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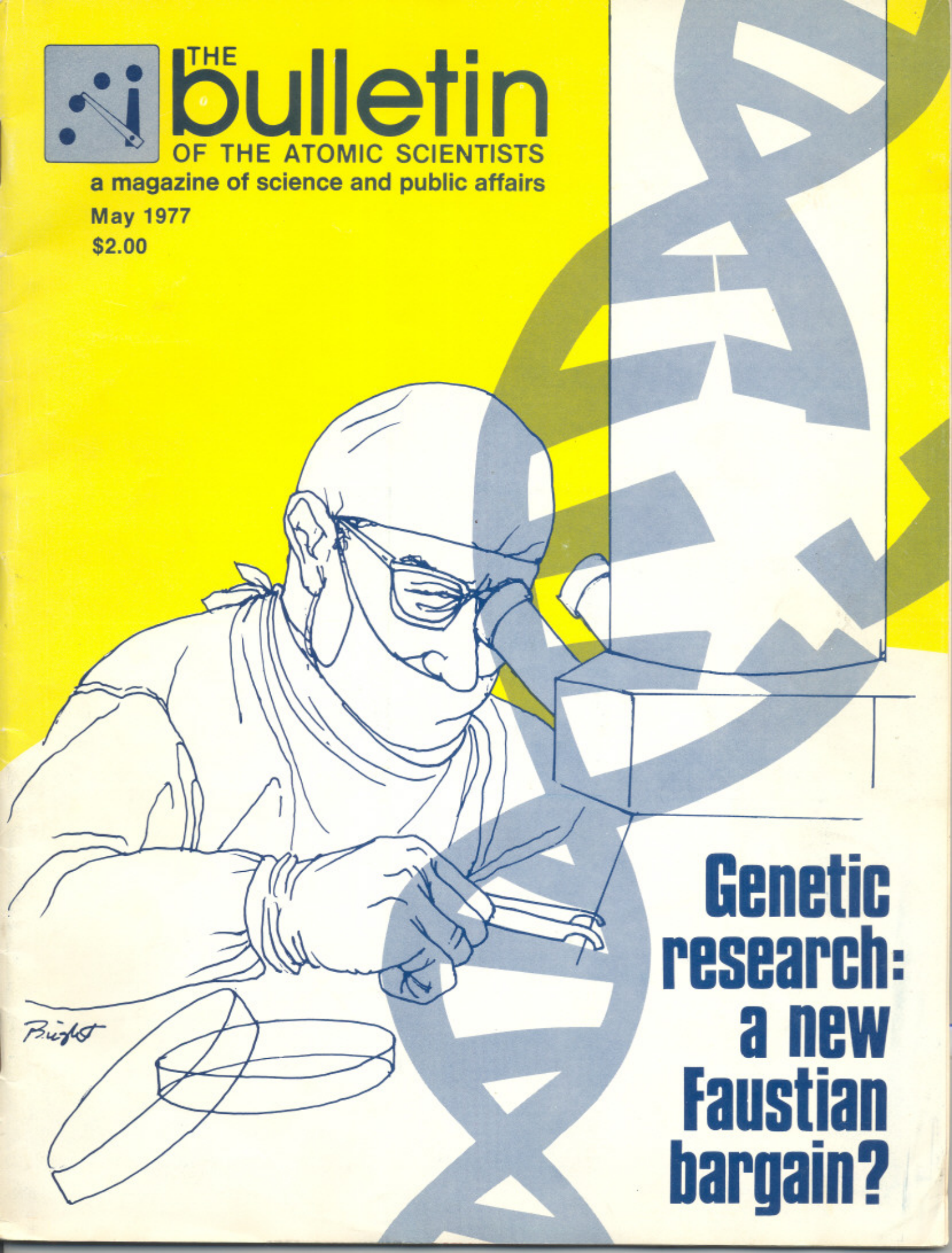
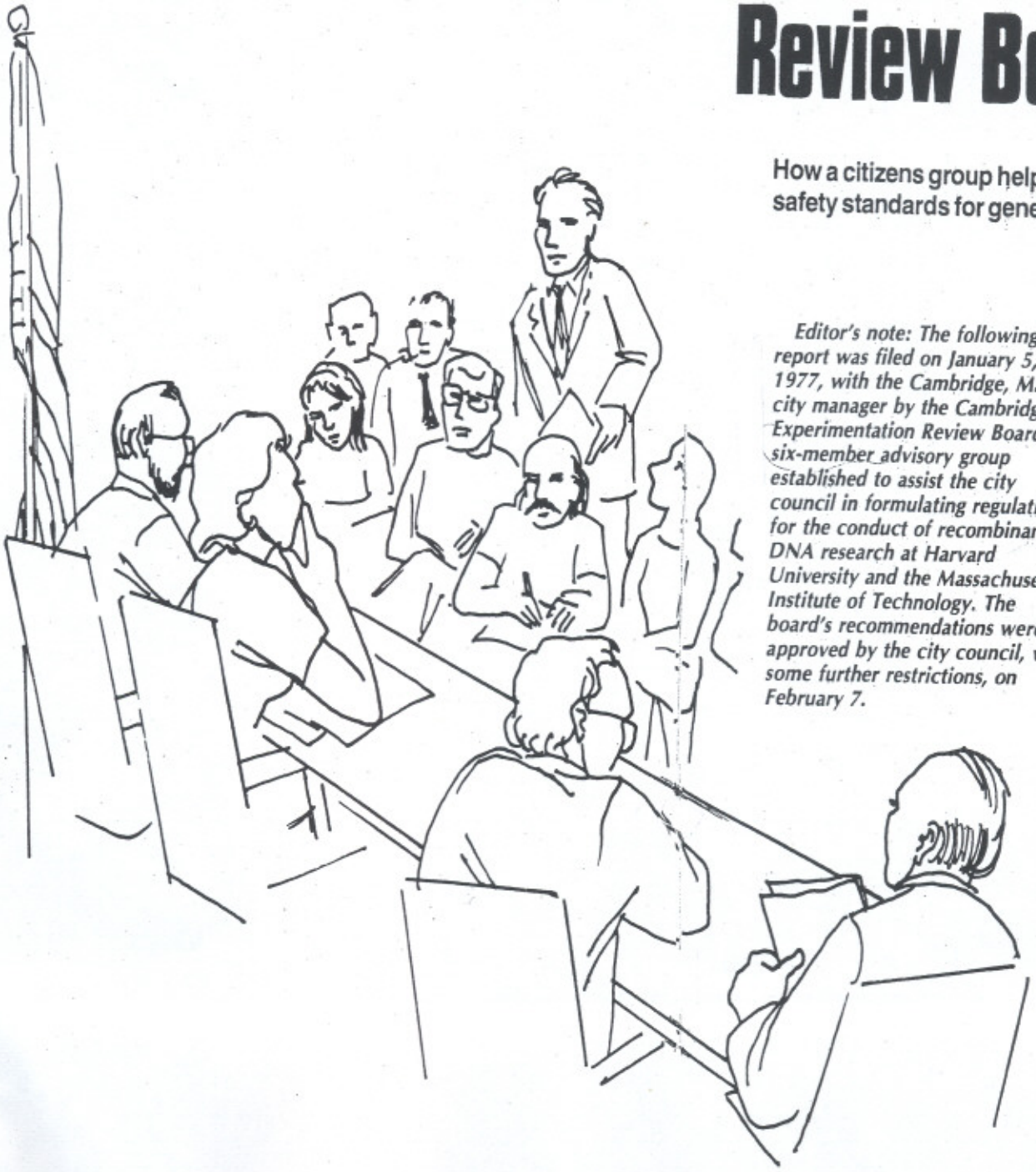


Genetic research: a new Faustian bargain?

The Cambridge Experimentation Review Board

How a citizens group helped a city council set safety standards for genetic research



Editor's note: The following report was filed on January 5, 1977, with the Cambridge, Mass., city manager by the Cambridge Experimentation Review Board, a six-member advisory group established to assist the city council in formulating regulations for the conduct of recombinant DNA research at Harvard University and the Massachusetts Institute of Technology. The board's recommendations were approved by the city council, with some further restrictions, on February 7.

The Cambridge Experimentation Review Board (CERB) has spent nearly four months studying the controversy over the use of the recombinant DNA technology in the City of Cambridge, Mass. The following charge was issued to the Board by the City Manager at the request of the City Council on August 6, 1976.

The broad responsibility of the Cambridge Experimentation Review Board shall be to consider whether research on recombinant DNA which is proposed to be conducted at the P3 level of physical containment in Cambridge may have any adverse effect on public health within the City, and for this purpose to undertake, among other studies, to:

- review the "Decision of the Director, National Institutes of Health to Release Guidelines for Research on Recombinant DNA Molecules" dated and released on June 23, 1976;
- review but not be limited to the methods of physical and biological containment recommended by the National Institutes of Health;
- review methods for monitoring compliance with applicable procedural safeguards;
- review methods for monitoring compliance with safeguards applicable to physical containment;
- review procedures for handling accidents (for example, fire in recombinant DNA research facilities;
- advise the Commissioner of Health and Hospitals on the reviews, findings and recommendations.

Throughout our inquiry we recognized that the controversy over recombinant DNA research involves profound philosophical issues that extend beyond the scope of our charge. The social and ethical implications of genetic research must receive the broadest possible dialogue in our society.

That dialogue should address the issue of whether all knowledge is worth pursuing. It should examine whether any particular route to knowledge threatens to transgress upon our precious human liberties. It should raise the issue of technology assessment in relation to long range hazards to our natural and social ecology. Finally, a national dialogue is needed to determine how such policy decisions are resolved in the framework of participatory democracy.

In the several months of testimony, we have come to appreciate the brilliant scientific achievements made in molecular biology and genetics. Recombinant DNA technology promises to contribute to our fundamental knowledge of life processes by providing basic understanding of the function of the gene. The benefits to be derived from this research are uncertain at this time, but the possibility for advancement in clinical medicine as well as in other fields surely exists.

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 scien-

tific establishment.

Moreover, the public's awareness of scientific results that have an important impact on society should not depend on crisis situations. Many of the fears over scientific research held by the citizenry result from a lack of understanding about the nature of and the manner in which the research is conducted.

cial interests in promoting the research.

The uncertainty we faced was not something fabricated in our community. It was expressed most eloquently by Donald Frederickson, NIH Director, when he issued their guidelines:

> In many instances, the views presented to us were contradictory. At present, the hazards may be guessed at, speculated about, or voted upon, but they cannot be known absolutely in the absence of firm experimental data—and, unfortunately, the needed data were, more often than not, unavailable.

Decisions regarding the appropriate course between the risks and the benefits of potentially dangerous scientific inquiry...

Members of the Review Board have made a determined effort to assess the risks to the Cambridge community of recombinant DNA research at the P3 level of physical containment. The National Institutes of Health, in issuing its guidelines, sought a balance between "stifling research through excessive regulation and allowing it to continue with sufficient controls." The function of the Review Board was not to repeat the long and careful deliberations of the National Institutes of Health, perhaps one of the most intensive biohazards studies in the history of biology. 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.

Many of us felt that it was the role of the proponents of the research to justify that *no reasonable likelihood* exists in which the public's health would be compromised if the research is undertaken under the guidelines issued by the National Institutes of Health. We recognized that absolute assurance was an impossible expectation. It was clearly a question of how much assurance was satisfactory to the deliberating body, and in the case of the Cambridge Review Board that body was comprised of citizens with no spe-

Our recommendations call for more assurance 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, whereby appropriate personnel are responsible for the detection of hazardous agents, inadvertently produced, before they are able to threaten the health of the citizens in our community.

We recognize that the controversy over the use of the recombinant DNA technology was brought to the public's attention by a small group of scientists with a deep concern for their fellow citizens and responsibility to their profession. Many of these early critics are now satisfied that the potential hazards of the research are negligible when carried out under the NIH guidelines. There are also those scientists who continue to call for more stringent control over this technology, in many instances, against the majority view of their colleagues and amidst very strained personal relations. To them we owe our gratitude for broadening the context in which the issues are being discussed.

The willingness of scientists on both sides of the controversy to share their knowledge with us in our determination to arrive at a reasoned decision has been an inspiration.

The Cambridge Experimentation Review Board has spent over 100 hours in hearing testimony and carrying out its deliberations. Our decision is as unemotional and as objective as we are capable of offering. It provides a statement of conditions and safeguards that we deem necessary for P3 recombinant DNA research to be carried out in Cambridge.

The members of this citizen committee have no association with the biological research in question and no member of the Cambridge Review Board has ever had formal ties to the institutions proposing the research, with the exception of one member who has taught in unallied areas at both the institutions in question. Moreover, the City Manager in selecting a group of citizens representing a cross-section of the Cambridge community insured that the "empathy factor"—that is, the concern that the institutions proposing the research might lose valuable funds or that qualified researchers would leave in the event of a ban on the research—was never an issue in the deliberations.

In presenting the results of our findings 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.

Board's Recommendations

Section 1

After reviewing the guidelines issued by the Director of the National Institutes of Health for Research Involving Recombinant DNA Molecules (issued June 23, 1976) it is the unanimous judgment of the Cambridge Experimentation Review Board that recombinant DNA research can be permitted in Cambridge provided that:

The research is undertaken with strict adherence to the NIH guidelines and in addition to those guidelines the following conditions are met:

I. Institutions proposing recombinant DNA research or proposing to use the recombinant DNA technology shall prepare a manual which contains all procedures relevant to the conduct of said research at all levels of containment and that training in appropriate safeguards and procedures for minimizing potential accidents should be mandatory for all laboratory personnel.

II. The institutional Biohazards Committee mandated by the NIH guidelines should be broad-based in its composition. It should include members from a variety of disciplines, representation from the biotechnicians staff and at least one community representative unaffiliated with the institution. The community representative should be approved by the Health Policy Board of the City of Cambridge.

III. All experiments undertaken at the P3 level of physical containment shall require an NIH certified host-vector system of at least an EK2 level of biological containment.

IV. Institutions undertaking recombinant DNA experiments shall perform adequate screening to insure the purity of the strain of host organisms used in the experiments and shall test organisms resulting from such experiments for their resistance to commonly used therapeutic antibiotics.

V. As part of the institution's health monitoring responsibilities it shall in good faith make every attempt, subject to the limitation of the available technology, to monitor the survival and escape of the host organism or any component thereof in the laboratory worker. This should include whatever means is available to monitor the intestinal flora of the laboratory worker.

VI. A Cambridge Biohazards Committee (CBC) be established for the purpose of overseeing all recombinant DNA research that is conducted in the City of Cambridge.

A. The CBC shall be composed of the Commissioner of Public Health, the Chairman of the Health Policy Board and a minimum of three members to be appointed by the City Manager.

B. Specific responsibilities of the CBC shall include:

- Maintaining a relationship with the institutional biohazards committees.
- Reviewing all proposals for recombinant DNA research to be conducted in the City of Cambridge for compliance with the current NIH guidelines.
- Developing a procedure for members of institutions where the research is carried on to report to the CBC violations either in technique or established policy.
- Reviewing reports and recommendations from local institutional biohazards committees.
- Carrying out site visits to institutional facilities.
- Modifying these recommendations to reflect future developments in federal guidelines.
- Seeing that conditions designated as I to V in this section are adhered to.

Section 2

We recommend that a city ordinance be passed to the effect that any recombinant DNA molecule experiments undertaken in the city which are not in strict adherence to the NIH guidelines as supplemented in Section 1 of this report constitute a health hazard to the City of Cambridge.

Section 3

We urge that the City Council of Cambridge, on behalf of this Board and the citizenry of the country, make the following recommendations to the Congress:

I. That all uses of recombinant DNA molecule technology fall under uniform federal guidelines and that legislation be enacted in Congress to insure conformity to such guidelines in all sectors, both profit and non-profit, whether such legislation takes a form of licensing or regulation, and that Congress appropriate sufficient funding to adequately enforce compliance with the legislation.

...must not be adjudicated within the inner circles of the scientific establishment.

II. That the NIH or other agencies funding recombinant DNA research require institutions to include a health monitoring program as part of their funding proposal and that monies be provided to carry out the monitoring.

III. That a federal registry be established of all workers participating in recombinant DNA research for the purpose of long-term epidemiological studies.

IV. That federal initiative be taken to sponsor and fund research to determine the survival and escape of the host organism in the human intestine under laboratory conditions.

Section 4

In the event that the citizens of Cambridge, the members of the City Council or other interested parties wish to know how the Cambridge Experimentation Review Board carried out its charge to review P3 recombinant DNA research in the City, the final section of this report discusses the review process. In this discussion we include a brief chronology of events, some of the strategies undertaken by the Board for self-education and a description of its deliberation process.

On July 7, 1976, after having held two days of public hearings, the City Council of Cambridge voted a three-month "good faith" moratori-

um on all P3 level recombinant DNA research in the City and called for the establishment of a citizen review board to study the issue.

James L. Sullivan, City Manager of Cambridge, released the charge to the newly designated Cambridge Experimentation Review Board on Aug. 6, 1976, and issued the guidelines under which that body was to carry out its responsibilities. In addition, eight citizens and the newly appointed acting Commissioner of Health and Hospitals for the City were selected to constitute the Board. Members of the Board were chosen to reflect a cross-section of the Cambridge community. Of the eight citizen Board members, only three had ever met before. Seven of the eight had never had formal ties with either institution proposing the new research. The one individual who did have some formal ties with the universities has taught courses in structural engineering both at Harvard and M.I.T.

The Cambridge Review Board commenced its first meeting Aug. 26, 1976, and continued its hearings until the recommendations of the Board were issued to the Commissioner of Health and Hospitals on Dec. 21, 1976. Meetings were held twice weekly with each session lasting in excess of two hours.

At the Sept. 14 meeting, the Board arrived at a consensus on key policy issues related to the process of its inquiry. Dr. Francis Comunale, initially serving as chairperson, released the chair to the vice chairperson, Daniel Hayes. This decision was made to preclude any ambiguity or conflict of interest in having Dr. Comunale, the then acting Commissioner of Health and Hospitals in the role as chairman of the Board and the person to whom the Board advised on the matter in question. Dr. Comunale thereafter became an ex officio member of the Board. He attended meetings, without a vote, and excluded himself from the final deliberations leading to a decision.

At the same meeting the Board voted to request an extension of the moratorium for an additional three months, on the grounds that we needed the additional time to carry out the full scope of our charge, including a review of the Environmental Impact Statement, which at that time was not complete. The request for an extension of the moratorium was subsequently granted by the City Council and accepted by the institutions affected by the moratorium.

It was agreed that on all decisions undertaken by the Cambridge Review Board a consensus would be sought; if consensus could not be reached on an issue, the majority decision would prevail. Moreover, any Board member had the right to poll the entire membership on any issue requiring a vote. If consensus could not be reached on the final recommendation, then minority statements would be permitted in the Board's final report. The members agreed that Thursday meetings would be kept open for the public and the media, while Tuesday sessions would be held in private.

Among the more formidable problems facing this lay citizen board was its self-education. At the outset of the inquiry, the members of the Board were, for the most part, unfamiliar with the concepts, the basic scientific principles and the explanatory models underlying the recombinant DNA technology. The education of the Board members was carried out simultaneously with the inquiry process. We had to decide on the kind of information we would need to reach a decision as well as the kind of people who could provide us with that information.

There were several facets to the Board's information gathering and self-education strategies as exemplified in the following.

- Each Board member was provided with special technical documents on the controversy, including the NIH guidelines, the Environmental Impact Statement, and essays in journals such as *Science*. Along with technical materials, articles that were published in the more popular press and written for a wider readership were distributed to the Board members. As examples, the Board had articles from *Scientific American*, the New York Times Magazine, and *National Geographic*.
- A technical assistant to the Board, who had training in the biological sciences, offered help with translating technical concepts. The

technical assistant also made available to the Board current articles, news analyses, and essays in leading journals relating to the controversy.

- Spokespeople who appeared before the Board were asked to reduce technical concepts to layman's terms, to present simplified models of bio-chemical events, and to draw upon analogies that helped foster understanding whenever they were available.
- Members of the Board were witness to a forum on the recombinant DNA controversy in which proponents and opponents of the research presented their arguments and responded to questions from the audience.
- Two open-line telephone conversations were used to draw testimony from people outside the state. In one of these conversations, the NIH Director and a panel of experts responded to questions of the Board members.
- In a five-hour marathon session, the Board 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 cross-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. Medical researchers and clinicians were also on hand to respond to testimony.
- Board members were taken through laboratories at Harvard and M.I.T. In one case a mock experiment was carried out which exemplified the various stages of the recombinant DNA process. Visiting the laboratories also helped the Board members concretize many of the specifications found in the NIH guidelines relating to physical containment.

Speakers appeared before the Board both on a voluntary basis and at the Board's request. The schedule of speakers called for fair representation of the views of opponents and proponents, as well as other persons who were called upon to broaden our understanding of the issues. Individuals on each side of the issue were heard from on intermittent weeks.

Some members of the Cambridge Review Board visualized the Board as a kind of "citizen jury" whose function it was to review and assess the significance of the recombinant DNA controversy within science. The use of the legal metaphor helped members of the Board clarify for themselves the role of lay citizens in this complex issue. The analogy was of only limited value since Board members functioned in a greater variety of ways than citizens called upon to jury duty. The Board determined the rules of its inquiry, called upon people to testify, listened to the arguments, cross-examined scientists and finally came out with its recommendations.

A citizens group can face a technical matter of deep public concern, educate itself appropriately to the task and reach a fair decision.

The use of a "citizen court" in areas of controversy within science that have significant bearing on public welfare is quite new and untested. It encouraged discussions among Board members about where justification rests. At issue was whether the proponents of the research must prove that it is safe beyond all reasonable doubt or whether the opponents must prove that if recombinant DNA research were undertaken there would be significant potential hazards.

There was no clear consensus on the issue of who must justify what, and to what degree of satisfaction. However, the Board carried out its inquiry by seeking the strongest positions on both sides of the controversy, while simultaneously looking for weaknesses in the arguments.

Several intensive planning sessions were used to explore the Board's unresolved questions and to draw as wide a range of input from its citizen members as possible. The planning sessions were designed to overcome the factors that inhibit people from expressing their uncertainties. The aim was to eliminate any social hierarchies that could prevent full cooperation and participation from Board members. The success of full cooperation hinged upon the building of confidence for each individual member.

The planning strategy involved first covering the walls of a room with large sheets of paper. Then, a scribe wrote down suggestions from Board members, insuring that each individual completed his/her recommendations or queries before the issues were debated by the entire Board. Finally, the material on the sheets was reduced and synthesized by a technical assistant and sent out to the Board members for discussion at subsequent meetings. This method insured that each citizen member, whatever his/her stand on the controversy, and whatever his/her state of knowledge on the issues, had an unfettered opportunity for self-expression and participation.

Individuals appearing before the Board spent up to three hours discussing the issues and responding to questions. Members of the Cambridge ERB heard over 75 hours of testimony from more than 35 individuals representing both sides of the controversy. In addition, the Board spent over 25 hours in formal planning and deliberation as well as countless hours of reviewing related written material before arriving at our decision.

Finally, it is worthwhile noting that despite a considerable heterogeneity in the Board's makeup and differences in how its members initially perceived the controversy, we were able to reach a unanimous decision. □