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January 12, 1977

CAMBRIDGE, MASS.

Dear Councillor:

We are writing to you on behalf of employees in the Biological Laboratories to reiterate some of the concerns we have in regard to the research that will be done in the P3 facility being constructed here. We respect very sincerely the efforts and recommendations of the Cambridge Experimental Review Board, especially their concern for establishing a health monitoring system. Enclosed please find copies of correspondence which was originally addressed to Daniel Hayes and members of the CERB; We feel some of our concerns described in this first letter have not, however, been adequately addressed by the report, and thus wish to communicate them directly to you. Specifically, these are:

1. our preference for conducting the P3 research in a more isolated location and the question of limiting the proliferation of this research in Cambridge.
2. the need to reduce the level of insect infestation on a permanent basis by methods that are safe for personnel in the building.
3. the responsibility of the University to find alternative employment for workers who wish to transfer to another department if the P3 research is done here.
4. the question of establishing legal liability for illnesses or environmental disruption should containment fail.
5. the need to develop and administer a health monitoring system effectively.

1. It is not clear whether the CERB considered any alternative locations for the P3 facility at Harvard. Although the plans for the facility have been significantly revised since they were first made public last Spring, many employees still question the wisdom of constructing the facility in the Biological Laboratories when there are other alternative sites, such as the cyclotron building, which is within a few hundred yards of the BioLabs but removed from the student traffic. In regard to the proliferation of this research, it is our understanding that a P3 facility is also being constructed in one of the chemistry buildings on campus and another is planned for the new Biochemistry and Molecular Biology building. We are not aware of whether MIT has similar plans for extension of the

research, but certainly the environmental and human health risks associated with the recombinant and viral research planned are amplified as more and more researchers become involved in it. In all candor, many support staff who know the researcher involved are sceptical of the carefulness of some of them. (A safety poll taken in the labs indicated that a majority of principal investigators were not even aware of current University safety policy and had no one responsible for general safety conditions in their labs. Hopefully, increasing awareness of laboratory hazards will eventually change these attitudes). It does not appear that the CERB addressed itself to this concern, and we ask the Council to consider the advisability of limiting the research to one central facility at each campus, at least until the "firm experimental data" on the effectiveness of containment procedures is available (see page 3 of CERB report).

2. We realize that the insect problem is specific to the BioLabs but it is a problem we live with daily. We are aware that the Director of the BioLabs has commissioned an ongoing study of a building-wide extermination program, but we are not aware of the outcome. We ask you to investigate this further, since a proper insect control program is one of the essential guidelines for allowing even P1 and P2 research to proceed.

3. Our third concern involves a matter of Harvard University personnel policy. Since your decision to permit the research may directly effect the well-being of employees in the Biolabs, we feel the City Council would be acting on the citizens behalf to require Harvard to guarantee alternative employment within the University for those employees who have come to decide that the P3 research significantly alters the risks associated with their work and thus wish to transfer.

4. In regard to establishing liability, please refer to the statement prepared by the General Counsel of the University of Michigan. We have not been able to obtain a similar analysis from Harvard University's legal staff regarding assumption of liability under Massachusetts law in the event that containment should fail. Under the Massachusetts Workmen's Compensation Act it is our understanding that it must be demonstrated that an illness "more likely than not" resulted from the conditions of a person's employment. It is suspected that the most common manifestations of infection by the organisms used in recombinant DNA work would not always be exotic, but rather would be difficult to distinguish from other partially debilitating bacterial infections; however, we do not know whether such infections can be treated with available procedures. Without a comprehensive health monitoring system (see comments in 5. below) it would be most unlikely that any causal relationship could be established. It is even less clear, however, who would assume responsibility for compensating people in Cambridge or students should their health be affected, or who would assume responsibility for any environmental damages that might occur should containment fail. It should also be considered

that not only non-profit educational institutions, but also for-profit pharmaceutical companies will be engaged in this work, and it is not clear how the laws of the state would apply to them. These are questions we hope you will address to the Attorney General's office when considering the final form a regulatory ordinance might take.

5. The need to develop and administer an effective health monitoring system was addressed by the CERB report, but their treatment of this need was, perhaps unavoidably, incomplete. As far as we can ascertain, although the Harvard Biohazards Committee and University Health Services are investigating setting up a health monitoring system, enforcing its use effectively is still problematic. First, it is unclear what effects should be tested for, since alterations in the ecology of ~~intestinal~~ organisms cannot be predicted. At present there are few techniques available for monitoring possible infections, and those available tend to demand a large commitment of time and thus are expensive. It has not yet been determined whether this system should be available to all employees in the Biological Laboratories (which would have the advantage of establishing the data on containment which is now lacking), or who would assume the cost of such a program (the CERB suggestion that NIH include such monies in recombinant research grants seems a good one). When the Council requests the University's guarantee that it will comply with the CERB's recommendations, we request that that guarantee include a written outline of the proposed program, its administration, a breakdown of anticipated costs and a discussion of financial responsibility. The "good faith" the CERB anticipates (see page 6, paragraph V) may not be adequate; we understand that in some cases monitoring of personnel at the Medical School area, although required by guidelines governing their research, has not been maintained. We also wish to suggest a mechanism for insuring that (see page 3, paragraph 3) additional health and environmental monitoring will be effective for those "extremely unlikely possibilities": i.e., that every principal investigator, when submitting proposals for review by the University Biohazards Committee (and/or Cambridge Biohazards Committee) be requested to develop or indicate existing testing procedures that can be proven to detect the characteristics of the technically "new" organisms his/her experiment will produce.

In conclusion we wish to express our willingness to participate in any public hearings concerning the preparation of a city ordinance to govern this research. We feel that such a local action is required since without it, the guidelines will be difficult to enforce. We also hope these guidelines can be designed to govern other hazardous research.

Thank you for your efforts in regard to the issue of hazardous biological research.

Sincerely,

Clare D. Sullivan
Employee representative
Bio Labs Safety Committee

Mary D. Kochher
Employee representative
Biohazards Committee

John Venuti, HEOC / District 65 representative

John P. Venuti

HARVARD UNIVERSITY
THE BIOLOGICAL LABORATORIES

16 DIVINITY AVENUE
CAMBRIDGE, MASSACHUSETTS 02138

November 23, 1976

Mr. Daniel Hayes, Chairperson
Cambridge Laboratory Experimentation Review Board

Dear Mr. Hayes and members of the Review Board:

Your committee undoubtedly has heard from many experts in the area of recombinant DNA work and is struggling with a very complex policy decision. Employees in the Biological Laboratories, who have been very concerned with this issue too, will be directly affected by your Board's recommendation regarding the research, and we wished to communicate our concerns to your committee.

Enclosed please find a copy of the letter Ms. Macy Koehler, the employee representative to the Committee for the Regulation of Hazardous Biological Agents, sent to Dr. Branton and also a copy of the results of the employee poll of sentiment on the P3 Facility to which her letter refers. Her letter to employees explaining the results of the poll is also enclosed. These materials summarize well the way employees here are thinking about the issue. While some of us are willing to leave our positions rather than be exposed to the risks of the research, others of us feel the risks can be controlled if proper protocols are enforced. Most of us accept the facility with reluctance, however, and until the building permit was issued there was some hope that the facility could be moved to a safer, more isolated building.

Several concerns are underscored by the results of the employee poll:

1. the preference for conducting the research in a more isolated location;
2. the responsibility of the University to find alternative jobs for employees who have decided that the new research will alter the conditions of safety to an unacceptable level and thus wish a transfer;
3. the need to reduce the level of insect infestation on a permanent basis by methods that are safe for personnel in the building;
4. the need to develop and administer an effective health monitoring system.

In this letter we would like to elaborate on the following points:

1. The question of legal liability for illness resulting from research should an "accident" occur. In Michigan, where the issue of such a facility was also debated in a public forum, lawyers for the university prepared the outline attached (addendum C) on the "potential legal liability in connection with proposed DNA research". We have not been able to obtain a response from Harvard University's legal staff about liability under Massachusetts law in

the event that the health of people in the Cambridge community, of students, and of workers was harmed by the research. Under the Massachusetts Workmen's Compensation Act it is our understanding that it must be demonstrated that an illness "more likely than not" resulted from the conditions of a person's employment. It is suspected that the most common manifestations of infection by the organisms used in recombinant work would not be exotic, but rather would be difficult to distinguish from other bacterial infections; however, these infections might be difficult to treat with available procedures. Without a comprehensive health monitoring system, it would be most unlikely that any causal relationship could be established. Indeed, most of the controversy regarding health risks associated with the recombinant work is that no significant epidemiological studies have been attempted. The kinds of testing that would be required would probably include appropriate checks of blood serotypes and intestinal flora, for example. The costs of running these kinds of checks regularly and effectively will be expensive and setting up the mechanisms may be difficult, but it is right to argue that such potentially hazardous research should not be initiated until adequate monitoring techniques are available. In the event the research is approved we feel strongly that it should only be on the condition that a monitoring system is established for personnel in the Biological Laboratories, and perhaps for residents in the Cambridge community as well. (Similar programs can and indeed must be set up for lab workers involved in the type of viral research also proposed for the P3 facility according to National Cancer Institute guidelines.) We emphasize this point because we feel your committee's endorsement of such a proposal will carry considerable weight with the University. If any institution has the capability of developing such a comprehensive monitoring program, it has to be Harvard with its access to the resources of the Harvard Medical Area complex.

2. The question of proliferation of this research on the Cambridge campuses. According to our information, a P3 Facility is being constructed in one of the chemistry buildings on campus and another is planned for the new Biochemistry and Molecular Biology Building. We are not aware of whether MIT has similar plans for extension of their research, but certainly the environmental and human health risks associated with the recombinant and viral research planned are amplified as more and more researchers become involved in it. In all candor, many support staff who know the researchers involved are legitimately sceptical of the carefulness of some of them. We trust your committee will address itself to this question of proliferation and wonder if you might consider the advisability of limiting this research to one central facility, preferably a facility specially constructed and reserved for such research should it be approved.

We are very appreciative of your invitation to contribute to the deliberations of your committee. Please call on us if you wish to discuss any of these problems with us at future meetings.

Sincerely yours,

Clare Sullivan

Clare Sullivan, secretary
(in consultation with other employees in the
Biological Laboratories).

THE UNIVERSITY OF MICHIGAN
OFFICE OF THE GENERAL COUNSEL

February 27, 1976

Appendix D

MEMORANDUM

TO: DNA Research - Committee B

FROM: John D. Ketelhut

SUBJECT: Potential Legal Liability in Connection with Proposed DNA Research

FACTS

The University is contemplating engaging in DNA research. Concern is expressed about potential legal liability that may result therefrom. This is of particular interest because there is speculation that DNA research may create organisms that could cause injury, which organisms are presently unknown to science and therefore possibly uncontrollable.

QUESTION

What is the potential legal liability concerning the proposed DNA research?

SUMMARY

The potential legal liability in connection with the proposed DNA research is as follows:

I. Negligence and Strict Liability

Although the scientific and medical facts surrounding the DNA research quite probably would make it an ultrahazardous or abnormally dangerous activity, for which many jurisdictions would impose strict liability for damages to persons or property resulting therefrom, namely liability upon showing that injury occurred due to the research, Michigan presently does not follow this doctrine in connection with such activities conducted upon one's property. Instead, Michigan would currently apply the rule that there would be a high degree of care under the circumstances, namely the obligation on the part of the University to use more diligence than usually required in ordinary negligence situations to prevent liability. Most likely the University would owe a duty of reasonable care towards, and be

liable for, a breach of such obligation to any non-employee foreseeably injured who was on the property of the University at its invitation and for its benefit, and in certain other limited situations. Such obligation would also probably at least extend to non-employees off University property injured by its negligent operation of the research project when some injury of that nature to such person could have been reasonably foreseen. In any such negligence action, the defenses of contributory negligence and assumption of the risk by the injured party could be available to the University in specific cases. This risk of negligence liability, in connection with DNA research, would appear to be substantial.

II. Workman's Compensation

Since injuries from DNA research would appear to be compensable under Michigan Workmen's Compensation Law as an occupational disease or injury, University employees injured by such would be able to recover statutory benefits from the University specified by such law. It would be sufficient for the employee to show that the injuries were brought about by the nature and conditions of the employment. This would clearly apply to employees directly involved with DNA research and would most likely apply to University employees who are injured otherwise because they are attending their jobs at the University. However, in the latter situation, it is possible, though unlikely, that a court might permit an employee a larger recovery of damages than is permissible in negligence. Workmen's compensation would dispose of all questions of negligence and defenses of contributory negligence and assumption of risk. Because of this and the social policy behind it to make industry pay the losses of employees injured on the job without any fault concerning the employer, and the actual risk of injury involved, workmen's compensation liability would present a high risk of liability in connection with DNA research.

III. Nuisance

If the DNA research creates a substantial and unreasonable continuous interference with the health of the public or other rights held in common, or the real property or personal rights of private persons intimately associated with such, a common law or statutory nuisance would exist. Such a nuisance would exist despite any good faith effort to take steps to prevent it by the University. If a nuisance exists, then it may be subject to an injunction or will permit damages to those specially injured thereby. Also, reasonable self-help to abate it is available. The nuisance action is probably not available to any employees of the University. Most likely the DNA research would not be subject to any injunction unless and until the project has been put into operation and injuries begin to occur in more than an isolated fashion. However, when the nuisance is established, any special injuries suffered therefrom would be subject to payment for damages. Safety protection measures and the usefulness of such research would have a bearing on any such liability. The additional limitations on a nuisance cause of action not found in negligence or workmen's compensation liability would make it a less

substantial legal risk than the latter two, but it would still be one that is significant.

IV. MIOSHA

A special Michigan statute dealing with occupational safety for employees should be kept in mind. It contains a general obligation upon the University to keep its property free from recognized hazards that are causing or likely to cause death or serious physical harm to employees and provides for specific standards to be adopted against particular risks. The Act provides for the certification of violations by the State whose lack of correction may result in civil and criminal penalties or preventative court action. Also, there presently is a particular standard dealing with the labeling of hazardous substances which most likely applies to the DNA research. Thus, in conducting the DNA research, the University will have to comply with such general obligations and specific standards that are applied to such a project under MIOSHA. No private cause of action should develop therefrom, but the State will be able to take action by certifying violations and taking other measures if the DNA research presents any substantial hazard to the safety of employees. The lack of private lawsuits makes MIOSHA less of a problem than negligence, workmen's compensation, or nuisance liability, but it is still a significant risk in connection with DNA research.

V. Federal Statutes

The DNA research will have to comply with any specific requirements of federal grants concerned with it or statutes which provide for such grants. In addition, there are some general statutes dealing with the licensing and handling of hazardous substances in interstate commerce but not other areas. Thus, the problems in this area are minor or nonexistent.

VI. Immunity

DNA research is most probably a governmental function, namely one which is designed for the good of all. As such, it could be defended against negligence claims by sovereign or governmental immunity established in case law and Michigan statutes, assuming that the present cases concerning such before the Michigan Supreme Court do not alter or abolish it. Such defense obviously will be particularly useful if an unusual amount of injuries occur from the project.

VII. Insurance

The DNA research project should be evaluated initially and during its course to provide adequate insurance protection and restriction of risks. This review should be conducted with the University's Insurance Office, with any legal questions therefrom to be considered also with the Attorneys' Office. The preliminary review by the Insurance Office indicates that current adequate protection extends only to the areas of negligence and workmen's compensation liability.

HARVARD UNIVERSITY
THE BIOLOGICAL LABORATORIES



16 DIVINITY AVENUE
CAMBRIDGE, MASSACHUSETTS 02138

November 17, 1976

Dr. Daniel Branton, Chairman
Committee on the Regulation of Hazardous
Biological Agents
The Biological Laboratories
Harvard University

Dear Dr. Branton:

When you requested our vote on the P3 containment facility on October 27, I interpreted that request to mean two things:

1. Did I think the facility, as designed, met the NIH Guidelines?
2. Did I, as the employee representative, agree to the construction and use of the facility, irrespective of the Guidelines?

You received my reply about the Guidelines on October 29--I agreed that the plans met the NIH Guidelines. I did not feel it was possible then to make a decision about the whole facility without consulting the employees of the Biological Labs. We had held a staff meeting open to all employees to get opinions and answer questions. Probably as a result of an unclear announcement, few people understood the purpose of the meeting, and attendance was low. We then distributed the enclosed questionnaire in order to get a more comprehensive view of opinions. I am sorry that the results arrived too late for you to send with your letter of approval of the facility. I would appreciate it if you would forward them to Dean Rosovsky now.

The questionnaires were hand-distributed to all employees working in the Biological Laboratories (according to an update of the October 7, 1976 payroll). I stated in the introduction that all unreturned questionnaires would be counted as affirming my cover letter. I now realize that this was unwise. The results are expressed both as a number tally and as percent. The percent responses to each question are calculated using two base lines:

1. The number of questionnaires distributed (117)
2. The number of questionnaires returned (81)

~~I believe the percentage answers based on 117 -- 100% -- are an accurate representation of employee attitudes.~~

My own interpretation of the results of the questionnaire raise four major points:

1. While it is too late to recommend to Dean Rosovsky that he not approve construction of the facility, he should be aware that a substantial fraction (38%) of the personnel to whom the questionnaire was distributed did not approve of the facility being built according to the present plans. Because of the present condition and use of the Harvard Biological Labs, an alternative which would be acceptable to a much larger fraction of the employees is the location of the facility in a new or unused building near the Biological Labs (for example, the Electron Accelerator building). This would make monitoring of entrance and exits, as well as insect control, a much easier task.

2. Ten percent of the employees have indicated they will transfer out of the building once the facility is in use. Another 6% are undecided but are seriously considering this possibility. The change in the nature of research in the Biological Laboratories may involve increased risks to the employees. Because the University has chosen to endorse this change, they have a responsibility to find equivalent jobs for all employees who feel they have to leave because of the facility.

3. I state again my feeling that we must reduce the level of the insect infestation in the entire building to a level commensurate with other labs containing P3 and P2 facilities, and acceptable to Mr. Gary Alpert. It should be shown that these conditions can be maintained permanently, without harm to personnel, before the facility is used.

4. In the questionnaire I asked for opinions about a system to monitor people's health. To some, this question implied that there could be a meaningful correlation between the organisms used in the facility and the illnesses contracted by employees. I have since learned that while it may be possible to test for certain types of infections, in most cases correlations will be difficult to substantiate. However, we feel strongly that we would like to be able to assess the effectiveness of physical and biological containment, and to learn much more about the behavior of E. coli strain K12. We need to investigate the possibility of establishing a program of medical testing of people working in the Biological Labs. I would hope the University Health Services will take an active interest in pursuing questions of this nature.

It is apparent to me that many employees have made decisions based upon large gaps in information--and misinformation. We plan to hold a series of employee-oriented informal seminars on the biology of viruses and recombinant DNA to give people a larger information base with which to make a decision. I have no illusions that this will change anyone's basic opinion, but some of the fears based upon misinformation may be alleviated. It would be helpful if the Dean would support released time for staff to attend these sessions.

I hope we can meet in the near future to discuss some of the issues raised in this letter. I would also like your permission to distribute this letter and the questionnaire results to the rest of the members of your committee. Thank you.

Sincerely,

M. Macy D. Koehler

M. Macy D. Koehler

Enclosure

Copy to: Dean Rosovsky

EMPLOYEE CONTAINMENT FACILITY QUESTIONNAIRE

We hope this survey will indicate how you feel about the basic issue of the construction of the containment facility. If a survey questionnaire is not returned to us by 5 P.M. Friday, October 29, it will be counted as affirmative.

The results will be summarized and sent to the Dean with the vote of the Branton Committee. They will also be posted on the bulletin board opposite the front office Monday, November 1.

RETURN TO BOX IN MAIN OFFICE.

1. Do you agree to the containment facility being built in the Biology Labs, according to the current plans (can be found in Mr. Pollitt's office)?

Yes 32 No 45 Undecided 4

If you said no:

Would you approve the building of the facility if changes were made in the plans?

Yes to above 32 Yes 5 No 38 Undecided 6

Please list the changes you feel are necessary in as much detail as you like.

Examples:

- 1 Maintenance protocols need to be reviewed
- 2 Equipment and parts from facility equipment need to be permanently marked so that they can be recognized by repair personnel
- 3 If lab coats, why not lab shoes
- 4 Proof of insect elimination first

Would you rather have the facility in a different location?

Yes 44 No 31 Undecided 6

Where? { In nearby but separate building 21

{ In less populated area 15

2. The facility is designed to be used for three different types of research:

animal cell culture
virus work
recombinant DNA

Are your objections to the facility based upon opposition to research which may be done in the facility, rather than the facility itself?

Both 2 Yes 26 No 48 Undecided 5

It would be helpful if you could comment:

animal cell culture 5

virus 8

recombinant DNA 20

other

3. Would you feel it necessary to transfer to another department if the facility were built?

unanswered 9 Yes 12 No 52 Undecided 7

Please comment.

4. If the facility is used, do you feel that a system to monitor people's health should be established?

Unanswered 3 Yes 74 No 4

Whose health should be monitored (please check)?

- 14 a. People working directly in the facility?
7 b. People working in the facility and on the 4th floor
49 c. Everyone in the building
4 d. Other: Visitors; families of employees; general Cambridge pop.

Comments:

5. Would you find it helpful if we held an informal meeting to explain the basic biology of recombinant DNA, viruses and animal cell culture?

Yes 57 No 24

S-10

Communication from Claire Sullivan relative
to the genetic DNA experimentation.

In City Council,
January 17, 1977