

D. The Office of Research Integrity, US Department of Health,] produced in 1993 a detailed report indicting Robert Gallo for medical fraud. These charges are extraordinary important as they were drawn up by a panel of scientists appointed by America's most prestigious scientific institutions, the Academy of Science and the Institute of Medicine, in 1992. They had spent months investigating the veracity and integrity of the research into the cause of AIDS carried out by Laboratory Chief Robert Gallo and Senior Investigative Scientist Mikulas Popovic. I include the opening pages – and then one of the key conclusions concerning the above Popovic paper, but as finally edited by Gallo and published in *Science*.

BEFORE THE UNITED STATES
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

RESEARCH INTEGRITY ADJUDICATIONS PANEL

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In the matter of:) Board Docket No. A-93-91
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Robert C. Gallo, M.D.))
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OFFER OF PROOF
OF THE
OFFICE OF RESEARCH INTEGRITY

COMES NOW the Office of Research Integrity ("ORI") and files this Offer of Proof in compliance with the Board's Preliminary Determination of Respondent's Motion (July 9, 1993) and Clarification of Panel's Order and Ruling on Request for Extension of Time (July 21, 1993). In support of its Offer of Proof, ORI would respectfully show as follows:

I. INTRODUCTION

In addition to the Offer submitted by ORI, the Witness and Exhibit Lists will be finalized with additional information concerning the areas noted by the Board, including designations as expert/fact witness, area(s) of testimony, and academic and other relevant credentials. Copies of supplemental exhibits will be provided with the revised exhibit list. Witnesses and exhibits listed in the Offer are identified to satisfy the purposes of the Offer rather than to preclude presentation of additional or different testimonial or documentary evidence at the hearing which may be necessary for logistical reasons.

In its Final Report on the allegations of scientific misconduct against Dr. Robert C. Gallo, the ORI concluded that Dr. Gallo committed scientific misconduct with respect to his following statement published in his article in *Science*:³

These findings suggest that HTLV-III and LAV may be different. However, it is possible that this is due to insufficient characterization of LAV because the virus has not been transmitted to a permanently growing cell line for true isolation and therefore has been difficult to grow in quantity.

ORI Report at 28, 52.

This finding of scientific misconduct was made by ORI after an extensive investigation, including the efforts of its predecessor the Office of Scientific Integrity ("OSI"), the NIH, the Richards Panel (a panel of ten preeminent extramural scientists/scholars nominated by the National Academy of Science and appointed by the Acting Director of the NIH), and an Expert Scientific Panel (three extramural experts appointed by the OSI and ORI to provide advice on the conduct of the investigation and evaluation of the evidence). See Exhibits H-184, H-185, H-186, H-188, H-199, H-200, H-224.

³ "Detection, Isolation, and Continuous Production of Cytopathic Retroviruses (HTLV-III) from patients with AIDS and Pre-AIDS." Popovic, M; Sarnqadharan, M.G., Read E., and Gallo, R.C.; *Science* 224: 497-500 (May 4, 1984). This publication is referred as the "Popovic Paper" or the "Science paper."

In its Final Report, ORI also specifically identified four findings of inappropriate conduct Dr. Gallo which had provided the essential context for its evaluation of the allegations against Dr. Gallo.¹ These are summarized below:

Allegation A1.² In April - May 1983, Dr. Gallo inappropriately inserted changes into a paper written by scientists at the Pasteur Institute (the "Barré-Sinoussi paper."³ The paper had been forwarded to Dr. Gallo for his assistance in having it accepted for publication by Science. Exhibit H-8. In the process of shepherding the paper, and eventually serving as its peer reviewer, Dr. Gallo both authored an Abstract and made significant substantive modifications which advanced his own hypotheses rather than those of the Pasteur scientists. Exhibits H-11 through H-13. These representations were not identified as comments by Dr. Gallo but rather added as gratuitous and self-serving changes purportedly representing the views and findings of the French authors. Exhibit H-13.

Allegation A2. Dr. Gallo was Senior Author on the Popovic paper. Exhibit H-81. ORI has found that Dr. Popovic committed scientific misconduct based on four groupings of nine separate

¹ These allegations were raised publicly in an article in the Chicago Tribune by John Crewdson, "The Great AIDS Quest - A Special Report" (November 19, 1989 (Exhibit H-177).

² These findings are identified with the number and letter assigned by the Board in its Preliminary Determination.

³ F. Barré-Sinoussi, et al., Science 220: 868 (May 20, 1983). (Exhibit H-13). This publication will be referred to as the "Barre-Sinoussi paper."

falsifications in that paper. However, the 3-1/2 page paper contains 13 additional erroneous statements, as well as the false statements concealing the use and significance of LAV (Allegation 6, *infra*) and the identity and origin of the cell line (Allegation A4, *infra*). Thus, the paper was replete with at least 22 incorrect statements concerning LTCB research, at least 11 of which were falsifications amounting to serious deviations from accepted standards for conducting and reporting research. See also Allegation A3.

Allegation A1. Dr. Gallo was the Laboratory Chief at the Laboratory of Tumor Cell Biology during the relevant period. As Laboratory Chief, Dr. Gallo was responsible for ensuring the research in his laboratory was conducted and reported in a manner consistent with the applicable standards. The fulfillment of this responsibility included the institution and management of recordkeeping and data retrieval systems sufficient to support the methodologies and reports of research in the laboratory. His responsibilities also included supervision of laboratory activities concerning the appropriate use and release of reagents. See Allegation A4, *infra*. As Laboratory Chief, Dr. Gallo was responsible for ensuring the accuracy, integrity, and safety of the conduct of scientific research in the LTCB as well as the reporting of that research.

GRI found that Dr. Gallo's failure or refusal to meet his obligations as Laboratory Chief created an atmosphere which interfered with, rather than ensured, the accurate and

appropriate conduct and reporting of scientific research. See Allegations 8, A2, A4.

Allegation A4. ORI determined that Dr. Gallo failed to determine the source of "H9" in a timely manner and placed inappropriate restrictive conditions on access of other scientists to LTCB reagents. See also Allegations A2, A3 supra. Dr. Gallo knew or should have known that the cell line termed "H9" in the Popovic paper was merely a clone of a widely-known and readily available T-cell line, HUT-78. Dr. Gallo's obscuring the identity and origin of this cell line, especially when coupled with his selective and restrictive release of this and other reagents, constitutes a serious deviation from accepted standards for the conduct and reporting of scientific research.

ORI noted the perhaps singular importance of the research reported by LTCB scientists in their four Science papers in May 1984. The failures and deficiencies noted above have marred these advances because of the unacceptable circumstances of the research, the interwoven inaccuracies and falsifications in its manipulated reporting, and the monopolistic hoarding of its reported reagents. These activities have permanently clouded any legitimate discoveries made by the LTCB, inviting and culturing indefensible allegations ranging from fraud to misappropriation.

ORI determined that the preferable course of reporting its findings was to announce its finding of scientific misconduct that Dr. Gallo misrepresented the use and significance of LAV in the Popovic paper in light of the inseparable context of its four

other findings. Thus, in its Final Report, ORI not only explained its finding of scientific misconduct in Dr. Gallo's false reporting of the use and significance of LAV but also explained the context in which that finding was made and should be evaluated, i.e., the pattern of inappropriate conduct and scientific misconduct articulated in Allegations A1 through A4.

The inclusion of these four areas of deficiencies is particularly important in light of the recommended sanctions of placing the ORI Report in Dr. Gallo's personnel file and supervision for a period of three years. The Report should be as complete as possible both to relay the appropriate information to the limited number of officials with access to the personnel file and to inform those charged with the laboratory supervision of the appropriate areas for special scrutiny during the period of supervision.

The Board, however, has now ordered ORI to parse its findings to identify which of these areas of censurable conduct either separately or in the aggregate, constitute scientific misconduct and, for each instance of scientific misconduct, to identify sufficient documentary and testimonial evidence to support a finding of scientific misconduct. In response to this directive, ORI submits this Offer of Proof.

II. ALLEGATIONS OF SCIENTIFIC MISCONDUCT

ORI alleges the following findings of scientific misconduct:

(The pencil lines above are on the copy released.)

I jump forward to page 18 of the conclusion to the report... please note that the ORI stated that Gallo has 'seriously undermined the ability of the scientific community to reproduce and/or verify the efforts of the LTCB (Gallo's Lab) in isolating and growing the AIDS virus'... making retracing the steps extremely problematic and, in some aspects, impossible.' This greatly damages the credibility of his team's work, as it is normal for scientists to have their work so verified.

knew or should have known of the laboratory's deficiencies. He had an affirmative obligation to take steps to ensure that the LTCB operated in a responsible and appropriate manner. Nonetheless, Dr. Gallo took no such steps. Indeed, his failings as a Lab Chief are evidenced in the Popovic ~~Science~~ paper, a paper conspicuously lacking in significant primary data and fraught with false and erroneous statements." ORI will prove that each of Dr. Gallo's deficiencies as a Lab Chief is significant and each can be clearly seen to manifest itself in concrete ways that, at worst, put the public health at risk and, at a minimum, severely undermined the ability of the scientific community to reproduce and/or verify the efforts of the LTCB in isolating and growing the AIDS virus.

Thus, ORI will demonstrate that it was the manner in which Dr. Gallo operated his lab that cultivated an environment which made retracing the steps of the LTCB's AIDS research extremely problematic and, in some respects, impossible. ORI will show that Dr. Gallo has demonstrated a pattern of behavior which effectively disregards and violates the acceptable standards of conduct at NIH and the scientific community at large. He has demonstrated a pattern of conduct that repeatedly misrepresents, distorts and suppresses data in such a way as to enhance his own claim to priority and primacy in AIDS research. Exhibit B-124.

⁴ Despite the numerous inaccuracies and problematic contentions in the paper, Dr. Gallo has filed no retraction or correction to the paper.

This is a pattern that can be clearly seen in Dr. Gallo's statement in the Science paper that LAV had not been fully characterized or transmitted to a permanent cell line. See Allegation 8:

In short, ORI will demonstrate through testimony and documentary evidence that there was a standard of conduct in 1983 and 1984 for Laboratory Chiefs at NIH, including Dr. Gallo, requiring them to, among other things, ensure that the scientists within the lab adequately document their experiments, share cell lines and reagents with other scientists and abide by commonly accepted practices within the NIH for the conduct and reporting of research.

4. ORI Witnesses

ORI will present the following witnesses to establish the duties of a Lab Chief at NIH and elsewhere and how Dr. Gallo's conduct seriously deviated from the commonly accepted practice in the scientific community and NIH in 1983-1984: Dr. Richard Adamson; Dr. Edward Brandt; Dr. Walter Dowdle; Dr. Alfred Gilman; Dr. Robert Goldberger; Dr. Suzanne Hadley; Dr. Arthur Levine; Dr. Malcolm A. Martin; Dr. James O. Mason; Dr. J. Michael McGinnis; Dr. Howard E. Morgan; Dr. Mary Jane Cabern; Dr. Joseph E. Rall; Dr. William H. Raub; Dr. Frederic Richards; Dr. Joseph Sambrook; Dr. Priscilla Schaffer; Dr. John Stobo; Dr. Robert R. Wagner.

Ultimately, since this case was dropped and none of these witnesses were summoned, this Popovic/Gallo scientific paper was allowed to remain available uncorrected, despite being found seriously flawed and deceptive. It is thus still scandalously undermining the work of the many AIDS scientists who rely on its veracity. It is unfortunately and incredibly today one of the most scientifically referenced scientific papers every printed.