

**Memorandum**

Date September 4, 1991

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

Subject See below

To Director, OPRR, OD, OER, OPR, NIH

I now have had a chance to evaluate the OPRR report.

I find a few serious misunderstandings or at least statements which left out of context may and probably already have distorted the impressions of readers of the report as well as the media.

1. P. 9 states Dr. Picard presented data on deaths at the LTCB, NCI annual laboratory meeting which I organized in August 1990. It further states I said I first became aware of these deaths in January 1991. Both statements are true. As you were informed by Dr. Zagury and by me I was not present at that session. Moreover, no one informed me later, and even if they did I doubt I could have linked the brief statements presented to a problem with vaccinia virus since this connection was not made. All these patients had less than fifty T cells and the survival of most such people is less than six to eight months. Like others, I believed the deaths were due to AIDS.

2. P. 10, last paragraph states I co-authored "with Dr. Zagury no fewer than 14 scientific publications reporting research that appears to have involved human subjects" and "Dr. Zagury has indicated to OPRR that Dr. Gallo supplied him with HIV material as early as 1984, although he notes Dr. Gallo also supplied the same material to many other scientists worldwide."

Left as such (in the context of this document) the first statement will infer that these papers I published with Dr. Zagury concern human trials. As I review the publications the vast majority are in vitro basic science studies, having nothing to do with clinical trials but often do include human blood samples. There are only a few papers I co-authored with Dr. Zagury that deal with vaccines, and my role was purely intellectual (conceptual) in the earliest phase of his work. I believe it was proper and essential for OPRR to have made this clear.

Regarding the 1984 supply of HIV, it is true as you stated, I made such reagents generally available to people all over the world. Moreover, at that period Dr. Zagury was not even discussing ideas for clinical programs. This virus was purely for basic research.

3. The reference to the deaths of the patients has since been the subject of still another Crewdson distortion about me. In a recent publication he slanders me again stating I lied to OPRR about the date I learned of the deaths. He uses as his source an interview I gave with the *New York Times'* Larry Altman in 1986. There are several problems. In the first place I did not keep records of the moment I learned of the deaths. I did my best to recall for OPRR as best I could. Second, I was never led to believe the deaths had anything to do with the vaccinia. To the contrary, I assumed the deaths were due to AIDS! Third, I never believed I was really involved as a collaborator in any of these studies. As I indicated I gave some conceptual input at the start, virology training, and early reagents for *in vitro* and for animal use - period. Fourth, I checked the Altman interview. It is Crewdson who lied. My comments to Altman were that I discussed the concepts of immune therapy with Dr. Zagury not any protocols. I also stated (of course not quoted by Crewdson) that I told Dr. Zagury I would not do it because he will get into trouble. This was in the *Times* article.

4. I am surprised that late in the appendix of your report the whole affair becomes "Zagury/Gallo." Why am I so singularly honored? I fear we are simply led by brainwashing Crewdson allegations. You can be sure his goal is me. If Mr. Dingell's staff is also interested in me this does not justify misusing my name. Please avoid this in the future.

5. In your final specific findings you state that Dr. Zagury and I have "demonstrated a continuing lack of understanding about HHS human subject regulations..." I'm not sure why this statement was made. What is it based on? Surely, if it was true it is not true anymore. I suppose it is solely based on the memorandum to the record made on September 10, 1990 by Dr. Rosen after his interview with me. Indeed, I forthrightly told Dr. Rosen I was unaware of the rule that to simply do any test on a human specimen, even a blood sample, or saliva, or whatever (of any kind of test) required a committee approval. Indeed, this did shock me, and I did not remember ever hearing of the rule before. I also said I believed that most NIH scientists at that time did not know this rule. I also said I thought it was bureaucratically excessive. I still believe this to be the case. However, it is not true that I continually do not understand. Like all NIH scientists, I now understand and follow this regulation.

6. Frequently, appendix A refers to the 1984 shipment from me to Zagury as involving "collaboration with our lab." I repeat that this had nothing to do with clinical studies. Such statements will unfairly and

unnecessarily add fuel to the fire of those who wish to see wrongdoing in every bush. Also, that statement was from a routine form recommended prior to transfer of HIV and H9 cells in 1984 by the NCI associate director. In fact, collaboration with me has never been established simply for providing reagents.



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cc:

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