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

January 21, 1982

Director, ORDA
Building 31, Room 4A52
National Institutes of Health
Bethesda, MD 20205

Re: Proposed changes in Guidelines
Federal Register of 12/4/81

Dear Sirs:

The Cambridge Biohazards Committee was established by local city ordinance in 1976-77, and has since that time reviewed recombinant DNA use in Cambridge, Massachusetts. Within the last two years we have reviewed in detail every change in the NIH Guidelines, reviewed in detail (and helped to revise) the local ordinance governing recombinant DNA use in this city, listened to extensive testimony from experts on large scale and small scale recombinant DNA use, inspected local laboratories using recombinant DNA, conducted a public hearing on recombinant DNA use, and testified before our city councillors on this issue. We have also had many extensive and detailed discussions with the Biological Safety officers of Harvard and MIT. Since we are local citizens not personally involved in recombinant DNA research, we think our comments on the recently proposed Guidelines can provide an unusual and useful perspective to the Federal Government as it considers these proposed revisions. Each of us has long experience in local civic affairs.

We recognize the need to simplify the Guidelines, particularly the specification of containment levels. We do not, however, think it is wise or necessary to abolish Institutional Biosafety Committees. We believe such committees provide a useful restraint on careless or overconfident researchers and an essential reassurance to local communities. The selection of appropriate containment levels for certain uses of recombinant DNA will remain complex, even with simplified Guidelines. Complex decisions are often improved by consultation with other thoughtful people. Secondly, whenever individuals use potential pathogens, or other potentially harmful materials for personal gain or financial reward, a conflict of interest can arise. In this situation, it is

inadequate for the institution to leave responsibility for safety regulations entirely in the hands of individuals involved in the work. The potential conflict of interest is unreasonable, and is immediately obvious to the surrounding community even when it is not obvious to the institution or the individuals. For these reasons, we think Institutional Biosafety Committees should remain mandatory. For the same reasons, we support the continued requirement that such committees include at least two members who "represent the interests of the surrounding community." Such members give local communities a "window" through which to assess an industry's impact on local health and environment in a reasoned manner, and simply by their presence can provide a healthy balance to the deliberations of a safety committee.

We realize that in many institutions Biosafety Committees have had little work and will have even less if the Guidelines are further simplified. We believe, however, that IBC review is essential for recombinant DNA use involving disease-causing agents or the generation of toxins or pharmacologically-active substances. IBC's without such issues to review could either not meet, or could profitably direct their attention to the other potential biological hazards of their institution (radioactivity, toxic chemicals, etc.).

The other changes proposed in the December 4 Federal Register essentially abolish the present regulatory structure. Although the periodic revisions of the Guidelines have been moving slowly in this direction, we think such a marked acceleration of this trend is unreasonable. The well-intentioned mistakes of the general scientific and technical community on other issues have left many people in Cambridge (and perhaps elsewhere) cynical about scientists' abilities to extrapolate very far beyond their immediate past experience, particularly if the scientists' own self-interest is involved. For example, it seems unreasonable to us to have only an admonition against deliberate release into the environment of organisms containing recombinant genes for antibiotic resistance and harmful toxins. It also seems unreasonable to abolish the Guidelines for biological containment and at the same time make the Guidelines for physical containment mere recommendations. Finally, we think that elimination of the voluntary compliance program will leave institutions that use recombinant DNA without NIH funding in a peculiar position.

Our own perception is that the measured evolution of the Guidelines has been a model of the way new technologies can be introduced into densely populated areas with maximum safety and public reassurance. To abandon this process now would be

a major error. We recognize that a continuation of the Guidelines is expensive. Abolition of the Guidelines (i.e., the December 4 RAC proposal) may, however, in the long run be even more expensive, by inviting multiple conflicting state and local regulations, or by inviting a backlash of mistrust and revulsion if public health hazards are eventually associated with the use of recombinant DNA in the future.

Sincerely yours,

Robert M Neer, Chairman/mc

Cambridge Biohazards Committee

Robert M. Neer, M.D., Chairman
Melvin Chalfen, M.D., Commissioner of Health
Oliver E. Farnum
Elsa Stern
Zelia Kelleher

bkm

cc: Robert Healy, City Manager
/Paul Healy, City Clerk
Walter Milne, M.I.T.
Lewis A. Armistead, Harvard
Robert A. Fildes, Ph.D., Biogen
Thomas Coor, Biotechnica
Thomas H. Fraser, Ph.D., Repligen

8. S-44,

Comm. from Robert M. Neer, M.D., Chairman, Cambridge Biohazards Committee Re: proposed changes in the NIH Guidelines regarding recombinant DNA reseearch.

In City Council,

January 25, 1982

1/25/82

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