DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
Building :
Room :
(301) 496-

JUL 9 1991

TO: CAPT Robert C. Gallo
Chief
Laboratory of Tumor Cell Biology
Division of Cancer Etiology, NCI

FROM: Director
National Institutes of Health

Director
National Cancer Institute

SUBJECT: Management Directives

In accordance with Public Health Service (PHS) regulations prescribed in the Commissioned Corps Personnel Manual (CCPM), Subchapter 46.4, INSTRUCTION 1, you must comply with the lawful orders of your official superiors. Therefore, effective immediately, you are directed to implement the following actions with respect to your duties as Chief, Laboratory of Tumor Cell Biology, National Cancer Institute (NCI):

1. Familiarize yourself with and comply with all applicable Department of Health and Human Services (DHHS) and National Institutes of Health (NIH) regulations applicable to the performance of your duties as Chief, Laboratory of Tumor Cell Biology. This includes, but is not limited to, the standards of conduct for Federal civil service employees and PHS commissioned officers and the standards of conduct for human subjects experimentation.

2. Terminate all professional or consultative outside work activities, whether with or without compensation. Any prior approvals for you to engage in professional or consultative services, whether for compensation or not, are hereby rescinded.

3. Obtain advance written permission from the Director, NCI, or his/her designee, prior to submission for publication of any manuscript, abstract, or related document pertaining to your official duties.

4. Obtain advance written permission from the Director, NCI, or his/her designee, to participate in any interview, whether in person, by telephone, or by other communications device, with a representative of the press or other communications media if such interview pertains to your official duties, whether past or present.

5. Obtain advance written permission from the Director, NCI, or his/her designee, to make any speech or appearance or to engage in any interview, whether in person or through other means, when the subject of the speech, appearance, or interview pertains to your official duties, whether past or present.

6. Sign all documents related to your official duties in your own hand and without delegation to other parties.

7. Refrain from any and all travel related to your official duties, whether within or outside the United States, when such travel is paid for in whole or in part by individuals or entities other than the United States Government. If such travel has been scheduled for the future, it must undergo reconsideration by the Director, NCI, or his/her designee.

8. Obtain advance written approval from the Director, NCI, or his/her designee, prior to the initiation of any collaboration involving scientists who work outside the United States or that involves, or may involve, human subjects outside the United States. For any ongoing collaboration involving scientists who are outside the U.S. or that involves, or may involve human subjects outside the U.S., immediately obtain approval from the Director, NCI, or his/her designee, prior to continuing such collaboration.

9. Refrain from shipping or releasing any biological agent or substance, cell line, or any other laboratory product to any other party except after having ensured that such shipment or release is in compliance with all applicable DHHS, PHS, NIH, and NCI regulations and policies.

10. Suspend any membership and/or participation in any committee, function, or organization outside the United States if such membership and/or participation relates to your official duties until all such activities are re-reviewed for approval by Director, NCI, or his/her designee.

11. Review personally all primary data involving any person under your supervision or involving any co-author prior to the submittal for publication of any manuscript, abstract, article, or other document related to their official duties.

12. Maintain (and assure through personal audit by you that employees under your supervision maintain) written laboratory notebooks and records sufficient to permit scientific peers and supervisors to adequately interpret and duplicate the work carried out as part of your official duties.

13. Cooperate fully with periodic reviews and audits of your laboratory notebooks and records, and those of individuals under your supervision, at all stages of research projects as directed by the Director, NCI, or his/her designee.

14. Within ten working days of the date of this memorandum, submit to the Director, NCI, or his/her designee a written report of the specific steps you have taken to comply with these directives. Submit with this report copies of all documents you may have created to terminate or cancel any ongoing or scheduled activity prohibited by these directives.

These directives will be effective immediately, and they will remain in effect until further notice. These directives are intended to maximize your scientific productivity and managerial effectiveness as the Chief of the Laboratory of Tumor Cell Biology. This Laboratory is the largest research unit in the National Cancer Institute and its research is among the most important in the National Cancer Program. Your supervisors will evaluate your compliance with these directives as a PHS commissioned officer not later than 60 days from the date of this memorandum. Additional evaluations will be conducted not less than once every 6 months thereafter until further notice. The evaluations will be conducted using the form PHS-838, "Commissioned Officers' Effectiveness Report."

Bernadine Healy, M.D.

ASG Samuel Broder

Attachments
CCPM, 46.4, INSTRUCTION 1
FORM PHS-838

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Cancer Institute

Memorandum

Date July 16, 1991

From Chief, Laboratory of Tumor Cell Biology, BCP, DCE, NCI

Subject Response to Your Confidential Memorandum of July 9, 1991

To Director, NIH
Through: Director, NCI
Director, DCE, NCI
Associate Director, BCP, DCE, NCI

1. I have re-read the regulations on performance of my duties as a Laboratory Chief at NIH.

2. I do not have any real consulting outside activities with or without payment. I had been listed as a consultant to a few pharmaceutical companies and a few organizations, such as foundations. None involved remuneration.

(a) The activity on file with Farma-Biagini was cancelled in January of this year, but the effective date of the cancellation was 8/30/88.

(b) For Sorin Biomedica in Italy I attended one meeting and lectured. I have not visited them in over two years. A letter of resignation to Dr. Denti is enclosed herein.

(c) I am a member of the University of Pennsylvania's Wistar Institute's Scientific Advisory Board, serving without remuneration (except expenses). It usually involved two-three days per year. I am enclosing me letter of resignation letter to Dr. Koprowski.

(d) I have been a member of Michael DeBakey's Foundation for Biomedical Research. Their purpose is to promote understanding on the need for animal research. It meets yearly but I have never attended. I enclose a copy of my resignation letter to Dr. DeBakey.

(e) I have been an advisor on the Coordinating Council for Cancer Research of France. My role has been to give some input on their scientific annual meeting (which I have not attended in about three years). I enclose a copy of my resignation letter to Mr. Jacques Crozemarie.

(f) I was an advisor to the Blood Cancer Foundation in England. It was a spin-off of the Leukemia Research Fund and is designed to help develop ideas on the causes of leukemia. I received notice last year that they were now terminating the Foundation. I never went to a meeting, but have been asked about opinions and possible U.S.-English collaborations on Hodgkin's disease. I indicated to the Ethics Officer of NCI that I wished this activity cancelled as of June 1, 1989.

(g) In March of this year, I was invited to serve on the Medical Science Advisory Committee of the U.S. Information Agency, as Vice Chairman of the committee. I requested approval of this as part of my official duties from Dr. Adamson and this was granted. To date the committee has not met due to the resignation of Bruce Gelb. After the appointment of Henry Catto as new USIA director, the first meeting will be scheduled. I will resign if this is requested.

(h) A Foundation called L.I.F.E., for its Italian name, asked me to be a member of the Scientific Advisory Committee. Its purpose was to promote education and care relating to AIDS. This request was initiated July 1, 1990 and for one year. I attach a letter of resignation.

(i) I am an Honorary Professor of Biology in the Graduate School of Johns Hopkins. This involved a discussion with students about once every two years. I have been doing this for the past 6-8 years or so. Similarly, but with no time at all on my part, I have been an adjunct Professor of Genetics at GW (it gives us an occasional student) and of Virology at Cornell (Ithaca) and of Microbiology at Rutgers. Unfortunately, some of these seem to date back so far that no record of them is currently on file, except for Cornell. Actually, I have given a total of about one lecture to each in the past five years.

I receive no money for this involvement. I will request through Dr. Edward Tabor permission to do these activities as official business.

(j) Basic Books. The ongoing activity related to the book involves one or two things I agreed to do in Europe in the Fall, in preparation for foreign language editions. If you approve this (so that I am not in major trouble for breaking a contract) I will assure you in writing that is would only be discussions of the science (not history etc.) that is in the book. Promotional activity has been concluded as far as radio and TV interviews, with the exception of the Sam Donaldson interview which I have cancelled. I cannot cancel entirely the Basic Books Outside Activity because of contractual agreements allowing translation for several foreign editions. I will request approval for two events as Outside Activities, concerning this promotional activity.

3. I already make it a practice to send all my manuscripts for approval. I must admit it did not always occur to me to send "related documents." I assume this means all material that could ever be published.

4. I will be certain to obtain advance written approval for interviews pertaining to my official duties.

5. I will obtain advance approval to present any lecture. However, I do not think any scientific lecture I have ever given has caused trouble for NIH or me.

6. I have been signing all documents designated by Dr. Adamson as relevant to bear only my signature. There may be some very routine documents that, if I am not immediately available, would cause significant and

possibly harmful delays if not signed by the Acting Laboratory Chief and forwarded.

7. Regarding travel: I will comply, (like #4 above). It would help me if I understood how it is determined when travel is official business and when it might be considered not official duty. In some cases it gets borderline.

8. This one about collaborations scares me, i.e., I am afraid that no matter how hard I try, some day some sample will escape my attention.

   Our lab is almost 100% focused on human disease. We interact a great deal with others.

   I will do my best to get approvals from Dr. Broder or his designee as fast as possible for all our work. At present there are no experiments in progress in our lab which involve human therapy or vaccines. I hope there will be in vaccines some day.

9. We have conscientiously followed policies set down regarding shipping of research materials. In fact, this caused some difficulty for me in the OSI report. I was criticized in that report for following some of the guidelines set down by the NCI Director! (i.e., making too many requirements of people).

   I feel that I have complied with NIH guidelines. I think we may be served best by having a repository for NCI and/or NIH with a shipping office attached. This is similar to what NIAID did for AIDS.

10. a) I have been one of four members of an advisory group to the Swedish Agency for Research in Developing Countries, a program set up specifically to provide help in Africa and always performed as official business. Specifically, I was asked to help guide their HIV vaccine program, not with involvement or publication but by scientific critique. This involves one meeting a year of one and a half days. Only a week before meeting with you, I agreed to stay on. The next meeting is not for almost six months. This interaction has provided significant information to my own lab program and directly led to our involvement in a monkey B-cell lymphoma system which greatly mimics the lymphomas of AIDS and opens the first model for therapy. It has also provided my lab with much early information on mother-child HIV transmission and its possible control.

    A copy of my resignation is enclosed. This one hurts more than most. I would like to ask that you consider allowing this to continue, but please let me know because I will have to move quickly if you wish me to resign.

    b) The World Laboratory. I have been a chairman of a committee of European scientists who study cancer viruses and HIV in Africa. We have met once a year, usually in Italy, during the annual meeting of

the whole organization. The meeting is a purely scientific meeting. (The one segment on medical research is only one of the World Laboratory's many scientific interests). All are to help third world nations. It involves several Nobel prize winners, all of whom find time away from their lab for this project. The purpose of the projects on which I have been advising involves training for young African scientists. One direct scientific benefit to my lab has been the uncovering of new variants of viruses (and possibly newly discovered viruses) sent to our laboratory for molecular analyses.

My letter of resignation is enclosed. I wish however that you would reconsider this case now or later.

I wish both of you to know that neither of these activities has ever discredited NIH, and none were for financial gain. I believe they enhanced the image of the NCI and NIH and I believed in all of them as a scientist and as a person. Also there were all done with necessary papers and approvals.

11. I generally review primary data of people with whom I co-author. I also do the same with junior colleagues. As we agreed, tenured senior scientists should not be included. Are you serious about all co-authors? What if we have a Japanese collaborator? How do I get and understand the notebooks? Please clarify Number 11.

12. On Friday, July 19, I reviewed notebooks of all investigators in my laboratory with the exception of three postdocs and one visiting associate and I will review these also. The notebooks are extremely good, as they almost always have been in this lab, and as have been the vast majority over the years. Do you know that in 1990-1991 we documented almost every sentence of many papers written in that period for OSI?

13. Obviously, I will cooperate with any audits imposed upon me, as I always have, including OSI, for about two years now.

14. The actions I have taken are indicated in the above responses. In addition, I have met with my staff on several occasions to disseminate this information. I will, in the near future, reorganize the laboratory, partially in response to the site visit and also due to administrative discussions Dr. Adamson and I had about better management within LTCB.

Regarding human research, the OPRR and the future: Somewhere, somehow, someone has to define clearly what is meant by collaboration. I heard during the meeting with OPRR outside advisers that they were "just then thinking about making the rules..." in regard to whether one's name on a paper always meant collaboration. Obviously, they made their decision, and it didn't help. Rules are being made as we go along, and if one did something ten years ago for which there was no such rule, nonetheless, we can be guilty today.

I also believe we need more flexibility on the definition of human research. You have not asked me my opinion, but I would feel bad not to express a few of many: This current policy will greatly restimulate research on E. coli.

I end by saying that I know of and greatly appreciate your help to my science program. I want you to know and understand that I want to, and will, do my best to comply with your requests.
I believe my past administrative failures were chiefly two: I trusted some people too much, and I did not know about the need for approval before analyses of human blood samples. Dr. Broder would add at least two more: I have traveled too much and had a penchant for speaking too much to the press. I cannot disagree.

I ask you to consider that I have also been in the center of a fairly extensive and rather long-term hostile propaganda campaign which has been greatly inflamed by one or two scientists who have influenced some others including Mr. Crewdson.

R. Gallo

Robert C. Gallo, M.D.