Appendix II
The Birth of Antibodies Equal Infection

The following timeline, and its accompanying commentary, was composed by Rodney Richards, a former Amgen employee who worked with Abbott Laboratories on the development of the ELISA HIV test. It lays out the historical events leading to the CDC declaring that persons who test positive for antibodies to HIV are also infected with HIV. Note that "human T-lymphotropic virus type III," "HTLV-III," "lymphadenopathy-associated virus," "LAV," and "HIV" are synonymous. Also, other than "*Pneumocystis carinii,*" all italicized words in the selected quotes below represent Richards' emphasis.

APRIL 1984: DHHS announces the probable cause of AIDS has been found.

MAY 4, 1984: Gallo and colleagues publish four back-to-back articles in the journal *Science*. One of these papers reports on the "isolation" of virus from 36% (23/64) of AIDS patients investigated, and from 86% (18/21) of pre-AIDS patients investigated. (Gallo RC, et al. *Science* 1984; 224: 500-03.)

Comment: Assuming for a moment that the criteria used to declare "isolation" of HIV in these studies were valid, it is important to note that nearly two-thirds (64%) of the AIDS patients evaluated in this study had no evidence of infection with HIV whatsoever. In spite of this observation, the authors contend this provides "strong evidence of a causative involvement of the virus in AIDS." This is remarkable, because prior to the publication of these articles, scientist were reluctant to suggest a causative role for a germ even if it were found in 100% of patients with a particular illness. Here, a 36% correlation is held out as "strong evidence" of causality; strong enough for the Department of Health and Human Services to announce to the global media that the probable cause of AIDS had been found.

JULY 13, 1984: The CDC comments on the significance of antibody tests as follows (CDC. "Antibodies to a retrovirus etiologically associated with acquired immunodeficiency syndrome (AIDS) in populations with increased incidences of the syndrome." *MMWR* July 13, 1984; 33: 377-79):

"For some, the result may be a false positive caused by infection with an antigenically related virus or nonspecific test factors. The determination of the frequency and cause of falsely positive tests is essential for proper interpretation of test results, but remains to be established, particularly in populations, such as blood donors who belong to no known AIDS risk groups, where the prevalence of true infection with HTLV-III/LAV is expected to be very low."

Regarding the significance of antibodies in those at risk: "A positive test for most individuals in populations at greater risk of acquiring AIDS will probably mean that the individual *has been* infected at some time with HTLV-III/LAV. *Whether the person is currently infected or immune is not known*, based on the serologic test alone..."

And regarding the notion that antibodies equal infection; "...*the frequency of virus in antibody-positive persons is yet to be determined.*"

JANUARY 11, 1985: The CDC comments on the pending FDA approval of Abbott Laboratories ELISA for screening the blood supply (CDC. "Provisional public health services inter-agency recommendations for screening donated blood and plasma for antibody to the virus causing acquired immunodeficiency syndrome." *MMWR* January 11, 1985; 34: 1-5):

"Tests to detect antibody to HTLV-III will be licensed and commercially available in the United States in the near future to screen blood and plasma for laboratory evidence of infection with the virus."

"Persons accepted as donors should be informed that their blood or plasma will be tested for HTLV-III antibody. Persons not wishing to have their blood or plasma tested must refrain from donation. Donors should be told that they will be notified if their test is positive and that they may be placed on the collection facility's donor deferral list..."

"When the ELISA is used to screen populations in whom the prevalence of HTLV-III infection is low, *the proportion of positive results that are falsely positive will be high*. Therefore, the ELISA should be repeated on all seropositive specimens before the donor is notified."

"If the repeat ELISA test is positive or if other tests are positive, it is the responsibility of the collection facility to ensure that the donor is notified." Regarding the significance of a repeatedly positive ELISA: "At present, *the proportion of these seropositive donors who have been infected with HTLV-III is not known*. It is, therefore, important to emphasize to the donor that the positive result is a preliminary finding that may not represent true infection. To determine the significance of a positive test, the donor should be referred to a physician for evaluation."

And even if infected: "*The prognosis for an individual infected with HTLV-III over the long term is not known.*"

MARCH 2, 1985: The FDA approves Abbott's ELISA for blood screening. Among other things, the package insert for this product emphasizes:

"At present there is no recognized standard for establishing the presence or absence of HIV-1 *antibody* in human blood." And: "The risk of an asymptomatic person with a repeatably reactive serum sample developing AIDS or an AIDS-related condition is *not known*."

AUGUST 9, 1985: The CDC reports on the use of ELISA for screening blood, and hints at the possible use of antibody tests for diagnosing infection (CDC. "Update: Public Health Service Workshop on Human T-Lymphotropic Virus Type III Antibody Testing – United States." *MMWR* August 9, 1985; 34: 477-8.)

"The Atlanta Region of the American Red Cross (ARC) and CDC reported data from testing more than 51,000 blood donors, of whom 0.23% were repeatedly reactive by the Abbott EIA method. Among the specimens from 106 blood donors with repeatedly reactive tests, thirty-four (32%) were strongly reactive.... EIA tests categorized as strongly reactive correlated highly with both positive Western blot tests (94%) and culture for HTLV-III/lymphadenopathy-associated virus (LAV) (56%)."

In other words, 44% of blood donors found to be strongly positive for antibodies to HIV had no evidence of virus by culture.

[Note, the full results or this study–along with the notion that antibodies can be used to diagnose infection–would come to be published in July of 1986. See below.]

Regarding high risk individuals: "...virus isolations were attempted from homosexual men attending a clinic for sexually transmitted diseases in San Francisco, California. None of seventy men with negative HTLV-III antibody tests had a positive culture, while forty-three (60%) of seventy-two with repeatedly reactive tests were culture positive."

Or stated conversely, 40% of confirmed antibody positive high-risk individuals had no evidence of virus by culture.

MARCH 14, 1986: The CDC says antibody positive individuals should be *presumed* to be infected (CDC. "Additional recommendations to reduce sexual and drug abuse-related transmission of human T-lymphotropic virus type III/lymphadenopathy-associated virus." *MMWR* March 14, 1986; 35: 152-5).

"Since a large proportion of seropositive asymptomatic persons have been shown to be viremic (5), all seropositive individuals, whether symptomatic or not, must be *presumed* capable of transmitting this infection."

Remarkably, the reference (5) used to justify this statement is the January 11, 1985 CDC publication referred to above which states among other things:

"At present, the proportion of these seropositive donors who have been infected with HTLV-III is not known."

MAY 23, 1986: The CDC again hints that antibody positive individuals should be considered to be infected (CDC. "Current trends classification system for Human T-lymphotropic virus type III/lymphadenopathy-associated virus infections." *MMWR* May 23, 1986; 35(20): 334-9).

"*For public health purposes*, patients with repeatedly reactive screening tests for HTLV-III/LAV *antibody* (e.g., enzyme-linked immunosorbent assay) in whom *antibody* is also identified by the use of supplemental tests (e.g., Western blot, immunofluorescence assay) *should be considered both infected and infective* (8-10)."

References 8-10 are to: 8) The July 13, 1984 CDC report that states, "...*the frequency of virus in antibody-positive persons is yet to be determined*;" 9) The August 9, 1985 CDC report, which makes no mention of whether or not antibody tests should be used to declare infection; and 10) the March 14, 1986 CDC report, which references the January 11, 1985 report that states, "*the proportion of these seropositive donors who have been infected with HTLV-III is not known.*"

Comment: It is important to note that up to this point, study after study has demonstrated that a large proportion of patients considered positive by antibody testing had no evidence of virus by culture (and this further presupposes that the criteria used to call a culture positive for HIV is valid in the first place). So why on earth would the CDC tells us that all such patients should be *considered*, or *presumed* to be infected? Well, it is important to note the distinction, "*for public health purposes*," in the above quote. In other words, what is the proper thing to do with antibody test results if we want to keep the hypothetical HIV from spreading (i.e., further infecting the general public)? Well, given that there may be, lets say a 50-60% chance that persons with positive antibody tests are also "infected" (i.e., they would score positive on culture if it could be done), you have to consider, or presume, all of them to be infected (i.e., sacrifice the individual for the well being of the public).

JULY 18, 1986: Researchers from the CDC publish an article in the *Journal of the American Medical Association (JAMA)*, which *defines* antibodies as equal to infection (Ward JW, et al. "Laboratory and epidemiologic evalustion of an enzyme immunoassay for antibodies to HTLV-III." *JAMA* July 18, 1986; 256: 357-61).

This study is a final report of the data collected on blood donors in Atlanta, which the CDC reported on in their August 9, 1985 report.

Regarding "isolation" of virus from blood donors found to be positive for antibodies (i.e., positive on ELISA and WB), the authors report: "23 (63.9%) of the 36 Western blot-positive specimens cultured for HTLV-III/LAV were positive..."

In other words, no evidence of virus could be found in 36% of "confirmed" antibody positive blood donors.

Regarding the notion of using antibody tests for diagnosing infection, the authors emphasize: "Evaluation of a new test requires an established or known standard for comparison. At this point, however, *no established standard exists for identifying HTLV-III infection in asymptomatic people.*"

How can that be? Citing Gallo's work (*Science* 1984; 224: 500-03), they emphasize, "Current culture methods for HTLV-III identify virus in only 36% to 85% of persons with AIDS or related conditions and *cannot* be used as an absolute standard for HTLV-III/LAV infection."

Comment: The reason these researchers assert that culture *cannot* be used as an absolute standard for the detection of HIV is because it is not telling them what they want to hear. They want 100% of persons with AIDS or related conditions to test positive on culture—a necessary (but not sufficient) requirement to declare a possible causative role between HIV and AIDS. So somehow, they already know HIV is the cause of AIDS, and since culture does not score positive on 100% of these patients, there must be something wrong with the culture.

The authors go on: "For this reason, we *defined* specimens positive on Western blot or culture as positive for infection with HTLV-III/LAV."

In other words, for those samples that don't behave properly (i.e., positive for antibodies, but negative on culture), one must simply *define* them as positive. [Note, five of the six authors on this paper worked at the CDC. Clearly, the CDC is pushing the notion that antibodies equal infection.]

MARCH 19, 1987: FDA approves AZT (Retrovir) for "management of certain adult patients with symptomatic HIV *infection* (AIDS and advanced ARC) who have a history of cytologically confirmed *Pneumocystis carinii* pneumonia (PCP) or an absolute CD4 (T4 helper/inducer) lymphocyte count of less than 200/mm^3 in the peripheral blood before therapy is begun."

APRIL 30, 1987: FDA approves Western blot "for screening blood and for validating an initial screening of donated blood for *antibodies* to the virus that causes AIDS, acquired immunodeficiency syndrome." "Robert E. Windom, MD, HHS assistant secretary for health, emphasized that individuals with antibody-positive Western blot results should be referred for medical

evaluation, which may include additional testing. *The significance of antibodies in an asymptomatic individual* [blood donor] *is not known*" (Susan Cruzan. *FDA News* 4/30/1987; P87-11).

According to the manufacturer of this test (Biotech Research Laboratories, Inc. of Rockville, Md. Marketed by Du Pont de Nemours and Company of Wilmington, Del.), "a Positive result *may* indicate infection with HIV-1." According to the manufacturer of another Western blot, "A sample that is reactive in both the EIA [i.e., ELISA] screening test and the Western blot is *presumed* to be positive for *antibody* to HIV-1." (Epitope, Inc. U.S. License #1133.)

So what you do here is first *presume* that samples reactive on ELISA and WB are positive for *antibodies*, and since the CDC says so (well, they are going to say so on August 14, 1987; see below), you get to further *presume* that persons with antibodies are infected. Logically, then, all persons reactive on ELISA and WB should likewise be *presumed* to be infected (i.e., If A = B, and B = C, then A = C; with the exception that in the above equation, there are NO equal signs).

JULY 23, 1987: Researchers/Burroughs Welcome Corporation publish the results of their clinical trial demonstrating "AZT administration can decrease mortality and the frequency of opportunistic infections in a selected group of subjects with AIDS or AIDS-related complex, at least over the 8 to 24 weeks of observation in this study." (*N Engl J Med* July 23, 1987; 317: 185-91).

AUGUST 14, 1987: Without reference to any scientific study, or any previous report from the CDC, the CDC announces: "*The presence of antibody indicates current infection*, though many infected persons may have minimal or no clinical evidence of disease for years." (CDC. "Perspectives in disease prevention and health promotion public health service guidelines for counseling and antibody testing to prevent HIV infection and AIDS." *MMWR* August 14, 1987; 36(31): 509-15.) Gone is "presumed," "considered," "for public health purposes," etc. Gone is any distinction between "blood donors" and "high risk;" between "asymptomatic" and "symptomatic."

It is important to note that the designated mission of the CDC is public disease surveillance, education, and prevention. Here they are implicitly setting standards

for medical practice. More precisely, they are establishing standards for medical practice without any scientific justification. Why the FDA (our consumer protection agency) choose to completely ignore this blatant violation of medical ethics remains an enigma. This is particularly the case when only four months earlier, the FDA warned, "*The significance of antibodies in an asymptomatic individual is not known*" (Susan Cruzan. *FDA News* 4/30/1987; P87-11). Without doubt, August 14, 1987 will ultimately come to be known as the day modern science came to an end.