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Tragedy and Challenge:
Canada's Blood System and HIV

REPORT OF THE STANDING COMMITTEE ON HEALTH AND WELFARE, SOCIAL AFFAIRS, SENIORS AND THE STATUS OF WOMEN

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CHAIR

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SUB-COMMITTEE ON HEALTH ISSUES

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CHAMBRE DES COMMUNES

Fascicule nº 19

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Issue No. 19

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Minutes of Proceedings and Evidence of the Standing Committee on

Health and Welfare, Social Affairs, Seniors and the Status of Women

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CONCERNANT:

Étude du troisième rapport du Sous-comité sur les questions de santé

Y COMPRIS:

Sixième rapport à la Chambre: Le sang contaminé par le VIH et d'autres questions connexes

RESPECTING:

Consideration of the Third Report of the Sub-Committee on Health Issues

INCLUDING:

Sixth report to the House: HIV infected blood and other related matters

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The Standing Committee on Health and Welfare, Social Affairs, Seniors and the Status of Women has the honour to present its

SIXTH REPORT

In accordance with its mandate under Standing Order 108(1), your Committee established a Sub-Committee and assigned it the responsibility of examining the subject of HIV-infected blood and other related matters.

The Sub-Committee submitted its Third Report to the Committee.

Your Committee adopted the following Report which reads as follows:

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HIV-INFECTED BLOOD

INTRODUCTION

The complex illness that has become known as acquired immunodeficiency syndrome or AIDS was first reported in the United States by the Centers for Disease Control in June 1981. The first cases were recognized because of unusual clusterings of diseases such as *Pneumocystis carinii* pneumonia (PCP) and Kaposi's sarcoma (KS), a rare type of cancer. The first case of AIDS in Canada was reported approximately seven months later, in February 1982. However, retrospective studies have revealed that cases of AIDS occurred in Africa, Europe and North America in the 1970s.

The virus that is believed by most medical scientists to cause AIDS, the human immunodeficiency virus or HIV, has been found to have had a much longer history in humans than was originally believed. Although the early history of this virus remains obscure, there exist individual case reports of apparent HIV infection dating from the 1960s,[1] and the first documented infection with HIV-1, based on detection of antibodies, occurred in 1959.[2] The major continuous spread of HIV, in North America and elsewhere, appears to have begun in the mid-to late-1970s.

When the first cases of AIDS were described in the United States and Canada, the cause of the syndrome was unknown. The fact that the ailment was first identified in specific population groups, notably young homosexual/bisexual men with multiple sex partners, and intravenous (IV) drug abusers, led to much speculation about the cause of the disease, including the possibility that the disease might be associated with certain lifestyles, rather than an infectious agent. The possibility that AIDS could be transmitted through blood was not immediately recognized.

By July 1982, however, three hemophiliacs were discovered to have developed AIDS, and the possibility that the disease could be transmitted through blood or blood products began to be understood. In November of the same year, three persons were reported by the United States Centers for Disease Control to have developed AIDS following blood transfusions and it was fully appreciated that exposure to blood could transmit this disease.[3]

Since that time, and most acutely over the past year, the linkage between HIV/AIDS and infected blood has become very widely appreciated by the affected individuals, groups and institutions in this country, and also by the general public. And with good reason. The contamination of blood and blood products in Canada, and elsewhere, is truly a medical and social

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1 Jonathan M. Mann and Seth L. Welles, "Global Aspects of the HIV Epidemic", In, Vincent T. DeVita, Samuel Hellman and Steven A. Rosenberg (Eds.), *AIDS—Etiology, Diagnosis, Treatment and Prevention*, Third Edition, J.B. Lippincott Company, 1992, (hereafter, DeVita et. al.), p.89.

2 Myron Essex, "Origin of AIDS", In, DeVita et. al., 1992, p. 5. Two variants of HIV have been identified. HIV-1 is the variant associated with most cases of AIDS in North America and Europe. HIV-2 is more typically found in West Africa.

3 Dr. Norbert Gilmore, Minutes of Proceedings and Evidence of the Sub-Committee on Health Issues of the House of Commons Standing Committee on Health and Welfare, Social Affairs, Seniors and the Status of Women (hereafter, Proceedings), Issue 20, 11 February 1993, p. 23.

tragedy. Between 1980 and 1987, approximately 800 hemophiliacs—mostly Hemophilia A patients requiring Factor VIII concentrate—became infected with HIV,[4] as did 261 non-hemophiliacs who received blood transfusions contaminated with the AIDS virus.[5]

The Sub-Committee's study of this issue has developed along two lines of concern. First, we wanted to determine, if possible, those events and factors that led to the infection of more than 1,000 Canadians by HIV from contaminated blood and blood products during the 1980s. Second, we were seeking assurance that the Canadian blood supply today is as safe as it can reasonably be made and, moreover, that the system that is in place can respond effectively and with dispatch to any future crisis along the lines of the AIDS disaster of a decade ago.

This report will deal with the issue of HIV-infected blood under a number of headings which reflect the major points of concern and contention. Many questions have been raised about the screening of donated blood in Canada, and elsewhere, and the rapidity with which blood testing was instituted in this country in comparison with that in other countries, notably the United States. The matter of Factor VIII coagulation products, and the change from non-heat-treated products to heat-treated, will constitute another point of discussion. Connected with this point is the issue of a Canadian facility for producing the various blood fractions, including coagulation Factors VIII and IX which are needed for medical treatment.

The organization of Canada's blood system of today, compared to the system that existed in the mid-1980s, was the subject of considerable comment and a large amount of concern. The blood system is in some ways unique among health-care programs in Canada in that it is an essentially national system under the jurisdiction of the provinces and the territories, which provide all of the government funding. The federal government's active role currently is limited to that of regulator in that blood, blood products, and blood-testing kits fall under the jurisdiction of the federal *Food and Drugs Act.*

Two other important areas of concern have also been brought to the Sub-Committee's attention. First, there is the question of compensation for those persons who became infected with HIV through the blood system. The federal government instituted its Emergency Assistance Plan (EAP) in 1989. The provinces and territories to this point, with the recent exception of Nova Scotia, have not offered compensation to infected persons or their families; neither has the Canadian Red Cross Society. Partly as a consequence, there are a number of civil actions under way in provincial courts as the affected persons and their families seek redress of their grievances.

The final area of concern to the Sub-Committee is the matter of an inquiry into the Canadian blood system, past and present. Most of the witnesses who appeared before us recommended that an inquiry of some kind should be held, although the individual reasons for requesting an inquiry were varied. Moreover, there was a lack of unanimity as to the type of inquiry that should be held. The spokespersons variously recommended a "judicial inquiry", a "public inquiry", or a "public review" into the blood system. Clearly, the term "inquiry" means different things to different people, and the Sub-Committee has dealt with this complex question in a separate section of this Report.

The testimony on which this Report is based is to be found in Issues Nos. 17-27 of the Sub-Committee on Health Issues of the Third Session of the Thirty-fourth Parliament.

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4 David Page, Canadian Hemophilia Society, Proceedings, Issue 18, 3 December 1992, p. 18.

5 John R. McDonald, Gerald M. Devins and Man Chiu Poon, *Canadians HIV Positive Secondary To Blood Transfusion*, Final Report, Health and Welfare Canada, National Health Research and Development Program, Project # 6609—1694—AIDS, 1992, p. 13. (The total of 261 persons represents the number identified by 31 October 1992.)

THE CANADIAN BLOOD SYSTEM

Every single day in Canada a person requires a blood transfusion . . . one every 20 seconds . . . there are still hundreds of thousands of people in a year who require blood transfusions and hundreds of thousands who require blood products that come from volunteer blood donations in Canada.

George Weber
Canadian Red Cross Society[6]

The Canadian blood system is an essential part of Canada's health-care system and there are few individuals or families in this country that are not touched in some way by the ongoing requirement for blood and blood products of high quality and assured safety. Just as blood is a complex health resource requiring careful and intelligent management, the Canadian blood system itself is equally complex, its structure and management fairly reflecting the political and social realities that make up this country.

The Canadian blood system is strongly identified with the Red Cross, more correctly the Canadian Red Cross Society or CRCS. The system includes a number of other players as well, each of whom has an essential role to play. Over the past ten years, and more particularly over the past year, the HIV/AIDS tragedy of the early- and mid-1980s has brought the nature and operations of Canada's blood system under scrutiny. Serious concerns have been raised about the safety and security of our blood supply.

While the principal focus of this Report appropriately is on the events that led up to the HIV/AIDS disaster, our discussion must be framed in an understanding of how the blood system operated ten years ago, how it is operating now, and what are some of the implications for the future.

In the early 1980s, when the AIDS epidemic was in its early stages, the Canadian blood system had three major stakeholders. The Canadian Red Cross Society, then as now, was the operational arm of the system. There were two major components of the Red Cross system: Blood Donor Recruitment (BDR) and the Blood Transfusion Service (BTS). The main task of BDR was to recruit donors into the Red Cross system to donate blood or plasma. Once the donor walked into a clinic, however, he/she became the responsibility of the BTS which took the donation and guided that unit of blood, plasma, or blood product through the system to its ultimate destination.

The Canadian Red Cross collection and distribution system is national in terms of organization and operation, and is carried out through 17 regional centres which follow national procedures, guidelines and policies. The regional centres report to the National Director, Blood Services of the Canadian Red Cross Society. Blood centres currently exist in all provinces but their scope is regional, and the centres operate without regard for provincial boundaries. Blood and blood products are freely exchanged between provinces; distribution, therefore, is on a national basis.

A second major player in the system in the early 1980s was the Canadian Blood Committee or CBC. This Committee has been described and discussed in many of the media reports on the HIV/AIDS tragedy, and by some witnesses, as an impediment to rapid decision-making in the face of a growing crisis. It is important, therefore, that the origins, structure and role of the CBC be understood by the readers of this Report.

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6 George Weber, Canadian Red Cross Society, Proceedings, Issue 17, 26 November 1992, p. 28.

The Canadian Blood Committee had its origin in 1974 when the Federal-Provincial Programme and Budget Review Committee was established by the Conference of Deputy Ministers of Health. That Committee included two provincial representatives and "acted as an agent for the provinces, with the objective of reviewing the budget from a national perspective so as to avoid the many difficulties that arose in the past from having proposals from ten different jurisdictions".[7]

A major step in the creation of the CBC was made in the Summer of 1981 when an Ad Hoc Committee on a Canadian Authority on Blood Policy was struck. Its report was presented to the Conference of Ministers of Health in September/October 1981. At that time also, four principles for the Canadian blood system were enunciated, as follows:

- To protect the voluntary donor system in Canada by enhancing the opportunities of Canadians to voluntarily donate a gift for society's general benefit and by responsibly managing that resource;
- To ensure self-sufficiency of blood products by reducing Canada's dependence on foreign sources of blood product supply, particularly those that rely on purchased plasma for raw material;
- To ensure gratuity of blood products by reinforcing the Canadian tradition whereby no payment is made for a donation of blood and/or plasma and no specific charge is made to recipients of blood and blood products;
- That a Canadian non-profit policy be maintained and that any charge to recover more than the real cost of producing a blood fractionation product for Canadians in Canada should be considered profit.[8]

A major recommendation in the Ad Hoc Committee's report was that the "Health Ministers agree to establish the Canadian Blood Authority with the mandate to direct the Canadian blood collection, processing and distribution system. . ."[9] This recommendation was endorsed by the Ministers of Health at that meeting. The "Canadian Blood Authority" was subsequently renamed the Canadian Blood Committee. The Committee was established with thirteen members representing the federal, provincial, and territorial Ministers of Health, and it reported to the Conference of Ministers of Health. The mandate of the CBC was "to direct the Canadian blood system in accordance with the four principles adopted by the Ministers of Health" at the Interprovincial Conference in September/October 1981.[10]

The CBC first met on 3 December 1981 and draft Terms of Reference were prepared. These Terms of Reference were approved at the second meeting of the Committee in February 1982 (see Appendix A). In 1983, the members of the CBC agreed to set up a Committee Secretariat within

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7 The Canadian Red Cross Society, *The Canadian Red Cross Blood Programme From 1974 to 1990—A Report to the Canadian Hematology Society*, (hereafter, *CRCS Report*), Ottawa, 1990, p. 4.

8 *CRCS Report*, 1990, p. 23.

9 *CRCS Report*, 1990, p. 24.

10 *Ibid*.

Health and Welfare Canada. The Secretariat was headed by an Executive Director who was an employee of the federal Health Department, and it was staffed by officials of the Department who were administratively responsible to the Assistant Deputy Minister of the Health Services and Promotion Branch.[11]

A perusal of the Terms of Reference of the CBC (Appendix A) shows that the Committee was responsible for establishing policies in all aspects of the blood system; for assuring adherence to policies by the operational side of the system, including the Canadian Red Cross; for consulting with relevant federal departments, including the Bureau of Biologics at Health and Welfare Canada; and for reviewing and approving "the programs and budgets of Blood Donor Recruitment and Blood Transfusion Services of the Canadian Red Cross Society, *subject to the concurrence of all provinces and territories*. (Emphasis added)" It follows, therefore, that any major new budget item would have had to be approved by all of the provinces and territories before the CBC could give its approval. As will be seen later in this Report, this approval process had an impact on decision-making when new funding was required in 1985 for the implementation of an HIV-antibody test by the Canadian Red Cross.

A new entity, the Canadian Blood Agency (CBA), has been created to replace the Canadian Blood Committee. The CBA was incorporated in May 1991 and commenced operations on October 1 of the same year, when an Executive Director was appointed. The corporate object, or mission, of the Agency is: "To direct, coordinate and finance the various elements of the Canadian blood system requiring national direction in accordance with the principles established by the Ministers of Health for the therapeutic use of human blood, blood products or their substitutes."[12]

The mandate of the CBA is based on seven principles which have been established for the Canadian blood system. These principles are as follows:

- The voluntary donor system should be maintained and protected.
- National self-sufficiency in blood and plasma collections should be encouraged.
- Adequacy and security of supply of all needed blood, components and plasma fractions for Canadians should be encouraged.
- Safety of all blood components and plasma fractions should be paramount.
- Gratuity of all blood, components and plasma fractions to recipients within the insured health services of Canada should be maintained.
- A cost-effective and cost-efficient blood system for Canadians should be encouraged.
- A national blood system should be maintained.[13]

Implicit in these principles is the reality that, although Canada has a national blood system, we are not self-sufficient in plasma collections, or in blood products. Canada does not have a blood-fractionation facility at the present time, and a decision is pending on a Canadian Red Cross proposal, among others, to construct such a facility in this country.[14]

The Canadian Blood Agency is a federally-incorporated non-profit corporation, but the members of its Board of Directors are all representatives from the Assistant Deputy Minister level of the provinces and territories. The federal government is not represented on the Board of Directors

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11 Dr. Denise Leclerc, Proceedings, Issue 22, 25 February 1993, p. 5.

12 Canadian Blood Agency, *Implementation Proposal for The Deputy Ministers of Health*, June 1990.

13 *Ibid.*

14 Canadian Red Cross Society, personal communication, 16 April 1993.

and, in fact, the federal government, by choice, is not directly involved in the operations of the Agency.[15] The federal government's involvement with the CBA, through Health and Welfare Canada, has been described as two-fold; providing information on products used in the blood system, and exchange of scientific information on topics of mutual interest.[16]

The Agency's effective mandate is similar to that of the former Canadian Blood Committee, but the CBA's corporate structure gives it a greater degree of effective autonomy from the component governments. It has also been stated that, in a crisis, the Agency could respond more quickly and effectively than could the CBC, if for example, contingency funding were needed to finance a new blood-screening test. William Dobson, the Executive Director of the Canadian Blood Agency, made the following statement to the Sub-Committee:

> "I have a signing level at the bank for $3.5 million. We don't use that line of credit for financing our regular activities, but it is available. What I've indicated is that if a consensus were emerging that there was a serious safety risk—and you have to remember that we have immediate access to expert opinion from our scientific advisory committee and others — I would have no hesitation [in] signing for $3.5 million to get this thing funded."[17]

The existence of a line of credit is a clear improvement over the previous system of funding decisions being made through consensus meetings involving all the member governments. However, the system is still based on a consensus approach to decision-making. We shall return to this point later in our Report.

The federal government, although not directly involved in the administrative or operational structure of the Canadian blood system, plays a number of essential roles in the overall process. In addition to the two functions described above, the federal authority is brought to bear on the system through the regulation of blood and blood products, and of testing kits used to ensure blood safety. Blood products have been regulated under the *Food and Drugs Act* since these products were first developed. The first Factor VIII coagulation product, for example, was licensed for sale in Canada in 1968. In December 1989 blood itself was classified as a drug and placed on Schedule D to the *Act*, bringing it, like blood products, under the regulatory purview of the Bureau of Biologics.[18]

The Department also regulates diagnostic and blood-screening test kits for ensuring blood safety. At the present time, this function is carried out under the Medical Devices Regulations. The Department is in the process of transferring the regulation of test kits to Schedule D of the *Act,* where the kits will be regulated in the same manner, and with the same stringency, as drugs of biological origin. This change in regulatory status will introduce "lot-release procedures and specific inspection and licensing of manufacturing facilities as elements of the regulatory process."[19]

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15 Janice Hopkins, Health and Welfare Canada, Proceedings, Issue 25, 25 March 1993, p. 9.

16 Dr. D.W. Boucher, Bureau of Biologics, Proceedings, Issue 25, 25 March 1993, p. 7.

17 William Dobson, Canadian Blood Agency, Proceedings, Issue 19, 4 February 1993, p. 14.

18 Janice Hopkins, Health and Welfare Canada, Proceedings, Issue 25, 25 March 1993, p. 4.

19 *Ibid*, p. 5.

In addition to the three major actors in the Canadian blood system, there are a number of players who perform specialized functions or represent specific interest groups. The Canadian Hemophilia Society is an important national organization that represents the interests of Canada's hemophilia community, described as "one of the largest consumers of blood and blood products" in Canada, and the group most severely affected by the HIV/AIDS epidemic.[20]

Canada's hospitals and physicians also have important roles to play in the blood system:

> "The hospitals have a clear role in interim storage [of blood and blood products], in preparing individual products for individual patients, and the surveillance of adverse effects. However, this must be limited to the time when the patient is in the hospital. We cannot readily carry out surveillance of patients who were discharged from the hospital two or three months ago.
>
> "The physicians are responsible for the decision to prescribe products. They are responsible for the clinical administration, and they are responsible to some extent for the evaluation of the effects."[21]

The Canadian Council for Health Facilities Accreditation is responsible for the accreditation of hospitals, and included in their criteria are those relating to the surveillance and operation of blood banks and blood-transfusion services in hospitals. Canadian medical schools, the Royal College of Physicians, and the various national societies—such as the Canadian Hematology Society and the Canadian Society for Transfusion Medicine—concern themselves with education and research, functions that are basic to a modern and progressive health-care system.[22]

BLOOD SCREENING FOR HIV ANTIBODIES

Given the level of scientific knowledge and medical technology available at the time, I think we moved with as much haste as possible to get testing in place.

George Weber
Canadian Red Cross Society[23]

Why did the Red Cross wait until May 1985 to propose its plan for implementing testing? Why did the Canadian Blood Committee, faced with a crisis, take three months to approve funding for the proposal?

Lindee David
Canadian Hemophilia Society[24]

The screening of donated blood for infectious agents is a principal line of defence in ensuring the safety of a nation's blood supply. The institution of testing of blood donations for antibodies of the AIDS virus, HIV, by the Canadian Red Cross is one of the most controversial issues that the

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20 Lindee David, Canadian Hemophilia Society, Proceedings, Issue 18, 3 December 1992, p. 16.

21 Dr. Peter Pinkerton, Canadian Hematology Society, Proceedings, Issue 26, 1 April 1993, p. 12.

22 *Ibid.*, pp. 12-13.

23 George Weber, Canadian Red Cross Society, Proceedings, Issue 17, 26 November 1992, p. 39.

24 Lindee David, Canadian Hemophilia Society, Proceedings, Issue 18, 3 December 1992, p. 23.

Sub-Committee has had to consider. It is also a very complex matter in terms of the uncertainties that shrouded the AIDS issue in the early and mid-1980s, and in terms of the technologies involved in testing blood for HIV antibodies.

It is sobering to consider the fact that the HIV/AIDS tragedy, as bad as it was and is, could have been a great deal worse, had the virus appeared ten or twenty years earlier. By the late 1970s, however:

> ". . .the whole biotechnology scene was at a level where this could be dealt with relatively promptly. It's astonishing that an agent that we didn't know existed in 1982 was isolated by 1984 and the specific tests for it were in place by 1985."[25]

Historically, the Canadian blood supply has been subjected to tests for infectious agents since 1940 when a test for syphilis first was instituted. In 1972, a test for the hepatitis B virus (HBV) was adopted, based on a "rather crude" test for the surface antigen of the virus. The original test for hepatitis B virus was superseded by a much more sensitive and specific test in about 1976.[26]

It is important to note that HIV is very different from most viruses that health authorities had to deal with prior to 1981, when AIDS was first described. For one thing, although there was strong indication by mid-1982 that AIDS could be transmitted through blood, a virus later identified as HIV was not discovered until 1983 when Luc Montagnier and his associates at the Pasteur Institute in Paris isolated a virus which they named the "lymphadenopathy-associated virus", or LAV. A year later, in the United States, Robert Gallo and his co-workers also isolated a virus which they named the "human T-lymphotropic retrovirus-III", generally known as HTLV-III. Eventually, the two isolates were shown to be identical and to represent a new group of retroviruses. This new virus was named the human immunodeficiency virus, or HIV, in 1986.

In May 1984, a paper was published in the journal *Science* which described the detection of antibodies to HTLV-III in the serum of patients with AIDS.[27] Clearly, this was an important development in AIDS research, with significant implications for AIDS-prevention strategies, particularly respecting the safety of the blood supply. However, the ability to detect AIDS-virus antibodies in blood serum, while holding the promise for mass-testing of donated blood units to determine whether a donor had been exposed to the virus, raised important questions in the medical community:

> "In 1984 and 1985 there was the debate about the validity of the HIV (antibody) assay. We didn't know then, and it took us three years to find out, that the virus could be recovered from all persons with a positive antibody result. This virus represented a new class of human pathogens."[28]

For most viruses that cause human and animal diseases, the existence of antibodies in the blood serum indicates that infection has occurred, the body's immune system has responded in a positive way by forming antibodies to the pathogen, and the virus usually then disappears after the initial bout of disease. For common diseases such as influenza and measles, this is the normal course of events. For some other viral diseases, such as hepatitis B for example, this may not be the case: a small percentage of persons infected by the hepatitis B virus will remain chronically, although sub-clinically, infected and be capable of transmitting the virus for their lifetimes.

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25 Dr. Peter Pinkerton, Canadian Hematology Society, Proceedings, Issue 26, 1 April 1993, p. 17.

26 *Ibid.*, p. 8.

27 M.G. Sarngadharan, et al, "Antibodies reactive with human T-lymphotropic retroviruses (HTLV-III) in the serum of patients with AIDS", *Science* Vol. 224, 1984, p. 506-508.

28 Dr. Michael O'Shaughnessy, Proceedings, Issue 23, 11 March 1993, p. 8.

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."[29]

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.[30]

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.[31]

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.[32]

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29 *Ibid.*

30 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.

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

32 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".

The testimony received by the Sub-Committee indicates some disagreement over test-implementation dates outside Canada, but it seems clear that several countries had implemented testing by the spring of 1985. Health and Welfare Canada testified that the United States FDA had confirmed 99% implementation of blood screening by the end of March 1985.[33] In testimony to the Sub-Committee, Dr. Norbert Gilmore, former Chairman of NAC-AIDS, stated that blood screening for HIV antibodies was fully implemented in Australia in mid-April 1985;[34] however, an official of the Australian Department of Health has since stated that the Australian Red Cross instituted screening at all Blood Transfusion Services "in late April/early May 1985".[35]

Blood screening for HIV antibodies in Canada, on a national basis, lagged behind that in the United States and Australia. The chronology of events, taken from testimony to the Sub-Committee, is clear on that point. At a time when screening of blood was virtually complete in the United States and Australia, the Canadian Red Cross Society's implementation plan for screening was still working its way through Canada's blood system. On the first of May 1985, the Red Cross plan was submitted to the Canadian Blood Committee, NAC-AIDS, and Health and Welfare Canada, and it was indicated that the system could be fully operational in 12 weeks, after receipt of "administrative and funding approval". This suggested that an August 1st starting date was possible.[36]

The Canadian Blood Committee approved the Red Cross plan "in principle" on June 5 but final approval was withheld pending discussions with provincial authorities. These discussions, in the form of a Consensus Meeting of provincial and territorial representatives took place in Ottawa on 4 July 1985. According to Health and Welfare Canada's chronology of events of the time, the Consensus Meeting agreed that the Red Cross plan could be implemented on 14 October if the Canadian Blood Committee approved the budget by 12 July. All the members of the Canadian Blood Committee, except Ontario, approved the Red Cross plan on 17 July; Ontario's approval was given on August 1st.[37] The plan was fully implemented by the Red Cross approximately 12 weeks later, on November 1st, 1985. Some blood centres were doing tests by late summer or early fall, 1985.

The implementation of a blood-screening system is a difficult and complex process, as was made clear to the Sub-Committee by several witnesses. Dr. Peter Pinkerton, representing the Canadian Hematology Society, noted that:

> ". . .the introduction of testing cannot really be simply seen as dates on a calendar. A number of other considerations, I believe, must be borne in mind. I will try to list some of these. These are not offered as excuses. They are not even necessarily offered as reasons, but as factors that at the time appeared important and that, in retrospect, with the pure vision of hindsight, may seem inappropriate, irrelevant or minor impediments not expeditiously overcome."[38]

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33 Bureau of Biologics, Health and Welfare Canada, Record of Events, 24 March 1993, (hereafter, BOB, Record of Events) tabled with the Sub-Committee on 25 March 1993.

34 Dr. Norbert Gilmore, Proceedings, Issue 20, 11 February 1993, p. 24.

35 Letter from Dr. Lance Sanders, Department of Health, Housing and Community Services, Commonwealth of Australia, 4 March 1993.

36 See Appendix B, Chronology of Events.

37 BOB, Record of Events, 24 March 1993.

38 Dr. Peter Pinkerton, Canadian Hematology Society, Proceedings, Issue 26, 1 April 1993, p. 7.

First of all, there was the question of laboratory space appropriately fitted and equipped. Many of the provinces "had to build or significantly alter existing facilities to meet the safety requirements for handling this virus."[39] Infection by HIV is, after all, believed to be fatal. This fact raised concerns about the proper training and protection of staff who would be carrying out the tests of donated blood.

The availability of test kits is an issue that was raised several times during the public hearings. Although FDA approval of commercial kits in the United States occurred on March 2nd, 1985, the Sub-Committee has received no evidence on the commercial availability of kits, in Canada or internationally, when testing was being implemented in various countries. However, Health and Welfare Canada has stated that in June 1984, the United States Department of Commerce issued licences to five companies to begin production of HIV test kits. While this may indicate that production of the kits may have begun nine months prior to the granting of regulatory approval, the question of availability remains unanswered.

The availability of alternate testing sites was also important at the time. In 1985 there was a fear that knowledge of the fact that the Red Cross was testing donated blood for AIDS-virus antibodies would prompt high-risk persons to donate, simply to find out if they were antibody-positive. The problem was more serious and complex than its obvious logistical aspect:

> ". . .we had the concern represented by the alternative testing dilemma, which is that people were being asked to exclude themselves from donating blood if they had in any way been exposed to AIDS or in any way might be a carrier of it. If we suddenly made testing available, might not people then go in [just] to get tested? If the test was not perfect, we might actually increase the problem of infection rates in the blood supply."[40]

The ELISA test at the time was not perfect in that it produced a large number of false positives; it also produced false negatives, particularly when an infected person donated in the "window period", a span of time variously lasting weeks or months before antibodies to the virus showed up in the blood serum. In 1985, the window period was probably 16 weeks long between infection and antibody production. False negatives still occur, but the window period has been reduced to about 6 weeks.[41]

The real difficulties involved in implementing a national blood-screening system cannot be underestimated. Presumably, however, the Australian and United States authorities had to confront similar difficulties; yet, their systems were apparently up and running five or six months earlier than the Canadian system. It is unlikely that there was any significant knowledge gap between Canada and these two countries which can explain the delay. Scientific information on AIDS flowed freely across international borders at that time, as it does now. Furthermore, we have the testimony of Dr. O'Shaughnessy (then with Health and Welfare Canada) that he was working, with his colleagues, on the forefront of research in this area:

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39 Dr. Michael O'Shaughnessy, Proceedings, Issue 23, 11 March 1993, p. 8.

40 Dr. Norbert Gilmore, Proceedings, Issue 20, 11 February 1993, p. 33.

41 Dr. Michael O'Shaughnessy, Proceedings, Issue 23, 11 March 1993, p. 19.

> "In May 1984 I read the three papers in the publication *Science*, and I spoke with my bosses at Health and Welfare and gave them the opinion that in fact Gallo's paper seemed to represent the major breakthrough that we were all awaiting . . . I visited Gallo's lab in 1984 and I trained at the National Institutes of Health (in the United States)."[42]

Thus, in May 1984, the breakthrough which eventually would lead to a commercial test for HIV antibodies in blood had been made and that fact was widely known. The questions posed to the Sub-Committee by the Executive Director of the Canadian Hemophilia Society can be repeated here with increased relevance:

> "Why did the Red Cross wait until May 1985 to propose its plan for implementing testing? Why did the Canadian Blood Committee, faced with a crisis, take three months to approve funding for the proposal?"[43]

The Sub-Committee believes that these are important questions that should be answered. We are aware that our present study is being conducted almost ten years after the events transpired and that we have the advantage of hindsight. Information on AIDS at the time was tumbling in great profusion from clinics and laboratories into the offices of decision-makers in the public-health field. Clearly, it was a difficult time. A critical period in this story, for which complete information on events is still lacking, is the time between May 1984 and May 1985 when the Red Cross implementation plan for blood screening was submitted to the Canadian Blood Committee.

The testimony of Dr. Norbert Gilmore, Chairman of NAC-AIDS during the period under discussion, states that in August 1984, the Director of the Canadian Red Cross Blood Transfusion Service (CRC-BTS) "wrote to NAC-AIDS, asking that the Committee assist the CRC with its plans to implement donor screening in 1985."[44] NAC-AIDS responded by establishing, in October 1984, a "Task Force on AIDS-Associated Retrovirus Testing in Canada". In March 1985, according to Dr. Gilmore's testimony, the Task Force requested that the CRC develop an implementation plan for blood and plasma screening and submit a report to NAC-AIDS by 30 April 1985. The Task Force also asked the Canadian Blood Committee and Health and Welfare Canada, in association with the CRC, to determine the resources necessary for screening all donations.[45]

A number of questions come to mind in connection with these events, and we have listed these below.

We believe that it is important to know why an implementation plan for blood screening could not have been developed by the Red Cross in late 1984 or early 1985 for implementation as soon as commercial test kits became available. If there is a valid explanation for the apparent delay between August 1984 when the Red Cross wrote to NAC-AIDS about blood screening, and March 1985 when the Task Force requested the CRC to submit its implementation plan, that explanation should be made public by the Canadian Red Cross.

Even more perplexing to this Sub-Committee is the three-month period, between May 1 and August 1, 1985, that it took the Canadian Blood Committee to approve funding for the Red Cross screening plan. In a crisis situation, such as that which existed at the time, there should have been contingency funding available from governments, through the Canadian Blood Committee, to implement blood screening as soon as a plan had been developed by the principal agency involved, the Canadian Red Cross Blood Transfusion Service.

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42 Dr. Michael O'Shaughnessy, Proceedings, Issue 23, 11 March 1993, p. 4-5.

43 Lindee David, Canadian Hemophilia Society, Proceedings, Issue 18, 3 December 1992, p. 23.

44 Dr. Norbert Gilmore, Brief to the Sub-Committee, 11 February 1993, p. 4.

45 *Ibid.*

The Red Cross has stated to the Sub-Committee that it ". . .has no reason to believe that the implementation plan could not have been strictly adhered to if funding had been approved by the CBC. . .", although the Society has acknowledged that contingencies could have arisen to delay implementation. The principal contingencies identified by the Red Cross are the availability of commercial test kits at the time and the implementation of alternative test sites in the provinces.[46]

On May 1, 1985, the Red Cross submitted its implementation plan to the Canadian Blood Committee: the CBC responded on June 5 with "approval in principal" only. On 10 June, the CBC informed the Red Cross that final approval could not be given until other issues "beyond the Red Cross national blood program" were dealt with. These issues were discussed at a Consensus Meeting of provincial and territorial representatives in Ottawa on 4 July 1985. On 17 July, all of the provinces except Ontario approved the screening plan; Ontario's approval was given on August 1, 1985.

The Sub-Committee believes that a full disclosure of the events and discussions involving the major players in the Canadian blood system between May 1 and August 1, 1985 is essential. For example, what were the "other issues beyond the Red Cross national blood program" that had to be dealt with by the CBC before the implementation plan could be accepted? Why was a funding decision not made at the Consensus Meeting in Ottawa on July 4, 1985? What was the reason for the further two-week delay in approval by the Ontario government?

The availability of commercial test kits at the time also needs clarification. Information from the Canadian Red Cross suggests that the Chairman of NAC-AIDS advised the CRCS on June 4, 1985 that there would be ". . .a shortage of test kits for general, clinical, hospital or other diagnostic use (and) there would only be barely enough test kits available for Red Cross' blood donors screening by August or September. . ." This assessment was given at a meeting of the Canadian Blood Committee.[47] The minutes of that meeting, together with information on the availability of test kits, must be made public.

We shall revisit these important issues and questions later in this Report.

HEAT TREATMENT OF FACTOR VIII CONCENTRATE

Approximately 800 hemophiliacs were infected by HIV between 1980 and 1987. This represents about 40% of the total hemophiliac population. Among severe Factor VIII hemophiliacs the percentage is even higher—close to 75%.

David Page
Canadian Hemophilia Society[48]

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46 Canadian Red Cross Society, Supplementary Comment on HIV Test Implementation, 15 April 1993.

47 *Ibid.*

48 David Page, Canadian Hemophilia Society, Proceedings, Issue 18, 3 December 1992, p. 16.

Everything in my life is about going forward and has been since I've known I'm HIV-positive, and every time I'm forced to come back and deal with this, I really feel as if I'm going back. I'm angry about being forced to go backwards and I'm angry about being here today . . . I'm tired of things being unresolved for so many people . . . I want this finished.

Rick Waines
HIV-Positive Hemophiliac[49]

When three hemophiliacs in the United States were discovered to have developed AIDS in July of 1982, the possibility that the disease could be transmitted through blood or blood products was recognized. Since that time, the enormous tragedy that has struck the hemophilia community in Canada and elsewhere has become well known. Some 800 hemophiliacs in Canada, about 40% of the total hemophilia population, have become infected with HIV.[50] The chronological components of this tragedy are as complicated and controversial as those pertaining to the development and institution of blood screening by the Canadian Red Cross.

Hemophilia is an hereditary coagulation disorder which is sex-linked. This means that the defective genes which cause hemophilia are carried on a sex chromosome, in this case the X chromosome. Since females have two X chromosomes and males have one X and one Y chromosome, hemophilia affects only males. A woman with an X chromosome carrying a defective gene will not suffer from hemophilia because she will have a normal gene on the second X chromosome. The (male) Y chromosome does not carry complementary genes for production of coagulation factors, so all males with a defective X chromosome will have hemophilia.

All daughters of hemophiliacs will carry the defective gene inherited from their fathers. They will therefore be "carriers" of the disease, and each of their male offspring will have a 50% chance of inheriting the defective gene, and each daughter of a carrier will have a 50% chance of also being a carrier. The sons of hemophiliacs who only inherit the Y chromosome from the father will be neither hemophiliacs nor carriers of the father's hemophilia.[51]

There are two forms of hemophilia: hemophilia A is characterized by a deficiency of a clotting factor known as "Factor VIII"; hemophilia B affects persons deficient in "Factor IX". About 80% of hemophiliacs suffer from hemophilia A. The degree of clotting-factor deficiency can vary among hemophiliacs. The severest form of the disease occurs when the person has less than 1% of normal clotting-factor level; if the level is in the 5%-of-normal range, the individual is said to have mild hemophilia and usually will not suffer from the type of spontaneous bleeding that characterizes the severe form of the disease.[52]

The type of treatment required by hemophiliacs that is most strongly implicated in the tragedy of HIV-infection and AIDS is Factor VIII concentrate which is made from blood plasma. The Factor VIII concentrate is strongly implicated because concentrate is manufactured from pools of up to

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49 Rick Waines, Proceedings, Issue 18, 3 December 1992, p. 7.

50 David Page, Canadian Hemophilia Society, Proceedings, Issue 18, 3 December 1992, p. 18.

51 Certain hemorrhagic, or bleeding, disorders may affect persons of both sexes and require treatment with coagulation factors. One of these disorders is known as "von Willebrand's disease".

52 *THE MERCK MANUAL of Diagnosis and Therapy*, Sixteenth Edition, Rahway, N.J., 1992, p. 1218.

17,500 units of donated plasma each. Up to four pools could be combined to produce one lot of concentrate; therefore, there could be as many as 70,000 donated units per lot of concentrate. A single HIV-infected plasma unit was capable of contaminating the entire lot of concentrate.[53]

In the early 1980s, when there was no way to detect HIV infection among donors, the possibility that infected blood was entering the system was much higher than it is now. In 1985, for example, after donor self-exclusion programs were established and when testing of donated blood had been implemented, the detected HIV incidence in donors in Canada was about 17 per 100,000, compared to only 2.5 per 100,000 in 1992.[54] In the early 1980s, therefore, any lot of Factor VIII concentrate had a high probability of being infected by HIV.

The hemophiliacs most commonly affected by HIV infection and AIDS are the hemophilia A patients requiring Factor VIII concentrate to control their bleeding problems. In severe cases, the individual might be injecting Factor VIII concentrate several times per week. The probability of any individual having a contaminated supply of Factor VIII concentrate at the time was extremely high.

There are several interactive issues which make up the very complex situation regarding hemophiliacs and the contaminated Factor VIII story during the early-and mid-1980s. The most controversial part concerns the period between November 1984, when Health and Welfare Canada issued a directive for all coagulant products to be heat-treated to kill the AIDS virus, and July 1985, when heat-treated products fully replaced non-heat-treated product on the Canadian market. During the course of the Sub-Committee hearings, this approximate seven-month period was referred to as the "transition period".

Chronologically, the discussion can start in 1980 when a German company produced a Factor VIII product that was heat-treated to kill the hepatitis B virus. This demonstrated that Factor VIII could withstand heat treatment that would kill a virus. The product was accepted for use in Germany the same year.[55]

In August 1982, the Bureau of Biologics in Canada requested the Red Cross and the Canadian Hemophilia Society to increase surveillance of hemophilia patients for AIDS. As the chronology in Appendix B indicates, there was considerable activity by health authorities in the latter part of 1982 and the beginning of 1983, in both the United States and Canada, in regard to the possibility that hemophiliacs might be at risk of contracting AIDS through their use of blood products. At this stage, however, HIV had not been identified and there was no means of determining whether blood or blood products were contaminated.

On January 13 1983, a Joint Statement on AIDS and its possible relation to blood transfusion was issued by the American Association of Blood banks, the American Red Cross, and the Council of Community Blood Centers. The U.S. National Hemophilia Foundation, the American Blood Commission, and the National Gay Task Force assisted in developing this statement. Also in attendance at the meeting were the American Blood Resources Association, the Centers for Disease Control and the Food and Drug Administration.

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53 Canadian Red Cross Society, Personal Communication, 29 April 1993.

54 *Ibid.*

55 See Appendix B.

The Joint Statement acknowledged that there was a possibility that AIDS could be transmitted through blood but no agent had been isolated and there was no test for the disease or for potential carriers. Therefore, the evidence for transmission of AIDS by blood transfusion was still inconclusive at that time.[56]

By 1984, both Montagnier in France and Gallo in the United States had published reports on the isolation of putative AIDS viruses, and a blood test to detect virus antibodies was under development. In September of that year, the Canadian Hemophilia Society met with representatives of major suppliers of Factor VIII and raised concerns about the availability of heat-treated product in the United States (which supplied the Canadian market) and its apparent unavailability in Canada. There were concerns also that there was a general shortage of Factor VIII in Canada.

The general question of the supply of Factor VIII in Canada is a controversial issue by itself. Canada is not, and never has been, self-sufficient in Factor VIII. Even today, this country is not self-sufficient in blood plasma, the source of natural clotting factors: Canada's plasma resources approximate only about 75% of our current total requirements.[57] In 1976, the Canadian Red Cross submitted a proposal to the Minister of National Health and Welfare to build a Canadian plasma-fractionation facility "capable of providing all the therapeutic and diagnostic blood products (including clotting factors) required by Canadian hospitals".[58]The Red Cross proposal was not accepted, and a Canadian fractionation plant was never constructed.

In the early 1970s, Connaught Medical Research Laboratories had begun producing some blood fractions (but not clotting factors) for the Canadian market using outdated plasma supplied by the Red Cross. After 1978, Connaught began to produce Factors VIII and IX from fresh frozen plasma. The situation became more complicated after that. In September 1980, the Interprovincial Conference of Ministers of Health set up the Interprovincial Ad Hoc Committee on Plasma Fractionation, chaired by Chapin Key, Deputy Minister of Health for British Columbia, to find solutions for this issue. One of the recommendations of the Chapin Key Committee was for Connaught to expand its capacity to process annually up to 100,000 litres of Canadian plasma, following the non-profit principle that characterizes the Canadian blood system.

In June 1981, however, an Addendum to the 1980 Chapin Key Report was prepared recommending the establishment of three Canadian plasma fractionation plants, with the eventual distribution of Canadian plasma to the three plants to be as follows: 50% to Connaught Laboratories, and 25% each to the Winnipeg Rh Institute and Institut Armand-Frappier. The Winnipeg facility opened in October 1983 with a capacity to fractionate between 50,000 and 75,000 litres of plasma per year.[59] However, while the Rh Institute did produce a 5% albumin product, it never produced any coagulation factors. The Institut Armand Frappier facility was never built. Thus, only the Connaught facility ever successfully produced coagulation factors in Canada.[60]

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56 American Association of Blood Banks, American Red Cross, and Council of Community Blood Centers, *Joint Statement on Acquired Immune Deficiency Syndrome Related To Transfusion*, January 13, 1983. (Document supplied by Canadian Red Cross Society)

57 William Dobson, Canadian Blood Agency, Proceedings, Issue 19, 4 February 1993, p. 18.

58 CRCS Report, 1990, p. 37.

59 *Ibid.*, p. 39-40.

60 Canadian Red Cross Society, Personal Communication, 16 April 1993.

This issue is controversial because the Canadian Hemophilia Society has alleged that the failure to establish efficient Canadian fractionation facilities resulted in the wastage of large amounts of Canadian plasma and worsened the eventual impact of AIDS on Canadian hemophiliacs:

> "It was known at the time that [the Canadian] companies had no past record of providing high-quality, state-of-the-art blood products. Despite this knowledge, political pressures forced the Canadian Red Cross to cancel a contract with Cutter Laboratories in the U.S. in favour of Connaught Laboratories in Ontario at considerable additional cost to the taxpayer. In the end, Rh Institute and Armand-Frappier processed Canadian plasma but never produced a unit of usable factor VIII or IX concentrate.
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> "Connaught Laboratories was so inefficient that the equivalent of 200,000 volunteer blood donations was wasted between 1981 and 1984. This relatively safe Canadian-source plasma had to be replaced by American-source plasma that was long known to be a greater risk for viral contamination.[61] *This increased reliance on American-source plasma from which to manufacture blood products is the single most important cause of the high level of HIV infection among Canadian hemophiliacs.*" (Emphasis added)

This aspect of the overall fractionation issue is very important and the Sub-Committee believes that it bears directly on the question of how the decision-making process in Canada's blood system has been, and is, structured. If the supply of blood and blood products has been, or is, unduly influenced by regional rivalries, the overall safety of the system may be placed at risk.

By October 1984, evidence had been developed to show that the AIDS virus could be inactivated in Factor VIII concentrate through heat treatment. In November 1984, the Bureau of Biologics (BOB) licensed Cutter Laboratories in the United States to produce heat-treated Factor VIII for the Canadian market and also issued a directive for all Canadian coagulant products to be heat-treated as soon as possible. The BOB also recommended to the Red Cross that untreated products be replaced with heat-treated as soon as possible. On the 26th of November, 1984, the Canadian Red Cross advised Connaught Laboratories that all Canadian fresh frozen plasma would be sent to Cutter for heat treatment as of December 1st.

The questions which have arisen about events and actions during the "transition period" in 1984-1985, when both heat-treated and untreated coagulation products were on the market simultaneously, are very contentious and have caused consternation and animosity on the part of affected groups and individuals. A considerable amount of information pertinent to this issue has yet to be released, by the Canadian Red Cross and the companies involved, on the matter of inventories and availability of treated products at the time. We recognize that some of this information may be relevant to court cases and may not, therefore, be readily available.

However, some basic facts on this issue have been presented to the Sub-Committee. First, the switch-over from untreated coagulation products to heat-treated could not have been done immediately. Several witnesses stated that there was a minimum six-month period required to process new plasma once the decision was made to switch to heat-treated product.[62] Although, in retrospect, it may be a difficult concept to accept, the authorities—including the Canadian Red Cross, the Canadian Blood Committee, Health and Welfare Canada, and the Canadian Hemophilia Society—knew at the time that some of the untreated Factor VIII product remaining on the market was contaminated with the AIDS virus.

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61 David Page, Canadian Hemophilia Society, Proceedings, Issue 18, 3 December 1992, p. 20.

62 George Weber, Canadian Red Cross Society, Proceedings, Issue 17, 26 November 1992, p. 32.

The issue of the limited availability of heat-treated Factor VIII during the transition period is also controversial and the Sub-Committee has not received adequate information on this to resolve the controversy. The Canadian Hemophilia Society has testified that, in its opinion, the authorities in charge of the blood system did not act decisively or quickly enough to obtain heat-treated product for the Canadian market:

> "In October 1984, the National Hemophilia Foundation and the Centres for Disease Control in the U.S. recommended immediate switch-over to heat-treated products. Canadian Hemophilia Society representatives made four separate appeals during the month of October 1984 to the Canadian Red Cross and the Canadian Blood Committee to request the use of heat-treated products, even if this meant relying on American fractionators. Authorities resisted these recommendations despite the scientific evidence, and the Canadian Red Cross subsequently made spot purchases of non-heat-treated products."[63]

For its part, the Canadian Red Cross has testified that it attempted to obtain supplies of heat-treated coagulation products as quickly as possible at the time:

> "In November 1984, the Bureau of Biologics requested all manufacturers then licensed in Canada to start producing heat-treated Factor VIII for the Canadian market. At that time, the majority of plasma collected by the Canadian Red Cross was being processed by Connaught Laboratories. Some of it was already being processed down in the United States in a factory owned by Cutter Biologicals at the time. Just prior to that announcement by the Bureau of Biologics, Cutter Biologicals had their heat-treated process licensed in Canada. Unfortunately, Connaught at the time did not have a licensed heat-treated process. The Canadian Red Cross then moved plasma that was destined to go to Connaught, where it was in storage in preparation to be processed, down to the Cutter plant in North Carolina. We also notified Cutter that we wanted all product coming [to] Canada to be processed in this new heat-treated format.
>
> "Following that, there was the consensus conference [on 10 December 1984]. Shortly after that conference, we received approval from the CBC, the Canadian Blood Committee, to go out and buy heat-treated Factor VIII. We immediately placed orders at that time. Because of the long, six-month processing time, products didn't start coming into Canada until April [1985], even though we had switched to have it manufactured into the heat treatment back in November and had placed orders in December, as soon as we had approval from the government to go ahead and do so."[64]

As the regulator of blood products under the federal *Food and Drugs Act*, the Bureau of Biologics had the authority to demand that all untreated Factor VIII be removed from the Canadian market immediately, even though heat-treated replacement product was not available in sufficient quantity to meet the needs of the hemophiliac community. For hemophiliacs with severe Factor VIII deficiency, however, unavailability of product could have had serious, even fatal, consequences.

Dr. D. W. Boucher of the Bureau of Biologics, Health and Welfare Canada made the following statement to the Sub-Committee on this issue:

> "When we [the Bureau of Biologics] made our recommendation in November [1984] that there should only be heat-treated product on the Canadian market, we recognized the fact that it wasn't going to be available immediately. There was going to be a period when you were going to

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63 David Page, Canadian Hemophilia Society, Proceedings, Issue 18, 3 December 1993, p. 21.

64 Stephen Vick, Canadian Red Cross Society, Proceedings, Issue 17, 26 November 1992, p. 42.

have heat-treated and non-heat-treated [product] on the market at the same time. Then a decision had to be made. Who would get heat-treated and who would get non-heat-treated material?"[65]

This tragic dilemma was dealt with through a "Consensus Conference on Heat-Treated Factor VIII", convened by the Canadian Blood Committee and held in Ottawa on 10 December 1984. The purpose of the Conference was to discuss strategies for the phasing in of heat-treated product in compliance with the 16 November directive from the Bureau of Biologics.[66] All of the major stakeholders in the Canadian Blood System attended the Conference, including two representatives of the Canadian Hemophilia Society representing the community most affected by the situation.

The Conference endorsed the introduction of heat-treated coagulation products by May 1985, with full replacement of existing products by July 1985. The Conference made a total of nine recommendations, one of which stated, in part, that: "the criteria for the use of heat-treated and non-heat-treated concentrate during the transition period be agreed upon by the hemophilia treaters who are members of the Medical/Scientific Advisory Committee (MSAC) of the CHS, using existing national representation."[67]

On 20 April 1985, the MSAC recommendations on criteria for the use of heat-treated Factor VIII were approved by the CHS Board of Directors. There were six recommendations to identify priority recipients, as follows:

- Previously untreated or rarely treated patients, who require concentrate therapy during the conversion (transition) period.
- Previously treated patients known to be sero-negative for HTLV-III (HIV) antibodies.
- Young children who require concentrate during this period.
- Those regularly treated with cryoprecipitate who require factor concentrate for isolated indications, including major surgery or travel.
- The distribution across the country to be equitable.
- The decision of priorities to be done by Hemophilia Clinic Directors, in consultation with CRC BTS (Canadian Red Cross Blood Transfusion Service) Center Directors.[68]

It was generally known by medical and regulatory authorities at the time—late 1984 to early 1985—that there was probably already a significant level of HIV-infection among Canadian hemophiliacs. The selection criteria, listed above, implicitly make that quite clear since the criteria directed the heat-treated product to hemophiliacs who were either demonstrably seronegative for HIV antibodies, or to so-called "virgin" hemophiliacs who were unlikely to have received contaminated product in the past.

Also, on 6 December 1984, Dr. Chris Tsoukas of Montreal (with several colleagues) published a letter in the *New England Journal of Medicine* reporting preliminary findings among 54 subjects, suggesting that 56% of Canadian hemophiliacs were seropositive for the AIDS virus. Testimony to

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65 Dr. D.W. Boucher, Bureau of Biologics, Proceedings, Issue 25, 25 March 1993, p. 14.

66 See Appendix B.

67 Canadian Blood Committee, Recommendations of the Consensus Conference on Heat-Treated Factor VIII, December 10, 1984, Recommendation No. 8.

68 Dr. Robert T. Card, Chairman, MSAC, Canadian Hemophilia Society, Letter of 25 April 1985, to Dr. D.H. Naylor, Canadian Red Cross Blood Transfusion Service.

our Sub-Committee from Dr. Michael O'Shaughnessy indicates that the early evidence of significant levels of seropositivity among Canadian hemophiliacs was released in 1984, to a conference in Vancouver in November of that year, and in "mid-1984" to NAC-AIDS and to "several scientific meetings".[69]

For some Factor VIII hemophiliacs, there was an alternate coagulation product available during the transition period. That product is known as "cryoprecipitate" and it is prepared from the plasma of a single donor by a freeze-thaw technique. The technique involves removing the thawed plasma before the last ice crystals dissolve; this last portion contains the Factor VIII. The bags of cryoprecipitate are stored frozen and their contents are dissolved in saline before use.[70] Up to ten bags of cryoprecipitate might be pooled to treat a single patient.

There are significant disadvantages to cryoprecipitate compared to concentrate. The product is very crude, containing a number of proteins in addition to Factor VIII. Thus, there is a possibility of allergic reactions in the patient. The content of Factor VIII in any given lot of cryoprecipitate is variable and is not accurately known; thus, it is difficult to calibrate dosage. The volume of material that is used in treatment is large relative to that associated with the use of Factor VIII concentrate. The product is inconvenient to use during surgery, because of the uncertainty over Factor VIII content, and it is also difficult and inconvenient to use in a home-care situation. Because cryoprecipitate must be kept frozen, it is very difficult to use during travel and in many work situations.

However, cryoprecipitate had an obvious advantage over Factor VIII concentrate during the period when the AIDS epidemic was growing. With a maximum of ten plasma donors per treatment, there was a much lower probability of encountering HIV contamination, compared to the situation with Factor VIII concentrate where up to 70,000 donor exposures might be involved in a single product lot.

Dr. Roger Perrault, the National Director for Blood Services for the Canadian Red Cross from 1974 to 1986, stated that there were adequate amounts of cryoprecipitate available for use by hemophiliacs throughout the transition period in 1984-1985.[71] Red Cross records show that the quantity of cryoprecipitate transfused during that period increased significantly, from 141,599 units in 1982 to 164,549 and 192,935 units in 1983 and 1984, respectively. In 1985, when heat-treated Factor VIII became generally available, the number of transfused units of cryoprecipitate dropped to 153,307, and declined further in 1986-87 to 112,365 units.[72]

There are a number of parts of this history that need additional clarification, however. One that has been alluded to above is the need for full documentation on supplies and inventories of heat-treated Factor VIII during the transition period. Was the transition made as quickly as possible under the circumstances at the time? Was there an avoidable delay in decision-making in the blood system to make the switch from untreated to heat-treated coagulation products in the first place? Is it possible that financial considerations played a role, for example, in the availability of funds for the purchase of replacement product?

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69 Dr. Michael O'Shaughnessy, Proceedings, Issue 23, 11 March 1993, p. 7, 10.

70 *THE MERCK MANUAL of Diagnosis and Therapy*, Sixteenth Edition, Rahway, N.J., 1992, p. 1219.

71 Dr. Roger Perrault, Proceedings, Issue 22, 25 February 1993, p. 25.

72 *CRCS Report*, 1990, p. 113.

COMPENSATION FOR PERSONS INFECTED WITH HIV THROUGH THE BLOOD SYSTEM

I am absolutely terrified of getting sick, not only in terms of who is going to take care of my children, but the financial burden that comes along with it . . . We've worked hard for 20 years to build up some sort of security for ourselves and our children. I am just absolutely horrified by the financial burden I could place on my family. . .

Mrs. Marlene Freise
HIV-Positive From Blood Transfusion[73]

The compensation of persons who have become HIV-positive through contaminated blood and/or blood products was an important and recurrent theme throughout the public hearings. In addition to the pain and suffering, and the destruction of family units, there are the very large financial costs of treating HIV infection and AIDS. The impact of costs is perhaps greatest for HIV-positive hemophiliacs; all hemophiliacs are male and, in Canadian society, the male is still predominantly the principal wage-earner in the family. Moreover, most hemophiliacs cannot obtain life insurance, so they are unable to provide financial security for their families by this means.[74]

To date, only the federal government has provided financial compensation to persons infected by HIV through the blood system. On 14 December 1989, the (then) Minister of Health and Welfare Canada, Perrin Beatty, announced a program of assistance that would provide $120,000 to each infected person, payable in four equal annual instalments. For most affected persons, who began receiving payments in 1990, the program will end this year. One of the cruel ironies in this situation is the fact that persons with HIV infection and AIDS are living longer as a consequence of better HIV/AIDS therapies, and therefore they will possibly be facing the worst ravages of the disease, and their greatest expenses, after government assistance payments have ceased.[75]

At the time the assistance program was announced, Minister Beatty commended the Canadian Hemophilia Society (CHS) for its leadership and hard work, not only on behalf of its own members, but also on behalf of non-hemophiliacs who became infected through the blood supply. One of the services offered by the Canadian Hemophilia Society is the HIV-T Support and Information Service which assists HIV-positive, blood-transfused persons who are not hemophiliacs. This group was first organized in 1988, in Calgary, at the Alberta Children's hospital, to discuss ways to trace persons infected through the blood supply. The group developed into a national organization after that.[76]

The Minister's News Release made clear, however, that the federal assistance program was developed on the basis of the government's compassion for the affected persons and that the government did not assume any legal liability or responsibility for the situation.

In his statement on 14 December 1989, Minister Beatty noted that he and the CHS had "discussed this issue with the provinces and together we have recognized that there are opportunities for the provinces to contribute in their own way". Since that time, there has been no

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73 Marlene Freise, Proceedings, Issue 17, 26 November 1992, p. 11.

74 Canadian Hemophilia Society, Personal Communication, 29 April 1993.

75 Health and Welfare Canada, Beatty *Announces Assistance to Persons Infected With HIV From Blood Transfusions or Blood Products*, News Release, 1989-99, December 14, 1989. (The spouses or partners of infected persons, who themselves become infected secondarily, do not qualify for the federal program. Newly indentified HIV-infected persons continue to be accepted into the program, however.)

76 Dr. John R. McDonald, Proceedings, Issue 21, 18 February 1993, p. 5.

directed provincial compensation to persons infected with HIV through the blood system, although it has been stated that there were "initial indications" that the province of Quebec was considering the matter. It has also been stated that all of the provinces agreed jointly in1990 not to develop assistance programs for infected persons.[77]

On April 14th, 1993, the Minister of Health for Nova Scotia, George Moody, announced that the Nova Scotia government would develop a compensation program for persons infected by HIV-contaminated blood. Mr. Moody stated that he "did not feel bound by an agreement the provinces reached in 1990 to stick together on the compensation issue and take no unilateral action".[78] Minister Moody has assigned senior health officials to begin negotiations immediately with representatives of the Nova Scotia branch of the Canadian Hemophilia Society to develop the program. In making his statement, Mr. Moody said that this was not an issue of legal liability but, like the federal government's assistance program of 1989, was based on compassion for the affected persons and their families.

The Canadian Hemophilia Society has continued to insist that persons infected with HIV through the blood supply deserve more adequate compensation for the disaster that has struck their lives. The Society believes that most Canadians support provincial compensation for infected persons. This position is based on a national poll that the Society commissioned from Decima Research in April of this year.

The Decima survey involved 1,200 Canadians who were asked the degree to which they would support the point of view that "rather than having cases go to court, the provinces should fulfil their role in this plan approved (in 1989) by the federal government."[79] Overall, the Decima results indicate that 37% of those polled were "very supportive" of the point of view, 43% were "somewhat supportive", 10% were "not too supportive", and 6% were "not at all supportive". Thus, 80% of those polled were at least somewhat supportive of the proposition.

The matter of court cases in this area was brought up by several witnesses who appeared before the Sub-Committee. George Weber, the Secretary General and Chief Executive Officer of the Canadian Red Cross Society, referred to more than 80 law suits against the Society alone.[80] Other law suits are currently under way, or planned, against various governments, organizations and individuals. The Canadian Hemophilia Society has stated that its members would prefer to settle this issue out of court, in part because lawsuits are extremely taxing on individuals and families who are already under considerable strain as a result of HIV.

RECOMMENDATIONS

Public Inquiry Into The Canadian Blood System

The HIV/AIDS tragedy that struck more than 1,000 hemophiliacs and blood-transfused persons in the 1980s has done more than destroy lives and families. It has raised serious questions about how, and how effectively and safely, the Canadian Blood System is run. The Sub-Committee

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77 Dr. John R. McDonald, Proceedings, Issue 21, 18 February 1993, p. 15.

78 Rod Mickleburgh, "N.S. to compensate victims of AIDS-tainted blood", *The Globe and Mail*, 15 April 1993.

79 Canadian Hemophilia Society, *The Canadian Hemophilia Society's Position Concerning Provincial Compensation*, Press Release, April 15, 1993.

80 George Weber, Canadian Red Cross Society, Proceedings, Issue 17, 26 November 1992, p. 39.

believes that it is probable that public confidence in the safety and efficiency of the system has been shaken to a significant degree. On the question of safety, this is unfortunate and unnecessary.

One of the strongest critics of the Canadian Blood System testified that, in terms of AIDS, the current Canadian system is as safe as it can reasonably be made with existing technology and knowledge.[81] Prior to the onset of AIDS in the late 1970s and 1980s, however, the same claims about safety could have been made. Yet, when the Canadian system was challenged by a new and puzzling pathogen, it was not, in the opinion of this Sub-Committee, able to respond with the speed and flexibility that was necessary to protect clients of the blood system from HIV-infection to the degree that should have been possible. This having been said, we must recognize that the majority of the persons infected by HIV through the blood system were probably infected before HIV-antibody testing of donors and heat-treated Factor VIII were available.

We believe it is important that the events of the 1980s should be carefully reviewed to determine why the system did not respond to the HIV/AIDS challenge as quickly as it might have. Through our public hearings, and through the medium of this Report, we have brought forward and consolidated a considerable amount of information that will assist in a further review of events.

As we have indicated in the earlier part of this Report, there are numerous unanswered questions pertaining to the events leading up to the implementation of blood-screening in November 1985. Similar questions remain regarding the full replacement of untreated Factor VIII concentrate by heat-treated product on July 1, 1985. We recognize that some of the questions may never be answered because the necessary information will have been lost with the passage of time. However, we believe a great deal of information will be accessible, and a more thorough review of the blood system should reveal it. The intent of a more thorough examination of events is not to assign blame, but to ensure that the present blood system has made the necessary adjustments in its organization and decision-making process in order to avoid a repetition of the tragic events of the 1980s.

With respect to the introduction of the ELISA test for blood-screening, the period from May 1984, when a description of a laboratory assay for HIV antibodies was published in a major scientific journal, to May 1985, when the Red Cross submitted its implementation plan to the Canadian Blood Committee, must be closely examined. A question of major importance concerns the development of the Red Cross implementation plan for blood screening. Was it not possible to have developed the plan in a shorter period of time, so that the key decisions on implementation could also have been made earlier?

The events from May 1 to August 1, 1985 must also be clarified fully. The three-month period that the Canadian Blood Committee took to approve funding for the Red Cross implementation plan must be explained. Given the fact that the blood system was confronted with a major crisis, was it not possible for contingency funding to have been made available prior to May 1, so that implementation of the testing plan could have proceeded more quickly?

All of the available documentation, whether in the form of correspondence between the various players in the system, or minutes of meetings, must be made public and carefully reviewed. Of particular interest is the Consensus Meeting of provincial and territorial representatives of 4 July 1985. Almost four weeks elapsed after that meeting before the Red Cross plan was finally approved: the delay in Ontario's decision alone accounted for half of that four-week period.

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81 Dr. Gail Rock, Proceedings, Issue 20, 11 February 1993, p. 14.

The Red Cross suggestion that there might have been a shortage of commercial test kits on the international market until the fall of 1985 must be fully assessed. The available correspondence and inventory records of the Canadian Red Cross and the various companies involved, and the minutes of meetings of the Canadian Blood Committee must be made public, to the fullest extent possible.

The transition from untreated to heat-treated Factor VIII concentrate is an important and highly-charged issue. The principal issue concerns the availability of replacement product during the transition period between November 1984 and July 1985.

The Consensus Conference of December 10, 1984 stands as a major event in the history of heat-treated Factor VIII in Canada. The conference was convened by the Canadian Blood Committee and it was intended to discuss the implementation of the requirement by the Bureau of Biologics for a changeover to heat-treated coagulation products. All of the important events in the transition to heat-treated products flowed from the discussions and decisions of that conference.

All of the major players in the Canadian blood system were present at the Consensus Conference, including the Canadian Hemophilia Society (CHS), representing the client group directly impacted by the decisions made at that time. A full disclosure of all of the documentation and discussions that took place at that conference should be made, and the information carefully reviewed. The Sub-Committee has noted the concerns of the CHS in respect of the conclusions reached at that conference, although we have received no evidence that the conference itself was in any manner inappropriately conducted.

The principal action flowing from the Consensus Conference was the introduction of heat-treated coagulation products into the Canadian blood system. The questions and concerns that have arisen in the aftermath centre on the transition period, during which untreated product was replaced by heat-treated. A full disclosure of information on inventories of both classes of products is needed, the goal being the assurance that heat-treated product was brought into the Canadian system as quickly as possible, and that no person was denied heat-treated product for any reason other than actual product availability. The regulatory activities of the Bureau of Biologics in connection with new product applications for heat-treated Factor VIII must also be reviewed.

We have already stated that we are mindful of the various civil actions that are under way in the court system, but we see no good reason why a comprehensive review should not take place anyway. For one thing, court cases may, in many instances, carry on for a period of years before resolution is achieved. We feel that there is important information to be gained from a review of the events of the 1980s that can be gathered in a fairly short period of time.

The fact that the Canadian blood system is funded by the provinces and territories through the Canadian Blood Agency, which is also the policy-making body of the system, together with the fact that the federal government has no direct involvement in the Agency, places important limitations on federal action and authority in regard to any review of the system. This fact is pertinent to the current discussion because, as a Sub-Committee of the House of Commons, we are limited in that we can make recommendations only to the federal government. We are constrained from making recommendations to provincial governments, or to other organizations or individuals.

However, the Canadian blood system is a national system in fact, and the federal government is a major player in the system through its regulatory authority under the *Food and Drugs Act*. The Canadian Red Cross Society operates the blood system under Guidelines established by the federal government which, although they do not have the force of law, have the effect of requiring the Society to follow them in order to maintain certification of its operations under the *Act*.

The Sub-Committee is aware that changes have been made in the Canadian blood system through the activities of the Canadian Blood Agency and that further changes, intended to make the system more effective and more responsive to safety issues, are under way even as this Report is being written. We have no wish to interfere with, or in any way compromise, the current initiatives of the Agency. Still, we believe that a comprehensive review of the Canadian blood system is necessary at this time, in part to fully clarify the tragic events of the 1980s, in part to reaffirm public confidence in the system, and in part to ensure that the Canadian blood system will be able to deal with future challenges as well as the myriad requirements of day-to-day operations.

We believe that the best approach to structuring an inquiry into the Canadian blood system is for a *joint federal-provincial-territorial inquiry* to be established. The federal government would take the lead in organizing the inquiry, and would provide a significant amount of the funding but it would seek the consensus support of the provinces and territories before proceeding. In order for the inquiry to deal comprehensively with the complex range of issues that must be examined, and to formulate effective recommendations that will ensure that the Canadian blood system is as safe as possible, it should have the support of both levels of government.

A joint inquiry could take several forms. Ideally, a commission would be constituted for legal purposes under the federal *Inquiries Act*, and the same body then given the status of a public inquiry for the purposes of the comparable provincial and territorial statutes. There are precedents for this, but not involving more than the federal and one provincial government. Given the administrative difficulties of setting up a formal joint inquiry involving so many governments, it should be sufficient if a federally-constituted investigation proceeded with provincial agreement and support. If one or more of the provinces or territories chose to give the commission additional status under it's own public inquiries legislation, the effectiveness of the inquiry could of course be enhanced. These governments should also participate as fully as possible in the inquiry itself. The greater the degree of support and active participation, on the part of the provinces and territories, the more successful the inquiry is likely to be.

RECOMMENDATION NO. 1

The Sub-Committee strongly recommends that a public inquiry be carried out into the Canadian blood system, with the efficiency and safety of the system as the primary focus. The inquiry should also include, but not be limited to, a full examination of the events of the 1980s when the Canadian blood supply became contaminated by the human immunodeficiency virus, the pathogen associated with AIDS.

RECOMMENDATION NO. 2

The Sub-Committee further recommends that the federal government take the lead in organizing, funding and carrying out the inquiry as a joint federal-provincial-territorial initiative. The Terms of Reference of this public inquiry should be developed jointly and cooperatively by the federal, provincial and territorial governments, after consultation with affected groups and organizations.

While the best approach would be the joint governmental initiative which we have recommended above, it should not be regarded as the only way to proceed. The overriding need is for a review of the history and present state of the national blood system to be conducted, and its recommendations implemented, before the system is faced with a new threat or crisis. We are

mindful of the time that may be involved in organizing a joint inquiry, and of the administrative difficulties that may confront such an effort. It is imperative that the commencement of the inquiry not be unduly delayed, much less frustrated entirely, by the problems inherent in coordinating involvement of both levels of government.

The federal government must therefore be prepared to proceed on its own if a joint inquiry should prove to be unfeasible or unduly impeded by administrative problems. We suggest that a reasonable deadline for the organization of a joint inquiry would be the meeting of Federal/Provincial/Territorial Ministers of Health scheduled for September of this year. If by the end of that meeting any difficulties encountered in organizing the cooperative effort have not been resolved, the federal government should move quickly on its own to get an inquiry under way.

The final responsibility for ensuring that the blood and blood products supplied by the national system are safe and effective lies with the federal government. This responsibility cannot be discharged solely through the development and application of regulatory requirements for the operations through which blood is collected and processed. The federal government must ensure that the organization and administration of the system is adequate to produce a sufficient supply of blood that meets the standards that Canadians have a right to expect, standards for which it is ultimately responsible.

RECOMMENDATION NO. 3

The Sub-Committee recommends that, if the steps necessary to organize a joint inquiry have not been successfully completed by the end of the meeting of the Federal/Provincial/ Territorial Ministers of Health in September of 1993, the federal government should proceed as soon as possible thereafter with a federal inquiry.

A host of complex issues and questions need to be confronted and resolved. The inquiry must not only examine the present system, from the collection of the blood to its distribution, it must determine whether the structures in place at each point along the line represent the best possible approach, and are combined into an effective overall system. We are concerned that the interrelationships of all of the governments and organizations involved are not adequately structured and coordinated. It is not clear that the various elements of the system do or can work effectively together—the provincial and territorial governments as the source of funding and administrative authority, the Canadian Blood Agency as the directing and coordinating body, the Canadian Red Cross as the operational arm of the system, and the federal government as the regulatory authority.

We are particularly concerned about the overall role of the federal government. Should it be more directly involved in the Canadian Blood Agency or whatever national authority ultimately directs the system? Dr. Peter Pinkerton, representing the Canadian Hematology Society, stated that:

> "It astonishes me that probably the only national health care system in the country, the blood transfusion system, is operated by an agency on which the federal government is not represented. That to me is an anomaly."[82]

We agree that this seems to be a disturbing anomaly. We have noted that the federal government has a separate regulatory role, but we remain unconvinced that this should preclude or make unnecessary a further role. Does that regulatory responsibility conflict with direct

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82 Dr. Peter Pinkerton, Canadian Hematology Society, Proceedings, Issue 26, 1 April 1993, p. 13.

involvement in the administration of the system, or could the administrative and regulatory elements (and thus the safety and efficiency of the operational end of the system) not be better coordinated if the federal government were more involved in the national authority? What form should that involvement take?

The rather undefined nature of the relationship between the Canadian Blood Agency, which is mandated to direct and fund the blood system, and the Canadian Red Cross Society, which actually carries out all the operations of recruiting donors, and collecting and distributing blood, is another concern. This relationship at present is based solely on the traditional role of the Society in providing these services. Should there not be a formal contract or other concrete structural arrangements between the Agency and the Society? Are mechanisms required to ensure that the Agency has sufficient supervisory capacity regarding the financial processes of the Society's Blood Services to enable the Agency to be truly accountable for the public funding which it directs? We believe that all of these questions need to be addressed by the inquiry, and should be reflected in the inquiry's Terms of Reference.

An inquiry could look to the structures and experiences of other countries, particularly those which have a federal system similar to ours, for guidance in seeking to answer these questions. This might best be accomplished if one of the commissioners could bring to the inquiry the perspectives of other national blood systems, but it might well be sufficient for it to gather such evidence from other sources. For example, the experience of other national blood systems with directed donations, donations that are directed by the donors to specific recipients, should be looked at by the inquiry. At present, the Canadian blood system does not permit directed donations. International perspectives should thus be addressed in the inquiry's Terms of Reference.

RECOMMENDATION NO. 4

The Sub-Committee recommends that the Terms of Reference of a public inquiry should address, among other things, an examination of the interrelationships of the governments and organizations involved in the Canadian blood system, in particular the overall role of the federal government, and the lack of a formal contract between the Canadian Blood Agency and the Canadian Red Cross Society. The possible lessons to be drawn from blood systems in other countries should also be addressed.

A key to the success of an inquiry into a complex enterprise such as the blood system will be the makeup of the commission appointed to conduct the review. Although the federal Inquiries Act provides for the appointment of more than one commissioner, it is common for such inquiries to be conducted by a single person, often a judge. While this is an appropriate approach in many cases, particularly where the principal focus is on fact-finding, we believe that in this case a panel of commissioners would offer the broader range of expertise and experience that appears to us to be necessary. However, one member of the Sub-committee would have supported a further recommendation that the chairperson of the panel sould be a superior court judge.

The overall structure of the blood system must be analyzed from a variety of perspectives. The task of the inquiry will be to ensure that all of the system's different elements are integrated into an effective whole. The spectrum of considerations will go beyond the medical and scientific fields. They will involve also the application of managerial, financial and legal principles and concerns, and perhaps others. The combined experience and expertise of the commissioners will therefore need to be as wide as possible.

While the commissioners must be able to understand the intricacies of the Canadian blood system, and the scientific foundation that supports it, they must nonetheless be fully independent from the system itself. This would not preclude consultation with the affected groups and organizations. Indeed, we would recommend such consultations as part of a process that will ensure that the commissioners chosen combine the qualities of expertise and independence.

Because national public confidence in this vital system is involved, it must be clear to all that a comprehensive examination by persons who have no direct interest in the outcome of the inquiry has been conducted. Although the independence of those conducting public inquiries is always an important principle, it is particularly appropriate to emphasize its importance in this case.

RECOMMENDATION NO. 5

The Sub-Committee recommends that the public inquiry be carried out by an independent panel of commissioners with as broad a range of expertise and experience as possible.

A recurrent concern was voiced during our public hearings that there is no single controlling authority in charge of Canada's blood system. This is a concern that must be laid to rest.

It is clear that the Canadian blood system is national in scope, and we believe that this national focus must be affirmed and fortified. There are potential weaknesses, however, in a nationally administered system that is funded by the provinces and territories as part of their responsibility for health-care services, involving as this does twelve separate governments.

The Canadian Blood Agency is a cooperative venture of the provinces and territories. Its mandate to "direct, coordinate and finance" the national system would appear to designate it as the single controlling body, but the extent of its practical authority is not clear. The federal government has chosen not to be directly involved in the Agency, but has regulatory control over the system. This situation raises the concern and perception that no one national body is in charge.

The public inquiry will examine the overall structure of the system and its effectiveness. The inquiry must be free to be as creative as necessary in determining the best blood system for Canada. In our view, however, one key element of any structure must be an authority with a national focus and the necessary decision-making power. There needs to be a single authority in charge, and seen to be in charge, of the key areas of accountability, decision-making, communication, and response to emergencies.

The most feasible approach may well prove to be a cooperative governmental structure such as the Canadian Blood Agency. The inquiry will determine whether the appropriate body to fill this role is the Canadian Blood Agency itself, in its current or some modified form. For example, the federal government may need to be involved in the Agency in some formal way, although the primary source of the necessary authority would still appear to be the provincial and territorial governments.

Any national authority must have the necessary resources and real authority to do the job. Devising the mechanisms necessary to ensure this will, we believe, be one of the most important tasks facing the inquiry.

RECOMMENDATION NO. 6

The Sub-Committee recommends that an essential element of any Canadian blood system should be a national authority with the resources and effective power to administer the Canadian blood system, provide accountability, and respond

quickly and effectively to new challenges. The Terms of Reference of the public inquiry we have recommended should therefore include the determination of the best structure for such a body, and the mechanisms necessary to ensure that it can fulfil this vital role.

Compensation For Persons Infected With HIV Through The Blood System

We have discussed the issue of compensation earlier in this Report and, as a Sub-Committee, we are unanimous and firm in our conviction that persons who have been infected with HIV through the blood system should receive compensation from government. The federal government already has a program in operation but, to date, with the exception of Nova Scotia, the provincial governments have refused to provide direct compensation to the persons affected by this tragedy. As we have stated, we are constrained from making recommendations to provincial governments. We can, however, recommend that the federal government urge the provinces on compassionate grounds to reconsider their decision of 1990 not to provide compensation, and develop a compensation program in consultation with the Canadian Hemophilia Society representing the HIV-infected persons.

RECOMMENDATION NO. 7

The Sub-Committee recommends that the federal government, through the Minister of National Health and Welfare, urge and assist the provincial and territorial governments to develop and implement compensation programs for persons infected by HIV through the Canadian blood system, to complement funding already provided by the federal government.

The continued adequacy of the federal government's compensation program has been questioned in recent months. Although we acknowledge the generosity of the original commitment, the fact remains that, for many infected persons, the compensation will end at a time when their medical expenses continue to increase. At this time, also, many infected persons will be unable to work because of their declining health status. Partly as a consequence of improved therapies, HIV-infected persons are living for longer periods; it is also now recognized that there is a great variation among individuals in the severity of infection by HIV as well as in survival times.

For these reasons, the Sub-Committee believes that the federal government should reassess the adequacy of its compensation program and consider extending the compensation package beyond the original four-year period.

RECOMMENDATION NO. 8

The Sub-Committee recommends that the Minister of National Health and Welfare reassess the adequacy of the federal government's compensation program for persons infected by HIV through the Canadian blood system, taking into account the increased survival times of persons with HIV infection, and the mounting costs of therapies.

Tracing The Recipients Of HIV-Infected Blood

The tracing of persons infected by HIV-contaminated blood is still incomplete, although a great deal of progress has been made, largely because of the admirable efforts of the HIV-T group which operates under the umbrella of the Canadian Hemophilia Society. However, this difficult process did not appear to be greatly assisted at the outset by two of the principal actors in the Canadian blood system, the Canadian Red Cross Society and the Canadian Blood Committee.

As far as we can determine, the Canadian Blood Committee played no significant role in facilitating look-back and trace-back programs to identify infected blood recipients. We do know that the Canadian Red Cross responded positively when an infected donor or recipient was identified but, although we understand that there are legal complications where persons have become infected through the blood system, we are puzzled by the nature of the response of the Society to inquiries on the part of some infected persons. We find most disturbing the actions of the Red Cross as described in the testimony of Mr. Jerald Freise, whose wife Marlene was infected by HIV during surgery in 1982, and who was identified through a routine blood test for insurance purposes:

> "While we know that the blood system has failed for us, we also have reason to believe that it continues to fail in an area of great concern to us, and that is in the look-back, trace-back systems.
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> "I'm a representative of the Ontario HIV-T Group, and in our group we have 41 transfused, [HIV-infected] members. Of these 41 people, only five were ever contacted by the Red Cross. That's a success rate of 12%. In Ontario, there are 102 HIV-infected individuals identified, although it's estimated that there are still another 200 in Ontario alone who are infected and don't know.
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> "When I started to ask more questions . . . I would say that the first contact I made was to the Red Cross . . . I was given the name of a person to call, who I thought . . . could help me. That person turned out to be a Red Cross lawyer. So we have a case of a doctor referring me to a lawyer. That lawyer then sent to my lawyer a letter saying that his client had called the Red Cross, and to please make sure that it would not happen again."[83]

The possibility that there are still HIV-infected persons who contracted the virus from the blood system, and who are unaware of their seropositive status, is extremely serious. Some of these persons may still be asymptomatic for HIV-infection since we now know that the incubation period of the virus can be as long as ten years. However, an HIV-positive person is capable of infecting others with the virus. Thus, the urgency to identify HIV-positive persons is based on two factors: the need to start therapy as soon as possible to slow the development of HIV-disease and to deal expeditiously and effectively with opportunistic infections when they occur; and the need to contact the individual before he/she infects someone else.

The look-back and trace-back systems of the Canadian Red Cross, referred to above, need to be explained at this point. Both are dependent on the discovery of HIV seropositivity in an individual.

In the *look-back* system, if a person donating blood is found to be HIV-positive, that person's past donation record is checked. If there are past donations, the various blood units are traced through Red Cross records to determine where they were used. If they were used in transfusions, for example, the recipients of the blood are then contacted, if possible, and advised to have a test for HIV. Where recipients of the donated blood are found to be HIV-negative, it is assumed that the donor's earlier donations were also HIV-negative, and that his/her seroconversion occurred recently.

In the *trace-back* system, the search starts with an infected person who has received a blood transfusion sometime in the past. Then the transfused blood unit is identified and that unit traced back to the donor who is then contacted and asked to have an HIV test. In cases where the recipient

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83 Jerald Freise, Proceedings, Issue 17, 26 November 1992, p. 10, 19.

may have received blood or blood product from more than one donor—and in some cases, tens or even hundreds of donors might be involved—all donors must be contacted. This can be a difficult, even impossible, process because some former donors may be untraceable. It is also possible that some of the contacted donors may refuse to be tested for HIV infection.

In both systems, the procedure may be extremely difficult because the Canadian Red Cross records were not computerized in the 1980s. Thus, both the look-back and trace-back searches often have to be done manually, ". . .through thousands and thousands of sheets" to determine where a donated blood unit has gone, or who donated blood to an infected patient.[84]

The fact that the Red Cross records can only be searched manually at the present time does not mean that the record-keeping is inadequate. It only means that tracing a donated unit of blood from donor to recipient takes a long time and is, therefore, very inefficient. The Red Cross has now contracted with Etcom Canada Inc. to develop a computerized system that will, among other things, facilitate a rapid search to link future donations with donors, although past records will not be part of the new system. The new system is formally known as the Computerized Information System for Centre Operations, or "CISCO" for short. The system is not yet in operation but the Red Cross has stated that it should be up and running in the fall of this year.[85]

The Sub-Committee believes that a more proactive system is needed to identify persons who have become HIV-positive through the blood system. The identification of seropositive hemophiliacs was made possible because this group comprises a tightly knit community of individuals who are under constant medical care. For non-hemophiliacs who receive blood or blood products in the course of treatment, and there are hundreds of thousands of persons in any given year who require such therapy, the task of identification is immensely more difficult.

On 15 April 1993, the Hospital for Sick Children in Toronto revealed plans to notify the families of children who received blood transfusions between 1980 and 1985 that they may have been exposed to HIV. It is estimated that there are some 17,000 children who may have received transfusions in the late 1970s and early 1980s.[86] The program will start by sending letters to some 1,700 families of former pediatric heart patients. If this effort is successful, the identification program will be extended and enlarged. The Sub-Committee commends the Hospital for Sick Children for its initiative.

We have received some testimony in this particular area suggesting that a coordinated national identification program is needed. Robert St. Pierre is Coordinator of the HIV-T Support and Information Service, which is part of the Canadian Hemophilia Society. In his testimony to the Sub-Committee, Mr. St. Pierre suggested that:

> ". . .it would be beneficial to set up a committee made up of representatives from the Red Cross, the Hospital Association, the College of Physicians and the individuals affected. The mandate of the committee would be to put in place ways of tracking down these cases that are geared to the particular features of each region of Canada. It is high time that a partnership be established so that we can combine our forces to try to help infected individuals."[87]

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84 Dr. Roslyn Herst, Canadian Red Cross Society, Proceedings, Issue 17, 26 November 1992, p. 34.

85 Canadian Red Cross Society, Personal Communication, 29 April 1993.

86 Henry Hess, "Children's hospital to issue HIV alert", *The Globe and Mail*, April 16, 1993.

87 Robert St. Pierre, HIV-T Support and Information Service, Proceedings, Issue 17, 26 November 1992, p. 14.

At the same public hearing, the Canadian Red Cross Society responded positively to the suggestion of Mr. St. Pierre:

> ". . . we [the Canadian Red Cross Society] are prepared to cooperate and participate in any group or any committee to deal with this situation. If it's felt by the powers that be that this is going to help the current situation, we are prepared to cooperate and participate in this group."[88]

Dr. Jack McDonald, who was instrumental in founding the HIV-T group that has successfully identified at least 261 HIV-positive blood-transfused individuals since 1988, suggested the following recommendation to the Sub-Committee:

> "I would recommend that Health and Welfare Canada sponsor an intensive campaign to alert physicians through appropriate medical associations and to alert former transfusion patients through a carefully designed series of spot television announcements, simply saying to people that if they have continuing illnesses and have had blood transfusions, they should get themselves checked."[89]

The Sub-Committee agrees with the tenor and intent of these various suggestions. We believe that the effort to identify HIV-positive blood-transfused persons should be placed on a national footing and make optimal use of organizations and individuals who are skilled and knowledgeable in this area. It is important to avoid the duplication of effort because that will not make the most effective and efficient use of the available resources. We make the following recommendation.

RECOMMENDATION NO. 9

The Sub-Committee recommends that the Minister of National Health and Welfare, as a matter of urgency, take the lead in establishing a process to identify and notify HIV-positive blood-transfused persons in Canada. This process should enlist the assistance of resources and expertise within the Canadian Red Cross Society and the HIV-T Support and Information Service of the Canadian Hemophilia Society, the Canadian Medical Association, the Canadian Public Health Association, the Canadian Hospital Association, and other appropriate organizations.

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88 George Weber, Canadian Red Cross Society, Proceedings, Issue 17, 26 November 1992, p. 38.

89 Dr. John R. McDonald, Proceedings, Issue 21, 18 February 1993, p. 10.

APPENDIX A

Terms of Reference of the Canadian Blood Committee

(Adopted February 1982)

To establish policies with regard to the following:

a. the collection of blood, including plasmapheresis;

b. the processing of blood;

c. the distribution of blood products;

d. the utilization of blood products;

e. operational research; and

f. support and maintenance of the four enunciated principles concerning blood and blood products;

To recommend allocation of resources to meet costs of implementing the above policies;

To assure adherence to established policies by the Canadian Red Cross, plasma fractionation plants, and others involved in the collection, processing, distribution and utilization of blood and blood products;

To consult with the Department of Industry, Trade and Commerce on appropriate policies for the export and import of human blood and blood products;

To consult with the Bureau of Biologics, Department of National Health and Welfare, on appropriate policies for the regulatory control of the collection, processing, and distribution of blood, blood products and their substitutes;

In the short term, to monitor the development of fractionation plants to ensure that their establishment is in accordance with the recommendations of Ministers of Health and allocate resources and priorities for their implementation;

To determine the real costs of producing blood fractions for Canadians and the shareable portion of capital costs to be added to the price of blood fractions;

To ensure that standards for blood, blood products and blood substitutes are developed, and to monitor that such standards are met;

To review and approve the programs and budgets of the Blood Donor Recruitment and Blood Transfusion Services of The Canadian Red Cross Society, subject to the concurrence of all Provinces and Territories;

To report annually to the Ministers of Health on all activities of the Committee;

To be a national forum for the various organizations and associations of the Canadian blood program to discuss issues, and to coordinate the activities related to the management of the Canadian blood system.

Source: The Canadian Red Cross Society, *The Canadian Red Cross Blood Programme From 1974 to 1990 – A Report to the Canadian Hematology Society*, Ottawa, 1990, p. 95.

APPENDIX B

Blood Screening and Heat Treatment of Blood Products in Canada

CHRONOLOGY OF EVENTS

NG = Dr. Norbert Gilmore

GR = Dr. Gail Rock

CRCS = Canadian Red Cross Society

CHS = Canadian Hemophilia Society

JK = Ms. Joan Kent

HWC = Health and Welfare Canada

HIV, the virus believed to cause AIDS, originally was variously called "LAV" and "HTLV-III", by French and American researchers, respectively. The name "human immunodeficiency virus", abbreviated to HIV, was coined in 1986.

1980 - A German company, Behringverke, produced a Factor VIII product that was heat-treated to kill the Hepatitis B virus. The product was accepted for use in Germany in 1980, in Japan in 1981. The product was later licensed in Canada (1985) and the U.S.A. (1986). (HWC)

1981 - The Canadian Blood Committee was established by the federal, provincial and territorial Ministers of Health to assume the role of the Federal-Provincial Programme and Budget Review Committee. In 1983, the members agreed to set up a Secretariat within Health and Welfare Canada. (HWC)

June 1981 - AIDS was first reported by the Centers for Disease Control (CDC) in the United States.

1981 - Seven of the first 106 people who had developed AIDS and who were reported to the CDC had been exposed to blood by injection drug use. (NG)

February 1982 - AIDS was first reported in Canada.

July 1982 - Three hemophiliacs had been discovered to have developed AIDS and the possibility that AIDS could be transmitted by exposure to blood products began to be appreciated. (NG)

1 August 1982 - Eight cases of AIDS had been identified in Canada. Based on the possibility that the disease could be transmitted by blood, the Bureau of Biologics (BOB) asked the Canadian Red Cross Society (CRCS) and the Canadian Hemophilia Society (CHS) to increase surveillance of hemophilia patients for AIDS and to report cases to the federal Laboratory Centre for Disease Control (LCDC). (HWC)

November 1982 - Three persons were reported by the CDC to have developed AIDS following blood transfusions. These observations were not without controversy and there was an acrimonious debate about the association between exposure to blood and blood products and the transmission of AIDS. (NG)

11 December 1982 - The Canada Diseases Weekly Report from LCDC published a report of a pilot study on AIDS in hemophilia patients in Quebec, by a team that included the Chairperson of the CHS's Medical and Scientific Advisory Committee (MSAC). (HWC)

13 January 1983 - A Joint Statement on AIDS and its possible relation to blood transfusion was developed and issued by the American Association of Blood Banks, the American Red Cross, and the Council of Community Blood Centers, with the assistance of the U.S. National Hemophilia Foundation, and other affected organizations. The Statement acknowledged that there was a possibility that AIDS could be transmitted through blood but said that the evidence for this was inconclusive. The Statement also considered the matter of surrogate testing of donated blood using non-specific markers such as hepatitis B virus antibodies, but stated: "We do not advise routine implementation of any laboratory screening program for AIDS by blood banks at this time". (HWC, CRCS)

14 January 1983 - The U.S. National Hemophilia Foundation issued recommendations for the prevention of AIDS in hemophiliacs. (HWC)

January 1983 (between the 14th and the 24th) - The Canadian Hemophilia Society (CHS) and Health and Welfare Canada organized a meeting to discuss similar recommendations for Canadian hemophiliacs. (HWC)

7 February 1983 - The CHS's Medical and Scientific Advisory Committee (MSAC) met with the Director of BOB and the Director General of LCDC. The department's representatives were

present specifically to advise MSAC on the development of recommendations similar to those issued three weeks earlier in the United States. (HWC)

8 February 1983 - The CHS issued a press release to announce the appointment of a special scientific panel to study AIDS, as a basis for the Society to assess its impact on hemophiliacs. The President of the CHS stated: "Canadian hemophiliacs can be assured of the fact that this situation will be closely monitored and that there is no need at this moment for any hemophiliac to consider any major changes, either in method of treatment or life style, unless so advised by his treating physician. Just as quickly as new information becomes available, it will be disseminated to hemophilia communities." (HWC)

17 February 1983 - The CHS circulated draft recommendations to all participants who attended the 7 February meeting. The draft recommendations were to be made final at the end of the month. The CHS also drafted recommendations to the Canadian Red Cross Society and the Canadian Blood Committee. (HWC)

March 1983 - The Baxter Company received a licence from the United States FDA for a Factor VIII product heat-treated for Hepatitis B virus. (HWC)

March 1983 - The CDC announced that anyone at risk of developing AIDS should exclude themselves from donating blood. (NG)

10 March 1983 - The Canadian Red Cross Blood Transfusion Service made a similar announcement about the self-exclusion of blood donors at risk. (NG)

May 1983 - Montagnier and his colleagues in France announced the discovery of a virus - called "LAV" - which they considered might be a causative agent of AIDS. (NG)

Fall 1983 - The Medical Research Council of Canada funded a national study of hemophiliacs to determine problems with their immune response following treatment with various kinds of Factor VIII. Between 1983 and 1987, when the study ended, the project provided a continuing mechanism for the surveillance of hemophiliacs in the context of the AIDS epidemic. (HWC)

23 November 1983 - The Baxter Company (also known in Canada as Hyland) received a Canadian licence to sell the first heat-treated Factor VIII preparation (for Hepatitis B) in Canada. (HWC)

April 1984 - The Canadian Red Cross first printed a donor brochure identifying individuals and groups at high risk for AIDS. (GR)

May 1984 - Implementation by the Canadian Red Cross of a pamphlet incorporating general health questions and AIDS symptoms and requesting donors to self-defer. (CRCS)

Spring 1984 - Health and Welfare Canada circulated a public-information pamphlet to alert the public to the risk of AIDS transmission through blood. (HWC)

May 1984 - Researchers in the United States announced in the journal Science the discovery of an AIDS-associated virus - called "HTLV-III" - which they said was a potential causative agent of the syndrome. In the same issue of Science, an assay to detect antibodies of the virus in blood serum of AIDS patients was described. (NG)

June 1984 - The United States Department of Commerce issued licences to five companies to begin production of HIV test kits. This is not, however, a licence to use the kits in the blood system. (HWC)

10 September 1984 - The CHS met with representatives of the major suppliers of Factor VIII to the Canadian market and raised serious concerns about the availability of heat-treated product in the United States and its apparent unavailability in Canada, and about the general shortage of supply of Factor VIII. (HWC)

29 September 1984 - The British medical journal The Lancet published a report on heat inactivation of a murine retrovirus, a virus affecting mice and related to HIV, in a blood product. (HWC)

26 October 1984 - The United States CDC confirmed that the AIDS virus experimentally added to Factor VIII concentrate could be inactivated through heat treatment. (HWC)

30 October 1984 - The Advisory Sub-Committee of the Canadian Blood Committee (CBC) met to discuss the issue of availability and quality of Factor VIII in Canada, an issue raised by the CHS representative, and recommended that a consensus conference on the need for heat-treated Factor VIII be held at the earliest opportunity. (HWC)

13 November 1984 - The Bureau of Biologics (BOB) at Health and Welfare Canada licensed Cutter Laboratories in the United States to produce heat-treated Factor VIII for Canada. (CRCS)

16 November 1984 - The BOB issued a directive for all Canadian coagulant products (such as Factor VIII) to be heat-treated as soon as possible. The BOB also recommended to the Canadian Red Cross Society that untreated coagulation products be replaced with heat-treated products as soon as possible. (HWC, CRCS)

26 November 1984 - Connaught Laboratories was advised that all Canadian fresh frozen blood plasma collected by the Canadian Red Cross would be sent to Cutter Laboratories for heat treatment, as of 1 December. (CRCS, HWC)

6 December 1984 - A letter from Dr. Chris Tsoukas and his co-workers was published in the New England Journal of Medicine reporting preliminary findings of a study on Canadian hemophiliacs. Their research suggested that 56% of hemophiliacs were seropositive for the AIDS virus. These findings were based on only 54 subjects and there was wide variation among subsets of the study group. (HWC)

10 December 1984 - A Consensus Conference on Heat-treated Factor VIII was convened by the Canadian Blood Committee (CBC) to discuss strategies for the implementation of the 16 November decision by BOB. All the major stakeholders in the blood system attended the Conference, including two representatives of the Canadian Hemophilia Society. The Conference made nine recommendations to the CBC on the implementation of the BOB decision. The Conference endorsed the introduction of heat-treated coagulation products by May 1985, with full replacement of existing products by July 1985. The Conference recommended that the use of heat-treated and non-heat-treated products during the transition period would be based on criteria to be developed by the Medical and Scientific Advisory Committee of the Canadian Hemophilia Society. (CRCS, HWC)

11 January 1985 - An announcement by the United States Public Health Service (PHS) required that, as of this date, all donated blood should be screened for HTLV-III (AIDS virus) antibodies, a requirement that was contingent upon approval of screening tests by the Food and Drug Administration. (NG)

25 January 1985 - The Red Cross reported to the Canadian Blood Committee on progress in implementing the decisions of the Consensus Conference. The first delivery of heat-treated product from Cutter Laboratories in the United States was expected in late April. (HWC)

February 1985 - The first test for screening blood for HTLV-III antibodies was approved for marketing by the Australian government. (NG)

18 February 1985 - The first two lots of heat-treated Factor VIII were received from Cutter for review by BOB. The review process normally takes 4 to 6 weeks. (HWC)

2 March 1985 - The Food and Drug Administration (FDA) in the United States approved the first commercial test for screening donated blood. Blood collection agencies in the United States announced their intention to begin screening for HIV as soon as possible. (NG, HWC)

7 March 1985 - A task group of the National Advisory Committee on AIDS (NAC-AIDS) in Canada recommends that the Red Cross prepare a plan for the implementation of HIV screening of donated blood. (HWC)

15 March 1985 - The first supply of heat-treated Factor VIII from Cutter was released by the BOB for sale in Canada. (HWC)

End of March 1985 - The U.S. Food and Drug Administration confirmed 99% implementation of blood screening for HIV antibodies. (HWC)

1 April 1985 - The first commercial ELISA test kit for AIDS virus antibodies in blood specimens went on sale in Canada. A second test kit went on sale on 18 April 1985. (HWC)

12 April 1985 - Health and Welfare Canada licensed a second manufacturer (Armour) to sell heat-treated Factor VIII in Canada. (HWC)

Mid-April 1985 - Blood-screening for HIV antibodies was fully implemented in Australia. (NG)

19-25 April 1985 - The Medical and Scientific Advisory Committee (MSAC) of the Canadian Hemophilia Society (CHS) met to address the issue of criteria for use of heat-treated coagulation products. The criteria developed by MSAC were approved by the CHS Board of Directors on 20 April 1985. On 25 April, the Chairman of the Board of Directors wrote to the Director of the Red Cross Blood Transfusion Service to inform him of the criteria to be used to give preference to individuals for heat-treated Factor VIII during the transitional period. (HWC)

End of April 1985 - Most American Red Cross centres were testing donated blood for AIDS virus antibodies. (GR)

1 May 1985 - The Canadian Red Cross plan for mass-testing of donated blood for HIV antibodies was submitted to the Laboratory Centre for Disease Control at Health and Welfare Canada, to NAC-AIDS, and to the Canadian Blood Committee. A 12-week implementation period is required after receipt of administrative and funding approval. This suggested a 1 August starting date for blood screening in Canada. (CRCS, HWC)

1 May 1985 - The Canadian Red Cross made available the first of its purchased supplies of heat-treated Factor VIII through its Blood Transfusion Centres. The criteria approved by the Canadian Hemophilia Society guided its distribution. (HWC)

5 June 1985 - The Canadian Blood Committee approved the Red Cross blood-screening plan in principle, subject to consultation with provincial ministries of health. Final approval of the plan was to be given by 30 June 1985. (HWC)

10 June 1985 - The Canadian Blood Committee informed the Red Cross that the blood-screening plan could not be given final approval until other issues "beyond the Red Cross national blood program" were dealt with. These issues were to be discussed with provincial authorities. (HWC)

1 July 1985 - The date by which the American Association of Blood Banks, the major blood-bank association in the United States, with more than 2,000 members including the American Red Cross, mandated that AIDS testing of blood be performed. (GR)

1 July 1985 - All Factor VIII concentrate available in Canada was now heat-treated to inactivate the AIDS virus. On 28 June, the Red Cross had advised Health and Welfare Canada that full conversion to heat-treated products would occur on 1 July. The Red Cross further advised that all non-heat-treated products would be withdrawn from use and that health-care facilities and patients would be advised to return inventories of such products. The Red Cross issued a press release to that effect on the same day. (NG, HWC)

July 1985 - A Consensus Meeting of provincial and territorial representatives took place in Ottawa and agreed that the Red Cross screening plan should be implemented by 14 October, if the Canadian Blood Committee approved the budget by 12 July. (HWC)

17 July 1985 - All Canadian Blood Committee members but one - Ontario - approved the Red Cross screening plan. (HWC)

1 August 1985 - Ontario approved the Red Cross screening plan, allowing the Canadian Blood Committee to inform the Red Cross that their plan for HIV-antibody screening of donated blood had received budget approval. (CRCS, HWC)

Summer 1985 - Some Red Cross Blood Transfusion Service (BTS) Centres began to screen blood for AIDS-virus antibodies. (HWC)

1 November 1985 - All blood donations in Canada were being screened for AIDS-virus antibodies, and a network of alternate test sites for diagnostic services was also in place. (NG, HWC)

APPENDIX C

List of witnesses

Associations and Individuals	Issue	Date
BC Centre for Excellence in HIV AIDS	23	March 11, 1993
Michael O'Shaughnessy, Director.		
Canadian Blood Agency	19	February 4, 1993
William Dobson, Executive Director.		
Canadian Red Cross Society	24	March 18, 1993
Maung T. Aye, National Director, Blood Services;		
Stephen Vick, Assistant National Director, Manufacturing and Development;		
Roslyn Herst, Medical Director, Toronto Blood Centre;		
Francine Décary, Medical Director, Montreal Blood Centre.		
George Weber, Secretary General and Chief Executive Officer;	17	November 26, 1992
M.T. Aye, National Director, Blood Services;		
Stephen Vick, Assistant National Director, Manufacturing and Development;		
Roslyn Herst, Medical Director, Toronto Blood Centre.		
Canadian Hematology Society	26	April 1, 1993
Dr Peter Pinkerton		
Canadian Hemophilia Society	18	December 18, 1992
David Page, President;		
Lindee David, Interim Executive Director;		
John Plater, President, Hemophilia Ontario.		
Department of Health and Welfare Canada	25	March 25, 1993
Dr. W. Boucher, Acting Director, Bureau of Biologics;		
Janice Hopkins, Executive Director, Health Protection Branch.		

Associations and Individuals	Issue	Date
HIVT Group Rochelle Pittman, Representative; Marlene Freise, Representative; Pierre Desmarais, Representative; Robert St. Pierre, Coordinator; Jerald Freise, Representative.	17	November 26, 1992
Kent, Joan Individual.	21	February 18, 1993
Krassnitzky, Olaf Individual.	24	March 18, 1993
McGill Centre for Medicine, Ethics and Law Norbert Gilmore.	20	February 11, 1993
Perrault, Roger Individual.	22	February 25, 1993
Rock, Gail Individual.	20	February 11, 1993
University of Calgary John R. McDonald.	21	February 18, 1993
University of Montreal, Faculty of Pharmacy Denise Leclerc, Dean.	22	February 25, 1993
Waines, Rick; **Waines, Terry;** Individuals.	18	December 3, 1992

Request for Government Response

Your Committee requests that the Government table a comprehensive response to this report.

A copy of the relevant Minutes of Proceedings and Evidence (*Issue No. 19, which includes this report*) is tabled.

Respectfully submitted,

BARBARA GREENE,
Chair.

Minutes of Proceedings

THURSDAY, MAY 13, 1993
(25)

[Text]

The Standing Committee on Health and Welfare, Social Affairs, Seniors and the Status of Women met *in camera* at 10:10 o'clock a.m. this day, in Room 307, West Block, the Chair, Barbara Greene, presiding.

Members of the Committee present: Edna Anderson, Barbara Greene, Jim Karpoff, Rey Pagtakhan and Stan Wilbee.

Acting Members present: Mary Clancy for David Walker and Bruce Halliday for Jean-Luc Joncas.

In attendance: *From the Research Branch of the Library of Parliament*: Odette Madore and Tom Curren, Research Officers.

The Committee proceeded to the consideration of the Third Report of the Sub-Committee on Health Issues.

It was agreed,—That the Committee ask the Chair to present the Third Report of the Sub-Committee on Health Issues as the Sixth Report to the Standing Committee to the House of Commons.

It was agreed,—That pursuant to Standing Order 109, the Committee request that the Government table a comprehensive response to this Report.

It was agreed,—That, notwithstanding Standing Order 109, the Committee request that the Government table the comprehensive response within 30 days.

It was agreed,—That the Committee print 3,000 copies of this Report, in tumble bilingual format, with a distinctive cover page.

It was agreed,—That the Committee approve the transfer of $362.97 from its approved budget for the payment of working lunches on behalf of the Sub-Committee on Senior Citizen Health Issues during the study of its report.

It was moved,—That the Committee approve the transfer of $1664.84 from its approved travel budget for the purpose of sending the senior analyst, Marion Wrobel, of the Sub-Committee on Poverty to meet with Officials in Toronto and Fredericton in relation to Social Services and Food Banks.

After debate, the question being put on the motion, the result of the vote was announced: Yeas: 3; Nays: 3.

Whereupon the Chair voted in the affirmative.

Accordingly, the motion was agreed to.

At 10:32 o'clock a. m., the Committee adjourned to the call of the Chair.

Eugene Morawski
Clerk of the Committee