culture. For example, the Science paper did not inform the reader that ten different patient samples were "pooled" to create the culture. In addition, the Science paper misled the reader by stating these patient samples came from patients with AIDS or pre-AIDS.

e. The Science paper provided an inadequate description of the source of cells (HT and H4) used in the cultures depicted in Figure 2a and described in the methods section on page 498. (Allegation 1 of the ORI Report) July 25, 1990 Submission to OSI at 7(A3); See also Allegation A4. Dr. Gallo has admitted that samples used prior to January 13, 1984 should have been listed as "HT [HUT-78]" instead of "H4" as Figure 2a states. Dr. Gallo noted that H4 was used only between January 13, 1984 and February 28, 1984. Thus, Figure 2a is false. See also Allegation A4, infra.

f. The cell culture described in Figure 2a of the Science paper could not have provided "over 5 months of data" as stated in the text. (Allegation 2 in the ORI Report). In his Response to the OSI draft report, Dr. Gallo claimed that, if viewed from the middle of the bar graphs, figure 2a would represent at least five months of data. Exhibit H-216 at 23. Since the cell line was admittedly not infected until January 1984, it was impossible to have "over" five months of data by

March 30, 1984, i.e., the submission date of the paper. See Exhibit H-81. Thus, Figure 2a is false and misleading to the reader.

g. Figure 2b of the Science paper does not accurately represent the experiment it purports to describe. (Allegation 6 of the ORI Report). Dr. Gallo has admitted that he cannot provide supporting data for that experiment. Response A8b of July 25, 1990 responses to OSI. Since the RT results for the gradient described in Figure 2b are not available, Figure 2b is false and is misleading to the reader.

h. Table 1 of the Science paper reported IFA data against serum from patient BRU but labelled the value as against serum from patient ET. Exhibit H-327 at 30. Thus, this data entry is false and misleading to the reader. (Allegation 9 in the ORI Report).

i. Figure 1b represented an EM of HTLV-III of the H4 clone. Dr. Gallo has admitted this legend is false because Dr. Popovic actually used H31 not the H4 clone. Response A1b submitted on July 25, 1990. Thus, the legend to Figure 1b is false and misleading to the reader.

j. The Science paper provided insufficient description of the probable origin of the cells used to propagate HTLV-III in the HT cell line. (NOTE: The obscuring of the origin of the H9 cell line is more fully described

as a separate allegation at A4 infra.) The authors called the cell line "HT." (Allegation 16 in the ORI Report). The paper should have stated, at a minimum, that the cell line that was cloned and used to grow AIDS was probably HUT-78 even if the origin were not definitively known. However, the early drafts of the paper contained a specific statement that HT came from a patient with Sezary syndrome, thereby indicating that HT was HUT- 78. Exhibits H-48; H-49; H-50. Although the paper correctly identified the origin of HT as HUT-78 in the early drafts, it was changed in subsequent drafts to obscure the origin of HT/H9. The evidence will demonstrate that the HT cell line was HUT-78. Thus, the failure to describe the origin of HT is a falsification of its pedigree and misleads the reader.

k. The values for RT activity and electron microscopy for patients RF and SN in Table 2 of the Science paper were inverted in the published paper. (Allegation 12 in the ORI Report). Thus, the data for SN and RF are false and misleading to the reader. Exhibit H-327 at 29.

l. On page 498 of the Science paper, the authors state "... about 20 percent of the infected cell population was positive in an IFA in which we used serum from patient ET." However, ET was not known to react with the same specificity as the HIV specific rabbit antiserum until February 29, 1984. Thus, the use of ET

serum before that date was uninformative as to the presence of absence of the AIDS virus. In addition, after this "20%" sentence, the following statement was added: "Serum from E.T. also contained antibodies to proteins of disrupted HTLV-III," implying that ET serum was known to be specific for the AIDS virus during all the months it was used for IFA tests. However, this implication is false because ET serum was not tested and found to contain antibodies to HIV until April 12, 1984. Exhibit H-327. Thus, the statements about ET are false and misleading to the reader.

m. Dr. Gallo deleted Dr. Popovic's attribution of credit to the Pasteur scientists for their detection and isolation of LAV which acknowledged the significant part the use of this virus played in the research reported in the paper. The sentence added by Dr. Gallo not only failed to report any use of LAV in the LTCB, but specifically denied it had been grown in a permanent cell line. In fact, the LTCB had grown LAV in a permanent cell line both independently from September 1983 and as part of the reported "pooled" culture. Dr. Gallo added this sentence after the peer review. See also Allegation 8, infra.

n. "The cell line HT was tested for HTLV before being infected in vitro and was negative by all criteria..." This statement is false. There is no evidence that any

such tests were performed on "HT" before the cell line was infected.

Gallo attempted to support this statement by reference to assays of "HUT-78" performed "by March or April, 1993." But Popovic claimed in late 1983, he had to call his cell line "HT" precisely because he was not certain it was the real HUT-78. Thus, any assays performed on HUT-78 would not support the claim for the "HT" cell line.

Gallo also presented data on assays of "H" and "H4" performed in early March 1984. This is well <u>after</u> "HT" allegedly was infected, and thus, like the 1983 data, cannot support the claim in the paper.

o. <u>Page 499, Col 3:</u>

"HTLV-III has also been isolated in our laboratory from a total of 48 patients by the more conventional methods ...." This statement is untrue. As noted in the OSI draft report, at the time of publication of the Popovic et al. paper (as well as the Gallo et al. paper, whose focus <u>is</u> the 48 "isolates"), the LTCB had approximately 10 genuine isolates of the AIDS virus.

p. <u>Page 499, Col. 3:</u>

Several "EM" entries in Table 2 are misleading. SN, reported as EM "ND" in Table 2, actually was done and was negative. RF, reported as EM+, actually was not

reported positive by the EM expert until October of 1984.

BK and LS, both reported EM+, were supported by Dr. Gallo by undated EMs. There is no documentation concerning when the BK EM was actually performed. Neither is there any documentation that prior to the publication date of the Popovic et al. paper, either of these EMs was read as positive. In fact, it was not until 1986 that the EM expert read the "LS" EM and said that "if confirmed by RT and IFA data," the culture could be considered HIV+.

Concerning "WT" (TW), Dr. Gallo's account is misleading. On one occasion, he said that "Virus particles were not detected in EM sections of SN and TW (7/27/90 response). But in 9/90, Gallo said "The TW cultures were never sent for EM analysis, so the paper should state 'not done.'" However, M. Gonda's 2/22/84 report to Popovic listed sample #2 as "TW," and said the sample was "negative for virus particles."

4. Dr. Gallo Violated the Standards For Senior Authorship

There are at least 22 false and erroneous statements in the 3½ page Science paper, including the nine false statements at issue in the Popovic hearing and the 13 issues described separately in this Offer. See also Allegations A4, 8. Dr. Gallo's introduction of these false statements or failure to

correct them is, in the aggregate, a material breach of his obligation as senior author and Laboratory Chief of the LTCB to ensure the accurate and honest reporting of research.

5. ORI WITNESSES

Drs. Huth, Woolf, Schaffer, Morgan, Martin, Raub, Goldberger, Rall and others will testify to the standards articulated above applicable to senior authors.

Drs. Richards, Hadley, Schaffer, Chermann, Berns and others will testify regarding the falsifications of data that appear in the Science paper.

Drs. Schaffer, Martin, Hadley and Popovic will testify that Dr. Gallo is responsible for the false statements in the Science paper.

Drs. Richards, Hadley, Schaffer, Berns, and others will testify that the falsified statements reported in the Science paper deviated from accepted standards of scientific practice.

C. Allegation A3: Failure Of Dr. Gallo to Supervise The LTCB

In its Final Report, ORI found that:

> Especially in light of the groundbreaking nature of this research and its profound public health implications, ORI believes that the careless and unacceptable keeping of research records revealed by the OSI inquiry and investigation reflects irresponsible laboratory management that has permanently impaired the ability to retrace the important steps taken.

ORI Final Report at 53.

1. Summary of the Offer of Proof

ORI will show that Dr. Gallo failed to instruct, supervise and manage the scientists under his supervision in his Lab who were involved in AIDS research, particularly Dr. Popovic, in order to ensure that their practices and methodologies conformed to those which were acceptable within the NIH and the scientific community at large. The evidence will demonstrate that Dr. Gallo placed inappropriate pressure upon these scientists to publish frequent and important articles, pressure that Dr. Gallo knew or should have known compromised the accuracy and precision of the work performed in the lab and reported in the papers. While this pressure certainly does not absolve the individual scientists of their responsibility for accurate recordkeeping and reporting, it increases Dr. Gallo's responsibility as a Lab Chief, for their resultant inappropriate practices. Because Dr. Gallo's supervisory responsibilities included Dr. Popovic, Dr. Gallo must bear responsibility for both the deficiencies in Dr. Popovic's laboratory practices and for the numerous resultant discrepancies and false and deceptive statements in the Popovic paper. Dr. Gallo's acts constitute a serious deviation from those practices that were accepted in the scientific community, the NIH and the Commissioned Corps Personnel for conducting or reporting research.

2. Standards For Laboratory Supervision In 1983-84

A Chief of an NIH intramural research Laboratory has had, at least since 1983, significant duties and responsibilities. A

Laboratory Chief must ensure that every aspect of the Laboratory functions appropriately and in accordance with the accepted standards both within the NIH and within the scientific community at large.[15] In this role, the Lab Chief has numerous specific responsibilities, including, among other things, supervising the scientists working within the Laboratory, ensuring that they are aware of and abide by the applicable standards for the conduct of research at the NIH and the scientific community in the conduct and reporting of research. It is the responsibility of the Lab Chief to ensure that scientists conduct and report research within and for the Laboratory in a precise and detailed manner, generating and maintaining records sufficient to support the experiments performed in the Laboratory.

3. Dr. Gallo Failed to Meet the Standards For A Laboratory Chief

ORI will present both documentary and testimonial evidence of Dr. Gallo's failures as a Lab Chief, failures that effectively cultivated an environment which permitted publication of the numerous misrepresentations contained in the Science paper. For example, ORI will show that the records kept by the LTCB (Dr. Popovic in particular) were wholly inadequate to support the

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[15] Dr. Gallo is also a commissioned officer (Captain) in the United States Public Health Service. Therefore, in addition to being obligated to run his laboratory in accordance with the standards acceptable within the scientific community and the NIH, he is required to abide by the requirements prescribed in the Commissioned Corps Personnel Manual. Exhibits H-181; Commissioned Corps Personnel Manual Chapter. Winston Dean will testify on the responsibilities of a Commissioned Corps officer.

experiments purportedly evidenced in the Popovic Science paper, a paper that, by all accounts, was a seminal paper in research on the AIDS virus. Dr. Gallo had an obligation as a Laboratory Chief to ensure that Dr. Popovic and others in the Lab were instructed to be, and were in fact, meticulous in their scientific efforts and recordkeeping methods. See e.g., NIH Records Control Schedule. Dr. Gallo knew or should have known of Dr. Popovic's deficiencies and intervened with both preventive and corrective measures. Dr. Gallo, however, failed to take the necessary managerial actions to ensure that Dr. Popovic conformed to a minimally acceptable standard for the making and keeping of scientific records.[16] Id.

Evidence of Dr. Gallo's failure to supervise and manage the activities of Dr. Popovic and the LTCB adequately will include but not be limited to the following: the LTCB's failure to catalogue appropriately the receipt of the July shipment of LAV from the Pasteur Institute[17]; the LTCB's failure to record the

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[16] The evidence will demonstrate that Dr. Gallo has virtually never reviewed the lab notebooks of the senior LTCB scientists, such as Dr. Popovic, even though he was fully aware of Dr. Popovic's recordkeeping deficiencies. Exhibit H-298 at 69-70; Exhibit H-314 at 45-46.

[17] Because of the absence of LTCB documentation of the receipt of "July LAV," there is no objective record of such important parameters as the precise date of receipt of the virus sample; the identification of the sample, including the identification of normal donor cells, if any, used for culturing; the quantity of the sample; and whether the RT level of the sample was provided, and if so, what this level was (an important index of the potential of the sample for successful inoculation of cord blood, PBLs or permanent cell lines).

culturing of the July shipment of LAV[18]; the LTCB's failure to keep adequate contemporaneous records of Dr. Popovic's alleged reinfections of the Ti7.4 and HUT-78 cell lines with LAV in November 1983[19]; the LTCB's failure to record adequately the results of alleged IFA experiments performed before December 1983 on the LAV sample received by the LTCB from Pasteur in September 1983[20]; the Laboratory's failure to record adequately the

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[18] Due to the paucity of culture records of July LAV, --- a few fragmentary undated records--- there is no comprehensive record of when and with what frequency July LAV was used to attempt infections of cord blood of adult PBLs, what quantities of virus supernatant and normal cells were used, or whether alpha interferon, IL-2, or any other supplement to the culture media was used. These are all important parameters of the potential success of attempted infections. The absence of information leaves the scientific community much in the dark about the actual viability of July LAV. (Note: Drs. Gallo and Popovic claimed, for years, that there was no viable virus in the sample, but this claim is contradicted by several of the few records that do exist.) See, e.g., Exhibit H-98.

The absence of dated culture records also means that the few records that exist of subsequent assays (e.g., September 13, 1983 IFAs) cannot be adequately evaluated because the duration of the cultures that were assayed remains unknown. This is a particular concern vis-à-vis RT assays, because RT is known to fluctuate as a function of time in AIDS virus cultures.

[19] The absence of any records of Popovic's alleged reinfection of the two LAV cell lines in mid-November 1983 means that there is only Dr. Popovic's unsubstantiated word to support that these crucial reinfections took place, or even were necessary.

[20] The absence of any pre-December IFA data for the LAV cell line infections is significant, since the requirement for early IFA assays is clearly delineated in the laboratory notes. The absence of pre-December IFA data leaves highly questionable the claims of Drs. Gallo and Popovic that the October 1983 LAV cell line infections did not survive and that reinfections of the LAV cell lines were performed in November 1983.

initiation of the culture later identified by the Lab as MOV[21]; the Laboratory's failure to record adequately any RT, IFA, or EM data for the "HT"/"pool" purportedly created and used by the LTCB in isolating and growing the AIDS virus[22]; the Laboratory's failure to record adequately the repeated infection of the eight HUT-78 clones purportedly infected with the "pooled" virus[23];

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[21] The absence of any record of the initiation of the cultures that would later be labelled "MOV" is extraordinary, given that MOV was: a) the first suspected AIDS virus isolate produced in large quantities at the LTCB; b) the isolate that was used to make the first HIV-specific reagent, the hyperimmune rabbit antiserum; c) the isolate that was used to make, refine, and for two months test the AIDS virus antibody blood test; and d) the isolate that was the source of the LTCB's first HIV-specific cDNA probes. The sample identified as "MOV" was analyzed by Roche Laboratories and found to be LAV/LAI. See, e.g., Exhibits H-220, 231.

[22] The absence of virtually any assay data for the parent cell line, "HT"/"pool", (save for a single, unidentified RT datum) is simply unbelievable. The "pooled" isolate, after all, was the LTCB's alleged prototype isolate, the isolate the LTCB allegedly transmitted to a permanent cell line and used to develop and patent its HIV antibody blood test. RT data from the pooled isolate allegedly were used to compose Figure 2A of the Popovic paper. Yet we are told that no "pool" data exist.

The need for data on the "pool" is of extreme importance in this seminal AIDS study. This importance is emphasized by the fact that the "pool" samples analyzed by Roche Laboratories were found to be LAV/LAI, not HTLV-III. See Exhibits H-220, 231. Thus, with the absence of data to the contrary, the veracity of the entire experiment is, and remains, in doubt.

[23] The absence of any record of the infection of the HUT-78 clones with the "pooled" virus means that the subsequent assays (e.g., 6- and 10-day IFAs) cannot be adequately evaluated, since the alleged duration of the cultures cannot be confirmed. Furthermore, the absence of infection records renders even more problematic the fact that none of the subsequent assays on the clones identifies the isolate that was used. Consequently, on this, as on so many other important points, there is only Dr. Popovic's unsubstantiated word for how the experiment was performed, which isolate was used, etc.

the laboratory's failure to record adequately the infection of the critical samples included in what Dr. Popovic and Dr. Gallo have called a "host range" (February 13, 1984) experiment or to make any record of any experiments other than EMs performed upon the most important of those samples[24]; the laboratory's failure to record adequately, or even to identify, the two samples labeled "L" that were the first two samples purportedly tested with the rabbit antiserum and found positive for the AIDS virus on February 21, 1984[25]; the LTCB's failure to retain any sample of the pooled culture that was purportedly referenced in the Science paper[26].

ORI will present witnesses to establish that the very essence of science rests upon adequate recordkeeping. It is incumbent upon scientists to make and keep records sufficient to

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[24] The absence of any records for the so-called "host range" experiment, other than EMs, is striking. Because we do not know when the cultures were initiated, the definitiveness of the EMs cannot be adequately evaluated. Furthermore, given the well-known insensitivity of EM as an index of virus infection, it is simply not credible that EMs were the only measure taken. Finally, due to the lack of even minimal records of the "host range" experiment, the true identity of one of the few positive cultures, "HTLV-A," remains in doubt (although Gallo and Popovic claim, with no substantiation, that it is the "pooled" virus).

[25] The absence of any records documenting the identity of the "L" cultures assayed with the rabbit antiserum on February 21, 1984 speaks for itself. Gallo stated to OSI that he cannot identify the source of these cultures. The possibility that the "L" cultures were LAV cannot be ruled out. If this is true, it would be very significant, for it would show that early on, notwithstanding repeated later denials, the LTCB had compelling incontrovertible evidence that LAV was the cause of AIDS.

[26] See Allegation A2 supra.

document each step taken in an experiment in order to allow others to retrace those steps, to evaluate the research and to reproduce the experiment. These witnesses will testify that, in the absence of such records, a negative inference is drawn by the scientific community. These witnesses will testify that such recordkeeping is all the more important when a scientist intends to publish his results, especially where those results purport to be ground breaking and the paper is seminal to an area of research. The resources available to the LTCB make these lapses both indefensible and incredible.

ORI will prove that the LTCB's failure to record appropriately the experiments allegedly performed in the lab was a serious deviation from the practices which were accepted in the scientific community and the NIH for conducting research during the relevant time period (1983-1984) through the present.[27] As the Chief of the LTCB, Dr. Gallo bears primary responsibility for these deficiencies.

Other evidence of Dr. Gallo's failure to fulfill his responsibilities as a Lab Chief include his failure to ensure that the samples of cell lines and viruses were maintained in a

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[27] Additionally, ORI will demonstrate that Dr. Gallo failed to take appropriate steps to maintain the security of scientific papers in the lab or to ensure that the papers published by those in the lab were fully supported by primary data.

manner within the lab that would protect against contamination.[28] Moreover, ORI will show that Dr. Gallo failed in his responsibilities as Lab Chief of the LTCB by failing to ensure that his laboratory tracked the origin of HT/H9 when he knew that the origin was in question because of inadequate LTCB records, and when he knew or should have known that the true origin was the HUT-78 cell line that was already widely available to others in the scientific community. See Discussion of allegation A4, infra. ORI will show that Dr. Gallo further obfuscated the origin of HT/H9 by refusing to share the cell line openly with other researchers, thereby denying them the ability to conduct and report their own research.

ORI will present evidence that Dr. Gallo's emphasis on speed, volume, and priority of LTCB publications required

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[28] It is Drs. Gallo's and Popovic's contention that such contaminations were commonplace and resulted in the LAV virus infecting HTLV IIIB. Indeed, ORI will demonstrate that Dr. Gallo should have learned from personal prior experience that every effort must be taken to protect against contaminations. Ironically, Dr. Gallo noted the possibility of contamination at the press conference heralding his isolation of the AIDS virus and groundwork for a blood test, while claiming to have avoided use of LAV to avoid such contamination. In 1975, Dr. Gallo published a paper purporting to report the discovery of the first human retrovirus, only to have it later revealed that his virus was the result of a simian contaminant. The facts reveal that Dr. Gallo's failure to carry out his responsibilities as Lab Chief directly contributed to the contaminations in the lab. Numerous contaminations in the lab reportedly were caused by the movement of Dr. Popovic's lab in December 1983. This move took place with little or no advance warning to Dr. Popovic. However, Dr. Gallo has admitted that he had sufficient advance notice of the move but failed to inform Dr. Popovic. Exhibit H-298 at 50; Exhibit H-299 at 68-69; See OSI Interview of Dr. Robert C. Gallo (April 8, 11, 1990).

paper, in addition to his personal responsibility for the false representation of LAV. ORI will show that there are at least 23 incorrect statements and at least 11 false statements in this 3½-page paper, and Dr. Gallo must accept responsibility for those statements. See discussion of Allegation A2, supra.

Additionally, ORI will document Dr. Gallo's continued supervisory deficiencies with (1) the dismissal and felony convictions of Drs. Prem Sarin (the LTCB's second in command) and Salahuddin, two scientists under Dr. Gallo's direct supervision in the LTCB[30]; (2) a report from the Office for Protection from Research Risks (OPRR) censuring Dr. Gallo for failing to comply with HHS human subjects regulations and NIH human subject policies in his collaboration with Dr. Daniel Zagury in 1986 and 1987, experiments which resulted in the deaths of several subjects[31]; (3) a 1988 report from the NIH Division of Management Survey and Review (DMSR) documenting Dr. Gallo's abuse of leave and suggesting that Dr. Gallo may have been absent from the LTCB for at least six months in 1987, absences that suggest an abrogation of his duties as a Lab Chief; and (4) a 1991 Memorandum from the Director of NIH and the National Cancer Institute imposing restrictions on Dr. Gallo's activities and

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[30] In the criminal conviction of Dr. Salahuddin, it appears that Dr. Philip Markham was called to give testimony and did so under a specific grant of immunity from the United States Attorneys' Office. U.S. v. Sarin, No. MJG-91-0455 (Jan. 23, 1992); U.S. v. Salahuddin, No. HAR-90-0285.

[31] OPRR Report: Memo, Director, NIH to Dr. Gallo, June 21, 1991.

mandating certain affirmative steps to bring Dr. Gallo's conduct within accepted standards for NIH.[32] H-214. See also H-141, 216, 223. Finally, ORI will present testimony from NIH Scientific Directors that at a meeting to discuss Dr. Gallo's behavior as a Lab Chief, his conduct was determined to be wholly outside the standards acceptable for a Lab Chief within NIH.[33]

Therefore, ORI will demonstrate that the responsibility for ensuring that the LTCB's AIDS research efforts were appropriately documented, conducted and reported was first and foremost the responsibility of the Lab Chief, Dr. Robert Gallo. Dr. Gallo

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[32] The restrictions and mandates placed upon Dr. Gallo include, among other things, that Dr. Gallo must "familiarize [himself] with and comply with all applicable [HHS]and [NIH] regulations applicable to the performance of [his] duties as Chief, LTCB...; terminate all professional or consultative outside work activities, whether with or without compensation...; 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 [his] official duties; obtain advance written permission from the Director, NCI, or his/her designee, to participate in any interview...; obtain advance written permission from the Director, NCI or his/her designee, to make any speech or appearance...; obtain 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...; review personally all primary data involving any person under his 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...; maintain (and assure through personal audit by him that employees under [his] 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 [his] official duties...." Exhibit H-214; See also Commissioned Corps Personnel correspondence.

[33] NIH scientific directors, including Dr. Arthur Levine, will testify on this point.

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.[34] 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 H-224.

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[34] 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 Osborn; Dr. Joseph E. Rall; Dr. William H. Raub; Dr. Frederic Richards; Dr. Joseph Sambrook; Dr. Priscilla Schaffer; Dr. John Stobo; Dr. Robert R. Wagner.

D. Allegation A4: Dr. Gallo'S Failure to Determine the Origin of and Freely Share The H9 Cell Line

The ORI found in its Final Report that:

> Dr. Gallo's failure to determine in a timely manner the derivation of the cell line that supported the HTLV-IIIB culture and the imposition of restrictive conditions on its distribution reflect Dr. Gallo's indifference to acknowledging promptly the contributions of others and to sharing of research materials of critical public health importance.

ORI Final Report at 53.

1. Summary of the Offer of Proof

The evidence will show that Dr. Gallo took a cell line identified by another scientist -- "HUT-78" -- and used it to successfully, continuously grow the AIDS virus, first LAV, then LAV as "MOV," then the "pool" isolate, "HTLV-IIIb." Dr. Gallo renamed the cell line "HT," and when he published his findings, he misrepresented and obscured the origins of the cell line so that its true identity could not be discerned. Thereafter, for a prolonged period, Dr. Gallo failed to diligently seek out the truth about the origins of "HT." Even faced with important evidence from multiple sources that HT was HUT-78, Gallo failed to acknowledge this fact to the scientific community. Not until 1989 did Dr. Gallo finally admit that the cell line he used and called "HT" was, in fact, HUT-78. Exhibit H-179 at 254; H-315. Dr. Alan Rabson will testify about the study, published in 1989, that confirmed the identity of H9 and HUT-78.

Dr. Gallo also took two actions that significantly restricted the availability of the HT/H9 cell line to other researchers: (1) some scientists were denied access to the cell line altogether, while others were provided it only after significant delay and/or only with onerous conditions associated with its use and (2) for years, Dr. Gallo failed to deposit the cell line at the American Type Culture Collection (ATCC), a repository for generally-available reagents, so that scientists were forced to seek the cell line from its sole source, Dr. Robert Gallo. (Dr. Hay will testify that the ATCC serves as a national repository and resource for researchers and how the ATCC identifies and "authenticates" samples. See Exhibit H-318.)

The evidence will show that by obscuring the identity and restricting the availability of the cell line in which he successfully mass-produced the AIDS virus, Dr. Gallo seriously hindered progress in AIDS research. ORI will demonstrate that these actions by Dr. Gallo violate fundamental tenets of scientific research and that they seriously deviate from accepted standards for the conduct and reporting of research.

2. Dr. Gallo's misappropriation and misrepresentation of the HUT-78 cell line

(a) Factual background. In the Fall of 1983, Dr. Popovic used several cell lines, including a cell line he found at the LTCB, identified as "HUT-78," for his initial attempts to infect a permanent cell line with suspected AIDS virus isolates. HUT-78 had, some years before, been provided to the LTCB by its

discoverer, Dr. Adi Gazdar. Dr. Gazdar had published a paper in 1981 reporting the discovery of the cell line, including the fact that it was derived from a patient with Sezary Syndrome, a type of lymphoid leukemia. Exhibit H-1.

Shortly after his initial experiments with HUT-78, Dr. Popovic cloned the cell line on two separate occasions, reportedly for two reasons: one, to ensure that the cell line line did not contain any potential contaminating agents and two, to obtain single-cell clones that would be highly permissive for growth of the AIDS virus. On both occasions, the parental cell line was identified as "HUT-78," although by the time of the second cloning, "HT" was added. Exhibit 147; H-210 at 13 et seq.; H-323. Also, testimony of Dr. Popovic and Ms. Read-Connole. The "best grower" resulting from these experiments was a clone identified as "H9."

Meanwhile, Dr. Popovic renamed the parental cell line, changing the name from "HUT-78" to "HT." Drs. Popovic and Gallo claimed that the principal reason for the renaming was their uncertainty that the cell line which they cloned and with which they succeeded in growing the AIDS virus, was authentic HUT-78. Thereafter, in numerous scientific papers, talks, and internal memoranda, Gallo represented "HT/H9" and "H9" to be a new "discovery," a "breakthrough" accomplishment for the LTCB.

The evidence will show that Gallo knew or should have known that HUT-78 and HT were one and the same cell line. Yet in none of the fora in which he described the HT cell line, at no time,

did Gallo advert to even the possibility that HT was HUT-78, that H9 was a clone of HUT-78. In fact, as the evidence will show, Dr. Gallo systematically misrepresented the origins of the HT cell line so that his fellow-scientists could not discern HT was really HUT-78. Consequently, Gallo's fellow scientists were not aware that HUT-78, a readily available cell line, was permissive for the AIDS virus, and they devoted considerable effort to attempting to obtain Gallo's cell line, upon which he placed onerous conditions for its use. See discussion infra.

Two scientific papers published by Gallo et al. in 1984 were particularly significant in misrepresenting the origins of HT/H9. In May 1984, in the Popovic paper, Dr. Gallo and his colleagues described the "discovery" of the cell line as follows:

> "We subsequently found a cell line that is highly susceptible to and permissive for cytopathic variants of HTLV. This cell line can grow permanently after infection with the virus. We report here the establishment and characterization of this new immortalized T-cell population and its use in the isolation and continuous high-level production of HTLV variants from patients with AIDS and pre-AIDS." (emphasis added). (H-81; pp. 497-8). The evidence will show that Dr. Gallo personally was responsible for key aspects of this passage.

Dr. Gallo and his fellow authors further described the derivation of "HT":

> Several neoplastic human cell lines established in vitro were assayed for susceptibility to infection with HTLV-I and -II and with many of the more cytopathic retroviruses isolated from AIDS patients. One neoplastic aneuploid T-cell line derived from an adult with lymphoid leukemia was found to be susceptible to infection with the new cytopathic virus isolates. This cell line, termed HT . . . was extensively cloned in order to select the most permissive clones that would preserve high rates of growth and virus

> production. . . . We have used clones H4 and H9 for the long-term propagation of HTLV-III from patients with AIDS and pre-AIDS. (H-81; p. 498).

(Early drafts of the Popovic paper indicate that Dr. Popovic knew there was a high probability that the HT cell line and the H9 clone were derived from HUT-78. The early drafts of the papers clearly identify the cell line as HUT-78, by stating that the HT cell line was derived from a patient with Sezary syndrome. Exhibits H-48; H-49. See also Gallo transcript #3 stating that it was Gallo's decision to call the cell line "HT," in the Popovic paper.)

Clearly, the Popovic paper presented HT/H9 as "new" cell lines, discovered by the LTCB. There was no reference to an origin in any other cell line, nor even a reference to such a possibility. Moreover, the description of HT as "derived from an adult with lymphoid leukemia" further obscured the derivation of HT from HUT-78, because "lymphoid leukemia" is a very broad term encompassing numerous specific illnesses, while the real diagnosis of the patient source for HUT-78, Sezary Syndrome, is highly specific, being one of the more rare forms of lymphoid leukemia. Exhibit H-180.

The obfuscation and misrepresentations concerning the origins of HT/H9 were significantly advanced in a subsequent scientific publication, a letter to The Lancet, published in December 1984. (H-129) In the Lancet Letter, Dr. Gallo distinguished HT and H9 from HUT-78 and described HT and H9 as

derived from a patient with Adult T-cell leukemia, ATL, while the HUT-78 cell line was described as derived from a patient with Sezary Syndrome. (The fact that Drs. Gallo and Popovic used and reported a cell line they called "HUT-78" for the experiments in the Lancet letter raises the obvious question of how, given their professed "uncertainty" about HUT-78, they were able to make this identification. Neither Dr. Gallo nor Dr. Popovic was able to answer this question.)

Dr. Gallo also described HT as "the best studied" of "certain human permanent leukaemic cell lines with characteristics of mature T cells," while HUT-78 was cited as one of several other cell lines "permissive for cytopathic variants of HTLV-III and the very similar lymphadenopathy virus (LAV) and capable of continuous virus production ... " (H-129; p. 1472).

Dr. Gallo did not reveal in either the Science article or the Lancet Letter that the HT cell line and its clone H9 were both derived from HUT-78, although Dr. Gallo knew, or should have known, that the origin of the HT and H9 cell lines was HUT-78. In fact, the evidence will show that by the time of submission of the Lancet letter, several studies had been performed showing the identity of these cell lines. (Drs. Dean Mann and Paul Bunn will testify about these studies.) The submission of the Lancet letter, claiming the distinctiveness of HT/H9 from HUT-78, in the face of the results of these studies, can only be viewed as an act of willful deception.

Other statements by Gallo similarly obfuscated and misrepresented the identity of H9 and HUT-78. Exhibits H-68; H-169; H-203; H-204; H-205; H-210; H-358. Drs. Hampar and Cabradilla will testify concerning these matters.

(b) Standards For Identifying the Source of Cell Lines: In 1983, as now, it was the commonly accepted practice in the scientific community to accurately and completely identify the derivation of a cell line. This is an essential step to allow other scientists to confirm or replicate research findings and to advance the science. In cellular and molecular biology, the precise lineage of cell lines used as research resources is critical information to advance the science. Acknowledgement of the identity and source of a cell line also provides appropriate recognition to the original discoverer of a cell line.

Finally, it goes without saying that willful misrepresentation of the identity and origin of a cell line, as with any significant element of an experiment, is proscribed conduct that seriously deviates from commonly accepted practices for reporting research, and thus, constitutes scientific misconduct.

(c) Significance of Gallo's Deviations from This Standard: Gallo's unattributed use and subsequent obfuscation of the identity and origins of the cell line he used to grow the AIDS virus is significant in at least three respects. First,

Dr. Gallo's failure to identify the origin of HT/H9 introduced a wholly unnecessary void in AIDS research, at the time as it is now, a particularly critical area of public health concerns. Second, it denied other scientists immediate access to HUT-78, a readily-available cell line, while they delayed progress by securing, or attempting to secure, Gallo's "new" cell line.

Finally, Gallo's obfuscation/misrepresentation of the identity and origin of "his" cell line denied Dr. Adi Gazdar, the scientist principally involved in the discovery of the HUT-78 cell line, rightful recognition for his discovery. See Exhibit 1.

Numerous ORI witnesses will testify that it was a serious deviation from accepted practices for Dr. Gallo not to identify HT/H9 as a derivative of HUT-78, or at least to disclose this possibility, both in the initial Science paper describing HT and H9 and in subsequent communications.[35] The Richards Panel, a blue ribbon panel composed largely of eminent members of the National Academy of Sciences, noted the impropriety of Dr. Gallo's failure to identify the subclones with reference to the originating cell line, stating that "the so-called HTLV-III virus was thus established and introduced to the world with no reference to or discussion of two crucial facts ... (2) the cell line utilized (HUT-78) was one that had been obtained from the

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[35] Among the witnesses who will testify regarding the need to identify the origin of a cell line used in experiments and the impropriety of concealing that origin, are Dr. Schaffer, Dr. Curran, Dr. Richards, and Dr. Tramont.

Minna laboratory ... Although others could have obtained HUT-78 from the ATCC ... the essential identity of HUT-78 with H9 had been effectively obscured." Exhibit H-224 at 3.

The OSI Investigative Team, comprising scientists knowledgeable about standards of conduct in biomedical research, including AIDS research, made the following observations about Gallo/Popovic's actions:

> "A thoughtful, careful scientist embarked on the task that engaged Dr. Popovic -- the search for a cell line permissive for the HIV -- would have recognized the need to use a cell line which was accurately and completely characterized ... If not possible at the beginning of the experiments, the attempt at definitively identifying the cell line should have come soon after the HIV was successfully grown, and certainly by the time the letter to The Lancet was submitted" (OSI Draft Report, 6/91, pp. 117 - 118).

Further, according to the OSI Investigative Team,

> "... it was important to establish the identity of the cell line being used, for the experiments using HUT-78 were crucial ones in the attempts to culture and mass produce the AIDS virus. It was equally important in the experiments published in the letter to The Lancet, where the focus was on the unique distinguishing characteristics of a number of different cell lines (Id. at 116).

Some or all of the members of the OSI Investigative Team will testify on these points (Drs. Priscilla Schaeffer, Kenneth Berns, Michael McGrath).

Dr. Gallo's failure to acknowledge the identity/origins of the HT/H9 cell line, including the fact that the cell line of origin, HUT-78, was in widespread use, and his significant misrepresentations of the characteristics of his alleged "new" cell line, led many scientists to believe that Dr. Gallo had discovered a new cell line. Some scientists suspended work while they attempted to secure the "new" cell line from Dr. Gallo.[36] If Dr. Gallo had revealed that the probable origin of the HT/H9 cell line was HUT78, other scientists could simply have used their own supply of HUT-78 or obtained HUT-78 quickly and easily from the ATCC or another source.[37] In short, the consequence of Dr. Gallo's deception was that other researchers were prevented from the recognition that they could grow their own isolates of HIV in a readily-available cell line.

Several witnesses will testify to the negative consequences for their own and their colleagues' AIDS virus research

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[36] Among other witnesses, Dr. McGrath will offer testimony on this point.

[37] Numerous scientists will testify that they would have, and could have, used HUT78 if they had known that it was the parental cell line from which H9 was derived.

occasioned by Dr. Gallo's misrepresentations of the identity and origins of HT/H9 (Drs. McGrath, Martin, and Poisez).

Coupled with Gallo's egregious, wholly unwarranted conditions on providing H9 to his fellow-scientists, Gallo's failure to acknowledge the identity (even the probable identity) of HT/H9 and HUT-78, at a vital juncture in AIDS research, constitutes a most serious deviation from accepted practices for conducting and reporting research and, accordingly, is scientific misconduct.

3. Dr. Gallo's Restrictive Conditions on Provision of the H9 cell line

(a) Factual background: Shortly after publication of the Popovic Science paper, in May 1984, numerous scientists contacted the LTCB, seeking to obtain both Gallo's infected cell line (H9/HTLV-IIIB) and the uninfected cell line (H9). The uninfected cell line was particularly important, because it allegedly was a "new" cell line that was uniquely permissive for growth of the AIDS virus. Gallo's fellow scientists wanted to use the H9 cell line to attempt to grow their own AIDS virus isolates, to produce those isolates in quantity, and to initiate the numerous, varied experiments that were the obvious "next steps" in AIDS research, most of which required the existence of substantial quantities of HIV.

The evidence will show that despite clear standards in the scientific community that reagents should be freely distributed to responsible scientists, Dr. Gallo (1) refused outright to

provide the uninfected H9 cell line to some researchers; (2) delayed providing the cell line for substantial periods of time for some scientists, while other scientists were promptly provided the reagents; (3) imposed restrictive conditions on the cell line to virtually all to whom he supplied it, with particularly onerous conditions for scientists not in his favor; and (4) otherwise gave preferential treatment to scientists whom he favored.

Gallo's personal role in these actions is clear. The evidence will show that Dr. Gallo regularly reviewed the correspondence of individuals requesting reagents and cell lines, instructing Drs. Ann Sliski or Howard Streicher how to deal with each request. Furthermore, Dr. Gallo developed the transfer agreements that were used when the cell line was provided (Exhibit H-151), personally individualizing the conditions for various scientists, to make them more or less restrictive, depending on the relationship of the requestor to Gallo and the LTCB. Gallo also authored correspondence that extended the restrictions he placed on the cell line for some scientists, and outright denied the cell line to others.

(1) Favoritism in distributing the reagents: The basic transfer agreement for receipt of either the infected or uninfected cell lines, developed at the LTCB, contained five conditions. Most of these were standard conditions related to safety and patent considerations. However, one of the conditions was decidedly non-standard: "Work performed will be on a

collaborative basis with Dr. Gallo and his laboratory unless stated otherwise." Particularly favored scientists were not required to sign a transfer form (e.g., D. Zagury); other favored scientists had their transfer form annotated by Gallo himself (e.g., Dr. R. Weiss' form was annotated, "Collaboration at will for Dr. Weiss O.K. R. Gallo").

Further evidence of Gallo's favoritism in distributing his valuable reagents is seen in letters written by Dr. Gallo to several of his close associates, prior to publication of the May 1984 Science papers, offering them both the infected and uninfected cell lines, while other scientists who requested these reagents were turned down cold or received no response at all. Similarly, while most requestors of Gallo's infected cell line were told they would have to arrange to pick up the cell line in person, because the FDA would not allow the LTCB to transport it, several scientists had special arrangements made for them through the LTCB, permitting them to obtain the cell line from nearby colleagues who had received it earlier. In addition, although the basic transfer agreement required recipients of the infected cell line to agree that "Use of the line or virus produced from it will be in P3 containment," for certain of Gallo's collaborators who did not have P3, this condition was modified to specify that "P2" would suffice.

A comparison of Exhibits H-65, H-76, H-77, H-78, H-79, H-80 and H-110, responses to Dr. Gallo's friends, with Exhibits H-70,

H-73, H-75, H-100, H-109 and H-114 shows contemporaneous[38] contradictory responses to requests for the same reagents. The evidence clearly shows that contrary to accepted practices, Dr. Gallo provided reagents to his friends with little or no restrictions while imposing onerous restrictions on others. ORI will prove that Dr. Gallo admitted to OSI that he did not provide the uninfected cell line to certain qualified investigators because he first wanted to see what would grow in

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[38] Compare Exhibit H-65 (Gallo providing H4 and HT/HTLV-III to Zagury on 4/13/84, with the only restriction that it be used for research purposes) with Exhibit H-70 (letter to Pereira from Gallo of 4/23/84 in which Gallo states that, before he can distribute the cell lines, he must have the papers published and get other assurances). Compare also Exhibit H-73 (request for probes which Gallo denied on 5/10/84, ostensibly because the LTCB was still characterizing them (Exhibit H-85)) and Exhibit H-75, (request by Murphy of 5/3/84 for HTLV-III, HT and H4/HTLV-III), with agreements of 5/3/84 sent to friends, Exhibits H-76, H-77, H-78 (Bolognesi), H-79 (Haynes), H-80 (Essex) (five point restriction agreement). Dr. Weiss signed the agreement on May 13, 1984. He received H9, H9/HTLV-IIIB, H4, H4/HTLV-IIIA and the terms of the agreement were altered so that it was collaboration at will between Dr. Gallo and Dr. Weiss, and the P3 facility requirement was modified to include an equivalent. Exhibit H-87. Almost simultaneously, Dr. George Miller, M.D., from Yale was told that he personally had to come pick up the HT cell line. Other individuals were told that the "control cell line was not available" and that they would need to pick up the infected cell line. Exhibit H-88. Some requesters were told that all who had received the infected cell line had picked it up in person. Exhibit H-100. Compare also Exhibit H-109 (Dr. Gallo refused to provide the HTLV-III clones to Dr. McDougall on 7/3/84) with Exhibit H-110 (Dr. Gallo offers to permit a colleague to get the cells from a nearby institution) and Exhibit H-114 (Dr. Gallo's refusal to provide the uninfected cell line, claiming that it needed to be further characterized and stating that FDA restrictions prohibited mailing of the virus and that an in-person pick-up would be necessary).

it.[39] A comparison of Exhibits discussed above shows the disparate treatment that Dr. Gallo gave to requests for the cell lines and reagents.

(2) Refusal/delay in providing reagents: Gallo's treatment of certain of his PHS colleagues was particularly outrageous. For example, ORI will present evidence showing that on May 14, 1984, Dr. Malcolm Martin, a laboratory chief at the National Institute On Allergy and Infectious Diseases, NIH, requested the uninfected cell line from Dr. Gallo. Exhibit H-89. Although Dr. Gallo's practice was to review the requests on an almost daily basis, Dr. Gallo did not respond to this request until June 22, 1984. Dr. Gallo refused Dr. Martin's request, stating that it (the uninfected cell line) was "still being characterized." Exhibit H-102. Dr. Gallo also demanded to know what Dr. Martin intended to do with the uninfected cell line; Dr. Gallo explicitly stated that he did not want Dr. Martin to attempt to grow LAV in the cell line. Exhibit H-102.

Dr. Gallo said he would send Dr. Martin the infected cell line, and he sent to Dr. Martin a transfer agreement specially designed for him. Besides the five conditions in the basic agreement, the agreement sent to Dr. Martin contained two additional, particularly outrageous conditions:

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[39] Testimony of Dr. Suzanne Hadley.