

CONFIDENTIAL

Memorandum

Dete : February 25, 1992

From Scientific Director, NHLBL

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Bullect

OSI Report on Drs. Popovic and Galle

Director, NIH

To

I have read the OSI Report and the Richards Report. To maintain an independent view, I wrote my comments on the OSI Report before reading the Richards Report. I confess to some discomfort in relying totally on the OSI Report rather than seeing the primary data. In the one OSI case in which I have seen essentially all the primary data, the draft reports and the final report I found myself in substantial disagreement with the OSI. Also, I feel the process - in which the OSI appears to serve the multiple roles of prosecuting attorney, grand jury, petit jury and judge - is seriously flawed. A brief, 5-minute discussion with Dr. Hallum while I was reading the OSI Report on Popovic/Gallo did nothing to allay my concerns - as I understood it only the OSI investigative team saw all of the primary data and interviewed all of the

OSI Report

A. Overview: This Report must have been written by two different people. The section summarizing the OSI inquiry is very badly written, very diffuse and discursive and very difficult to follow. If possible, it should be re-written in a drastically reduced form essentially just presenting the reasons for recommending a full investigation. The section summarizing the OSI investigation is very much better and its principal conclusions appear to be reasonable.

As an aside, however, I think the Report goes far astray in criticizing SCIENCE for a hasty (19 days) and inadequate review and for publishing the paper too rapidly. From my extensive experience as an Associate Editor of the JOURNAL OF BIOLOGICAL CHEMISTRY, I know that reviews are frequently completed in less than 19 days and that there is no correlation between the quality of the review and the length of time in review; the review time reflects the time the paper sat on the reviewer's desk.

Also, there is no evidence that anything was wrong with the SCIENCE review. A reviewer can be expected to note inconsistencies within the paper or between the paper and other publicly available information (and to evaluate the importance of the conclusions), but the reviewer cannot know if the paper accurately reflects the experimental results. The OSI investigators found 20 "errors" in the paper but only by comparing

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the paper to the laboratory notebooks which the SCIENCE reviewers could not have done, and should not be expected to have done.

I discuss this issue only because OSI has in the past suggested making journals responsible for the integrity of that which they publish. The gratuitous criticism of SCIENCE in this Report appears to be an example of that mistaken policy - a recommendation also made, as I recall, by Walt Stewart and Ned Feder in their first paper in NATURE. I recommend this section of the Report be deleted.

B. Popovic: The findings of misconduct by Popovic on 4 of the allegations encompassing 8 specific issues seem reasonable. None of them affects the major conclusions of the paper. Giving Popovic the benefit of the doubt, they appear to be examples of extreme carelessness (as are the other 12 issues examined by OSI). At worst, they are conscious efforts to make some of the data look better than they were and/or to claim more credit than the Gallo laboratory deserves. The misconduct is less than if data had been fabricated or falsified to reach conclusions that did not have substantial and convincing experimental support. The sins are venal not mortal. Nonetheless, there was misconduct, its costs have been real and substantial, and penalties should be invoked.

C. Gallo: Gallo presents a more complicated problem. The OSI Report takes the position that Gallo should not be found guilty of scientific misconduct, presumably because he did not personally conduct the experiments nor write the first draft of the paper. Thus, the OSI apparently places Gallo as one removed from Popovic whose own misconduct was judged to be minimal.

However, I would take a different position. As the head of the Laboratory, Gallo must assume responsibility for the way it operates. I would not hold him directly responsible if a collaborator falsified or fabricated experimental data. However, as one whose native language is English, as an experienced investigator and author, and as one who must set the "tone" of the Laboratory, Gallo should be held responsible when he is co-author of a paper that misrepresents and misstates the experimental results that he (Gallo) should have reviewed. Conceivably, Popovic could be a careless investigator and confused by the meaning of English phrases or abbreviations (although I doubt it) but these are specifically Gallo's responsibilities as head of the Laboratory and research team. I have no difficulty in finding Gallo more responsible than Popovic for what has occurred.

Specifically, in essentially all 20 of the issues examined (grouped into 16 allegations) Gallo failed in his responsibilities as the head of the Laboratory. His behavior was seriously discordant with the "Guidelines for the Conduct of research in the Intramural Research Program at the NIH", which can reasonably be taken as a standard. Although I think it would be a mistake to

take these Guidelines to be a set of rules and regulations, Gallo's behavior extends well beyond allowable limits.

For example, although as a Visiting Scientist Popovic might not be properly considered to have been a "trainee", Gallo clearly did not "impart(ed) appropriate standards of scientific conduct" (Guidelines, p. 7) to him, and by inference also to others in the laboratory. Data management (Guidelines, p. 8) has obviously been faulty - the data for one of the 4 SCIENCE papers are not available and the "reduction and analysis of primary data" (Guidelines, p. B) for the Popovic et al. paper were so bad as to support 4 conclusions of misconduct and 12 other conclusions of questionable practices. As the senior co-author and head of the Laboratory, Gallo must "accept full responsibility for the defence of the study" (Guidelines, p. 10). Gallo cannot take the position, as he does in his rebuttal to the OSI Draft Report, that there are limits to his control of a senior Visiting Scientist. Also, although Gallo states that he "never go(es) into a senior scientist's notebook" he also states that he sees all primary data for a paper. Thus, Gallo must accept responsibility for inaccurate descriptions of primary data in the published paper, especially when he says he reviewed them. For example, Gallo must have, or should have, known what "n.d." meant, what "continuous culture" meant, and that LAV had been grown in their laboratory as an important part of their research.

D. Conclusions: The evidence in the DSI Report, taken together with past incidents, leads me to conclude that Dr. Gallo has failed to fulfill the responsibilities of scientific leadership. Dr. Gallo's scientific accomplishments are many and notable but these accomplishments neither justify nor excuse his failings. Specifically, publication of the Popovic paper would not have been significantly, if at all, delayed and its import would not have been diminished had the research been conducted more carefully and described more accurately.

The consequences of Gallo's failings have been substantial. At a minimum, an enormous amount of time and effort has been spent on these investigations, the efforts of both the French and American groups have been diverted into unproductive activities and considerable damage has been inflicted on the scientific enterprise, in general. As one specific example, much of the dispute about the identities and origins of the several viruses would have been avoided had the laboratory practices been more scrupulous and had Dr. Gallo responded more responsibly when questions were raised. Most importantly, the practices in the Gallo laboratory could, if not corrected, lead to major problems in the future - either in his own laboratories in this way. "trainees" if they were to run their own laboratories in this way.

E. Recommendations: If Br. Popović is to be found guilty of misconduct, so should Dr. Gallo. Irrespective of whether

misconduct is found, as was discussed on February 18th, I recommend that you remove Br. Gallo from his position as Chief of the Laboratory, explicitly for failing to fulfill the responsibilities of scientific leadership as, for example, they are expressed in the MIH Suidelines for the Conduct of Research. I further recommend that his own research continue to be supported at a level sufficient to allow him to be productive. With fewer scientists to supervise and fewer outside entanglements, Dr. Gallo's research might even profit. A small committee of intramural NIH (but not NCI) and non-NIH scientists could be convened to implement your decision, i.e. to recommend the appropriate level of support for Or. Gallo. An even smaller committee of intramural scientists might then be asked to monitor Dr. Gallo's performance to ensure that it is consistent with the NIH Guidelines. I would reserve the privilege of modifying these recommendations following further group discussion.

Richards Report

The Report is brief, clear and correct. It is entirely consistent with my own view.

Edward D. Korn, Ph.D.