DATE: March 8, 1977

TO : Don Kennedy
Human Biology Program

FROM : Joshua Lederberg
Department of Genetics

SUBJECT: Safety regulations with regard to recombinant DNA.

Dear Don,

I do not know if events will overtake this message before you are in a position to even think about it. But I think there is a great contribution that you could make about settling unnecessary anxieties with respect to "commercial transgressions" of the NIH guidelines. Apart from the question whether research on recombinant DNA should be conducted at all, the main sore point in this issue may well be the perception that although government funded activity is properly regulated, industrial-commercial interests may be able to "get away with murder".

My suggestion is that in your new role you issue an "advisory bulletin" that pharmaceutical developers and manufacturers who intend to explore the use of DNA recombinant technology should take pains to be sure that they can document that they are and will have been adhering to relevant NIH guidelines throughout the entire process. Whatever may be the appropriate mechanism of ongoing inspection, this documentation can certainly be called for at the time that a prospective new product is presented to the FDA for IND or NDA review.

If you were to make this statement as an interim measure, pending what ever other steps may be undertaken either by regulation or other legislation, I think it would go a long way to assuring the public that there is not likely to be an instant emergency that requires what may be an either impossible or excessive reaction.

Of course, I would urge nothing on you in this direction without your having taken great pains to consult others about its possible side-effects. At the moment it would seem to me to offer a great deal to gain and absolutely nothing to lose. I am sure that the industry would be more than eager to comply, indeed would be grateful to have some definable framework in which compliance will be possible.

I am not suggesting that this approach will satisfy every critic nor would I want you to put yourself on the spot as implying that it is a sufficient permanent response to the controversy. But I do think that as an interim measure it would have an effect that could only be positive.

Sincerely yours,

shortly before he actually left Stanford to be FDA commissioner