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Program in Social Management of Technology

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Dr. Patricia Harris
Secretary
Department of Health, Education and Welfare
Washington, D.C. 20201

Dear Dr. Harris:

I am writing to you in regard to actions taken at the September 6-7 meeting of the NIH Recombinant DNA Advisory Committee and Director Fredrickson's recommendations to lower safety standards by exempting some 85% of Recombinant DNA work from the NIH Guidelines, I testified before Departmental officials a year ago on the proposed Guideline revisions and participated in a subsequent meeting held with about 10 public interest representatives. I am a member of the IBC here at the University of Washington, and was nominated for RAC membership by Senator Magnuson.

I am dismayed by the RAC proposals to exempt E. coli K12 host research from the Guidelines and permitting exemptions for the 10-liter limit on culture volume, and I urge you to reject these recommendations.

First of all, as I have stated on several occasions, proper science as well as proper regulatory practice would seem to require that risk assessment activities be carried out prior to widespread experimentation and especially to widespread unregulated experimentation. NIH has announced a proposed risk assessment program but has not instituted it yet, not to mention that there are -- of course -- no results from such a program on which to base exemptions.

I am aware that certain studies funded by NIH may have some utility re: risk assessment; indeed, I have discussed these extensively with Dr. John Nutter. But these studies are clearly not sufficient, and have already produced results which should lead us to a more cautious and conservative regulatory approach -- e.g., that supposedly debilitated strains of E. coli can survive in numbers and duration far in excess of espectations; that naked polyoma DNA can cause infection in mice, etc.

Procedurally also, the operations of the RAC are quite questionable. The RAC does not have clear procedural rules, conducts important business through rump minority sessions, is chaired by a person of strong biases which become reflected in the way the Committee does its work and in the materials presented to it, etc.

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At the very least, environmental impact statements under the National Environmental Policy Act should be prepared, be made available for public comment, etc. before such drastic changes in regulatory policy are effectuated. In the past (with the issuance of the original Guidelines), the NIH has been insufficiently sensitive to NEPA requirements; I urge you to be more attentive to them now. Any action which Director Fredrickson is contemplating which would seriously alter the Guidelines ought to be published in the Federal Register for comment as well.

Very truly yours,

Philip L. Bereano
Associate Professor

PLB:sf