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JUL 26 1967

July 26, 1967

Dr. Joshua Lederberg
Department of Genetics
Stanford Medical Center
Palo Alto, California 94304

Dear Doctor Lederberg:

Thank you for your letter of July 20 with the very interesting enclosures.

Your testimony of February 28 before the Harris Committee prompts me to enclose the draft I prepared in 1966 for an almost identical assignment for an Ad Hoc Committee appointed by COSPUP under Harvey Brooks to prepare a report for the Dadderio Subcommittee of the House Committee on Science and Astronautics. The report was presented a few months ago and will be published by the Committee shortly. We have stressed many of the same points. The only point on which I may disagree with you is in connection with the priority we should give to R and D in connection with artificial organs like the heart. I take such a dim view of the probability of "success" in the sense of a reliable prosthesis that I believe the people's money had better be spent largely on other approaches.

As to the drug-testing issue, I do not believe that we are far apart. My remarks on excessive requirements for toxicity-testing by the F. D. A. were based on the experiences of Dr. Marvin Bacaner, one of my colleagues, in connection with the testing of bretylium as an anti-fibrillatory agent. Bretylium was to be tested for that effect in patients with myocardial infarctions and in similar critical situations in which ventricular fibrillation is a major acute cause of death. The drug had already been used for other purposes (lowering blood pressure) in a half million persons in Britain and Canada. The questions raised had to do with local tissue damage from intramuscular injection and similar peripheral questions. (A man with coronary occlusion wouldn't worry very much about some local tissue damage in his gluteus maximus if his life could be saved by the drug.)

All necessary studies on survival of dogs treated for proper periods of time at the dose levels and methods of administration to be used had already been presented to the F. D. A. In other words, the important data on lethal doses were already in F. D. A. hands and the "harmlessness" as to survival, of the proposed dosage regimen had been indicated.

You are right, of course, that the key word is "excessively." My real point is that the civil service personnel should not be expected to take the responsibility for deciding what is or is not an excessively elaborate set of requirements prior to clinical investigation by qualified experts.

I would not give approval for general use by physicians without very elaborate study, because as you intimate, they don't read the fine print and perhaps wouldn't understand it fully anyhow.

I guess that my greatest worry is that if clinical investigation becomes too heavily bound up with red tape, only the "pedestrians" in medicine will be willing to continue to work in such fields. Humanity would certainly suffer as a result.

Your implied suggestion that the more general use of new drugs be limited to a more elite fraction of the medical profession is interesting, but I predict will meet with a lot of opposition, if proposed by Congress. I would favor it, along with better data collection.

I cannot refrain from complimenting you on your forthright stand on the abortion issue. It is to its credit that the AMA has this year endorsed the American Law Institute position. It is significant, of course, that it was necessary for jurists to take the lead in a matter of medical ethics. It is sad that physicians were not themselves in the vanguard.

I have not seen the California Senate Committee report on the use of pound dogs, but I shall get hold of it. Thanks for the information.

Sincerely yours,

Maurice Visscher

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Maurice B. Visscher

P. S. I see you have trouble in proof-reading too. As you will note from various corrections in my draft, I missed a lot of things the first time over. But on your page 11 of the testimony on line 3, I don't think you meant "<u>under</u>-estimated"!