Research Under Community Standards: Three Case Studies

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Editor's Introduction—*Of all the topics discussed in* Science, Technology, & Human Values *through the years, few have touched as many nerves and have seemed as complex as the question of whether, and how, society should regulate scientific research. Sheldon Krimsky originally prepared these case studies for "The Regulatory Environment for Science," an Office of Technology Assessment (OTA) technical memorandum (February 1986) that describes the spectrum of contemporary social and political regulation of research in the United States. In the OTA report, the two Massachusetts case studies are presented in one chapter, the New Jersey case in another. We asked Professor Krimsky, a consulting editor to this journal, to combine the analyses, with the intention of providing some provocative, common information for future commentaries. What—if any—are the implications of such cases for the new regulatory environment for science?—MCL*

This article describes three cases involving interventions into scientific inquiry by local governments in Massachusetts and New Jersey. The first describes a city's two-phase regulation of recombinant DNA molecule technology—in 1977, passage of the first U.S. law regulating rDNA research, and in 1981, a revised law, enacted in response to the research and development activities of newly-established biotechnology firms. The second case describes the same city's efforts about three years later to proscribe the handling and testing of certain chemical warfare agents by a consulting firm under contract with the U.S. Department of Defense (DOD). The third, more recent case involves a New Jersey township protest to the siting of a semiconductor research facility, on the grounds that toxic chemicals would be stored at the site.

The summaries of these cases which 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 for and against local regulation of research. At the end, I will suggest briefly the general policy implications of these cases in regard to freedom and accountability in the conduct of scientific research.

Case 1: Research Involving Recombinant DNA Molecules[1]

The controversy in Cambridge, Massachusetts, over research involving the use of recombinant DNA molecules began in Spring 1976. At that time, the Harvard University administration 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 National Institutes of Health (NIH) requirements 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 pro-

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hibited 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 research laboratory were being discussed by the university administration, several Harvard scientists began to question the wisdom of 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, which responded by holding an open meeting for the Harvard community. That meeting 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 8 June 1976.[2] Troubled by the story, Cambridge Mayor Alfred Vellucci decided to hold hearings on DNA research at Harvard. Mayor Vellucci was supported and advised by several scientists in the city, including some of Harvard's own faculty.[3] When the city council held hearings on 23 June and 7 July 1976, scientists and physicians affiliated with Boston-area universities and hospitals were among those who testified. Many biomedical researchers who were contemplating rDNA research at the P-3 level worried that Cambridge's imposition of a city-wide ban on certain rDNA experiments could 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 14 June 1976, a week prior to the first Cambridge hearing, the Harvard Corporation authorized construction of the P-3 laboratory.[4]

Subsequent to the public hearings, the city council, frustrated by the technical complexity of the issues and perplexed by the polarization of viewpoints, voted 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 three-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. Because the new laboratory was expected to be completed by Spring 1977, the city's moratorium on research did not postpone any work. Harvard decided to proceed 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 biologists 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 four months, between September and December 1976. Harvard and MIT agreed to a three-month extension to the good-faith moratorium 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 to oversee all rDNA research in the city. The committee's recommendations were enacted into law on 7 February 1977. 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 four 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 local and Federal regulations.

The Cambridge Biohazards Committee (CBC) called a public hearing on 28 October 1980, but, 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, beyond those employed by Biogen, no Boston-area scientists were 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 upon the Cambridge Experimentation Review Board to respond. Since the CBC was responsible for implementing the rDNA ordinance, the CERB considered it wise to involve this body in any decisions on revising the law. Thus, the CERB chose to hold its hearings in collaboration with the 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 somewhat lesser degree, against occupational hazards. The Cambridge city council voted the recommendations into law on 23 April 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 genetically modified organisms in volumes greater than ten liters. The deliberate release into the sewers, drains, or 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.[5]

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 delayed as a consequence of the city's deliberations. Similarly, Harvard's P-3 laboratory was scheduled for completion in Spring 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.

Case 2: Testing Chemical Warfare Agents[6]

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 has a workforce of 2500.

Around June 1982, ADL decided to renovate an existing chemical laboratory, adding 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 Department of Defense (DOD) specifications for working with "chemical surety materials," a euphemism for chemical warfare agents consisting mainly of nerve and blister agents.

The company's investment in the laboratory exceeded three quarters of a million dollars. 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 10 December 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 to 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 U.S. Army. Ac-

cording to an ADL representative, none of the city officials asked the company to provide "specific names and toxicities of the materials it was planning to test in the new laboratory."[7]

ADL requested that, for reasons of public safety, city officials keep confidential the location of the laboratory and the type of work to be undertaken there. The firm maintained that a policy of confidentiality would reduce the chances that the laboratory would be a target for vandalism or terrorism. The city manager and the police and fire chiefs complied with the request. ADL filed for an occupancy permit on 18 May 1983. The certificate of occupancy was issued on 25 May. DOD approved the laboratory for operation on 19 September 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 operation of the new facility. At a meeting with Arlington's town manager, officials of the Arlington 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, 14 October 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 20 October, the story of the laboratory was reported in the *Arlington Advocate* and *The Boston Globe*. The *Globe* speculated that chemical warfare agents might be among the agents handled at the facility. On 17 and 24 October, respectively, the Arlington selectmen and the Cambridge city council held public meetings at which the ADL matter was discussed.

At the 24 October Cambridge council meeting, company officials disclosed the nature of the chemical warfare agents supplied to ADL under DOD contract. 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, the city council voted at the same meeting 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 implementation of the orders passed by the city council was in the hands of 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 all council orders. In this instance, however, political rather than budgetary factors were responsible for the delay: 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 without a citizen review process. In late winter, however, the conflict intensified when the Cambridge Commissioner of Health and Hospitals issued an emergency regulation (13 March 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 completed and these recommendations have been reviewed by the Commissioner's office."[8]

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

The city manager appointed the membership to the Cambridge Scientific Advisory Committee on 26 March 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 on 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 upon those calculations, SAC concluded:

> The benefits of research with these chemicals, in the opinion of the Committee, 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.[9]

The majority of the SAC members judged the risks associated with any such work to be unacceptable.[10]

Upon receipt of the SAC report, the Commissioner of Health and Hospitals made his interim order—prohibiting any person from testing or handling any of three nerve agents and two blister agents—into a permanent regulation on 18 September 1984. Hearings before the Massachusetts Superior Court resumed. The judge severed the issues into the questions of Federal supremacy and of the reasonableness of the Cambridge order. On 14 December 1984, the Court ruled in favor of the city on the supremacy issue. The decision on whether the Cambridge regulation was reasonable and whether it conformed to state law was rendered on 26 February 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 eleven months, was removed by the court order.

ADL appealed the case to the Massachusetts Appeals Court on 12 March 1985. 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 Commonwealth's Supreme Judicial Court (SJC) and asked that it take the case over from the Appeals Court. The SJC agreed and heard the case on 4 April 1985. In a four to one decision issued on 1 August 1985, the SJC upheld the Cambridge regulation banning the testing, storage, transportation, and disposal within the city of the five chemical warfare agents.

Case 3: Solid State Science and Technology Research[11]

From February 1984 to May 1985, Morris Township, New Jersey, was embroiled in a controversy over the siting of a new research facility for Bell Communications Research, Inc. (Bellcore). The site plan of the proposed telecommunications research complex was debated extensively before the township planning board. At issue was the storage, use, and disposal of highly toxic and flammable gases. A group of residents formed an organization that spearheaded opposition to the research facility on the grounds that the work being planned there was potentially hazardous to public health and environmental quality.

This case began like many land use decisions in communities throughout the United States. In the late 1970s, residents of a suburban neighborhood in Morris Township, New Jersey, raised concern over the development of a parcel of land adjacent to single-family subdivisions and a recreational area. The issues expressed during this period were predominantly those of traffic, noise, density, and aesthetics. In February 1980, after 15 public hearings over a 12-month period, the Morris Township planning board approved a plan submitted by the Southgate Corporation, developer of the site. The 58-acre parcel, called the Southgate Office Park Complex, was designated exclusively for office use.

Three years later, during the summer of 1983, with three office buildings under partial completion, the Southgate Corporation leased the site to Bellcore, a research organization owned by seven regional telephone companies. Bellcore is a by-product of AT&T's court-ordered divestiture of the Bell System. The Bell System Plan of Reorganization stipulated that the regional telephone companies create a central services organization to provide them with research and technical services, just as Bell Laboratories continued to do for AT&T.

On behalf of its tenant, the Southgate Corporation submitted an amended site plan on December 1983 which included the construction of an additional building devoted to research, and the use, as a laboratory, of two floors of a building previously approved as office space. Bellcore had planned to locate its Morris Research and Engineering Center at the Southgate location. A number of AT&T employees at Bell Labs facilities in

Murray Hill, New Jersey, and Whippany, New Jersey, were expected to be transferred to the new center as part of the court-ordered changes.

The proposed facility was devoted to advanced research in semiconductors and fiber optics. This type of research commonly employs such toxic gases as arsine, phosphine, and diborane as well as liquified hydrogen.

When residential abutters to the site attended a planning board meeting in February 1984 to discuss traffic patterns, they learned that under the amended site plan, toxic and flammable gases would be used at the facility. Within a month, a core group of residents organized themselves into Concerned Citizens of Morris Township (CCMT).

The citizens framed their opposition to the research facility on two principal grounds: (a) the risk of adverse health effects from an accidental release of toxic gases; and (b) the risk of environmental damage from release of untreated or partially treated toxic effluent from the research facility into Loantaka Brook—a major tributary of the Great Swamp National Wildlife Refuge.

CCMT's main effort to prevent construction of the research facility was directed at the Morris Township Planning Board, a body consisting of nine appointed members legally responsible for land use decisions. The planning board held over two dozen public hearings on the Bellcore case between December 1983 and May 1985. CCMT brought in paid consultants, some from outside the state, to testify in its behalf on the potential hazards to the community of the proposed facility. Eventually, the citizens group drew support from a broad range of constituencies covering Morris Township and neighboring communities. Included among these were: Harding Township Environmental Commission; over fifty Harding residents; the Great Swamp Watershed Association; representatives of 14 civic associations, with a reported membership of 2,000 households in Morris Township and neighboring communities; and an official of the U.S. Fish and Wildlife Service.

A letter signed by the coalition of civic associations expresses the intensity of public opposition:

> We question the need for Bellcore to impose the laboratory on a community that does not want it. . . . We emphatically state that the Bellcore laboratory is not welcome and that we will pursue every means available to expose and publicize the fact that, in this instance, Bellcore has failed to fulfill its role as a responsible corporate citizen. . . .[12]

What started out, therefore, as a controversy involving abutters to an industrial site, soon evolved into a regional conflict over a proposed research and engineering center. As community pressure grew, so did Bellcore's discomfort with the uncertainty of locating its new research home. The company made serious attempts to communicate its position that "the small quantities of chemicals that [the company] plans to use and the 'state-of-the-art' safety systems and procedures that it plans to employ will make the Southgate facility safe beyond any reasonable question whatsoever."[13]

In May 1984, Bellcore submitted an environmental information document to the planning board, describing its prospective laboratory operations, providing a representative chemical inventory for the new complex, and outlining safety procedures for the storage and handling of toxic materials. The company also hired risk assessment consultants to present its case before the planning board. Bellcore scientists provided an additional source of technical assistance to the company during the protracted debate.

In the 18-month period during which the planning board held public hearings on Bellcore's proposed research complex, proponents and opponents of the amended site plan were assigned scheduled sessions at which to present their respective arguments. On 3 May 1985, the planning board prepared for a final vote on the site plan. However, at the outset of the session prior to the vote, Bellcore made an unexpected announcement that it was withdrawing several controversial elements of its site plan, including the new laboratory building and the use of certain toxic and flammable gases. The planning board hastily accepted the modified proposal by a vote of 9–0. Realizing that even a vote in its favor would not end the controversy or the delay in construction, the company appears to have capitulated to the concerns of the citizen protestors and to have decided to site the research facility elsewhere. In response, the citizen's group chose not to appeal the final decision of the planning board—despite some uneasiness among CCMT members that they had not seen a completed version of the adopted site plan. This decision brought the 18-month controversy to a close.

Comparison of the Cases

Origins of Local Regulations

The involvement of the city of Cambridge in regulating both rDNA research and chemical weapons testing started with citizen concerns over the research slated for *renovated* laboratory facilities. 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

Table 1. Comparison of Three Cases Involving Local Control of Research

Category of comparison	rDNA-Cambridge	Arthur D. Little (ADL)—Cambridge	Bellcore—Morris Township
Type of research	Basic science	Applied chemical and engineering	Basic and applied science and engineering
Nature of institution	Academic/nonprofit	Consultant/for profit	Private sector/for profit
Stage of the research at outset of local intervention	Not yet begun	7 months ongoing	Not yet begun
Source of research funding	NIH and NSF primarily	DOD	Private sector: regional telephone companies
Origins of controversy	National and within scientific community	Local and centered on a city and two towns	Local and centered on a township
Stimulus of local involvement	Newspaper story on Harvard's plan to build P-3 genetics lab	Newspaper story on ADL's new lab for testing chemical warfare agents	Planning board hearing on site plan for commercial development
Primary regulatory agent	City council	Public health commissioner	Township planning board
Time period of controversy	Stage 1: 7 months Stage 2: 5 months	21 months	18 months
Codification of ruling	Municipal ordinance regulating rDNA activities	Public health order banning uses of certain chemical warfare agents	None; withdrawal of planned research by firm
Institutional response to community reaction	Universities accept temporary moratorium	ADL rejects moratorium; litigates public health order	Followed process through planning board; finally withdrew proposal, no litigation
Actual interference with research	No appreciable delay	Not prevented or appreciably delayed for 21 months; final court decision upheld ban	Research was delayed and finally prevented at site
Judicial action	No legal test of moratorium or rDNA ordinance	Litigation initiated on research ban	No litigation
Nature of community involvement	Primarily from academic sector; no grass roots organizations	No organized opposition at the early stages; intense community organizing after release of SAC[a] report	Organized opposition at the outset; coalition-building with other townships and regional groups
Perceived community risk	Unspecified speculative scenario of creation and release of disease-carrying organisms	Explosive release of nerve agents exposing residents	Explosion of hydrogen tank and release of arsine gas; also release or toxic chemicals into fragile preservation area and groundwater

[a] Scientific Advisory Committee.

contrast, Arthur D. Little's testing laboratory for chemical toxins was completed and set for operation by the time its use became widely known to the Cambridge citizens. In both instances, however, existing facilities owned by the respective institutions were significantly renovated, and the organizations obtained building permits and allocated (and spent) several hundred thousand dollars in renovation costs. Bellcore's total investment in its planned facility is not public knowledge, but it is clear that the company lost research time and that the uncertainty over the site may have inconvenienced researchers who were waiting to move.

Funding for the renovated moderate containment P-3 laboratory at Harvard and for the research for which it was designed came from science funding agencies of the Federal government. ADL's Levins Laboratory and the Bellcore research facility were paid for entirely out of their companies' funds. The Bellcore facility was to be a diversified in-house research facility whose "clients" would have been primarily the regional telephone companies. The ADL laboratory was planned specifically for the testing of toxic substances and, as such, the company's principal source of funding, at least initially, was the Department of Defense; but other potential clients included state and Federal environmental agencies and those segments of the private sector that, increasingly, have become responsible for the control of toxic chemicals.

The planned P-3 laboratory at Harvard 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. ADL sought to have its laboratory's purpose and function known only to a select number of local officials in the surrounding towns, claiming public safety as the reason. 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. At the outset, Bellcore's proposed solid state laboratory was a matter of public record since the company was required to submit the site plan to the planning board for review. The specific chemicals and their quantities to be stored at the facility, however, were not presented in the original site plan, but were divulged only during the hearings.

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 the 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 16 February 1984 ADL did agree to a 30-day moratorium on performing any work on new contracts involving chemical warfare agents.

In neither of these 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).

The Bellcore case is a clearer example of how local opposition to a laboratory has actually delayed research. The extant public documents contain no specific data on how the delay affected the company's research efforts; but the prospect of continued opposition was probably a factor in the company's eventual decision to relocate the facility.

In response to ADL's unwillingness to accept a testing moratorium, an action that might have threatened its contract with DOD, the Cambridge 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. 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, but to date, the proposed supertoxin ordinance has not been acted upon 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, which are periodically amended by the National Institutes of Health. The Cambridge 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, but incorporated 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 Melvin Chalfen issued a report that included a proposed ordinance on toxic chemicals and hazardous materials. That 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 of a military interest. 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.

Bellcore, however, was a new corporation seeking a site for its solid state research when it became embroiled in the controversy. Many of its scientists were to be transferred from Bell Labs after the court-directed breakup of AT&T, and as a consequence of the organized opposition, that transfer process was delayed for many scientists. In sharp contrast to the two Cambridge cases, no research agenda was the subject of community inquiry; rather, concern centered on the stored gases. The uses to which these gases would be put was barely mentioned during the hearings, and so one cannot say that, in this case, the social value or purpose of research was ever under fire.

Social Risk Assessment

The three cases illustrate quite different approaches to making social risk assessments. This

is particularly evident in the composition, goals, and functions of the two Cambridge citizens' committees. CERB was a committee comprised of non-experts 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, and 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 proceedings.[14] This memo clarified the role of non-experts 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.

In contrast, the Cambridge Scientific Advisory Committee created in response to the ADL case was comprised of experts and non-experts with respect to the problems of highly toxic agents. Of the 16 members, ten 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.

In Morris Township, two social risk assessments were carried out in tandem. CCMT constructed a process befitting an adversarial group, while the planning board used its legally constituted role to evaluate the potential adverse public health impacts of the proposed laboratory. Both groups had technical advisers. The process took on a quasi-judicial form, with the planning board functioning as both judge and jury, somewhat like CERB in Cambridge.

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 name any specific institution. However, no institution other than ADL is known to have been directly affected. The names of 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 recommended 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 three months prior to the date of planned entry into the city. The substances designated for reporting include: 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 the Commissioner review each use of the regulated agents and give each a site evaluation in writing after the research facility provides appropriate information. Should the Commissioner find that the use of the regulated chemical presented an unacceptable hazard to public health or safety, then the commissioner could prohibit the use of the materials by refusing a site assignment to the petitioner. 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 local 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 on 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).[15] 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.

In the Bellcore case, the eventual outcome was a change of venue of the research facility. No existing research was proscribed, impeded, or regulated; however, the lengthy community review probably affected the research of the scientists awaiting transfer from Bell Labs.

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 a city or town 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 state and/or Federal laws or authority?

No legal challenges were directed to either of the Cambridge rDNA laws. Similar laws of other cities and towns were also enacted and implemented without challenge.[16] 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. The 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 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 between 1977 and 1981 have placed undue burdens on scientific research, and scientists apparently have adapted 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:

a) 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.

b) 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.

c) 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.

d) Because ADL is a contractor of the government, the firm is invested with "derivative sovereign immunity," which allows the su-

premacy 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 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 14 December 1984, a state Superior Court judge ruled that Federal supremacy was not in effect for this case. Subsequently, on 26 February 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 1 August 1985 decision that the regulation constituted a permissable attempt by the city to protect its inhabitants under local police powers derived from state statutes. The court rejected ADL's arguments that the ruling violated the firm's right to due process or constituted an unjustified interference in its DOD contract. 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 any 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.

The Bellcore case revolved around quite different legal issues. Local planning boards derive their authority to exercise land use controls from state statutes. In New Jersey, Chapter 57 of the state Land Development Ordinance sets forth principles of municipal land use controls which include the promotion of public health and safety and protection against man-made and natural disasters. In the written opinion of the Morris Township counsel, "both municipal land use law as well as the Morris Township ordinances provide sufficient legal basis to deny the [Bellcore] application if the Board feels it would present an unacceptable risk." The key to the planning board's authority to proscribe research is in the interpretation of "unacceptable risk"—a vague and elusive term that was the centerpoint of much of the public debate.

The Southgate Office Complex is on land zoned for both office and laboratory use, a point emphasized by Bellcore in its repeated contention that the amended site plan was in conformity with zoning requirements for the parcel. CCMT claimed, however, that it was within the purview of the planning board to restrict research activities that pose a threat to human health, public safety, or environmental quality, even though the parcel is zoned for laboratory use. The protestors argued that the zoning classification "research" is only a guide. Each activity must be carefully examined under this broad category (which includes everything from pencil and paper operations to the storage and use of hazardous chemicals) to determine whether it conforms to community standards of acceptable risk.

Acting in a quasi-judicial manner but without strict rules of evidence, the planning board heard testimony from both sides, cross-examined witnesses, and permitted adversaries to question one another. In New Jersey, a decision by the planning board is subject to an appeal in the state courts if the petitioner files the appeal in accordance with accepted guidelines.

Impacts Outside the Political Jurisdiction of the Communities Involved

The 1976 rDNA debate was covered extensively by the national and international media. Little research has been published on the other impact of the debate outside the United States, but there

is documentation about direct and indirect effects on other U.S. 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 to 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 the first U.S. law prohibiting human genetic engineering.

The rDNA events in Cambridge also had reverberations in the 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.[17] 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 excess 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 influence 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 also 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% of its membership was drawn from the fields of public health and public interest.

The ADL debate over the testing of chemical warfare agents was 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," 3 October 1984, describing the Cambridge-ADL debate.

In 1984, Cambridge was one of at least 12 cities in the United States containing firms that 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. However, in response to the ADL case, a bill was introduced to the Massachusetts legislature which would regulate certain highly toxic chemicals.

Outside of Morris Township, the events around Bellcore's proposed laboratory drew attention from several neighboring communities that were potential sites for the facility. As of this writing, there is no evidence of a "domino effect" of protest, however. And, despite CCMT's efforts, there has been scant national media coverage of the events at Morristown.

Arguments For and Against Regulations

Recombinant DNA Controversy

For Regulation

The National Institutes of Health released its first set of guidelines for rDNA research on the same day the City of Cambridge held public hear-

ings 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 research or development activities that were not funded by DHHS. At the time, no biotechnology firms were setting up laboratories in the city, but that was not thought to be far off. Third, opponents argued that NIH had not incorporated sufficient participation from the general public and other segments of the scientific community. Some scientists maintained their 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 three years. The principal rationale for passage of the revised law was the concern over large volumes (over ten liters of culture) of genetically-modified organisms, and the potential hazards associated with occupational exposure and environmental release.

The citizen's committee was not aware of any regulatory body at the state or Federal 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."[18] 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 insure 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 that the vast majority of scientists had confidence 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 non-existent 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 ac-

cidental 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.[19] The committee cited an independent consultant report that estimated between ten to thirty 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.[20]

The SAC report stated that there were no satisfactory regulatory mechanisms, state or Federal, 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 research and development or between university and non-university uses of supertoxins.

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; they believed that any work on chemical weapons is morally reprehensible and that no clear distinction can be drawn between offensive and defensive research. The city's legal arguments for 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 arguments 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 was 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, the 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 the ADL site. 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 maintained 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 argued that it had been selected out for regulation. According to the company, there are many risks to the people of the city which 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 upon whether the research is done at a profit or non-profit 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.[21]

(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 had no authority to interfere with a contract of the Federal government when all state and Federal safety standards were met. The city's ban on the testing and storage of the agents was argued to conflict with the Federal authority governing national defense and was 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, university representatives also expressed some criticism of SAC's proposed regulations for supertoxins. MIT officials, for example, 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.

Semiconductor Research

For Regulation

The group, Concerned Citizens of Morris Township (CCMT), was uncompromising on the matter of storing toxic gases on the roof of the proposed facility. The citizens group was not persuaded by company statistics on the low probability of hydrogen explosions, or the gas detection and monitoring systems planned for the new facility. In addition, the risk assessment consultant to CCMT developed a worst-case scenario that differed considerably from cases cited by Bell-

core. The storage of 1500 gallons of liquid hydrogen on the roof of the laboratory building was the basis of one potential worst-case accident. A CCMT consultant cited as a plausible event a large hydrogen leak that could cause an explosion, rupture the arsine tank, and send toxic gases out toward the neighborhood. Opponents of the facility fixed their attention on such a worst-case explosive release of toxic gases. That became the standard against which they judged acceptable risk.

An article in *Technology Review* which was distributed widely among members of CCMT also apparently, fueled the citizens' resolve against accepting a compromise on the storage of toxic gases. Passages of that article read:

> Acute inhalation [of arsine gas] can cause rapid destruction of red blood cells, followed by severe kidney damage, and if the patient is not immediately treated—death. Given sufficient low-level exposure over time, arsine also may be carcinogenic. The accidental release of the contents of a 20-pound cylinder of 100 percent phosphine would have to be spread over 1,792 acres—or 276 city blocks—before being diluted to the permissible exposure level of 0.3 ppm.[22]

A second argument, which evolved somewhat later in the controversy, centered around the environmental protection of the Great Swamp National Wildlife Refuge. The proposed laboratory facility borders on Loantaka Brook, which flows into the Great Swamp. In response to the prospect of having pretreated emissions from the research facility flush into Loantaka Brook, a spokesperson for the Great Swamp Watershed Association said:

> [A]ny accidental discharge of hazardous materials from [the] Bellcore facility could impair the Woodland Treatment plant operation and seriously degrade water quality in the brook and further downstream in the Great Swamp.[23]

Environmentalists also expressed concerns about seepage of toxic materials into the groundwater from accidental spillage or a gas cylinder rupture. It was stressed that two streams running through Southgate feed a major drinking water source for 600,000 people. By dramatizing the potential environmental impacts, CCMT was able to build a broad coalition of supporters, consisting of civic associations and environmental protection groups, to oppose the Southgate site of the research facility.

Against Regulation

In its presentation before the planning board, Bellcore maintained that the site plan was in conformity to the zoning requirements of the parcel. Moreover, the proposed laboratory facility was designed to meet or exceed all state, Federal, and local laws on handling toxic materials. Company officials argued that "their plans are a logical extension of work done safely since 1941 at Bell Labs in Murray Hill where Bellcore scientists are working now until their company opens a home for them."[24]

Bellcore cited results of its commissioned risk assessment studies that examined the case of a worst-credible arsine leak. The conditions defining the worst-credible case were a failure in the mechanical scrubber [a device that filters out unwanted gases] resulting in a slow leak of arsine, or an accidental release of arsine as a result of a tube fracture. According to those studies, the maximum exposure of any citizen in the community would be about one-fortieth of the safe arsine levels permissible for workers.

A key difference between Bellcore and CCMT on the conceptualization of risk is exemplified by the terms "worst-credible case" and "worst-possible case" as applied to an accidental release of hazardous substances. In emphasizing the former phrase, Bellcore urged the community, in evaluating the risks, to consider plausible accidents and not extremely remote or unrealistic events. However, CCMT fixed upon the worst event that was conceivable, without considerations of probability. Neither side introduced a quantitative assessment of the likelihood that any accident could take place. Each party argued its case within a preferred model of risk assessment, the choice of which is more a question of culture than of science. This difference made a negotiated settlement between adversary groups extremely difficult.

General Policy Implications

The central issue underlying all three 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, although about private contract research, also involved city government and a Federal funding agency. But in the ADL case, a well-defined scientific constituency was absent.

The Morris Township case centered around the siting of a laboratory that happened to require toxic gases for its research program, something common to other types of industrial activities (e.g., microchip manufacturing). As in the ADL case, community reaction was not directed against a specific research field or set of techniques, but against physical substances present on the site because of the research.

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 the 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?

The National Institutes of Health 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 upon 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 option 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.[25]

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 upon 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.

The restrictions of ADL's Federal contract research were apparently not viewed by either other scientists or the media as a conflict between the scientific community and local citizens. Scientists at other Boston-area research institutions did not seem to interpret the ban on testing chemical warfare agents as a threat to scientific inquiry. In part, this apparent lack of concern relates to attitudes within the scientific community. Contract research, especially that which is client-directed and profit-generating, is frequently not perceived as contributing to a research program that conforms to the established norms of science. This attitude is reinforced if the research results will not be reported in the open literature and are subject to classification by the Federal government. These conditions are perceived by many members of the scientific community to be in contrast to standards of openness, shared information, and free inquiry that contribute to a cohesive scientific culture. Perhaps as a consequence of such

attitudes, ADL's legal battle with the city did not attract much sympathetic support from scientists elsewhere in the area.

The Morris Township case is also not one of a community regulating a form of objectionable research, but rather the risks posed by the substances used in the research. As previously emphasized, barely any interest was expressed by citizens about the nature of the semiconductor and fiber optic research planned for the site. The entire focus of the debate was on the types of chemicals on site and the possibilities of their release into the environment. Had the planning board ruled against Bellcore, the decision would also not have established a legal precedent for similar cases that might arise elsewhere in the township. Planning board decisions are rendered for specific circumstances and do not accumulate as in case law. However, had such a decision been made, it is likely to have created for the township an informal regulatory precedent against similar proposals involving research with highly toxic gases. Although the company withdrew the proposal before a planning board vote was taken, a mood has been created in Morris Township that, while not codified into law, may be no less effective in proscribing such activities should they arise in a future site plan.

The policy dilemma presented by these cases is best interpreted as a conflict between the rights of a university or commercial laboratory to develop research plans or 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 clearly has implications for any Federally-contracted research on non-governmental property which 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, for example, residents have expressed opposition to the testing of chemical nerve agents in the vicinity of a school. Certainly, Bellcore's withdrawal of its proposed solid state laboratory revealed the importance of a local cultural barrier to specific types of research. Such a barrier, although informal and uncodified, may have the persistence and efficacy of a law.

Neither Congressional policies nor case law has settled the debate over Federal supremacy in these cases. Had the ADL litigation continued beyond the Massachusetts courts, Federal judicial interpretation may have set some explicit parameters for local control of private sector research. But it is clear from the delays, disruption, and suspension of research which did take place that local assertion of the public's interest in controlling the risks of research is a topic that warrants further sudy.

The essential tension expressed in these cases is between federalism and the desire for a uniform regulatory environment for scientific research. The academic and private research sectors traditionally have considered community standards as either inconsistent with the aims of science—a transnational communitarian enterprise—or as responsible for an unfair competitive configuration among R&D groups.

The federalist proponents are strong advocates of maximizing local options for the determination of acceptable risk. How far can the principle of community standards be pushed? The protection of public health and safety is an established power, firmly rooted in the jurisdiction of towns and municipalities and subject to override only by the U.S. Congress. The Massachusetts Supreme Judicial Court decision in the ADL case reaffirms the substantial powers of a municipality's chief health officer. In the court's view, only a capricious or whimsical decision is subject to judicial override.

Although not explicitly treated in these case studies, research that raises ethical issues introduces another layer of complexity. With emerging public concerns about animal and human experimentation, the tension between federalism and the research enterprise is likely to surface again. Tradition, case law, and the U.S. Constitution offer little help in evaluating the role of community standards for setting ethical boundaries on research.

Notes

1. This section is based on information in Sheldon Krimsky, *Genetic Alchemy: The Social History of*

the Recombinant DNA Controversy (Cambridge, MA: The MIT Press, 1982).

2. Charles Gottlieb and Ross Jerome, "Biohazards at Harvard," *Boston Phoenix* (8 June 1976).
3. For a detailed account of Cambridge's involvement in the rDNA controversy, see Chapter 22, "Local Initiatives for Regulation," in Krimsky, *op. cit.*
4. Marc M. Sadowsky, "Rosovsky Approves DNA Research Lab," *Harvard Crimson* (15 June 1976). Also see Richard Knox, "Harvard and Genetics Controversy," *The Boston Globe* (22 June 1976).
5. 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).
6. This section is based on analyses of primary sources including legal briefs, memoranda, committee reports, taped meetings, and consultant studies. As Chairman of the Cambridge Scientific Advisory Committee I also was a first-hand observer of the case as it unfolded.
7. Reid Weedon, Vice President of Arthur D. Little, comments made on 7 March 1985, during a community debate between ADL and the North Cambridge Toxic Alert.
8. Melvin Chalfen, Commissioner of Health and Hospitals, City of Cambridge, "Order on the Testing Storage and Transportation of Chemical Nerve and Blister Agents," 13 March 1984.
9. Weedon, *op. cit.*
10. *Report to the City Manager on the Use of Chemical Warfare Agents at Arthur D. Little's Levins Laboratory* (Cambridge, MA: Scientific Advisory Committee for the City of Cambridge, September 1984), p. 2.
11. This section is based on readings of the transcript of Morris Township Planning Board meetings, on analysis of newspaper coverage, and on interviews with some of the citizens involved in the protests. Bellcore officials would not agree to interview with the author, although they did agree to respond to questions in writing.
12. Thomas Fuschetto, Jr., "Bellcore Protest Continues to Build," *Observer-Tribune* (28 March 1985).
13. N. Michael Grove, Vice President and General Counsel, Bellcore, letter to James Stenger, Concerned Citizens of Morris Township, 11 March 1985.
14. A detailed account of CERB's decisionmaking process is contained in Sheldon Krimsky, "A Citizen Court in the Recombinant DNA Controversy," *Bulletin of the Automic Scientists,* Volume 34, Number 8 (October 1978): 37–43.
15. In 1985, a scientist at the Tufts University Medical School was awarded a grant from DOD to study the effect of chemical warfare (nerve) agent on lung tissue. After a short pulse of media attention and an investigation by Boston City Health Officials, the research proceeded without interruption.
16. Sheldon Krimsky, "Local Monitoring of Biotechnology: The Second Wave of rDNA Laws," *Recombinant DNA Technical Bulletin,* Volume 5, Number 2 (June 1982): 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; and Waltham. In other states: Berkeley, CA; Princeton, NJ; and Emerville, CA.
17. The leading congressional bills were introduced by Representative Paul Rogers (D-FL), H.R. 4759, on 9 March 1977, and Senator Edward Kennedy (D-MA), S. 1217, on 1 April 1977.
18. Krimsky *et al., op. cit.*
19. *Report to the City Manager on the Use of Chemical Warfare Agents at Arthur D. Little's Levins Laboratory, op. cit.,* p. 2.
20. *Community Risks from Experiments with Chemical Warfare Agents at Arthur D. Little* (Hartford, CT: TRC Environmental Consultants, Inc., 1984).
21. John F. Magee, President of Arthur D. Little, *Letter to the Public,* 28 January 1985.
22. Joseph La Dou, "The Not-So-Clean Business of Making Chips," *Technology Review* (May/June 1984): 23–25, 32, 36.
23. Sally Dudley, letter to the editor, *Observer-Tribune* (21 March 1985).
24. Timothy Mullaney, "Neighbors, Firm Struggle Over Chemical Risk," *Daily Record* (22 April 1985).
25. *Research with Recombinant DNA: Academy Forum* (Washington, DC: National Academy of Sciences, December 1977).