

A selection of HIV documents

Unearthed by US Governmental Investigations into the scientific work of Dr. Robert Gallo.

A. In this Gallo explains why HIV (here called HTLV) is 'extremely rare' in the AIDS patients. This is dated 1 day before he sent his papers claiming HIV causes AIDS for publication in *Science*.

Building 37, Room 6A01
(301) 496-6807

March 29, 1984

Jun Minowada, M.D.
Staff Physician
Edward J. Minos, Jr. Veterans
Administration Hospital, and
Professor of Pathology and Surgery
Loyola Univ. Stritch School of Med.
Mines, Illinois 60141

Dear Jun,

In answer to your letter of March 9, I would like to address some of the points you made. First, there is no evidence that the situation with HTLV is similar to EBV. On the contrary, the epidemiological evidence shows a close association between disease and HTLV infection. EBV is ubiquitous. Second, I don't understand why there is a problem with one virus causing "clonal inducer T-cell malignancies" and immunosuppressive disorders. In the cat system it's been accepted for years (at least 10) that FeLV more often induces an immunosuppressive state than leukemia. The age of initial infection, route of exposure and whether there is repeat exposure are all apparent factors in the disease outcome of FeLV infection. If the T4 cells are the target of HTLV and this infection abrogates their function (as shown by M. Popovic, B. Dupont, A. Fauci and myself), then I can easily see that infection could lead to immunosuppression. Third, I'm not surprised that you have not found p19 expression on fresh cells of "AIDS" patients. It's extremely rare to find fresh cells expressing the virus. As in the bovine system, cell culture seems to be necessary to induce virus. This is probably due to removal of inhibiting factors present in the patient. The antigens p24 and p19 are almost always detected simultaneously. Finally, we know now there are many variants of HTLV-1. We believe the cause of AIDS is a more highly cytopathic variant.

Sincerely yours,

Robert C. Gallo, M.D.

ANS:tas

B. Letter from Dr. Gonda, the Head of Electron Microscopy at the NIH, to Popovic, copied to Gallo. He reports that images wanted for the *Science* papers, do not contain HIV (HTLVIII) as Gallo had claimed, but only cellular rubbish. This was received only 3 days before Gallo sent in the *Science* papers for publication. When the papers appeared in print, they still contained photos credited to Gonda, with Gallo saying they contain HIV.

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P.O. Box 8, Frederick, Maryland 21701

MAR 27 REC

March 26, 1984

Dr. Mika Popovic
Laboratory of Tumor Cell Biology
NIH
Building 37, Room 0922
Bethesda, MD 20205

Dear Mika:

I am sending you 4 extra copies of results requested by Betsy Read. She said Dr. Gallo wanted these micrographs for publication because they contained HTLV particles. If this assumption is based on the cultures being antigen positive, I would like to point out that the "particles" in micrograph 0905 are in debris of a degenerated cell. No other extracellular "virus-like particles" were observed free between cells anywhere in the pellet. The small extracellular vesicles in 0904 are at least 50% smaller than HTLV mature particles seen in type I, II, or III. Again, these vesicles can be found in any cell pellet. I do not believe any of the particles photographed are HTLV I, II, or III.

Best regards,

Matthew A. Gonda, Ph.D.
Head, Electron Microscopy Laboratory

MAG:jah

Enclosures

cc: *Dr.* Gallo
Betsy Read



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C. The first and the most important of the four *Science* Papers said to prove HIV the cause of AIDS. This is the typed draft produced by the Lead Author M. Popovic, with all the handwritten editing and comments made by R. Gallo just 7 days before the manuscript went in for publication. (The cover page unfortunately has faded.)

Science - First draft

Popovic



RESCUE AND CONTINUOUS PRODUCTION
OF HUMAN T-CELL LYMPHOTROPIC RETROVIRUS (HTLV-III)
FROM PATIENTS WITH AIDS

— WAY TO deal w/ this
LAV - originally

- ① Lack of cross hybridization: I, II
- ② " " Ag, " reaction
- ③ Relationships to CIA
- ④ unpublished Sealing

When the
hell are the
Sealing

ABSTRACT

A ~~permissive~~ ^{permissive} human neoplastic T-cell population is described for ~~cytopathic variants of human T-cell lymphotropic retroviruses (HTLV-III) isolated from pre-AIDS or AIDS patients.~~ ^{cytopathic variants of} The infected T-cell population preserves the capacity for permanent in vitro growth, ~~and~~ ^{and} exhibits continuous virus expression ~~and is suitable for isolation of cytopathic variants of HTLV from patients with lymphoproliferative (pre-AIDS) and AIDS.~~ ^{and is suitable for isolation of cytopathic variants of HTLV from patients with lymphoproliferative (pre-AIDS) and AIDS.} ~~Production of virus in high amounts enables us to prepare specific viral probes for immunological and nucleic acid studies.~~ ^{Production of virus in high amounts enables us to prepare specific viral probes for immunological and nucleic acid studies.} ~~The cytopathic effect of HTLV-III infection on the population is characterized by induction of multi-nucleated giant cells which can be used as an indicator for the detection of this virus.~~ ^{The cytopathic effect of HTLV-III infection on the population is characterized by induction of multi-nucleated giant cells which can be used as an indicator for the detection of this virus.}

This abstract is rather trivial for our journal. ~~It is a~~ speculative breakthrough paper for Science.

A family of human T-cell lymphotropic retroviruses (HTLV) comprises two major and well characterized subgroups of human retroviruses, called HTLV-I () and HTLV-II (), and recently a new variant of HTLV has been isolated from a patient with lymphadenopathy named also as lymphadenopathy associated virus (LAV) () which is described here as HTLV-III. The most common isolate obtained from patients with mature T-cell malignancies is HTLV-I (). Seroepidemiological and nucleic acid hybridization data indicate that HTLV-I, including the new subtype, is etiologically associated with T-cell leukemia/lymphoma of adults (). The disease clusters in the south of Japan (), the Caribbean (), Africa () and can be found in other parts of the world. HTLV of subgroup II (HTLV-II) was first isolated from a patient with a hairy cell form of a T-cell variant of hairy cell leukemia (). To date, this virus represents the only isolate obtained from a patient with neoplastic disease. However, isolation of retroviruses and seroepidemiological data suggest that HTLV of both subgroups, including non-variants from subgroup-II, may be involved in the pathogenesis of the acquired immune deficiency syndrome (AIDS) (). Here we report seroepidemiologic data for HTLV in patients with AIDS. Epidemiologic data strongly suggest that AIDS is caused by an infectious agent which is transmitted by intimate contacts or blood products (). To date, over 3000 cases of AIDS have been reported in the U.S. (). Patients with the disease include mainly homosexuals (), intravenous drug users (), Haitian immigrants to the U.S. (), and hemophiliacs (). Recently, an increased number of AIDS cases have been reported in children whose parents have AIDS or intimate contact(s) with a person having the disease (). Although the disease in patients is

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 10/29/81
 100/100

and: have local infection for detailed characterization

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 p-25:
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 which
 in call
 HTLV-II*

manifested by opportunistic infections, predominantly Pneumocystis carinii pneumonia and Kaposi's sarcoma, the underlying disorder affects the patient's cell-mediated immunity (). The T-cell dysfunction is often marked by an absence of delayed hypersensitivity, absolute lymphopenia and reduced helper T-lymphocyte (OKT4+) subpopulation(s). ~~There is a~~ reverse ratio of helper to suppressor T-lymphocytes (OKT4+/OKT8+). Poor lymphocyte responsiveness to antigens () in some cases, a decreased ~~cytotoxic cell activity~~ ~~of the~~

Despite intensive research efforts, the causative agent of AIDS has not yet been identified. Although patients with AIDS are often chronically

infected with cytomegalovirus (), or hepatitis B virus (), we have proposed that a ~~retrovirus~~ ²⁰ causing AIDS be a member from a family of HTLV. This assumption, besides being a well-known precedence of causing immune deficiency in cats (feline leukemia virus ()) is based on the facts that retroviruses of the HTLV family are characterized by T-cell tropicity, preferentially infect "helper" T-cells (OKT4+); exhibit cytopathic effects on various human and mammalian cells as demonstrated by syncytia induction (); and the infection of T-cells results in an ~~inhibition~~ ^{(5) attack on} of asymptomatic T-cell function. In some cases may result in a selective cell killing (). ~~Human~~ ^{antibodies} serological studies showed that the presence of antibodies directed to cell membrane antigens of HTLV infected cells is from 30-40% of patients with AIDS (). In addition, over 20 HTLV isolates of both subgroups and new variants were obtained from patients with AIDS (). The successful detection and isolation of HTLV was made possible by the discovery of TCRF which enabled selective ~~to~~ ^{to} grow different subsets of normal and

(4) may have
(5) attack on
antibodies
selective
highly T-8p

end to the development of ^{and in} structural assays for ^{reverse transcriptase} ~~reverse transcriptase~~

neoplastic mature T-cells () The viral rescue and transmission of

HTLV into permissive cells followed a well established procedure (1981)

^{first} worked out, in the system of avian sarcoma virus transformed mammalian cells

(). The cocultivation procedure using cord blood T-cells from newborns as recipient cells for ^{HTLV} ~~HTLV~~ ^{isolation of HTLV} ~~isolation of HTLV~~ enabled preferential ^{to obtain} ~~to obtain~~

HTLV variants with immortalizing (transforming) capability () HTLV

variants which possess "weak" or lack the immortalizing properties for

normal T-cells ~~from peripheral blood~~ and exhibit

mainly cytopathic effect on them ^{may be more important in vivo} ~~can only be detected transiently using~~

^{the novel T-} cells as targets in cocultivation or cell-free transmission experiments.

This ~~was the~~ ^{was the} main obstacle for more frequent isolation and

particularly for detailed biological, immunological and nucleic acid char-

acterization of cytopathic variants of HTLV. To overcome these obstacles,

^{we have} performed an extensive survey for a cell population which would be

highly susceptible to and permissive for cytopathic variants of HTLV and

^{could preserve} capacity for permanent growth after infection with the

virus. We report here the establishment and characterization of an immort-

alized T-cell population which is susceptible to and permissive for HTLV

cytopathic variants and can be used for their rescue and continuous pro-

duction of these ^{from patients} ~~variants~~ ^{with} ~~with~~ ^{AIDS and/or AIDS} ~~with~~

Several ^{in vitro} established permanent cell lines originated from

human malignancies were ^{initially} assayed for susceptibility to infection with ^{HTLV} ~~HTLV~~

(antigen) ^{has been} used in the first series of experiments. Two cell

lines with characteristics of mature T-cells ^{show} ~~show~~ susceptibility to

^{with all types of HTLV} ~~with all types of HTLV~~ infection as determined by reverse transcriptase (RT) assays,

and will be used to study the role of HTLV in AIDS and other diseases.

AIDS is not such a virus's which frequently infected for only

MYKA You are CRAZY

was in the problems

One of them, however, was positive for hemophilic particles, the second one isolated from a patient with AIDS. The first one was negative for HIV infections as well as no viral particles were found by an extensive electron microscope examination. The ~~isolated~~ parental cell line by HTLV-III ~~was~~ *same patient* for particulate reverse transcriptase activity in culture fluids, and about 20% of the infected cell population was positive in indirect immune fluorescent assay (IFA) using serum from a hemophilic patient (E.T.) with lymphadenopathy. The serum of the patient (E.T.) inhibited ~~particulate~~ *reverse transcriptase*, disrupted HTLV-III and reacted with p61 of HTLV transformed human T-cells in the precipitation assays.

mixed name on cell line

one was selected for study after initial studies showed that it was negative for HIV or for any other viral particles by electron microscopy. When it was cultured, the clones were positive for HTLV-III. Comparison of HTLV-III in the clones with the clones of HTLV-III in the patient's blood. The clones were positive for HTLV-III. The clones were positive for HTLV-III. The clones were positive for HTLV-III.

... susceptible and highly permissive T-cell population for HTLV-III. In spite of the ~~extensive cloning~~ *extensive cloning*, we were able to preserve the permanent growth and continuous virus production. ~~the~~ *the* extensive cloning of the parental T-cell population was performed. A total of 51 single-cell clones were obtained by both capillary ~~()~~ *()* and limited dilution ~~()~~ *()* techniques. ~~the clones were~~ *the clones were* ~~assayed for~~ *assayed for* proliferation capacity of ~~the~~ *the* HTLV-III infection.

A representative example of a response to the virus infection of B T-cell clones which are susceptible to and permissive for HTLV-III is shown in Table 1. In parallel experiments, 2×10^5 cells of each T-cell clone were exposed to 0.1 ml of concentrated virus ~~containing~~ *containing* 10^5 cpm of reverse transcriptase (RT) activity. Then the cell growth, morphology, positivity of cells for the viral antigen(s), and RT activity in culture fluids were assessed after 6 and 14 days of infection. Although all B clones were susceptible to and permissive for the virus, ~~the~~ *the*

the two clones of the susceptible patient were also positive with this patient and the patient of HTLV-III suggest common B cell envelope determinants common in HTLV-I, II, & III.

Redundant

~~in the presence of viral antigen(s) and RT activity in culture fluids.~~
 there were considerable differences ^{on each in day} between infected clones in capability
 to proliferate after infection. ^{Within} ~~the~~ ¹⁰⁻¹⁵ days of infection ^{to increase from}
 cytopathic effect was manifested by ~~the~~ ¹⁰⁻¹⁵ days of infection ^{10,000} of the
 initial cell number and ~~the~~ ¹⁰⁻¹⁵ days of infection a high proportion of multinucleated
 (giant) cells were consistently found in all 8 infected clones. The per-
 centage of T-cells positive for viral antigen(s) ^{detected by immunofluorescent assay} in ^{from A.7.05 infected (G-T.)} ~~the~~ ⁱⁿ ~~the~~ ^{with the previous}
 serum ^(100%) and hyperimmune rabbit serum raised against the whole dis-
 rupted virus ^{was in the range from 10% to over 80%.} After 14 days of infec-
 tion, total cell number ~~was~~ ^{and the proportion of} ~~the~~ ^{HTLV-III} positive cells ~~was~~
~~increased~~ ^{increased} in all 8 clones. The highest proliferation ^{was}
~~found~~ ^{found} in clone W/4, W/6; ~~and~~ ^{the} ~~lowest~~ ^{lowest} was in clone W/3. The virus
 positive cultures exhibited consistently round giant cells which ^{in Wright-}
 Giemsa staining revealed ~~a~~ ^{contained numerous} ~~large~~ ^{multinucleated} ~~nuclei~~ ^{These multinucleated giant} (Fig. 1a). Electron
 microscopic examinations of the infected cultures showed ~~an~~ ^{an} abundant number
 of ~~free~~ ^{released} ~~particles~~ ^{considerable amounts of virus} (Fig. 1b).

To determine whether HTLV-III is continuously produced by the infected
 T-cells in long term cultures, both ~~the~~ ^{the} virus production and cell viability
 of the ~~HTLV-III~~ ^{HTLV-III} infected clone W/4 were followed for several months. As shown
 in Figure 2a, there was a fluctuation in the amount of virus production,
 however, culture fluids harvested from the W/4/HTLV-III cell cultures at
 approximately 14 day intervals consistently exhibited particulate RT
 activity which ~~has~~ ^{has} been followed for ~~several~~ ^{several} months. Immediately
 the viability of the cells ~~was~~ ^{was} in the range from 55-85% and the doubling time
 of ~~the~~ ^{the} W/4/HTLV-III cell culture was approximately 36-48 hours (data not
 shown) ~~after~~ ^{after} ~~3~~ ³ weeks of infection. Thus, the data clearly indicate ^{that}

giant
 cells, con-
 similar
 to those
 observed
 by
 HTLV-III
 and
 HTLV-III
 except
 that
 can
 nuclei
 exhibit
 a
 distinctive
 ring
 formation.

can continuously produce ~~the~~ ^{that can} permanently growing T-cell population in long term culture.

The yield of the virus produced by H4/HTLV-III cells was assessed by purification of concentrated culture fluids through a sucrose density gradient and particulate RT activity was assayed in each fraction collected from the gradient. As shown in Figure 2b, similar to

other retroviruses, the highest RT activity was found at density 1.16g/ml. Electron microscopic (EM) examinations of aliquots from the fractions with highest RT activity revealed that the banded virus particles were

highly purified. An approximate estimation of the number of viral particles determined by EM and RT activity suggests

that the yield from the culture is about 10^{11} particles per ml of culture fluid.

These data clearly indicate that the established T-cell clones are susceptible to and highly permissive for cytopathic variants of HTLV-III, and all of them preserved proliferation capacity after infection; and

as demonstrated in the case of H4/HTLV-III clones, that some of them can proliferate and continuously produce a large amount of HTLV-III in long term culture.

We have used two clones, H/4 and H/9, for the rescue of cytopathic variants of HTLV from patients with lymphadenopathy (pre-AIDS) or AIDS.

As shown in Table 1, cocultivation of HTLV-III isolates with H/4 and H/9 cells were effective for virus rescue. HTLV-III isolates have been successfully obtained from 4 patients and 1 patient by cocultivation of T-cell clones (H/4 and H/9) as target cells. In all five cases, the virus released into culture fluids was found by RT assay and extracellular virus particles were detected in cases of H/4

more than additional nucleic acid detection of HTLV-III have been obtained in our laboratory.

~~with the use of~~
~~method~~
 all ~~these detected by other techniques will now be adopted~~
~~to~~ ~~the~~ ~~cell clone to~~ ~~generate~~ ~~positive~~ ~~isolated~~ ~~medium~~
~~isolated~~ ~~in~~ ~~the~~ ~~laboratory~~ ~~and~~ ~~it~~ ~~is~~ ~~not~~ ~~clear~~ ~~if~~ ~~it~~ ~~is~~ ~~an~~ ~~HTLV~~ ~~III~~ ~~clone~~
~~the~~ ~~positive~~ ~~clone~~ ~~reacted~~ ~~with~~ ~~acetonified~~ ~~cells~~ ~~and~~
 and ~~the~~ ~~positivity~~ ~~was~~ ~~detected~~ ~~by~~ ~~ELISA~~ ~~method~~ ~~of~~ ~~1983~~. ~~the~~ ~~data~~ ~~indicate~~ ~~that~~
 the T-cell clones are suitable for HTLV-III rescue either by cocultivation
 or by cell-free infection. The transient expression of cytopathic variants
 of HTLV in cells from AIDS patients and ~~the~~ ~~presence~~ ~~back~~ ~~of~~ ~~a~~
 system which would be susceptible to and permissive for the virus repre-
 sented a major obstacle in detection, isolation, and elucidation of the
 agent of this disease. The establishment of a T-cell population which
 after virus infection can continuously grow and produce virus, ~~is~~ ~~the~~ ~~key~~
 the possibility for detailed biological, immunological and molecular
 studies of this agent. ~~has~~ ~~been~~ ~~proposed~~ ~~could~~ ~~be~~ ~~used~~ ~~to~~ ~~investigate~~ ~~the~~ ~~way~~ ~~to~~ ~~maintain~~ ~~the~~ ~~high~~ ~~level~~ ~~of~~ ~~HTLV~~ ~~III~~ ~~in~~ ~~AIDS~~ ~~patients~~

for
all cases
where
this has
already been
done - the
system is
HTLV and HIV
clone

CONCLUSION NOT COMPLETED

REFERENCES NOT DONE
(per Mike)

cytopathic
 cytopathogenic variants
 detection of the high
 level of HTLV in
 AIDS
 and provides
 the first
 opportunity
 for a detailed
 molecular
 immunological
 analysis
 also ~~is~~ ~~an~~ ~~important~~

lowest - here at end

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 extraordinarily 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*.

920820 5

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

RESEARCH INTEGRITY ADJUDICATIONS PANEL

_____)
In the matter of:)
) Board Docket No. A-91-91
Robert C. Gallo, M.D.)
_____)

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 6, 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,¹ ORI would respectfully show as follows:

I. INTRODUCTION

¹ 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*:¹

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.

¹ "Detection, Isolation, and Continuous Production of Cytopathic Retroviruses (HTLV-III) from patients with AIDS and Pre-AIDS," Popovic, M; Sarnadharan, 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.³ These are summarized below:

Allegation A1.⁴ In April - May 1983, Dr. Gallo inappropriately inserted changes into a paper written by scientists at the Pasteur Institute (the "Barré-Sinoussi paper.")⁵ The paper had been forwarded to Dr. Gallo for his assistance in having it accepted for publication by Science. Exhibit H-6. 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

³ These allegations were raised publicly in an article in the Chicago Tribune by John Crawford, "The Great AIDS Quest- A Special Report" (November 19, 1989 (Exhibit H-177)).

⁴ These findings are identified with the number and letter assigned by the Board in its Preliminary Determination.

⁵ 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 8, *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 A3. 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.

ORI 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.¹⁴ 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.

¹⁴ 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 M. 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.