CITY OF CAMBRIDGE
DEPARTMENT OF HEALTH, HOSPITAL AND WELFARE
1493 CAMBRIDGE STREET CAMBRIDGE, MASSACHUSETTS 02139
Telephone 354-2020

January 4, 1977

TO: Mayor Alfred Vellucci, City Manager James L. Sullivan, and Honorable Members of the City Council

FROM: Francis L. Comunale, M.D., Acting Commissioner of Health and Hospitals for the City of Cambridge

RE: Determination of possible health hazard in relation to Recombinant DNA Research

On July 8, 1976, acting in accordance with Council orders submitted by Mayor Alfred Vellucci and Councillor Daniel Clinton, City Manager James L. Sullivan appointed me Acting Commissioner of Health and Hospitals, and charged me with the responsibility of determining whether or not proposed P3 level Recombinant DNA research performed within the City limits would constitute a health hazard to those who live and work in the City of Cambridge.

Early in August, in response to another council order submitted by Mayor Alfred Vellucci, and in order to aid me in arriving at a decision, Mr. Sullivan announced the selection of an eight member Cambridge Experimental Review Board. Since the city's main concern in this controversy revolved around the potential dangers to the health and safety of the citizens of Cambridge, the board was justifiably composed of seven lay persons who had little or no scientific background or interest, but represented a broad geographical, social, ethnic and economic base of the Cambridge population. The eighth member selected was a physician who is a native of Cambridge, and whose medical specialty is in the field of Infectious Diseases.

I have spent the past four months working closely with the Review Board in studying the controversy which has arisen over the proposed use of the Recombinant DNA technology in relation to biological research. I attended all Board meetings at which testimony was given, and reviewed all printed materials submitted to the board for review. During this time, I have come to respect and admire the way in which the entire membership of the board accepted their charge, and the diligence, open-mendedness and intelligence with which they set about to carry out their responsibilities towards their fellow citizens.

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As pointed out in the introduction of the enclosed copy of the board's final report, it is obvious that much of the controversy over recombinant DNA research stems from profound philosophical, social, moral and ethical beliefs. However, I have previously mentioned that as the City's chief Health Officer, I have been charged with the task of determining whether or not a health hazard would exist should P3 level recombinant DNA research be performed within the City of Cambridge.

Therefore, although I am sure that these philosophical, ethical and moral issues raised throughout the controversy are extremely important to many individuals, including myself, my decision and recommendations concerning the performance of this research in Cambridge are based solely on the potential health hazards.

After careful consideration of all the data submitted during the past four months, it is my opinion that P3 level recombinant DNA research carried out under the NIH Guidelines established for the performance of this type of research and the additional guidelines proposed by the Cambridge Experimental Review Board, will not pose a health hazard to the citizens of Cambridge.

Therefore, I accept the report of the Experimental Review Board in its entirety and urge:

1. that the City Council take immediate action to officially adopt and implement the recommendations contained therein;

2. that a city ordinance be passed making it mandatory that all recombinant DNA research performed within the city be carried out under the guidelines set forth in the review board's report;

3. that all cases of unusual illnesses occurring in workers associated with all recombinant DNA research being carried out in Cambridge be fully investigated and be reported in detail to the Commissioner of Health and Hospitals for the City of Cambridge;

4. that the City Council take appropriate action to officially commend the members of the Cambridge Experimental Review Board, including Miss Barbara Franks, who served as technical advisor to the board, for their outstanding work in preparing this report. I am sure that through their actions, these citizens have greatly narrowed the large gap in communications which previously separated the lay and scientific communities.

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Telephone 354-2020

January 5, 1977

TO: Mayor Alfred Vellucci, City Manager James L. Sullivan, and members of the Cambridge City Council

As Acting Commissioner of Health and Hospitals, I am well aware of my duty to protect and promote the health and welfare of the Citizens of Cambridge.

In addition, I am also aware of my duty as an appointed city official, to advise you, the elected members of the city government on all matters related to health care and public health.

As a professional in the field of medicine, it is my further obligation to insure that I base all this advice on sound medical principle, and not to allow myself to be swayed by other political, social or philosophical pressures. I can assure you that the knowledge of these duties and obligations weighed heavily on my mind in preparing the enclosed report and recommendations. In fact, I feel that any other action on my part would not only be a dereliction of my duty, but also would have to be based on other than sound medical principles and knowledge.

Respectfully,

Francis L Comunale MD

Francis L. Comunale, M.D.
Acting Commissioner of
Health and Hospitals for the
City of Cambridge

FLC/jlb

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1493 CAMBRIDGE STREET, CAMBRIDGE, MASSACHUSETTS 02139
Telephone 354-2020

January 5, 1977

Mr. Paul Healey
City Clerk
Cambridge City Hall
Cambridge, MA 02139

Dear Mr. Healey:

In compliance with the Council Orders introduced by Mayor Alfred Vellucci and Councillor Daniel Clinton dated July 7, 1976, I submit for council acceptance the final reports and correspondence of the Cambridge Experimental Review Board and myself concerning Recombinant DNA research in Cambridge.

Very truly yours,

Francis L. Comunale

Francis L. Comunale, M.D.
Acting Commissioner of
Health and Hospitals for the
City of Cambridge

FLC/jlb

enclosures

Guidelines for the Use of Recombinant DNA Molecule Technology in the City of Cambridge

Recommendations and Findings Submitted to:

Commissioner of Health and Hospitals: December 21, 1976

City Manager: January 5, 1977

City of Cambridge

Commonwealth of Massachusetts

Submitted by:

Cambridge Experimentation Review Board

Accepted in its entirety
by [illegible]
Submitted to City Council
for their adoption.
Francis L. Cosgrove
Acting Comm. of Health & Hosp.

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CAMBRIDGE EXPERIMENTATION REVIEW BOARD

Letter of Transmittal
January 5, 1977
To: Mr. James L. Sullivan, City Manager

The Board herewith submits its report related to recombinant DNA research as outlined in your letter to the City Council of August 6, 1976.

Contained in this report is our opinion and recommendations as well as background material that may be helpful in assessing the manner in which the Board arrived at its decision.

We request that this report be forwarded to the City Council in order that they might take appropriate action on our recommendations.

The Board would like to thank the staff of the Cambridge Hospital for their cooperation and apologize for any inconvenience we might have caused.

Our appreciation is extended to Mr. Reid Weedon and Arthur D. Little, Inc. for allowing us to have Ms. Barbara J. Franks as our technical assistant. Her work was extremely helpful in enabling the Board to understand the many technical aspects of this controversy.

The Board considers its work complete, but the members stand ready to assist in any appropriate manner to see that their recommendations are carried out.

Sr. Mary Lucille Banach

John L. Brusch, M.D.

Daniel J. Hayes, Chairperson

Mrs. Constance Hughes

Sheldon Krimsky, Ph.D

William J. LeMessurier

Mrs. Mary Nicoloro

Mrs. Cornelia Wheeler

Introduction

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

(a) 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;

(b) review but not be limited to the methods of physical and biological containment recommended by the NIH;

(c) review methods for monitoring compliance with applicable procedural safeguards;

(d) review methods for monitoring compliance with safeguards applicable to physical containment;

(e) review procedures for handling accidents (e.g. fire) in recombinant DNA research facilities;

(f) 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 scientific 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.

The members of CERB have made a determined effort to assess the risks to the Cambridge community of recombinant DNA research at the P3 level of physical containment. NIH, in issuing its guidelines, sought a balance between "stifling research through excessive regulation and allowing it to continue with sufficient controls." The function of CERB was not to repeat NIH's long

and careful deliberation, 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 NIH. 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 CERB, that body was comprised of citizens with no special interests in promoting the research. The uncertainty we faced was not something fabricated in our community. It was expressed most eloquently by Donald Frederickson, the Director of NIH, when he issued the 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."

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, inadvertantly 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.

CERB has spent over one hundred 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 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.

Section 1:

After reviewing the guidelines issued by the Director of the National Institutes of Health (NIH) for Research Involving Recombinant DNA Molecules (issued June 23, 1976) it is the unanimous judgement 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 bio-technicians 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:

1. Maintaining a relationship with the institutional biohazards committees.
2. Reviewing all proposals for recombinant DNA research to be conducted in the City of Cambridge for compliance with the current NIH guidelines.
3. 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.
4. Reviewing reports and recommendations from local institutional biohazards committees.
5. Carrying out site visits to institutional facilities.
6. Modifying these recommendations to reflect future developments in federal guidelines.
7. Seeing that conditions designated as I-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.

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" moratorium 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 (CERB) on August 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 (see Appendix A). 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 at both Harvard and M.I.T.

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

At the September 14th 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 CERB 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 CERB 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 CERB 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.

* The members of CERB 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 Director of NIH and a panel of experts responded to questions of the Board members.

* 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 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 opponents and proponents views, 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 CERB 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. CERB 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.

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, CERB carried out it's 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 CERB's unresolved questions and to draw as wide a range of input from it's 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 insures 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. The members of CERB heard over 75 hours of testimony from more than 35 individuals representing both sides of the controversy. In addition, we 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.

APPENDIX A

CERB'S Charges and Responsibilities From the City Manager

CITY OF CAMBRIDGE

CAMBRIDGE, MASSACHUSETTS 02139
Tel. 876-6800

EXECUTIVE DEPARTMENT
JAMES L. SULLIVAN
City Manager

August 6, 1976

To the Honorable, the City Council:

In accordance with the request of the City Council I have during the past weeks reviewed in detail the material generated by the two public hearings conducted by the City Council and also the material provided by both the proponents and opponents of D.N.A. genetic research. The Council has requested that the City Manager establish a Cambridge Experimentation Review Board and prepare a plan for the organization of the Board.

Many recommendations have been made to me from many sources concerning the make-up of the board. There were those who felt that the board should consist of both proponents and opponents to the experimentation and some neutral citizens. After some deliberation I rejected this approach because it would tend to set up antagonistic positions on the committee whose approach would be to attempt to sway neutral members. Others felt that since the experimentations to take place were of a scientific nature and extremely complex that the committee should consist of knowledgeable scientists, biologists and geneticists who would approach the problem scientifically and come to a conclusion. I rejected this approach as well for the issue is before us because of a dispute within the scientific community as to the hazards involved and it would be extremely difficult to find knowledgeable scientists who did not have preconceived views on the subject.

Since the issue has been raised by many who have expressed concern about the potential hazards of experimentation to the citizens of Cambridge, and the problems that can be generated by scientists who have a self interest in experimentation controlling the experimentation, it seemed only reasonable to create a committee of Cambridge citizens who could approach the subject in an unbiased manner and insure that the public safety is at all times the foremost consideration.

I therefore contacted a number of Cambridge residents from different walks of life and different parts of the Community to request that they consider service on the committee. I am pleased to state that the following citizens have agreed to serve:

1. Dr. Francis Comunale - Commissioner of Health and Hospitals, chairperson.

2. Mary Nicoloro - 15 Harding Street, member Wellington-Harrington Citizens Committee, Board of Directors of Cambridge Family and Children's Services.

3. Sr. Mary Lucille Banach - 799 Concord Avenue, Secretary to the Board of Directors, Sancta Maria Hospital.

4. Sheldon Krimsky - 59 Sacramento Street, Associate Director, Program in Urban, Social, and Environmental Policy, Tufts University.

5. Daniel J. Hayes - 60 Rindge Avenue, vice-chairperson, Businessman, former Mayor and City Councillor.

6. William J. Le Messurier - 94 Brattle Street, Partner - Le Messurier Associates - Structural Engineers.

7. Cornelia Wheeler - 123 Coolidge Hill, former chairperson Health and Hospitals Committee; former City Councillor.

8. Dr. John L. Brusch - 831 Massachusetts Avenue, Medical Doctor, Board Certified in Infectious Diseases.

9. Constance Hughes - 24 Gorham Street, Public Health Nurse and Social Worker.

Responsibily of the Board

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

(a) review the "Decision of the Director, National Institutes of Health to Release Guidelines for Research on Recombinant D.N.A. Molecules" dated and released on June 23, 1976;

(b) review but not be limited to the methods of physical and biological containment recommended by the N.I.H.;

(c) review methods for monitoring compliance with applicable procedural safeguards;

(d) review methods for monitoring compliance with safeguards applicable to physical containment;

(e) review procedures for handling accidents (e.g. fire) in recombinant D.N.A. research facilities;

(f) advise the Commissioner of Health and Hospitals on the reviews, findings and recommendations.

Powers of the Board

In carrying out their responsibilities the Board shall be empowered to:

(a) employ such scientific and other consultants and such clerical assistance as it may determine is necessary to assist it with the approval of the City Manager;

(b) through its chairperson it may ask for and receive reports from the biohazard committee of Harvard and M.I.T.;

(c) through its chairperson it may ask for and receive information from other relevant sources;

(d) may ask for and receive plans for laboratory designs and modifications for P3 level containment;

(e) may call upon the advice and counsel of those in the employ of the City with the approval of the City Manager;

(f) should establish a procedure whereby the committee may request and receive advice, reports, and opinions from federal, state and local officials and from citizens of Cambridge and other interested people;

(g) may also receive and respond to questions and concerns of citizens of Cambridge regarding recombinant D.N.A. research.

Relationship of the Board to the Internal Bio-Hazard Committees at Harvard and M.I.T.

In addition to the relationships between the Board and the Biohazards Committees of Harvard and MIT that are already built into the functions

of the Board itself, the following additional relations are to be requested of the Universities:

(a) The Commissioner of Health and Hospitals or his representative shall be invited to attend any and all meetings of the Harvard and MIT Biohazards Committees;

(b) Notices of all meetings, whether regular or special, of the universities' Biohazards Committees shall be sent to the Commissioner of Health and Hospitals;

(c) Copies of all local guidelines for practices and procedures related to recombinant D.N.A. research at all levels shall be sent to the Commissioner;

(d) Copies of the minutes of all meetings of the universities' Biohazards Committees shall be sent promptly to the Health Commissioner;

(e) All plans for designs and modifications of containment facilities, if any, shall be sent to the Commissioner of Health and Hospitals and the Cambridge Building Commissioner;

(f) Each of the universities' Biohazards Committees shall render to the Commissioner of Health and Hospitals in summary form at the close of each academic year an annual report of their principal activities.

The Committee has been provided with copies of the NIH guidelines and substantial material on both sides of the issue. The members have been advised to review the material provided. They will hold their first meeting at the call of the Chairman, Doctor Francis Comunale, Commissioner of Health and Hospitals. As has been outlined in the descriptions of the responsibility and powers of the Committee they are free to call upon assistance from many sources in the course of their study.

It is my belief that the Committee as constituted will thoroughly review the subject and will provide the Commissioner of Health and Hospitals valuable insights into the problems with reasonable recommendations for a course of action to be adopted by the City Government.

Respectfully submitted,

James L. Sullivan
City Manager

JLS/nwc

APPENDIX B

List of Invited Guests

9/2/76	Members, Harvard and MIT Biohazards Committees
9/9/76	Dr. Sherwood Gorbach, Chief Infectious Disease Department New England Medical Center
9/16/76	Dr. Jon Beckwith, Professor of Microbiology and Immunology Harvard Medical School
9/21/76	Visitation to proposed P3 laboratory Cancer Research Center, MIT
9/23/76	Dr. Matthew Meselson, Chairman Department of Biochemistry Harvard University
9/29/76	Cambridge Forum on Recombinant DNA First Parish Church in Cambridge Harvard Square, Cambridge
9/30/76	Dr. Jonathan King, Assistant Professor of Biology MIT
10/5/76	Dr. Robert Sencer, Director Communicable Disease Center Atlanta, Georgia
10/7/76	Dr. Salvatore Luria, Director Cancer Research Center MIT
10/12/76	Dr. Robert Neer Massachusetts General Hospital Harvard Medical School Faculty
10/14/76	Mrs. Francine Simring, Representative Friends of the Earth New York, New York
10/19/76	Inspection of site of proposed P3 laboratory Harvard Biological Laboratories
10/21/76	Dr. Mark Ptashne, Professor of Biochemistry Harvard University
10/28/76	Dr. Robert A. Alberty, Dean School of Sciences MIT
10/29/76	Telephone conference with Dr. Erwin Chargaff Department of Biochemistry Columbia University
11/2/76	Dr. Howard Hyatt, Dean School of Public Health Harvard University

11/4/76 Dr. Richard Goldstein, Assistant Professor of Microbiology Harvard Medical School

11/23/76 Debate: Participants included:

Opponents: Dr. George Wald, Harvard University
Dr. Jonathan King, MIT
Dr. Richard Goldstein, Harvard Medical School
Dr. Jon Beckwith, Harvard Medical School

Defendants: Dr. David Baltimore, MIT
Dr. Mark Ptashne, Harvard University
Dr. Walter Gilbert, Harvard University
Dr. David Nathan, Pediatric Oncology, Hematology Childrens Hospital
Dr. Edward Kass, Chief, Infectious Diseases Boston City Hospital

11/30/76 Telephone Conference:

Dr. Donald Frederickson, Director of NIH
Dr. Maxine Singer, Head of Nucleic Acid Enzymology, NIH
Dr. Dewitt Stetten, Deputy Director of Sciences, NIH
Dr. W. Emmett Barkley, Director, Research Safety, NIH

12/2/76 Representatives of Biohazards Committees, MIT and Harvard

Harvard: Dr. D. Branton, Chairman, Professor of Biology
Dr. Benjamin Ferris, Professor of Environmental Health and Safety, Harvard
Mr. Geoffrey Pollitt, Director Biological Laboratories, Harvard
Dr. Warren Wacker, Director University Health Services, Harvard

MIT: Dr. Melvin Chalfen, Director Environmental Medical Service, MIT
Dr. Maurice Fox, Professor of Biology, MIT
Dr. Melvin Rodman, Medical Director, MIT
Mr. Richard Chamberlin, Industrial Hygiene Officer
Dr. Robert Alberty, Dean School of Sciences, MIT

Additional meetings of the Board were set aside for planning and discussion of testimony witnessed

APPENDIX C

Principal Reference Documents

Berg, Paul et al, "Asilomar Conference on Recombinant DNA Molecules" Science 188; 991 - 994 (June 6, 1975)

Berg, Paul et al, "Potential Biohazards of Recombinant DNA Molecules." Science 185; 303 (July 26, 1974)

Cavalieri, Liebe F., "New Strains of Life - Or?" The New York Times Magazine August 22, 1976

Cambridge Proceedings, Hearings on Recombinant DNA Experiments, Official Transcript, June, 1976

Crossland, Janice, "Hands on the Code" Environment 18;7 (September, 1976)

Department of Health, Education and Welfare, "Recombinant DNA Research Guidelines." Federal Register, July 7, 1976

Department of Health, Education and Welfare, "Recombinant DNA Research Guidelines: Draft Environmental Impact Statement." Federal Register; September 9, 1976

Department of Health, Education and Welfare, "Recombinant DNA Research, Volume I: Documents Relating to NIH Guidelines Involving Recombinant DNA Molecules, February 1975 - June 1976." Public Health Service Publication #(NIH) 761138.

Gore, Rick, "The Awesome Worlds Within a Cell" National Geographic (September, 1976)

Science for the People, "The Health Hazards of Gene Implantation." A pamphlet written by the Genetics and Social Policy Group.

Sinsheimer, Robert L., Personal Correspondance, Division of Biology, California Institute of Technology.

University of Michigan, "Report of the University Committee to Recommend Policy for the Molecular Genetics and Oncology Program." Unpublished Report, March, 1976

Wald, George, "The Case Against Genetic Engineering." The Sciences (September/October, 1976)

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Final Report of the Cambridge Experimentation Review Board.

1/17/77
Placed on File
on Motion of
Mayor Vellucci-

In City Council,
January 17, 1977

1/6/77 Report Received-