Chapter 1

Executive Summary

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This OTA technical memorandum examines the social and legal forces that act to restrict or regulate scientific and engineering research in the United States today. Recent controversies over the use of animals in experimentation, the risks associated with recombinant DNA research, and national security controls on scientific communication have focused congressional attention on the policy issues raised when government intervenes in the research process. As each issue has arisen, Congress has been called on to decide when and where intervention is appropriate, and how to structure intervention so as to protect public health and safety or national security without unduly retarding scientific progress. At the request of the Task Force on Science Policy of the House Committee on Science and Technology, OTA looked at the entire "regulatory environment" for research, with the goals of analyzing the structures and mechanisms for regulation and of identifying significant policy issues that may require congressional attention in the future.

Although scientists have always exercised restraints on their work, the present system of government-based, legally enforceable regulations is relatively new (ch. 2). Until 1945, constraints were limited to social prohibitions on sensitive topics, some controls on agricultural research, and national security controls on technical communication during wartime. Post-1945 arrangements for the support of science treated it as distinct from other types of government programs in that it should be free from direct government control or economic self-interest and that scientists could be trusted to govern their own affairs.

The uncovering of a number of examples of abuses of human subjects, growing fears that scientific research was posing high risks to human health, the identification of research with government-sponsored activity, and the social and political climate of the 1960s and 1970s (ch. 2), led to a series of regulatory actions that began to constrain not just what topics scientists should pursue, but also how they should be pursued and the results disseminated. More recent controversies over controls on scientific and technical information deemed vital to national military or economic interests indicate further erosion of the trust in scientists' governance which characterized the postwar arrangements. The increased regulation may also indicate that science is simply included as a target of society's increasing willingness to regulate all types of institutions, professions, or activities.

A wide spectrum of social and political rationales (ch. 3) may justify controls linked to a specific part of the research process: selection of topic, experimentation or other procedures, and dissemination of results. The moral and ethical concerns expressed in attempts to restrict research are not new. What is new, however, is the raising of such concerns to the level of government action or legally enforceable regulations. Some governmental regulations manifest concerns about the potential risks of a line of research; they demonstrate that society wants to protect the health and safety of experimental subjects. Government restraints on the communication of scientific and technical information seek to protect militarily sensitive information or to curtail economic losses associated with international technological competition. Public opinion data show that such regulation may reflect the American public's willingness to restrict research when the risk is perceived to be too great, despite the concurrent existence of widespread public support for science as a cultural activity deserving Federal support.

Analysis of the mechanisms by which restraints are imposed at the laboratory, institutional, or governmental levels (ch. 4) shows that controls in the modern research environment are widespread, synergistic, and cumulative. They affect every stage of the research process—what topics may be pursued, how they may be pursued, and when and to whom the research may be disseminated. Institutional mechanisms include formal administrative policies, institutional review committees, or institutional cooperation with external requests for constraints. Professional societies set up codes and guidelines and may cooperate

with government attempts to impose dissemination controls. Government control mechanisms include: review commissions and ethics advisory boards, legislative review of proposals or projects, moratoria, regulations on the use or possession of substances used in research, interpretation of agency regulations, contract provisions, and dissemination or publication controls. The channels through which government can affect research—legal regulations, formal administrative controls, judicial actions, priority-setting through budget allocations—have increased in the last decade, largely because of increased Federal support of science (and, therefore, increased channels for implementation of regulations), but also because of general demands for accountability and the widening impact of science on society. The very multiplicity of mechanisms for restraint increases the possibility that such regulations will be implemented piecemeal, in isolation, and without coordination, and that they therefore may produce an adverse synergistic effect on the progress of science and the research base for innovation.

As the case study in chapter.5 shows, the regulatory effects, especially on the research process, are not confined to basic research in universities, even though most of the discussion of and complaints about overregulation has been concentrated there. Many of the mechanisms described in chapter 4—e.g., controls on research materials, human subjects regulation, dissemination controls—apply with equal force to research in industry and private laboratories.

In many cases, science may not have been so much singled out for control, however, as simply sharing in society's growing propensity for regulating all types of specialized institutions or activities. Such regulations include administrative reporting requirements for Federal grants and contracts, social programs legislation (e.g., affirmative action), Occupational Safety and Health Administration (OSHA) regulations and right-to-know laws, and laws and policies relating to international diplomatic relations. Although these actions are designed to serve a public objective and not to restrain research, they can add to an existing financial and administrative burden of intentional controls and their effects can be much more difficult to avoid after they are legally in force. Such regulations could have a long-term adverse effect on innovation and progress in research, There is clearly a need for better documentation and monitoring of possible unintentional adverse effects on research and, in some cases, there may be a need to consider specific legislative exemptions for research.

The local government interventions described in chapter 7, and in the case study in appendix C, point to a potential for increased confrontations between State and local authorities and the Federal Government regarding the jurisdiction for regulation. Should science be controlled through a combination of self-regulation and broad Federal oversight, insulated from local laws? The emergence of a number of cases in which research facilities have been the subject of local protests indicates that research no longer wears a mantle of unquestionable civic respectability. Instead, it is subject to the same political influences and attitudes at the local level as are other institutions.

Given these circumstances, several changes may occur in the near future (ch. **8).** One is a shift in who must bear the burden of proof for control of research. That responsibility is increasingly shifting to the regulated researcher, who must prove that the research is safe or anticipate whether dissemination of the research results may have some adverse effect on the national interest. As this situation changes, the Federal Government will increasingly have to consider the appropriate role for scientists in the regulatory process itself. How much should be left to informal practice and how much required through legally enforceable regulation? Congress can also expect to confront a number of communications-related issues in the future. These issues relate to the need to protect both freedom of speech and the freedom of scientific inquiry necessary to cultivate progress and innovation. How should these freedoms be balanced with the very real need to protect national military and economic interests? Whether through ex post facto restrictions on hitherto unclassified research or through the broadening of "gray areas" of sensitive information, the short-term goals of communication controls must be balanced carefully against their long-term effects on the Nation's science and technology base and on opportunities for U.S. scientists

to benefit from interactions with foreign colleagues.

Computerization of the scientific communication system may also raise in the next decade equally difficult issues regarding not only the protection of intellectual property but also the ease and speed of classification of information. Issues of patent reform will continue to create the potential for significant secondary effects on the research system—both in what type of basic research is sponsored by industry and in interference with intercollegial communication of ideas. Finally, the apparent increase in regulatory activity at the State and local level may be an indication of a jurisdictional shift in the initiative for regulation, from Federal to State or local, with the accompanying potential for "Balkanized" regulations and differential strictness of regulation.

This new "regulatory environment for research" raises many important questions for the Science Policy Task Force and for Congress. First, how can Congress assure balance among the protection of public health and safety, the rights of citizens to govern their local communities, and the freedom of individual scientists, whether of speech or action? Second, how can the regulatory process and the opportunities for public discussion of regulation be structured so that competing interests are negotiated before issues reach a stage of controversy and hostility? Third, which issues should receive congressional or State or local attention and which are best left to the self-regulation of the research communities? And, fourth, what can Congress do to assure that this environment does not unduly erode innovation and creativity in U.S. industry or unreasonably damage the Nation's investment in university research?

FORCES SHAPING SCIENCE

Scientific research* —i.e., the organized, systematic search for knowledge about, insight to, or understanding of a subject—is significantly influenced by its social and political context. For example, the pressures of U. S, economic competition in world markets and the linking of research accomplishments to national stature affect which research is funded and which research results may be widely disseminated. Increased public awareness of the negative side effects of the research results or processes have created pressure for government control. Thus, scientific research can be constrained both for political and social purposes, and when it is regarded as a negative force out of control or a force that may become negative if allowed to continue.

No matter what the field or institutional setting (university, government, or industry), the research process has certain common characteristics—e.g., in the use of a scientific knowledge base, in the methods of investigation, and in the training and education of its participants—that are independent of specific project goals. Restraints on research may affect the choice of which subject to investigate or which to fund (controls on topic); the method by which that investigation proceeds, including the tools of research and the objects or animals manipulated during the research (controls on procedure); and the timing of and audience for descriptions of the research and its results (controls on communication). This report analyzes the influences at each of these stages.

Different social or political mechanisms can influence the research process in different ways. Public approval or disapproval of research topics or procedures may be expressed in political demonstrations against laboratories, through referenda and local initiatives, as well as through moral condemnation and social pressure.[1]

More formal control is exercised through, for example, laws passed specifically to direct some

● The report is not concerned with controls on the application of research knowledge in medical practice, commercial development of a product, or similar exploitation of research results.

[1]Loren R. Graham, "Concerns About Science and Attempts to Regulate Inquiry," *Limits of Scientific Inquiry,* Gerald Holton and Robert S. Morison (eds.) (New York: W.W. Norton & Co., 1979), pp. 1-22.

aspect of the research process, through Federal interpretation of the language of such laws, or through the provision or denial of research funding.

Other economic or political forces can affect research through government actions intended to have some other effect. Economic considerations, the need to protect proprietary interests, Federal protections on public health and safety, and other Federal and State legislation may influence industrial or other nonacademic research, For example, the Food and Drug Administration's (FDA) regulatory requirements, which govern the introduction of new drugs, are reported to have slowed pharmaceutical industry research on new drugs, particularly on "orphan drugs" (drugs for rare diseases), [2] where the cost of those regulations has not been outweighed by favorable economic and market conditions. In contrast, however, the even more stringent requirements of Nuclear Regulatory Commission and FDA regulations on radiopharmaceuticals appear not to have affected that research adversely. More favorable economic and market forces allow these firms to overcome the effect of any regulatory burden.

The attitudes and professional values of the scientific community itself have played a prominent role in influencing and sometimes constraining research activities. Self-imposed constraints were used in the 1970s, for example, during the debate over recombinant DNA. Molecular biologists exercised "restraint and caution" in their research procedures and adhered to a voluntary moratorium on recombinant DNA research, even though they "had no certain proof that the need for limitation existed or that the consequences of it would be positive. "[3]

Finally, control on the communication of scientific and technical information may be implemented for reasons associated with economic or military protection. For both basic and applied research, such controls may take the form of a prior restraint on research publication or a denial of access to laboratories. When controls are imposed on basic research in universities, however, the benefits of such controls may not be perceived by the institution as outweighing the adverse effects on the education and training of students. Because such restrictions often appear to violate traditions of academic freedom, universities may oppose their implementation. Critics of sweeping controls argue that, in the long run, such restraints could harm the quality of the scientific work force, the traditional climates for creativity, and the progress in basic science which is necessary to technological advancement.

This OTA report takes a look at the entire range of social, political, and economic forces that restrain all stages of the research process, in all types of institutional settings, and that prompt changes in research projects or create sufficient political pressure for the development of legislation or administrative controls. In examining this "regulatory environment, " the OTA project attempts to locate the common ground, the similarities among what on the surface may seem to involve dramatically different issues and controversies. Restrictions on communication, for example, are not only confined to basic researchers in universities. Controls and regulations—both internally and externally imposed—also affect scientists in industry and in government at all stages of research. The OTA study looks at research—regardless of where or by whom it is conducted—as a universal activity, searching for common factors in the mechanisms, justifications, and effects of the regulatory environment. A few restrictions apply equally to all parts of the research system, to industries as well as universities; others apply to specific parts of the process or only to one field. The differences may be only in the extent to which restrictions are enforced or publicly discussed.

[2] Barry S. Roberts and David Z. Bodenheim, "The Drug Amendment of 1962: The Anatomy of Regulatory Failure, " *Arizona State Law Journal, vol. 1982,* No. *3, 1982,* p. *587,*

[3] Clifford Grobstein, *A Double Image of the Double Helix* (San Francisco, CA: W.H. Freeman & Co., 1979), p. *2.*

IMPORTANCE OF THIS ISSUE FOR CONGRESS

Increased awareness of how science and technology affect both social structure and social values and vice versa has prompted increased pressure for political intervention in what heretofore has been a decisionmaking activity dominated by scientists or science managers; but such interaction worries researchers who are accustomed to substantive control over all aspects of their own work. So there is a search underway for institutional forms that could permit more public involvement in critical policy decisions and yet still preserve "the flexibility y needed for the pursuit it of scientific research."4 Congress may desire or may be asked to play a role in developing these new arrangements.

Agency regulations-and many of the secondary controls on research —are also related directly to the amount of Federal support available to scientific and engineering research and to priority setting for allocation of that support. As the Task Force document, *An Agenda for a Study of Government Science Policy,* states:

> . . . the immediate goals to which science can be expected to contribute, such as improved health, a cleaner environment, and enhanced technological innovation, cannot be considered in isolation. Broader societal goals . . . should be taken into consideration when formulating the goals for science.[5]

Another aspect that relates directly to the work of Congress is the suggestion that some regulations instituted for legitimate and laudable social or political reasons may be having secondary, unanticipated, and adverse effects on the quality of science and may thereby diminish science's usefulness to society. Regulation, according to the Task Force *Agenda,* "is one of the few areas in which the aims of science and the aims of society are not necessarily congruent. The manner in which these conflicting aims are accommodated is of significant importance to both science and society. . . ." The Task Force has focused on two aspects of this issue in particular: 1) how to shape the future regulatory environment for science while still responding to the necessity to avoid the ill effects arising from regulating science;[6] and 2) how "the legislative and regulatory authorities representing society as a whole can protect public health, safety, and values while avoiding the imposition of unnecessary restraints on science."7

The topic of the regulatory environment for research thus involves discussion of some of the most basic questions of American political philosophy: public control v. self-rule, Federal v. local jurisdiction, the feasibility of regulation and the importance of consent by the regulated, government regulation v. individual liberty, and how to balance the conflicting rights and values of different social institutions. The events and the debate will continue. Congress can expect to confront these issues again and again.

For many research areas, the question in the 1980s is not *whether* there should be any limits but, instead, "what those limits should be. . . . [A]nd, if we can define those boundaries, what control options will maintain them most effectively?"[8] The organized scientific community now appears to acknowledge the need for "some political and public input to the setting of the general directions and agenda of scientific research, " just as the political sphere appears to have accepted the importance of "some degree of self-governance and internal agenda-setting" by the scientific community. The real issues have become, as Harvey Brooks notes, "where the lines should be drawn and the appropriate processes by which the scientific and political communities should negotiate the scientific agenda."9

[4] *Panel on Science and Technology:* Science *and Dangers* (Washington, DC President's Commission for a National Agenda for the Eighties 1 980), p 19.

US Congress, House Committee on Science and Technology, Task Force on Science Policy *An Agenda for a Study of Government Science Policy* 98th Cong 2d sess (Washington, DC: US. Government Printing (1 fice, 1 985), p 8

[6] Ibid., p. 40.

[7] Ibid.

[8] Judith P. Swazey, "Protecting the 'Animal of Necessity': Limits to Inquiry in Clinical Investigation," *Limits of Scientific Inquiry,* Gerald Holton and Robert S. Morison (eds.) (New York: W.W. Norton & Co., 1979), p. 142.

[9] Harvey Brooks, Benjamin Peirce Professor of Technology and Public Policy, Harvard University, personal communication, 1985.