DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
BETHESDA, MARYLAND 20014

July 11, 1975

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

Dear Dr. Morris:

This is an advance notice in accordance with Civil Service and Department regulations, that I propose to remove you from your position of Supervisory Research Microbiologist GS-14 in the Section on Slow, Latent and Temperate Viruses, Division of Virology, Bureau of Biologics, Food and Drug Administration, no earlier than 30 calendar days from the date you receive this notice. The reasons for this proposed action are:

I. Insubordination

II. Inefficiency

I. The charge of "Insubordination" is based upon the following specifics:

A. Since January 1974, the Director, Division of Virology, has required all Supervisory Research Scientists of the Division to attend and participate in regularly scheduled scientific conferences dealing with ongoing and proposed research of the Division. To date, your participation in conferences at which you were scheduled to make presentations has been inadequate, inappropriate or nonexistent, as follows:

1. On February 6, 1974, you presented data on hypersensitivity to myxovirus and paramyxovirus vaccines in guinea pigs. When asked what data supported your statement that influenza vaccine sensitized laboratory animals to adverse effects from live influenza virus infection, you replied that it was in a publication by Dr. Jerome Schulman. When the Division Director requested a copy of the publication, you failed to respond. The Division Director has been unable to find such a publication by Dr. Schulman supporting your statement.

2. On March 27, 1974, you presented your previously published work on the effect of antibiotics on Marek's disease. This was not ongoing or proposed research, which is the subject of the conferences, but in fact research which had been completed and submitted for publication nearly a year earlier.

3. By memorandum dated June 7, 1974, you were scheduled to make a presentation on July 3, 1974, and you failed to appear or offer an excuse in advance of your nonappearance. This failure caused cancellation of the meeting and inconvenience to other scientists and staff members.

4. When you were rescheduled to make a presentation on July 10, 1974, rather than presenting your research, your primary presentation consisted of showing a film discussing the democracy of science. This was inappropriate.

5. At the conference at which you were scheduled to make a presentation on December 18, 1974, you were absent and substituted an outside speaker, contrary to the instructions of your supervisor.

6. By memorandum dated April 15, 1975, you were scheduled to make a presentation on June 4, 1975. You advised Dr. Hicks by memorandum dated May 27, 1975, that you did not feel it necessary to make a presentation. By memorandum dated June 2, 1975, your supervisor directed that you make the scheduled presentation. You replied by handwritten memorandum in which you questioned the integrity of your supervisor. You subsequently failed to make your scheduled presentation on June 4, 1975, again in direct disobedience of your supervisor.

The above cited actions, in addition to demonstrating a blatant disregard for required participation, adversely affect the Division Director's ability to be aware of, and monitor, ongoing and proposed research within the Division. It also deprives him of the benefit of peer review, which he relies on in assuring that Division resources are used in a manner that best accomplishes the mission of the Division. Your attitude toward your supervisor seriously affects your supervisor's ability to direct the operation of the Division, and cannot be tolerated (Enclosure 1).

B. In a memorandum dated May 28, 1974, the Director, Bureau of Biologics, notified all Division Directors that he would require project

reports for the period July 1, 1972, to June 30, 1974. The reports were due to him on July 15, 1974. Your Division Director requested your report by June 21, 1974. On June 28, 1974, a member of your section advised the Division Director that your report would not be ready until July. When your report was submitted to the Division Director it was in draft form, inaccurate, incomplete, and had to be returned for corrections (Enclosure 2).

C. At the weekly conference of April 10, 1974, you, and all other scientists of the Division of Virology, were advised by the Division Director that he required all orders for $100.00 and over to be approved in advance by him and be accompanied by supporting justification. Notwithstanding this requirement, you, or employees under your control, have ordered animals without approval on at least two occasions. In January 1975, an employee under your supervision ordered 200 mice for delivery to your laboratory on January 28, 1975. Because of lack of space for these animals, the order was cancelled by the Division Director. Also, on May 1, 1975, you ordered and personally took delivery of 305 mice without approval and in willful disregard of your Division Director's instructions. When directed by your supervisor to explain this conduct, you failed to respond (Enclosure 3).

D. In September 1974, and again in December, 1974, your supervisor requested you to provide him with protocols of your planned animal experiments. You failed to comply with those specific requests. This has compromised the ability of your supervisor to evaluate the research (or quality thereof) which you have conducted (Enclosure 4).

II. The charge of "Inefficiency" is based upon the following specifics:

A. In your annual report of July 1974, you indicated that you had observed tumors in four female mice inoculated with the ts-1(E) attenuated strain of influenza virus. You did not discuss this matter with your supervisor, nor did you present this research at any of your scheduled presentations at Division conferences. When scientists of the National Institutes of Health, who were working with the ts-1(E) virus, made a presentation at your Division's scheduled conference of November 13, 1974, which you attended, you failed to discuss your findings. Further, during a live influenza vaccine workshop held by the Bureau of Biologics on December 11, 1974, you were given a specific opportunity to discuss your findings on the ts-1(E) virus, but declined, stating that your findings were "too preliminary." Not until January 8, 1975, did you bring your findings to the attention of Dr. Robert Chanock of the National Institute of Allergy and Infectious Diseases. You failed

to discuss your findings, despite repeated requests, until February 4, 1975, when specifically instructed to do so by the Bureau Director. This is not the normal conduct of a scientist in dealing with a collaborator or with his supervisors. In so conducting yourself, you created an unnecessary crisis which was wasteful of resources and detrimental to the systematic review of research data. You did not avail yourself of the many mechanisms available for review of your work and for input from your peers. This conduct is not expected in a senior scientist and cannot be tolerated in the Bureau (Enclosure 5).

B. In a memorandum to Mr. Sherwin Gardner, Deputy Commissioner of the Food and Drug Administration, dated February 19, 1975, by which you initiated a formal grievance, you requested as relief:

"A detailed investigation into the current state of my research program, the program of the Bureau in general and an evaluation of the general state of national vaccine policy in which I can take an active part." The Deputy Commissioner granted that relief by requesting the FDA Panel on Review of Viral Vaccines and Rickettsial Vaccines to conduct such an investigation. The Panel conducted an investigation and, incident thereto held open meetings at which you and your attorney were present and participated. The Panel has completed its work and has submitted its report, a copy of which is hereby furnished to you (Enclosure 6). The Panel concluded that in most cases your research was poorly conceived, poorly designed, and poorly executed. The Panel also concluded that in most cases your research had little relevance to the mission of the Bureau of Biologics. It was their judgement that because of this inefficiency, your work was wasteful of Government resources. I agree with these conclusions and adopt them. The specific situations involved are:

1. Inefficiency in research project rationale and relevance.

   a. Effects of antibiotics on Marek's disease.

These experiments were poorly planned as an investigation of the effects of trace antibiotics in vaccines because of the choice of the antibiotics tested, thereby rendering the relevancy of the experiment questionable. Another deficiency in rationale concerns the selection of the animal model employed.

b. A_2 virus (SV-4, SV-28) project.

The studies included a hypothesis that the A_2 agent may be present as a contaminant of viral vaccines, which hypothesis is not sound because this agent is cytocidal for tissue cultures and thus would be readily detected if present. By the same type of reasoning, it would appear unlikely that the agent would be the cause of human hepatitis. Consequently, this deficiency in rationale made it predictable that the A-2 project would have little relevance to the mission of the Bureau.

c. African epidemic icterus virus investigation.

The rationale that lymphocytic choriomeningitis virus is a sufficient cause of influenza-like disease in the general population is not reasonable and therefore the study is not relevant to the mission of the Bureau. (Exhibit 6, Transcript pp. 339, 340)

2. Inefficiency in research project design and execution.

a. In experiments with ts-1 (E) strain of influenza virus, the selection of an outbred strain of mice reflects poor judgement since study of the oncogenic potential of the virus appears to have been a primary objective of the experiment. This error was compounded by the failure to individually identify or to randomize mice from the various litters. In addition, as a result of inappropriate housing, you failed to safeguard the mice involved in this experiment from acquisition of other agents. (Exhibit 6, Panel Report)

b. In experiments with ts-1(E) your failure to include parental strains of viruses and control fluid from embryos incubated at the same temperature seriously flawed the experiments. (Exhibit 6, Panel Report)

c. In conducting your research on ts-1(E) your record keeping was demonstrably inadequate making evaluation of your results impossible. This inefficiency in an experiment, involving considerable time and expense, is unacceptable. (Exhibit 6, Panel Report)

d. In your studies to determine the effects of antibiotics on Marek's disease your failure to keep adequate records and to randomize inoculated animals raises serious questions of the validity of your published results. (Exhibit 6, Panel Report)

e. In your studies of A_2 virus (SV-4, SV-28), your failure to perform the appropriate serological tests on specimens collected from experimental vaccine recipients and from hepatitis patients makes it impossible to determine if these viruses infected the subjects studied. Therefore, your work with these agents cannot be considered an efficient expenditure of resources.

f. Your failure to include adequate control animals in certain of your experiments with WI-38 cells and your unnecessary duplication in others resulted in generation of no useful information and considerable waste of resources. (Exhibit 6, Panel Report)

g. In your studies concerning viral vaccine-induced delayed hypersensitivity, the inadequate use of controls and the unsatisfactory measurement of possible hypersensitivity created defects in the experimental design and execution that made it impossible to draw meaningful conclusions relating to virus-induced hypersensitivity. (Exhibit 6, Panel Report)

The above cited instances of inefficiency demonstrate that you largely pursue whatever problems strike your fancy with little evidence of consultation with, or scientific review by, your professional peers or administrative superiors. The scientific consequences of such ill-directed efforts have led to data that have little significance or that, because obtained in poorly designed and implemented experiments, are inconclusive and provide no resolution of problems.

Documentary evidence of the above charges is enclosed. In addition, you are advised that the agency file regarding this action is available for your inspection in Room 129 of Building 29. You should contact Mr. James O. Gesling to make such arrangements.

In view of the above specifications and reasons, it is proposed to separate you from the service. You are allowed 15 calendar days from the date you receive this notice to reply in person or in writing or both in person and in writing and you may submit affidavits in support of your reply, if any. This should be addressed to Dr. Alexander Schmidt, Commissioner, Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Maryland 20852, or whoever is acting for him if he is absent. Consideration will be given to extending the reply period if you submit a request to Dr. Alexander Schmidt, Commissioner, Food and Drug Administration, stating your reasons for desiring more time. Full consideration will be given to any answer you submit.

In addition to your oral and/or written reply, you may request, within 15 calendar days of receipt of this notice, a hearing in accordance with the provisions of DHEW Instruction 752-1 (Enclosure 7). A hearing would be conducted by a hearing officer of the Division of Policy and Planning, Office of Personnel and Training, Office of the Secretary, Department of Health, Education, and Welfare. This request should be in writing and addressed to Dr. Alexander Schmidt, Commissioner, Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Maryland 20852.

You have the right to be represented and accompanied by a person of your own choosing throughout the adverse action proceedings. A reasonable amount of official time will be allowed to review the material relied upon to support your reply. You may contact your supervisor, Dr. Francis Ennis, to arrange for such official time.

You will continue in an active duty status pending a determination on this proposed action. In the event you have any questions regarding the procedures to be followed in this matter, you may contact Mr. Frank Mischou on 496-6297.

Harry M. Meyer, Jr., M.D.
Director
Bureau of Biologics

Enclosures