Chapter 5

Mechanisms for Indirect Control of Research

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Mechanisms for Indirect Control of Research

Research can often be as effectively restrained by the secondary or tertiary impacts of laws or policies intended to do something else as by deliberate imposition of regulatory law or policy. Governmental activity can control the nature and direction of science even when regulations would seem to have very little to do with regulating the scientific enterprise.[1] In fact, many of the constraints that have been most burdensome to research institutions—both financially and administratively—were not intended to affect the substance of scientific work. Such constraints as the clerical and managerial burdens of social security taxes, equal opportunity and affirmative action requirements, environmental protection, or occupational health and safety "limit the autonomy of administrators and the freedom of research workers."[2] Research institutions that do not question the importance of such general domestic policy actions may nevertheless question the use of research grants or contracts and in particular the withholding of Federal funds in order to force an institution to comply. They argue that constraints are imposed not to sustain or ensure the quality of research but in an effort to secure "short-term practical results, regional distribution of funds, and other criteria more or less irrelevant to scientific excellence."[3] In these cases, science has not been so much singled out for regulation as caught up in society's growing willingness to regulate all kinds of specialized institutions and activities.[4]

The most pervasive control on the scientific agenda is, of course, the supply of money, but that control is uncoordinated. Such influences are more likely to result in what historian Melvin Kranzberg terms a "shotgun approach" to regulation via funding. This situation occurs when, in response to a new government program directed at a narrow topic (e. g., some form of cancer), researchers alter their research descriptions in order to obtain funding for basic or arcane research they are already pursuing.

This chapter looks at some examples of government laws or actions that, without so intending, appear to be exerting some regulatory influence on research. They can be distinguished from the forces discussed in chapter 4 by the fact that they are not intended to restrain or inhibit the process of scientific research. This chapter addresses first those forces that act both at the project and the institutional level through the grant and contract funding mechanisms of the Federal Government. Such restraints were among those most frequently mentioned in OTA's survey of university administrators and laboratory directors. A second type of restraint results from the implementation of legislation or rulemaking related to social programs, such as antidiscrimination statutes or privacy legislation, and from occupational and public health and safety legislation.

[1] Melvin Kranzberg, Georgia Institute of Technology, personal communication, 1985.

[2] Don K. Price, "Endless Frontier or Bureaucratic Morass?" *The Limits of Scientific Inquiry*, Gerald Holton and Robert S. Morison (eds.) (New York: W. W. Norton & Co., 1979), pp. 75-92.

[3] Ibid., pp. 75 and 81.

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

ADMINISTRATIVE REQUIREMENTS ON UNIVERSITIES THAT ACCEPT FEDERAL GRANTS OR CONTRACTS

In the last 40 years, rules governing the research grant system, the procedures for assuring accountability in the administration of such grants, and the system of Federal support to higher education in general have placed ever more administrative and legal requirements on the universities.[5] These requirements have stimulated considerable antagonism and hostility because many university

[5] David Dickson provides some discussion of the larger issues in *The New Politics of Science* (New York: Pantheon Press, 1984).

administrators have seen it as an intrusion into their autonomy. In the 1970s, Steven Muller expressed these feelings during congressional testimony when he called for universities to:

> . . . resist the tendency of the federal government to attach a growing body of regulations and conditions to its measures of support for higher education. . . . At stake is the essential need of the university to maintain the unfettered freedom of the human mind to apply its powers and methods of reason. [b]

To many observers, relations between the government and the universities appear to have deteriorated over the last decade; they attribute this change to policies and practices inherent in Federal support of research. These policies act as a form of indirect regulation on research. Under most conditions, Robert Sproull observes:

> . . . the principal investigator does not feel the weight of this pyramid on his back. Although no one has ever calculated how much more research could be supported if this towering apparatus was made leaner, the investigator can frequently ignore it all. There is a growing intrusion, however, into the control of an investigator's research.7

A major change in public control of science—and a handle for enforcing regulation—has been the increased requirement for financial accountability imposed by the Federal Government. The post-war "contract" between government and science allowed scientists, through the process of peer review, to make decisions about the allocation of government funds to specific projects, but required that universities be accountable fiscally to the government. The universities do not argue over the need for accountability, rather about how it can be accomplished. This indirect regulation derives in part from the retroactive application of increased standards and from the interpretations applied to key principles contained in indirect cost calculation, and Office of Management and Budget (OMB) Circulars A-21 and A-110.

Indirect costs. Donald Kennedy, President of Stanford University, has referred to the university-government indirect cost reimbursement system as "the basic fabric of understanding and trust that has supported science for 30 years."[8] During those decades, "government policy has held indirect costs to be an entirely legitimate part of total research costs, " but as these cost rates have increased, and the resources for research at the Federal level have become more constrained, the rates-–and the accounting necessary to calculate them-–have become an increasing source of tension, Many university administrators and scientists argue that the process of including an indirect cost rate in a research proposal significantly affects research because it can act to array a principal investigator and his/her sponsor or granting agency against the institution—a polarization that is "damaging to morale and, ultimately, to research."9

Indirect costs are paid as grant overhead to institutions to cover maintenance, administrators' salaries, and other operating expenses. A 1984 General Accounting Office (GAO) Report calculated that, in the last decade, indirect costs have increased so much that they now account for about 30 percent of all National Institutes of Health (NIH) extramural grant expenditures (up from 21 percent in 1972) .[10] Each institution receiving a grant negotiates its rate. The Department of Health and Human Services (DHHS) may audit an institution to determine whether indirect cost claims are valid. OMB's Circular A-21 "Cost Principles for Educational Institutions" lists allowable categories of indirect costs. Government rules allow for the varying circumstances of institutions, but they do require that methods used for calculations be consistent with sound accounting principles. The disagreement over the reality of indirect costs, and what the costs of research should include, form a major part of the problems surrounding this topic.

Indirect cost rates are based on the most recent actual expenditures for indirect costs. The costs

[6] Steven Muller, "A New American University, " testimony before the U.S. Congress, House Committee on Science and Technology, published as *National Science and Technology Policy Issues, 1979.*

[7] Robert L. Sproull, "Federal Regulation and the Natural Sciences, " *Bureaucrats and Brainpower: Government Regulations of Universities,* Paul Seaburg (ed,) (San Francisco, CA: Institute of Contemporary Studies, 1979), p. 72.

[8] Donald Kennedy, "Government Policies and the Cost of Doing Research, " *Science,* vol. 227, Feb. 1, 1985, p. 482.

[9] Sproull, op. cit.

[10] National Academy of Sciences, *Strengthening the Government-University Partnership in Science* (Washington, DC: NAS, 1983), p. 129.

rates are recomputed annually and submitted to a granting agency for evaluation, which uses one of two main systems for determining and reimbursing indirect costs. The NIH requires that principal investigators submit proposals that specify only the direct costs of the research proposed, Peer reviewers see only the direct cost budget. A separate award is made to the institution for indirect costs. Other agencies, such as the National Science Foundation (NSF), the Department of Defense (DOD), and the National Aeronautics and Space Administration (NASA), require that proposals include both direct and indirect costs, and reviewers see the complete budget. If an award is made, the approved budget must be based on the last negotiated indirect costs rate for the institution on the grant. If this rate is out of date (as can occur), then rising indirect cost rates can limit the funds available to a researcher on a project-by-project basis.

As indirect cost rates rise, research budgets buy less. Some researchers "consider payment of indirect costs a subsidy for higher education and a diversion of support for research."[11] University administrators, however, see indirect cost recovery as essential to maintaining the research infrastructure.

Budget Circulars A-21 **and** A-110. Relations between the universities and the Federal Government were strained considerably in 1979 as a result of revisions to OMB Circular A-21 (Cost Principles for Educational Institutions). In order to allocate indirect costs, the universities were required to institute "time and effort" reporting for employees whose salaries were charged in any part to the research grant. The rule required faculty to account for 100 percent of the time for which they were compensated, regardless of the fraction devoted to federally supported work. Although the OMB believed these procedures to be necessary to determine if research funds were being used for the purposes designated by Congress, academic scientists considered them a violation of their autonomy. Emotions ran high. A. Bartlett Giametti, President of Yale, proclaimed: "Never have I seen the lash of federal regulations applied to a crucial area of the nation's intellectual life with such seeming indifference to financial and human consequences."[12] The stringency of these OMB requirements has since been relaxed somewhat. In fall 1982, for example, DHHS awarded 22 contracts to large universities to test a procedure whereby coordination audits would be carried out by public accounting firms and university auditing staff. For research administrators, this change meant added responsibility and the imposition of a cost previously borne by the Federal granting agency, but it allowed the independent auditors to conduct an audit that better reflects the research environment in the institution under investigation. This single-audit concept, now allowable for all grantee institutions under 1982 revisions to Circular A-21, provides for greater flexibility in university reporting of time and effort, Some universities, Yale University and Stanford University, in particular, have negotiated agreements with OMB that allow them to eliminate time and effort reporting for the time being. '3

Concerns about the regulatory nature of the Federal grant relationship date back to the 1960s. A U.S. Commission on Government Procurement—set up in response to widespread concern about grants and contracts administration rules—found that procurement-type Federal controls were being inappropriately applied to grant-type assistance relationships. The Commission's recommendations to deal with this problem were implemented eventually in the Federal Grant and Cooperative Agreement Act of 1977 (Public Law 95-224), which distinguished Federal assistance from Federal procurement and required that grant relationships entail minimal government involvement in grantee affairs. However, OMB guidance issued to implement the act failed to require that Federal agencies use the grant in the fashion envisioned by the act, thereby vitiating its regulatory-reducing effect .14

[11] U.S. General Accounting office, *Assuring Reasonableness of Rising Indirect Costs on NIH Research Grants—A Difficult Problem* (Washington, DC: 1984).

[12] See discussion of these agreements in *Report of the Workshop on the Effort Reporting Requirements of OMB Circular A-21* (Washington, DC: National Academy of Sciences, 1984).

[13] Quoted in Dickson, op. cit., p.98.

[14] Robert Newton, National Science Foundation, personal communication, 1985.

In the late 1970s, the National Commission on Research concluded that the administrative and fiscal controls used by Federal agencies in the support of academic research interfered with the conduct of research. During the same period, NSF and the Association of American Universities conducted an experiment in grant administration that resulted in NSF delegating to grantees the responsibility for administering most Federal controls. More recent discussions have focused on problems caused by discrepancies between Federal rules, and so there are proposals now for a simplified and standardized Federal approach to the support of academic research. Such an approach might reverse or remedy the fragmentation of research programs caused by multiple sources of Federal support, might reduce overall research costs, and might increase research productivity. Federal administrative and accounting rules might begin to match the realities of how research is conducted. One way would be to recognize the researcher's program of research as the administrative and accounting unit. Under the aegis of the National Academy of Sciences Government-University-Industry Research Roundtable, a Federal effort is being undertaken to demonstrate such a simplified arrangement, including a demonstration project for the Federal support of academic research in Florida.

PROTECTIVE LEGISLATION AND AGENCY RULEMAKING

Antidiscrimination Statutes

Several statutes bar recipients of Federal financial assistance from excluding persons, because of their color, race, sex, or national origin, from participation in federally supported activities. These antidiscrimination statutes apply to recipients of NSF and NIH grants and compliance must be assured prior to receipt of funds.

Section 602 of the Civil Rights Act of 1964 requires Federal agencies and programs to issue regulations implementing Title VI of the Civil Rights Act. The act provides that no person shall, on the grounds of color or national origin, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program or activity receiving Federal financial assistance. These regulations are also applicable to sub-grantees, contractors, and subcontractors of a grantee. Grant applicants must issue an "Assurance of Compliance" to be filed with the agency. * Similar assurances must be filed by the grantee to assure compliance with the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.

Title 1X of the Education Amendments of 1972 prohibits the exclusion of persons on the basis of sex from any education program or activity receiving Federal financial assistance. NSF interprets this to apply to grants under their Science Education Programs but not to grants for scientific research. Public Health Service (PHS) grantees, however, are required to submit an assurance to the Office for Civil Rights, Office of the Secretary, DHHS, before a grant, sub-grant, or contract under a grant maybe made. In addition, all PHS grantees are encouraged to "adopt practices that will eliminate sex discrimination and encourage sex fairness, including but not limited to, using language that represents both genders, avoiding sex stereotyping, and representing women equitably in leadership and policymaking positions. "

*See National Science Foundation and National Institutes of Health Grant Policy Manuals.

Small Business Innovation Research Programs and Use of Services Regulations

Federal research funding and how the grantees use those funds are subject to laws and guidelines that are intended to promote opportunities for small businesses and minority-owned businesses, and to favor American businesses over foreign interests. Under Public Law 97-219 (the Small Business Innovation Development Act) each agency with a qualifying research and development (R&D) budget in excess of $100 million must establish a Small Business Innovation Research Program (SBIR). Each agency must set aside 1.25 percent of its extramural R&D obligations for its SBIR

program. The SBIR program is intended to provide a mechanism for opening up Federal R&D opportunities for small high-technology firms. The Departments of Agriculture, Energy, Transportation, and Interior; the National Research Council; the Environmental Protection Agency (EPA); DOD; DHHS; NASA; and NSF are all required to participate in this program. In addition, funds flow indirectly to small firms through the subcontracting requirements of Public Law 95-507, which requires that large prime contractors must subcontract part of their Federal work to small firms.

Executive Order 12138 of 1979 establishes a national program to foster the role of women in business, by encouraging preference in procurement and the deposit of Federal funds. Executive Order 11625 of 1971 strives for the same goals for minority-owned businesses. Recipients of NSF grants are also encouraged, but not required, to use banks owned at least 50 percent by minority groups or women. In addition, according to the International Air Transportation Fair Competitive Act of 1974, grantees must use a certified U.S. flag carrier for foreign transportation of persons or property, for purposes of the research, unless not available.

Privacy Legislation

The Privacy Act of 1974 (Public Law **93-579)** provides certain safeguards for individuals against invasions of personal privacy. These include: 1) the right of individuals to determine what information about them is maintained in Federal agencies' files and to know how that information is used; and 2) the right of individuals to have access to such records and to correct, amend, or request deletion of information in their records that is inaccurate, irrelevant, or outdated .15

The act imposes requirements on Federal agencies with respect to the manner in which they collect, use, disseminate, and maintain records containing information pertaining to specific individuals. Thus, information obtained for one purpose cannot be used for other purposes without the consent of the concerned individual. This regulation applies to records maintained by PHS with respect to grant applications, grant awards, and the administration of grants, as outlined in DHHS regulations that implement the Privacy Act.[16] Records maintained by grantees, however, are not subject to these regulations.

"Public Health Service, "Grants Policy Statement, " December 1982, p. 15.

[16] 45 CFR 5b.

ENVIRONMENTAL LEGISLATION

Until the end of 1984, EPA regulations for the control of hazardous wastes under the Resource Conservation and Recovery Act (RCRA)[17] had limited influence on some research activities, because they established regulatory exemptions for "small quantity" generators[18] but held all other generators subject to the full range of regulatory requirements. To avoid regulatory costs and other burdens, many research institutions sought to stay within EPA's limit for small quantity generators. Chemical associations also promoted the concept and practice of waste stream reduction in process industries and laboratories. 1[9] In November 1984, amendments to RCRA severely limited these exemptions by requiring EPA to regulate generators of as little as 100 kilograms a month .20 It will be more difficult for research facilities to avoid RCRA regulations in the future.

Other laws administered by EPA have led to further unintentional regulations of research activities. Research laboratories that emit air and water

[17] 42 U.S.C. Sections 6901 et seq

[18] 40 CFR Part 261,

[19] See *Less Is Better: Laboratory Chemical Management for Waste Reduction* (Washington, DC: American Chemical Society, 1985).

[20] 42 U, S.C. Sections 6931(D), added by Public Law 98-616 (1984).

pollutants are subject to EPA regulations under the Clean Air Act[21] and the Clean Water Act,[22] as well as corresponding State statutes. Researchers will have to secure permits and comply with EPA and State permit restrictions on the discharge of these pollutants. These "end-of-pipe" emission restrictions can influence the research process significantly, especially when the research involves highly toxic substances.

Laboratory research in industry, universities, and government may also be affected by such things as EPA regulations on disposal of hazardous waste, health regulations set by the State or city in which the laboratory is located, and regulations on handling nuclear and other hazardous substances.

[21] 42 U.S.C. Sections 7401 et seq.
[22] 33 U.S.C. Sections 1251 et seq.

OCCUPATIONAL AND PUBLIC HEALTH AND SAFETY REGULATIONS

As will be illustrated chapter 6, government regulations intended for business and industry can have quite different effects when applied to laboratory-based, university research activities. Richard W. Lyman has observed that "universities are not quite the uniquely subtle and complex organisms they like to consider themselves, but they do possess a good many characteristics that make regulations suitable to a steel mill not always relevant or appropriate [to a university]."[23] Most of these regulations are of two types: regulations designed to apply to production, or pilot plant activities and regulations aimed at achieving some social goal.

Some observers propose that, in principle, the cost imposed on various economic or research activities by regulation should be proportionate to the potential environmental, health, or safety impact of these activities; but others disagree sharply with the argument that such regulation takes industrial financial resources away from research, and cite a lack of evidence for those effects.[24]

The protection of worker health is required by such legislation as the Occupational Safety and Health Act,[25] by the Occupational Safety and Health Administration (OSHA), and by other regulations.[26] The act concerns the general duty of employers to provide safe working conditions for their employees and for employer compliance with OSHA regulations. The regulations limit worker exposure to various physical, chemical, and other agents and hazards to health and safety, such as noise, radiation, or toxic chemicals. In addition to requirements for recordkeeping, medical surveillance, and monitoring, the regulations also set forth, on a generic basis, employee rights to request OSHA inspections and to obtain access to medical records, exposure records, and labels on hazardous chemical containers.

Right- To-Know Legislation

The need for people to obtain information on the risks they run by working with hazardous chemicals has recently prompted more specific legislation, which could have a significant unintended regulatory impact on research laboratories, especially those based in universities. Although current Federal regulations in this area do not apply to such laboratories, the recent State and proposed Federal "right-to-know" legislation could have the secondary effect of creating new controls on university laboratories. These laboratories work with hundreds of chemicals in an experimental situation or do research on hazardous chemicals.

[23] Richard Lyman, quoted in Seaburg, op. cit.
[24] Brooks, Op. cit.; for a general discussion of the effect of health and safety regulation on R&D, see, for example, Nicholas Ashford and George Heaton, "Regulation and Technological Innovation in the Chemical Industry," *Law & Contemporary Problems*, vol. 46, No. 3, summer 1983, pp. 109-137; also see Nicholas Ashford, et al., "Using Regulations to Change the Market for Innovation," *Harvard Environmental Law Review, vol. 9, No. 2, 1985.*
[25] 29 U.S.C. Sections 651 et seq.
[26] 29 CFR part 1900.

In November 1983, OSHA issued a "hazard communication" rule,[27] which establishes that workers in the manufacturing industry have a right to know about the chemical and physical hazards in their workplaces. Manufacturers and importers of hazardous chemicals, and their customers who use the chemicals in subsequent manufacturing activities, thus have disclosure duties under the rule.

The rule initially requires that manufacturers and importers of chemicals provide their customers with labeled containers and a Material Safety Data Sheet (MSDS) for each purchased chemical that has been determined to be hazardous. It also requires that all firms in the manufacturing sector—both "downstream" customers and chemical manufacturers themselves—institute hazard communications programs to provide information to and train workers who could potentially be exposed to the chemicals.

The rights created by the OSHA rule do not currently extend to workers in research laboratories that are not within the manufacturing sector. For research laboratories within the manufacturing sector, however, employers must:

- ensure that labels on incoming containers of hazardous chemicals are not removed or defaced;
- maintain any MSDSs that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible to laboratory workers; and
- provide laboratory workers with information and training on hazardous chemicals in their work areas at the time of their initial assignment, and when a new hazard is introduced into their work area.

Chemical manufacturers must comply with its labeling and MSDS requirements by November 25, 1985. Employers, thereafter, must meet the worker communication requirements by May 25, 1986.

The rule provides that it is intended to preempt any state law pertaining to this subject, although the OSHA administrator has indicated that OSHA would not assert preemption over any State rules until the effective date of the Federal standard (Nov. **25, 1985).** Nevertheless, in the past 3 years, numerous State and local governments have enacted right-to-know laws and ordinances. These enactments can be classified as follows:

1. Worker *right-to-know* laws are designed to expand the rights created by OSHA by giving workers in other sectors access to technical information concerning the hazardous substances to which they are exposed, and by increasing the list of hazardous substances to which such access rights apply.
2. *Comprehensive community right-to-know* laws are designed to give local officials and/or residents access to technical information concerning hazardous substances at facilities within a community, without regard to the use to be made of that information.
3 *Limited community right-to-know* laws are designed to give specified local officials access to technical information concerning hazardous substances at facilities within a community, for the purpose of facilitating appropriate responses in the event of emergency and/or protecting emergency response personnel.

Such laws are likely to face a legal challenge on the grounds that right-to-know requirements have been preempted by the OSHA rule.[28] Like the OSHA rule, typical State right-to-know laws are limited in their application to a specific list of hazardous substances, rather than to hazardous substances generally. For example, the Massachusetts law[29] directs its Commissioner of Public Health to compile a substance list. The initial list included approximately 2,000 substances.

New Jersey's law[30] has been challenged, and found invalid by a U.S. District Court, in its application to the manufacturing sector, due to OSHA preemption.[31] It is still in effect for other

[27] 29 CFR Sections IQ IO. 1200

[28] See, for example, *New Jersey Chamber of Commerce v. Hughey, 12* OSHC 1121 *(t).* N.J., Jan, 3, 1985), which invalidates New Jersey's right-to-know law insofar as it applied to manufacturing industries.

[29] Massachusetts General Laws c 11 IF.

[30] Chapter 315 of the Acts of 1983,

[31] *New Jersey Chamber of Commerce v. Hughey,* op. cit.

industries, however, and requires State agencies to compile three sets of lists: a short list of "Environmental Hazardous Substances" (now approximately 154 substances); a more comprehensive list of "Workplace Hazardous Substances" subject to less thorough reporting requirements (about 800-1,000 substances); and a "Special Health Hazard" list of substances that pose special hazards because of their known carcinogenicity, mutagenicity, teratogenicity, flammability, explosiveness, corrosivity, or reactivity.

The New Jersey law, as still valid, applies to research laboratories that are part of facilities engaged in:

- pipelines, transportation, communications, electric, gas, and sanitary services;
- wholesale trade, nondurable goods;
- automotive repair, services, and garages;
- miscellaneous repair services;
- health services;
- educational services; and
- museums, art galleries, botanical, and zoological services.

The law also applies to State and local governmental laboratories. By exclusion, therefore, the law does not apply to retail trades, the professions, most service industries, and R&D laboratories that are not part of a covered facility.

The Massachusetts law, as yet unchallenged and now being implemented, exempts research laboratories not involved in the production or manufacture of goods for direct commercial sale.

Comprehensive right-to-know laws, of course, are far less restrictive. Massachusetts, for example, requires that an MSDS for each substance at an installation be filed with the Department of Environmental Quality Engineering (DEQE) and, on request, with a designated municipal coordinator from the community in which the installation is located. Thereafter, any community resident who has reason to believe that a hazardous substance may be endangering public health or safety may request an investigation by the municipal coordinator. If an investigation is deemed necessary, DEQE can provide relevant MSDSs to the petitioning resident in appropriate cases. The investigation is intended to ascertain what, if any, State or local action is necessary to protect the health or safety.

The New Jersey law is even less restrictive. It requires employers to submit environmental surveys to the Department of Environmental Protection (DEP) and the health department of the county in which the facility is located, as well as pertinent parts of the survey to local fire and police departments. Any person making a written request would obtain a copy of the survey from the DEP. In addition, a list of workplace hazardous substances at each installation and the MSDS for each one were to be maintained by the Department of Health and made available on request to any person.

In the 99th Congress, a number of legislative proposals have sought to extend community right-to-know and accident control provisions. H.R. 963, introduced February 6, 1985, by Representative James Florio (D-NJ), would amend the Occupational Health and Safety Act of 1970 to permit States to adopt more stringent right-to-know provisions for access to information. The "Chemical Manufacturing Safety Act of 1985, " H.R. 965, also introduced on February 6, 1985, by Representative Florio, amends the Toxic Substance Control Act to add provisions concerning a community's right to know of the risks, emergency planning, and liability for hazardous substances releases. Research laboratories and hospitals are exempt, if the substance is used under the direct supervision of a technically qualified person.

H. Con. Res. 53, introduced by Representative Bob Edgar (D-PA), is a concurrent resolution expressing the sense of the Congress that all persons have a fundamental right to know when they are exposed to hazardous substances that may be dangerous to their health. In part it declares that the Assistant Secretary for Occupational Safety and Health should immediately revise the hazard communication standards to extend right-to-know protection to employees in any service or industry that employs hazardous substances and that the Federal right-to-know standards should set only the minimum requirements that the States must follow. On March 6, 1985, Senator Alfonse D'Amato (R-NY) introduced S. 606, the "Community Right to Know Act of 1985 ." It provides

for the annual notification to a city or county of the presence of hazardous substances in or near such city or county (within a lo-mile radius) by the owner or operator of such a facility.

On March 21, 1985, Representative Robert Wise (D-WV) introduced H.R. 1660, the "Hazardous Materials Manufacturing Safety Act of 1985." Similar to H.R. 965, the bill would amend the Toxic Substance Control Act to add provisions concerning a community's right to know of the risks, emergency planning, and liability for hazardous substances releases. And finally, H.J. Res. 225, "The Hazardous Substances 'Right-to-know' Resolution, " introduced by Representative Bruce Vento (D-MN) on April 4, 1985, mirrors the H. Con. Res. 53 expression of a person's fundamental right to know when they are handling or are exposed to a hazardous substance that may threaten their health and well-being. It also declares that OSHA should immediately revise its Hazardous Communication Standard to extend "right-to-know" protection to all workers in industries and services and that the Federal standards should only be minimum requirements that the States must follow. *

*These legislative initiatives contrast sharply with the political assumptions directing similar European efforts, where public disclosure is limited, In 1979, the European Community adopted a Directive, commonly called the Sixth Amendment, containing provisions for the testing of chemicals to be placed on the market, and for the notification to governments of the results of such tests, as well as for chemical classification, packaging, and labeling. The Sixth Amendment requires an importer or manufacturer proposing to place a new chemical on the market to submit a premarket notification to the appropriate regulatory body of the member nation where the substance is produced or imported. The notice must contain health, environmental, and physio-chemical test data on the substance, estimated volume and uses, and recommended precautions. On the basis of the data submitted, packaging and labeling requirements may be imposed, Exempted are substances subject to other regulatory programs, such as medicinal and radioactive substances, waste substances and pesticides, research substances for evaluation, and substances marketed in quantities less than 1 metric ton per year per manufacturer.

The most important European Community enactment on risk communicant ion for the control of chemical accident hazards is the "Seveso Directive. " This Directive is named for the town in Italy where explosions at a Hoffman-LaRoche plant in 1976 spewed dioxin into the community, necessitating removal and testing of its inhabitants.

Adopted in 1982, the Seveso Directive is to be fully implemented by the member nations in 1989. Under the directive, a manufacturer who conducts activities which involve one or more of 178 designated substances must provide to the competent national authority: information on the substances and the processes used, information on the installation (facility), information on possible major accident situations, new information relevant to safety and hazard assessment on a periodic basis, and special information on multiple installations close to dangerous substances.

Each member nation is required to designate a competent authority who will be responsible for receiving the information from the manufacturer, examining it, requesting additional information, developing an off-site emergency plan, organizing inspections, and determining that the manufacturer takes the most appropriate steps to prevent major accidents and limit accident consequences. The directive thus represents the most complete and integrated approach taken to date to prevent chemical accident hazards. The directive reflects European values in vesting full responsibility for public safety in public officials, in restricting the flow of risk information to protect industrial secrecy, and in affording citizens and interest groups no access to the risk communication process or to the information outputs of the process.