designed not only to increase knowledge and awareness about the methods to assure the protection of subjects but also to create a workforce that understands, appreciates, and values the rights of human beings who participate in research.

Third, we have changed the composition of our IRBs to assure that members reflect the race, ethnicity, gender, and experiences of the persons who volunteer to be subjects in our studies. By having IRB members who represent the study populations, issues about consent are raised from the study population's perspective and the consent process and consent form can be tailored to meet the needs of the study population.

DETAILS ON TWO SPECIFIC CDC RESEARCH STUDIES

Comparative Trial of Different Schedules of Edmonston-Zagreb (EZ) and Moraten Measles Vaccines in the United States (EZ Measles Vaccine Study)

You have asked me to respond to issues of informed consent regarding two specific research studies conducted by CDC. The first is a measles vaccine study we conducted in Los Angeles

between 1990 and 1991, generally known as the EZ measles study. EZ stands for Edmonston-Zagreb, the strain of virus used to make the vaccine. The second are studies of hepatitis A vaccine we conducted in North and South Dakota in 1991 and 1992. I will address the EZ measles vaccine study first.

From 1989-1991, the United States experienced a measles epidemic with more than 55,000 cases and more than 120 deaths, most in young children. Many cases occurred in children too young to be vaccinated with the standard Moraten measles vaccine, which has low efficacy among children younger than 12 months of age, which is the routine age for vaccination in the US.

During the 1980s, multiple studies conducted around the world indicated that EZ measles vaccine administered in a 10- to 100- fold greater potency than the standard dose for measles vaccine, showed promising results in children below 12 months of age. The EZ vaccine was not a new vaccine. It was being produced in several countries, including some European vaccine manufacturers, and approximately 200 million doses of the vaccine had been administered as part of routine immunization programs in many countries. What was new in the United States, however, was its use in children under 12 months of age, as well as its use at a higher potency.

Based on a growing body of evidence, the World Health Organization (WHO) had recommended in 1989 that high potency EZ vaccine be used routinely at 6 months of age in areas where there was a substantial risk of measles mortality among young children. Because of measles cases and deaths in children less than 12 months old, CDC undertook a study in May 1990 in U.S. infants

to determine whether the results found in other countries could be duplicated in this country.

Beginning in June 1990, under the auspices of the Kaiser Foundation Research Institute and the Los Angeles County Health Department, approximately 1500 children were enrolled and randomly allocated into 5 different study groups to receive either high or standard doses of EZ vaccine, or standard doses of the Moraten vaccine. Approximately 1200 children were ultimately vaccinated with one of the study vaccines at either 6, 9, or 12 months of age. The EZ vaccines that were used were approved for investigation by the Food and Drug Administration (FDA) following the procedures that FDA uses to approve any new drug for investigation of safety and efficacy. In addition, the protocol for the study was reviewed and approved by the IRB at CDC prior to awarding a contract to Kaiser Permanente and was later approved by the IRB at Kaiser.

The parent or parent's representative for each child enrolled in the measles study signed the consent form which described the purpose of the study, the procedures to be followed, and the benefits and risks of participation. Thus, the parents of the children who participated in the study were aware they were participating in a vaccine study. However, we later acknowledged that the consent form was deficient because the EZ measles vaccine was not identified as experimental, and parents were not given an adequate description of the foreseeable risks of vaccination and alternative treatments.

During the time the EZ measles study was being conducted, data became available from a study in Senegal, West Africa, suggesting lower survival in girls who received high potency measles

vaccines compared with girls who received standard potency vaccines. In November 1990, CDC staff attended a meeting in Senegal to review the status of the Senegal measles vaccine study. It was recommended at that time, that WHO should convene a group of independent consultants to review data from the study and other similar studies.

In February 1991, WHO convened a panel of experts to review data from studies in Senegal and Guinea Bissau which showed lower survival in girls (but not boys) who received high potency measles vaccines; studies in other locations, however, showed no differences in survival. The WHO concluded that the data did not support a change in the recommendation to continue use of high potency measles vaccines. Reasons were that the studies were not designed to assess mortality, the statistical methods limited interpretation, there was no specificity in the causes of deaths, and the disproportionate mortality in girls did not have biological plausibility. In May 1991, CDC consulted with outside experts who reviewed the evidence from the studies showing lower survival in children who received high potency vaccines and the experts recommended that the Los Angeles measles vaccine study should be continued.

In October 1991, additional information became available from a study of high potency measles vaccine in Haiti which suggested that girls vaccinated with the higher potency measles vaccines were at increased risk of dying in the two to three years following vaccination. No serious adverse effects were attributed to standard potency vaccines, including EZ. Because of this new information on high potency measles vaccine, CDC stopped all use of EZ vaccine in the Los Angeles study in October 1991. Eight months later, in June 1992, the World Health

Organization reached a similar conclusion and recommended that high potency measles vaccines of any strain should not be used to vaccinate children. EZ vaccine in standard doses continues to be used around the world.

Following the termination of the EZ measles vaccine study, all children who participated in the study were asked to enter a follow-up study to determine whether the vaccine had any adverse health effects. Parents were informed of the reason for the follow-up study, including the fact that some studies had found lower survival in those children who received the high potency vaccine. Most have been medically followed and evaluated until reaching fours years of age.

To date, of all the children who have been evaluated, no child who took part in this study and received the high potency EZ vaccine has suffered a significant health problem that can be associated with the vaccine. CDC estimates that 95 percent of the children who were followed up and revaccinated have serologic evidence of protection against measles. One child died approximately 1 year after receiving a dose of standard potency EZ measles vaccine. Experts reviewed the death certificate, the circumstances surrounding the death, and the autopsy report and all agreed with the conclusion that the death was in all likelihood unrelated to the vaccine. Standard potency measles vaccine has never been associated with higher mortality in any of the vaccine studies. Recently, CDC working with Kaiser has conducted a special mortality search to identify children who were in the study and died. A second death has been identified due to child abuse. The child had received the Moraten vaccine at 12 months of age.

In a thorough review of this study, the Office for Protection from Research Risks (OPRR) concluded in 1995 that the EZ measles vaccine study was "scientifically and ethically justified"; however, the consent form was deficient because it failed to include a) an adequate explanation of the purposes of the research and identification of the EZ vaccine as experimental, b) an adequate description of the foreseeable risks of the experimental EZ vaccine and the standard Moraten vaccine, and c) adequate disclosure or description of alternative treatments. Parents were informed that any new vaccine may have side effects and risks which are currently unknown and unforeseeable; however, they were not told specifically about the potential risk of a failure to be protected by the vaccine. Instead, parents were told that if their child was not protected, he/she would receive a dose of the standard Moraten vaccine.

In light of these findings, OPRR required that a letter be sent to the parents describing the current status of the research, plans for completion of the research and notification of subjects about results, and any reasonably foreseeable future risks of participation in the research. In response to the recommendations from the OPRR report, a letter signed by Kaiser Permanente was sent in June 1996 covering the topics required by OPRR and approved by the IRB's at both institutions. In addition, CDC and Kaiser Permanente sent a jointly signed letter of apology in September 1996 to the parents of the children enrolled in the study. In this letter, an apology was made for the mistake on the consent form of the study, acknowledging that the parents who enrolled their children in the study were not adequately informed.

CDC, in collaboration with Kaiser Permanente, is continuing follow-up of children who

participated in the original study and analysis is ongoing. Analyses are expected to be completed by the summer of 1997, at which time CDC will convene a group of experts to review the results. Following the experts' review, CDC will inform parents about the conclusions from the study.

We acknowledge that we were in error by not fully informing parents of children who participated in the EZ measles vaccine study. In addition to the steps taken to inform parents and following the report of OPRR, CDC developed written information for investigators about the IRB review process which included a checklist of elements to be included in consent forms. The number of IRBs was increased, an additional member from the community was added to each board, the number of staff who work with the IRBs was increased, and training on human subject protections was implemented.

Evaluation of the Safety, Immunogenicity and Protective Efficacy of an Inactivated Hepatitis A Vaccine in Healthy Children (North and South Dakota)

Now I would like to discuss the studies CDC and its collaborators conducted to evaluate the performance of inactivated hepatitis A vaccine prior to its licensure. These studies were done primarily among American Indian populations living in North and South Dakota.

Prior to 1970, nationwide epidemics of hepatitis A occurred approximately every 10 years and approximately 50 percent of persons born before 1950 have been infected. While the incidence of hepatitis A has declined substantially since the 1950's, more than 28,000 cases were reported to CDC in 1996. CDC estimates that more than 150,000 Americans are infected with hepatitis A

virus each year. Most people become infected because of community-wide epidemics that often go on for several years. In addition, rates of hepatitis A vary among racial and ethnic groups. American Indians and Alaska Natives have a rate of hepatitis A infection that is 20 times higher than for whites and African Americans. Epidemics of hepatitis A occur approximately every 6 to 8 years in American Indian and Alaska Native communities throughout the United States, and more than 80 percent of adults in these populations have been infected with the hepatitis A virus.

Prevention of hepatitis A has been somewhat problematic and has primarily relied on improvements in hygienic conditions, including improved waste disposal, food sanitation, and general living conditions. Until recently, the only immunization against hepatitis A was the use of immune globulin, which only provided short-term protection and was not useful in preventing community-wide epidemics. In the 1980's, a number of prototype hepatitis A vaccines were developed and offered the potential to control and prevent this disease.

The most widely evaluated hepatitis A vaccines have been those produced in the same manner as inactivated polio vaccine -- hepatitis A virus is grown in tissue culture and is then inactivated (killed) and formulated into a vaccine. In the late 1980's, experts in hepatitis questioned whether the immunity produced by inactivated hepatitis A vaccine would protect against hepatitis A in human populations. This question and the best means to evaluate the protective efficacy of hepatitis A vaccine were discussed at several meetings, including an international meeting of hepatitis, public health, and infectious disease experts which was co-sponsored by NIH and CDC in November 1989. The consensus among the experts was that double-blind, placebo-controlled

clinical trials should be conducted to determine the protective efficacy of hepatitis A vaccines. To determine whether these vaccines protected against infection and/or disease, these studies had to be carried out in populations that experienced high rates of hepatitis A virus infection. Since these studies had to be carried out when these infections were occurring and because high rates of hepatitis A do not occur uniformly over time, the best time to perform these studies was during a community-wide epidemic.

As I previously indicated, CDC's national surveillance for viral hepatitis showed that the highest rates of hepatitis A were in American Indian/Alaska Native populations. In addition, CDC and Indian Health Service (IHS) epidemiologists had collaboratively characterized the epidemiology of hepatitis A among various Native American populations. They had identified these high rates of infection and the recurrent nature of community-wide epidemics in these populations, and they had accurately predicted when these epidemics would occur in some of these communities. It was anticipated that several American Indian communities in North and South Dakota would have hepatitis A epidemics during the early 1990's. The evaluation of hepatitis A vaccine in controlled clinical trials during those predicted epidemics could determine the vaccine's efficacy, its potential to provide long-term protection against hepatitis A, and its potential to control these epidemics.

These epidemiologic issues and the logistics of such trials were discussed in a 1989 meeting of CDC epidemiologists and laboratory scientists, IHS clinicians and epidemiologists, and scientists from the vaccine manufacturers. It was the predicted recurrence of epidemic hepatitis A on reservations in the IHS Aberdeen Area in South and North Dakota and the need to determine the

efficacy of inactivated hepatitis A vaccine in preventing hepatitis A that led to the collaborative effort between CDC, IHS and SmithKline Beecham (SKB).

The study was designed to determine the efficacy of inactivated hepatitis A vaccine in protecting 3 to 12 year-old children against hepatitis A. Children participating in the study were to receive either the investigational, unlicensed (for commercial use) hepatitis A vaccine or the licensed hepatitis B vaccine produced by SKB. Because hepatitis B vaccine does not provide protection against hepatitis A, it was used as a placebo treatment in the study. The protocol, the consent forms, and the informational materials were reviewed and approved by the CDC and IHS IRBs. The study was also approved by the IHS Aberdeen Area Research Committee.

Participation in the study was voluntary and only occurred after the child's parent provided written informed consent, and children 7 years and older gave assent. In addition to the requirement of individual informed consent for participation, it was also required that all studies conducted among American Indians be approved by the local tribal council or health board. This was also done for these studies. In obtaining consent for participation in the study, every effort was made to ensure that the parents understood the reason for the study, the potential risks and benefits of the study, and what was expected if their child participated. They were told the number of shots their child would receive, the number of blood specimens that would have to be drawn, and that neither they nor the study nurse would know which vaccine was being given to their child until the study was completed or unless the child experienced an adverse event. While most of the informational material was written in English, some materials were written in the

Lakota language. In addition, most of the study nurses were tribal members and Lakota-speaking personnel were available, if needed.

Studies to evaluate the efficacy of inactivated hepatitis A vaccine were initiated on two reservations. The first study was conducted on the Pine Ridge reservation in South Dakota where it was approved by the Pine Ridge Oglala Sioux Tribal Council in June 1990. An estimated 2400 children were needed for the study and recruitment began in April 1991. Written informed consent had been obtained from parents of more than 500 children and assent obtained from children 7 years and older when the Pine Ridge Oglala Sioux Tribal Council rescinded approval of the study in October 1991 as a result of concerns raised by residents of one reservation community. At the time the study ended, only one child had been vaccinated. During 1991, the epidemic of hepatitis A on the Pine Ridge reservation went on unabated with more than 500 cases and one death from hepatitis A.

In February 1991, the Standing Rock Sioux Tribal Council gave approval for the same study to be conducted on the Standing Rock reservation in North Dakota. Between then and the summer of 1991, extensive community education was undertaken through radio talk shows, newspaper articles, and information pamphlets. Participant recruitment began during the summer of 1991 and was conducted by three study nurses who were American Indians. As was the case in Pine Ridge, written informed consent was received from parents for their child's participation in the study; children older than 7 years provided assent. A total of 245 children were enrolled in the study, 41 percent of whom were not American Indian.

In February 1992, the Standing Rock Tribal Council passed a resolution halting the study, although many parents wanted the study to continue. In March 1992, the tribal council decided that children who were already enrolled in the study could continue but no further enrollment could take place. However, the IHS and CDC decided that, given the interruption of the study and the limited number of children enrolled, a scientifically valid determination of the efficacy of the hepatitis A vaccine could no longer be made. Therefore, the study on the Standing Rock reservation ended and the codes were broken to reveal which vaccine was received by each child. For those who received hepatitis B vaccine, they were given the opportunity to receive the doses needed to complete the vaccination series. For those who had received hepatitis A vaccine, they were offered the complete hepatitis B vaccination series and informed they could receive the remaining doses in the hepatitis A series when a hepatitis A vaccine was licensed for commercial use. These children were offered the hepatitis A vaccine series when it was licensed in 1995.

On both reservations, the studies were stopped when the tribal councils withdrew their support. The tribal councils rescinded their approvals of the studies because a small group of citizens on each reservation raised concerns about the conduct of government research in the American Indian population. Among their concerns was that informed consent was not obtained. However, in these studies the written consent forms identified the study as research, contained all the information about the vaccines and the study, and provided the parents with full disclosure. The consent forms were typed on stationary identifying the vaccine study as the Hepatitis A Vaccine Prevention Program and may have been perceived as a misrepresentation of the study to the participants. The use of the stationary was an oversight by the CDC and IHS investigators.

In 1995, the inactivated hepatitis A vaccine we attempted to evaluate in these studies was licensed for commercial use by FDA based on efficacy data obtained in a clinical trial conducted in Thailand. CDC's Advisory Committee on Immunization Practices (ACIP) currently recommends that children 2-14 years of age in American Indian or Alaska Native communities, or other communities with high rates of hepatitis A, be routinely vaccinated to prevent and control this disease. Currently, widespread hepatitis A immunization programs are being conducted in the IHS Aberdeen Area and in other American Indian and Alaska Native populations and have effectively interrupted and prevented community-wide epidemics in those areas.

Mr. Chairman, I would like to describe to you the importance of conducting vaccine-related research. Vaccines are the most powerful tools to prevent infectious diseases like measles and polio. The introduction of polio vaccine into the childhood immunization program has led to a reduction of wild virus induced disease from about 20,000 cases annually to zero in the United States. Widespread use of measles vaccine has decreased reported measles from more than 500,000 cases annually during the decade prior to vaccine availability to less than 1,000 cases per year from 1993 to 1996 in the United States. Vaccines have led to the worldwide eradication of smallpox, and the elimination of polio from the Americas.

Currently, according to a CDC maintained database using manufacturer reports of net doses distributed, approximately 140 million doses of the most commonly used vaccines are distributed each year in the United States. These vaccines are used for both children and adults. The current

immunization schedule calls for children to be protected against 10 diseases using 8 vaccines. Research is one of the best strategies to improve those products and develop new ones which are essential for the health and well-being of America's children and adults. Vaccine-related research has been an ongoing activity at CDC for many years and will continue to be a central focus; it is critical to preventing diseases and saving lives. While continuing this very important research endeavor, we will continue to work toward perfecting the informed consent process.

SUMMARY

I want to close by iterating several points. Good, ethical science is the foundation of sound public health practice. We cannot carry out our public health mission without the benefit of the knowledge gained through research and we cannot carry out research that does not protect the individuals or communities who participate. Assuring the rights and welfare of persons who participate in research is of paramount importance and the informed consent process is integral to assuring individuals' rights.

Concerns about the EZ measles vaccine study and the hepatitis A vaccine study have heightened sensitivity to issues surrounding the protection of human subjects. Moreover, these studies point to the important and significant role the community has in conducting research. We have made changes in our human subjects review process and will continue to make changes to achieve the best review process possible. We are also exploring ways to improve involvement of the community in the research process. Just as it is imperative to inform individual subjects, it is imperative to inform the community from which the subjects come and to encourage active

participation of the community in the conduct of research. The quality of research is greatly enhanced by the community's participation and trust in the research.

CDC's goal is to ensure the fullest possible disclosure and the greatest possible protection from harm for persons and communities who participate in public health research studies. We are committed to building and maintaining the trust that is necessary between researchers and persons who participate in health studies.

I would be glad to respond to any questions that the Subcommittee may have.

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

Gulf War

Divider Title: _____

Governance of Research

Final Report
PAC Gulf War Vet Illnesses

EXECUTIVE SUMMARY

President Clinton established the Presidential Advisory Committee on Gulf War Veterans' Illnesses in May 1995 to ensure an independent, open, and comprehensive examination of health concerns related to Gulf War service. The Committee, a 12-member panel made up of veterans, scientists, health care professionals, and policy experts, held 18 public meetings between August 1995 and November 1996. We heard invited testimony and received public comment at each meeting. Staff held in-house consultations, received briefings, conducted literature reviews, interviewed veterans, and reviewed government documents throughout our tenure. We analyzed information on the full range of activities specified in our charter—research, coordinating efforts, medical treatment, outreach, reviews conducted by other governmental and nongovernmental bodies, risk factors (exposure and health effects), and chemical and biological weapons—to reach our findings and recommendations. The *Final Report* presents the Committee's conclusions in three major parts:

- an evaluation of the government's response to Gulf War veterans' illnesses;
- an evaluation of available data on the nature of Gulf War veterans' illnesses; and
- an evaluation of available data on the health effects of Gulf War risk factors.

Findings and recommendations specific to the needs of Gulf War veterans appear throughout the *Final Report* and are summarized here.

The Committee's primary focus was on Gulf War veterans' illnesses, but parallels with the health concerns of Vietnam veterans became increasingly obvious over time. Thus, the Committee also decided to include in its analysis, recommendations on how to anticipate and avoid post-conflict health concerns.

ADDRESSING GULF WAR VETERANS' ILLNESSES

Overall, the Committee is encouraged by the government's response to the range of health-related problems experienced by Gulf War veterans. We found the Vet Centers and Persian Gulf Family Support Program established by the Department of Veterans Affairs (VA) to be effective outreach programs and recommend that these field-based initiatives serve as models for health education and risk communication campaigns.

The Committee agrees with the Institute of Medicine's conclusion that the clinical evaluation programs of the Department of Defense (DOD) and VA are excellent for the diagnosis of Gulf War veterans' illnesses. We found some shortcomings in the availability of treatment, particularly with regard to mental health and reproductive health, and recommend better follow-up care in these areas.

The Committee found that the government's research portfolio is appropriately weighted toward epidemiologic studies and studies on stress-related disorders that are likely to improve our understanding of Gulf War veterans' illnesses. To close gaps in the current knowledge base, we recommend additional research on the long-term health effects of low-level exposures to chemical warfare agents and on the synergistic effects of pyridostigmine bromide—a chemical warfare agent pretreatment— with other Gulf War risk factors. We also recommend more emphasis on basic and applied research on the body's physical response to stress.

The existing knowledge base, including results from epidemiologic studies of Gulf War veterans, data from clinical evaluation and treatment programs for Gulf War veterans, and published literature from decades of toxicologic research, enabled the Committee to reach some conclusions about the nature and causes of Gulf War veterans' illnesses. We found that:

- among the subset of the Gulf War veteran population examined in the ongoing clinical and research programs, many veterans have illnesses likely to be connected to their service in the Gulf.
- current scientific evidence does not support a causal link between the symptoms and illnesses reported today by Gulf War veterans and exposures while in the Gulf region to the following environmental risk factors assessed by the Committee: pesticides, chemical warfare agents, biological warfare agents, vaccines, pyridostigmine bromide, infectious diseases, depleted uranium, oil-well fires and smoke, and petroleum products.
- stress is known to affect the brain, immune system, cardiovascular system, and various hormonal responses. Stress manifests in diverse ways, and is likely to be an important contributing factor to the broad range of physical and psychological illnesses currently being reported by Gulf War veterans.

Currently, the extent of service-connected illness among Gulf War veterans is unknown, but the Committee anticipates results from the large, population-based epidemiologic studies now underway will shed light on this issue. In addition to the government's existing research, the Committee also recommends that mortality studies of Gulf War veterans continue, since some health effects, such as cancer, would not be expected to appear until a decade or more after the end of the Gulf War.

Although somewhat slow to act at the end of the Gulf War, the government is now providing appropriate medical care to Gulf War veterans and has initiated research in the areas most likely to illuminate the causes of their illnesses. The Committee identified ways to fine-tune those efforts, but found that, for the most part, the government has acted in good faith to address veterans' health concerns.

The Committee takes issue with the government's performance in one key area: investigation of possible exposures of U.S. troops to chemical

and biological warfare agents in the Gulf. We found substantial evidence of site-specific, low-level exposures to chemical warfare agents. Moreover, we found DOD's investigations to date superficial and unlikely to provide credible answers to veterans' and the public's questions. DOD's failure to seriously investigate chemical warfare agent exposures also adversely affected decisions related to funding research into possible health effects of low-level exposures to chemical warfare agents. At the Committee's final meeting in November 1996, DOD announced plans to revamp its investigatory and research programs related to low-level chemical warfare agent exposure. The Committee believes these efforts—combined with independent, high-quality oversight—could begin to restore public confidence in the government's investigations of possible incidents of chemical warfare agent exposure. Given that these steps come too late for the Committee to evaluate, however, we emphasize the importance of the following recommendation:

- To ensure credibility and thoroughness, further investigation of possible chemical or biological warfare agent exposures during the Gulf War should be conducted by a group independent of DOD. Openness in oversight activities—including public access to information and veteran participation—public notice of meetings, opportunity for public comment, and regular reporting are essential. Full public accountability is critical.

The government has a significant amount of ground to recover with Gulf War veterans and the American public, who have come to question whether a lack of data—on possible chemical warfare agent exposures, on the pre- or post-deployment health of veterans, or on the location of troops in-theater—indicates a lack of commitment to veterans' health. We recognize the many laudatory actions taken to address the concerns of Gulf War veterans, but the Committee believes the government can do a better job of anticipating and avoiding these types of problems. We offer the following findings and recommendations in that spirit.

AVOIDING POST-CONFLICT HEALTH CONCERNS

The Committee was impressed by the professionalism of the individuals responsible for the government services we evaluated. We believe the expertise needed to improve technical performance and implement policy and procedural changes resides within the government, but we also believe that DOD and VA have much to learn from their peers in other agencies. Therefore, the Committee recommends that:

- A Presidential Review Directive (PRD) be issued to instruct the National Science and Technology Council (NSTC) to develop an interagency plan to address health preparedness for and readjustment of veterans and families after future conflicts and peacekeeping missions. The President's Committee of Advisors on Science and Technology and other nongovernmental experts, as appropriate, should be asked to review the plan 12 months after the PRD is

issued and again at 18 months to ensure national expertise is brought to bear on these issues.

The NSTC's agenda should include the following recommendations for better communication, data, and services, which were developed during the Committee's evaluation of issues related to Gulf War veterans' illnesses (see *Final Report*, chapters 2-4).

Better Communication

Clearly, the volunteers who serve in defense of our Nation deserve complete and accurate information about the risks they face. An open democracy demands that the public, as well, has the opportunity to engage in policy debates that accompany the commitment of troops abroad. Therefore, the Committee recommends that:

- DOD and VA immediately develop and implement a comprehensive risk communication plan. This effort should move forward in close cooperation with agencies that have a high degree of public trust and experience with risk communication, such as the Agency for Toxic Substances and Disease Registry and the National Institute for Occupational Safety and Health.
- FDA solicit timely public and expert comment on any rule that permits waiver of informed consent for use of investigational products in military exigencies. Among the areas that specifically should be revisited are: adequacy of disclosure to service personnel; adequacy of recordkeeping; long-term followup of individuals who receive investigational products; review by an institutional review board outside of DOD; and additional procedures to enhance understanding, oversight, and accountability.

Better Data

Many of the health concerns of Gulf War veterans may never be resolved fully because of the lack of data. The Committee identified problems related to missing medical records, the absence of baseline health data, inaccurate records of troop locations, and incomplete data on the health effects of what should have been viewed as reasonably anticipated risks. To help prevent similar problems in the future, we recommend that:

- DOD officials at the highest echelons, including the Joint Chiefs of Staff and the Commanders in Chief, assign a high priority to dealing with the problem of lost or missing medical records. A computerized central database is important. Specialized databases must be compatible with the central database. Attention should be directed toward developing a mechanism for computerizing medical data in the field (including classified information, if and when it is needed). DOD and VA should adopt standardized recordkeeping to ensure continuity.

- the Persian Gulf Veterans Coordinating Board and other appropriate departments and agencies be charged to develop a protocol to implement the following recommendation, which was made in the Committee's *Interim Report*: Prior to any deployment, DOD should undertake a thorough health evaluation of a large sample of troops to enable better postdeployment medical epidemiology. Medical surveillance should be standardized for a core set of tests across all services, including timely postdeployment followup.
- the government develop more accurate and reliable methods of recording troop locations to facilitate post-conflict health research. DOD should make full use of global positioning technologies.
- the government plan for further research on possible long-term health effects of low-level exposure to organophosphorus nerve agents such as sarin, soman, or various pesticides, based on studies of groups with well-characterized exposures, including: a) cases of U.S. workers exposed to organophosphorous pesticides; and b) civilians exposed to the chemical warfare agent sarin during the 1994 and 1995 terrorist attacks in Japan. Additional work should include followup and evaluation of an appropriate subset of any U.S. service personnel who are presumed to be exposed during the Gulf War. The government should begin by consulting with appropriate experts, both governmental and nongovernmental, on organophosphorus nerve agent effects. Studies of human populations with well-characterized exposures will be much more revealing than studies based on animal models, which should be given lower priority.
- the government continue to collect and archive serum samples from U.S. service personnel when feasible.
- research on possible causes and methods of prevention of excess mortality from external causes among veterans receives high priority.
- the government consider methods for routinely sampling military populations regarding reproductive health so that an appropriate baseline exists for evaluating reproductive outcomes following deployment. In particular, DOD should consult with the National Center for Health Statistics and strongly consider implementing its National Survey of Family Growth and related methodologies for collecting data.
- the entire federal research portfolio place greater emphasis on basic and applied research on the physical effects of stress and on stress-related disorders.

Better Services

The Nation has long provided care to veterans for service-connected health problems. Unfortunately, the government continues to give short shrift to veterans' legitimate concerns about reproductive health, and society at large continues to stigmatize mental health concerns. Therefore, the Committee recommends that:

- the government conduct a thorough review of VA's policies concerning reproductive health and seek statutory authority to treat veterans and their families for service-connected problems. When indicated, genetic counseling should be provided—either via VA treatment facilities or referral—to assist veterans and their families who have reproductive concerns stemming from military service.
- the government continue and intensify efforts to develop stress reduction programs for all troops, with special emphasis on deployed troops.

CONCLUSION

Approximately 697,000 men and women answered the call to serve in Operations Desert Shield/Desert Storm. In many important ways—through medical care, outreach, and research—the Nation has begun to pay its debt to these service members. It is essential, now, to move swiftly toward resolving Gulf War veterans' principal remaining concerns: How many U.S. troops were exposed to chemical warfare agents, and to what degree?

A continued and sustained commitment to a healthy future for Gulf War veterans—for all current and future veterans—is a priority for all Americans. This *Final Report* represents the Committee's contribution to that goal. We have given our full dedication to President Clinton's charge and have appreciated the opportunity to serve Gulf War veterans and their families.

vices. The surveillance process shall be specifically configured to assess the effects of deployment on the health of the service member.

Finally, DOD has informed the Committee that it is completing a revision of its accession and retention physical standards. New policies and separation review procedures for members who do not meet physical standards are under review. Moreover, the frequency of routine physical examinations is now five (rather than four) years, with increased emphasis on the annual certificate of physical fitness.

Use Of Investigational Products

During Operations Desert Shield/Desert Storm, DOD anticipated the threat of exposure of U.S. military personnel to chemical and biological warfare. DOD used two investigational products in the Gulf War as prophylactic measures against chemical and biological warfare agents: pyridostigmine bromide (PB), a drug that is classified as an anticholinesterase that binds reversibly with acetylcholinesterase, and botulinum toxoid (BT) vaccine. Anthrax vaccine, an approved (licensed) product, also was used as a prophylactic measure during the Gulf War.

DOD used two investigational products in the Gulf War as prophylactic measures against chemical and biological warfare agents: pyridostigmine bromide (PB) and botulinum toxoid (BT) vaccine.

Since PB and the BT vaccine were investigational product as used in the Gulf War, DOD could not have administered them under normal circumstances without the informed consent of the military personnel who received them. The Food and Drug Administration (FDA), however, issued a new regulation in December 1990 that permitted use of these products without informed consent under specific military circumstances. Controversy exists about whether creation of a waiver of informed consent mechanism for these circumstances and use of these particular products with the waiver was appropriate from an ethical, regulatory, and military perspective.

Issuance of the New Rule. An October 30, 1990, letter from the DOD Assistant Secretary of Defense (Health Affairs) to the Department of Health and Human Services (DHHS) Assistant Secretary for Health, requested an amendment to FDA's informed consent regulations to include a combat exigency as a circumstance in which medical professionals could deem it "not feasible" to obtain the informed consent of a person receiving an investigational drug or vaccine. In response FDA formed a task force of government employees that concluded it would be possible to develop a rule that would meet DOD's needs and be protective of the health and welfare of military personnel. FDA published an interim final rule on December 21, 1990, that took effect immediately because of the urgency presented in the military situation;[10] the rule was upheld by the courts.

Under the interim rule, DOD initiates the process of obtaining the waiver of informed consent for a combat exigency by filing a written request with FDA along with an investigational new drug application (IND), a treatment protocol, and evidence that an institutional review board (IRB) has reviewed and

approved the use of the investigational drug or vaccine without informed consent in the specific circumstances. Subsequently, the Commissioner of Food and Drugs may find that informed consent is not feasible (and thus may be waived) only when withholding treatment would be contrary to the best interests of military personnel and there is no available satisfactory alternative therapy. The rule stipulates four additional, nonexclusive criteria the Commissioner must consider: 1) the strength of the evidence of the safety and efficacy of the drug (or vaccine) for the intended use; 2) the context in which the drug will be administered (e.g., battlefield or hospital); 3) the nature of the disease or condition for which the preventive or therapeutic treatment is intended; and 4) the information to be provided to the recipients of the drug concerning its potential risks and benefits.

Implementation of the New Rule. One week after the interim final rule was issued, DOD requested waivers of informed consent for PB (30 mg tablets) and BT vaccine. The request followed months of deliberations—encompassing political, diplomatic, resource, logistical, and ethical considerations—within DOD. Ultimately, the decisionmaking involved the Secretary of Defense, the Joint Chiefs of Staff, and Central Command (CentCom) in what has been characterized as an intense timeframe extending from August through December 1990. After extensive consultation and scientific analysis, the Commissioner of Food and Drugs approved DOD's waiver requests for BT vaccine and PB on December 31, 1990, and January 8, 1991, respectively.

About 8,000 troops received BT vaccine. Approximately 250,000 military personnel took at least one dose of PB, according to DOD estimates.

Decisions about who would actually receive BT vaccine or take PB were made by CentCom based on perceived threat and unit locations. Although FDA issued a waiver of informed consent for PB and BT vaccine, CentCom determined that service personnel designated to receive the BT vaccine should be given a choice as to whether they received the vaccine. CentCom's decision was based on concerns about the ethics of giving investigational vaccines to service personnel and on the insufficiency of vaccine supplies. The perception about PB appeared to differ—i.e., even though this drug was investigational for use in theater, it had been widely used as an approved drug in other populations and, therefore, absence of informed consent was not a cause for concern.

DOD estimates 150,000 service members received at least one dose of anthrax vaccine (an approved biologic) between January 23 and February 28, 1991. About 8,000 troops received BT vaccine in the same period. Approximately 250,000 military personnel took at least one dose of PB, according to DOD estimates.

DOD currently is pursuing approval of BT vaccine and PB. DOD also has asked FDA to make the interim regulation permanent.

Medical Recordkeeping in Theater

During the deployment period for the Gulf War, both active and reserve personnel who developed medical problems were evaluated, treated and returned to duty, hospitalized and returned to duty, or evacuated from the theater of operations. Interactions between deployed forces and medical care providers were recorded in a paper-based system, and much of this information was not incorporated in service members' permanent health records. This breakdown was particularly common for the recording of immunizations given in the theater of operations.

DOD guidelines required field units to maintain rosters of personnel receiving vaccines that included name, Social Security number, rank, and unit. In addition, vaccinations could be recorded on PHS-731 (Yellow shot record) or on SF-601 (Immunization Record).

The secrecy of the vaccination program complicated recordkeeping and created some confusion and fear among service members. Medical personnel in the field received instructions that receiving the shots was classified "Secret" and that the shots were not to be discussed with anyone. DOD asserts the secrecy protected troops since it limited Iraq's knowledge of U.S. defensive capabilities.

The secrecy of the vaccination program complicated recordkeeping and created some confusion and fear among service members.

When the vaccinations were recorded in medical records retained by individual service members, they were encoded to eliminate document classification problems. Some medical officers have suggested, however, that field personnel were unprepared to deal with what appeared to be classified entries in centrally-maintained medical records, presenting a serious obstacle to proper records management.

According to testimony presented to the Committee, in the flurry of personnel anxious to come home at the end of the Gulf War, much of the documentation about vaccinations was lost or destroyed. DOD maintains rosters of a fraction of the service members who received anthrax and BT vaccines; most are missing. DOD also has reported to the Committee that it is not possible to determine with certainty who actually ingested PB, or in what doses, because service members were supplied PB for self-administration.

FINDINGS

- No uniformity existed among the services in their predeployment or demobilization policies and procedures at the time of Operation Desert Shield/Desert Storm.
- There is little evidence that quality control procedures were employed to ensure that existing policies were actually carried out during deployment or demobilization.

- DOD's policies and procedures were not adequate in all cases to prevent members with preexisting conditions from deploying or to identify health problems extant at the time of demobilization, and these conditions could have contributed to some current health concerns.
- FDA and DOD undertook an urgent and orderly course of action under the circumstances to devise a means to address the real threat of chemical and biological warfare in the Gulf War.
- FDA has not been proactive in addressing public comments on the interim final rule or in devising better long-term methods for governing military use of drugs, vaccines, devices, and antibiotics intended for chemical and biological warfare defense.
- When a waiver of informed consent is granted, the government has a strong obligation to conduct long-term followup of military personnel who receive investigational products.
- DOD did not keep adequate records on who received anthrax and BT vaccines and PB in the Gulf War theater. There is little possibility now of developing reliable data about which or how many persons received those products.
- DOD and VA admit to problems with missing or lost medical records, but neither system appears to place a priority on correcting these problems.
- DOD's rationale for the requirement that records of vaccinations be kept secret was not well understood. This requirement confused and complicated recordkeeping procedures and hindered systematic followup of health issues.
- The issue of accurate medical and vaccination records is central to the concerns of many ill veterans, and the absence of records has been suggested by some as evidence that the government is engaging in a cover-up of its own predeployment practices.

RECOMMENDATIONS

- DOD should regularly review and update the policies and procedures to govern the pre-, during, and postdeployment medical assessment of the Ready Reserve to ensure they are current and adequate.
- DOD should establish a quality assurance program to ensure compliance with pre-, during, and postdeployment medical assessment policies.

- Prior to any deployment, DOD should undertake a thorough health assessment of a large sample of troops to enable better post-deployment medical epidemiology. Medical surveillance should be standardized for a core set of tests across all services and include timely postdeployment followup.
- Given that FDA's interim rule is still in effect, DOD should develop enhanced orientation and training procedures to alert service personnel they may be required to take drugs or vaccines not fully approved by FDA if a conflict presents a serious threat of chemical and biological warfare.
- If FDA decides to reissue the interim final rule as final, it should first issue a Notice of Proposed Rule Making. Among the areas that specifically should be revisited are: adequacy of disclosure to service personnel; adequacy of recordkeeping; long term followup of individuals who receive investigational products; review by an IRB outside of DOD; and additional procedures to enhance understanding, oversight, and accountability. The Committee, at this time, withholds judgment on the adequacy of the current rule.
- DOD should assign a high priority to dealing with the problem of lost or missing medical records. A computerized central database is important. Specialized databases must be compatible with the central database. Attention should be directed toward developing a mechanism for computerizing medical data (including classified information, if and when it is needed) in the field. DOD and VA should adopt standardized recordkeeping to ensure continuity.

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

Divider Title: **Tuskegee Legacy Report**

Bioethics
#4
end

REPORT OF THE TUSKEGEE SYPHILIS STUDY LEGACY COMMITTEE

FINAL REPORT

VANESSA NORTHINGTON GAMBLE, MD, PhD, CHAIR
JOHN C. FLETCHER, PhD, CO-CHAIR

May 20, 1996

TUSKEGEE SYPHILIS STUDY LEGACY COMMITTEE[1]

In 1932, the United States Public Health Service (USPHS) initiated the Tuskegee Syphilis Study to document the natural history of syphilis. The subjects of the investigation were 399 poor black sharecroppers from Macon County, Alabama, with latent syphilis and 201 men without the disease who served as controls. The physicians conducting the Study deceived the men, telling them they were being treated for "bad blood".[2] However, they deliberately denied treatment to the men with syphilis and went to extreme lengths to ensure that they would not receive any therapy from other sources. In exchange for their participation, the men received free meals, free medical examinations, and burial insurance.[3]

On 26 July 1972 a front-page headline in the New York Times read, "Syphilis Victims in U.S. Study Went Untreated for 40 Years."[4] The accompanying article publicly revealed the details

---

[1] The Committee was established at a meeting at Tuskegee University, January 18-19, 1996. All communications with the Committee should be addressed to the Chair of the Committee, Vanessa Gamble, M.D., PhD, History of Medicine Department, 1300 University Ave., Madison, WI 53706 (608) 262-5319. FAX: (608) 262-2317; email: vngamble@facstaff.wisc.edu. A list of the Committee members is attached. The Committee wishes to thank Judith A. Houck for her assistance in the preparation of this report.

[2]The term "bad blood" encompassed several conditions including syphilis, anemia, and fatigue.

[3]For a complete history see Jones, James H, Bad Blood: The Tuskegee Syphilis Experiment, new and expanded ed., New York: Free Press, 1993.

[4]Jean Heller, "Syphilis Victims in the U.S. Study Went Untreated for 40 Years," New York Times, 26 July 1972: 1, 8. The story first broke the previous day in the Washington Star.

of the Tuskegee Syphilis Study - "the longest nontherapeutic experiment on human beings in medical history"[5]. In the almost twenty-five years since its disclosure, the Study has moved from a singular historical event to a powerful metaphor. It has come to symbolize racism in medicine, ethical misconduct in human research, paternalism by physicians, and government abuse of vulnerable people.

The Tuskegee Syphilis Study continues to cast its long shadow on the contemporary relationship between African Americans and the biomedical community. Several recent articles have argued that the Tuskegee Syphilis Study has predisposed many African Americans to distrust medical and public health authorities.[6] The authors point to the Study as a significant factor in the low participation of African Americans in clinical trials and organ donation efforts and in the reluctance of many black people in seeking routine preventive care. As one AIDS educator put it, "so many African American people that I work with do not trust hospitals or any of the other community health care service providers because of that Tuskegee Experiment. It

---

[5]Jones, Bad Blood, 91.

[6]See for example, Asim, Jabari, "Black paranoia far-fetched? Maybe, but understandable," The Phoenix Gazette February 23, 1993 Op-Ed: A13; Karkabi, Barbara, "Blacks' health problems addressed," The Houston Chronicle April 10, 1994 Lifestyle: 3; "Knowledge, attitudes and behavior; conspiracy theories about HIV puts individuals at risk," AIDS Weekly, November 13, 1995.

is like ... if they did it then they will do it again."[7]

The Tuskegee Syphilis Study Legacy Committee is dedicated to preserving the memory of the Study while moving beyond it, transforming the legacy into renewed efforts to bridge the chasm between the health conditions of black and white Americans. To this end, the Committee is pursuing two inseparable goals: 1) to persuade President Clinton to publicly apologize for past government wrongdoing to the Study's living survivors, their families, and to the Tuskegee community, and 2) to develop a strategy to redress the damages caused by the Study and to transform its damaging legacy.

In his recent apology for the government's role in human radiation experiments (1944-1974), President William J. Clinton claimed that "the American people ... must be able to rely upon the United States to keep its word, to tell the truth, and to do the right thing," and that "when the government does wrong, we have a moral responsibility to admit it."[8] President Clinton is not alone in his belief that an apology for past wrongs is "doing the right thing." Recently, the Southern Baptist Church apologized to all African Americans for its stand on slavery during the Civil War and the Prime Minister of Japan similarly apologized to the people of the United States for the attack on

---

[7]Thomas, Stephen B. and Quinn, Sandra Crouse, "The Tuskegee Syphilis Study, 1932-1972: Implications for HIV Education and AIDS Risk Programs in the Black Community," Am J of Pub Health. 1991; 81: 1503.

[8]President William J. Clinton, "In Acceptance of Human Radiation Final Report," Washington, DC, October 3, 1995.

Pearl Harbor.[9]

And yet, these apologies do not merely acknowledge wrongdoing: they act as a first step toward healing the wounds inflicted. President Clinton, for example, saw his apology as "laying the foundation stone for a new era"[10] in trying to regain the trust of the country.

It is within this context of doing the right thing, redressing past injuries, and regaining trust that the Committee adamantly believes that a Presidential apology to the victims of Tuskegee is critical to heal the devastating wounds that remain from this shameful episode in the history of medical research.

1. A Presidential Apology for the Tuskegee Syphilis Study

a) Moral and physical harms to the community of Macon County

It is clear that the U.S. government scientists irreparably harmed hundreds of socially and economically vulnerable African-American men in Macon County, their family members, and their descendants by deliberately deceiving them and withholding from them state of the art treatment. When the Tuskegee Study began, the standard therapy for syphilis consisted of painful injections of arsenical compounds, supplemented by topical applications of mercury or bismuth ointments. Although this therapy was less

---

[9]See for example, Niebuhr, Gustav, "Baptist group votes to repent stand on slaves," New York Times 21 June, 1995: A2 and Watanabe, Teresa and David Holley, "Japan Premier offers apology for WWII role," Chicago Tribune 15 August, 1995: A10.

[10]Clinton, 3 October, 1995.

effective than penicillin would later prove to be, in the 1930s every major textbook on syphilis recommended it for the treatment of the disease. After penicillin became available, the researchers withheld its use as well. Published medical reports have estimated that between 28 and 100 men died as a result of their syphilis.[11] Due to a lax study protocol, we cannot be sure that all the men had latent syphilis. It is therefore entirely possible that the infected men passed syphilis to their sexual partners and to their children in utero.[12] Thus physical harm may not be limited just to the men enrolled in the Study.

b) No public apology has ever been made

In the aftermath of a Health, Education and Welfare task force report, a Senate hearing, and an out of court legal settlement, the U.S. government provided economic compensation and continues to give free health benefits to the surviving subjects and their families. However, no public apology has ever been offered for the moral wrongdoing that occurred in the name of government medical research. No public official has ever stated clearly to the nation that the Tuskegee Syphilis Study was morally wrong from its inception, and no public official has ever apologized to the survivors and their families. Yet, an apology is sorely needed. The Committee believes that an apology from

---

[11]Jones, Bad Blood, 2.

[12]Hammonds, Evelynn M, "Your silence will not protect you: Nurse Eunice Rivers and the Tuskegee Syphilis Study," in The Black Women's Health Book: Speaking for Ourselves ed. Evelyn C. White, 2nd ed., Seattle: Seal Press, 1994: 323-331.

the President could facilitate the healing of the victims and the nation.

c) The harmful legacy of the Study

The historical record makes plain that African American's distrust of the medical profession predates the revelations of the Tuskegee Syphilis Study and involves a myriad of other social and political factors. Nevertheless, the Study has become a powerful symbol for the fear of exploitation in research and the deprivation of adequate medical care that is widespread in the African-American community. Recent articles argue that Tuskegee has created a climate of suspicion that taints the relationship between many African Americans and the medical profession. The Tuskegee Study is offered as the reason why few blacks participate in research trials,[13] why the need for transplant organs by African Americans widely surpasses the supply,[14] and why African Americans often avoid medical treatment.[15] It is also offered as an explanation as to why rumors about genocide persist in the African-American community, ranging from the notion that AIDS is a plot to exterminate black people to the idea that needle exchange programs fuel a drug epidemic that

---

[13]Gamble, Vanessa, "A Legacy of Distrust: African Americans and Medical Research," Am J of Preventive Medicine, November/December 1993: 35-38.

[14]"Fear Creates Lack of Donor Organs Among Blacks," Weekend Edition, National Public Radio, 13 March 1994.

[15]See for example, Voas, Sharon, "Aging black sick, scared; past abuses, tradition keep them from clinic," Pittsburgh Post-Gazette, August 27, 1995: B1.

disproportionately affects black neighborhoods.[16] For many African Americans, the fact that the Tuskegee Study occurred at all proves that black life is not valued. The Committee believes that an apology combined with a strategy for addressing the damages of the Tuskegee legacy would begin the process of regaining the trust of people of color.

d) The harm done to the community and the University

Because the name of the Study points to Tuskegee Institute (now Tuskegee University) rather than the United States Public Health Service, it clouds the funding and responsibility for the Study. Although facilities and staff of the Tuskegee Institute were involved, primary direction came from the government under the auspices of the USPHS. The notoriety of the Study obscures the achievements of the Tuskegee Institute in improving the health care of African Americans. These achievements include initiating the National Negro Health Week, building the John A. Andrew Hospital, creating the John A. Andrew Clinical Society, establishing a nurse training school, and organizing a school for midwives.

---

[16]Bates, KG, "Is it Genocide?" Essence, September 1990: 76; Thomas, Stephen, and Quinn, Sandra, "Understanding the Attitudes of Black Americans," In Stryker, J. and Smith, MD, eds. Dimensions of HIV Preventions: Needle Exchange, Menlo Park: The Henry J. Kaiser Family Foundation; 1993: 99-128; Kirp, David and Bayer, Ronald, "Needles and Race," Atlantic. July 1993: 38-42.

The Apology: Context and Opportunity

The Committee urges President Clinton to apologize on behalf of the American government for the harms inflicted at Tuskegee. The apology should be directed to those most directly harmed: to the elderly survivors of the Study, to their families, and to the wider community of Tuskegee and its University. Also included within the apology should be all people of color whose lives reverberate with the consequences of the Study.

As the highest elected official of the United States, the President should offer the apology for the Study which was conducted under the auspices of the United States government. The significance of a presidential apology was recognized recently when the President apologized to those harmed by Cold War radiation experiments as a way to regain confidence of the American people. In the context of President Clinton's stated desire to bridge the racial divide, this apology provides the opportunity to begin to heal the racial wounds that persist in this country.

Given the ages of the living participants and the period of time since the Study was disclosed, we believe that the apology should be offered swiftly. There are only eleven survivors; a twelfth died as recently as March 3, 1996. We recommend that the government issue the apology from Tuskegee University, perhaps linked with an early meeting of the new National Bioethics Advisory Commission (NBEAC). Because the Tuskegee

Study is a starting point for all modern moral reflection on research ethics, a meeting of the NBEAC at Tuskegee in conjunction with a presidential apology would be an ideal new beginning.

2. Transforming the Legacy

Although a public apology is necessary to heal the wounds of Tuskegee, it alone would not be sufficient to assure the nation that research like the Tuskegee Syphilis Study will not be duplicated. Despite the significance of a Presidential apology, it must not be an isolated event. Consequently, the Committee also recommends the development of a mechanism to move beyond Tuskegee and to address the effects of its legacy. The Committee strongly urges the development of a professionally staffed Center at Tuskegee University, focused on preserving the national memory of the Study and transforming its legacy.

Regret for past mistakes must be accompanied by a determination to prevent future wrongs. Until now for black Americans the legacy of the Tuskegee Syphilis Study has been a negative one - a symbol of their mistreatment within American society. The proposed Center could help transform the legacy of Tuskegee into a positive symbol for all Americans by demonstrating the importance of acknowledging past wrongs, rebuilding trust, and practicing ethical research.

The new Center's mission would be to preserve the national memory of the Syphilis Study for public education and scholarly

research, and to analyze and disseminate findings on effective and ethically acceptable ways to address the profound mistrust that is the tragic and enduring legacy of this Study, especially among African Americans and other persons of color. (See Appendix 1.)

Although the Committee sees the creation of a Center as the most valuable attempt to redress the damages of Tuskegee, we envision several possible concurrent programs. These include:

1) a Minority Health Initiative, similar in scope to the newly established Women's Health Initiative;

2) training programs for health care providers to better understand the social and cultural issues of providing health care and of conducting research in communities of color;

3) a clearinghouse to help investigators conduct ethically responsible research.

The Committee recommends that funding for the Center must combine government and private funding. The announcement of a federal challenge grant would be very useful as a catalyst for future fundraising efforts.

It is undeniable that the Tuskegee Syphilis Study has adversely affected the attitudes that many African Americans hold toward the biomedical community and the United States government. But despite the long shadow that it casts, we now have an opportunity to challenge this legacy and create a more beneficial one.

APPENDIX 1

Possible functions for a Tuskegee research center:

a) to create and maintain a public museum in Tuskegee, Alabama, to preserve the memory of the Study and to provide a focal point for efforts to transform its negative legacy;

b) to provide a place for scholars to examine the ethical, legal, and social significance of the Study and other issues in bioethics;

c) to conduct public education on the Study and its legacy in schools, community organizations, and medical institutions;

d) to aid in the production of audiovisual aids for public education that will place the Study within its broadest social and historical context and provide suggestions for transforming its past legacy;

e) to assure the rigorous preservation of presently endangered documents and other records to further encourage studies of race, ethnicity, and medicine;

f) to offer support for medical researchers seeking ways to conduct research in diverse populations that is both scientifically sound and ethically responsible.

APPENDIX 2

TUSKEGEE SYPHILIS STUDY LEGACY COMMITTEE

Ms. Myrtle Adams
Chairman, Macon County Health Care Authority
704 Patterson St.
Tuskegee, AL 36088

Ms. Patricia Clay
Administrator, Macon County Health Care Authority
PO Drawer 180
Tuskegee, AL 36088

Dr. James A. Ferguson
Dean, School of Veterinary Medicine
Patterson Hall
Tuskegee University
Tuskegee, AL 36088

Dr. John C. Fletcher, co-chair
Director, Center for Biomedical Ethics
Cornfield Professor of Religious Studies
University of Virginia
Box 348 HSC
Charlottesville, VA 22908

Dr. Vanessa Northington Gamble, chair
Associate Professor of History of Medicine and Family Medicine
University of Wisconsin Medical School
1300 University Ave.
Madison, WI 53706

Dr. Lee Green
Assistant Professor
University of Alabama
PO Box 870312
Tuscaloosa, AL 35487

Ms. Barbara Harrell
Director, Division of Minority Health
Alabama Department of Public Health
434 Monroe St.
Montgomery, AL, 36130-3017

Dr. Bill Jenkins
Epidemiologist
Centers for Disease Control and Prevention
1600 Clifton Road, NE, MS-E02
Atlanta, GA 30333

Dr. James H. Jones
Professor of History
University of Houston
2202 Swift Road
Houston, TX 77030

Dr. Ralph Katz
Professor
Department of Behavioral Sciences and
Community Health
School of Dental Medicine
University of Connecticut Health Center
Farmington, CT 06030

Ms. Joan Echtenkamp Klein
Assistant Director for Historical
Collection and Services
Health Sciences Library, Box 234
University of Virginia Health Sciences Center
Charlottesville, VA 22908

Dr. Susan Reverby
Luella LaMer Professor for Women's Studies
Wellesley College
106 Central St.
Wellesley, MA 02181

Dr. Reuben Warren
Associate Director for Minority Health, CDC
Centers for Disease Control and Prevention
1600 Clifton Road, NE, MS-D39
Atlanta, GA, 30333

Mr. Anthony Winn
Program Analyst
Minority Health Professions Foundation
20 Executive Park Drive, #2021
Atlanta, GA 30333

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

Divider Title: **S & T and Economy**

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

Returns to R & D

Divider Title: _____

S+T+ Economy

Scott Wallsten

10/16/95

-10/13/95-

RETURNS TO RESEARCH AND DEVELOPMENT*

Increasing the productivity of the American workforce is the key to higher living standards and stronger economic growth. Over the past two decades, the rate of increase in productivity -- output per worker hour -- has been far lower than in the previous decade. There is a general consensus that a principal reason for the productivity slowdown is a slowdown in the pace of technological change -- the flow of new innovations that enable the economy to produce more with less. Though the reasons for this slowdown are not fully understood, we do know this: investments in research and development (R&D) have large payoffs.

R&D yields new products, improving the quality of life, and new processes, enabling American firms to reduce costs of production and become more competitive. Indeed, investments in R&D are estimated to account for half or more of the increase in output per person.[1] And increases in productivity are essential if we are to continue to have increases in living standards.

The Federal role in the promotion of science and technology was recognized in the Constitution, which gave Congress the right to grant patents to "promote the progress of science. . . ." However, the Founding Fathers could hardly have anticipated the transformations in our economy that were to come in the following two centuries! Today, technological advances most often occur not so much by individual inventors like Benjamin Franklin, but in large research laboratories, often employing thousands of individuals. The Federal government spends billions of dollars on research. And these dollars yield high returns.

This paper documents the high returns to R&D investments and addresses the role for government involvement. First, however, it is important to examine the amount of U.S. expenditures on R&D, how they have been changing over time, and how they compare with other countries.

U.S. INVESTMENTS IN R&D

The United States leads the world in absolute spending on R&D (see Chart 1).[2] This finding is not surprising, given that the U.S. economy is by far the largest in the world.

Chart 1

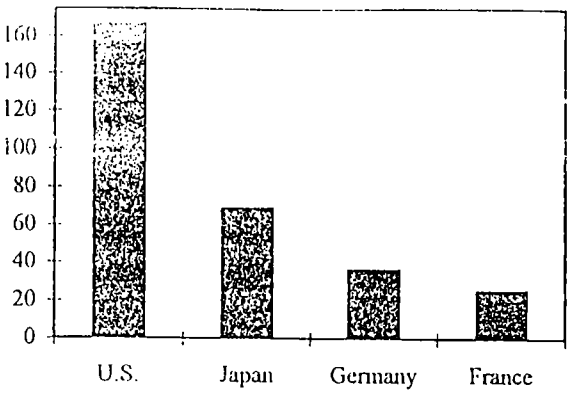
---

* Federal R&D investments are obviously critical in the pursuit of many national objectives, such as defense and the education of scientists and engineers. However, this paper will focus exclusively on economic returns.

[1] Griliches, Zvi. "The Search for R&D Spillovers." Scandinavian Journal of Economics. Vol 94, supplement, pp. 29 - 47. 1992

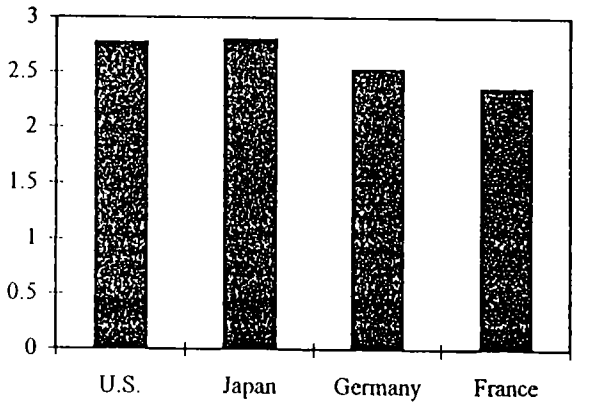
[2] Data for Charts 1 through 5 and Table 1, unless otherwise noted, are from National Science Foundation. National Patterns of R&D Resources: An SRS Special Report. NSF 95-304. 1995.

1992 Total Expenditures on R&D
(billions of dollars)



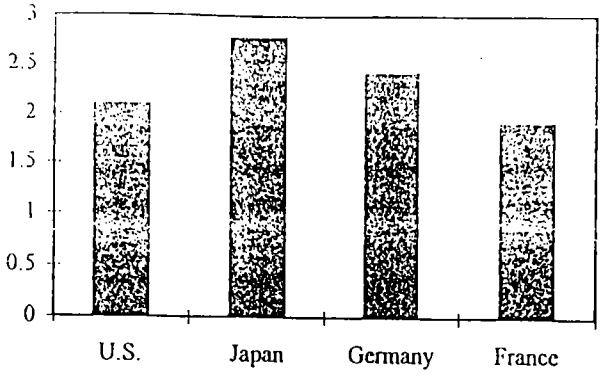
A better comparison is R&D expenditures *as a percentage of GDP*, in order to account for differences in the size of economies. Using this comparison, the United States is just behind Japan and slightly ahead of (unified) Germany and France (see Chart 2).

Chart 2
1992 Total R&D Expenditures
as a Percentage of GDP



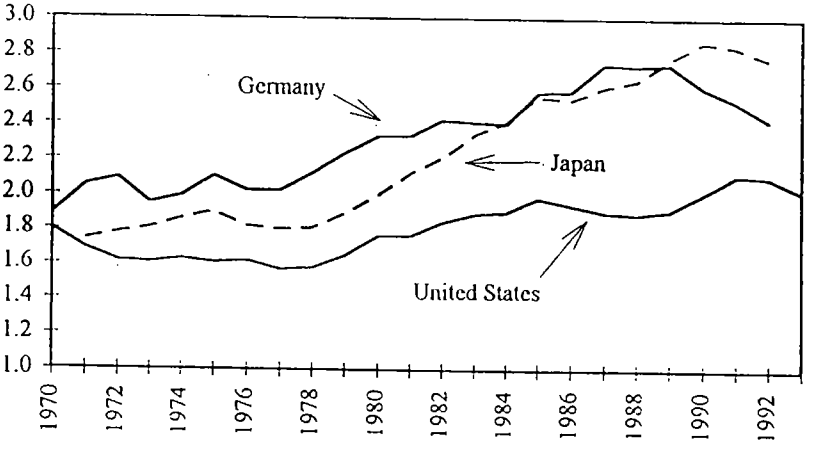
But this does not really tell the whole story. We must look not only at how much we spend, but on what we spend it. Aggregate R&D expenditures can be broken down into defense and non-defense R&D expenditures. The United States falls behind Germany, even further behind Japan, and remains just ahead of France in terms of non-defense R&D expenditures (see Chart 3).

Chart 3
1992 Non-Defense R&D Expenditures
as a Percentage of GDP



As seen in Chart 4, the United States consistently has been behind in this measure over the past two decades.

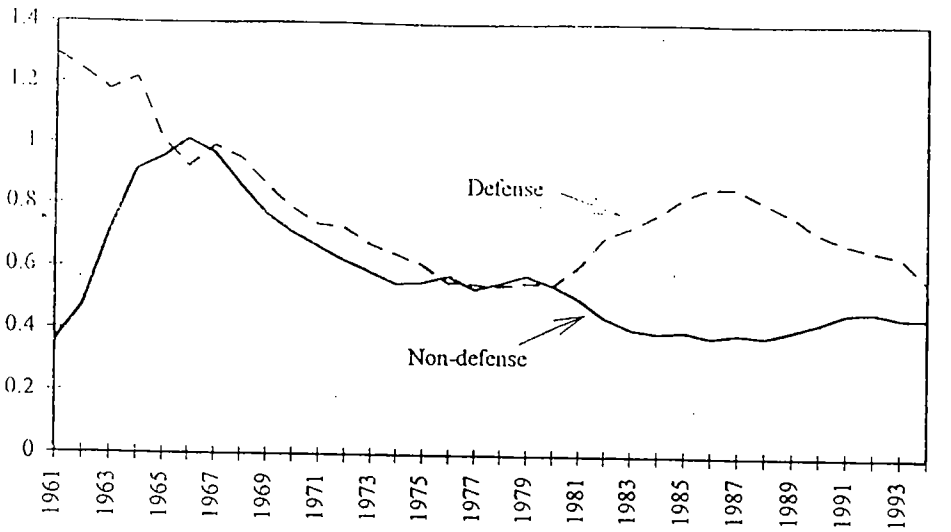
Chart 4
Non-Defense R&D Expenditures as a Percentage of GDP



Although total expenditures on non-defense R&D have remained relatively constant as a share of GDP in the last ten years (at a level well below those of Germany and Japan), Federal expenditures on non-defense R&D in the United States actually have fallen as a percentage of GDP over the last three decades (see Chart 5).[3]

Chart 5
Federal R&D Spending as a Percentage of GDP

[3] Defense and non-defense expenditures: 1961 - 1979: Office of Management and Budget: "Budget of the United States Government: Historical Tables." Fiscal Year 1996; 1979 - 1994: NSF, 1995; GDP figures from Council of Economic Advisers, "Economic Report of the President." 1995.



In the United States in 1994, the Federal government provided approximately 36 percent of all R&D funds and industry provided about 59 percent, with the balance comprised of funds from universities and colleges and other non-profit organizations.[4] Industry primarily funds product-related applied research and development, as these areas are most likely to yield immediate payoffs. Government funds most basic research, since the results of this type of research are the most uncertain and applications may not be realized for quite some time. Table 1 details the breakdown of support for different types of research.

While the rationale for the preeminent position of government in basic research are set forth in the next section, the consequences are clear: cutbacks in Federal funding will translate directly into cutbacks in basic research. Basic research is the *basis* of future innovations. That quantum theory would lead to today's electronics or lasers, or that investigations of DNA structures to genetic engineering and an emerging biotechnology industry could not have been anticipated. These advances built upon the steady progress of fundamental science.

Thus, reduced investments in basic research today will translate into fewer innovations in the future. To be sure, we cannot tell if a researcher who was not be funded might have discovered a cure for AIDS, or developed an idea that led to a breakthrough in plant productivity, or would have formed the basis of an enormous increase in energy efficiency, but we do know this: with less investment in R&D, there will be fewer breakthroughs, the pace of science will slow, and long-term growth will be slower than it otherwise would have been.

[4] National Science Foundation. 1995.

Table 1
Sources of Funds for R&D in 1994[5]

	All R&D		Basic Research	Applied Research	Development
	$ billions	percent	percent		
Federal Government	62.20	36	58	35	29
Industry	102.05	59	26	58	70
Universities and Colleges	5.30	3	10	4	*
Non-Profits	3.00	2	5	2	*
TOTAL	172.55	100	100	100	100

* less than one percent

Current Congressional proposals would cut Federal R&D expenditures. The impacts of reduced Federal R&D spending would not be trivial. A 1986 study confirmed that increased investment in R&D leads to greater productivity and output. The study concluded that the slowdown in the growth of R&D in the mid-1970s may have been extremely costly to the economy in terms of lost opportunities.[6]

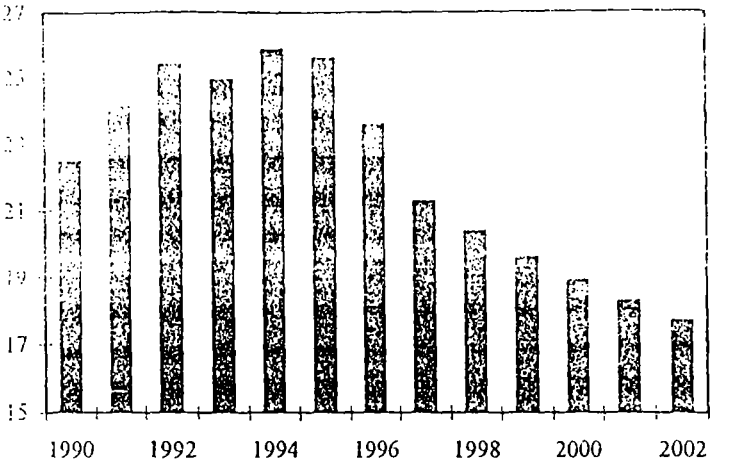
Today, we face not just the possibility of a slowdown in the growth of Federal R&D expenditures, but that of unprecedented cuts from existing levels. The American Association for the Advancement of Science estimates a cut of about 30 percent in Federal support of R&D by the year 2002 if the Congressional budget resolution were to become a reality. Chart 6 below details the estimated results of the Congressional plan.

Chart 6
Projected Congressional Non-Defense R&D Allocations 1990 - 2002
(billions of 1987 dollars)[7]

[5] NSF. 1995.

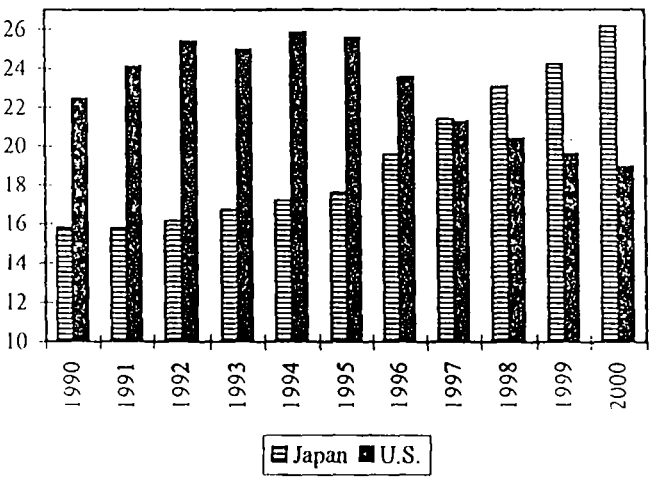
[6] Griliches, Zvi. "Productivity, R&D, and Basic Research at the Firm Level in the 1970s." American Economic Review. Vol 76, No 1. March, 1986. pp. 141 - 154.

[7] 1990 - 1995 are actual expenditures, 1996 - 2002 are estimated results of Congressional proposals; deflators 1994 - 2000 are estimates from OMB, Analytical Perspectives: Budget of the United States Government. FY 1996.



By contrast, the Japanese government recently announced plans to *double* its R&D spending by the year 2000. Chart 7 highlights the effect of Congress' plan and the Japanese plan: by 1997 Japan will overtake the United Stated in government support of non-defense R&D -- and in total dollars, not just as a share of GDP.

Chart 7
Estimated U.S. and Japanese Governmental Expenditures on Non-Defense R&D
(in billions of 1987 dollars)



THE ROLE OF GOVERNMENT INVESTMENTS IN R&D[8]

[8] The Federal government has a long history of involvement in science and technology. For example, in 1842 the government appropriated $30,000 for Samuel Morse to build a telegraph line from Washington to Baltimore to demonstrate the feasibility of his new technology. The Second World War brought great technological advancements from government research, all in the name of the war efforts. Many of those

Investments in R&D pay off in many key ways: through the devising of more efficient ways to produce existing goods and services, the discovery of entirely new products and processes, the increase in our knowledge base, and the education of world class scientists and engineers. Consider, for example, the production of automobiles. Because of technological advances, cars are produced much more efficiently today than they were 30 years ago. New technology also makes today's cars vastly superior to those produced 30 years ago.

Why does the government need to invest in R&D? The private sector on its own will not commit the level of resources to R&D that is best for society or even for the individual firms. A firm bases its investment expenditures, including those on R&D, on how large is the expected return on that investment *to that firm*. Because firms realize only a portion of the total returns to an investment in R&D, they will not invest enough from a societal standpoint. R&D is a unique input in the production process.[9] Its results can spread quickly throughout the economy, with applications far beyond those imagined by the original researcher -- the so-called "spillover" effect. Spillovers mean that an individual firm or innovator will realize only a fraction of the total returns to an innovation; that is, the innovation yields benefits to others *for which the original researcher is not fully compensated.*

---

technological accomplishments had applications in civilian life, as well. President Franklin Roosevelt recognized the potential of the R&D machine that had been built up during the war, and requested that Vannevar Bush, director of the wartime Office of Scientific Research and Development, devise plans on how to use the wartime experience in peacetime.

In response to President Roosevelt's request, Bush authored Science: The Endless Frontier in 1945, which became the guiding document for much of U.S. postwar science policy. But much of postwar scientific research was driven by cold war concerns. In this post-cold war era, we must examine Federal support for R&D to ensure that cuts do not have an inadvertent, but long-lasting detrimental impact on the American economy.

[9] The chain from idea to usable product or process can be long. R&D is comprised, most generally, of basic research, applied research, and development. The National Science Foundation (Science and Engineering Indicators, 1993) as follows:

- Basic Research: The objective of basic research is to gain more complete knowledge or understanding of the subject under study, without specific applications in mind. In industry, basic research is defined as research that advances scientific knowledge but does not have specific immediate commercial objectives, although it may be in fields of present or potential commercial interests.
- Applied Research: Applied research is aimed at gaining knowledge or understanding to determine the means by which a specific, recognized need may be met. In industry, applied research includes investigations oriented to discovering new scientific knowledge that has specific commercial objectives with respect to products, processes, or services.
- Development: Development is the systematic use of the knowledge or understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including the design and development of prototypes and processes.

Examples abound. Lasers and transistors are now a part of everyday life. The inventors of the laser probably had no idea that it would eventually be used for removing cataracts or for playing music in a compact disc player. Likewise, the American physicists who invented the transistor at Bell labs in 1948 could not have imagined that their invention would be used today in radios, computers, spaceflight and guided missiles, and countless other electronic devices. In both cases, even if the inventors' imaginations did reach such heights, today they receive no additional monetary benefit for the further huge advantages that society reaps from their insights.

Sometimes the spillovers are far more subtle. The discovery of nylon showed that it was possible to create man-made fibers with remarkable properties--and this knowledge affected the direction of research efforts applied by thousands of other researchers.

The consequences of the presence of important spillovers is that private firms will not invest in enough R&D from a national perspective. This point is not merely theoretical: many studies have demonstrated that investments in R&D yield high returns to investors and even higher returns to society. One recent review of econometric studies concluded that the average private rate of return to an innovation seems to be between 20 and 30 percent, while the social rate of return is closer to 50 percent.[10,11] An earlier, extensive, case-study approach found that the median private return to the innovations studied was 25 percent while the median social rate of return was 56 percent.[12] While estimates of the rates of return are just that -- estimates -- a wealth of studies over the past two decades have confirmed these high private returns and even higher social returns.[13]

In addition, some firms -- especially small ones that lack funds -- may not invest enough in R&D even from their own perspective. To make R&D investments, a firm may

---

[10] Nadiri, Ishaq. "Innovations and Technological Spillovers." NBER Working Paper Series. Working Paper No. 4423. August, 1993.

[11] Rates of return can be estimated by computing the benefits (including discounted future benefits) and the costs of the innovation.

[12] Mansfield, Edwin, J. Rapoport, A. Romeo, S. Wagner, and G. Beardsley. "Social and Private Rates of Return from Industrial Innovations." Quarterly Journal of Economics. Vol 77, pp 221 - 240. 1977.

[13] See, for example, the following studies in addition to those already cited:

- Terleckyj, N. "Effects of R&D on the Productivity Growth of Industries: An Exploratory Study." National Planning Association. Washington, DC. 1974.
- Sveikauskas, L. "Technology Inputs and Multifactor Productivity Growth." Review of Economics and Statistics. Vol 63, pp. 275 - 282. 1981.
- Goto, A. and K. Suzuki. "R&D Capital, Rate of Return on R&D Investment and Spillover of R&D in Japanese Manufacturing Industries." Review of Economics and Statistics. Vol 71, pp. 555 - 564. 1989.
- Bernstein, Jeffrey and M. Ishaq Nadiri. "Interindustry Spillovers, Rates of Return, and Production in High-Tech Industries." American Economic Review: Papers and Proceedings. Vol 78, pp. 429 - 434. 1988.
- Scherer, Frederick. "Using Linked Patent and R&D Data to Measure Interindustry Technology Flows." in R&D, Patents, and Productivity, Z. Griliches (ed.). University of Chicago Press, pp 417-464. 1984.
- Bernstein, Jeffrey and M. Ishaq Nadiri. "Product Demand, Cost of Production, Spillovers, and the Social Rate of Return to R&D." NBER Working Paper No. 3625. 1991.

need to go to capital markets for funding, and to provide these funds, financiers must have sufficient information to be able to assess the risks of the investments. Firms may not want to provide this information for fear of losing future private gains if somebody else were to use that information. Thus, the firm must either pay higher interest rates for loans or use its own funds to pay for the research. In fact, evidence suggests that small firms' investments in R&D are limited by their internal cash-flow.[14]

What is the Federal government's role? Because firms will underinvest in R&D, there is an important role for the Federal government. The fact that there is a government role in promoting science and technology has been long-recognized. The earliest and most widely used government incentive for encouraging innovation is granting patents, which essentially gives an innovator temporary monopoly rights on a new product or process. Thomas Jefferson recognized that "in the arts, and especially the mechanical arts, many ingenious improvements are made in consequence of the patent-right giving exclusive use of them for fourteen years." Indeed, the recognition that innovation must be encouraged is enshrined in the Constitution, which gives Congress the right to grant patents "to promote the progress of science and the useful arts, by securing limited times to authors and inventors the exclusive right to their respective writings and discoveries."

While important, patents alone are not a solution to the underinvestment problem. Even with strong patent protection, inventors capture only a small fraction of the benefits to society which accrue from their innovations, so that there will still be a problem of underinvestment. This is particularly important for basic research and other research with large spillovers and for research that yields results only far in the future or which is extremely risky.

What should the Federal government do? Most people recognize the need for government funding of basic, or fundamental, research. Indeed, as shown earlier in Table 1, the Federal government funds close to 60 percent of all basic research. The current debate focuses on the role of Federal investments in R&D as it gets closer to the marketplace. It is worthwhile to review the rationale for government support of basic research and discuss the issue of where in the "development pipeline" government's involvement in R&D should end.

Basic research is, by definition, not directed at solving an immediate problem or at inventing a particular product. Returns from investments in basic research may be many years away, and may not have applications bearing any similarity to what the researcher originally thought. For these reasons, firms may be reluctant to invest in basic research, implying that underinvestment is most likely to occur in basic research

Basic research ultimately can yield the highest returns of all to society. For example, two physicists in 1946 discovered nuclear magnetic resonance as the result of basic research. While they had no idea how this knowledge would eventually be used,

[14] Himmelberg, Charles and Bruce Petersen. "R&D and Internal Finance. A Panel Study of Small Firms in High-Tech Industries." Review of Economics and Statistics. Vol 76, Issue 1. 1994. pp. 38 - 51.

others soon realized the potential applications of this knowledge. Today, most major hospitals have magnetic resonance imaging (MRI) machines for use in noninvasive scanning of patient's internal organs. The MRI is a direct outgrowth of basic research leading to the nuclear magnetic resonance discovery.

Universities and colleges comprise the largest single group of performers of basic research, accounting for approximately 45 percent of all basic research in 1994.[15] This research is funded primarily by the Federal government. Universities and colleges create "knowledge for knowledge's sake," help develop an educated population, and train the scientific and engineering workforce. However, academic research itself also plays a crucial role in industrial innovation.

Measuring academic research as an input into innovation is exceedingly difficult; however, one researcher recently undertook just that task.[16] A study involving 76 major firms representing one-third of all output in seven industries revealed that these firms could not have developed approximately 11 percent of their new products and about 9 percent of their new processes without academic research conducted in the previous 15 years. Further, the study estimated the median social rate of return to academic research to be 28 percent.

While the "28 percent" figure is clearly a rough estimate, it shows that the returns to academic research are high. Moreover, this estimate is likely to be too low for two reasons. First, the study used academic research done only in the 15 years prior to the innovation -- much academic research may not be used in industrial innovations until more than 15 years after the initial discovery or publication, or may continue to be used for many years thereafter. Second, the study examined only seven industries. The academic research useful for innovations in these industries likely was useful in other industries, as well. Clearly, investing in academic research is another area with high payoffs.

Government support for academic research is crucial. In 1994, the Federal government funded 60 percent of all R&D at universities and colleges.[17] Moreover, many studies have shown a strong correlation between decreases in graduate fellowship support and a drop in the number of Americans pursuing graduate studies in science and engineering, and an increase in the proportion of foreign nationals entering engineering faculties at U.S. research universities.[18]

---

[15] Universities and colleges actually performed close to 55 percent of all basic research when one includes work done at Federally-funded research and development centers located at universities and colleges.

[16] Mansfield, Edwin. "Academic Research and Industrial Innovation." Research Policy. Vol. 20 1991. pp. 1-12.

[17] NSF, 1994. Table B-2. This estimate does not include funding for Federally Funded Research and Development Centers (FFRDCs) located at universities and colleges. Including FFRDCs brings Federal support to almost 70 percent of all R&D done at universities and colleges.

[18] Mowery, David and Nathaniel Rosenberg. Technology and the Pursuit of Economic Growth. Cambridge University Press. 1989. p. 152.

The government's role should not end at funding basic research, however. While government should not be involved in deciding what is commercializable, some R&D, called "precommercial," has the potential to yield a useful new product or process but is still too far from commercialization, and thus too risky, for a single firm to pursue. Underinvestment is likely to be particularly severe in those cases where there is the potential of significant spillovers to other applications. Government can help by absorbing some of the risk of such precommercial research. These arguments become particularly compelling when industry is forced to take a short-term view on their own R&D investments. Any government involvement must, however, substantially involve the private sector since government is unlikely to anticipate market outcomes correctly.

Returns to government R&D investments: It is difficult to measure the returns to publicly-funded R&D, primarily because such a large percentage of Federal R&D support traditionally has been defense-related.[19] The real impact of government-funded R&D is not the returns to the individual involved in the research, but the returns to society. Measuring such returns is not a simple task, since the results of public R&D weave their way through the economy in countless directions. Researchers have noted that because of such spillovers, one must examine Federal research on a case-by-case basis.[20] Because the Federal government can engage in high-risk, potentially high-payoff R&D, some government programs will be failures. However, other programs will be spectacularly successful, yielding enormous social returns.[21]

The aircraft industry is a prime example. The development of the United States aerospace industry was largely government-funded. As late as 1986, close to 80 percent of all R&D in this industry was Federally-supported.[22] Today this industry is a large employer and one of the largest exporters in the nation.[23]

Other examples include:

---

[19] In 1987, for example, about 70 percent of all Federal research was defense-oriented. Products resulting from defense R&D generally are purchased by the government and are not subject to a market test. Probably for this reason, studies have found *private* returns to publicly-funded R&D to be close to zero (Hall, Bronwyn. "The Private and Social Returns to Research and Development: What Have We Learned." June, 1995). Interestingly, however, one study of manufacturing firms found that increased government funding for applied research is correlated with increased productivity (Mansfield, Edwin. "Basic Research and Productivity Increase in Manufacturing." American Economic Review. Vol 70, No 5. December, 1980. pp 863-873). The unique feature of this study is that because it was not actually focused on government funding, the results were based on firms not necessarily involved in defense contracting.

[20] Bartelsman, Eric. "Federally Sponsored R&D and Productivity Growth." Finance and Economics Discussion Series, No 121. Federal Reserve Board, Washington, DC. April, 1990.

[21] Some programs that do not meet their specified goal may officially be classified as failures. However, even some "failed" projects can yield enormous positive spillovers.

[22] Mowery, David and Nathan Rosenberg. Technology and the Pursuit of Economic Growth. Cambridge University Press. 1989.

[23] In 1994 the industry employed about 480,000 people. From 1990 to 1994, exports averaged over $30 billion per year.

- **The discovery of DNA**. A small Federal grant in the early 1950s allowed a microbiologist to study genetic exchange in bacteria. Although many observers were skeptical, this work helped pave the way for the discovery of DNA -- perhaps the most important discovery of the century.

- **The atomic clock and the Global Positioning Satellite (GPS) system**. Super-precise atomic clocks were invented to help answer fundamental questions about the nature of the universe. However, a practical application for the atomic clock emerged. The GPS is a system of 24 satellites that depend on computer chips, miniaturized radio receivers, and atomic clocks. GPS, initially developed by the U.S. Air Force for military navigation, allows users to determine their location and altitude anywhere on earth to within 30 feet. Now GPS is also used for many civilian applications, including coastal navigation, emergency rescue, and the tracking of commercial vehicles. Over 160 manufacturers are developing GPS-based systems for an emerging multi-billion dollar industry.

- **The Hubble Space Telescope and cancer detection**. The Hubble Space Telescope was designed to gather more detailed information about the universe than is possible from ground-based telescopes. It turned out to have another use, as well. The image-processing software NASA developed to reconstruct and filter images can be applied to a digitized mammogram, and likely will be useful in identifying suspicious areas indicative of breast cancer.

- **The Internet and the Information Superhighway**. The Internet was originally a government-sponsored computer network designed to connect researchers. Today, it is the backbone of what is commonly referred to as "the information superhighway." Nobody knows exactly how the Internet will develop, but it is an increasingly active area, with more and more business involvement.

Results and spillovers from specific Federally-funded projects do not, however, exhaust the impacts of Federal funding. Federal funds have an additional benefit in that they stimulate private R&D expenditures.

Federal R&D expenditures stimulate additional private R&D expenditures. Many studies demonstrate that Federal spending on R&D stimulates additional private spending on R&D.[24] This complementarity holds up in basic, as well as applied, research.[25] In other words, an additional dollar of Federal R&D expenditures adds more than a dollar of R&D investment to the economy.

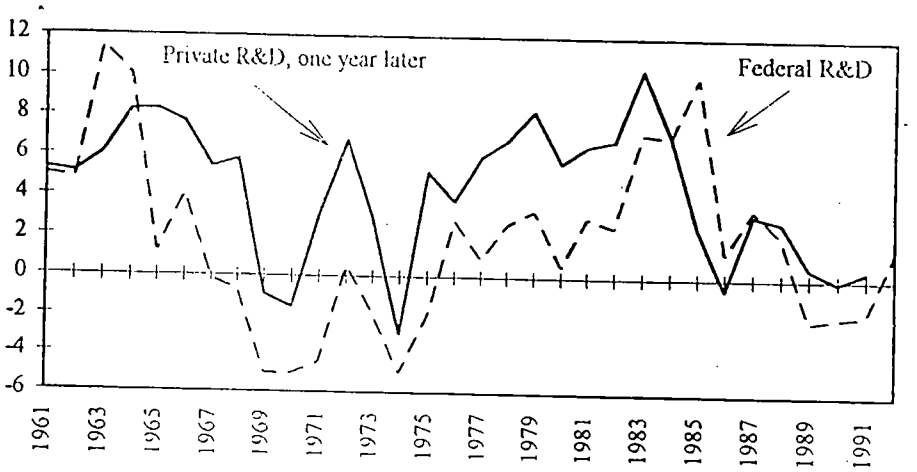
---

[24] Levy, David and Nestor Terleckyj. "Effects of Government R&D on Private R&D Investment and Productivity: A Macroeconomic Analysis." The Bell Journal of Economics. Vol 14, No. 2. Autumn, 1983. pp. 551 - 561.

[25] Robson, Martin. "Federal Funding and the Level of Private Expenditure on Basic Research." Southern Economic Journal. Vol 60, No 1. July, 1993. pp. 63 - 71

Unfortunately, complementarity also implies that if the Federal government cuts R&D expenditures, the private sector will cut R&D expenditures, as well. Chart 8 (below) shows a clear correlation between changes in Federal R&D expenditures and changes in private R&D expenditures one year later.

Chart 8
Percent Changes in Federal R&D Expenditures and Private R&D Expenditures One Year Later[26]



This correlation means that if Federal R&D support is cut, the nation is likely to lose future rewards not only from the Federally-supported R&D that will not be undertaken, but also from the industrial R&D that will not be done as the private sector scales back in response to Federal cuts.

CONCLUSION

Continued advances in R&D and technology are crucial to ensuring and increasing economic growth. Many studies have shown that while returns to a firm from investing in R&D are high, returns to society are even higher as new ideas are applied to areas far beyond what the innovator initially imagined. However, such spillovers imply that private firms will not invest in enough R&D from a national perspective. The Federal government can step in to fill the gap between the private level of R&D investment and the level and types of R&D investment that is best from the nation's perspective. Moreover, the nation benefits not just from the results of Federally-sponsored projects, but also because Federal R&D expenditures seem to stimulate additional private R&D expenditures.

Cutting Federal R&D expenditures conflicts with the goal of increasing economic growth and prosperity. Less R&D will lead to lower productivity, lower economic growth, and thus a lower standard of living for all Americans.

---

[26] Hill, Christopher. "Private Funds are Unlikely to Replace Cuts in Public Funds for R&D in the U.S." *Mimeo*. June 19, 1995
Data from NSF. "National Patterns of R&D Resources: 1992." NSF 92-330. October, 1992.

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

Divider Title: **Supporting R & D**

Subject: CEA Report on Economic Returns from R&D
Author: Rick E. Borchelt at ostp
Date: 11/1/95 3:15 PM

THE WHITE HOUSE

Office of the Press Secretary

FOR IMMEDIATE RELEASE Contact: (202) 395-5084
November 1, 1995

CEA REPORT CONFIRMS HIGH PAYOFF OF R&D INVESTMENTS

The President's Council of Economic Advisers (CEA), in a report released today, confirmed one of the basic tenets of the President's economic and national security strategy: Investments in research and development yield high returns to the economy and need to be protected from severe budget cuts.

The CEA report is an analysis of economic research on the societal benefits of federal spending on research and development (R&D). The report, "Supporting Research and Development to Promote Economic Growth: The Federal Government's Role," stresses that every federal dollar spent on R&D adds more than a dollar of R&D to the economy and brings social rates of return near 50 percent.

"Investments in research and development are the key to increasing productivity, accounting for half or more of the growth in output per person" in recent U.S. history, the report notes. "Successful R&D investments -- from the jet engine to transistors to lasers -- can and have changed the whole economy."

Moreover, it explains, "maintaining or increasing this country's R&D effort is essential if we are to increase the rate of productivity growth and improve American living standards." Continued R&D investments "will provide the basis of the America of the twenty-first century," the report concludes.

In releasing the report, CEA Chairman Joseph Stiglitz explained that deficit reduction is a means to an end goal of economic prosperity. "Cutting investments in R&D run counter to that end goal; without protecting key investments you may end up with a balanced budget but slower economic growth," he said.

The long history of government support of research is threatened by Congressional proposals to slash research funding by roughly 30 percent by the year 2002, the CEA says. At the same time, it warns, Japan expects to double its R&D spending by the year 2000. Under this scenario, by 1997 Japan -- for the first time in history -- will be spending more in absolute dollars on non- defense R&D than the United States.

The report also notes that federal investments stimulate private R&D expenditures, and that cuts in federal research will mean declines in private- sector R&D as well. Industrial spending on R&D already is on the decline, it says, and even under the best of circumstances, market forces alone would be insufficient to provide adequate investment in R&D.

The report is available from the Council of Economic Advisors at the telephone number above. It will soon be available on the World Wide Web via the Internet at http://www.whitehouse.gov.

# # #

SUPPORTING RESEARCH AND DEVELOPMENT TO PROMOTE ECONOMIC GROWTH: THE FEDERAL GOVERNMENT'S ROLE *

October 1995

A Report Prepared by
The Council of Economic Advisers

* Federal research and development investments are obviously critical in the pursuit of many national objectives, such as defense, health, and the education of scientists and engineers. However, this paper focuses exclusively on economic returns.

EXECUTIVE SUMMARY

- Increasing the productivity of the American workforce is the key to higher living standards and stronger economic growth in the future. Investments in research and development (R&D) are the key to increasing productivity, accounting for half or more of the growth in output per person, and to the creation of new products and processes.

- Investments in R&D have high rates of return. The social rates of return, which may be close to 50 percent, exceed the high private rates of returns, of 20 to 30 percent, by a considerable amount because of the "spillovers" -- benefits that accrue in applications far beyond those imagined by the original researcher. Because innovators realize only a fraction of the total return to an innovation, there will be an underinvestment in R&D.

- There has been a long record of successful government support for R&D, from its support of Samuel Morse's original telegraph line from Washington to Baltimore in 1842 to demonstrate the feasibility of his new technology, to the support of agricultural research, beginning with the 1862 Morrill Act establishing the land-grant colleges, to the development in more recent years of the Internet, the Global Positioning Satellite (GPS) system, and support of the basic research leading to the discovery of DNA. Examples of successful Federal R&D investments abound.

- Federal R&D expenditures stimulate additional private R&D expenditures. An additional dollar of Federal R&D adds more than a dollar of R&D to the economy, as the private sector expands its R&D effort. Accordingly, a cut in Federal R&D expenditures is likely to cause the private sector to cut back as well.

- The Congressional budget resolution would cut Federal R&D expenditures by about 30 percent by the year 2002. The Japanese government, by contrast, recently announced plans to double its R&D spending by the year 2000. While non-defense R&D expenditures in the United States, as a percentage of GDP, are already smaller than in Japan, as a result of the American decreases and the Japanese increases, the Japanese government will actually spend more, in total dollars, than the American government on non-defense R&D by 1997.

- Current debates not only focus on the level of support for R&D, but also on the composition. Increased living standards and faster productivity depends on increased support for civilian and dual-use research (that is, research that has both direct military and civilian applications), not just support of "star wars" and other military research. Opponents of government support for pre-commercial technological development erroneously characterize government efforts as "picking winners," interfering with what would otherwise be efficient market allocations, and try to draw a clear line between basic and generic research (which all agree government should support) and applied research. In reality, there is a continuum, with many applied research projects yielding significant spillovers, so that absent some government support, there may be marked underinvestment. Government can aid the development of such potentially high-payoff pre-commercial R&D with large spillovers, but must involve the private sector in such efforts. These government investments can yield high returns.

INTRODUCTION

Increasing the productivity of the American workforce is the key to higher living standards and stronger economic growth in the future. Evidence indicates that investments in research and development (R&D) have large payoffs in terms of growth. R&D yields new products, improving the quality of life, and new processes, enabling American firms to reduce costs of production and become more competitive. Indeed, investments in R&D are estimated to account for half or more of the increase in output per person.[1] Maintaining or increasing this country's R&D effort is essential if we are to increase the rate of productivity growth and improve American living standards.[2]

The largest part of R&D in the United States is funded by private industry. Small entrepreneurs see an opportunity, raise funds any way they can, and take their chances on an innovative idea. Large companies spend billions on R&D labs to develop a stream of new products and processes. Private companies know the markets they serve and the workers who must produce the products. Risking their own funds gives them a strong incentive to avoid costly failures.

Since the founding of this country, the Federal government has had an important role in the promotion of science and technology. Indeed, the Constitution gave Congress the right to grant patents to "promote the progress of science. . . ." But in today's complex and competitive world economy, promoting the progress of science goes beyond simply the granting of patents. First, successful R&D in private companies depends upon the flow of new ideas and trained people stemming from basic research and pre-commercial R&D.[3] Federal support for these activities is vital.[4] Second, the Federal government sponsors much applied research to improve its own capabilities in such areas as national security, health, and transportation. The government can then help transfer technologies developed for its own use to the private sector.

This paper describes U.S. expenditures on R&D, how they have been changing over time, and how they compare with other countries. It then examines the rationale and role for government involvement in R&D and documents the high returns to R&D investments. Finally, it projects the results of the Congressional budget resolution on R&D expenditures and contrasts that projection with Japanese plans.

---

[1] Griliches, Zvi. "The Search for R&D Spillovers." Scandinavian Journal of Economics. Vol. 94, supplement, pp. 29 - 47. 1992.

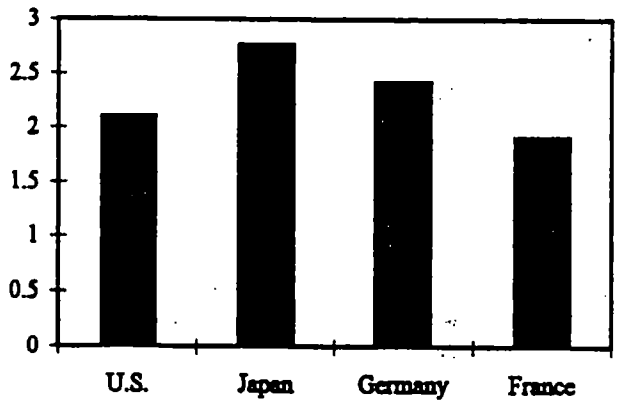
[2] Baily, M.N. and A. Chakrabarti, Innovation and the Productivity Crisis, Brookings Institution, Washington, DC 1988.

[3] Pre-commercial R&D may be loosely defined as R&D that is close to yielding a new product or process, but is still far enough away from commercialization to require a firm to take on substantial risk in pushing it towards the market, and may be such that the social returns to the investment will be much higher than the private returns.

[4] Industry also relies on the government to support the technical infrastructure -- for example, standards for weights and measures. Research in this area is essential for advancing commerce and trade.

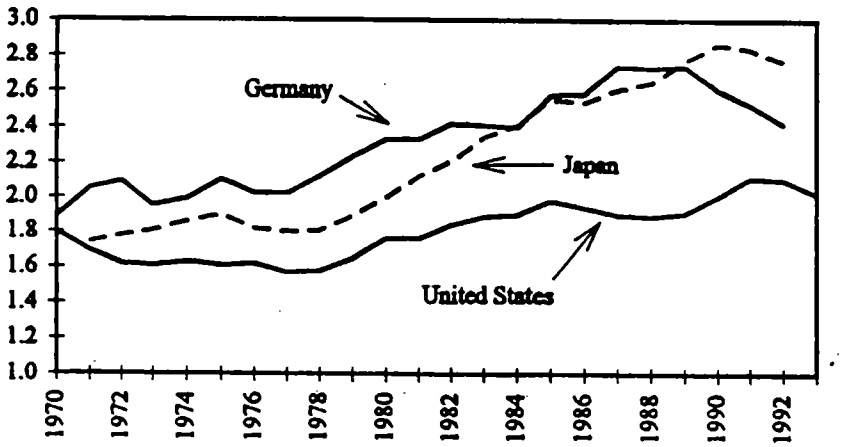
But this does not really tell the whole story. We must look not only at how much we spend, but also at what we spend it on. Aggregate R&D expenditures can be broken down into defense and non-defense R&D expenditures. The United States falls behind Germany, even further behind Japan, and remains just ahead of France in terms of non-defense R&D expenditures (see Chart 3).

Chart 3
1992 Non-Defense R&D Expenditures as a Percentage of GDP



As seen in Chart 4, the United States consistently has lagged behind in this measure over the past two decades.

Chart 4
Non-Defense R&D Expenditures as a Percentage of GDP



Although total expenditures on non-defense R&D have remained relatively constant as a share of GDP in the last 10 years (at a level well below those of Germany

Table 1
Sources of Funds for R&D in 1994[8]

	All R&D		Basic Research	Applied Research	Development
	$ billions	percent	percent		
Federal Government	62.2	36	58	35	29
Industry	102.1	59	26	58	70
Universities and Colleges	5.3	3	10	4	*
Non-Profits	3.0	2	5	2	*
TOTAL	172.6	100	100	100	100

* less than one percent

THE ROLE OF GOVERNMENT INVESTMENTS IN R&D

Why does the government need to invest in R&D? The private sector on its own will not commit the level of resources to R&D that is best for society or even for the individual firms. A firm bases its investment expenditures, including those on R&D, on the expected return on an investment *to that firm*. Because firms realize only a portion of the total returns to an investment in R&D, they will not invest enough from a societal standpoint. R&D is a unique input in the production process.[9] Its results can spread quickly throughout the economy, with applications far beyond those imagined by the original researcher -- the so-called "spillover" effect. Spillovers mean that an individual firm or innovator will realize only a fraction of the total returns to an innovation; that is, the innovation yields benefits to others *for which the original researcher is not fully compensated.*

Examples abound. Lasers and transistors are now a part of everyday life. The inventors of the laser probably had no idea that it would eventually be used for removing

---

[8] NSF. 1995.

[9] The chain from idea to usable product or process can be long. R&D is comprised, most generally, of basic research, applied research, and development. The divisions between these areas is not always clear, as they all interact in complex ways, with advances in one type of research influencing the direction of research in others. For conceptual purposes, though, The National Science Foundation (Science and Engineering Indicators, 1993) defines these terms as follows:

- Basic Research: The objective of basic research is to gain more complete knowledge or understanding of the subject under study, without specific applications in mind. In industry, basic research is defined as research that advances scientific knowledge but does not have specific immediate commercial objectives, although it may be in fields of present or potential commercial interests.
- Applied Research: Applied research is aimed at gaining knowledge or understanding to determine the means by which a specific, recognized need may be met. In industry, applied research includes investigations oriented to discovering new scientific knowledge that has specific commercial objectives with respect to products, processes, or services.
- Development: Development is the systematic use of the knowledge or understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including the design and development of prototypes and processes.

Table 2
Private and Social Rates of Return to Private R&D[14]

Author (year)	Estimated Rates of Return	
	Private	Social
Nadiri (1993)	20 - 30	50
Mansfield (1977)	25	56
Terleckyj (1974)	29	48 - 78
Sveikauskas (1981)	7 - 25	50
Goto-Suzuki (1989)	26	80
Bernstein-Nadiri (1988)	10 - 27	11 - 111
Scherer (1982, 1984)	29 - 43	64 - 147
Bernstein-Nadiri (1991)	15 - 28	20 - 110

In addition, some firms -- especially small ones that lack funds -- may not invest enough in R&D even from their own perspective. To make R&D investments, a firm may need to go to capital markets for funding, and to provide these funds, financiers must have sufficient information to be able to assess the risks of the investments. Firms may not want to provide this information for fear of losing future private gains if somebody else were to use that information. Moreover, R&D cannot be collateralized, in the way that an investment in a building or a machine can be. Thus, the firm must either pay higher interest rates for loans or use its own funds to pay for the research. In fact, evidence suggests that small firms' investments in R&D are limited by their internal cash-flow.[15]

The inadequacy of firms' incentives to invest in R&D creates an important role for the Federal government. The goal of technology policy, however, is not to substitute the government's judgment for that of private industry. Rather, the point is to correct a genuine and significant problem -- underinvestment in basic research and in pre-commercial R&D resulting from the divergence between private and social returns to those activities. A complementary goal is to design the technology investments that the government itself makes in public goods -- national security, public health, education, a clean environment, an efficient transportation system -- in ways that maximize the potential external benefits for the Nation's commercial technology base. In both cases, support for technological innovation enhances the Nation's economic and social welfare.

Expanding the R&D tax credit provides an additional incentive to the private sector to ameliorate the underinvestment problem discussed in this paper.[16] Indeed, the tax credit can be effective in increasing private sector R&D expenditures, and is an important component of a comprehensive technology policy.

---

[14] Table adapted from: Griliches (1992), and Nadiri (1993).

[15] Himmelberg, Charles and Bruce Petersen. "R&D and Internal Finance. A Panel Study of Small Firms in High-Tech Industries." Review of Economics and Statistics. Vol. 76, Issue 1. pp. 38 - 51. 1994.

[16] The R&D tax credit, officially known as the research and experimentation (R&E) tax credit, allows firms to deduct from their income taxes a portion of their R&D expenditures beyond a certain base level.

measure on government support. Students come from all over the world to learn from U.S. scientists and engineers.

Funding basic research. Most people recognize the need for government funding of basic, or fundamental, research. Indeed, as shown earlier in Table 1, the Federal government funds close to 60 percent of all basic research. Basic research is, by definition, not directed at solving an immediate problem or at inventing a particular product. While basic research has immediate returns in adding to our knowledge base and in educating scientists and engineers, economic returns from investments in basic research may be many years away, and may not have applications bearing any similarity to what the researcher originally thought. Since so much of the returns to basic research are not appropriated by the innovator (and indeed, in many cases, the output of basic research is not patentable), the gap between social and private returns is particularly large, and therefore the problem of underinvestment is particularly severe. Firms are typically reluctant to invest much in basic research.

Basic research ultimately can yield extraordinary returns to society. For example, two physicists in 1946 discovered nuclear magnetic resonance as the result of basic research. While they had no idea how this knowledge would eventually be used, others soon realized the potential applications of this knowledge. Today, most major hospitals have magnetic resonance imaging (MRI) machines for use in noninvasive scanning of patients' internal organs. The MRI is a direct outgrowth of earlier basic research.

Universities and colleges comprise the largest single group of performers of basic research, accounting for approximately 45 percent of all basic research in 1994.[20] This research is funded primarily by the Federal government. Universities and colleges create "knowledge for knowledge's sake," help develop an educated population, and train the scientific and engineering workforce. However, academic research itself also plays a crucial role in industrial innovation. One recent study of 76 manufacturing firms revealed that these firms could not have developed about 11 percent of their new products and 9 percent of their new processes without research done at universities and colleges. This study estimated the median social rate of return to research done at academic institutions to be 28 percent.[21,22]

---

[20] Universities and colleges actually performed close to 55 percent of all basic research when one includes work done at Federally funded Research and Development Centers located at universities and colleges.

[21] While the "28 percent" figure is clearly a rough estimate, it shows that the returns to academic research are high. Moreover, this estimate is likely to be too low for two reasons. First, the study used academic research done only in the 15 years prior to the innovation -- much academic research may not be used in industrial innovations until more than 15 years after the initial discovery or publication, or may continue to be used for many years thereafter. Second, the study examined only seven industries. The academic research useful for innovations in these industries likely was useful in other industries, as well. Clearly, investing in academic research is an area with high payoffs.

[22] Mansfield, Edwin. "Academic Research and Industrial Innovation." Research Policy. Vol. 20. pp. 1 - 12. 1991.

and environmental technologies, advanced materials, and a host of other commercially successful technologies.

This system worked well as long as military requirements represented the leading-edge applications of new industrial technologies. In many areas of basic research supported outside the defense establishment, including biomedical research and the development of pharmaceuticals, biotechnology, and medical diagnostic devices, the system continues to work well.

The circumstances that allowed the United States to rely primarily on a defense-led model have changed. With the end of the Cold War, demand for new defense systems is now less than it was. Commercial product spin-offs from military research have also diminished from their heyday of the 1950s and 1960s, and American companies face intense international competition from increasingly capable foreign firms. On the other hand, these changes also create exciting new opportunities: innovative defense technologies are now more likely to emerge first in commercial products and production techniques, and American companies are taking advantage of expanded opportunities in foreign markets. Accordingly, the Administration's technology initiatives are shifting the composition of Federal R&D from military to civilian concerns, and the composition of military R&D toward the development of so-called dual-use technologies -- those with applications to both military and commercial products.

Designing a successful program of technology support. The Administration's efforts to promote innovative technology contain design features meant to limit the possibility of government failure in the implementation of technology policy: in most cases, firms participating in the Administration's programs must cover at least 50 percent of the costs of the project; projects are initiated by private firms, which compete for limited funding; outside experts in the relevant scientific, technological, and economic fields evaluate competing proposals; and firms can compete for funds in a wide array of technological fields, to ensure that support for pre-commercial R&D support does not get "captured" by any particular technology or set of firms.

Even the best-designed technology program will have failures. Indeed, if it does not, then it certainly is too cautious. In the final analysis, the returns to government-funded R&D depend upon the returns to the successful projects outweighing the losses from the unsuccessful ones. By incorporating the above design features, the Administration's technology program provides the best chance for achieving high returns that benefit American living standards.

Returns to government R&D investments: It is impossible to provide a reliable quantitative estimate of the returns to publicly-supported R&D based upon historical data, primarily because such a large percentage of Federal R&D support has been defense-related, although as noted earlier the returns to other public investments have been

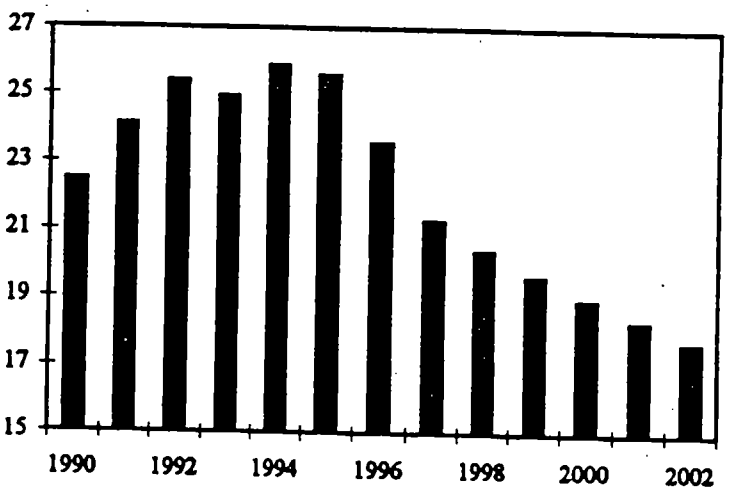
processing software NASA developed to reconstruct and filter images can be applied to a digitized mammogram, and likely will be useful in identifying suspicious areas indicative of breast cancer.

- **The Internet and the Information Superhighway.** The Internet was originally a government-sponsored computer network designed to connect researchers. Today, it is an important component of what is commonly referred to as "the information superhighway." Nobody knows exactly how the Internet will develop, but it is increasingly active, with more and more business involvement.

CONGRESSIONAL PROPOSALS CUT FEDERAL R&D EXPENDITURES

Today, we face the possibility of unprecedented cuts in Federal R&D expenditures. The American Association for the Advancement of Science estimates a real cut of about 30 percent in Federal support of non-defense R&D by the year 2002 if the Congressional budget resolution were to become a reality. Chart 6 details the estimated results of the Congressional plan.

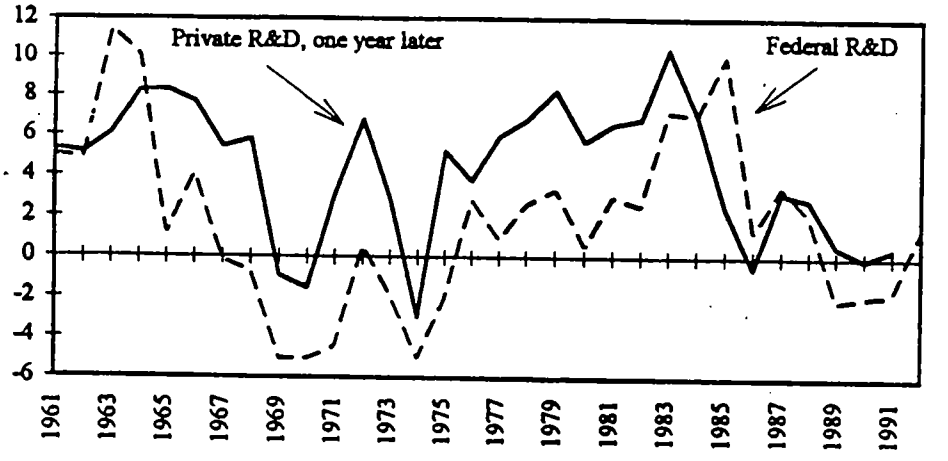
Chart 6
Projected Congressional Non-Defense R&D Allocations 1990 - 2002
(billions of 1987 dollars)[30]



By contrast, the Japanese government recently announced plans to *double* its R&D spending by the year 2000. Chart 7 highlights the effect of the Congressional plan and the Japanese plan: by 1997 Japan will overtake the United States in government support of non-defense R&D -- in total dollars, not just as a share of GDP.

[30] 1990 - 1995 are actual expenditures; 1996 - 2002 are estimated results of Congressional proposals; deflators 1994 - 2000 are estimates from OMB, Analytical Perspectives: Budget of the United States Government. FY 1996. Assumed 3.5 percent inflation from 2000 - 2002.

Chart 8
Percent Changes in Federal R&D Expenditures and Private R&D Expenditures One Year Later[33]



This correlation means that if Federal R&D support is cut, the nation is likely to lose future rewards not only from the Federally-supported R&D that will not be undertaken, but also from the industrial R&D that will not be undertaken as the private sector scales back in response to Federal cuts.

CONCLUSION

Continued advances in R&D and technology are crucial to ensuring and increasing economic growth. Many studies have shown that while returns to a firm from investing in R&D are high, returns to society are even higher as new ideas are applied to areas far beyond what the innovator initially imagined. However, such spillovers imply that private firms will not invest in enough R&D from a national perspective. The Federal government can step in to fill the gap between the private level of R&D investment and the level and types of R&D investment that are best for the nation. Moreover, the nation benefits not just from the results of Federally-sponsored projects, but also because Federal R&D expenditures seem to stimulate additional private R&D expenditures.

The competitive position of the United States -- and indeed future increases in standards of living -- depends on technological advances. These in turn depend on our entire scientific and technological infrastructure, which includes our educational institutions -- producing the scientists and engineers that will provide the creative advances of the future -- our research universities, and our nation's laboratories, both within the private and public sectors. Ideas flow from basic research, through pre-competitive development, to concrete applications, producing new products and developing new, better, and lower-cost production processes. Government has a vital role

[33] Hill, Christopher. "Private Funds are Unlikely to Replace Cuts in Public Funds for R&D in the U.S." Mimeo. June 19, 1995. Data from NSF. "National Patterns of R&D Resources: 1992." NSF 92-330. October, 1992.

Economic Report of the President

Transmitted to the Congress
February 1995

public are in the financial benefits that accrue from the use of the resource. Auctions are compatible with the pursuit of other societal goals: applicants can continue to be screened for basic qualifications, and license uses can be regulated as necessary to protect the public interest. Even with these restrictions, using auctions to license spectrum is more efficient and less costly than lotteries and comparative hearings.

In 1993 the Congress authorized the FCC to invite competitive bids for initial licenses for spectrum dedicated to commercial subscription uses. The first auctions, for spectrum devoted primarily to advanced and two-way paging, took place in 1994 and yielded substantially more revenue to the government than some industry forecasters had predicted. Auctions for spectrum devoted to personal communications services (PCS) are anticipated to generate billions of dollars over the next several years.

SCIENCE AND TECHNOLOGY

Scientific discovery and technological innovation play central roles in increasing productivity and economic growth. In the long run, it is the discovery of new ideas—better "recipes," as distinct from merely more cooking in the traditional way with more of the same limited supply of ingredients—that reduces the cost to society of producing any given amount of goods. Ultimately these cost reductions will translate into some combination of lower prices for consumers, higher wages for workers, and higher profits for investors. Over time these changes can lead to significant, cumulative increases in living standards. Today the pace of scientific and technological progress is accelerating in tandem with the pace of the product cycle in international markets. These twin accelerations blur the lines and shrink the intervals that formerly separated basic from applied research, fundamental science from engineering and technical progress, and technological innovations from their initial commercial applications.

Wherever they originate, in the laboratory or on the factory floor, new scientific and technological ideas are often expensive to discover, yet cheap to replicate. It still costs something to draft the blueprint that captures the new idea, and something to make each unit of the product that embodies it, but once created, the idea itself is easily and often beneficially copied. Thus the economic returns to one company's investment in innovation can pass quickly to others. Economists have estimated that, because of this tendency of new ideas to become rapidly diffused, innovators typically capture less than half the total social returns to their investments in research and development (R&D). In short, the difficulty of establishing and enforcing property rights to new ideas reduces the economically optimal level of R&D. Bolstering the incentive is therefore an important efficiency-enhancing function of government. Government can do so through enhanced patent protection—while bearing in mind the potential inefficiencies in production and innovation that can occur with even temporary market power—and through public support for R&D.

Even before this Administration came into office, historic changes in the global distribution of wealth and power had sparked a public reexamination of the nature and extent of Federal support for the Nation's science and technology enterprise. Much of this attention focused on the implications for Federal R&D spending of the end of the cold war and the growing technical competence of foreign-based firms in areas where U.S.-based industry had traditionally been the world leader. To respond to these changes, this Administration has reoriented the Federal R&D effort from primarily defense-related investments toward investments in a broader set of national goals, including health, prosperity, environmental responsibility, and improved quality of life, in addition to national security. Although the United States is still in the midst of a major transition in the way both the public and the private sector manage the development and commercialization of science and technology, recent changes are beginning to show positive results.

Trends in National R&D

Together industry, government, and universities in the United States have typically spent more money on R&D activities than their counterparts in any other country—an estimated $176 billion in 1994, or 2.6 percent of GDP. Indeed, in 1992, the most recent year for which comparative data are available, the United States spent 28 percent more on R&D than did Japan, Germany, and France *combined*. However, these countries collectively spent nearly as much as the United States on nondefense R&D. As a percentage of GDP, U.S. spending for civilian R&D stood at 2.1 percent in 1992, compared with 2.4 percent in Germany and 2.8 percent in Japan.

Long-term real growth in U.S. R&D has also been slow: just 0.9 percent per year on average between 1985 and 1993, compared with 5.3 percent per year between 1975 and 1985. This slowdown of total R&D growth has been paralleled by slower growth in private R&D. In 1994 R&D spending by U.S. industry decreased by 0.5 percent in real terms; this followed an average annual real growth rate of only 1.2 percent between 1986 and 1993, compared with a robust real annual growth rate of 6.7 percent between 1976 and 1985.

Some of the slowdown in R&D spending may reflect the recent recession. The slowdown may also reflect recent corporate cost-cut-

ting drives that have shifted R&D spending toward in-house development of technologies closer to commercialization and that have prompted collaborative research, which is less costly to individual firms. (More than 350 multifirm collaborative research ventures, among them many R&D consortia, have been created in the United States since 1985, as well as more than 1,000 university-industry research centers, 72 percent of which were established with State or Federal support.) Finally, the slowdown in R&D spending reflects the end of the cold war. R&D spending by industry is highly concentrated in the United States—eight industries account for more than 80 percent of the total—and the top two, aircraft and communications equipment, are closely related to defense.

The deceleration of growth in spending for R&D has been accompanied by a shift in the sources of R&D funds and a shift in where the R&D is actually performed. Nongovernmental sources of funding have become increasingly important. Universities' share of R&D performance rose to 12 percent by 1993 from just 9 percent in 1985. Although Federal spending on all university research has risen, the share of university research funding that comes from the government has declined and recent financial problems of some universities may jeopardize their direct expenditures on research. Meanwhile industrial support for academic research has grown dramatically, from 3.9 percent of the total in 1980 to 7.3 percent in 1993. Industrial firms are still responsible for performing most of the Nation's R&D—$125 billion worth, or 71 percent in 1994—but even if their increased support for academic research is included, their share of the total national R&D effort has fallen since 1985.

Recent trends in U.S. R&D investment leave some analysts concerned that the Nation is spending too little on the *basic* research that will drive tomorrow's revolutionary breakthroughs. This concern is supported by empirical evidence that suggests there are large unexploited economic gains to be realized from raising our society's level of scientific activity and technological research and development; in the past, the social rate of return on such investments has been high. As a central component and stimulus of U.S. innovation, Federal R&D investment can lead technological innovation nationwide and affect the Nation's military posture, a variety of important social objectives, and the competitive performance of U.S.-based firms in domestic and foreign markets.

Confronting the Cold War Legacy

This Administration has realigned Federal spending for R&D so that it more equally balances civilian and military priorities. The purpose of this shift is not only to strengthen civilian industry, but also to promote the cost-effective development of new technologies for national defense and stimulate the creation of an integrated civilian-military industrial base. The Administration is also reorienting the Federal Government's R&D portfolio toward the achievement of important social objectives that would otherwise be inadequately addressed. These include the development of cleaner and more efficient transportation systems, more rapid and widespread diffusion of technological and managerial innovations to small and medium-sized manufacturers, environmental remediation, and pollution prevention.

The Administration's R&D strategy relies on a combination of grant programs in which industry and government share the costs; national initiatives in areas such as manufacturing, transportation, high-speed computing and telecommunications, and environmental technology; defense reinvestment efforts; and enhanced technology-transfer mechanisms (for example, the increased use of cooperative research and development agreements, or CRADAs, which ease private companies' access to the scientific and technological resources in U.S. Government laboratories). These programs require Federal agencies to work more closely with commercial industry to strengthen the technological underpinnings of the entire economy.

Reflecting cold war concerns, national security long commanded the largest share of Federal R&D funds. Spending priorities shifted even further—dramatically so—toward defense programs in the 1980s. The defense share of Federal R&D spending reached its most recent peak in 1987, when it accounted for 69 percent of the total. The defense share declined from 59 percent to 56 percent between 1992 and 1994, indicating progress toward the Administration's goal of restoring a 50–50 split by 1998.

The national security focus of U.S. R&D spending during the cold war has also affected the agenda for government support of much industrial and university-based science. During the late 1980s, for example, the Defense Department provided 32 percent of all funds for academic engineering research. While Federal funds account for just one-fourth of the money private industry spends to support R&D, 76 percent of that Federal support goes to aerospace and communications equipment firms, primarily for development of weapons and related systems of military application. The cold war emphasis on defense also affected the structure and objectives of the Nation's Federal laboratory system.

In an era of increasing budget pressure—an era, too, in which commercial technology development defines the leading edge in key strategic areas—the maintenance of a defense industrial base separate from commercially oriented industry is in many areas economically inefficient. Recognizing this, the Defense Department is now working more closely with firms engaged in commercial and dual-use production than in the past (dual-use goods are those with both military and commercial uses). Dual-use R&D programs, in-

cluding the Administration's Technology Reinvestment Project (TRP), are a different—and more economically efficient—way of carrying out the Defense Department's traditional R&D activities. The TRP has played a role in facilitating new partnerships between defense and commercial industry. Combined with the procurement reforms discussed earlier, the program is expected to make the Defense Department a more attractive customer for civilian producers. It is also exposing traditional defense contractors to innovative management and production techniques that can lower their costs and encourage more rapid technology transfer from the commercial sector.

Other important examples of Defense Department dual-use R&D initiatives include the development of flat panel display technology (Box 4–7) and microwave and millimeter wave monolithic integrated circuit technology (MIMIC). Commercial applications for MIMIC devices include their use in collision avoidance systems for automobiles, satellite communications, and portable telephones. The development of dual-use components that can be built on the same production line as the military-only versions has resulted in lower cost devices for the military and new, commercially marketable products for U.S. firms. Commercial technology cannot supply defense needs in all instances—tanks and nuclear attack submarines, for example, require technology that is defense-unique. But a great many defense needs can be served more efficiently—and less expensively—by commercial firms and facilities. Indeed, as flexible manufacturing systems are developed and more widely adopted, it will be increasingly possible to produce in a single plant both low-volume military equipment and high-volume commercial equipment.

Private Innovation and Public Goods

Beyond reorienting the government's own R&D portfolio, this Administration has worked on many fronts to increase the level of private innovation—by supporting public-private partnerships for the provision of industry-specific public goods, by supporting the extension of the R&D tax credit (discussed in Chapter 3), and by proposing changes in intellectual property law that will increase the incentives for efficient creation and use of private inventions.

Industry-specific public goods. It has already been noted that individual firms typically have too little incentive to invest in R&D, because an innovation and its payoffs may pass quickly to other firms and to consumers, who paid little or nothing to create the innovation in the first place. The constant creation and rapid diffusion of scientific discovery and technological innovation are good for the economy as a whole, but investment in innovation may not appear to be a prudent move for any individual firm.

Box 4–7.—The National Flat Panel Display Initiative

Today's computers display information in one of two ways: on cathode ray tubes, the bulky devices now used in television sets and most desktop computers, or on flat panel displays, the thin, light, rugged screens used in laptop computers. Flat panel displays are already key components in many consumer products—facsimile machines, portable telephones, compact disc players, and videocassette recorders, as well as laptops. They will also transform future battlefields, where they will be used to satisfy the huge demand for information from myriad sensors, providing real-time intelligence to combatants in aircraft, ships, tanks, and the infantry.

A recently completed interagency study of flat panel displays shows them to be increasingly important in military applications. But with 95 percent of supply controlled by foreign producers whose willingness to work with the Defense Department cannot be taken for granted, access to the latest flat panel display technologies for timely incorporation into defense systems is not assured. The Department of Defense requires early, certain, and affordable access in order to integrate displays into systems and to work out tactics for their use in military situations.

To answer these national security concerns, the Defense Department is implementing the National Flat Panel Display Initiative as a 5-year, $587 million program of support for research and development into flat panel displays, including research on their manufacture. Part of this precompetitive R&D funding is focused on ensuring that the research leads to actual products that will be used in important military applications. A portion will go to an innovative program in which firms with a demonstrated commitment to build current generation displays share with the Pentagon the burden of developing dual-use technology for next-generation products and manufacturing processes. Matching funds will be awarded in competitions open to a variety of flat panel display technologies.

A similar logic is at work with regard to investments in industry-specific public goods. Investments in a particular technological breakthrough may create large economic benefits for the industry as a whole, from which no single producer or subset of producers can be excluded, even though the breakthrough was financed and achieved by others.

The Commerce Department's Advanced Technology Program (ATP) is a policy experiment to test whether government-industry

partnersh can overcome market barriers to the provision of industry-specific public goods. Take, for example, the barriers that have impeded some potentially lucrative technical improvements in the materials and manufacturing processes for printed-wiring boards (PWBs). PWBs comprise the backbone and much of the nervous system of virtually every modern electronic product. Each increase in the speed and complexity of electronic devices has increased the density of the PWB's lacework of copper lines, which must be embroidered to tiny plated holes. By the early 1990s, PWBs were beginning to reach the fundamental physical limits imposed by both materials and manufacturing processes. PWB market analysts understood that relatively minor material or process improvements could result in sizable cost savings for the entire industry, yet no single company or group of companies was willing to risk a large-scale investment.

The ATP stepped into the breach, agreeing to help finance a 5-year research plan developed by an industry consortium, as long as the consortium's members were themselves willing to put up at least half of the money. The $28 million effort began in 1991. A study conducted in 1993 found that after 2 years the project had already saved the participants about $13.5 million simply by helping them to avoid redundant research, to share results more rapidly, and to access each other's specialized know-how and facilities.

The ATP itself is only 4 years old, and the Administration is creating long-term and intermediate performance measures in order to rigorously evaluate its economic impact. This effort to promote innovation in the private sector is itself an innovation in the relationship between industry and the government, one that was begun during the previous Administration.

Intellectual property. Incentives for technological innovation are affected by the regime of intellectual property rights, including patents and copyrights. Absent well-defined and effectively enforced intellectual property rights, rivals could readily duplicate new inventions or writings without offering compensation; this reduces the innovator's likely profit and mutes the incentive to develop and market his or her creations in the first place.

The economics of patent protection have long been understood as posing the following policy tradeoff: patent protection encourages innovation, but that social benefit comes at the cost of allowing some successful innovators to price the resulting products well above marginal cost. In recognition of this tradeoff, patent protection is granted for a limited term of years. Yet appropriate public policy toward innovation must also recognize a second tradeoff, involving the scope rather than the term of patents.

The scope or breadth of patents refers to the extent to which a new innovation must differ from an existing one in order to avoid infringing on the latter's patent rights. Under some circumstances, narrowing the scope of patent rights would increase aggregate innovation rates. When an inventor's patent rights are broad in scope, extending to a relatively wide range of similar innovations, later inventors will not be permitted to use their own innovations that fall within that broad penumbra of similarity, without the first inventor's permission. Recognizing that such permission will frequently involve negotiating a payment to the first inventor (a negotiation in which the second inventor will sometimes have little bargaining leverage), the second inventor may be discouraged from exploring his or her new ideas to begin with. Or, if the second innovation is produced but the first and second innovators dispute its value, and in consequence are unable to reach a bargain, the second innovation may not be used until the patent expires. Giving broad scope to patent rights may thus discourage potential innovators from undertaking R&D effort in areas likely to produce follow-on inventions. Yet in other cases, narrowing the scope of intellectual property rights would reduce aggregate innovation rates by lowering the value of initial innovations, thus reducing the incentive for initial innovation.

In part to promote innovation, the U.S. Patent and Trademark Office has proposed legislation to permit greater third-party participation in patent reexamination proceedings. Under this proposal, industry experts and rivals would have a greater opportunity to present information about novelty or obviousness to the patent examiner after a patent is issued. In addition, the Department of Justice has drafted proposed new antitrust guidelines for the licensing and acquisition of intellectual property. By clarifying the conditions under which trade restraints involving intellectual property, like those involving other forms of property, can harm competition and run afoul of the antitrust laws, the Justice Department seeks to explain how antitrust law and intellectual property protections can be harmonized to encourage innovation and efficiency, and so benefit consumers.

CONCLUSION

Adam Smith published *The Wealth of Nations* in 1776, the same year Thomas Jefferson wrote the Declaration of Independence. Since that time the United States has become a vastly larger and more prosperous Nation. One reason is that, throughout our history, government has worked in partnership with the private sector to promote competition, discourage externalities, and provide public goods. The policy challenges that face us vary from generation to generation, and government institutions appropriate for addressing one era's problems must be reinvented for the next. But in every

era, the role of government in helping remedy market failures remains central for enhancing the Nation's well-being.

CHAPTER 5

Improving Skills and Incomes

BETWEEN 1973 AND 1994 the U.S. economy created 37 million additional jobs. This growth in employment absorbed an unprecedented number of new entrants, including millions of baby-boomers and women, into the work force and surpassed the record of the other large industrial nations. During this same period, however, slow productivity growth in the United States was reflected in slow growth in average real compensation. Indeed, real compensation per employed person increased more slowly in the United States than in the other large industrial countries (Chart 5–1). Even worse, income growth stagnated in the middle of the income distribution and declined sharply for those at the low end, causing insecurity and falling living standards for many Americans. The large declines in the real wages of less educated and lower paid workers were associated with increased inequality in family incomes and with growing rates of poverty among working families. For a growing number of workers without college degrees or significant on-the-job training, the American dream faded.

This chapter examines the factors that underlie the disappointing growth in the incomes of most American workers over the past 20 years and describes this Administration's policy responses.

The sluggish growth of incomes is due to dramatic changes in technology and in global competition that have affected industrialized economies around the world, reducing the relative demand for workers with less education and training. Industrialized nations have differed in their response to these common changes. Since 1973, the U.S. economy has created more jobs than all of the European Community. But at the same time the other industrialized economies have experienced more rapid growth in wages and productivity and slower growth in inequality.

Although these differing patterns appear to suggest a trade-off between rapid job growth and high wage and productivity growth, this Administration believes that such a trade-off is not inevitable. To sustain rapid job growth while increasing growth in wages and productivity, the Administration has undertaken an ambitious agenda of lifelong learning to help American workers respond to the challenges and grasp the opportunities afforded by the new economic realities.

Technology in the National Interest

Divider Title: _____

S+T + Economy

FORCES OF GLOBAL CHANGE

"Our Nation faces significant economic challenges. Markets are global, competition is fierce, technological change is swift and unabating. Meeting these challenges requires a strategy to equip American companies and workers to compete successfully in the 21st-century economy."

John H. Gibbons
Director, White House Office of Science and Technology Policy

"The United States must invest in technology and in our workforce if we are to meet the challenges of intensifying global competition. Our foreign competitors are shifting into high gear in the race for the future. They are rapidly expanding their technological capabilities and developing the skills of their people. Their governments are developing policies and programs to enhance the competitiveness of their industries and attract the engines of economic growth to their shores. America's future prosperity depends on answering these challenges loudly and clearly."

Michael Kantor
Secretary of Commerce

America's research-intensive industries—aerospace, chemicals, communications equipment, computers and office equipment, pharmaceuticals, scientific instruments, semiconductors, and software—have been growing at about twice the rate of the economy as a whole in the past two decades.

"...technical progress is by far the most important source of economic growth of the industrialized countries in our sample, accounting for half or more...."

Michael Boskin
Professor of Economics,
Stanford University, 1992
(former Chairman, President Bush's Council of Economic Advisors)

We live in an era of profound change—political, economic, and technological. Global competition has reached unprecedented levels. With the end of the Cold War and the demise of communism, new nations have emerged across the globe, building on a foundation of freedom, democracy, and free market principles. Today we compete not only with advanced industrialized nations such as Germany and Japan, but also with new competitors such as China, South Korea, Malaysia, and the states of the former Soviet Union.

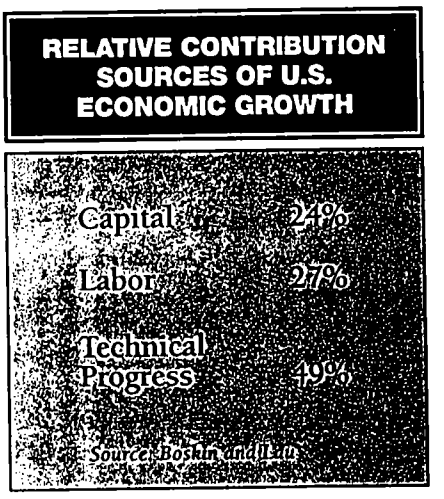
A new battlefield has emerged in the form of a global marketplace, and able competitors from around the world are fighting for a share. International accords, such as GATT and NAFTA, are fostering competition, opening new markets and expanding existing ones, and bringing consumers more choices and higher quality at lower costs.

Technology is reshaping our world at a speed unimaginable just a few decades ago. Competition to meet the increasingly high expectations of the world's consumers has accelerated the rate of technological progress to a breathtaking pace, with each advancement more dazzling than the last. Technology plays an increasingly important role in the global economy, in the lives of every American, and in our national defense.

In the wake of these forces, the way we live, learn, and work is being forever transformed. Each of these changes—the emergence of a global economy, unprecedented global competition, and rapid advances in technology—would be revolutionary on its own, but together they have produced staggering results that are deeply felt by Americans in all walks of life.

TECHNOLOGY AND THE AMERICAN ECONOMY

Technology is the engine of economic growth. It underpins America's fastest growing industries and high-wage jobs, provides the tools needed to compete in every business today, and drives growth in every major industrialized nation. Today, technological leadership often means the difference between success and failure in the global marketplace—for companies and countries alike.



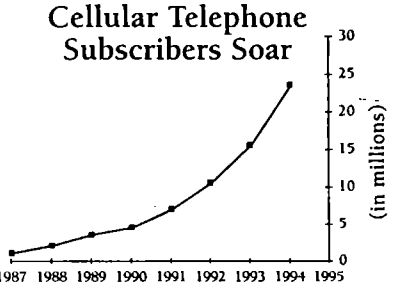
Technical progress is the single most important determining factor in sustained economic growth, estimated to account for as much as half the Nation's long-term economic growth over the past 50 years. Increases in productivity have long been recognized as one of the primary mechanisms by which technology contributes to growth. It is estimated that technology and advances in knowledge account for approximately 80 percent of total factor productivity growth. Ultimately, long-term, noninflationary growth is the only true path to real wage increases and an improved standard of living.

The performance of individual companies—the agents through which economic growth occurs—is strongly linked to their use of technology. A recent Department of Commerce analysis shows that the use of advanced technologies enhances manufacturing in virtually every important performance category. Firms that use advanced technologies are more productive and profitable, pay higher wages, and increase employment more rapidly than firms that do not. Between 1987 and 1991, employment at plants that used eight or more advanced technologies grew 14.4 percent more than plants that used no advanced technologies, and production workers' wages were more than 14 percent higher.

High-technology firms are associated with high rates of improvement in value-added manufacturing and success in foreign markets, which help support worker compensation that is 20 percent higher than the average for manufacturing.

Technology is transforming the very basis of competition—enabling small businesses to perform high-quality design and manufacturing work that previously required the resources of big business, while allowing big businesses to achieve the speed, flexibility, and closeness to customers that were once the sole domain of smaller firms.

Technology provides the tools for creating a spectacular array of new products and new services. It is creating new industries—advanced materials, mobile cellular communications, electronic commerce—and revitalizing old ones—steel, automobiles, textiles. The information industry as we know it now barely existed just decades ago. Today, however, the communications and information industries are among America's largest, constituting about 10 percent of U.S. gross domestic product and employing more than 4.5 million people in the United States. The economic importance of these technologies extends beyond the borders of the communications and information industries. By making it possible to manage vast quantities of information, these technologies are transforming every sector of our economy—manufacturing and services, transportation, health care, education, and government—and, in the process, changing forever the way people live, work, and interact with one another.



Employment in the cellular telephone industry has grown from 7,100 in 1987 to 53,900 in 1994.

In 1978, the cable television industry employed 23,500; today, the industry employs more than 112,000.

By the end of the 20th century, information will be the most important commodity in the world's economic system. The speed with which we create knowledge and our ability to put it to work for us will determine America's position in the international marketplace of the next century. Advances in information technology—software, semiconductors, microprocessors, telecommunications—are essential for managing this information explosion, putting a world of knowledge, global commerce, and communications at our fingertips.

In 1985, there were only 300,000 registered e-mail users. In 1993, an estimated 12 million Americans regularly used e-mail and related on-line services. Today, the number of e-mail users is estimated to exceed 27 million.

America is leading the world into the Information Age. The United States is laying the foundation for a National Information Infrastructure (NII) that will link schools and homes, offices and factories, hospitals and clinics, and a myriad of other business, academic, and social institutions. This network will enable a colossal leap in knowledge sharing, propelling scientific inquiry and discovery, business productivity, transportation system performance, and the education of our citizenry.

It has been estimated that accelerated deployment of the NII would increase U.S. GDP by $100 to $300 billion over the next decade.

The NII—and its international corollary the Global Information Infrastructure—will spur the growth and creation of American companies and jobs, facilitate the conduct of business worldwide, and accelerate the development of new products, services, and capabilities in the United States. American companies, large and small alike, will be able to respond quickly and flexibly to ever-changing global market demands with high-quality, customized goods and services at competitive prices.

"We are not the only nation with competence in defense technology. To sustain the lead which brought us victory during Desert Storm,...recognizing that over time other nations will develop comparable capabilities, we must...invest in the next generation of defense technologies."

William J. Perry
Secretary of Defense

TECHNOLOGY AND THE NATIONAL DEFENSE

On the battlefield, technology can be the decisive edge. America's technological superiority has provided our men and women in uniform the wherewithal to protect the freedom, democracy, and security of the United States. Beyond our own borders, U.S. military strength—built on a foundation of high-technology—has enabled the United States to stand in defense of our allies, preserve the peace, deter hostilities, repel aggression, and foster fledgling democracies across the globe.

During the Cold War, an arsenal of advanced weapons allowed the United States to field a technologically superior force to counter the numerically superior Soviet threat. Today, these high-technology weapons and the transportation and logistics systems that support their deployment provide the United States with the ability to undertake global military operations and conduct surgical strikes on strategic military targets—as in recent operations in Iraq and Bosnia—while minimizing the risk to U.S. soldiers and civilians. Continued technological leadership is essential to U.S. national security, military readiness, and global influence.

The top 15 U.S. pharmaceutical companies employed more than 350,000 people and earned profits of $13.3 billion on sales of $84.8 billion in 1994.

■ *Safer poultry products.*

TECHNOLOGY AND AMERICA'S QUALITY OF LIFE

New technologies are also improving the quality of life for all Americans. Medical research in pharmaceuticals, biotechnology, and medical devices promises new hope for the sick and a healthier life for all. Environmental research offers cleaner air, water, and soil through better monitoring, prevention, and remediation technologies. Advanced monitoring and forecasting technologies—from satellites to simulation—are helping save lives and minimize property damage caused by hurricanes, blizzards, microbursts, and other severe weather. Sophisticated traffic management systems for land, sea, and air transportation enable the movement of more people and goods in less time.

Agricultural research is producing a cornucopia of safer, healthier, and tastier food products. Automobile research is providing safer, cleaner, more energy efficient, and more intelligent vehicles—saving lives, preserving natural resources, and keeping our environment cleaner. Aeronautical technology is making air travel safer, less expensive, and environmentally compatible. Energy research is helping to deliver cleaner and less expensive fuels, reduce American dependence on foreign resources, and tap alternative sources of energy—solar, nuclear, geothermal, biomass, and hydroelectric. Information and telecommunications technologies have enabled instantaneous communications across the globe. And the ability to telecommute allows many American workers to spend more time with their families.

By 2001, there will be an estimated 15 million American telecommuters.

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

Scientific Freedom

Divider Title: _____

RESIDENT ASSOCIATE PROGRAM
SMITHSONIAN INSTITUTION
14 June 1977

Scientific Research: Determining the Limits

Statement

Gerard Piel
Publisher, SCIENTIFIC AMERICAN

A. The sovereignty of the citizen engaged in the public business is declared in the unambiguous language of the First Amendment.

1.) The enquiry of the scholar and scientist is the supreme exercise of that sovereignty.

2.) The pursuit of objective knowledge has made good the promise of sovereignty to the citizen (qualified by the failure of our economic institutions to secure equitable distribution of material goods).

3.) The proposal that "limits" somehow be set upon scientific enquiry (into any question) must be understood as imposition of limits upon the sovereignty of the citizen.

a.) To what agency or power could the citizenry delegate control over this crucial exercise of sovereignty?

b.) What agency will display greater sensitivity to the practical ("risk/benefit") and moral ("control of evolution") questions than the scientific community?

B. Historically, self-government derives moral and pragmatic sanction from the assertion of individual sovereignty by scientists and finds the model of its deliberations in the self-governing community of science.

1.) The autonomy of the scientist is absolute: he can recognize no external authority over his judgement and conscience.

2.) The exercise of that autonomy by the individual scientist (his work) derives its meaning from its relevance to the work of other scientists, and from the degree to which it stresses and reorders the context in which the work is done.

3.) The work of the scientist is supremely public business, as demonstrated by the identity of "publication" with the "doing" of the work.

C. Attempts to place limits upon science by creation of external agencies provide instances of the tyranny that scientific enterprise has otherwise so successfully helped to overthrow.

1.) The Nazi "doctors," as agents of the pathological doctrines of a dictatorship that had destroyed the autonomy of German science, performed bestial experiments with no relevance to the context of the work in human biology that has transformed man's comprehension of his identity.

2.) The establishment of the Lysenko overlordship of USSR agricultural research in the 1930's by the ignorant will of the Stalin dictatorship eradicated a significant tradition in genetics and set USSR agriculture on the disastrously regressive course that is reflected in crop failures of the 1970's.

D. Participatorily democratic "public" persons and organizations that presume to frame and impose limits upon scientific enquiry must recognize they are tampering with the moral and

pragmatic foundations of their own and of their fellow citizens' freedom and welfare.

1.) Their surprise upon their belated discovery of supreme issues in scientific research reflects their failure as citizens to keep themselves informed on important public business.

2.) If they are to contribute constructively to science policy they must cure themselves of the defect in their intellection that refers questions of truth to science and questions of value to other increasingly unspecifiable authority.

E. Scientists are also citizens. They are the members of the public best qualified to frame science policy.

1.) Scientists have the obligation to inform their fellow citizens of the nature and the implications of their work; to conduct their deliberations in the full view of their fellow citizens, and to invite the participation of fellow citizens who take the trouble to make themselves responsibly informed.

2.) On questions respecting the hazards that may attend research, scientists will necessarily be the first to recognize such hazards and to provide society's first line of defense against them.

3.) With respect to the propriety of research enterprises the open polity of science provides the surest institutional restraint upon irresponsible or reprehensible individual scientists.

Ram-
As promised
Vic

THE BOUNDARIES OF SCIENTIFIC FREEDOM

By Harold P. Green
Professor of Law
National Law Center
The George Washington University

Two and a half years ago a group of scientists called upon their colleagues throughout the world to establish a moratorium on certain kinds of experiments involving recombination of DNA molecules. This moratorium, apparently universally accepted, the subsequent NIH guidelines imposing positive restrictions on such experiments,[1] and prohibitions suggested or adopted by various state and local governments,[2] have all stimulated discussion as to whether such restraints in some way violate what has been characterized as "the right to scientific inquiry." More specifically, it has been suggested that scientists have a right to pursue knowledge and that this right is of the same dignity as freedom of speech and of the press guaranteed in the Constitution of the United States.[3]

It is not surprising, therefore, that upon establishment of the AAAS Committee on Scientific Freedom and Responsibility,[4] that committee would turn its attention in part to the question whether there are in our American system of government and law any boundaries to scientific freedom and, if so, where these boundaries are to be found. Specifically, a Subcommittee on the Boundaries of Scientific Freedom, of which I am Chairman, has been created to look into this matter.

In this paper, I discuss these issues from my dual perspective as a teacher of constitutional law and as a student of public policy for science and technology. My focus is not on whether there are or should be any limits on scientific freedom as a matter of morality or policy, but only whether limitations are permissable as a matter of constitutional law.

To begin with, I am not aware of any precedent or legal authority that clearly supports the proposition that there is a constitutionally protected right to pursue knowledge or to engage in scientific inquiry. I believe, and am prepared to argue, however, that such rights are implicit in the First Amendment freedoms of speech and press; and for purposes of this paper it is assumed that the Constitution guarantees and protects such rights to precisely the same extent as speech and press. Parenthetically, it seems clear that a right to scientific inquiry can have no greater constitutional dignity than freedom of speech. Let us therefore explore the boundaries of freedom of speech in the effort to understand the boundaries of scientific freedom.

It is impossible to offer a complete exposition of the boundaries of freedom of speech as enunciated in Supreme Court decisions. Suffice it to

---

Based on a presentation at the Annual Meeting of the American Association for the Advancement of Science, Denver, Colorado, February 1977.

say, some kinds of speech enjoy the protection of the First Amendment; other kinds of speech do not. Even where speech does enjoy such protection, the degree of protection is variable. A distinction of crucial significance is that between speech and action. Speech emanating from the vocal cords is generally protected, but amplified speech is not;[5] one is constitutionally protected in cursing the flag or a draft card,[6] but not protected when ripping or burning it;[7] one is protected by the First Amendment when engaged in vigorous debate with a foe, but not when using language (fighting words) calculated to provoke a violent response;[8] one may discuss aircraft hijacking in one's own home or office, but perhaps not when sitting in a commercial aircraft.

Such precedents are helpful in drawing the constitutional boundaries of scientific freedom. Surely a scientist has the freedom to think, to do calculations, to write, to speak, and to publish. When, however, the scientist leaves the area of such abstractions and turns to experimentation, he moves within the range of action that may enjoy only some, or perhaps very little or no, constitutional protection. To the extent that experimentation could be constitutionally protected, freedom would vary inversely with the degree of perceived impact on persons and the environment. Thus, where scientific research involves experimentation with human or animal subjects or where it impinges upon the community, it would clearly become subject to regulation. It is interesting to note that Han Jonas reaches the same conclusion from the moral perspective. He tells us, eloquently, "The granting of freedom to thought and speech...does not cover <u>action</u>, even if subsidiary to thought. Action is always subject to legal and moral restraints."[9]

I think, so far as I have gone, scientists would sense intuitively that what I have said is correct. They are, after all, surely aware of a multitude of legal restraints on what they can do and where, when, and how they can do it. Where many would probably part company with me is on the question of where the burden of proof lies before government may properly restrict scientific freedom.

Again, the freedom of speech analogy is instructive. When we are operating in the realm of pure constitutionally protected speech -- or abstract or theoretical scientific research -- a proponent of restrictions must carry a heavy burden of proof.[10] There must be a particularly strong governmental interest in the restriction (e.g., a clear and present danger to be protected against),[11] and the restriction itself must be designed to intrude to the minimum extent possible on the constitutionally protected right.[12] As, however, we move down the scale towards action and experimentation, the burden shifts dramatically, and no more than a rational basis will be required to sustain the constitutionality of the restriction. For example, since obscenity is not protected by the First Amendment,[13] it is not necessary for government to show a clear and present danger before it acts to restrict obscene speech. Obscenity may be prohibited without any showing that obscenity is harmful;[14] indeed, it is not even necessary to show that the government actually thinks that obscenity is harmful; it is enough that there is some rational basis for such a belief.[15] This attitude reflects the currently prevailing judicial

position that, at least where no constitutional limitation on government power is operative, the courts will not second-guess the legislature or executive as to the wisdom, desirability, or necessity for regulation.[16] Thus, there has never been any doubt in my mind that a city's prohibition against recombinant DNA molecule experiments within city limits does not violate any constitutionally protected right of scientific inquiry, where the city may rationally -- even though perhaps not reasonably -- have believed that such experiments might endanger the health and safety of the public.

At this point it is necessary to draw another kind of distinction -- between government regulation of a scientific activity and a government decision not to fund that activity. We sometimes forget that government has no moral or constitutional duty to support scientific research, no matter how beneficial the hoped for results,[17] and that no scientist has a constitutional right to have his research projects funded by the government. I am reminded of Freeman Dyson's 1965 article in which he argued that NASA's decision not to continue funding Project Orion represented "the first time in modern history that a major expansion of human technology has been suppressed for political reasons."[18] In the same vein, some scientists seem to believe that it is immoral or wrong if the government is really motivated by fear that resulting scientific knowledge will be misused. Personally, I do not understand why, if it is legitimate for government to fund research because it hopes for constructive knowledge, it is illegitimate for government not to fund research because of concern that the resulting knowledge will be destructive. Indeed, as I have argued elsewhere, it is probably not realistically possible for our democratic society to impose timely and effective regulation over abuse of knowledge resulting from government-sponsored research and development.[19]

When government, for whatever reason, chooses not to fund a particular kind of scientific research, it is not interfering with scientific freedom. Scientists remain perfectly free to do this research if they can find the money elsewhere. However, a direct prohibition or restriction on scientific research may indeed represent an infringement on scientific freedom.

It requires only a moment's reflection to appreciate that there is really nothing new or novel in the NIH guidelines on recombinant DNA molecule experiments, or the Cambridge restrictions on such experiments. We all realize, or should realize, that government in the past has imposed restrictions on where and when certain kinds of research may be conducted. Obviously, city zoning laws may preclude experiments with explosives in the center of an urban population center, and it would probably be regarded as a legal nuisance if the explosives were experimentally detonated within earshot of the community at 2:00 a.m. We know that scientists are not free to experiment with human subjects or the fetus as they see fit. We know that there have been restrictions on the use of animals or cadavers in scientific research. We know that the Food and Drug Act and the Atomic Energy Act restrict and regulate certain kinds of research. We know that limits on the use of classified information may impede or bar certain scientific research programs. Indeed, Dr. Barry Casper has recently raised the question of a moratorium on development of laser enrichment of uranium.[20]

It is not clear to me why, in the face of such precedents, the scientific community has become so edgy about scientific freedom in recent months. The Subcommittee on the Boundaries of Scientific Freedom, which I chair, hopes to examine precedents such as those I have just enumerated in which significant restrictions on scientific research have been adopted, some with the apparent acquiescence, at least, of the scientific community. We hope it will be possible through examination of these cases to acquire a better understanding of the decision-making and negotiation process through which such restrictions have been developed.

At the outset, I emphasized that this would be a discussion of the boundaries of scientific freedom as a matter of constitutional law and not as a matter of public policy. It is important to distinguish clearly between these two concepts. For example, one could argue in favor of the constitutionality of municipal prohibitions against recombinant DNA molecule experiments, but also argue against such prohibitions on policy grounds. In recent years, we have become excessively accustomed to looking to the courts to protect what we perceive to be our rights, and we have lost sight of the fact that the first, and in many cases the only, line of defense of these rights is our legislatures. While an argument about a right to scientific freedom may be a useful piece of rhetoric in political debate, we should not take the existence of such a right too seriously. In short, the principal point that I wish to convey is that the boundaries of scientific freedom, at least in terms of current issues, are established primarily through the political process and are not rooted in constitutional law.

NOTES

1. The chronology of events leading to the guidelines is summarized in the introduction to the Decision of the Director, National Institutes of Health, To Release Guidelines for Research on Recombinant DNA Molecules, 41 Fed. Reg. 27902 (7 July 1976).

2. See the report of the Science Policy Research Division, Congressional Research Service, Genetic Engineering, Human Genetics, and Cell Biology: Evolution of Technological Issues, DNA Recombinant Molecule Research (Supplemental Report II), published as a Committee Print by the House Committee on Science and Technology, December 1976, pp. 47-53.

3. DeWitt Stetten, Jr., "Freedom of Inquiry," Science 189 (19 September 1975): 953. This editorial is a condensation of a longer paper titled "Freedom of Inquiry" presented by Dr. Stetten before a meeting of the Genetics Society of America on August 19, 1975.

4. Science 193 (3 September 1976): 877, 921.

5. Kovacs v. Cooper, 336 U.S. 77 (1949); Grayned v. City of Rockford, 408 U.S. 104 (1972).

6. Street v. New York, 394 U.S. 576 (1969).

7. Id.; United States v. O'Brien, 391 U.S. 367 (1968).

Chaplinsky v. New Hampshire, 315 U.S. 568 (1942).

9. Hans Jonas, "Freedom of Scientific Inquiry: The Accountability of Science" in the Hastings Center Report (August 1976).

10. Organization for a Better Austin v. O'Keefe, 402 U.S. 415 (1970); New York Times Co. v. United States, 403 U.S. 713 (1971).

11. NAACP v. Button, 371 U.S. 415 (1963).

12. Shelton v. Tucker, 364 U.S. 479 (1960); United States v. Robel, 389 U.S. 258 (1967).

13. Roth v. United States, 354 U.S. 476 (1957).

14. Ginsberg v. New York, 390 U.S. 629 (1968).

15. Id.

16. Ferguson v. Skrupa, 372 U.S. 726 (1963).

17. See, for example, my exchange with Bernard Davis, Annals of the New York Academy of Sciences 265, Ethical and Scientific Issues Posed by Human Uses of Molecular Genetics (1976): 176.

18. Freeman J. Dyson, "Death of a Project," Science 149 (9 July 1965): 141.

19. See, for example, my paper "Law and Genetic Control: Public Policy Questions" in Annals of the New York Academy of Sciences 265, Ethical and Scientific Issues Posed by Human Uses of Molecular Genetics (1976): 170-175.

20. Barry M. Casper, "Laser Enrichment: A New Path to Proliferation," Bulletin of the Atomic Scientists (January 1977): 28.

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

Quotes

Divider Title: _____

Lewis Thomas ("Lives of a Cell")

It may be too much to say that we will become wise through such endeavors, but we can at least come into possession of a level of information upon which a new kind of wisdom might be based. It is a gamble to bet on science for moving ahead, but it is, in my view, the only game in town.

Tmazzaschi @ aamc.org
05/06/97 10:02:01 AM

Please respond to Tmazzaschi@aamc.org

Record Type: Record

To: adhoc @ aamcinfo.aamc.org

cc:
Subject: Adhoc: Clinton's "Medical Research" Remark

For the record, here is the President's remark on medical research in his May 2 statement on the budget accord:

"For more than four years now, I have worked hard to pursue a strategy that would keep our economy growing and creating opportunity for the American people, giving people a chance to be rewarded for their labors, and also imposing upon ourselves the discipline necessary to prepare for the future and to relieve ourselves of a lot of the problems that had been accumulated over the last several years, especially the deficit.

"Now, we have reached agreement in broad but fairly specific terms that I am satisfied will do that with the Republican leaders today that would balance the budget by 2002, continue to increase our investments in education, in science
and technology and
medical research, require us to continue to show great discipline in other areas and to continue to downsize some government operations. "

Tony Mazzaschi
AAMC

"Education is the progressive discovery of one's ignorance"

L. Thomas ?

In a letter he wrote in 1822, James Madison said: "A popular government, without popular information, or the means of acquiring it, is but a prologue to a farce or a tragedy; or, perhaps both. A people who mean to be their own governors, must arm themselves with the power which knowledge gives."[3]

Knowledge will ~~[illegible]~~ forever govern ignorance, and

3 "Writings of James Madison" G. P. Putnam, 1900, in a letter to W. T. Barry, written in 1822

~~Thesis~~

"True science knows no bounds. It penetrates into every domain without fear and serves all men without prejudice or favor. It's work is to substitute facts for appearances, demonstrations for impressions, and beneficial realities for those many things ignorance and greed proclaim to be impossible. For suffering humanity it is hope and promise."

O. W. Holmes ~~(from Harry Caudill)~~

(532)

"Sooner or later we sit down
to a banquet of consequences"

Robert Louis Stevenson

The world we live in is made of an immensely complex and mysterious tissue about which we know very little and which we must treat with utmost humility.

Vaclav Havel
N.Y.T. 4/3/92

"Zeal without knowledge
is fire without light"

John Ray (17th C. English
naturalist)

JFK and A.U. ~1963 586

"If we cannot now end our differences, at least we can help make the world safe for diversity.

I realize that the pursuit of peace is not as dramatic as the pursuit of war — and frequently the words of the peacemaker fall on deaf ears — But we have no more urgent task" —

* A.U. = American University

664

"Man masters nature not
by force but by understanding"

Jacob Bronowski

Edu: A progressive discovery of one's own ignorance

Will Durant

1313

Dr. Gibbons quoting Jack Kennedy at
AAAS Annual S&T Policy Colloquium

As President Kennedy once reminded us, "Scientists alone can establish the objectives of their research, but society, in extending support to science, must take account of its own needs."

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

Carl Sagan's
Widow's Statement

Divider Title: _____

Carl Sagan's Widow's Statement

Verbatim transcript from audiotape of remarks by
Ann Druyan accepting the posthumous
NSF Distinguished Public Service Award to Carl Sagan
May 7, 1997
Benjamin Franklin Room
Department of State, Washington, DC

My heart is bursting with pride tonight. The word 'passion' I note in the citation couldn't be more apt. Carl used to say when people would ask him why he so energetically pursued public science education, he'd say "When you're in love, you want to tell the whole world." And that's how it was for him. It was a love for science, not as a barrage of astonishing facts, but as a method of thinking, a way of looking at the world as the single most revolutionary error-correcting mechanism that human beings have ever devised. I can only think of the Bill of Rights as being a possible contender for that title.

Two error-correcting mechanisms that challenge authority, that make sure that the widest number of people can be involved in decision making and in the great adventure of finding out how nature is put together. When we educate the public about science we're not only making sure that there will be future funding, or a career path, or a competitive edge for our citizens—that's all completely true—but we're also doing something which means that we will have citizens who can make intelligent decisions in a society that is completely dependent on science and high technology. If we don't do this it's like saying that we really don't seriously intend to have a democratic society in the future. And Carl believed this so passionately and loved the liberating power of science which took him from Brooklyn, New York from a family that had never even met a scientist, a hard working family that had no access to higher education, and made it possible for him to become a teacher to the whole planet. I feel that if he were he tonight he would say something that would raise goosebumps and that you would never forget. And I feel, in a way, inadequate to rise to the heights that I saw him rise to on countless occasions. But I do know that he would tell you how profoundly honored he was. He believed that science was its own reward, but I know that your respect and your esteem would have pleased him so greatly. I humbly accept this Award on his behalf and thank you from the bottom of my heart.

END

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

Speeches

Divider Title: _____

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

Clinton S & T Strategy

Divider Title: _____

Testimony of the Honorable John H. Gibbons
Director, Office of Science and Technology Policy

before the

Subcommittee on Science, Space, and Technology
Committee on Commerce, Science, and Transportation
United States Senate

March 30, 1995

CLINTON ADMINISTRATION SCIENCE AND TECHNOLOGY STRATEGY

Mr. Chairman, members of the committee, thank you for inviting me here today to speak with you about the Clinton Administration's science and technology initiatives. These initiatives are an integral part of the President's New Covenant -- his pledge to reinvigorate middle class America.

We are now having a great debate about how we can best assure the American Dream for present generations and for those of the next century. The choices we make will have profound effects on our lives and those of our children and grandchildren.

In this historic era we have experienced the end of the Cold War, the dawn of the Information Age, a globalized economy, an explosion of entrepreneurialism. We have before us enormous opportunities. At the same time, we have profound challenges. We have experienced almost 20 years of stagnant incomes in the United States. We have growing inequality of incomes based primarily on educational differentials. We have challenges abroad in terrorism, environmental destruction, population explosion, and the proliferation of weapons of mass destruction.

Government has an important role to play as a partner in meeting the challenges of the future. The role of government is to increase opportunity as we shrink bureaucracy, to empower people to make the most of their own lives, and to enhance our security at home and abroad. We aim to expand the middle class and shrink the underclass. And we have to do it with a government that is smaller and less bureaucratic, but still effective.

The future is in our hands. We can have a globally competitive private sector that is creating new, high-wage jobs and educated citizens ready to take those jobs. Or we can have 20 more years of stagnant incomes and watch our industries lose ground in the race for global market share.

We choose prosperity, Mr. Chairman. Science and technology will help us cut the straightest path from here to there.

Why We Invest in Science and Technology

In his biennial report to the Congress, which we are releasing today, Mr. Chairman, the President reaffirms his belief that sustained investments in science and technology are absolutely essential to our knowledge-based society. Thoughtful investments in science and technology fuel economic growth, strengthen national security, and improve the quality of life. This Administration is focusing its science and technology resources on high priority areas, including:

- Economic growth and job creation
- Education and training
- Environmental quality
- Health
- Information technology
- National security
- World leadership and cooperation in science, mathematics and engineering

Success in each area will depend on advances in fundamental science, continuing technological innovations, and responsible governance.

Scientific knowledge is the key to the future. America's future demands an expanding knowledge base, which requires investment in our people, institutions, and ideas -- shared broadly with our global partners. Science lies at the heart of that investment -- it is an endless and sustainable resource with extraordinary dividends.

The public will receive a substantial return on this investment. While there is much room for uncertainty in measuring the impact of federal research spending, repeated studies suggest that the payoff to the Nation's economic welfare is great. The private rate of return on research and development spending -- meaning the return to the firm performing the research and development -- averages about 20 to 30 percent. But the social rate of return -- including spillovers to other firms and customers -- averages about 50 percent, or twice as high.

The nation's commitment to world leadership in science, engineering, and mathematics created the world's leading scientific enterprise, whether measured in terms of discoveries, citations, awards and prizes, advanced education, or contributions to industrial and informational innovation. Our scientific strength is a treasure we must sustain and build on for the future.

Technology is the engine of economic growth. Over the past 50 years, at least a quarter of U.S. economic growth -- possibly as much as half -- came from new technology built upon earlier fundamental discoveries. These advances created millions of good new jobs, a cleaner environment, better health and longer lives, new opportunities for individuals, and enrichment of our lives in ways we could not imagine half-a-century ago. For example:

- Early investments in ARPANet, the first national computer network, have brought us to the 25th anniversary of the Internet, a prototype of the Global Information Infrastructure. When it started out, ARPANet could transmit only 56,000 bits of data per second. Today networks using technology several generations more advanced routinely transmit 45 million bits a second -- almost a thousand times faster. The federal government provided a relatively small catalyst (a few tens of millions of dollars annually) that has been matched several times over by private-sector investment in the Internet. The federal government deliberately set out to commercialize and privatize the Internet. Today dozens of companies are investing millions of dollars and competing to provide Internet connections and new services to the tens of millions of Internet users around the world.

- Public investments in biomedical research spawned a multi-faceted biotechnology industry that already accounts for 100,000 jobs and $8 billion in annual sales. We owe extraordinary advances in agriculture and in chemical and pharmaceuticals processing -- as well as our ability to capture large markets in health care and other industries -- to fundamental research in molecular biology and applied research and development of advanced instrumentation funded by the U.S. government.

Our vision is of long-term economic growth that creates jobs while improving and sustaining the environment.

Responsible government advances science and technology. Government is an essential actor in making sure science and technology help the Nation reach its goals. Only the federal government can bring the benefits of science and technology to nonmarket areas, such as national defense, education and training, environmental quality, global health threats, or world-class fundamental scientific research.

A government role also is vital in promoting, in partnership with the private sector, those technologies critical to economic growth and to the creation of good jobs that cannot attract sufficient private investment. The U.S. government always has stepped up to this task. For example, federal investment in agricultural science and technology made it possible for our farmers to feed us and much of the world -- and do it profitably. Our investments in aeronautics helped U.S. companies capture global markets for aircraft and make air travel accessible to most Americans. We cannot walk away from our responsibility to ensure similar advantages are available to future generations.

A regulatory and economic environment favorable to capital formation and private-sector investment in research and development also is essential to advances in science and technology. To encourage private investment, the Administration has supported:

- extension of the research and experimentation tax credit;
- reduced capital gains taxes for small businesses;
- reduced antitrust barriers to the formation of joint production ventures;

- transfer to the private sector of a portion of the radio frequency spectrum previously used by federal agencies and competitive bidding on new licenses;
- liberalization of controls on the export of computers, telecommunications, and other technologically sophisticated equipment;
- bilateral and multilateral trade agreements that expand access to foreign markets for America's high-tech companies.

As with all aspects of governance, however, we must make our science and technology programs work better and cost less. We are already acting on this conviction, as you can see in the reinvention efforts at NASA. That agency's 1950's-style infrastructure will be brought into the information age -- at a likely savings of billions of dollars and thousands of government jobs.

We have made an excellent start on this effort on a government-wide basis with the National Science and Technology Council (NSTC). The NSTC is a virtual department -- a coalition of agencies that coordinate their efforts, divide tasks, and share resources to advance science and technology. This mechanism for direct communication between agencies cuts through bureaucracy and encourages the identification and coordinated pursuit of common goals and objectives.

The NSTC process led to a decision to converge the polar orbiting environmental satellite systems of the Departments of Defense and Commerce. This decision alone should save the American taxpayer several hundred million dollars by the turn of the century. Another Presidential Decision issued in 1994 directed continuation of the Landsat remote sensing satellite program and restructured federal agency responsibilities for acquiring and operating the next satellite (Landsat-7). That decision ensures the continuity and availability of the Landsat remote sensing capability which is used for civil, commercial and national security purposes. A third NSTC Presidential Decision articulated the new national space transportation policy and established clearly delineated roles and responsibilities for the principal agencies.

The NSTC is hard at work on science and technology initiatives designed to strengthen America's middle class. Our priorities include a healthy economy, global stability, and a cost-effective government. We have developed a conservative investment portfolio that balances the need for deficit reduction and immediate benefits for our citizens with the need to make long term investments in our country's future.

S&T Priorities in a Dynamic Economy

America's welfare hinges as never before on the way we manage the opportunities and the hazards of new concepts in science and technology. We have sustained our commitment to a strong fundamental science base and to science and technology in support of our national security strategy. We now recognize, however, that national security depends on a globally competitive economy that creates jobs and protects the environment as well as military

strength. And we intend to use science and technology to make government work better and cost less.

Commitment to Fundamental Science. Science provides an endless frontier of inquiry. Advancing that frontier feeds our sense of adventure and our passion for discovery. The unfolding secrets of nature provide new knowledge to address crucial challenges, often in unpredictable ways. These include improving human health, creating breakthrough technologies that lead to new industries and high quality jobs, meeting our national security needs, protecting and restoring the local, regional, and global environment, and feeding and providing energy for a growing population. Science is a critical investment in the national interest, and we have pledged to:

- maintain leadership across the frontiers of scientific knowledge;
- enhance connections between fundamental research and national goals, such as economic prosperity, national security, health, and environmental responsibility;
- stimulate partnerships that promote investments in fundamental science and engineering and effective use of physical, human, and financial resources;
- produce the finest scientists and engineers for the twenty-first century; and
- raise scientific and technological literacy of all Americans.

Commitment to National Security. Science and technology support the Administration's national security strategy in three important ways.

- Advances in science and technology ensure the technological superiority essential to maintaining our unparalleled military capabilities.
- A vibrant, dual-use high technology industrial sector enhances our national economic strength while also providing the technological base for advanced military capabilities.

- Technology is central to our efforts to: prevent and counter the proliferation of weapons of mass destruction and the means of their delivery; verify and monitor existing and prospective arms control agreements; and ensure the safety and reliability of our reduced nuclear weapons stockpile.

A strong domestic science base supporting a robust national security science and technology program is critical to preserving technological advantage. OSTP addressed this issue in the National Critical Technologies Report released last week. The report details the current competitive position of the United States relative to Japan and relative to Europe for each of 27 principal critical technology areas (from the broad areas of: 1) information and communications; 2) "living systems;" 3) environmental quality; 4) energy; 5) transportation; 6) manufacturing; and 7) materials). Overall the report shows the United States at parity with, or ahead of the positions of Europe and Japan in all areas. The report also shows, however, that the rate of progress is greater in Japan and Europe -- meaning our tenuous lead is shrinking in the midst of proposals to gut the core of our strategy to preserve American preeminence.

Our strategy to retain our lead in these critical technologies is to apply resources broadly at the basic research level and make further investment decisions as emerging technologies reveal the most promising payoff areas. Many of the technologies we need for advanced military capabilities are available in the commercial sector, and in some cases they are more advanced and cost less. We are working to enhance our relationship with private industry through partnerships that enable us to access and capitalize on those commercial technologies that offer the greatest military application. The long-term payoff will be better military capabilities at lower cost, and a strengthened economy.

Science and technology play key parts in our national strategy to stem the proliferation of weapons of mass destruction and their means of delivery. Verification and monitoring of compliance with arms control agreements is made possible by unique abilities provided by American basic and applied science in fields as diverse as chemistry, optics, and solid state physics. Technology also supports our policy goals of discouraging accumulation of weapons usable fissile materials, strengthening controls on those materials, and reducing global stocks. Science and technology also make vital contributions to the safe stewardship of our own nuclear weapons. We have structured a science-based stockpile stewardship program that will apply scientific understanding, predictive capability experiments, and simulation to ensure the safety, security, and reliability of our enduring nuclear stockpile.

Commitment to a Healthy Economy. Our Nation faces significant economic challenges. Markets are global, competition is fierce, technological change is swift and unabating. Meeting these challenges requires a strategy to equip American companies and workers to compete successfully in the 21st century economy. We have assigned high priority to developing the information infrastructure necessary to compete in the global economy, to enabling American manufacturers to produce globally competitive products that meet environmental goals, and to preparing the workforce for the high-wage, high-skill jobs of tomorrow.

- **Information Technology**. Our Nation leads the world in developing and applying information technology that is revolutionizing the way we live, learn, and work. Because of the strategic value of these technologies and their role in fostering economic growth, nations around the globe are investing heavily in the development and deployment of computer systems and telecommunications networks. Our vision for federal investment in information technology is to accelerate the evolution of existing technology and to nurture innovation that will enable its universal, accessible, and affordable application to enhance America's economic and national security in the 21st century.

  President Clinton and Vice President Gore have made development the National Information Infrastructure (NII) at top priority because they believe that access to advanced computing and communications technologies can dramatically improve the quality of life for every American. The NII will:

- Provide better access to health care.
- Make American workers more productive.
- Help our children learn.
- Make government more efficient.
- Create millions of new, high-paying jobs.
- Provide us all with instant access to a huge variety of information and entertainment.

As you and I have discussed, Mr. Chairman, the information highway is a great equalizer. One of my favorite cartoons shows two dogs in front of a computer, with one saying to the other, "On the Internet, nobody knows you're a dog." And it's true. The information age means that what you know and how hard you work count for a lot more than who you know and where you came from.

Rural states will compete more readily with urban states as the information age progresses if we take care to ensure equality of access. This committee has been a leader in telecommunications reform, and the Administration looks forward to continued cooperation on an issue essential to the health of America's middle class.

- **Manufacturing Technology**. The government is partnering with industry in a variety of industry-led research and development initiatives, including microelectronics, electronics manufacturing, aeronautics, and biotechnology. These initiatives combine goals of competitiveness and economic growth with public benefits of job creation, environmental protection, improved health and safety, and less dependence on foreign sources of energy. The Partnership for a New Generation of Vehicles (PNGV) is an example.

  PNGV is one of the federal government's premiere ventures into cooperative civilian technology development. In it, we are tackling a technological challenge as tough as putting a man on the moon -- that is, to develop within 10 years a car with three times the efficiency of today's automobiles with no sacrifice in cost, comfort, or safety. If the project succeeds, the payoff to the public will be huge in terms of less dependence on foreign oil and lower emissions of greenhouse gases. The project also holds the promise of an extremely attractive car for world markets in the 21st century and a thriving U.S. auto industry to produce them. The government (in this case, a consortium of seven federal agencies) and industry (the Big 3 automakers -- Ford, GM, and Chrysler -- and many suppliers of materials and equipment) are working closely on a cost-shared basis to break highly challenging technological bottlenecks where the benefits are at least as much societal as commercial. PNGV's research priorities are:

  - development of advanced manufacturing techniques that make it easier to get innovations into the marketplace quickly;

- use of new technologies for near-term improvements in auto efficiency, safety, and emissions; and
- research leading to production prototypes of vehicles, including such advanced technologies as fuel cells, ultracapacitors, and hybrid vehicle propulsion systems.

Over the life of this partnership, funding will be shared roughly equally between government and industry, with the government contributing a greater share to basic research and to technologically riskier projects, and industry putting up the greater share as practical results get closer.

- **Educational Technology**. The most important measure of success of this Administration will be its ability to make improvements in the lives of Americans. Few enterprises touch the lives of as many people as do those concerned with education and training. High-quality education and training benefit the individual whose knowledge and skills are upgraded, the business seeking a competitive edge, and the Nation in increasing overall productivity and competitiveness in the global marketplace. It is essential that all Americans have access to the education and training they need and that the teaching and learning enterprise itself becomes a high-performance activity that is interesting and challenging to the participants.

  The President has placed a high priority on upgrading the technology available in our schools and businesses, in order to improve education and training. The Administration recently announced a national program to help communities around the country incorporate new educational technologies into their schools. He has also directed that advanced information technologies developed by the Defense Department that could be used for education and training be transferred to the Departments of Education and Labor for civilian use. Unfortunately some rescission proposals hit educational technologies especially hard, particularly the Star School program and the Technology Learning Challenge.

Commitment to Efficient, Cost-Effective Government. Science and technology can help this government serve its citizens better. One of the most important areas in which S&T can contribute is in regulatory decisionmaking, and we will be briefing the Vice President shortly on ways that regulatory reform can help produce a more conducive environment for the conduct of business, research, and education. While we must not retreat from our commitments to ensure the wellbeing of every American, policies to address risks to public health, safety, and the environment must be fair, effective, and affordable. The Administration has taken several steps to advance risk analysis, a key linkage between science and policy, including establishing the following priorities for investigation:

- *Uncertainty analyses and risk characterization*: research on methods for improvement of risk characterization and transfer of scientific information about risks, and the uncertainties in the information, to decision makers.

- *Criteria and indicators for ecosystem health:* research to identify criteria and indicators for risks to ecological health and sustainability.
- *Human and ecological exposure:* research on chemical, physical, and biological stressors, particularly for mixtures, multiple and/or cumulative exposures, and alternative pathways of exposure.
- *Mechanisms of disease & ecological impacts:* research to identify and predict the magnitudes of new ecological risks and noncancer human health effects and to understand better the biological effects of carcinogens at very low doses.

The Administration is working within and across agencies to improve the methods by which risks are evaluated and the ways in which the resulting information is integrated with economic, social, and other considerations in making decisions that will ensure the appropriate and effective protection of public health, safety, and the environment.

These examples of the Administration's S&T priorities illustrate the critical roles science and technology play in our society. We have produced a science and technology program that, within the spending limits established by the new covenant with America, ensures a better world for our children and their children. We have integrated federal science and technology programs with efforts in the private sector and internationally in order to maintain a strong, vibrant, sustainable economy.

Are We Ants or Grasshoppers?

Mr. Chairman, all of us need periodic reminders about the necessity to invest for the future, but this country has an excellent track record of using science and technology investments to do just that. Our global competitors in defense, aeronautics, medical devices, pharmaceuticals, and computers have learned from our example. They now make similar or greater investments.

The charts attached to this statement provide some R&D spending data shown in terms of investment as a percentage of GDP, which helps us compare nations. This is similar to comparing IBM with much smaller companies. IBM invests in R&D as a percent of sales to support a big business. Small companies also invest a similar percent of sales in research and development.

The United States supports an almost $6 billion economy. On the other hand, Japan had a $2.5 billion economy in 1993.

As you can see from the charts, the U.S. still leads the world in total dollars spent on research and development. However, Germany and Japan equal or surpass our level of spending as a percent of GDP. As you can also see, they are far ahead of us in nondefense R&D spending.

Our competitors are becoming more and more like Aesop's fabled Ants, who put aside some seed corn for a cold, rainy day. We did that ourselves for many years. The federal government saw opportunities to invest in a better future, persevered in those investments, and reaped ample reward: For example:

- Fiber optics was a germ of an idea in an obscure area of basic physics in 1966 but now carry most U.S. long-distance telecommunications.
- The Global Positioning System represents a confluence of basic research in physics, software, communications, and high-speed electronics. First developed for military purposes, it is now rapidly expanding into commercial markets for navigation and air safety and monitoring Earth's large scale ecosystems.
- Severe weather prediction emerged from the integration of space platforms, immense computing power, and continued atmospheric science research to help prevent loss of life and property.
- DNA testing resulted from decades of basic research in molecular biology and computer science and now provides a way to identify people in the best of times -- for example, reuniting families after the civil unrest in Argentina -- and in the worst of times -- for example, associating suspects with crimes.

But I fear we may become like Aesop's Grasshopper, who sang the Summer away. In unison we sing "less government, lower taxes," but there's dissonance when we try to talk about preparing for the future, about putting something aside for our children and grandchildren. We must find some harmony, Mr. Chairman.

Scientific knowledge is the key to the future. Technology is the engine of economic growth. Together, science and technology build new businesses, provide good jobs, improve health and the quality of education, and protect us from threats as diverse as environmental degradation and military force.

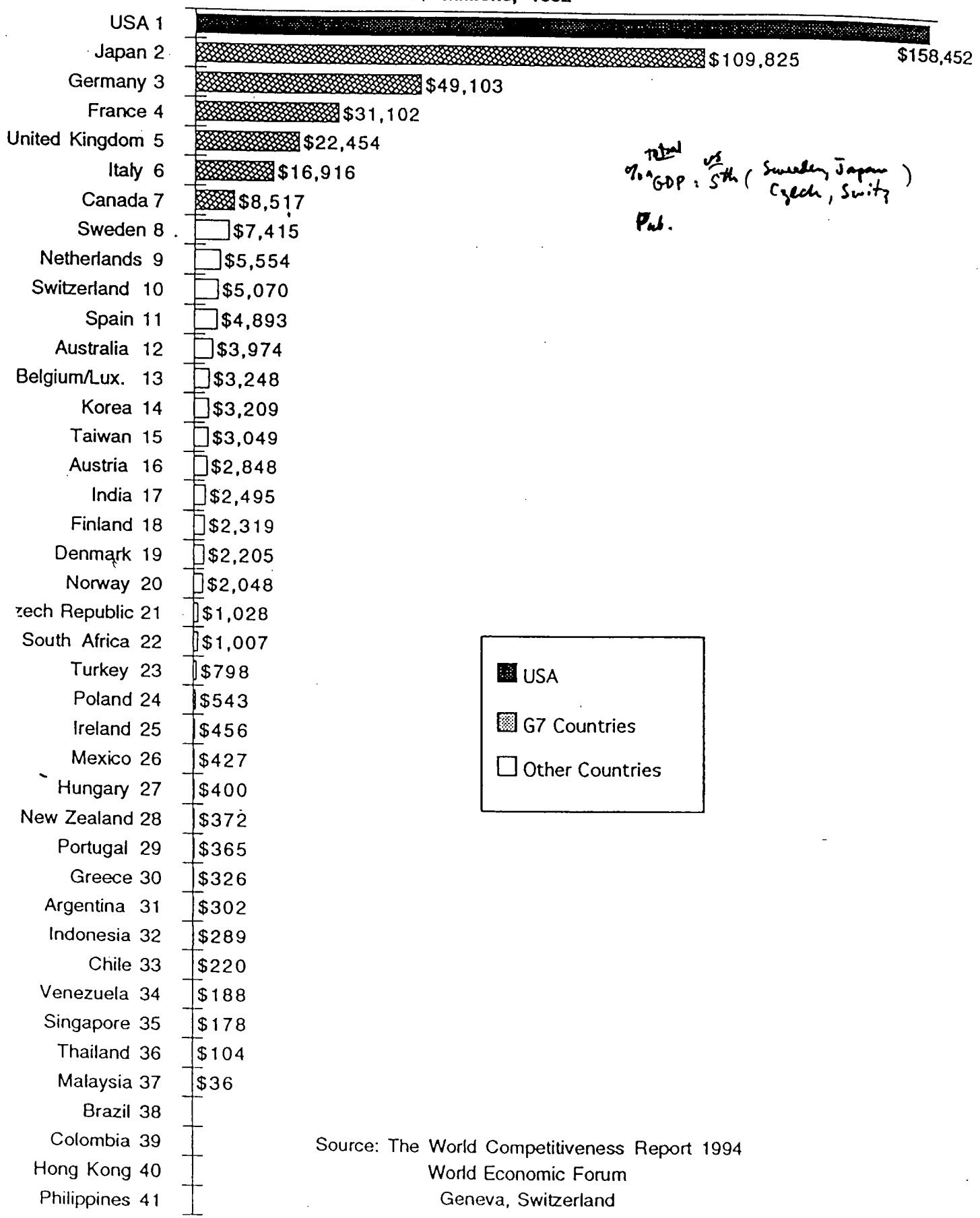
American mastery of science and technology will largely determine whether our citizens capture new opportunities -- good jobs, a higher quality of life -- and continue to enjoy basic amenities, including safe and affordable food and shelter. Innovations in myriad products and processes Americans count on for a better life, such as heart surgery, computing, and electric lighting, stem from scientific advances. The investments we make today in basic and applied research will assure the continuous flow of knowledge needed to develop new technologies for the future.

The federal government plays a crucial role in ensuring American leadership in science and technology. The Nation's world leadership in science, mathematics, and engineering fundamentally derives from federal sponsorship. Federal research investments led directly to the technological leadership of U.S. firms in agriculture, aeronautics, semiconductors, computers, communications, pharmaceuticals, and scores of other critical areas.

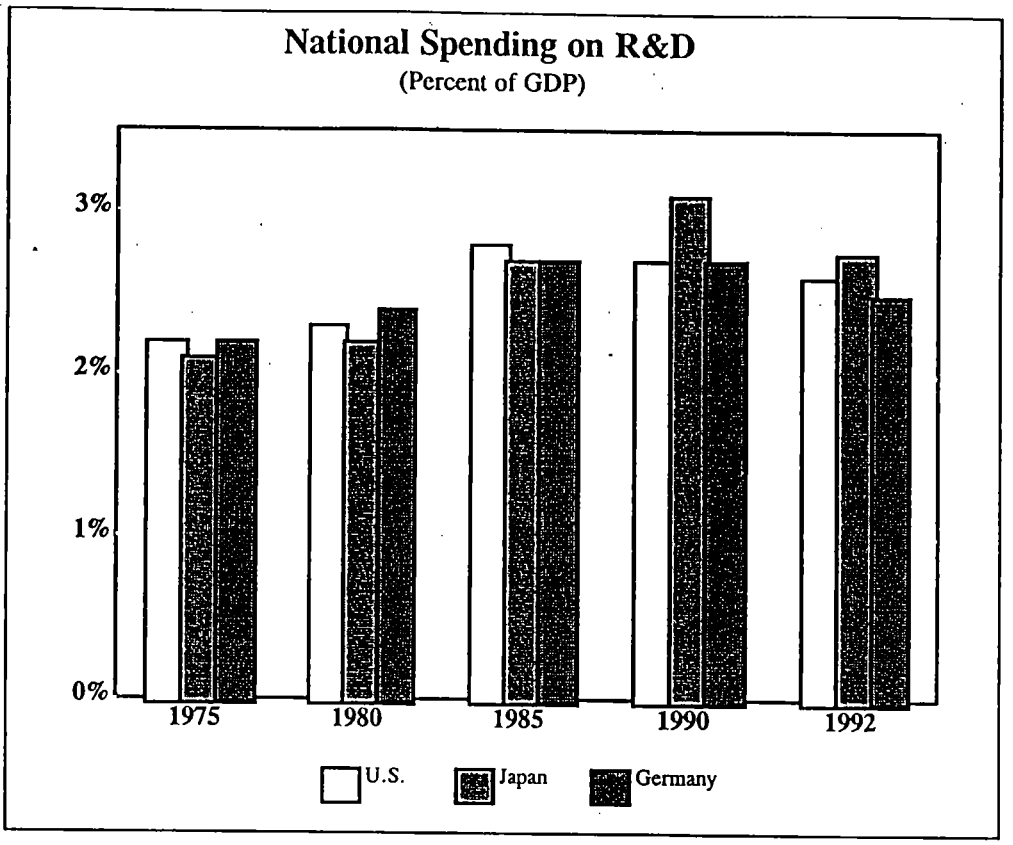
We remain convinced that: 1) the Nation's future depends on advances in science and technology; and 2) federal investment in research and development is an essential catalyst for such advances. The Administration is determined to continue investments in the future despite fiscal pressures today. We want to work with you in achieving this objective.

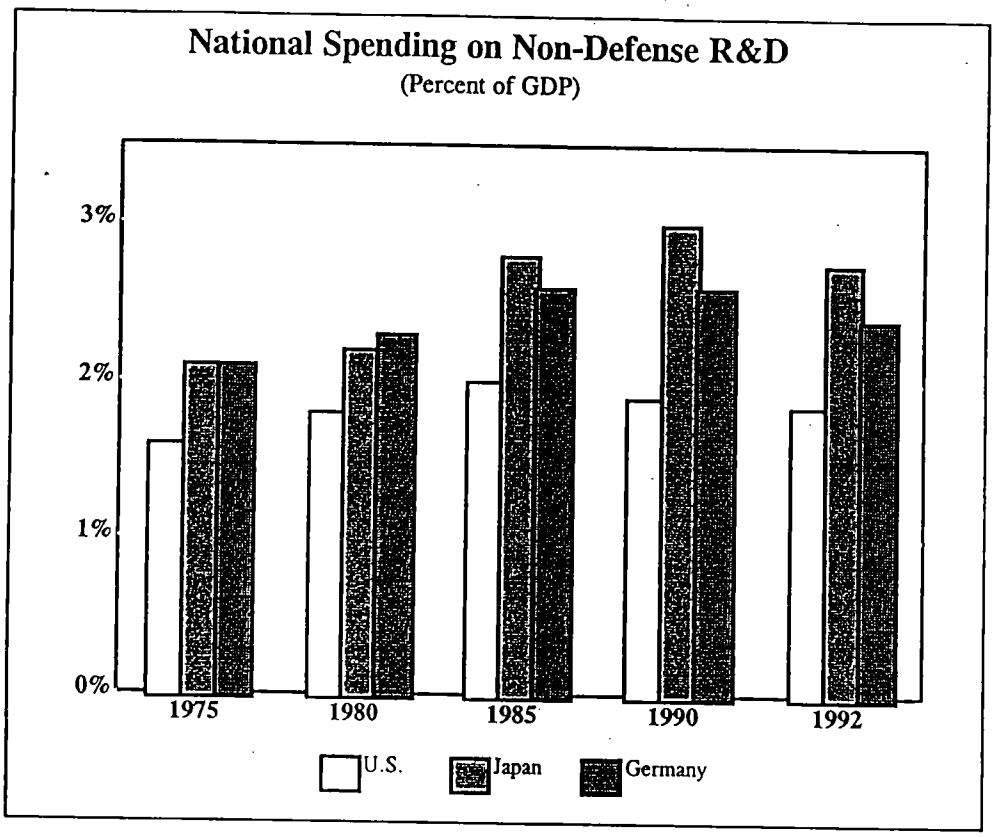
TOTAL EXPENDITURE ON R&D

US$ millions, 1992



Source: The World Competitiveness Report 1994
World Economic Forum
Geneva, Switzerland


National Spending on R&D
(Percent of GDP)
3%
2%
1%
0%
1975
1980
1985
1990
1992
U.S.
Japan
Germany



Pub. funded non-def. R+D as %GDP

vs: 28th behind UK, Fr, Ger, It, Can, Jap..
Korea, Israel, Taiwan, ...

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

AAAS 1997

Divider Title: _____

Remarks of

JOHN H. GIBBONS

Assistant to the President for Science and Technology

Director, Office of Science and Technology Policy

AAAS Policy Colloquium

April 23, 1997

Washington, DC

Science and Technology Policy in the Dawn of the Twenty-First Century

It is with special pleasure that once again I greet this distinguished body. The range and depth of scientific talent gathered here represent not only continued American leadership at the frontiers of science and technology, but a vital commitment to ensuring a better quality of life for future generations of all Americans.

Since I last addressed this colloquium, we have witnessed a remarkable string of scientific discoveries and technological advances. Hardly a week goes by without major breakthroughs reported in the

pages of that learned journal of science -- *The Washington Post*: possible water on our moon, and ~~perhaps~~ virtually for certain on one of the moons of Jupiter, the tantalizing prospect of ancient life on Mars, cloning of a mammal from a fully differentiated cell, confirming the existence of a third branch of life on earth, first steps toward demonstration of an "atom laser," and carbon nanotubes 100* as strong as steel and 1/6 the weight. Just last week, we read of the use of satellite and atmospheric data to document a significant response by Northern Hemisphere ecosystems to global-scale warming during the 1980s, which can be described as disturbingly a longer growing season in high latitudes. The list goes on and on. All are magnificent and sometimes troubling discoveries, all generating a new series of questions ~~and~~, possibilities, and challenges.

* [biennial report]

Contrary to these recent noteworthy discoveries, it is remarkable how much of the S&T policy discussion remains stuck on gloomy "budget talk," agency fortunes, and the outyears. There have been many dire predictions that balancing the budget would mean deep cuts in civilian research programs, on the magnitude of one-third over the next five years. Every year in this office, I have heard these rumbles.

I've even echoed some my

And every year I have warned that our research budgets *were* in real peril. This year is more hopeful, although the yellow caution flag is still out.

I will return to the budget later, but I first want to dwell on the overarching *national interest* with an eye on the future and its constituency. You are an integral part of that future and therefore have a stake in the *long view* of policy that OSTP seeks to provide as interagency coordinator and advisor to the President.

Budgetary and Policy Climate

First and foremost, let me assert that the President and Vice President remain unwavering in their support for science and technology as crucial investments in our future. They share our convictions that such investments enable our nation to compete aggressively in the global marketplace, protect our environment and manage our natural

resources in a sustainable manner, safeguard our national security from emerging threats, and spur the technological innovation that has contributed so much to our economic prosperity and quality of life.

Despite the prognosis of some pundits, last year we often sailed against the wind, but we always held our rudder true. And, as a result, with a lot of help from outside government, we successfully held the line in the purchasing power of the aggregate Federal S&T budget. This is the *fifth* year in a row that President Clinton has proposed to increase research and technology funding, while at the same putting our country on the path to fiscal sanity. This is especially encouraging news, and I believe that once Federal spending is brought under control, our Federal S&T investments should grow and track at least with the Gross Domestic Product.

Within the scientific community and in Congress, there have been calls for significant increases in federal R&D budgets above what the President has requested. Some proposals are genuine. Others are little

more than nicely wrapped, rhetorically-filled, empty presents. Yet, these calls for more research support signal an endorsement of one of the Administration's priorities, and hint of a welcome return to the traditional bipartisan political support for investing in future research.

I am heartened by those scientists, university and industry leaders, and policy makers advocating greater Federal investment in R&D. Such activism *has* made a difference by amplifying the scientific community's voice. But make no mistake: the constraints on Federal research funding are driven by a budget deficit and national debt that recklessly tripled during the 1980s, and that still stifles investment today. Would I like to see an increase in federal funding for research? Of course! Do I believe that our nation's taxpayers and future generations would be well-served by greater investments? Absolutely! Would better understanding of how S&T changes the lives of our citizens help the cause? Unquestionably! For I believe that the future is best-served if science and technology are widely understood and valued.

We struggle with these difficult choices to ensure, as the President consistently points out, that "the future does indeed *have* a constituency." S&T funding is a high-stakes, high-leverage investment in the Nation's continued stability and prosperity. Our President's economic plan is working. Our deficits are lower. Our economic growth is ~~higher~~ solid. And it is this steady growth that fuels the economy, making it easier to increase S&T investments and still reach a balanced budget by the year 2002. Look no further than the President's R&D budget projections that are *far* more favorable than anticipated even a couple of years ago. For the first time since 1981, I repeat, since *1981*, the budget deficit could slip *below* $100 billion this year, thanks to a robust economy that is boosting tax revenues. And that accomplishment is a lot tougher than in 1981 because in the 80's we shamefully tripled the national debt, adding about $150 B of annual interest charges to the bill.

Shaping the S&T Portfolio

How can you help shape the S&T portfolio? You need to continue to be political activists in explaining the intricate processes and beneficial outcomes, revealing the complexity, uncertainty, and inherently long time horizons that characterize your research and innovation. While the S&T enterprise may not be growing at the rate of the 1980s, our job is still to nourish American science in all its vitality. We are shaping an S&T portfolio that is consistent with existing budget projections, that addresses national goals, and that is faithful to the exciting opportunities we glimpse daily.

So how will we effectively expand the frontiers of knowledge under current budget scenarios? As the Cheshire Cat pointed out in *Alice in Wonderland*, "how you get there depends very much on where you want to go." In the final analysis, our Federal S&T investment priorities must be balanced against *all other* needs to invest in infrastructure such as

transportation and environment, crime prevention, national security, housing, health care, and education.

First of all,

Even as the Federal budget deficit is tamed, the Administration has protected the level of investment in key Federal basic science programs, not only those in the National Science Foundation and the National Institutes of Health, but also those in numerous mission agencies, such as the Department of Energy, and the National Aeronautics and Space Administration.

But

Our S&T leadership strategy is a *national* — not just a Federal — strategy. The benefits of research are not fashioned in Washington, they are forged in factories, laboratories, and universities and colleges across America. We must shape a national program to address national goals.

Therefore, a centerpiece of the Administration's portfolio is our commitment to S&T partnerships between the Federal government and

universities, states, and industry. Such collaboration is not only desirable, it is essential. No sector, sponsor, or performer can do it alone. The linkage of research and education – anchored in universities but practiced in facilities ~~built, staffed, and shared by state government and industry~~ many other public and private has proved an exceptionally effective public policy for decades. From planning to execution to evaluation, we are bringing to the table all the players in science and technology — the business community, research universities, non-profit institutions, and state and Federal governments.

In many research fields, the productive path to scientific advances increasingly involves international collaboration. Major research endeavors, such as space missions, particle accelerators, astronomical observatories, the quest for fusion energy, climate change research, and mapping the human genome, are so resource-intensive and necessarily one-of-a-kind that international cost-sharing, exchanges, or in-kind contributions have become commonplace. Reflecting the global growth

in sources of innovation, working with other nations on research activities for mutual benefit has grown as a priority.

The Federal investment in university-based research is about $13 billion annually in university research alone. This investment has yielded new knowledge, technological innovation, and a scientific and technical workforce that is the envy of the world. But national, political, corporate and education leaders have advised the President that the Nation's universities are experiencing growing stresses and strains. Such pressures stem from a constellation of changes, and the President's Committee of Advisors on Science and Technology (PCAST) recommended a government-wide policy and administrative review of our university research system. In response, last September, the President ordered a multi-agency review of the university-government partnership to identify the principal areas of stress, and to recommend ways of coping and adapting without sacrificing excellence or productivity. This review will assist us in developing strategies that

promote cost-effectiveness, allocate research costs fairly, strengthen the research-education linkage, and develop appropriate measures of accountability.

As many of you already know, the White House and the Nation's governors recently agreed to work together in an Innovation Partnership to promote economic growth by stimulating the development and use of improved technologies in areas such as advanced manufacturing, education, health care and electronic commerce. We will also extend the capacity of the Manufacturing Extension Partnership to help modernize the nation's 380,000 small- and medium-sized manufacturers. We will continue the work we have begun to streamline the regulatory environment for research and technology.

We will also persist in our efforts to have Federal agencies work more closely with each other, and with the private sector. We have had

some notable successes, including the Partnership for a New Generation of Vehicles, a cooperative effort among numerous government agencies and the U.S. automobile industry, to produce a production prototype vehicle capable of 80 miles per gallon by 2004. Another standout is the Commerce Department's Advance Technology Program which forms cost-shared partnerships with companies that have the greatest potential for developing technologies to achieve broad-based economic benefits with high rates of social return. These programs are now approaching a level of experience that should permit definitive review and optimization of future investments.

Other exciting initiatives interagency including the Global Climate Change Research Program, the High Performance Computing Initiative, convergence of civil and military weather satellites and advanced aviation and space launch technologies, and a major effort on Emerging and Re-emerging Infectious Diseases.

I cannot stress enough that bipartisan support will be critical for shaping a sustainable agenda. The American people want us to be partners, not partisans, and the vast majority in Congress support a strong Federal research program. The scientific and engineering communities also have the opportunity and the responsibility to help forge consensus about the future's requirements for America's research and education investments. ~~History suggests that the cost of not making these key investments in technical and human resources will be far greater than that of moving ahead.~~

Today, the challenge is to make the best use of the Federal investment to make each public dollar purchase more scientific impact and attract additional finding from other stakeholders in the R&D enterprise. Lean but accountable research administration, both in the federal government and in the performing institutions -- universities, medical schools, and national laboratories -- will help sustain our competitive position, even as expenditures are constrained. Consequently, the Administration has

begun a process of management reforms to improve the effectiveness of the investment. Examples include: revising and streamlining regulations and agency directives; ~~identifying regulations that are outdated or add no value~~; automating research support functions; and developing performance-based organizations. Identifiable goals, measures of progress, and accountability for the outcomes achieved with Federal S&T dollars are also needed -- and, I might add, a responsibility of researchers. The Government Performance and Results Act codifies this and will assure the investors in S&T, the American public, that their tax dollars are well spent.

In the President's FY98 budget request, we continue to promote the growth of programs that benefit basic research:

- NSF and NIH would each be increased by 3%;
- Basic research funded by DOE is proposed for a 4.6% increase above FY97 funding levels (remember that previous out year projections had DOE programs sharply decreasing);

- **The peer-review competitive grant programs at both the USDA (the NRI program) and EPA (the STAR program) are up 38% and 21%, respectively;**
- **DOD basic research in the 6.1 account is up by almost 8%; and**
- **Science research at NASA is up 3%, including a projected 7% increase in academic R&D.**
- **Support for environmental research, as well as health, food and safety research also rises.**
- **Investments in computing and communications grow by 10 percent. There is significantly enlarged support for programs to bring modern technology to America's classrooms to raise students' achievements to rigorous and challenging standards.**
- **Investment increases are also included for R&D essential for ensuring continued U.S. economic leadership and job creation.**

In sum, to maximize balance and effectiveness of the S&T investment portfolio, the Administration is promoting R&D programs

that are: selected through a merit-based competitive process; are planned, funded, and conducted jointly through partnerships; provide realistic and objective measures of progress and performance; enable technology development through sustained interactions with industry and state and local governments; build professional capacity in the workforce; and promote international cooperation.

The Research-Education Link

Let me return to an issue I only alluded to earlier. The S&T portfolio must reconsider the linkage of research and education, the connection between discovery and learning. In his recent State of the Union message, the President clearly placed the next generation at the top of his priority list. He has redoubled his commitment to excellence in education and is establishing performance goals, starting with 4th grade reading and 8th grade mathematics exams beginning in 1999.

In a Directive issued last month, the President created an NSF-Department of Education Working Group to Improve Math and Science Education, coordinated jointly through OSTP and the Domestic Policy Council. In June, we will recommend an action strategy to improve the teaching and learning of mathematics and science pegged to international benchmarks. We will focus on incorporating the best practices in teaching, identifying challenging instructional materials, and integrating technology into classrooms. Perhaps most importantly, we will seek to mobilize the professional communities to convince students that the math and science learned in the classroom today is critically related to the skills they will be need in the jobs of the 21st century.

We need to think of science and math as part of a seamless web of formal education not for a select few, but for *all* children who earn a high school diploma, a two-year, or a four-year degree. Today's 11-year-olds will be voters in 2004. They will need to understand and routinely use what we in this room consider "specialized" knowledge.

That is the legacy of the link between research and education, and between science and social progress. The Nation's colleges and universities must view their mission as the refinement of "works-in-progress" that begin, as researchers at last week's White House Conference on Early Learning reported, long before children enter school. Thus, the process of recruitment and growth must start with investments long before students arrive on a college campus.

Conclusions and Prospects

Over a half a century ago, the Manhattan Project demonstrated in graphic terms the power of applying the tools of science and technology to critical national needs. With a shift in our national priorities, our science policies, traditions, and practices must also evolve. Together we must seize the opportunity to shape our national research agenda and scientifically and tackle other large, technologically complex problems that enhance our quality of life and national security. For while we respect the principles

of excellence and competition that underpin the future health of U.S. research, we must continue to nurture the human capital that educates, invents, and administers – not just for the sake of science and technology, but for our society as a whole.

Once again, allow me to underscore this Administration's vision for science and technology:

- Advances in S&T – spectacular and often built on partnerships – are inseparable from the Nation's future.
- Despite dire predictions, we have held the line in the aggregate purchasing power of Federal S&T. Two years ago at this Colloquium during a period of S&T budget frenzy on Capitol Hill, I quoted the wise advice of Thomas Jefferson who once counseled "A little patience, and we shall see the time of witches pass over, their spells dissolve, and the people, recovering their true sight, restore their government to its true principles." I believe that after we've finished the task of getting the budget deficit under control, support for S&T should

The more recent signs are encouraging but not yet convincing!

grow and track at least with the GDP, ~~along with~~ conditioned on our continued success in demonstrating the economic added value from such public investments.

- Research links with education are absolutely essential, and not just in graduate school since developing human capital is a long-term, overarching goal.
- We are inventing new ways of doing business. By coupling research choices more explicitly to national priorities, we are reshaping the S&T portfolio, with advances in fundamental knowledge at the core.
- Unless the scientific community stays involved and talks to its "investors" – citizens and their elected representatives – we will suffer in the budget wars through "silence" and forfeit our competitive advantage.

This is part of a new social contract, one that demands explicit links between knowledge production and its applications in policy and practice. As President Kennedy once reminded us, "Scientists alone can

establish the objectives of their research, but society, in extending support to science, must take account of its own needs." I urge you to look under, over, and beyond budget trend lines. We must emphasize strategic thinking and organizational change, *not* budgets per se, since resources will inevitably lag our aspirations and promising ideas. As Congressman George Brown wisely points out that if we are to preserve the future health of the nation, we need to focus on *S&T* policy, not solely *budget* policy. The two are clearly linked, but too often we lose sight of the long-term S&T policy while getting exercised annually over numbers in the budget ledger.

However, in the dawn of the twenty-first century, I do not close on a somber note, for ours has been a century of scientific conquest and technical triumph.

Never in our country's short history or even in the longer history of science has the prospect been brighter, or the need greater for

collaboration between those in government shaping S&T policy and those of you ~~who work at the lab bench~~ in the laboratory.

The challenges we grapple with today are without precedent in human history. Let us always remember that wisdom is the child of experience, as we move toward a new era in which science will be increasingly challenged to fulfill its promise. And as we lean into the future, let us also resolve to encourage other talented young men and women to join us in these disciplines which require so much from them but which have so much to give to our citizens and to the people of the world.

So to each of you I express my deep appreciation for your contributions to the welfare of mankind, to the priceless storehouse of knowledge, and to the options of new technology so essential for the future.

Finally, I am reminded of what the great French Marshall Lyautey once said when he asked his gardener to plant a tree. The gardener protested that "the tree would not bear fruit for a hundred years. "In that case," Lyautey responded, "then plant it this afternoon."

That is how I feel about your work. Godspeed to each of you, and may the best be yet to come!

Thank you very much.