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DEPARTMENT OF BIOCHEMISTRY STANFORD UNIVERSITY SCHOOL OF MEDICINE

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April 22, 1981

Dr. William Gartland, Head Office of Recombinant DNA NIGMS, Bldg. 31 4A52 Bethesda, MD 20205

Dear Bill,

I am writing to you regarding the proposed changes in The Guide-lines for Recombinant DNA Research put forward by Drs. Baltimore and Campbell that appeared in the Federal Register of Friday, March 20, 1981 on pages 17994-7 (Vol. 46 #54). As I understand their recommendation it is 1) to convert the current NIH Guidelines for Recombinant DNA Research from mandatory regulations (for virtually all university and institute scientists) to a non-mandated, but recommended code of standard practices and 2) to reduce the recommended containment levels for certain experiments.

Lest there be any doubt about my views on this let me be quite direct. I strongly favor their suggestion and have done so for some time. Indeed, in a letter to Dave Baltimore of July 2, 1980, I said "I find it increasingly difficult to accept the maintenance of a nontrivial government bureaucracy to contend with the mythical possibility that recombinant DNA experimentation is hazardous. After all we have not imposed the same requirements on virus research or other 'potential hazardous' laboratory activities. In those instances, society and the government have accepted individual and institutional assurances for safe practices and culpability for negligence or deliberate violations. RAC has elected a strategy for evolutionary change in The Guidelines, but in my view, it has not been without paying a substantial price: the time and energy of ORDA, RAC members, institutional committee members and the scientists doing the research, as well as the expenditures to maintain ORDA, ORDA, RAC and the new layers of bureaucracy that have been spawned in the universities. I do believe it is time to seriously consider whether the ORDA-RAC format should continue I would favor its dissolution and replacement by something like the advisories put out by CDC in the field of pathogenic microorganisms and tumor virus research; that is, an effective and a relatively simple classification and advisory for handling pathogenic or potentially pathogenic organisms and viruses. Didn't that kind of advice serve us well for tumor viruses before recombinant DNA"?

I have no reason to change my views now. The present proposal seems eminently sensible and prudent. It transforms The Guidelines from regulations (which they were) to guidelines (which they should be). My own early concerns that some recombinant DNA experiments might carry risks have long been dissipated. The data, discussions and experience of the last six years have convinced me that our earlier concerns are no longer warranted. I now believe that there is more to fear from the intrusions of government in the conduct of scientific research than from recombinant DNA experiments themselves. Consequently, I welcome the changes put forward by Baltimore and Campbell and hope that RAC will approve them promptly.

With best wishes,

Sincerely,

Paul Berg

Willson Professor of Biochemistry

c.c. Dr. David Baltimore PB/hk