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STANFORD UNIVERSITY SCHOOL OF MEDICINE

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January 22, 1982

Dr. William J. Gartland
Department of Health and Human Services
National Institutes of Health
Bethesda, MD 20205

Dear Dr. Gartland,

I am writing in support of the RAC proposal to revise the NIH Guidelines for Recombinant DNA Research as set forth in the Federal Register of December 4, 1981.

I believe that the Guidelines for Recombinant DNA research are now dispensible. Based on the substantial amount of experience and experimentation with the recombinant DNA methodology during the last six years, there is widespread agreement that the risks that were once thought to be so plausible are actually remote or possibly nonexistent. If that judgement is indeed correct, and I know of no evidence to indicate otherwise, then it seems wasteful of effort and money, even counter-productive, to maintain the elaborate procedures and organizations that were setup to guard against the hypothetical threats. It has been my long-held view that the most beneficial feature of the Guidelines was their educational role; they highlighted the kind of concerns that were voiced and provided recommendations for workers in the field as to how safety considerations should be incorporated into their experimental designs and procedures. For that purpose referring to the revised Guidelines as a Guide (or Code) for Good Practice seems appropriate.

There is one minor point in the wording of the RAC proposal with which I differ. Emphasizing that the new recommendations are 'voluntary' places an unintended and unnecessary psychological focus on the change. I suspect that if the voluntary nature of the recommendations is emphasized, many will take that as an invitation to ignore them completely; after all who cares. But if the revised version makes strong recommendations and accompanying justifications for how such experiments should be carried out, there is a stronger liklihood that people would accept the recommendations as being reasonable. I prefer the approach the CDC uses, namely, to advise scientists of the concerns about certain organisms and make recommendations for how to work with various types of microbial pathogens and viruses. Voluntarism, while implicit, is deemphasized in favor of urging compliance.

I am strongly in favor of maintaining RAC but not necessarily ORDA except in so far as it serves a small staff function for RAC. RAC could well serve

as an 'antenna' and 'intelligence' group in that their role would be to monitor progress and developments of recombinant DNA technology being alert to any developments that could bear on the issue of safety. RAC could be the trigger to initiate an appropriate response to any perceived or actual risk. I think that if RAC were constituted to provide such a 'watchguard' function and was responsible for responding to unanticipated developments, there might be less concern on the part of the public by what will be perceived as a drastic change in the regulations of this research.

Sincerely,

Paul Berg

PB/hk