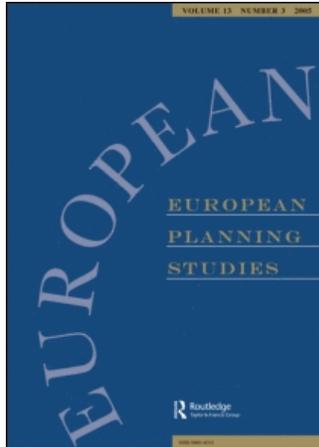


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Consensus from Controversy: Cambridge's Biosafety Ordinance and the Anchoring of the Biotech Industry

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ABSTRACT *This paper provides an interpretative history of the early genesis of biotechnology in Cambridge and attempts to reconcile how the 1976 adoption of the most restrictive biosafety ordinance in the US created an unexpected business friendly environment that subsequently anchored the industry. The regulation was motivated by community concerns about the environmental effects of recombinant DNA and ignited a lively debate, characterized by an open process with activities to inform and involve citizens in decision-making.*

Introduction

The tendency for innovative activity to concentrate spatially provides the foundation for current cluster-based economic development policies. Resources such as prominent universities, investment capital or industrial R&D are seen as critical and offered as a prescription for technology-based economic development. However, many attempts to dictate industrial development do not yield the expected results, and we still have a limited understanding of the factors that anchor an industry in a region. Rather than a function of resources or initial endowment, developing an industry concentration may be best viewed as a social process that involves temporal stages of development (Feldman & Braunerhjelm, 2006). Different from recruiting a firm, anchoring an emerging industry in a location is facilitated by the construction of institutions that provide shared conversational space and generate trust.

Technologies that offer potential for economic growth entail great uncertainty about the degree of human and societal risk. While potential rewards accrue to private companies, these risks are borne most immediately by local communities where experimental research, scale-up and production activities are based. In seeking to regulate against risk and protect

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the public interest, communities often fear undermining the potential for future growth, reflecting conventional wisdom that a pro-business climate is required for industrial development. The conventional wisdom argues that limited government regulation is part of this favourable business climate. Yet, innovation is fundamentally a social process that requires construction of a common language for describing and understanding a new technology and building consensus about potential use, product applications and an appropriate business model. The process of defining the regulation, including evaluating the technology to ensure public safety and establishing a risk mitigation strategy, can increase public comprehension of a new technology field, leading to greater innovative local capacity. Community building activities have the beneficial effect of generating trust among participants that can enhance economic development. Moreover, regulation can play a role in industrial development by providing clear guidelines about what is acceptable business practice, thus reducing uncertainty. Regulation through engaged dialogue can be a powerful tool for bringing together society and science and, in turn, provide public conversation that can enhance a region's potential as a locus for entrepreneurial activity.

The Cambridge Biosafety Ordinance is an illustrative example of the efforts of a jurisdiction to manage a new technology in a socially responsible way. While this industry is now known as biotechnology or life sciences, the earlier terms recombinant DNA or genetic engineering conjured up a more sinister and less benign image. In 1976, there were national concerns about potential health hazards when Harvard University began renovations to a laboratory to conduct research with genetic and viral biological agents. An action as simple as a request for a construction permit initiated the controversy and provided the vehicle for community oversight. Because adverse effects would immediately be felt locally, geographic proximity created a community of common interest around the unproven technology.

When applied to commercial biotechnology in 1981, the Cambridge Biosafety Ordinance benefited from a 5-year process of institution building and shared public conversation. The process of crafting the ordinance and subsequently monitoring the technology provided information that not only eased safety concerns but also informed public officials and ordinary citizens about what the emerging industry needed in order to develop. The regulation, once enacted, reduced risk for companies and made Cambridge a location of choice for biotech industry pioneers. Overtime biotech companies settled in Cambridge, filling in the industrial landscape. The area around Kendall Square has become known as the place to be for the industry, as witnessed by Novartis's decision to locate in Cambridge in 2002 (Reisch, 2002). Indeed, Cambridge currently has the densest concentration of bioscience firms of any jurisdiction in the world.

This paper documents the history of the Cambridge Biosafety Ordinance, highlighting the social process of defining the regulation and raising public appreciation about the science and its potential. Most notably, the regulation called for the creation of a new profession of technology intermediaries with oversight responsibility for ensuring industry compliance and protecting the public interest. We advance the thesis that the process of enacting the regulation created conditions favourable to the nascent biotech industry. Specifically, the process of debating the merits of the technology created public awareness of, and broad-based support for, biotechnology. The active public process of responsibly understanding the science and providing oversight and structure for its use was part and parcel of creating a business-friendly climate. While regulation is often regarded as a negative in recruiting firms, we argue that the process of anchoring a new science-based industry in a location is enhanced by institution building and open, public conversation. This occurred as individuals

in the larger community became conversant about the technology and aware of both employment and investment opportunities. Certainly, the greater the understanding of a technology and the larger the community supporting an industry the greater will be the potential to facilitate innovation and encourage subsequent economic development

Origins of the Recombinant DNA Controversy

Many authors have written about the early controversies related to recombinant DNA from a variety of perspectives (Altmore, 1982; Fredrickson, 2001; Hughes, 2001; Krimsky, 1982; Wade, 1977). Our purpose here is to frame events leading to the Cambridge ordinance within the larger national debate over the safety of recombinant DNA and to understand the confluence of activity that turned a controversy into an advantage.

In the early 1970s, developments in genetic engineering, what we now term biotechnology, were pushing the frontiers of biological research. Within the bioscience community, concerns were raised about the safety of new research techniques that enabled researchers to clone genetic material. Specifically, scientists focused on the health and safety risks associated with exposure to, or an accidental release of, recombinant DNA material. At the centre of this discussion were Stanford University Professor Paul Berg and one of his graduate students, Janet Mertz. In 1971, at a seminar at Cold Spring Harbor, Mertz described her doctoral research project, which entailed the introduction of recombinant DNA into the *Escherichia coli* bacterium (Berg, 1977). The work seemed straightforward and incremental to Mertz and her advisor Berg, however, senior researchers at the seminar felt that it represented a radical break with existing technology and raised concerns about its potential hazards.

Paul Berg responded to the concern of his scientific peers by organizing two Asilomar conferences, which were important in establishing a conversation around public risk and scientific accountability. The first conference held 22–24 January 1973, entitled “Biohazards in Biological Research”, focused on tumour virus hazards associated with prolonged exposure to recombinant DNA. On 17 April 1974, Berg participated in a meeting of concerned scientists held at Massachusetts Institute of Technology (MIT), after which a decision was made to draft a public statement, referred to as the Berg letter, calling for the deferral of certain types of recombinant DNA experiments. The letter was sent to the National Academy of Sciences and subsequently published in the journals *Nature* (19 July) and *Science* (26 July). The outcome was a national moratorium on recombinant DNA research until federal biohazard guidelines could be provided. A second Asilomar conference, held on 24–27 February 1975, involved 150 scientists from around the world, including invited press. The goal was to determine which types of recombinant DNA research were permissible. National Institutes of Health (NIH), as the primary funder of biological research, was assigned primary responsibility for recombinant DNA oversight. Drawing on the advice of a panel of scientific experts, the agency issued federal guidelines for recombinant DNA research on 23 June 1976. The guidelines covered activities at all NIH-funded research laboratories and determined the level of physical and biological containment for specific types of recombinant DNA experiments (Fredrickson, 1976).

Recombinant DNA Research at Harvard

NIH was still deliberating the recombinant DNA guidelines in May 1975 when Mark Ptashne, a Harvard professor, submitted a funding request to the NIH to build a P3

laboratory to conduct virus and genetic research. In planning for the new facility, Harvard filed a petition with the City of Cambridge for a building permit on 19 February 1976. Building permits and zoning requests fall directly into the legal jurisdiction of local government and provided the basis for initial oversight. A building permit hearing was scheduled for 26 February 1976, which Mark Ptashne attended along with other university representatives (Ptashne, 1977, pp. 28–29).

Wally Gilbert, Harvard Professor and Biogen co-founder, noted that “the desire to do recombinant DNA work became very strong in the spring of ‘76, and we wanted to have that laboratory—the P3 laboratory—here” (Gilbert, 1988, p. 4). Still, the siting of the proposed Harvard laboratory was not without controversy, especially within the Cambridge academic community. On 14 April 1976, an internal meeting was scheduled at Harvard to announce the plan for the new facility. The meeting lasted approximately 6 hours. Two senior faculty members at Harvard, biologists George Wald and Ruth Hubbard Wald, initiated arguments against the proposed facility.

In response to this internal criticism, Harvard’s Committee on Research Policy held a university-wide meeting on 28 May 1976. At the request of Ruth Hubbard Wald, Cambridge city councilperson Barbara Ackerman attended. Ruth Hubbard Wald noted that her decision to get more people involved was greatly influenced by the comments of a Harvard secretary who suggested discussions about the proposed laboratory should not be isolated to faculty members in the biology department, but were a matter of general interest and should therefore involve non-scientific university staff, among others (Hubbard, 1978, p. 4). Ackerman, who knew Hubbard from the peace movement, was also motivated to attend the meeting after watching the movie *The Andromeda Strain*, a techno-thriller about a mutated life form (Ackerman, 1977, p. 6). Ackerman called the city manager, James Sullivan, who was “somewhat aware” of the meeting and sent George Hori, the city’s chief of pathology, to attend. Hori walked out halfway through the meeting but Ackerman stayed to the end, reporting:

It was a very good meeting, as good as any that’s been had. Very little new argument has come to my attention since. People press one thing, or they press another thing, but by and large, I thought the issues were put out pretty well. And at the end of the meeting I got up and said that I wasn’t clear whether this was a matter of public interest or not but I just wanted to register my presence. (Ackerman, 1977, p. 6)

Reporters Charles Gottlieb and Ross Jerome also attended. On 8 June 1976, the *Boston Phoenix* published an article by Gottlieb and Jerome entitled “Biohazards at Harvard: Scientists will create new life forms—but how safe will they be?” The article—along with the notoriety of the Harvard faculty critical of the facility—helped attract the attention of Cambridge Mayor Al Vellucci. As Ackerman later noted about Vellucci’s growing interest in the issue and in reference to George Wald’s Nobel Laureate status, “you can’t ignore Nobel Prize winners” (Ackerman, 1977, p. 13).

On 14 June 1976, Harvard Dean Henry Rosovsky announced internal approval of plans for the P3 lab and requested funding authorization from the Harvard Corporation for a \$500,000 match to the NIH funds. On that same day, the Cambridge City Council, at the urging of Mayor Vellucci, voted unanimously to hold a series of public hearings on Harvard’s plans.

Consensus from Controversy

The first Cambridge City Council meeting on the proposed facility was scheduled for 23 June 1976 and started the public review process. In light of the significance of the proposed facility, Maxine Singer, Head of Nucleic Acid Enzymology at NIH, attended to discuss the agency's recently published recombinant DNA research guidelines. The emerging public debate also attracted the attention of scientists and recombinant DNA proponents outside of Massachusetts, as witnessed by biologist Dr David Botstein's drive from Iowa to participate in the public hearing. Despite the NIH guidelines coverage of the facility, city councillors still raised concerns about the effectiveness of existing federal monitoring mechanisms. Councilwoman Barbara Ackerman (1977, p. 25) recalled that from this first hearing she felt that,

The university laboratories were being inadequately checked by outside people . . . no matter what anybody says, a committee of people who are involved in one way or another in research is not an appropriate group to be making the kind of safety decisions that they're making.

On 7 July 1976, a second public hearing was scheduled. The university community was better organized to present their case. Professor Mark Ptashne presented letters of support for recombinant DNA research from numerous Nobel Laureates in the US. Councillor Ackerman expressed surprise when she realized that student activists attending the meeting were overwhelmingly in favour of the research (Ackerman, 1977, p. 17). At the 7 July meeting the idea of a citizen review board was presented as a governance option for advising the councillors. This was seen as a natural outcome for the activist city council, which believed strongly in citizen's participation (Ackerman, 1977, p. 28). A resolution was passed establishing the special purpose Cambridge Experimentation Review Board (CERB). A 3-month moratorium on recombinant DNA experiments in Cambridge was also adopted to allow for sufficient review by CERB members.

The next issue was the appropriate composition of the CERB. Ackerman (1977, p. 29) recalled saying to the city manager, "you'd better put somebody on there who's not awed by scientists coming in and saying 'this is so'." As Ackerman (City of Cambridge, 1976, p. 54) noted,

People really don't trust real estate brokers to be assessors, but nobody else knows how. People don't trust policeman to police themselves, but the police think they know best about it. People don't trust doctors to monitor other doctors when this is a self-interest. I generally come out for letting the educated layman in there even if it's slower; it may turn out better in the long run.

The question of public participation in scientific decision-making is controversial with some scientists believing that the public cannot make informed choices (Miller & Conko, 2000; Wright, 2001). Yet, in the example of these public hearings, an education function was certainly advanced. Ackerman (1977, p. 23) notes that during the hearings she gained sufficient knowledge to read and enjoy Crick and Watson's book *The Double Helix*; Ackerman, who had an undergraduate degree in Greek and Latin, noted that she would not have been able to read the book without the benefit of the hearings.

Most notably, she reveals that through her participation she gained an understanding and empathy towards the scientific enterprise, noting the process “. . . made me understand why the scientists were saying [in response to proposed restrictions on research] that they couldn’t do creative work between ten o’clock and twelve o’clock every alternate Wednesday” (Ackerman, 1977, p. 24). Rather than imposing restrictive and unrealistic expectations, the hearings informed subsequent regulation. After attending the public sessions Ackerman found that she was able to engage in technical discussion with scientists. In this way public dialogue was enhanced and a community of common interest formed.

On 10 August 1976, the Cambridge city manager announced the appointment of a nine-member review board comprised of Cambridge residents, including a nun, a nurse, a community activist, an engineer, a physician, two former city councillors, and a professor of environmental policy and planning. Francis Comunale, Commissioner of Health and Hospitals for the City of Cambridge, was named ex-officio member. There were no scientists on the board. A consultant from Arthur D. Little, Inc. was hired to support the work of the committee.

In an effort to broaden the discussion and educate the public, the city also scheduled a public science fair in Harvard Yard in summer 1976. This provided an opportunity for molecular biology researchers to publicly present their research and discuss their work with everyday citizens. Mayor Vellucci initially viewed this as a defeat for the city by deliberately inconveniencing the academic research community. He would describe the process as forcing scientists to act as “peddlers selling their wares in the street trying to get people to buy their project—DNA” (Vellucci, 1977). Interestingly, scientists, for their part, actually perceived this in a more positive light and as a powerful tool for accessing and educating the public at large. Harvard Professor Walter Gilbert put it best during his testimony to the City Council in 1976, “I think it is useful for the public to get involved in these questions, to educate themselves in science because I as a scientist find science the most exciting thing going and I’m always delighted when anybody else is interested” (City of Cambridge, 1976, p. 246). These activities placed the research before the general public and, in turn, created greater understanding and familiarity with the technology.

The first CERB meeting was held on 26 August 1976, and meetings continued every Tuesday and Thursday evening throughout the fall (autumn), with Tuesday meetings open to the general public. In total, the committee met for over 100 hours hearing testimony, discussing and deliberating the technology merits. The review board consulted widely and sought to educate themselves rather than set up an adversarial debate. The list of individuals who testified before the board covered the range of opinions from Donald Frederickson, Director of NIH and members of his staff, to Francine Simring, representative from Friends of the Earth, and professors of various ranks, disciplines and institutions. The board also visited biology laboratories at MIT and Harvard and participated in a Cambridge Forum on recombinant DNA. As noted in a CERB report to city officials, “our role was to examine the controversy within science. We called upon people from diverse fields to testify. We encouraged skepticism, and in doing so were able to determine the locus of the controversy” (CERB, 1976/1977, p. 3).

The locus of the controversy focused on balancing public safety with the need to conduct scientific experiments. While it is easy to say that scientific and public interests were in conflict (Mendelson, 1978, p. 59), some scientific proponents of the research still raised concerns about public safety and the need for safeguards and oversight. Dr David Nathan, a biologist at Boston Children’s Hospital, noted during this testimony

to CERB on 23 November 1976, that he was raising a family in Cambridge and would not want to put them at risk (Waddell, 1976, p. 6).

A turning point occurred with an open public debate that involved two Noble Laureates arguing different sides of the controversy. Harvard Professor Mark Ptashne (Ptashne, 1977, p. 55), who felt that the earlier shorter public meetings had become “an unbelievable joke” suggested that “. . . if the citizen’s committee [CERB] wanted a debate and wanted testimony, it would have to be in a small room, with lots of time, where one could have a chance to go into some kind of detail.” The CERB accommodated his request and arranged for a structured debate which took place on 23 November 1976. A CERB report describes this as follows:

In a five hour marathon session, CERB carried out a type of mock courtroom affair. Board members served as a kind of jury, while advocates on both sides of the issue presented their case, were given an opportunity to examine one another, and responded to questions raised by the “citizen jury.” This format enabled the Board members to evaluate how well scientists on each side of the controversy responded to the critical issues. (CERB, 1976/1977, pp. 10–11)

Mark Ptashne became less skeptical of the process noting, “they [CERB] were genuinely trying to do what was right” (1977, p. 69).

The CERB issued its final report to the city council on 7 January 1977, stating that:

Our recommendations call for more assurances than was called for by the NIH guidelines. We feel that under our recommendations, a sufficient number of safeguards have been built into the research to protect the public against any reasonable likelihood of a biohazard. For extremely unlikely possibilities, we have called for additional health monitoring. (CERB, 1976/1977, p. 3)

The CERB said of itself, “We wish also to express our sincere belief that a predominantly lay citizen group can face a technical scientific matter of general and deep public concern, educate itself appropriately to the task, and reach a fair decision” (1976/1977, p. 4).

Ready, Set, Regulate

On 7 February 1977, based on CERB’s recommendations, Cambridge City Council enacted the nation’s first municipal-level biosafety ordinance. The local law mandated that the NIH Biosafety Guidelines be followed for research using biological agents regardless of funding source. In addition, research conducted within the Cambridge city limits was subject to additional local regulatory oversight to ensure compliance. The ordinance required scientists leading projects involving recombinant DNA to submit an application for external review to a newly created five-member citizen review board known as the Cambridge Biohazards Committee (CBC). Additionally, lead scientists were asked to be available to participate in public hearings on their project, agree to regular site inspections by local public health officials and, if necessary, demonstrate proof that laboratory staff had completed a pre-approved biosafety training course. The latter also provided a mechanism for diffusing information and ensuring worker safety, especially for non-scientific staff and personnel, like academic secretaries and cleaning crews that might have access to these

regulated facilities. Failure to comply could potentially result in the loss of operating permits in Cambridge and, in some cases, the closure of a violating laboratory.

CERB justified the additional oversight on the following grounds:

While we should not fear to increase our knowledge of the world, to learn more of the miracle of life, we citizens must insist that in the pursuit of knowledge appropriate safeguards be observed by institutions undertaking the research. Knowledge, whether for its own sake or for its potential benefits to humankind, cannot serve as a justification for introducing risks to the public unless an informed citizenry is willing to accept those risks. Decisions regarding the appropriate course between the risks and benefits of potentially dangerous scientific inquiry must not be adjudicated within the inner circles of the scientific establishment. (1976/1977, p. 2)

The ordinance generated considerable negative publicity nationally and was initially viewed as a potential research deterrent (Radding, 1982). Despite initial predictions that this would hinder local economic development, the city's nascent biotechnology industry flourished nonetheless. The first biotech company to locate in Cambridge was Biogen and an examination of its location decision is instructive for understanding the influence of the regulatory process on industry concentration.

Biogen Searches for a US Location

Biogen got its start as a European company, incorporated in the Netherlands in May 1978, and with a R&D base in Geneva, Switzerland (Biogen, 1980). In 1980 the company began to look for locations for commercial and managerial headquarters to oversee its expanding research operations in the US (Krimsky *et al.*, 1982). The search was limited to sites in New England, due primarily to the location of three founding scientists at MIT and Harvard, Dr Walter Gilbert, Dr Phillip Sharp and Dr Daniel Wang. Boston, Somerville and Cambridge were included in the initial list of prospective municipalities. Cambridge was quickly selected as the ideal location choice and a facility was identified in an industrial section of east Cambridge that could accommodate the company's managerial and research functions.

Cambridge's ordinance, while certainly not the only influential factor, played a key role in this location decision. The fact that Cambridge had already addressed the debate and had proposed a reasonable solution, which appealed to both sides of the recombinant DNA debate, significantly reduced the chances of public outcry or a politically motivated research stoppage. In essence, the ordinance provided an "established" and well-defined review and regulatory process and symbolized the city's "more mature understanding of the field" (Lipson, 2003). This was especially appealing to Biogen's large corporate financiers, which included Monsanto and INCO (International Nickel Company), who were eager to avoid any potential negative press that could arise from public opposition to this emerging technology.

As Biogen officials stated in a letter of inquiry to city officials in 1980,

Cambridge is our first choice for the location of our proposed research and administrative center for several reasons, including the proximity to Harvard and MIT, the availability of necessary personnel, and good communications with Europe. We are

also attracted by the fact that the city, as a result of the initial work of the (Cambridge Experimentation Review) Board, has made the political and scientific decision to permit the use of recombinant DNA techniques within the framework of the City's Ordinance and the NIH Guidelines; the City, through the Committee, has had approximately four years of experience in monitoring such activities; and the City appears receptive to Biogen Inc. (Biogen, 1980, emphasis added)

Founding scientist Phil Sharp reiterated this statement in a 2005 interview, stating that being in Cambridge,

... allowed us to fit into a set of regulations that the university and the community had already accepted. It is easy to see why (this was important). Let's say you are two guys with the responsibility and the pleasure of finding a building and hiring 20–30 people and starting the company. You had to make investments that had years time periods on them. ... What you don't want to do if you are making those long-term commitments, is to have to go to the city and say, "well we are doing this new type of science, which the newspapers have said could be potentially dangerous, and therefore we need your approval on how to do it" At the time we were making these decisions, Cambridge had already had a year or two years of debating the technology, putting in place an ordinance, establishing a city process—a council member I believe—that would sit on NIH review committees here at MIT. The public health officer had to be informed. And, a whole set of regulations were put in place. Biogen was then able to say, "we are doing the same thing as what is going on at MIT and Harvard. We will adhere to all their same rules. Anything you (the City) want or need done, you can do. And by the way, we pay taxes." That was very reassuring because, if the city had not gone through that process, you would have to initiate it. And I would say for certain, that it would be a year or two-year process, even if you were absolutely sure the answer was going to be yes. (Sharp, personal communication, 2005)

Still, the ordinance in its original form was not designed to regulate private enterprise in Cambridge, but rather focused narrowly on the technologies used in university laboratories. Therefore, in the summer of 1980, Biogen initiated discussions with the city manager and members of the CBC in order to explore the possibility that the original ordinance could be extended to permit large-scale DNA uses and proposed commercial applications (Sharp, personal communication, 2005). In response to this request, the city council reconvened the nine-member CERB and established a joint review process with the members of the CBC in the fall of 1980 (Lipson, 2003). The outcome of this exchange was a detailed report that proposed a number of procedural changes to the existing ordinance.

Their recommendations included: updating the city's existing ordinance to remain in step with revised NIH guidelines published in November 1980; establishing a formal permitting system for recombinant DNA establishments, both institutional and commercial; granting authority to the CBC and Commissioner of Health and Hospitals to determine monitoring procedures for all large-scale applications; and, assigning personal liability to individual members of internal Institutional Biohazard Committees (IBCs) in the cases of non-compliance. As with the first ordinance, all facilities using recombinant

DNA techniques were required to establish an internal IBC and provide the CBC with copies of the minutes from monthly committee meetings. In addition, each recombinant DNA facility was required to have one community representative on the board. This individual was to have no academic or financial interest in recombinant DNA research.

In late 1980, their report was circulated for input and comment to key representatives of Harvard and MIT, as well as Biogen's core management team. All three groups submitted written letters to the CERB-CBC in December of that year which outlined suggested changes. In some cases, these recommendations entailed minor rewording or simple edits. Three items, however, were raised as serious concerns, in so far as they created undue risks for individuals and organizations associated with this technology.

All three letters strongly recommended the elimination of personal liability for internal review board members. In requesting this change, Harvard's Professor William Lipscomb convincingly argued in a letter to the CERB-CBC that "such a burden of responsibility placed upon committee members, including community members, will make it extremely difficult to find persons willing to serve on such a committee." While the need to create accountability was acknowledged by all, it was suggested the city remain in step with NIH guidelines, which assigned liability to the principle investigators of the proposed project. Second, it was suggested that containment procedures not be "determined by," but rather "reviewed by" the CBC and commissioners and that monitoring procedures themselves reflect existing NIH protocol for large-scale uses. Finally, all three reviewers recommended that permits be granted indefinitely, rather than on an annual basis. As Robert Fildes, Biogen's president at the time, stated in his letter to the CERB and CBC:

We believe that potential users of recombinant DNA techniques (including but not limited to commercial enterprises) would be most reluctant if not unwilling to locate in Cambridge . . . if their right to continue to operate were subject to annual exercise of discretion notwithstanding their compliance with the city ordinance. (Biogen, 1980)

Still all the groups recognized the need for oversight and, therefore, suggested giving CBC the authorization to review and revoke permits in all cases of non-compliance. Robert Fildes, speaking on behalf of Biogen, added an important caveat, stating that the city also provide "reasonable assurances of due process" by initially granting non-compliant facilities an "opportunity to correct such failures." Wording from this section of Biogen's letter would eventually become part of the revised ordinance and reflected CERB and CBC's recognition that Biogen and, for that matter, future commercial facilities, were not "willing to locate there at any cost" (Krimsky *et al.*, 1982, p. 12).

CERB-CBC recommended incorporating most of these suggested changes into a proposed ordinance that was submitted for review to the Cambridge City Council in spring of 1981. The city council scheduled a public hearing prior to its vote in March of that year. In contrast to the earlier hearings, turnout for this event was minimal. Furthermore, no individuals present at the hearing voiced their opposition to the proposed changes—in contrast, 18 members of the audience stated their support.

The amended ordinance passed eight to one. In 1982, Biogen proceeded with its application for a city permit to conduct recombinant DNA research at its east Cambridge facility on Boney Street. This permit request was reviewed and approved by the CBC at a permit-related public hearing. "Opposition to the site chosen by the firm was mild

compared to the events that took place four years (before) when university research (was) being questioned” (Krimsky *et al.*, 1982, p. 12, parentheses added).

The willingness of CERB and CBC to translate the recommendations of recombinant DNA researchers and research institutes into substantive procedural changes should not be viewed as evidence of the power of special interests. Rather, “the committee’s deliberations took place in an atmosphere which was supportive of accommodation and negotiation” (Krimsky *et al.*, 1982, p. 12). In fact, as a result of this open and deliberative process, citizen oversight was reinforced, in so far as input from interested parties in Cambridge helped to identify and eliminate potential obstacles to IBC participation by Cambridge residents. As will be evidenced later, this process also increased the attractiveness of the city for nascent biotechnology entrepreneurs, thereby benefiting society-at-large. Biogen’s positive experience with the city would eventually become a crucial factor in the location decisions of fellow biotechnology entrepreneurs and, as a result, would help to anchor New England’s emerging biotechnology industry to a municipality that had experience and success with regulatory oversight.

Through these same information channels, prospective entrepreneurs learned of growing industry support from key political actors in Cambridge, including Mayor Al Vellucci. Despite his well-earned reputation as a vocal opponent of recombinant DNA and strong critic of the MIT and Harvard scientific community, Vellucci surprised most biotechnology executives by warmly welcoming them to the city. At a ribbon-cutting event to celebrate the opening of Biogen’s research division in 1982, Vellucci announced that he had “no fear of recombinant DNA as long as it paid taxes” (Sharp, personal communication, 2005). That same year, he escorted executives from the Genetics Institute on a 2-hour tour of Cambridge, proudly exhibiting the city’s infrastructure and diverse residential neighbourhoods. During this meeting, he mentioned the ordinance and its requirement to hold a public hearing before granting a recombinant DNA permit. He went on to note that “at that hearing, there might be some people that attack you. Just stay calm. Those people don’t know what the hell they’re talking about” (Schmergel, personal correspondence, 2006).

His role as advocate for small start-ups added to Cambridge’s desirability. As Gabe Schmergel of the Genetics Institute explained it, “when we are talking about fledgling companies, new technologies, talking about entrepreneurs dealing with 200 things at the same time, uncertainties, etc. having reasonable regulations, yes, but *also* the personal contact, personal touch, and contact with *political figures*. Essentially, Cambridge (and Vellucci) welcomed us with open arms” (Schmergel, personal communication, 2006). Vellucci’s support for this emerging industry also helped to alter his reputation within the scientific community. Once dismissed as ignorant and combative, his role as an early critic was soon valorized and respected. As one former MIT affiliate put it, Vellucci was “a wonderful man. [He] had the best interests of the citizens at the top of everything he did” (Chalfen, personal communication, 2006). Gabe Schmergel of Genetics Institute articulated it best, stating that he felt Alfred Vellucci “just wanted the best for Cambridge” (Schmergel, personal communication, 2006). Most notably, Vellucci was a populist and his thinking evolved over time.

The Devil You Know

It has been suggested that public fear of recombinant DNA had greatly subsided by the early 1980s, therefore reducing the likelihood of significant public opposition to Biogen

and Cambridge's ordinance extension for large-scale commercial use. This, however, ignores the heated debates surfacing in neighbouring Somerville and Boston in early 1981. As with Cambridge four years earlier, local concern in Somerville over the environmental and health impacts of recombinant DNA resulted in a temporary research moratorium. This process took approximately nine months to complete, ending in October 1981, when the town's aldermen passed a recombinant DNA ordinance designed to regulate both institutional and commercial applications of the technology.

Across the Charles River in Boston, intense debate ensued in the spring of that same year, initially sparked by the public statements and actions of a well-organized neighbourhood group in Mission Hill. While a research moratorium was not called in the Boston case, the atmosphere was described as "combative" and "highly-politicized" and greatly influenced the perceptions and location decisions of scientists and entrepreneurs involved with this technology.

In contrast to Cambridge's initial recombinant DNA debate (1976–1977), which focused narrowly on research activities at Harvard and MIT, the primary target of the 1980s actions in Somerville and Boston was private industry and, specifically, the location choice of a small Harvard spin-off firm called Genetics Institute. The company's founders, Harvard faculty members Dr Mark Ptashne and Dr Thomas Maniatis, had originally planned to lease space in a former silver processing factory at 260 Beacon Street in Somerville along the Cambridge-Somerville line (*Somerville Community News*, February, 1981). Initially, the town's aldermen were "receptive" to the firm and, specifically, the "idea of high technology research being done in the city" (Krimsky *et al.*, 1982, p. 23). Strong opposition at a public meeting on 9 January 1981, however, resulted in the formation of a citizen review committee. As with their counterparts in Cambridge, members of this committee were responsible for conducting research on the recombinant DNA controversy and making policy recommendations to elected officials. Somerville's mayor and aldermen imposed a moratorium on recombinant DNA in order to give the committee sufficient time to educate themselves on the issue (Krimsky *et al.*, 1982).

Genetics Institute responded quickly, withdrawing its building permit request and searching for an alternate location in a neighbouring jurisdiction. In the spring of 1981, the company leased a small section of Boston's Brigham and Women's Lying-In Hospital. Community groups organized quickly and, in response to strong protests by Mission Hill residents, the hospital amended its standard lease to require the company to comply with all NIH guidelines for recombinant DNA research and commercial activity (Krimsky *et al.*, 1982, p. 8).

This organizing effort sparked additional interest from Boston's elected officials and resulted in a series of heated exchanges between city council leaders and company executives. As one illustration, Boston city council member Joseph Flynn—then a mayoral candidate—showed up unannounced at the hospital's doorsteps with 20 or so supporters, with the intension of publicly confronting the company's chief executive officer (CEO), Gabe Schmergel. Reporters were invited to document the exchange. At the time, Flynn was on record supporting an outright ban on commercial recombinant DNA facilities in Boston (Schmergel, personal communication, 2006).

While these exchanges did not directly affect the R&D activities of the company, they did influence the company's decision to exclude Boston and Somerville from their list of possible locations for a new research and development facility. As Gabe Schmergel, the CEO at the time, described it, "the whole process . . . gave me a very bad taste in my

mouth.” As a result, the company’s executives narrowed their search to Cambridge in 1982. Their experiences in Somerville and Boston not only shaped their views on local regulation, but gave them a new-found appreciation for the subtle, but important differences in how local regulation was developed and enacted. As Schmergel explained it, “Boston was not really working properly in establishing regulation. . . . We *were* interested in having something in place that set the rules of the game and that the local population, would accept and wouldn’t be nervous [about]” (Schmergel, personal communication, 2006).

Interestingly, both Boston and Somerville adopted recombinant DNA ordinances similar to that of Cambridge in early 1982. Still, the politicized and polarized nature of the debates in Boston and Somerville—compared to the deliberative process underway in Cambridge—raised concerns that this issue was not fully resolved in the minds of local residents and could result in additional demands for more restrictive regulation.

Walter Gilbert used the term “inoculated” to describe the relationship between Cambridge’s early recombinant DNA debates and the more mundane set of proceedings that resulted in changes to the city’s existing ordinance in 1981. He compared this to the emotionally-charged atmosphere in Somerville and Boston. In contrast to Cambridge, which had already worked through its concerns over this emerging technology and developed a reasonable and predictable set of safety regulations, these “places that hadn’t been inoculated blew up entirely” (Gilbert, 1988, p. 3). Similar comparisons were noted by other regional entrepreneurs. According to one of the founding scientists of Applied Biotech (established in 1982), this difference in atmosphere ultimately “tipped the balance between Boston and Cambridge, because Boston, at that time, was still a little vague and it was a concern.” Ultimately, “Cambridge was the *devil you knew*” (Jacobson, personal communication, 2006).

Singing Cambridge’s Praise

Interestingly, a very different image emerges from media accounts of Cambridge’s 1980s public hearings and ordinance review process. According to a 1981 *Boston Herald* article, the Cambridge hearings were designed to establish “restrictive legislation” on commercial uses of the technology. A 1981 flyer circulated by one of Boston’s community coalitions also indicated their neighbours across the river were advocating for “stricter laws governing private recombinant DNA” (Krimsky *et al.*, 1982). The group went on to recommend coalition attendance at the Cambridge hearings as a means to show support for, and learn from, Cambridge’s experience. Similarly, a *New York Times*’ article portrayed local regulation in Massachusetts as a source of possible “confusion” for nascent entrepreneurs, stating that “the debate over safety has grown so divisive that the towns, the state and the companies are arguing with each other and even among themselves” (Radding, 1982). The article contrasted Massachusetts and California, with the latter portrayed as mostly regulation free—with the exception of Berkeley—and thus, pro-business. The paper quoted Thomas Kiley—vice president and general counsel of California’s first biotechnology firm, Genentech—as saying “I would much rather be operating in this industry in California than in Massachusetts. The purpose of this industry is *not served* by Draconian regulatory measures” (Radding, 1982).

Based on these reports, it is understandable why state officials—especially those interested in nurturing high-technology industry—considered pre-emptive laws that would

overturn local efforts to regulate recombinant DNA (Radding, 1982). It is also easy to see why technology advocates initially feared the expanding scope of the debate would undermine Cambridge's efforts to hold-down this emerging industry. Still, a less visible dynamic allowed nascent entrepreneurs to develop a more sophisticated understanding of this issue and ultimately reinforced a widening belief that Cambridge—as a result of its specific regulatory setup—remained a good place to start a technology business. The key here was the existing social and professional networks that linked recombinant DNA scientists and industrialists and supported intra-industry information sharing and exchange.

As an early example of this dynamic, founding scientists and executives from Biogen acted as *de facto* advisors to emerging companies interested in securing commercial space in Cambridge. Cambridge's second wave of entrepreneurs was quick to follow Biogen's lead. As Genetics Institute CEO, Gabe Schmergel explained it,

We, the biotech CEOs, [we] all talk to each other because everybody was working on those projects . . . The issues out there were common issues. So, for example, somebody would formally or informally call me up and say "how are you guys doing in Cambridge? Is it good? We are thinking about locating there." I would make very very positive comments. (Schmergel, personal communication, 2006)

As this illustrates, the social and professional networks, long touted as an innovation catalyst, played a decisive role in establishing early regional clustering patterns. The location choice of subsequent start-ups was influenced by the positive experiences of Cambridge's early entrants. Thus, the self-reinforcing cycles of cluster development anchored the industry in the jurisdiction as entrepreneurs located there. Specifically, Kendall Square in Cambridge, at the time an area in decline due to industrial restructuring, provided affordable real estate in close proximity to MIT and Harvard and has become the locus of the biotech industry.

Reflective Conclusions

Cambridge, Massachusetts contains what is arguably now one of the most vibrant concentrations of biotech firms in the world. Of course, Cambridge also contains several prominent research universities, but to simply assume that the location of the industry is due solely to proximity to the universities would underestimate the social processes influencing this economic development. Ultimately universities are about providing education, encouraging debate on timely topics and creating social consensus and cohesion. As universities become both the most important employers in localities and a source of new technology there is a dual responsibility to engage with the local community. Krimsky (1982) examines similar debates at the University of Michigan where regulation was contained within the university and not subject to public debate. Interestingly, the University of California at Berkeley adopted a similar biosafety ordinance without a public debate. Lowe and Feldman (2007) examine differences in the implementation of identical ordinances between these two jurisdictions.

Nanotechnology is a contemporary example of an uncertain new technology. Perhaps because biotech has provided a reasonably successful model of technology based economic development many places are attempting to develop nanotechnology clusters.

Interestingly, there is an emerging debate about the health and environmental consequences of nanotechnology. The Cambridge example offers an opportunity to consider ways to address the safety concerns while encouraging public education about the new technology.

In a complex context, with so many interacting variables, it is difficult to prove causality. Yet the example provided here suggests that the development of the Cambridge biotech cluster, rather than a deliberate and articulated goal, was the result of a social process that created conditions favourable to the industry. Local activism, open citizen participation, institutional support for public education about the technology and scientists acting as advocates created favourable conditions motivated towards a larger goal of ensuring public safety. From this foundation, the industry became anchored in the jurisdiction and economic benefits eventually followed.

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