NIH

July 9, 1963

Dr. Luther Terry
Surgeon General
Public Health Service
Bethesda 14, Maryland

Dear Dr. Terry:

I am writing this letter as a Principal Investigator on NIH research grants in reply to your memorandum of June 12, 1963.

1. Perhaps my main comment is puzzlement as to the significance of the publication of these regulations in the Federal Register. Would this publication then supersede the Administrative Manual which was recently issued? Or does it furnish the legal basis for the perpetuation of these and other regulations?

2. I deeply regret that these regulations have been submitted as prospective rules without the formality of a public hearing of the many interested parties. Such a hearing could at least serve to establish the significance of such publication and would allow intercommunication among the very widely dispersed and disorganized community which is bound to be affected by them. I am sure that you will not hear many useful comments, simply because the busy research man who might make them will take it for granted that someone else will have the same thing to say.

3. These rules do indeed rectify, at least by omission, some of the most irksome discrepancies of previously published rules. However, the principal force of the regulations seems to be to confer upon the Surgeon General the authority to make such rules as required for the protection of the public interest. Again, I regret to note the lack of any procedure to insure a hearing on the effect of proposed regulations on the public interest with respect to the quality and efficiency of the research accomplished. Any consensus that may be reached with respect to the appropriateness of the present rules must not be misunderstood as applying to further at present unspecified regulations, nor in particular to many features of the previously distributed Administrative Manual.

   For example, I wish I could concludedotherwise than that Section 52.42 still requires a battery of advance approvals for the purchase of equipment, of a totally unrealistic character, from the period of budget specification on through the actual purchase.

4. May I point out a serious inconsistency that must develop in practice in the actual execution of research, if Sections 52.33 b. and 52.42 are strictly interpreted without further qualification. On the one hand 52.33 b., and current administrative procedure requiring endorsement by the department head and by other university authorities seeks (a laudable purpose, however clumsy the implementation) to insure the maximum utilization of expensive equipment. On the other hand, Section 52.42 appears to make it practically impossible within the regulations to allow any piece of equipment to be used on any other project except for the one for which its purchase had been authorized. I trust that you will either disclaim any intention of interpreting the rules in this fashion, or else make specific provision for de facto, honest sharing of the use of materials and equipment on the basis of equitable reciprocity, and particularly as among several research projects at the same institution.

5. 52.20 b. "Changes in Project". I find this statement very difficult to understand, and have no idea how a lawyer might interpret it. Perhaps that is the intended strategy, to leave the matter sufficiently confused that only a serious moral abuse in intent is in fact proscribed. I would be happy to hear a confirmation of this understadding.

   However, how much more ennobling and constructive it would be to have a positive statement of encouragement such as we used to have in our research grants! A lawyer might well interpret the phrase following the word including in a restrictive sense: what about changes that do not grow logically out of the approved project, but are the result of new insights for surprising facts?

   I believe, personally, that the matter of direction of research cannot be phrased in legal terms. Instead, I believe it would be apposite to remind the investigator that he has a moral obligation to prepare a project application that outlines his best understanding of the work that he plans to do and that, consistent with the progress of his research, he should resubmit his application in the circumstance of a really important deviation from his first intentions that deserves the scrutiny of the reviewing committees. There will, after all, be a cogent opportunity to evaluate the investigator's judgment when the issue of renewal of the grant arises. If you foresee any real abuse of this provision, you might insert one additional proviso, that it would be dishonest to divert funds from an approved project to one that had been explicitly disapproved in a previous review, as would be the intention to use the grant for purposes other than those outlined in the application.

6. The patent obligations of grantees under NIH grants are perhaps the most poorly understood of any. The evident intentions of the Public Health Service to pursue the protection of patent rights in the most

legalistic fashion can only result in the capricious enforcement of an unworkable relationship, and will have the most disastrous effects on the mutual confidence of investigators and the government. There is no question here of the government's right and interest in significant patents, only in the manner of the implementation of those rights. The problem hinges on the universal extensability of the concept of "possibly patentable". One should point out that "discoveries" are in fact not patentable. (Refer to the next to last line of the statement "Development of the proposed regulations"). Who can possibly say whether something is "possibly patentable"? The courts long ago ruled that triviality is no bar to patentability. It is certain that any laboratory could keep a team of 100 lawyers fully occupied with filing application on "possible patents" of which an unpredictable fraction will result in the issuance of a patent, and of course a very much smaller number in which this piece of paper will have any substantive value. For reporting purposes, the concept of "possible patentability" could only lead to the complete documentation and review of every datum in the laboratory, not to mention every thought that goes through the investigator's mind. And what purpose will all this achieve?

May I suggest that the government's and the public's interest would be served much better in the following way:

1. A statement of the nature of the interest that the Public Health Service in fact determines to reserve, and the purposes to which these will be put.

2. The enunciation of the principle of moral responsibility in accepting a grant to serve as the government's agent in protecting such interests to the best of the grantee's capability.

3. Provision for voluntary reporting of inventions which might reasonably be expected to have some significance within the provisions of (1).

4. This reporting should initially be simple and informal until there is a determination of significance that would warrant a complete formal invention report.

5. Grantee would warrant that grant personnel would not apply for any patent on grant subject matter without clearance from the Public Health Service and, if this is legally feasible, an automatic assignment to the government of any rights under patents that may be improperly obtained.

It is of course possible for the government to pursue possible benefits more aggressively than the framework just given, and even more doggedly than most reasonable commercial organizations would. But the complete exploitation of every possible patentable invention is utterly inconsistent with the actual progress of scientific research. If good reasons remain for the government to maintain such an interest in patents, then this should be pursued through

a revision of the fundamental patent legislation, vesting such rights automatically in the government, rather than a completely obstructive scheme of reporting which will simply force investigators to either abandon government support or prevaricate about their responsibilities, with the attendant risks, and for worse, moral irresponsibility.

If these comments are overdrawn, they merely illustrate the consequences of the substitution of a system of legal and fiscal accountability on the one hand for a system of mutual understanding of common objectives, moral responsibility to an ethical code, and judgments within the framework of scientific integrity, on the other hand. That nothing about these matters appears in the rules is to me perhaps their most distressing feature.

The above comments are strictly my own private opinions and may or may not come to be embodied in general statements more representative of the reactions of the officers and staff of this university.

Yours respectfully,

Joshua Lederberg
Professor of Genetics