DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

July 12, 1976

J. Anthony Morris, Ph. D.
Division of Virology
Bureau of Biologics
8800 Rockville Pike
Bethesda, Maryland 20014

Dear Dr. Morris:

I have received the Examiner's Report of Findings and Recommendations dated May 24, 1976, concerning the proposal by Dr. Harry Meyer, Director, Bureau of Biologics, to remove you from your position of Supervisory Research Microbiologist, GS-14, which was issued on July 11, 1975, and supplemented by a letter dated July 16, 1975.

I have given careful consideration to the Examiner's Report. I have read and considered the transcript of the hearing in its entirety. I have previously read and considered the advanced notice and all of the attachments, including the transcript of the sessions of the Panel on Review of Viral Vaccines and Rickettsial Vaccines dealing with a review of your research projects and with a review of scientific issues that you presented to the Panel, as well as the Panel report and your written response and its attachments and your supplementary responses. I personally heard and considered your oral response.

I have decided that the charges of insubordination and inefficiency are fully supported by so many of the specifications contained in the advanced notice of July 11, 1975 and as set forth on page 1-6 of that advanced notice to be sustained and relied upon for my decision to effect your removal.

Specifically, I have determined that specifications A1, A3, A5 and A6 of Charge I (insubordination) which concern your participation in the Division of Virology's regularly scheduled scientific conferences dealing with ongoing and proposed research of the Division are fully supported by the evidence and are therefore sustained.

Specifications A4, B and C of Charge I (insubordination) are not sustained. I have previously withdrawn specific charges A2 and D of Charge I (insubordination).

Specification A of Charge II (inefficiency) which concerns your

conduct in dealing with your ts-1 (e) virus findings and specification B1c of Charge II (inefficiency) which concerns the rationale and relevance of your African epidemic icterus virus investigation are fully supported by the evidence and are fully sustained.

Specifications B2a, B2b, B2c, B2d, and B2g of Charge II (inefficiency) concerning the design and execution of your research projects are fully supported by the evidence and sustained.

Specifications B1a, B1b, B2e, and B2f of Charge II (inefficiency) are not sustained.

I agree with the finding of the Examiner that, "There is little doubt that Dr. Morris deliberately failed to accept or to follow proper directions, and orders of his supervisors." I cannot agree, however, to the characterization of the sustained charges of insubordination as being "of minimal seriousness." On the contrary, the kind of behavior exhibited by you toward your scientific colleagues and administrative superiors directly challenges the integrity of scientific process and the ability of the Food and Drug Administration to carry out its mission.

I have spent nearly all of the past 15 years as an administrator, first directing an academic cardiovascular laboratory, later as Dean of the Faculty of one of the nation's largest medical schools, and currently as Commissioner of Food and Drugs. During much of this time I have been responsible for preserving, simultaneously, the integrity and quality of the science being performed within an institution, and the effective conduct of the institutional mission. Both of these depend upon the willingness of the scientists involved to submit their work, at any and all stages, to review by scientific peers and administrative superiors, and to follow proper direction.

The principal external mechanism for quality control of science is peer review -- of work planned, work being conducted, and work completed. One of the most useful, and therefore most common, settings for peer review within an institution is the scientifc conference dealing with proposed and ongoing research. Participants in such conferences must be forthcoming, even eager, if the process is to work. Without this, there can be no review of quality or relevance of the research to colleagues.

The sustained charges of insubordination amply document your blatant disregard for the required participation in scientific conferences and, indeed, your direct disobedience of your immediate supervisor. In such circumstances, there can be no effective quality control of your research program.

The Food and Drug Administration is not in the business of supporting

undirected, undifferentiated, basic research. Our research is goal-oriented and must be relevant to Agency goals, not an individual investigator's desires. Research programs are thus directed in nature, and investigators must follow directions. The Examiner's findings that you have deliberately failed to follow proper direction and orders relate directly to whether or not the Agency can efficiently and effectively fulfill its mission. At the least, your direct disobedience of your immediate supervisor signifies to me your unwillingness to exist within a necessary chain of administrative command, and removes from anyone above you in that chain the ability to direct the goals of a significantly large research program. This is contrary to the prudent conduct of any institution, least of all one with a clear-cut mission.

Further, I most emphatically disagree with the Examiner's thought that, "The sustained reasons concerned with scientific inadequacies are found to be less substantial even than the reasons related to insubordination." The purpose of all research is to answer questions. For research to be productive, a proper question must first be posed; a series of manipulative steps toward the answer must then be carefully planned in detail; these steps must be meticulously carried out and documented; proper controls must be utilized; the data properly handled, etc. Failure to observe any of the rules of good science can render the entire study useless, as can selection of the wrong test animals, use of improper or inadequate measuring techniques, improper care of animals, failure to randomize test animals, etc.

The sustained reasons for your inefficiency include violations of many, if not most, of these elemental rules, including poor experimental design, improper selection and randomization of test animals, poorly controlled experiments or no controls, poorly kept or non-existent records, and inadequate measuring techniques. In some instances, these flaws were such as to render the experimental results, not to mention the original experimental purpose, meaningless to your scientific peers.

In recent testimony to the U.S. Senate, I stated that research done for this Agency must be "impeccable." I said, "...it is essential that... studies be technically complete, be conducted according to sound protocols, and be scrupulously controlled for quality." I then described research that was being rejected for consideration by the Agency because of procedural flaws.

It is, if anything, more important for research done within FDA to be "impeccable" than research done by commercial industry, for we must be able to rely ultimately on our own research results to settle scientific controversy. For FDA-conducted research to be meaningless because of procedural flaws is unacceptable.

There is no excusing research rendered meaningless by poor design, lack

of controls, wrong test animals, etc. That something might have been learned regardless, that the research was somehow related to a serious problem, that findings of importance are occasionally serendipitous: none of these excuses the inefficiency and waste of space, time, and money for research not within the Agency's mission or research so flawed as to be meaningless.

Therefore, it is my decision that your removal is warranted for the reasons, charges, and specifications contained in the advanced notice, excluding specifications A2, A4, B, C, and D of Charge I (insubordination) and specifications B1a, B1b, B2e, and B2f of Charge II (inefficiency). Consequently, you will be removed from your position on Friday, July 16, 1976, in order to promote the efficiency of the service.

You may appeal this decision to the U.S. Civil Service Commission, Federal Employee Appeals Authority, Room 300 H, Washington, D.C. 20415. Your appeal must be in writing and must set forth reasons for contesting your removal, together with such offer of proof and pertinent documents as you wish to submit. You may submit an appeal any time after receipt of this letter, but no later than fifteen (15) calendar days after the effective date of your removal. If you have any questions concerning your appeal rights, you may contact Mr. Frank Mischou, Acting Operations Branch Head, Division of Personnel Management, Food and Drug Administration, Parklawn Building, Room 4B-44, 5600 Fishers Lane, Rockville, Maryland 20852 (telephone, 443-5490).

Sincerely yours,

A M. Schmidt

Alexander M. Schmidt, M.D.
Commissioner of Food and Drugs