



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

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Date: February 18, 1992

From: Director, Office of Scientific Integrity

Subject: Supplemental Administrative Comments on the
Laboratory of Tumor Cell Biology, NCI

To: Deputy Director for Extramural Research
National Institutes of Health

As we discussed, and your requested, I am bringing to your attention several administrative findings and observations of the OSI investigative team concerning the activities of Dr. Robert Gallo, Chief of the LTCB. These activities, in themselves, did not constitute scientific misconduct, as defined by the PHS. However, the investigative team believed these activities may have contributed to the establishment and maintenance of an environment which may have been conducive to the scientific misconduct which occurred in that laboratory.

These observations were included in the draft report of the investigation. Dr. Gallo addressed them in his "Response to the OSI Draft Report," dated August 13, 1991. The relevant portion of Dr. Gallo's "Response" is attached to this memorandum. The OSI investigative team reviewed Dr. Gallo's rebuttal of the administrative and management issues and were not swayed in their belief that Dr. Gallo's actions were not those of a responsible laboratory chief. However, it was decided that since these matters did not constitute misconduct in science they should not be addressed specifically in the OSI report.

The OSI did not find evidence that Dr. Gallo actually participated in the falsification/fabrication of data or falsification of scientific reports, and thus did not propose that he be found to have committed scientific misconduct. However, the OSI did observe Dr. Gallo's failings as laboratory chief and senior author of the papers. These failings were significant, but not a sufficient basis for a finding of scientific misconduct absent evidence of direct involvement in fabrication, falsification or other clearly defined misconduct. However, the investigative team believed that Dr. Gallo's conduct had in numerous respects fallen well short of the conduct expected of a responsible senior scientist and laboratory chief.

Dr. Gallo was not directly involved as was Dr. Mikulas Popovic with preparation of the Popovic et al. Science paper and the letter to The Lancet. However, the drafts of the Popovic et al. paper demonstrate that Dr. Gallo, as senior author, had a role in reviewing and editing parts of the paper.

Substantial

Dr. Gallo has stated that he accepted ultimate responsibility for the papers on which he was senior author. However, the investigative team believed that his conduct was lacking in accountability: accountability as laboratory chief and accountability as senior author, where accountability means promulgating and enforcing standards for responsible scientific conduct, exercising appropriate scientific oversight, and modelling of responsible scientific conduct as the absolute minimum standard for a laboratory. On these counts, and in this instance, Dr. Gallo failed.

Moreover, Dr. Gallo did not discourage the conditions that may have fostered the misconduct. Dr. Popovic clearly respected Dr. Gallo. Dr. Popovic apparently tried to meet Dr. Gallo's expectations and to fulfill his instructions. There seems little doubt that, had Dr. Gallo set and enforced rigorous standards, Dr. Popovic would have made a strenuous effort to live up to them; and if he had not, he probably would not have remained in the laboratory.

The OSI team observed that Dr. Popovic did not perform in the LTCB as a rigorous, methodical scientist. He evinced little patience for good record-keeping, careful execution of protocols, and meticulous scientific reporting. Unfortunately, there was neither an expectation nor a requirement in the LTCB that he fulfill such expectations. By failing to exercise proper oversight, Dr. Gallo permitted the worst of Dr. Popovic's habits to flourish; by actively rejecting such reasonable measures as the review of original primary data, Dr. Gallo enabled Dr. Popovic to enjoy freedom from accountability for his scientific conduct. When coupled with occasions where Dr. Gallo set for Dr. Popovic demanding tasks and very short deadlines, the stage was set for serious problems. In summary, where Dr. Popovic was concerned, Dr. Gallo failed significantly as a laboratory chief.

The investigative team noted that Dr. Gallo's approach to management of his laboratory seemed almost to be an avoidance of management, an approach that signalled an indifference to good laboratory practices. Nowhere was this exemplified better than in Dr. Gallo's disdainful attitude toward laboratory records, and his lack of responsibility for oversight of those records. The

investigative team noted that good laboratory records are not antithetical to good science; indeed, they are its foundation. Good notes and reliable data are particularly important in ground-breaking research with the potential for immense consequences for the public health, precisely the kind of research in which Dr. Gallo and his colleagues were engaged in 1983-84. Thus, it is deeply troubling that Dr. Gallo continues to deny his responsibility for ensuring that reasonable laboratory notes were kept, notes that could enable attempts at replication and support published accounts of the research. For example, in responding to questions about whether he had confirmed the actual duration of the "pool" culture, Dr. Gallo responded "this is not how I think, nor how the lab runs, nor how I care to run a lab or ever will" (12/2/90 interview, transcript page 161).

The potential damage in a laboratory from an attitude such as this on the part of the laboratory chief is minimized if the laboratory scientists have their own internalized standards for scientific rigor. But when, as in the case of Dr. Popovic, they do not, the potential for problems is very great. Dr. Gallo's seemingly casual attitude concerning scientific rigor was precisely the wrong attitude needed with respect to Dr. Popovic. The investigative team believed that Dr. Gallo knew from the outset that Dr. Popovic kept very poor laboratory notes; Dr. Gallo told the investigative team that European colleagues of Dr. Popovic intimated that the quality of his notebooks was poor. [In the attached rebuttal, Dr. Gallo claims that information from European colleagues was not received until quite recently, but the investigative team maintains that, even if this is true, Dr. Gallo's own observations should have alerted him to the problem and its potential dangers.] Moreover, Dr. Gallo said about his own observations of Dr. Popovic, ". . . he did not keep a daily laboratory notebook. He relied on technician notes as far as I can tell, his brain, his observations and cryptic notes periodically" (12/2/90 interview, transcript page 45).

Thus, Dr. Gallo apparently knew well the poor quality of Dr. Popovic's records, yet, Dr. Gallo said, "As a senior scientist, obviously I did not go into and examine his personal lab notes ever" (interview transcript page 45). And, Dr. Gallo asserted, ". . . I never go into a senior scientist's notes or notebooks. Frankly, I would consider it ludicrous and even tyrannical. And under no circumstances would I work at this place if I were told I had to review senior scientist notebooks. That is a good time for everybody to leave in my opinion" (12/2/90 interview, transcript page 30).

The investigative team believed that Dr. Gallo's approach might be appropriate with respect to the typical "senior scientist," operating as a colleague, who can be relied upon to be rigorous in his/her methods and to keep reasonable records. The issue is whether it is a reasonable approach vis-a-vis a scientist under the direct supervision of an NIH laboratory chief, whose records are notoriously poor, and known to be so by his colleagues and by the laboratory chief himself. The investigative team believed it was not.

Dr. Gallo's responses to the revelations of possible problems in the Popovic et al. Science paper and The Lancet letter were themselves very troubling, all the more so in light of his stature and position as chief of one of the largest biomedical research laboratories in the world. Dr. Gallo seemed both to seek to excuse the problems in the papers and to trivialize their significance. Dr. Gallo and his counsel, Joseph Onek, emphasized the need for speed in preparation of the four Science papers, and presented a dramatic view of how urgent it was that the papers be published. The implication seemed to be that a certain amount of error in the papers was acceptable, given the urgent public health needs at the time. This argument was made repeatedly and at considerable length.

During Dr. Gallo's March 4, 1991 interview, Mr. Onek asserted that "the errors were, in part, due to the need for speed in producing the paper. I would want to remind so there would be no mistake about it. The blood test depended on the publication and submission of the papers . . . without these papers, there would have been no blood test" (transcript page 37). Later, Mr. Onek argued that "If this committee came out that this paper should have been published later than it was, I think that would not only be utterly wrong, but to the extent that that became the standard for the future, . . . what impact will it have so that in a future, similar circumstance, somebody better not publish this paper now. Let's wait another four weeks. You would have blood on your hands. Because that is what it is about" (3/4/91 interview, transcript page 54).

The investigative team believed this argument was without merit. The time required to ensure the accurate reporting of the data and methodology would not have significantly delayed publication of the manuscript.

Mr. Onek went on to assert, "Obviously, with more time and more questioning and more review, that first paper could have been less imprecise. . . . I don't believe it was worth a second of time, or a day" (3/4/91 interview, transcript, page 67).

In these remarks, Mr. Onek seemed to downplay the significance of the misrepresentations in the paper. This was a theme voiced at several points by both Dr. Gallo and his counsel. Particularly in the case of Dr. Gallo, the investigative team found it very troubling that he repeatedly attempted to trivialize the significance of the inaccuracies in the paper. Mr. Onek said the papers ". . . had to be submitted quickly. Every day or week, or two weeks, that these papers had been delayed would have cost lives. That is a very serious harm. Not a single harm was done by the errors in these papers. Indeed, nobody even noticed the errors in the paper, or ever would have noticed them, except for this investigation" (3/4/91 interview, transcript page 38). To this, Dr. Gallo added, "Not error, imprecision."

Later, Dr. Gallo himself added that ". . . If you are talking about a few weeks on a chart this way or that way of what was imperfect, misconduct is when you do it knowingly, or if the results are simply irreproducible and stupid and misled the field. To the contrary, those results moved the field in the only right direction more than any paper and series of papers anybody can define in the history of this field" (transcript, page 58).

Referring to some of the errors in the Popovic et al. paper, Dr. Gallo said, "who cares if RF was EM positive or SN was EM positive? Both viruses are positive. We all know that today, and we all know we had that data" (transcript page 54). Dr. Gallo pressed the investigative team about the standards of responsible research and he asserted ". . . if there are now standards of you have got to be this precise and that precise, this gets--for me, both publicly and privately, really is ridiculous." And he added, "There is no Ten Commandments. Only to do your best and do it honestly" (transcript page 50).

The investigative team agreed enthusiastically with the latter formulation. But "the best" was not done in the Popovic et al. paper, where "best" means conducting experiments in a manner in which the results are authentic and reliable, and recording the procedures and results in a manner that enables replication of the procedures and confirmation of the results. Neither did Dr. Popovic "do it honestly," for he deliberately falsified both the methods and results in his reporting of the experiments. The investigative team found it deeply troubling that Dr. Gallo continued to defend these actions.

The fact that the misrepresentations did not have discernible serious negative consequences is a mitigating circumstance, but one that must be attributed to good fortune and not one that can

be credited to Drs. Popovic and Gallo. Some significant harm to the public interest and/or to biomedical research could have resulted from the misrepresentations in the papers. Moreover, the lack of discernible serious negative consequences does not change the fact that methods were misrepresented and data were falsified.

In this vein, Dr. Gallo told the investigative team that ". . . I am in no mood for writing letters of apology on anything right now . . . We were almost going to do it . . . to write 'okay, these maybe we could have done better.' Then I started talking, and I said, 'Damn it, this is crazy. What am I apologizing for?'" (3/4/91 interview, transcript page 52). The investigative team saw this as a significant failure on Dr. Gallo's part to comprehend the need for accuracy and complete truthfulness in research. If he conveys these attitudes to other scientists in his laboratory, then Dr. Gallo's influence is a harmful one.

As to the HUT-78 issues, particularly the letter to The Lancet, Dr. Gallo appears to have taken more initiative in this matter than did Dr. Popovic in trying to sort out the origins of HT/H9. It was appropriate that as Laboratory Chief, Dr. Gallo do so. But Dr. Gallo did not follow through with these efforts. Moreover, he co-authored the Lancet letter in December of 1984, even though he knew there was uncertainty about the origins of HT/H9, even though he knew there was a possibility that HT/H9 and HUT-78 were the same cell line, and even though he had sent Dr. Popovic to Dr. Bunn (once and perhaps twice) in the months preceding submission of the letter, in an effort to determine the origins of HT/H9. Several years elapsed before Dr. Gallo took decisive action to determine if HT/H9 were the same as HUT-78. Those actions were not taken at his own initiative, but because Mr. John Crewdson, a reporter for the Chicago Tribune, and Dr. Gazdar had raised the issues anew. In short, Dr. Gallo's actions in respect to the HUT-78 issues were careless and fell short of his responsibilities as laboratory chief and senior author of the relevant papers.

(who developed those cells)

The investigative team was mindful of Dr. Gallo's significant contributions to biomedical research. The team also was mindful of the scientists in Dr. Gallo's laboratory whose work appears to be rigorous and reliable. Fortunately, the problems with Dr. Popovic's research appear not to be pervasive in the laboratory. All other laboratory notebooks from the LTCB examined by the OSI investigative team were well organized and well documented.

*probably can
work on
cells with
Dagmar
CSE laboratory
Crewdson
Gallo.
They had
known all
cells were not
They would not
have had to
go thru "Se"*

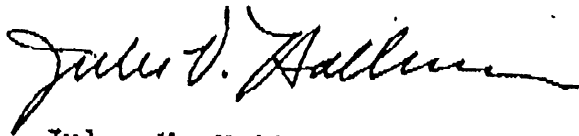
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In addition to the activities associated directly with the Popovic et al. paper, other actions by Dr. Gallo were of concern. As noted in the Proposed Final Investigative Report (page 115),

throughout the deliberations that led to this report, the members of both the inquiry and investigative teams were struck by the numerous instances in which Dr. Gallo's behavior was less than collegial but decidedly beneficial to himself and his causes. Examples of such self-serving behavior include altering the scientific content of published papers purporting to describe data previously presented orally to favor his own purposes, inclusion of statements in the Barre-sinoussi et al. 1983 Science paper without the unequivocal agreement of the authors, and misrepresenting the origin of the HT and H9 cell lines. Although no individual instance of self-serving behavior was considered to constitute scientific misconduct, the expert advisors believed that, taken together, this behavior reflects a disregard for accepted standards of professional and scientific ethics.

Serious problems, such as those revealed in this investigation, were traceable in substantial measure to Dr. Gallo's hands-off approach to management of his laboratory. Responsible conduct for a laboratory chief means serving as a scientific leader. It means setting standards for scientific rigor; it means serving as a role model for responsible scientific conduct; it means exercising appropriate scientific oversight of subordinate scientists to ensure that all work originating in the laboratory is authentic and accurate. Dr. Gallo failed in these responsibilities, and with respect to the matters examined in this investigation, he thereby fostered conditions which provided the opportunity for the creation of falsified/fabricated data and falsified scientific reports.

I hope these administrative comments are useful to you.



Jules V. Hallum, Ph.D.

ATTACHMENT: Excerpt from Dr. Robert C. Gallo's "Response to the OSI Draft Report," pp.36-47.

cc: Dr. John Diggs
Mr. Leslie Platt