DEPARTMENT OF MICROBIOLOGY AND MOLECULAR GENETICS
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/dissent/goldstein

29 December 1979

DNA

Dr. Donald S. Fredrickson
Director
National Institutes of Health
Bethesda, Maryland 20205

dna/nihgl/dissent/scntists/goldstein

Dear Dr. Fredrickson:

I believe that you should reconsider the question of the E. coli exemption as voted for by the RAC at its September 1979 meeting. I am certain that both of us agree that recombinant DNA technology will generate interesting and exciting new results. My only qualms lie in the speed at which this work proceeds. Exemptions and/or lowering of containment increase this pace and the potential hazards involved.

I have again read through all of the NIH sponsored risk assessement results. Present results in this area make me believe that we are not ready for the wide scale E. coli exemption as voted for at the September RAC meeting and recently published is the Federal Register. Many important questions of risk assessment have not yet been addressed as posed at the NIH sponsored Falmouth Risk Assessment Conference. Equally as important, results which are in are far from clear cut in demonstrating lack of risk. In fact, the Martin-Rowe polyoma virus results suggest just the opposite as is clearly pointed out in the article on this subject in Nature by Rosenberg and Simon (see Nature 282, 20-27 December, 773-774, 1979). Likewise, the results of Stuart Levy on survival of supposedly 'disabled strains' of E. coli again provide reason to not approve the E. coli exemption. Here, disabled strains were found to survive in humans at greater levels than predicted. This point was brought to your attention previously in a letter from Roy Curtis who developed the strains in question. It should also be mentioned that Levy's risk assessment studies on transfer of genetic information from disabled strains are far from complete since they do not consider transfer to the major bacterial inhabitants of the human gut - the anaerobes. The most recent NIH sponsored conference on risk assessment (August 1979) also suggested that the best test for survival and transfer be done not with disabled strains but with wild type since if transfer was not found in this case we could feel more assured that it would not occur with disabled or laboratory strains of E. coli K-12. Such studies have not been carried out. And lastly, other NIH sponsored risk assessment studies on survival of E. coli in sewage plants and in the air and on the bench top all demonstrate that the organism survives at higher than expected levels. Hence, the bulk of the results from NIH sponsored risk assessment studies suggest that we should not be lowering containment for this work as specified by the E. coli exemption.

Granting the exemption for E. coli studies will also induce many scientists to broaden the overall scope of their work which will in turn bring about more and more pressure for further exemptions for other systems of even greater risk. This has been the situation with previous exemptions granted by the RAC. Already the RAC is under such enormous pressure that 'here-say' is accepted as fact and facts are often overlooked in the name of expediency. The well orchestrated letter writing campaign originating at the University of Wisconsin (Madison) in support of exemptions demonstrates the lenghts many scientists are willing to go to push for lowering or doing away with guidelines. This campaign is a political one which may backfire

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in case of accident. HEW and NIH will not fare very well when basic science turns into political science. We will all suffer because of the self-interest of a minority of the scientific community.

A typical example of what has occurred at RAC meetings is the proposal presented at the December meeting for cloning and cross country shipment of segments of the highly infectious foot and mouth disease virus (FMD). If I understand correctly, FMD is a CDC Class 5 Agent, and therefore is so potentially hazardous that it is by law forbidden entrance into this country. At the December meeting we spent the good part of a morning discussing this proposal. We also heard from scientists from the Plum Island Animal Disease Center who proposed to collaborate on this work with scientists from the private firm Genetech Inc. (of South San Francisco). We were told that the last outbreak of the disease was in 1929 and that since then embargo of the virus and animals from certain countries has eliminated outbreak. Yet, despite the presence of experts involved with this proposal we were never informed by them that a more recent outbreak had occurred only last year. And, that the outbreak occurred in the immediate vicinity of the one institution working with this virus, i.e. nearby to Plum Island. All animals in the area had to be slaughtered. We learned of this fact only after the vote on the proposal had occurred. This information was presented to us not by one of the experts in this area but by Shelly Krimsky, a lay member of the RAC.

The FMD proposal also involved shipping clones of segments of this virus from the high containment facility at Plum Island to the minimal containment P2 facilty at Genetech Inc. in South San Francisco. This appears to be a particularly irresponsible proposal both because of the infectious nature of HMD and because it is to be shipped to a company which has previously according to NIH records been in overt violation of NIH recombinant DNA guidelines. Rationale for cross country shipment from an isolated high containment facility to a low containment facility in a densly populated area was that Genetech scientists would be inconvenienced if they were to travel to Plum Island to carry out their studies on vaccine development. That is almost as absurd as carrying out potentially hazardous cloning experiments to develop a vaccine which has not been needed in this country since 1929. Except of course, in the vicinity of those working with the virus.

The FMD proposal is not an isolated one. We have received others of similar potential hazard especially from private industry which I am not able to mention because of proprietary rights involved. Granting of the E. coli exemption will have the certain affect of bringing more such proposals to the RAC and more pressure to approve them. This pressure caused the RAC to vote for elimination of even simple registration of experiments with local biohazard committees for those experiments falling under the E. coli exemption. The rationale here was that it would eliminate tedious paperwork. This may benefit the scientists involved but it is not in the public interest.

It is not easy nor pleasant to take the position I have taken in opposition to most of my peers. However, lowering of guidelines for containment or granting of exemption will not make the potential hazards disappear, scientific or political. Based on NIH sponsored risk assessment studies the biological hazardous appear no less than they were considered to be when the guidelines were written several years ago.

Sincerely,

Richard Goldstein
Associate Professor

cc: Bill Gartland, Jane Setlow, Shelly Krimsky, Roy Curtis, Stuart Levy, Richard Krause