

For retroviruses such as HIV, however:

"...the presence of antibody (in the serum) indicates that the infection is ongoing and most likely permanent. I know of no person who has ever been cured naturally of HIV disease. Persons with antibody are not only actively infected, they are capable of transmitting the agent. We didn't have this information in 1984 and 1985. Hence, in a way, the danger of the HIV-antibody positive person, the danger that person posed to the blood supply, was the subject of keen debate, because we didn't have the answer. What we had was an antibody assay. The other answers came three years later."<sup>29</sup>

Although there was uncertainty about the meaning of a positive blood test for HIV antibodies, it was decided that HIV-positive persons should not donate blood. The central questions in this issue are whether antibody testing was instituted as quickly as it could have been, given the state of technology and expertise at the time; and whether the decision-making process within the blood system in Canada at the time caused, or contributed to, an avoidable delay in the instituting of testing.<sup>30</sup>

In dealing with these important questions, the Sub-Committee has had to recognize that they form the substance of some of the court cases that are now taking place, or will soon take place, in a number of provinces. It is necessary, then, that we approach these questions with an appropriate degree of circumspection and care. While we have had the benefit of considerable testimony in this area, and the expression of many opinions, the issue will only be resolved completely—if, in fact, resolution is possible—after all of the available and relevant documentation of the Canadian Red Cross, the Canadian Blood Committee, and the Department of Health and Welfare, among others, has been carefully reviewed. With that caution in mind, we have examined the chronology of events, and we discuss the main points below.

As noted above, a laboratory HIV-antibody assay had been developed, and the details published in a recognized journal, in May 1984. This was not, however, a commercial system suitable for use in testing very large numbers of units of donated blood. Until well into 1985, according to Dr. Michael O'Shaughnessy, the only location in Canada able to carry out an HIV-antibody test was at the Laboratory Centre for Disease Control (LCDC) in Ottawa. From mid-1984 to late-1985, Dr. O'Shaughnessy's laboratory tested some 25,000 blood samples.<sup>31</sup>

During this period, however, rapid progress was being made in the development of a commercial test kit suitable for testing large numbers of blood donations. In February 1985, the first commercial test for screening blood for HIV antibodies was approved for marketing by the Australian government. On 2 March 1985, the United States Food and Drug Administration (FDA) approved the first commercial test for screening donated blood in that country. On March 7th, Canada's National Advisory Committee on AIDS (NAC-AIDS) recommended that the Red Cross prepare a plan for the implementation of HIV screening of donated blood. On 1 April 1985, the first ELISA screening test kit for AIDS-virus antibodies in blood went on sale in Canada; a second test went on sale on April 18th.<sup>32</sup>

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<sup>29</sup> *Ibid.*

<sup>30</sup> A chronology of events in the HIV-infected blood issue is presented in Appendix B. Items from this chronology will be cited as parts of the various discussions throughout the body of this Report.

<sup>31</sup> Dr. Michael O'Shaughnessy, Proceedings, Issue 23, 11 March 1993, p. 7.

<sup>32</sup> See Appendix B, Chronology of Events. The ELISA test, the third generation of which is now used to screen blood for HIV antibodies, is named for the technology that the test embodies: ELISA stands for "Enzyme-Linked Immunosorbent Assay".