Chapter 8

# Research Policy Issues That May Warrant Congressional Attention in the Future

*Photo credit: National Institutes of Health*

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In OTA's brief survey of laboratory directors and research administrators, * the respondents were asked to reflect on how things have changed from when they were just starting out in science and to list the major constraints then as opposed to now, The trend most noted by both groups is understandably the increase in administrative and "bureaucratic" requirements of grant procurement and administration. Fifty percent of the university administrators and 32 percent of the lab directors noted that administrative requirements for the investigator have increased substantially. Time spent on detailed administrative work means less time and money spent on research.

Other changes in the regulatory environment noted by the respondents were the greater chance of litigation and the appearance of more actors involved in the scope and definition of research. Respondents see this latter trend as a result of increased Federal funding for research, which necessarily involves more political actors, and increased media coverage, which attracts more public attention to the research process. Many also mentioned increased controls on dissemination of research results as being a significant difference between the climate of, say, 30 years ago and today.

About one-third of the respondents stated that they were not aware of any research areas where the trend is toward fewer rather than more controls. Of those laboratory directors who did cite an area where controls have eased, 16 percent felt that changes in the National Science Foundation (NSF) procurement and granting procedures have helped to ease the administrative controls resulting from grants arrangements with that agency. Recombinant DNA research was also listed as an area where the trend has been toward more relaxed regulations, Other areas mentioned were human subjects research (where expedited review processes and exemptions have made the approval process less difficult) and a tendency toward decreased controls at the Federal level with simultaneous increase in controls at the State, local, and institutional levels.

If these research policy issues which have dominated the discussions for the last decade appear to be either resolving or, at least, not creating major controversies among the research community, then what issues do appear to be emerging for congressional attention?

*For details, see box in ch. b .

## WHO BEARS THE BURDEN OF PROOF?

The burden of proof for control of research appears to be changing. Increasingly, the individual researcher or research facility must prove that the research is safe rather than the regulator prove that it is unsafe.

A shift in responsibility is clearly occurring in the case of restrictions on scientific and technical communication. Under schemes proposed in 1980 by the American Council on Education, for example, cryptology researchers were asked to carry the burden of deciding which papers to submit to the National Security Agency for review.[1] A similar shift in the burden of responsibility occurred in 1980 changes in NSF grant policy, which made the grantee responsible for notifying

[1] Massachusetts Institute of Technology, *Interim Report of the Committee on the Changing Nature of Information* (Cambridge, MA: Mar. 9, 1983), Section 4.5.

NSF if, in the course of an NSF supported project, "information or materials are developed which may affect the defense and security of the United States."[2]

If a fundamental constitutional right is involved, then in the past the courts have placed the burden of proof on the government to show a compelling need to infringe. But some legal scholars argue that the situation is now muddied because it is increasingly difficult to distinguish between pure speech and "impure" special action.

[2]National Science Foundation, *Grant Policy Manual,* Section *794c.*

## THE SCIENTIST'S ROLE IN ASSURING SAFE RESEARCH

One of the principal unresolved issues is that of who should be involved in the regulatory process. What is an appropriate role for the individual scientist, for a professional science or engineering society, or for the public?

To what degree should the scientific community itself take central responsibility for both policing its own safety procedures and participating in the broadscale development of regulation? There are differing views on the extent to which scientists should be involved. Do scientists have some special right to be exempted from consideration of these issues? Or is it as John Edsall wrote in 1975:[3]

> The responsibilities are primary; scientists can claim no special rights, other than those possessed by every citizen, except those necessary to fulfill the responsibilities that arise from the possession of special knowledge and of the insight arising from that knowledge.

The conflict between these varying interests is made clear in the specific provisions of the Export Administration Act, for example, where scientists, whether employed by academic institutions or industry, are expected to comply with the requirements of the Act and other "applicable provisions of law" when communicating research findings "by means of publication, teaching, conferences, and other forms of scholarly exchange."[4]

Many agencies have reached out to the affected research community, asking scientists to review proposed regulations, both formally and informally, and thereby hoping to assure that the regulations are written in such a way that they are enforceable and can and will be complied with (i.e., are not far-fetched). Such an approach tests those scientists' belief that the regulations are necessary to protect society. For example, some . . . social scientists argue that in the case of recombinant DNA the process was flawed, precisely because the political authorities put too much reliance in the judgement of the researchers themselves" and that this situation led to "the capture of a regulatory agency by those it is supposed to regulate."[5] Others argue that the recombinant DNA case was "a model of responsible public policy decisionmaking for science and technology.'"[6]

How much should research be controlled by legal regulation, how much by institutional rules, and how much left to informal practice or to the codes or guidelines of professional societies? Strong arguments can be made that, when restraint is desirable, it should not involve the government. Regulatory enforcement, court cases, or congressional legislation may be inappropriate settings in which to make social decisions about the dangers and risks of research. Neither the current regulatory laws nor the agencies that enforce them are geared to address social or ethical issues. For many of the recent regulatory debates involving

[3]John T. Edsall, *Scientific Freedom and Responsibility,* report of the American Association for the Advancement of Science, Committee on Scientific Freedom and Responsibility (Washington, DC: American Association for the Advancement of Science, 1975), p. 5.

[4]Harold C. Relyea, "The Export Administration Act of 1985: Implications for Scientific Communication, " memorandum to the Committee on Scientific Freedom and Responsibility, American Association for the Advancement of Science, June *8, 1985,* p. 9.

[5]Susan Hadden, as quoted in Sanford A. Lakoff, "Moral Responsibility and the Galilean Imperative, " *Ethics,* vol. 191, October 1980, pp. 110-116.

[6]Harold P. Green, "The Boundaries of Scientific Freedom, " *Regulation of Scientific Inquiry, Keith* M. Wulff (ed. ) (Boulder, CO: Westview Press, 1979); reprinted from *Newsletter on Science, Technology, & Human Values,* June 1977, p. 118.

science, Congress has legislated solutions to fit one particular situation or crisis, While these procedures or rules may work well to adjudicate among differing scientific or legal aspects of problems, they are not always constructed in such a way as to resolve or negotiate compromise easily on moral or ethical points. Critics of a new line of research may be left to feel that they have no real forum from which to effect change.

How extensive and complete should regulatory legislation be? If the decision is to rely on self-regulation, what criteria will be used? The philosophy behind both the Institutional Review Board (IRB) system and the Institutional Biosafety Committees is a form of "monitored self-regulation, "[7] in which the process of regulation is subject to review and monitoring by government authorities. The extensive use in the U.S. regulatory system of consensual voluntary codes and standards* is in this tradition, but this self-regulation for certain forms of research appears to have been questioned in many recent cases (e.g., animal experimentation). Should sanctions be imposed on professional communities or institutions that fail in their self-regulation? Or shall the disciplinary action continue to be directed at individuals?

One alternative to increased regulation might be better education of the young scientists in the rationale for and the ethical aspects of regulation. Today, such education occurs primarily through apprenticeship, through informal learning. Congress might be asked to consider encouraging—e.g., through fellowships—education in the ethics or procedures of regulation.

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

*See discussion in ch. 4.

## EX POST FACTO RESTRICTIONS ON RESEARCH COMMUNICATION

An individual researcher and the Federal Government often can have overlapping but not identical interests in suppressing or disseminating scientific and technical information. In this respect, controls on research resemble government controls in all parts of society. "Most decisions about regulation involve decisions among competing societal 'goods, ' not decisions between 'goods' and 'bads'."[8] To achieve greater benefits, society may be inclined to accept greater risks; but in some situations the risks are experienced differentially by particular groups or individuals. The Department of Commerce has, for example, interpreted such normal scientific activities as presenting papers and talking with colleagues as a potential "export" of technology, which could be construed as requiring a scientist to obtain an export license before participating in such activities. In the opinion of some observers, this interpretation constitutes a prior restraint on speech, a "governmental intrusion on the scholarly exchange of ideas."[9]

These interests have been placed in especially sharp contrast when the Government has attempted to restrict communication about research undertaken independently and without Federal support, or when the Government classifies retrospectively research that was not conducted under classification or even with military funding. Similar issues are raised when there are attempts to control the dissemination of militarily or internationally "sensitive" but previously unclassified information or to control access to facilities. [10] In the decision to classify or control scientific information, the risks to national security must be weighed against the long-term value of free flow of information among a nation's scientists and against principles of scientific and academic freedom.

One consequence of U.S. restrictions may be the inhibition of U.S. scientists' access to information abroad. Several European members of the

[8]Ibid.

[9]American Civil Liberties Union, *Free Trade in Ideas: A Constitutional Imperative* (Washington, DC: May 1984), p. 18,

[10]Harold C. Relyea, *National Security Controls and Scientific Information* (updated 09 '11 84), issue brief IB 82083, Library of Congress, Congressional Research Service, Government Division, Washington, DC, 1984.

North Atlantic Treaty Organization (NATO) are reported to be considering the establishment of a new technology transfer agency to coordinate their political response to the controls placed by the United States on the flow of advanced technology." The NATO Science Committee recently wrote that, around the world, "certain important research institutions are . . . already being overcautious" in communication of research results. [12]

[12] "NATO Science Committee, "Open Communication in Science, " *NATO Science & Society, 1983.*
[13] Ibid.

The Committee expressed fear that the combination of an increasing amount of classification—for reasons relating both to national military and economic security—and increased international industrial competition could impede cooperation between the scientific communities of friendly nations, They also emphasized that restrictions will make it more difficult for small nations to obtain access to much-needed research results and that more classification may lead to more costly duplication.

## "GRAY AREAS" OF SENSITIVE INFORMATION AND BROADER CLASSIFICATION

"Significant attempts have been made to restrict the flow of information in cases where it has been felt that, though unclassified, it was of such sensitive nature that our 'enemies' could use it to their advantage." [13] For example, Executive Order 12356, a classification order issued by President Reagan, "appears to allow classification to be imposed at any stage of a research project and to be maintained for as long as government officials deem prudent." [14] John Shattuck, of Harvard University, observes that that order "could inhibit academic researchers from making long-term intellectual investments in nonclassified projects with features that make them likely subjects for classification at a later date." [15]

As discussed in chapters *3* and 4, the *use* of Export Administration Regulations and International Traffic in Arms Regulations to identify and control "gray areas" of research previously unclassified and usually not considered covered by those regulations has raised a number of questions about the potential of long-term adverse effects on the U.S. scientific base. Increasing the areas of unclassified but severely restricted information not only inhibits communication among colleagues who could benefit from interaction but may also point out to opponents those scientific areas of potential fast progress.

[13] Alan McGowan, Scientists' Institute for Public Information, New York, NY, personal communication, 1985,
[14] John w. Shattuck, *Federal Restrictions on the Free Flow of Academic Information and Ideas* (Cambridge, MA: Harvard University, January 1985).
[15] Ibid.

## IMPACT OF NEW COMMUNICATION TECHNOLOGIES

The information revolution creates new opportunities or methods for delaying or classifying information as well as opportunities for more open dissemination. "As long as there were significant delays in publication of new scientific results, the review process for commercially sponsored research offered only modest impediments to scientific openness." [16]

If recognized by the scientific community as a legitimate publication that signifies a claim to priority, publication on electronic networks could provide a new channel for scientific interaction. It could also have the effect of increasing the amount of classification of scientific information if, because of the speed of publication on such networks, the Government feels compelled to act quickly to classify without adequate information to justify such classification.

[16] Brooks, op. cit,

New technologies also give rise to questions about how much control an originator/creator has over the research project's results or data, its intellectual property. This issue is discussed in OTA's forthcoming report on intellectual property.

## PATENTS

Many observers propose the need for revision of the patent system because they believe that the existing policy inhibits the progress of science and stifles invention and innovation. Federal Government policy has been to retain title and rights to inventions resulting from federally funded research and development (R&D) made either by government contractors or grantees or by in-house government employees.[17] However, only about 5 percent of the 25,000 to 26,000 patents currently held by the government have been used.

A related issue is whether there is a need for a uniform government-wide patent policy. Several pharmaceutical firms have also begun to use the patent law to restrict research uses of patented products and procedures, even for experimental use (heretofore regarded as exempt).[18] Such action raises new questions about the interpretation of current law when there is competition in a fast-moving field and where the language of the law may be at variance with contemporary research practices.

An Organisation for Economic Co-Operation and Development (OECD) task force has recently recommended that OECD countries adopt the U.S. policy of making the date of conception, rather than the date of filing, the legal date of a patent. If this were followed, then pressure to keep data confidential pending patent filing would be much reduced because there would be a grace period of 12 months after publication for filing of a patent application. The main reason for delay of publication in most university-industry agreements is to allow time for filing for foreign patents. Revisions in the patent laws could therefore result in significant long-term effects on research.

[17] William C. Boesman, "Government Patent Policy: The Ownership of Inventions Resulting From Federally-Funded R& D," issue brief IB78057, Library of Congress, Congressional Research Service, Science Policy Research Division, 1985.

[18] Jeffrey L. Fox, "Patents Encroaching on Research Freedom," *Science*, vol. **224,** June **3,** 1984, p. **1080.**

## PUBLIC EDUCATION ON THE BASIS AND PROCEDURE FOR REGULATION

Understanding of and education in science play a vital role in the public's willingness to support the regulation of research. If the public understands the inadvertent and unintended effects of government regulations, then it may be more likely to support changes in policy which more accurately implement the intent of the law. Many observers have described to OTA a growing disassociation between what the public believes should be controlled and what the government actions are controlling. The government is presumed to be acting on behalf of the public, but, for example, is there evidence of public support for the increased controls being placed on scientific communication?

As the case studies presented in chapter 7 and appendix C show, how the public perceives or calculates the risks of research may greatly influence its willingness to control research and may similarly influence public beliefs about *when* controls or legal regulation should be imposed.

## SHIFT IN THE JURISDICTION FOR REGULATION

The discussions of such actions as the right-to-know legislation, the Arthur D. Little and Bellcore cases (chapter 7 and appendix C), and the animal experimentation controversy show that the public—through either community protest or referendum—can act to control, direct, or influence the topic choice, experimental procedures, or communication of science. Although the evidence is limited, such cases hint at the beginning of a jurisdictional shift in the regulatory arena for science, especially from the Federal to the State and local. This change may be a reaction to either real or perceived laxity in Federal regulations for health and safety protection, it may relate to broader issues of the exertion of local control over land use and community activity, or, in some cases, it does relate to the larger agenda of national political groups—e.g., protests linked to nationwide efforts to stop all nuclear power, abortions, or the use of animals in research.

This jurisdictional shift raises the spectre of a number of negative effects on research caused by inconsistencies or variations in the strictness of Federal and local regulations. **As** Allen G. Marr, Dean of the Graduate Division of the University of California, argued in a letter to OTA:

> Regulations promulgated uniformly on the basis of federal law are far superior to patchwork regulation by state law or local ordinance. Codes of ethical professional practice are art important complement but not a full substitute.

An issue raised by participants in the Arthur D. Little case (see ch. 7), was that protests over research involving hazardous chemicals might have the unintended result of segregating such research. States without the resources for developing comprehensive regulations (or for assuring compliance) might become dumping grounds for research no other States want.

Is there a need for a new jurisdictional framework by which Congress can deal with these issues, or are they best resolved at State and local levels"!

## GENERAL ISSUES

Underlying many of these issues are questions not resolvable through legislative activity but to which the Science Policy Task Force of the House Committee on Science and Technology, in its deliberations, should attend. Once societal constraints may be imposed, a fundamental question is that of what constitutes "research. " For example, does there exist some constitutional protection for research, and if so what does the legal definition of "research" include? Does it include not only thinking about a problem or talking to other scientists but also experimentation? The definition of what is or is not basic research currently plays a role in the dissemination of Department of Defense (DOD) -sponsored research results. Defining a project as falling within Federal budgetary category 6.1 (fundamental research), for example, can determine whether or how it is classified by DOD. '9 The definition of what is or is not research also plays a role in regulation of biomedicine. Experimental surgical procedures, for example, may be justified as therapeutic and not be subjected to review by an ethics committee. A medical researcher who refers to a project as a "pilot study" or as "innovation" can keep it outside such regulatory control mechanisms as IRBs.[20] Better understanding of these and other definitional questions will be essential to future attempts to resolve many of the issues mentioned above.

In setting an agenda for science, should policymakers look only to the potential benefits of the research proposed or should equal consideration be given, before funding, to the risk posed by the research? If so, what parameters should be used to make those determinations? Andre´ Hellegers once said that he, for example, would "assign a

[19] Janice R. Long, "Scientific Freedom: Focus of National Security Controls Shifting," *Chemical & Engineering News,* July 1, 1985, pp. 7-11.

[20] Arthur Caplan, The Hastings Center, Hastings-on-Hudson, NY, persona] communication, 1985.

very low priority" to any inquiry that "does not, in the *inquiry,* harm nature, but which may be dangerous in its consequence. . .".[21] Ruth Macklin made a similar point in her essay "On the Ethics of Not Doing Scientific Research" when she wrote:

> There is surely some disutility attached to an outcome that fails to benefit people who might otherwise have been helped by research. But unless we subscribe to a research imperative that places freedom of scientific inquiry above all other values when potential danger lurks, we need to examine closely the value dimensions of each instance of decisionmaking under certainty. 'z

To approach full understanding of this question, one must also consider what consequences—e.g., only the most probable or only the most negative—are to be included in such a determination and also what relative weights should be assigned to various potential outcomes. Is there not just one but a spectrum of possible ways in which society might use the results, and what relative weights can be assigned to the better or worse consequences?[23]

In setting funding priorities, Congress may increasingly have to confront determinations of what are the boundaries of control of science's overall agenda. Such questions have been raised in connection with the current shift toward military dominance of basic research funding and with the increased numbers of arrangements between universities and industry. Will such shifts result in increased, long-term restrictions on communication, and in controls on procedures as well as on agenda-setting? How might such changes affect—positively and negatively—the research process and the openness of scientific communication?

And, finally, as the case studies and many of the examples show, the flow of public information plays a significant role in the regulatory environment for science. There is, of course, an urgent need for truly sensitive information to be protected by the classification system, whether for reasons of military security or economic protectionism, and such arguments are equally valid for industrial or academic protection of intellectual property. Arbitrary and capricious use of secrecy and classification, however, may inadvertently damage the progress of science by inhibiting the free flow of information among researchers and the flow of information to the public. In the latter case, inadequate or incomplete information could, in fact, increase the probability of arbitrary regulation at the local level and, on matters relating to national policy debates, inhibit free political discourse.

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[21] André Hellegers, *Regulation of Scientific Inquiry,* Keith M. Wulff (cd. ) (Boulder, CO: Westview Press, 1979).

[22] Ruth Macklin, "On the Ethics of *Not* Doing Scientific Research, " *Hastings Center Report,* vol. 7, December 1977, pp. 11-15.

[23] "Brooksf op. cit.