Chapter 7

Community Control of Research: Two Case Studies

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Community Control of Research: Two Case Studies*

This chapter describes two cases involving precedent-setting interventions into scientific inquiry by a local government in Massachusetts. The first describes the city's two-phase regulation of recombinant DNA molecule technology—in 1977, passage of the country's first law regulating rDNA research, and in 1981, a revised law, enacted in response to research and development (R&D) activities of newly established biotechnology firms. The second case describes the city's efforts to proscribe the handling and testing of certain chemical warfare agents by a consulting firm under contract with the Department of Defense (DOD). The public controversy over the second case was kindled in October 1983 and has been the subject of litigation since March 1984 when the city promulgated its first regulation.

The case studies that follow describe the events leading up to the respective regulations, discuss the possible national impacts of these types of cases, and survey the arguments presented in favor of and opposed to local regulation of research. The report also examines the general policy implications of these cases on the issue of freedom and accountability in the conduct of scientific research.

RESEARCH INVOLVING RECOMBINANT DNA MOLECULES

The controversy in Cambridge, Massachusetts, over research involving the use of recombinant DNA molecules began in Spring 1976. At that time, the administration of Harvard University was considering a proposal for the renovation of one of its biological laboratories. The purpose of the renovation was to construct a facility that would conform to requirements of the National Institutes of Health (NIH) for performing certain classes of rDNA experiments, designated at the time as "moderate risk." NIH was also in the process of issuing guidelines that defined six classes of gene-splicing experiments: research exempted under the guidelines; P-1; P-2; P-3; P-4; and research prohibited under the guidelines. The planned Harvard laboratory was expected to meet the performance and physical containment specifications of a P-3 facility, designed to provide a protective barrier against the release of experimental organisms. A laboratory of this type required several hundred thousand dollars in equipment and special construction techniques.

When plans for the $380,000 research laboratory were being discussed by the university administration, several Harvard scientists questioned having an rDNA facility in a densely populated area close to other research and teaching activities. The issue was taken up by Harvard's university-wide Committee on Research Policy. The Committee responded by holding an open meeting for the Harvard community which was also attended by a member of the Cambridge city council and a reporter from a weekly newspaper, *The Boston Phoenix.* A news story on the meeting, "Biohazards at Harvard' '-the first media report of the controversy surrounding the new laboratory—appeared in the Phoenix on June 8, 1976.1 Troubled by the story, Cambridge Mayor Alfred Vellucci decided to hold hearings on rDNA

*This chapter was prepared by OTA staff, based largely on work performed under contract for OTA by Sheldon Krimsky and on reviewer comments thereon. Dr. Krimsky is Associate Professor in Urban and Environmental Policy, Tufts University, and in **1984** was appointed Chairman of the Cambridge Scientific Advisory Committee that played a major role in the Arthur D. Little controversy detailed in this chapter. Professor Krimsky's contract report was reviewed by numerous experts, both within and outside of OTA, includlng Arthur D, Little, Inc. , and other participants in the controversy.

'Charles Gottlieb and Ross Jerome, "Biohazards at Harvard, " *Boston Phoenix,* June **8, 1976,**

research at Harvard. Mayor Vellucci was supported and advised by several scientists in the city, including some of Harvard's own faculty. [2] When the city council held hearings on June 23 and July 7, 1976, scientists and physicians affiliated with Boston-area universities and hospitals were among those who testified. Academic and biomedical research centers outside of Cambridge, contemplating rDNA research at the P-3 level, were concerned that the imposition of a city-wide ban on certain rDNA experiments would eventually affect their own institutions.

Harvard's Committee on Research Policy agreed unanimously that the research should proceed despite its potential hazards. According to the Committee, the new facility provided a sufficient margin of safety. Harvard set up a parallel review committee comprised exclusively of scientists. Known by the name of its chairman, the Branton Committee also issued a favorable response to the proposed rDNA facility. On June 14, 1976, a week prior to the first Cambridge hearing, the Harvard Corporation authorized construction of the P-3 laboratory.[3]

Subsequent to the public hearings, the city council, frustrated by the technical complexity of the issues and perplexed by the polarization of viewpoints, voted on the recommendation of one of its members to establish the Cambridge Experimentation Review Board (CERB). The city council order contained no specifications about the composition of the citizen board, leaving the appointments to the discretion of the city manager. The city council also requested that Harvard and the Massachusetts Institute of Technology (MIT) accept a 3-month, good-faith moratorium on any P-3 level rDNA research. Both universities accepted the moratorium, thus giving the newly established review board an opportunity to evaluate the risks. Since the new laboratory was expected to be completed by the spring of 1977, the city's moratorium on research did not postpone any work. However, Harvard proceeded with the laboratory's construction without assurances that an occupancy permit would be issued.

Members of CERB were appointed by the city manager in late August 1976. The manager consciously avoided the appointment of any biologists to the nine-member committee on the grounds that they were already divided on the question. (Initially appointed as a full member, the Commissioner of Health and Hospitals subsequently became ex officio.)

CERB met over a period of 4 months between September and December 1976. Harvard and MIT agreed to a 3-month extension to the good-faith moratorium on P-3 experiments otherwise scheduled to elapse in September, The citizens' committee issued its report to the city manager and the Commissioner of Health and Hospitals in January 1977. The report stated that P-3 rDNA research may be permitted on the stipulation that additional safeguards be added to the requirements of the NIH guidelines. CERB also recommended passage of a new ordinance that included the creation of a Cambridge Biohazards Committee (CBC) to oversee all rDNA research in the city. The committee's recommendations were enacted into law on February 7, 1977. The law was not subjected to legal challenge by any of the affected parties. Overall, public reaction to the outcome was favorable and controversy subsided quickly.

A second debate over rDNA activities erupted in Cambridge during 1980. This time the issue was over R&D activities in genetics. Biogen, a newly formed Swiss biotechnology firm, seeking its commercial and management headquarters in the United States, chose a site in an area of Cambridge zoned for manufacturing and light industry. Undaunted by the city's reaction to rDNA experiments 4 years earlier, Biogen officials notified the city manager and the health commissioner of the firm's interest in selecting a site and its willingness to conform to all Federal and local regulations.

CBC called a public hearing on October 28, 1980. Unlike the first rDNA debate, public opposition was mild. No biologists testified against siting the new biotechnology facility or spoke in support of additional local controls. Furthermore,

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[2] For a detailed account of Cambridge, MA's involvement in the rDNA controversy, see ch. 22, Sheldon Krimsky, "Local Initiatives for Regulation, " *Genetic Alchemy: The Social History of the Recombinant DNA Controversy* (Cambridge, MA: The MIT Press, 1982).

[3] Marc M. Sadowsky, "Rosovsky Approves DNA Research Lab, " *Harvard Crimson,* June 15, 1976. Also, Richard Knox, "Harvard and Genetics Controversy, " *Boston Globe,* June 22, 1976.

beyond those employed by Biogen, Boston-area scientists were not present at the hearing. Public reaction centered around the release of genetically modified biological agents into the air and water, particularly when cultures of rDNA molecules were prepared in large scale.

In response to public anxieties over commercial gene splicing, the city manager once again called on the Cambridge Experimentation Review Board to respond. Since CBC was responsible for implementing the rDNA ordinance, CERB considered it wise to involve this body in any decisions on revising the law. Thus, CERB chose to hold its hearings in collaboration with CBC. The joint committee developed a consultative relationship with representatives of Biogen, Harvard, and MIT. After several months of hearings and deliberations, the CERB-CBC review panel issued recommendations emphasizing safeguards against the promiscuous release of genetically modified organisms and, to a somewhat lesser degree, against occupational hazards. The Cambridge city council voted the recommendations into law on April 23, 1981. In contrast to the extensive publicity surrounding the passage of the first rDNA law, this new enactment was accompanied by little public discussion, and was only mildly acknowledged by the national media.

The new law established a permit system for all institutions intending to use recombinant DNA molecule technology. The ordinance distinguishes between small scale and large scale permits, the latter being required for cultures of geneticall, modified organisms in volumes greater than 10 liters. The deliberate release into the sewers, drains, or the air of any organism containing rDNA molecules is prohibited. For fermentation processes, the law also requires effective sterilization of spent organisms before they are released into the waste stream.4

During the second rDNA debate, the city convened a citizen review process while Biogen was in the planning stages of siting and constructing its new facility. None of the firm's research was held up as a consequence of the city's deliberations. Similarly, Harvard's P-3 laboratory was scheduled for completion in the spring of 1977, several months after the city's moratorium on P-3 experiments was terminated. Neither of the two Cambridge rDNA laws was subjected to a legal challenge. The universities considered that option but favored a negotiated settlement that avoided litigation. The 1981 Cambridge rDNA law is still in effect and is administered by the Commissioner of Health and Hospitals, who currently heads the Cambridge Biohazards Committee.

[4]A brief history of the passage of rDNA legislation in nine cities and towns (including Cambridge, MA) and two States is presented in Sheldon Krimsky, et al., *Municipal and State Recombinant DNA Laws* (Medford, MA: Tufts University, June 1982)

TESTING CHEMICAL WARFARE AGENTS

The second case centers around Arthur D. Little, Inc. (ADL), a multi-faceted management and technology consulting firm with its world headquarters in Cambridge, Massachusetts. The firm, which has been operating in Cambridge since the early part of the century, has offices in Europe, Canada, and South America, and a work force of 2,500.

Around June 1982, ADL decided to renovate an existing chemical laboratory with state-of-the-art safety features that would enable the firm to take on work with highly toxic chemicals. The renovated laboratory was designed to meet the specifications of DOD for working with "chemical surety materials, "—chemical warfare agents—consisting mainly of nerve and blister agents.

The company's investment in the laboratory exceeded $750,000. The Philip L. Levins Laboratory was planned to occupy 1,300 square feet in ADL's Acorn Park, a 40-acre complex located at the northern boundary of Cambridge, near the adjoining towns of Arlington and Belmont. Because of the extensive renovation required, ADL applied for and was issued a building permit on December **10, 1982.** Approximately a month later, ADL personnel met with the Cambridge city manager,

the fire chief, and officials of the police department to inform them about the new testing facility. Notification of the police was in conformity with DOD stipulations; surface shipments of the chemical nerve and blister agents require a police escort. ADL disclosed the general nature of the facility and indicated that, among its functions, it would be used for testing chemical agents supplied by the army. According to an official of ADL, the company was not requested to provide "specific names and toxicities of the materials it was planning to test in the new laboratory."[5]

ADL requested that city officials keep confidential the location of the laboratory and the type of work to be undertaken there. Public safety considerations were given by the firm as the reason it requested nondisclosure. The firm maintained that its policy of confidentiality would reduce the chances that the laboratory would be a target for vandalism or terrorism. The city manager, police, and fire chiefs complied with the request. ADL filed for an occupancy permit on May 18, 1983. The certificate of occupancy was issued on May **25.** The laboratory was approved for operation by DOD on September 19, 1983.

Responding to the cooperative arrangement that existed between the fire departments of Cambridge and its neighboring towns, ADL also contacted officials of Arlington and Belmont in September 1983 to inform them of the new facility. At a meeting with Arlington's town manager, officials of the police and fire department, and the town's civil defense officer, ADL continued its policy of requesting confidentiality about the nature of its facility.

Arlington's town manager, however, informed ADL that he planned to introduce the issue of the laboratory at the upcoming meeting of the town selectmen. On that same day, October 14, 1983, ADL issued a press release announcing the establishment of a laboratory to be used for "advanced chemical analysis of toxic and hazardous chemicals so as to develop improved methods for detecting, identifying, and detoxifying such materials and new means of protecting people from them. " The news release omitted any mention of chemical nerve or blister agents. On October 20, 1983, the story of the laboratory was reported in the *Arlington Advocate* and the Boston *Globe.* The Globe speculated that chemical warfare agents may be among the agents handled at the facility. On October 17 and 24, 1983, respectively, the Arlington selectmen and the Cambridge city council held public meetings at which the ADL matter was discussed.

At the October ***24*** Cambridge council meeting, the nature of the chemical warfare agents supplied to ADL under DOD contract was disclosed by company officials. By that time, the company had begun work on the DOD contract. The council also heard residents of the North Cambridge community voice a strong protest against ADL's testing of chemical nerve and blister agents adjacent to a densely populated area. In response to public concerns, at the same meeting the city council voted to establish a "citizens' scientific advisory board" to review the risks associated with the ADL laboratory. Individual councillors requested that ADL accept a moratorium on its tests of chemical warfare agents until the city completed its risk assessment. ADL, having to contend with its DOD contract requirements, did not accept a moratorium.

By early winter, the Scientific Advisory Committee (SAC) had still not been appointed, although responsibility for implementing the orders passed by the city council had passed to the city manager. Long delays between council orders and their implementation are not unusual in Cambridge. As the city's principal fiscal agent, the manager must consider the financial impacts of council orders and the practical consequences of its policies. In this instance, however, the hiatus between the time the SAC was created by the council and the time its members were appointed is indicative of the city manager's hope that the controversy could be resolved quickly. In late winter, however, the conflict intensified when the Cambridge Commissioner of Health and Hospitals issued an emergency regulation (March 13, ***1984)*** that prohibited "testing, storage, transportation and disposal of five specified nerve and blister agents within Cambridge, until SAC and an independent hazard assessment has been com-

[5]Reid Weedon, Vice President of Arthur D. Little (ADL), comments made on Mar. 7, 1985, during a community debate between ADL and the North Cambridge Toxic Alert.

pleted and these recommendations have been reviewed by the Commissioner's office."[6]

Three days later, ADL received a temporary restraining order against enforcement of the regulation from a Massachusetts superior court judge. On March 27, 1984, the temporary restraining order was converted into a preliminary injunction. The injunction against enforcement of the city regulation remained in effect until February **27, 1985,** after a decision was issued by the Superior Court.

The city manager appointed the membership to the Cambridge SAC on March **26, 1984.** Following established tradition, the manager accepted recommendations from the council. The committee was comprised of 16 members, including scientists, individuals in the fields of public and occupational health, and residents from North Cambridge.

SAC completed its inquiry and issued a report in September 1984. The cornerstone of its decision was a series of worst-case scenarios in which different volumes of nerve agent are hypothetically released into the environment. The analytical calculations for the worst-case scenarios were developed by a risk assessment consultant hired by the city. Building on those calculations, SAC concluded:

> . . . the benefits of research with these chemicals do not justify lethal risks to the general public. For this reason, the SAC believed that storage and testing of these chemical warfare agents within the densely populated city of Cambridge in the quantities and concentrations used by ADL is inappropriate.

The majority of the SAC members judged the risks associated with any such work to be unacceptable.[7]

On receipt of the SAC report, the Commissioner of Health and Hospitals made his interim order—prohibiting any person from testing and handling three nerve agents and two blister agents—into a permanent regulation on September 18, 1984. Hearings before the Massachusetts Superior Court resumed, The judge severed the issues into the questions of Federal supremacy and the reasonableness of the Cambridge order. On December **14, 1984,** the Court ruled in favor of the city on the supremacy issue. The decision on whether the Cambridge regulation was reasonable or not and whether it conformed to State law was rendered on February 26, 1985. Once again the ruling favored the city. On the following day, the Superior Court judge proclaimed the September 1985 order of the city "valid and enforceable." The injunction, which had been in effect for 11 months, was removed by the court order.

ADL appealed the case to the Massachusetts Appeals Court on March 12, 1984. The court gave ADL immediate relief by reinstating the injunction against the order, pending the outcome of the appeal. In response, the city petitioned the Supreme Judical Court (SJC) of the State and asked that it take the case over from the Appeals Court. The SJC agreed and heard the case on April 4, **1985.** In a four to one decision issued on August 1, 1985, the SJC upheld the Cambridge regulation banning the testing, storage, transportation, and disposal within the city of the five chemical warfare agents.

[6]Melvin Chalfen, Commissioner of Health and Hospitals, City of Cambridge, "Order on the Testing, Storage and Transportation of Chemical Nerve and Blister Agents, " Mar. 13, 1984.

[7]Scientific Advisory Committee for the City of Cambridge, *Report to the City Manager on the Use of* Chemical *Warfare Agents at Arthur D. Little's Levins Laboratory* (Cambridge, MA: September 1984).

COMPARISON OF THE CASES

Origins of Local Regulations

The city's involvement in both rDNA research and chemical weapons testing started with citizen concerns over the research slated for a renovated Laboratory facility. Harvard's P-3 laboratory, designed to conform to NIH specifications for working with rDNA molecules, was in its planning stages when the city council learned of its prospective use. In contrast, Arthur D. Little's testing laboratory for chemical toxins was completed and set for operation by the time its use

became known to the Cambridge citizens. In both instances, existing facilities owned by the respective institutions were significantly renovated. Building permits were obtained and several hundred thousand dollars in renovation costs were allocated. The planned P-3 laboratory was reported in the media after information was obtained at a university hearing attended by several outsiders. Harvard neither attempted to keep the laboratory's presence confidential nor sought to inform city officials and the public of its intentions to construct the facility. Funding for the renovated moderate containment P-3 laboratory and for the research for which it was designed came from science funding agencies of the Federal Government.

ADL's Levins Laboratory was paid for entirely out of company funds. The laboratory was planned specifically for the testing of toxic substances. It was anticipated that one major source of funding for recouping the investment in the laboratory was DOD. Other potential clients were Federal and State environmental agencies and those segments of the private sector that, increasingly, have become responsible for the control of toxic substances. ADL sought to have the laboratory's purpose and function known only to a select number of local officials in Cambridge, Arlington, and Belmont, Massachusetts. Public safety was the company's reason for nondisclosure of the laboratory's purpose to the general public. ADL's efforts to preserve the confidentiality of the lab and the chemical warfare agents it was testing was thwarted when a local official from the neighboring town of Arlington, informed about the facility, filed a report with the town selectmen.

Types of Local Interventions

When the Cambridge city council learned of Harvard's plans for a new laboratory, it requested both Harvard and MIT to accept a good-faith moratorium on rDNA experiments classified as P-3 or greater under the 1976 NIH guidelines, until CERB issued its recommendations. Harvard and MIT complied. No other intervention was taken by the city until the release of CERB's report.

In contrast, ADL was unwilling to accept a general moratorium on its testing of chemical nerve and blister agents pending investigation by a citizens' committee. However, on February ***16, 1984*** ADL did agree to a 30-day moratorium on performing any work on new contracts involving chemical warfare agents.

In neither of the two cases did the city attempt to withhold building permits or change the zoning regulations. ADL obtained its building permit in December 1983, long before the city council became involved in the issue, Neither of the voluntary moratoria affected any ongoing research projects. The ADL voluntary moratorium was short-lived and probably not disruptive. The rDNA moratorium was targeted to research that awaited completion of the new laboratory. There were several months between the end of the rDNA moratorium (January 1977) and the opening of the P-3 facility at Harvard (spring 1977).

In response to ADL's unwillingness to accept a general testing moratorium, an action that might have threatened its contract with DOD, the city council urged the Commissioner of Health and Hospitals to act. After several months of discussion and consultation, the commissioner issued an interim public health order that prohibited the testing of five chemical warfare agents. A court injunction kept the order from being enforced during the entire period of litigation. As of the writing of this report, the commissioner's order was the sole nature of the city's intervention into ADL's testing program. SAC did recommend an ordinance that, if passed, potentially could affect research at universities and other R&D firms. To date, the proposed supertoxin ordinance has not been acted on by the city.

One month after CERB issued its report on rDNA research, the city council passed an ordinance incorporating the principal elements of the recommendations. The rDNA law, amended in 1981, requires that all individuals or institutions undertaking experiments involving the production of recombinant DNA molecules must be licensed. Except for minor differences, the requirements for research are ostensibly equivalent to the guidelines issued and periodically amended by

NIH. The law sets additional requirements for a large scale permit for which there is no counterpart in the NIH guidelines.

In conclusion, the Cambridge rDNA ordinance followed the general framework of the Federal NIH guidelines. It permitted academic and commercial research to continue while incorporating additional safeguards. The city's intervention in the testing of chemical warfare agents involved a specific, local prohibition against the use of five chemicals. This was the first stage in a long-term plan supported by some city officials to regulate all highly toxic chemical agents in research and commerce. In May 1984, Health Commissioner Murray Chalfen issued a report that included a proposed ordinance on toxic chemicals and hazardous materials. The proposal, along with the SAC's recommendations, is currently under review by the city.

Stage of the Scientific Enterprise Affected

The first rDNA ordinance in Cambridge had its direct impact on university research, particularly the field of molecular genetics. The regulatory intervention was directed at a specific technique of scientific inquiry, namely, plasmid-mediated gene transfer, which is of fundamental significance to genetics research. Any scientific discipline that planned to use the technique was ipso facto under local regulation, however.

The revised rDNA law of 1981 was a direct response to the emergence of commercial biotechnology. Its principal effect was on R&D applications of gene splicing. Special attention was given to large volumes of genetically modified organisms, The utilization of large cultures represents a stage beyond basic science. Organisms genetically modified to produce a desired product are tested in pilot plant bioreactors with capacities of a hundred to several hundred liters, a stage in product development prior to manufacturing and production. The Cambridge law sets environmental and occupational safety requirements specifically for large cultures of rDNA-generated organisms.

ADL contracted with DOD to develop detection kits for nerve agents, to study the means by which fabrics may be made impermeable to them, and to investigate methods of detoxification. The firm's R&D work incorporated the expertise of analytical chemists, product development chemists, and electronics specialists. The order issued by the city on chemical warfare agents was not targeted to a particular research technique or methodology, as in the rDNA case; instead, it prohibited the use of five substances cited in an ADL-DOD contract. The regulation was, therefore, directed at the application of science and technology for solving targeted problems. In distinction to the rDNA case, ADL's research was not designed to generate new science. The purpose of the research was to supply the army with new information on the handling, detection, and detoxification of chemical warfare agents.

Social Risk Assessment

The two cases illustrate different approaches to social risk assessment. This is particularly evident in the composition, goals, and functions of the two citizens' committees. CERB was a committee comprised of nonexperts in the subject matter under consideration, namely molecular genetics. Out of eight members, the one who came closest in expertise to the field was a physician, board-certified in infectious diseases. The membership of the committee was chosen to reflect racial, ethnic, and neighborhood diversity. It was divided equally between men and women. In an internal memo, one member likened CERB's function to that of a jury in a legal proceeding.[8] This memo clarified the role of nonexperts in a technical controversy. CERB was asked to review the debate among scientists on the safety of rDNA research; but it was not asked nor was it equipped or prepared to undertake a risk assessment. After receiving testimony from experts, CERB members weighed the strengths of the arguments and on that basis made their decisions.

[8] A detailed account of CERB's decisionmaking process is contained in Sheldon Krimsky, "A Citizen Court in the Recombinant DNA Controversy, " *Bulletin of the Atomic Scientists,* vol. 34, No. 8, October 1978, pp. 37-43.

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In contrast, the Cambridge Scientific Advisory Committee was comprised of experts and non-experts with respect to the problems of highly toxic agents. Of the 16 members, 10 had advanced degrees in one or more of the relevant fields: physics, chemistry/biochemistry, chemical engineering, biology, and public health. SAC was presented with three tasks: 1) to undertake a risk assessment of ADL's use of chemical warfare agents, 2) to make a determination about acceptable risks, and 3) to advise the city council on a risk management plan.

Although the structures and goals of the two social risk assessment processes differed, both SAC and CERB were given the charge of determining whether the respective research activities should be prohibited, unconditionally permitted, or conditionally permitted. Also, both processes resulted in a proposed framework of risk management involving the creation of a new institutional structure for the city.

Parties Affected by the Proposed or Actual Regulations

The first Cambridge rDNA law had a direct impact on biomedical scientists, including biochemists and molecular geneticists who study gene structure and function. The revised law primarily affected R&D firms that were investigating commercial and medical applications for genetically modified organisms. In the former case, scientists responded as a community to the prospect of being regulated and opposed differential standards of research between Cambridge and other parts of the country. In the latter case, Harvard and MIT joined with Biogen to ascertain the impacts of licensure on rDNA research in their respective institutions. The revised law created new formal requirements for academic and commercial institutions but the actual requirements for individual investigators in academe remained unchanged.

The Cambridge emergency order on nerve and blister agents did not single out the names of any institutions. However, no institution other than ADL is known to have been directly affected. The agents prohibited for use were taken directly from an ADL-DOD contract. For all practical purposes, therefore, the order was directed at ADL. The regulations covering the use of supertoxins recommended by SAC were, however, much broader in scope and, if passed, probably would affect research at other institutions. For example, SAC proposed that certain designated hazardous materials proposed for testing, use, storage, or disposal within the city must be reported to the Commissioner of Health and Hospitals at least 3 months prior to the date of planned entry into the city. The substances designated for reporting inclucle: chemical warfare agents (as provided in a list), other nerve agents of different chemical structure to those listed when used in chemical weapons R&D, biological warfare agents, and other highly toxic agents as the Commissioner may designate. SAC also proposed that each use of the regulated agents be reviewed by the Commissioner and given a site evaluation in writing after appropriate information is provided. Should the Commissioner find that the use of the regulated chemical presented an unacceptable hazard to public health or safety, then a site assignment could not be given and the commissioner could prohibit the use of the materials. And, finally, SAC recommended that in addition to chemical warfare agents, the City of Cambridge develop policies to regulate other supertoxins.

To date, the city has not acted on these recommendations, which, if adopted, could significantly affect university research. At the least, the proposed regulations would apply to any experimental uses of substances designated by DOD as chemical warfare agents. Most broadly interpreted, the rules might regulate research employing any highly toxic chemical such as dioxins, chemotherapy agents, or potent mutagens. In the former case, the impact to academic scientists would be minimal for chemical warfare agents are not widely used in university laboratories (although analogs and close derivatives of them may be more readily found). In the latter case, many chemical and biomedical facilities would be affected because it is not uncommon to find some quantities of highly toxic agents in most well-equipped laboratories.

Legal Issues

The authority of cities and towns to enact health and safety regulations is firmly established under State laws. Both the rDNA law and the order on chemical warfare agents are examples of such powers exercised by the city of Cambridge. Three generic legal questions arise when the city regulates an activity under public health and safety statutes: 1) Are there any procedural errors in the process of issuing regulations? 2) Is the regulatory action arbitrary or capricious? 3) Is the regulation preempted by or does it conflict with Federal and/or State laws or authority?

No legal challenges were directed to either of the Cambridge rDNA laws. Similarly, laws of other cities and towns were also enacted and implemented without challenge.[9] Because no Federal rDNA laws were passed and because Congress has yet to express a policy on whether it occupies the field of regulations for gene-splicing, the issue of preemption in either of the rDNA cases is generally considered weak. NIH guidelines may have the force of law to those who receive Federal funds, but the agency lacks legislative authority to preempt other political jurisdictions from passing more stringent rules.

Harvard and MIT were prepared to challenge the legality of the rDNA laws if they had prohibited or substantially inhibited scientific research. As it turned out, the universities avoided litigation and accepted rDNA standards somewhat stricter than those which were required of other academic institutions in the country. The "Balkanization" of standards for scientific research was a great concern to researchers during the Cambridge debate and for years thereafter as Congress considered Federal legislation; but the predicted adverse consequences on scientific research from local rDNA laws never materialized. None of the ***13*** communities that passed rDNA legislation have placed undue burdens on scientific research, and scientists have adapted easily to the additional local requirements.

Cambridge's public health regulation on chemical warfare agents took a different legal course. ADL challenged the order immediately after it was issued. Counsel for ADL argued that the regulation was invalid on all three grounds cited above. The legal question with the widest implications was whether DOD-sponsored research performed at a private facility was protected against local regulations. Is this a case where Federal supremacy over local authority applies?

ADL offered the following arguments:

1. Congress authorized DOD to establish a chemical warfare program and this includes the authority to issue requirements for handling and disposing of chemical warfare agents.
2. The framers of the U.S. Constitution as well as Congress intended the Federal Government to have exclusive responsibility for national defense. The city's regulation prohibiting ADL from conducting defense-related testing of chemical warfare agents is tantamount to interference with government functions and represents a clear conflict with the Federal interest.
3. If Cambridge is free to prohibit such work by a duly contracted agent of the Federal Government, then so too is any other community. If all jurisdictions followed Cambridge, Federal programs in chemical warfare research would be frustrated.
4. Because ADL is a contractor of the government, the firm is invested with "derivative sovereign immunity, " which allows the supremacy clause of the Constitution to apply to it with equal force to that of the Federal Government.

Counsel for the city argued that two conditions must be satisfied for Federal supremacy to hold. Either the Federal Government has explicitly preempted the field of toxic substances regulation or a fundamental conflict exists between the Federal and local governments on the regulation of

[9] Sheldon Krimsky, "Local Monitoring of Biotechnology: The Second Wave of rDNA Laws, " *Recombinant DNA Technical Bulletin, vol. 5, No.* 2, June 1982, pp. 79-85. To date, the following cities and towns have passed ordinances on recombinant DNA research. In Massachusetts: Amherst; Belmont; Boston; Cambridge; Canton; Lexington; Newton; Shrewsbury; Somerville; Waltham. In other States: Berkeley, CA; Princeton, NJ; Emery vine, CA.

these substances. According to the city, Congress never stipulated that testing of toxic substances would be exclusively regulated by the Federal Government. Moreover, on the question of jurisdictional conflict, the city maintained that the Federal Government possesses other facilities at which to carry out such tests. The facts do not demonstrate that prohibition of such tests in Cambridge represents a fundamental conflict between local and Federal purpose.

On December 14, 1984, a State Superior Court judge ruled that Federal supremacy was not in effect for this case. Subsequently, on February 26, 1985 after reviewing arguments on the reasonableness of the regulation and its legality with respect to State law, the same court found the regulation "valid and enforceable. " The city's arguments prevailed on all the legal points.

The Massachusetts Supreme Judicial Court also upheld the regulation, stating in its decision on August 1, 1985, that the regulation constituted a permissible attempt by the city to protect its inhabitants under local police powers derived from State statutes. The court rejected arguments by ADL that the ruling violated the firm's right to due process or constituted an unjustified interference in its contract with DOD, The court also ruled that the regulation is not invalid under the Supremacy Clause of the U.S. Constitution. The SJC failed to find within Federal statutes congressional intent to preempt local communities from passing health and safety regulations for chemical warfare agents. The court affirmed the right of local health authorities to prohibit activities as long as the regulations are not "unreasonable, arbitrary, whimsical, or capricious. "

The context of legal similitude for the rDNA and the chemical weapons issues is very narrow. In both cases there are Federal guidelines or regulations for certain experimental activities. In both cases, the city chose to augment or supersede the role of a Federal agency. But from that point, the legal issues evolved quite differently.

IMPACTS OF THE CITY'S INTERVENTIONS BEYOND ITS BORDERS

The 1976 rDNA debate was covered extensively by the national and international media. Little research has been done on the impact of the debate outside the United States, but within this country there is documentation about direct and indirect effects on other municipalities and on national policies. Nearly two dozen city/town governments and State legislatures considered passing laws that would have extended coverage of the NIH guidelines to privately funded institutions. In response to the first Cambridge debate, two States and four local governments enacted rDNA legislation. Several communities modeled their citizen review process closely on that of Cambridge. The City of Berkeley passed an rDNA law that incorporated verbatim sections of the Cambridge ordinance. By 1978, however, the ripple effect of the first Cambridge rDNA controversy had taken its course and was affecting only a handful of university communities. The national debate subsided and so did the involvement of town and municipal bodies.

A second wave of community responses broke after Cambridge passed its 1981 law. An additional seven communities in the greater Boston area, including the City of Boston, passed similar laws directed at commercial biotechnology but also applicable to scientific research. In an unusual case, a law passed in the City of Waltham, Massachusetts, prohibited the use of human experimental subjects in recombinant DNA research. This is, perhaps, the first U.S. law prohibiting human genetic engineering.

The rDNA events in Cambridge also had reverberations in Congress. The publicity surrounding the Cambridge controversy was one of the key factors influencing some Members of Congress to file bills that would place gene-splicing under Federal regulation. Of the two leading bills, the Senate version, sponsored by Edward Kennedy (D-MA), paid close attention to the events in Cambridge, '" The Kennedy bill contained weak preemption language, signifying a respect for the rights of communities like Cambridge to establish standards of safety for rDNA research in ex-

[10]The leading congressional bills were introduced by Representative Paul Rogers (D-FL), H.R. 4759, on Mar. 9, 1977, and Senator Edward Kennedy (D-MA), S. 1217, on Apr. 1, 1977.

cess of those required by the Federal Government. Despite considerable congressional activity, however, no legislation emerged during the years of peak public interest between 1977 and 1980.

The extensive publicity around the citizen participation process in the Cambridge rDNA affair probably did have some influence in the reorganization of the Recombinant DNA Advisory Committee (RAC) in 1978. Department of Health, Education, and Welfare (HEW) Secretary Joseph Califano expanded the size of the RAC from 16 to 25 members to accommodate more public participation. Cambridge became a model for environmental groups like Friends of the Earth and the Sierra Club which lobbied Congress and HEW for broadening public involvement in the decision-making process. One of the members of the Cambridge citizens' committee was appointed to an expanded RAC in ***1979*** when ***30*** percent of its membership was drawn from the fields of public health and public interest.

The ADL debate over the testing of chemical warfare agents is over a year old. It has been accompanied by a limited amount of national publicity. Lower court decisions were picked up by three national television news networks. The ABC TV news magazine program "20/20" produced a segment on the debate. National Public Radio also broadcast a program on "Morning Edition, " October 3, 1984, describing the Cambridge-ADL debate.

Cambridge is one of at least 12 cities in the United States containing firms that have contracted with DOD to conduct research with chemical warfare agents. This list became public as a consequence of the "20/20" broadcast. There have been no reported actions taken by any of these communities in response to the Cambridge prohibition, but it is too early in the legal process to speculate whether the case might serve as a precedent for local regulation of research involving highly toxic chemicals.

ARGUMENTS FOR AND AGAINST REGULATIONS

Recombinant DNA Controversy

For Regulation

NIH released its first set of guidelines for rDNA research on the same day the city of Cambridge held public hearings to discuss Harvard's planned P-3 laboratory. The guidelines were issued in response to concerns by molecular biologists that gene splicing might result in the unexpected creation of a new epidemic pathogen, toxin-producing bacteria, or a coliform bacteria harboring a human cancer virus. In Cambridge, the debate centered on whether the research should be done at all and whether the NIH guidelines provided a sufficient margin of safety against an accident or unintended outcome.

Scientists spoke forcefully on both sides of the issue. Those against the use of a P-3 facility at Harvard for rDNA experiments cited three deficiencies in NIH's role as the overseer of the research. First, they argued that the guidelines were constructed from untested a priori hypotheses and they placed little confidence in the regulation's effectiveness as a containment strategy. Second, it was pointed out that the NIH guidelines had no force over R&D activities that were not funded by the Department of Health and Human Services. At the time, biotechnology firms had not sought entry into the city, but that was thought not to be far off. Third, opponents argued that NIH had not enlisted sufficient participation from the general public and other segments of the scientific community. Some scientists maintained that rDNA molecule technology was an unknown and uncharted area of research with unpredictable risks. They felt it should not be done in proximity to classrooms and other research activities.

When the city was approached by the first of several biotechnology firms planning to locate in Cambridge, a new set of public anxieties arose. By that time the city's rDNA law had been in effect for 3 years. The principal rationale for passage of the revised law was the concern over large volumes (over 10 liters of culture) of genetically modified organisms, and the potential hazards

associated with occupational exposure and environmental release.

The citizens' committee was not aware of any regulatory body at the Federal or State level which set standards for large-scale work involving rDNA molecules. After consultation with experts in fermentation engineering and the sterilization of spent organisms in large vessels, the citizens' committee proposed revisions in the 1977 law. Among the restrictions cited in the revised law was:

> There shall be no deliberate release into the environment, that is the sewers, drains, or the air, of any organism containing recombinant DNA and further that any accidental release shall be reported to the Commissioner of Health and Hospitals within five days. "

The new law created a system of accountability according to which biotechnology firms were required to have special licenses for large scale work. The system included periodic inspections to ensure that the environmental release provision was respected by the technology and practiced by the institution.

Against Regulation

The principal opposition to local regulation of rDNA research in 1976 came from scientists, graduate students, and university administrators. They emphasized the confidence that the vast majority of scientists had in the NIH guidelines. RAC was cited as an exemplary system of oversight and one that a local community could not duplicate. The importance of uniform national guidelines was stressed. Science, it **was** said, cannot flourish in a patchwork of regulations. If Cambridge enacts restrictive rDNA regulations, scientists will find it necessary to move away from the city to other areas more conducive to their research. The universality of the scientific method requires uniformity in the social context within which research is carried out. This norm would be violated if each community passed its own research guidelines.

Opponents of regulation also stressed the benefits of rDNA research. These benefits might be delayed significantly if restrictive local regulations were established. Those critical of local regulation emphasized that the risks of rDNA research were at best hypothetical and quite likely nonexistent, while the benefits were real. Not a single case of illness was linked to an agent of an rDNA experiment. In their view, a significant margin of safety was already provided by the NIH guidelines.

The Case of Chemical Weapons Research

For Regulation

The arguments for regulating chemical warfare agents centered around the potential adverse public health consequences associated with their accidental or intentional release. The Cambridge Scientific Advisory Committee examined several worst-case scenarios in which quantities of 10, 100, and 500 ml. of nerve agent were hypothetically released from the testing facility. SAC concluded that such an accident was unlikely but not impossible; in the event of a 100 ml. release, members of the general public might be located within range of lethal doses of such agents .12 The committee cited an independent consultant report that estimated between 10 to 30 members of the general public might be located within range of lethal levels of such agents in one of several worst-case scenarios. The case in question involved a sudden release of 100 ml. of sarin in the form of a gaseous cloud. '3

The SAC report stated that there were no satisfactory regulatory mechanisms for managing the use of supertoxic agents in the city. Having concluded that even relatively small quantities of chemical warfare agents used in R&D could pose a risk to the public, the committee proposed a municipal ordinance for regulating such agents in particular and supertoxins in general. SAC made no distinctions in its regulatory program between R&D or between university and nonuniversity uses of supertoxins.

[11] Krimsky, et al., *Municipal and State Recombinant DNA Laws,* op. cit.

[12] Scientific Advisory Committee for the City of Cambridge, op. cit., p. 2.

[13] TRC Environmental Consultants, Inc., *Community Risks from Experiments with Chemical Warfare Agents at Arthur D. Little* (Hartford, CT: 1984).

More than half the members of the committee favored a ban on any research involving chemical warfare agents on the grounds that the "risks associated with any such work [are] unacceptable. " A smaller number of members expressed opposition to the research on ethical grounds—that any work on chemical weapons is morally reprehensible. They believed that no clear distinction can be drawn between offensive and defensive research. The city's legal arguments for its regulation, however, focused exclusively on issues of public health and safety. City council debates also centered on public health issues in contrast to the rDNA episode when some councillors questioned the morality of genetic engineering. To some degree, the psychological impact of the term "chemical warfare agents" was a relevant factor, however, in the public's sensibility to the issue.

Against Regulation

Arthur D. Little's case against the city's ban can be classified according to the following categories: 1) safety of the facilities; 2) errors and deficiencies of the SAC report; 3) discriminatory nature of the action; 4) misunderstood goals of the research; 5) compliance by ADL to all Federal, State, and local laws and regulations; and ***6)*** violation of Federal supremacy.

1. The company maintained that its laboratory is among the safest that exists for the work intended. The laboratory satisfied DOD specifications for handling chemical warfare agents. ADL was also in compliance with Federal and State environmental regulations. The firm argued that its laboratory advances the state of the art for the safe handling of hazardous substances. To further increase the margin of safety, ADL agreed not to store more than certain minimum volumes of the chemical agents.

2. ADL also argued that the committee's technical analysis was flawed. According to company spokespersons, the report drew conclusions from assumptions that do not reflect ADL's operations. One of the risk scenarios developed by SAC assumed greater quantities of chemicals than ADL claimed it would ever have on hand. Furthermore, SAC did not determine the probability of its worst-case accidents. It did not describe how chemicals stored in secure containers could be released into the environment from some accident. The SAC report did not take account of the many barriers there are to the kind of accident it postulated. In fact, if there were an accident, the company held, the effects would not be felt beyond ADL. According to the company, the city's attempt to ban the five chemicals was unreasonable and invalid because it was not shown that the research posed any potential health hazard.

3. The company also believed that the city's action was discriminatory. Selected city officials, including the city manager, were first informed about ADL's plans for the laboratory in January 1983, but it was more than a year later, and after an occupancy permit was issued, that ADL was ordered to cease its testing. In its letter to the public, ADL wrote: "We worked closely with the Cambridge City Manager and the relevant public safety officials throughout the planning and construction of the facility, and they expressed complete confidence in its safety and security. We hired outside consultants to check our findings and designs. "

ADL also faulted the city for not allowing the company to remedy any defects that may have been found in its safety program. As a result, the city's prohibition imposed upon ADL nearly a million-dollar loss in the cost of the laboratory in addition to substantial losses in present and future DOD contracts.

ADL also argued that it had been selected out for regulation. According to the company, there are many risks to the people of the city that are far greater than its testing program, yet the city focused attention on a state-of-the-art testing laboratory that uses small quantities of chemicals. If the city wishes to regulate toxic substances, ADL proposed, it should treat all institutions and all substances on a comparable basis. The determination to regulate should not depend on whether the research is done at a profit or nonprofit institution, involves basic or applied science, or is carried out under contract from DOD or under a grant from NIH.

4. ADL correctly surmised that some of the public concern over its research was motivated

by concerns over the morality of chemical weapons research. In a letter to the public, ADL clarified the ethical basis of its contract with DOD:

> We believe something must be done to control the threat of uncontrolled toxic chemicals in the environment. We have the professional capabilities and the resources to help solve some of the inherent problems. That is why we went to the expense of constructing a safe, secure, facility for research designed to find better ways of protecting people from the effects of uncontrolled environmental hazards, "

The firm assured the citizenry that its research on chemical and nerve agents is exclusively for "defensive and protective purposes."

> We are using existing substances in analytic tests in order to develop better methods of detecting minute quantities of these agents in the environment and safer, more effective means of destroying them on a large scale. We are also working to develop better protection, including clothing for people who might be exposed to these substances .14

5. All Federal, State, and local regulations had been met before ADL's lab went into operation. The facility had been inspected by DOD, State agencies, and city officials. The company received an occupancy permit. The city's ban thus was perceived by the company as an afterthought to all regulations that were in effect prior to and during the time the laboratory was under construction.

6. The supremacy arguments have been outlined in detail in the section of this report comparing the rDNA research and chemical weapons testing. In summary, ADL contended that the city has no authority to interfere with a contract of the Federal Government when all Federal and State safety standards are met. The city's ban on the testing and storage of the agents is argued to conflict with the Federal authority governing national defense and is therefore unconstitutional. If other municipalities passed similar prohibitions, there would be a direct conflict between the policies of the U.S. Government and the actions of local communities. Under such conditions, the policies of the Federal Government are preemptory, the company stated.

Although the principal opposition to the city's action banning the testing and storing of five chemical warfare agents came from ADL, there was some criticism expressed by university representatives about the proposed regulations for supertoxins contained in the SAC report. MIT officials argued that SAC's approach to chemical regulation would have a "harsh and adverse effect on the conduct of research in chemistry, biology, nutrition and food science" at universities. Because SAC made no provisions for volume exclusions in its proposed regulations of chemical warfare agents or closely related chemicals, many substances used in the course of research would fall under the proposed criteria. According to the MIT officials, if enacted, these criteria would be an obstacle to scientific research without offering any additional protection to public health.

[14]John F. Magee, President of Arthur D. Little, Letter to the Publie, Jan. 28, 1985,

GENERAL POLICY IMPLICATIONS

The central issue underlying both case studies is the extent to which local communities are justified in regulating research. Beyond this similarity, there is considerable variation in how these cases relate to issues of scientific freedom and social accountability. The rDNA case involves a well-defined scientific population, a Federal funding agency, local universities, and a city government. The case of chemical weapons testing is about private contract research. It too involves city government, and a Federal funding agency. But a well-defined scientific constituency is absent.

Three policy issues stand out in the rDNA episode. First, should science be self-regulated and therefore insulated from State and local laws? Second, does NIH oversight of rDNA experiments provide a legal basis for Federal supremacy and, if not, should Congress establish legislation toward that purpose? Third, to what extent, if at

all, is scientific research a right granted under the First Amendment?

NIH has been the de facto regulator of federally funded rDNA experiments. Scientists, however, have had an influential role in the establishment and implementation of guidelines. Through the NIH structure, the molecular geneticists have had what has been ostensibly a self-governing apparatus somewhat analogous to a peer review process. The Cambridge debate threatened this tradition of self-governance which began at Asilomar and evolved into the formation of the Recombinant DNA Advisory Committee. The city also challenged the idea of uniform safety standards for experiments in molecular genetics.

Although Cambridge scientists were the only ones directly affected by the city's intervention, the possibility of multiple sets of guidelines for rDNA technology, based in part on local standards, troubled scientists throughout the country, Many biologists who opposed congressional intervention, preferred it over a patchwork of regulations. According to Rockefeller University biologist Norton Zinder, the uniformity of scientific practice transcends local interests:

> The proliferation of local options with different guidelines in different states and different cities can only lead to a situation of chaos, confusion, and ultimately to hypocrisy amongst the scientists involved. [15]

Most legal scholars agreed that the NIH guidelines did not provide a-basis for preempting the Cambridge law. No judicial challenge was made on the reasonableness of the Cambridge rDNA law in the context of the Federal guidelines. Perhaps because the Cambridge rDNA laws (first and second) added very little to the substance of the NIH guidelines, a legal challenge was avoided. Had the city banned rDNA research, the question of preemption most certainly would have been addressed in litigation, if not through congressional action.

Preemption was not the only legal question raised in the early rDNA debate. Facing the prospect of Federal regulation, some scientists argued that rDNA legislation would infringe on their rights to engage in research. Prompted by several inquiries, in 1977 the American Civil Liberties Union (ACLU) began a task of formulating a policy on whether, or to what extent, scientific inquiry is a civil liberty protected under the first amendment. Special committees of the ACLU began drafting policy statements that provided a civil liberties perspective on scientific research. Thus far, the Board of Directors of ACLU has not reached a consensus on the wording of such a policy.

ADL's legal battle with Cambridge did not attract sympathetic support from other scientists. Most university-affiliated scientists did not view the possible restriction on specific contract research as a conflict between the local community and freedom of scientific inquiry. The applied nature of the testing work and the fact that the results would probably be classified contributed to this attitude.

The policy dilemma is best interpreted as a conflict between the rights of a firm to accept Federal contract research under Federal guidelines and the rights of a city to set its own standards of public health and safety including a prohibition of research it deems hazardous. The outcome of the ADL case has implications for any federally contracted research on nongovernmental property that involves hazardous or potentially hazardous procedures or materials. For example, a community might decide to establish prohibitions against certain animal experiments. As a consequence, contract research and basic science would be affected adversely. Cases of this nature have not been widespread; but they are appearing. In Washington Grove, Maryland, residents have expressed opposition to the testing of chemical nerve agents in the vicinity of a school. Morris Township, New Jersey, has been the site of a controversy involving Bell Communications Research (Bellcore), an AT&T spin-off company. At issue has been the use and storage of highly toxic gases, such as arsine, commonly used in semiconductor research (see discussion in app. C). Neither congressional policies nor case law has settled the debate over Federal supremacy in these *cases*. If the ADL litigation continues beyond the Massachusetts courts, Federal judicial interpretation may set some explicit parameters for local control of private sector research.

[15] National Academy of Sciences, Research *With Recombinant DNA: Academy Forum* (Washington, DC: December 1977).