THE CANADIAN BLOOD DELIVERY SYSTEM: LIABILITY FOR BLOOD RELATED INJURIES

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I. INTRODUCTION

In early 1988 I undertook an examination of the rules with regard to liability for injuries caused by blood.** I anticipated that such a study would be brief and straightforward. I assumed that it would be easy to identify a significant volume of reported Canadian cases dealing with liability for blood related injuries and assumed that there would be a number, perhaps many, learned articles written by Canadian scholars on the subject. This proved not to be the case. Such a study was timely, as blood products had been implicated in transmission of the virus that results in "Acquired Immune Deficiency Syndrome" (AIDS). The Canadian manufacturer of blood products, Connaught Laboratories, had recently withdrawn from blood products manufacturing, citing liability fears as a major determinant of its decision.

My original assumption that the question of legal liability for blood products could be outlined simply and by reference to existing and classic tort doctrines proved to be seriously mistaken. Rather, it became clear that an understanding of the Canadian blood industry would be necessary, and that the rules concerning liability for blood products touched on broader questions of Canadian health policy, federal-provincial relations and international trade policy. This study is the result.

II. A HISTORY AND DESCRIPTION OF THE CANADIAN BLOOD DELIVERY SYSTEM

The Canadian Red Cross Society was established by Federal Charter in 1909 and has operated since that time as a charitable institution. During the Second World War it assumed responsibility for

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the collection of blood for the Canadian Armed Forces.[1] Whole blood was collected from volunteer donors. The Canadian Red Cross supplied more than one million bottles of blood in 1943 alone.

Prior to the War, each Canadian hospital had collected the blood required to meet its needs on an independent basis. After the War, the existence of a corporation with a proven ability to supply blood needs resulted in requests from several provincial Ministries of Health and from a number of hospital associations that the Canadian Red Cross continue to operate a collection service that would provide the transfusion needs of civilian and military hospitals.

Dr W.S. Stanbury was asked to prepare a study of the needs of Canadian hospitals. In 1945 he reported to a joint committee of the Canadian Hospital Council, the National Research Council and the Red Cross Society. That report resulted in identification of the mandate under which the Canadian Red Cross continues to operate today: that the Red Cross should supply blood and blood products, free-of-charge, to all Canadian hospitals.[2]

The recommendation of Dr Stanbury's report was that the Canadian Red Cross provide whole blood and dried plasma, as well as necessary supportive equipment, to any hospital that would provide blood and blood products without charge to patients. It was anticipated that the provision of these services would be in cooperation with provincial departments of health. These departments would be expected to supply laboratories as well as the financing to maintain them. The Canadian Red Cross would provide the necessary equipment, expertise, personnel and transport facilities, as well as management and organization from a central headquarters in Toronto. Services would be provided through a series of regional locations, preferably associated with medical schools across the country. Dr Stanbury's plan received the endorsement of the Central Council of the Canadian Red Cross and of the Canadian Medical Association. The first regional centre was opened in British Columbia in 1947. The service provided by the Canadian Red Cross has continued since that time, although it was not until 1961 that every province had at least one regional centre.[3]

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[1] W.S. Stanbury, ORIGIN, DEVELOPMENT AND FUTURE OF THE CANADIAN RED CROSS BLOOD TRANSFUSION SERVICE (Toronto: Canadian Red Cross Society, 1961).

[2] W.S. Stanbury, THE CANADIAN RED CROSS SOCIETY: SURVEY OF BLOOD TRANSFUSION FACILITIES IN CANADIAN HOSPITALS AND PROPOSED PLAN FOR A CANADIAN NATIONAL BLOOD TRANSFUSION SERVICE (Toronto: Canadian Red Cross Society, 1945).

[3] Regional distribution centres are located as follows: British Columbia and the Yukon (Vancouver), Northern Alberta and the Northwest Territories (Edmonton), Southern Alberta and Southeastern British Columbia (Calgary), Saskatchewan (Regina and Saskatoon), Manitoba and Northwestern Ontario (Winnipeg), Ontario (London, Hamilton, Toronto, Sudbury, Ottawa), Quebec (Montreal, Quebec City), New Brunswick (St John), Nova Scotia (Halifax), Prince Edward Island (Charlottetown), Newfoundland and Labrador (St John's).

Dr Stanbury's report on the design of a Canadian blood service appeared at the same time as other fundamental organizational initiatives in the structure of the Canadian health care system.[4] His involvement in all of the aspects of planning a Canadian health care delivery system ensured that there would be a unity of purpose and of planning between the provision of hospital services and provision of blood products. The determination that blood products would be provided without cost to persons in need embodied, for the purposes of that sector, the fundamental policy determination that Canadians would be entitled to health care services regardless of financial ability. This decision has profoundly influenced the direction of the Canadian health care system to this day and has equally shaped the profile of the Canadian blood delivery system. Canadian health care policy objectives must be kept in mind in any assessment of the blood delivery system.

During the Second World War, blood products processing, specifically the process of drying plasma for the Canadian Armed Forces, was carried out by the Canadian Red Cross in concert with the Connaught Medical Research Laboratories, then associated with the University of Toronto. After the War, this collaborative arrangement between Connaught Laboratories and the Canadian Red Cross continued. In 1954, Connaught Laboratories built a blood fractionation plant. From that time the use of blood fractions began to replace the use of dried plasma. Manipulation of whole blood products to produce blood fractions continues to be central to the issue of the role of the Canadian Red Cross and to corporate and institutional issues relating to production and liability within the Canadian blood distribution system.

The increasing complexity of the Canadian blood delivery system has required increasingly sophisticated financing arrangements. Prior to the War, the blood distribution service provided by the Canadian Red Cross was financed largely through the charitable monies of the Canadian Red Cross itself. The value of the time donated by its volunteers was also significant. However, the growing complexity of the transfusion distribution network as well as the growing sophistication of blood products and the manipulation required to produce these blood products was such that more and more of the financial resources of the transfusion service have come from the federal and provincial governments. With this increased financial commitment at the government level has come increased government participation through the Federal-Provincial Canadian Blood Committee, first established in 1981. The complex issues of public policy that surround the distribution of blood products, in addition to the significant infusion

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[4] For example, in 1948 the introduction of the National Health Grant Program involving cost-sharing grants to the provinces for a number of health care initiatives, particularly hospital construction and in 1957, the *Hospital Insurance and Diagnostic Services Act*, R.S.C. 1970, c. H-8, *as am.* S.C. 1976-77, c. 10, s. 51, rep. S.C. 1984, c. 6, s. 32.

of federal and provincial tax dollars, argue for the continuation of federal-provincial involvement at both policy and funding levels.

Access to blood and blood products by persons in need touches fundamental chords within us all. The donation of blood can easily be understood as perhaps the quintessential gift. Access to blood on the basis of need, rather than on the basis of ability to pay is perhaps a fair indicator of a nation's social attitudes. Thus, the sale of blood products is heavily imbued with social significance. The sale of freely donated blood products is equally socially contentious. Profit-taking, an issue that should be regarded as separate from that of sale of the components themselves, is also contentious. The possible exploitation of disadvantaged populations, or of disadvantaged nations by wealthy ones raises concerns of a fundamental nature. Some of these have an impact on liability issues. All must be taken into account in considering the design of the Canadian blood delivery system.

Titmuss, in his book THE GIFT RELATIONSHIP,[5] a book which has had a profound impact on thinking about blood distribution systems, argues that the voluntary nature of a blood distribution system has a positive impact upon blood quality and therefore has a potential impact upon liability issues. While his argument has been the subject of some disagreement,[6] the voluntary rather than remunerated nature of a blood distribution network is of significance to this study. Finally, the changing nature of the production of blood products will also have an impact on blood distribution networks and liability issues. These issues are, of course, exacerbated by the public response to the threat of transmission of AIDS through the transfusion of blood products. This response, and the response of blood fractionators to the threat, is part of the larger response to the threat of AIDS itself, as well as to the known common methods of infection.

Several international bodies have endorsed the principle of a voluntary, gratuitous blood distribution system. The World Health Organization, at its twenty-eighth assembly in May 1975, endorsed the principle of voluntary blood donation[7] as did the International Society of Blood Transfusion.[8] Similar resolutions were passed by the Board of Governors of the League of the Red Cross[9] and the International Conference of the Red Cross.[10] Domestically, the principle of volunteerism was endorsed by the provincial Ministers of Health at a

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[5] R.M. Titmuss, THE GIFT RELATIONSHIP; FROM HUMAN BLOOD TO SOCIAL POLICY (New York: Vintage Books, 1972).

[6] *See, e.g.*, R.A. Kessel, *Transfused Blood, Serum Hepatitis, and the Coase Theorem* (1974) 17 J. OF LAW & ECONOMICS 265.

[7] Thirteenth plenary meeting, 29 May 1975, Geneva.

[8] XIVth Congress of the International Society of Blood Transfusion, 30 July 1975, Helsinki.

[9] Resolution No. 20, October 1977, Bucharest.

[10] Twenty-third International Conference of the Red Cross, October 1977, Bucharest.

conference held in Charlottetown in 1973[11] and affirmed by the federal Minister of Health in 1976.

III. The Current Structure of the Red Cross Blood Distribution System

The organization of the Canadian Red Cross reflects its charitable origins, which date back to 1909. At the head of its corporate structure is the national office, recently relocated from Toronto to Ottawa. There are ten provincial divisions. The management boards of both the national and provincial offices are run by volunteer members. The transfusion service is the largest program run by the Canadian Red Cross, but is far from the only program. Each provincial division is responsible for its own donor recruitment as well as for enlisting the aid of volunteers to staff donor clinics.

Following the 1945 Report which established a volunteer donor system for all of Canada, organized and provided by the Canadian Red Cross, Connaught Laboratories continued to provide the greatest part of plasma processing. In 1954 Connaught Laboratories built the first Canadian fractionation plant at the Dufferin Division at the University of Toronto. Connaught continued to provide processing for the bulk of Canadian blood plasma for the Canadian Red Cross.

In the early 1970s several events combined to create increasing disquiet about the ability of Connaught Laboratories to meet the needs of the Canadian blood transfusion system. The concerns that these events generated raise issues that persist to this day. It is possible that they persist because they have never been fully or successfully addressed.

In 1972 Connaught Laboratories was purchased from the University of Toronto by the Canadian Development Corporation. The sale resulted in part because the University of Toronto had realized that a large capital investment would be needed to improve the existing Connaught facilities. Both the construction of new buildings and renovation of existing structures would be required. Prior to the sale, the Government of Ontario had declined to finance the necessary improvements. It is significant to later conflict that the objectives of the Canadian Development Corporation at that time were to develop and maintain Canadian control in the private sector, to widen investment opportunities for Canadians and to operate at a *profit* in the interests of shareholders.

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[11] Final Communique of the Conference of Provincial Health Ministers, 2 September 1973, Charlottetown: "The continued capability of the Canadian Red Cross to supply enough whole blood and blood products for Canadians was discussed. The ministers recognized the essential services provided by the Red Cross through its voluntary donor system. The ministers were unanimous in their wish to increase their financial support, including assistance from the federal government, to the Red Cross organization to strengthen the voluntary blood donor service."

At the same time, the Canadian Haematology Society had undertaken a study of the Canadian blood transfusion system, arising out of the Society's concerns with the shortcomings of that system as it had developed. The terms of reference of the study required the Committee to study the needs for blood and blood products, to examine the capability of the existing system to meet those needs, to identify the causes of any discrepancies between those needs and existing capabilities of the Canadian Red Cross and to propose specific recommendations to remedy any perceived difficulties.

The first major impulse for modernization and reorganization of the Canadian blood distribution system came as a result of the report of the Canadian Haematology Society. This report was submitted in 1973 to the eleven Ministers of Health and to the Canadian Red Cross. It identified a deteriorating technical ability in Connaught Laboratories and in the Red Cross, and an inability of the Red Cross to meet the increasing financial demands placed on it by the increased use of transfusion therapy and by the increasing sophistication of that therapy.

A full examination of the management and use of Canada's blood resources was called for to ensure that optimal use was being made of all blood collected. Concern was also expressed as to the level of importation of commercial blood products from outside of Canada and increasing encroachment of commercial blood product manufacturers within Canada, with a resulting impact on the gratuitous donor system of the Canadian Red Cross. The report identified a significant level of blood imports to the Canadian market, particularly from the United States. The continuing availability of blood products from that country was questioned by the Haematology Society Committee. The Committee was particularly concerned that increased social welfare benefits might make blood and blood fractions financially accessible to more Americans, thereby increasing demand within that country and decreasing available blood stocks for export purposes. It is important to note that this concern was with United States source products and not Canadian blood processed in the United States.

The Committee had concluded that there were deficiencies in both intake and distribution of blood, in collection and processing of blood group antisera, in the production and distribution of Coomb's serum and in the production of a full complement of plasma fractions that were of essential clinical value. Problems occurred in both the fresh product and in the processed product. A suggestion was made that production facilities at the fractionation plant be increased as necessary. The creation of a new or second plant was suggested in the event that the plant in existence "cannot meet the challenge and/or if more than one plant is deemed advisable for the population at risk".[12] The Committee concluded that the Red Cross was a valuable structure,

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[12] THE BLOOD RESOURCES OF CANADA: FOUR-YEAR FOLLOW-UP TO THE CANADIAN HAEMATOLOGY SOCIETY REPORT (Toronto: Canadian Red Cross Society, 1977) at 8.

whose major objective should be to supply the total need for blood and blood products, while not necessarily producing all products. In the view of the Committee, an adequate donor pool was available, but the Canadian Red Cross service was not sufficient to prevent significant purchase of both therapeutic plasma fractions and diagnostic reagents from commercial sources located at that time both within and outside Canada. The estimated cost of this in the year 1971 was $2.5 million. The Committee identified the lack of inventory control by the Red Cross and the failure to provide satisfactory arrangements for plasma fraction production as serious problems.

As a result of this report, government funding of the blood transfusion system was increased to one hundred percent.[13] It was agreed that the federal government, in consultation with provincial health authorities, would evaluate the budget of the Red Cross' blood transfusion and donor recruitment programs and would approve the budget of these services to be provided on a cost-sharing basis. A federal-provincial program and budget review committee was established to perform this function.

Between the years 1973, the year of the Haematology Society Report, and 1977, the budget of the blood transfusion system was increased from $5 million to $30 million.[14] Three million dollars was spent on the acquisition of major production items for the Canadian Red Cross transfusion system. Full government funding continues to this day.

The Canadian Red Cross received permission and funding from the federal and provincial governments to conduct a study of Canadian fractionation and fractionation capabilities. Dr John Watt of the Scottish National Blood Transfusion Service was retained to undertake a study of Canadian needs and existing abilities. His report, while complimentary to various senior staff in the Canadian blood fractionation industry, whether public or private, was highly condemnatory of all parties then engaged in producing blood fractions in Canada. Watt inspected the Connaught fractionation plant and expressed his disappointment with it. He also commented on the poor quality of plasma delivered by the Red Cross for fractionation on at least the occasion of his site visit. He concluded with regard to the Connaught facility: "I found it disappointing to discover that [capable senior staff] had been so poorly equipped and suffered so obviously from lack of realistic capital investment."[15]

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[13] After receipt of the report of the Canadian Haematology Society, Red Cross officials met with representatives of the federal and provincial governments to request that funding for the blood transfusion system be increased from 90 to 100 percent and that funding for the donor recruitment program be increased from 30 to 80 percent over a three-year period. This was agreed at the December 1973 Conference of Deputy Ministers of Health.

[14] *Supra*, note 12 at 16.

[15] J.G. Watt, PROPOSALS FOR PLASMA FRACTIONATION IN CANADA, presented to the Canadian Red Cross Society Blood Transfusion Service, February 1976 at 5.011.

Canada's second fractionation facility, the Winnipeg Rh Institute associated with the University of Manitoba, was described as "grossly overcrowded and is not . . . a suitable place for the production of clinical fractions by any method. . .".[16] The method employed by the Rh Institute was described as "[a] fine example of a medical solution to a problem which properly belongs in the field of chemical engineering."[17] A paid plasmapheresis session was described as crowded, noisy and confused. Dr Watt was critical of the paid nature of the plasmapheresis operation and suggested that even the peripheral involvement with a commercial approach to plasmapheresis by allowing its location on Red Cross premises was inappropriate to an organization that held itself out as providing and supporting a gratuitous system of blood donation.[18]

The Institut Armand-Frappier of Montreal fared no better. While the Institut was apparently interested in entering the plasma fractionation field, Dr Watt reported that the director of the Institut made a "fragmented statement", indicating that the possibilities had not been thoroughly explored. Dr Watt also concluded that the Institut was interested in sharing in the profit that it perceived Connaught had made as a result of its relationship with the Canadian Red Cross. A later review of the plans provided by the Institut as to possible use in the construction of a new fractionation facility led Dr Watt to conclude that the plans were "almost exact copies of the type of centre being constructed in the United States around 1947. . .".[19] He concluded: "The most disturbing feature of this meeting was the obvious lack of knowledge of the real problems and need for plasma fractions. The opinions expressed on order of priorities were those one might have expected to hear in 1955 but no later. There is no way that the Blood Transfusion Service would gain scientific advantage by direct partnership with the Institute."[20]

Dr Watt concluded his report by commenting on the relationship between Connaught and the Red Cross. Noting the difficulty of unravelling the relationship and the lack of a written record of it, he commented upon the change that might have been effected by the altered status of Connaught Laboratories, purchased by the Canadian Development Corporation in 1972. He noted the likelihood that the relationship had its historical origin in a mutual self-help arrangement "founded on the need to respond to the emergency situation occurring in time of war and to have proceeded by a series of ad hoc temporary arrangements. . .".[21] He noted that, in 1974, Connaught profited from

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[16] *Ibid.* at 5.012.
[17] *Ibid.*
[18] *Ibid.*
[19] *Ibid.* at 5.013.
[20] *Ibid.*
[21] *Ibid.* at 5.03.

the export of $225,597 in immune serum globulin.[22] He added that "in 1974 when the blood transfusion service was clamouring for increased supplies of albumin it was also possible for Canada to make a bulk sale of albumin amounting to $35,455.70".[23] Part of the shortfall, he reported, was made up by individual hospitals making purchases from commercial suppliers for importation into Canada.

Dr Watt concluded that "the Canadian Blood Transfusion Service, in pursuance of a policy of national self-sufficiency in respect to blood and its fractions, should maintain the whole process of supply from the donor organisation through the taking and processing of blood to the supply of all fractions to the clinical services".[24] Connaught, the Rh Institute and Institut Armand-Frappier all were rejected as long-term suppliers. Nor did Dr Watt recommend purchase of their substantially outdated facilities. Today, this same issue is again the subject of study by the Canadian Blood Committee following the 1987 decision of Connaught Laboratories to withdraw from the fractionation field.[25]

Following the Watt report, and the more detailed study of plant design prepared for the Canadian Red Cross by Surveyor, Nenninger & Chenevert Corporation, the provincial governments decided that the Canadian Red Cross would not become directly involved in plasma fractionation.[26] Having so decided, the provincial governments appointed an Interprovincial Ad Hoc Committee on plasma fractionation (the Dr Chapin Key Committee). In its report to the provincial Ministers of Health, that Committee recommended that at least two separate plasma fractionation plants should be built in Canada, despite the associated financial penalty of establishing two or more smaller plants.

At the last moment Quebec suggested the inclusion of a third facility at the Rh Institute in Winnipeg. Connaught, the Rh Institute and the Institut Armand-Frappier were all to be expanded and modernized, and to provide plasma fractionation on a non-profit basis, and with the financial support of their various provincial governments.[27] These fractionators were required to be non-profit in nature:

> [A]ny charge to recover more than the real costs of producing a blood fractionation product for Canadians in Canada should be considered profit. Savings due to economies of scale from the importation and subsequent processing of additional raw blood materials should be reflected in lower production costs of Canadian products. . .[i]n the event that any labora-

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[22] *Ibid. See also* J. MacAnthony, "Blood Money: What Red Cross Donors Didn't Know", *McLean's Magazine*, Vol. 89, no. 23 (27 December 1976) at 40.

[23] Watt, *ibid.* at 5.03.

[24] *Ibid.* at 6.00.

[25] *See* below Part VIII.

[26] Conference of Deputy Ministers of Health, March 1979; confirmed at Interprovincial Conference of Ministers of Health, September 1980.

[27] *Report to the Provincial Ministers of Health by the Interprovincial Ad Hoc Committee on Plasma Fractionation*, November 1980 at 20.

> tory is unable or unwilling to accept this principle, steps should be taken to ensure non-profit prices to the provinces through subsidies or other actions by the host province.[28]

Should the impact of this policy have resulted in Connaught suffering a net loss of income, the Ad Hoc Committee recommended that "[any] loss of profit for Connaught not adequately compensated by custom fractionation of foreign plasma be a matter of discussion between the company and the government of Ontario."[29] Ontario dissented from the endorsement of a non-profit policy. An additional five percent was promised to Connaught for investment in research and development.

What motivated this decision which directly declined to follow the recommendations of the Watt report prepared for the Canadian Red Cross? By 1981, Canada was committed to a non-profit Canadian fractionation industry utilizing the capacities of the three existing Canadian facilities. These facilities were conveniently located at appropriate geographic locations: Quebec, Ontario and in the West. Funding for expansion would come, at least in part, from federal and provincial governments.

In 1983, it was finally agreed at a conference of the Ministers of Health that this funding would equal fifty percent of capital costs and seventy-five percent of development costs. No existing facility would be excluded. The principle of non-profit gratuitous distribution of blood products had been confirmed. However, certain economies of scale had clearly been sacrificed to other concerns, including security of supply should any one plant experience significant technical difficulties or in the event of political uncertainties.

The Ad Hoc Committee had concluded that while the most economical solution would be to establish one fractionation plant, that conclusion had to be compromised "in view of the interest among several provinces in developing expertise in fractionation and, more importantly, to offer better assurance of supply and improved ability to adapt to new technology".[30] They reached this conclusion, as they say "[f]rom a technological development, assurance of supply and a political point of view. . .".[31]

At the same time, the Inter-Provincial Ad Hoc Committee on a Canadian Authority on Blood Policy recommended a permanent overview authority be established.[32] The Ad Hoc Committee contemplated the establishment of a central authority to direct, co-ordinate, monitor and evaluate the various activities of the organizations involved in the Canadian blood system. It was envisaged that such a central authority

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[28] *Ibid.* at 60-61.
[29] *Ibid.* at 70.
[30] *Ibid.*
[31] *Ibid.*
[32] *Report to the Provincial Ministers of Health by the Interprovincial Ad Hoc Committee on a Canadian Authority on Blood Policy*, September 1981.

would be accountable to the various Ministers of Health while co-ordinating the development of the Canadian blood delivery system in accordance with the principles adopted by the Ministers of Health. The Committee would be charged to direct, co-ordinate, monitor and evaluate the implementation of the fractionation decisions made by the Ministers in 1980. The Canadian Blood Committee was established to serve this function.

The Canadian Blood Committee first met in December 1981. A draft document entitled *The Canadian Blood Policy*, written by the Canadian Blood Committee in consultation with the various interested parties in the Canadian blood delivery system, was circulated for comment in December 1987.

By 1987, the Institut Armand-Frappier had made no move towards establishing a capability in blood fractionation. The Rh Institute had yet to be licensed to produce the blood fractions (factor VIII, factor IX, albumin and gamma globulin) that they were interested in producing. There was some indication in 1985 that Connaught's plant and facilities were now so out of date that the Bureau of Biologics, the licensing authority of the federal government under the *Food and Drugs Act*, was threatening to withdraw Connaught's licence to produce fractions.

In 1985, the insurance carrier for the Canadian Red Cross informed that organization that it wished to exclude AIDS-related injury and other elements of the blood program of the Red Cross from coverage. Apparently fearful of liability implications, Connaught, which had continued to fractionate blood products for the Canadian Red Cross, ceased processing stored plasma and refused to release existing blood fractions to the Red Cross for distribution. In 1986, the Red Cross, unable to find adequate insurance coverage at a reasonable cost, determined to self-insure and considered divesting itself of its assets. Connaught refused to provide continuing plasma fractionation unless indemnified by the Red Cross and the various governments against all liability.

While various offers were made to satisfy Connaught, none was acceptable to the company. Finally, in June 1987, Connaught Laboratories informed the Canadian Blood Committee of its decision not to invest in a new fractionation facility. The decision was based on the failure of the interested parties to provide Connaught with protection against liability for blood products and the fast changing biotechnology that was likely to affect seriously blood products and make investment decisions exceedingly difficult.

Following that decision by Connaught, the Canadian Blood Committee determined to impose a moratorium on investment in fractionation facilities in implementation of the 1981 decision and to review again the future of fractionation of blood in Canada. Fractionation by Connaught was phased out over a period of some six months and contracts for fractionation of Canadian plasma were arranged with private profit-oriented organizations in the United States at a substantial

dollar saving in the cost of the service. The Canadian Blood Committee reported to the federal and provincial Ministers of Health in the fall of 1988 with a recommendation as to the future course of blood fractionation in Canada. This recommendation has not yet been made public.

The technology has changed significantly in the intervening seven years. The threat of AIDS transmission has replaced the threat of hepatitis transmission as a major health concern. The predictions as to the impact of biotechnology on production of synthetic blood components are that there are profound changes coming in the next decade in the blood industry. Nonetheless, the question that the Canadian Blood Committee must review and that the Ministers of Health must decide is virtually the same as that decided by the Ministers of Health seven years earlier.

IV. Blood Products and Regulatory Control

The increasing sophistication of medical procedures and technologies has resulted in significant increases in the use of blood products since the War. Increased understanding of the human immunological system has led to a better understanding of the components of blood therapy and an increased ability to provide advanced therapies. Advances in transfusion techniques have resulted in changes in blood therapy, requiring plasma fractions, apheresis and the use of sophisticated cell separator technologies.

Blood is a fluid made up of a complex mix of specialized cells, including white cells, red cells and platelets, as well as special proteins and other molecules. This complex liquid performs many functions within the human body, some of which determine the therapeutic uses to which blood fractions are currently put. Blood is a transporter of oxygen and other nutrients to body tissues, and provides for the removal of carbon dioxide and other body wastes, the transfer of hormone messages between organs, prevention of bleeding, and the transport of antibodies and infection-fighting cells to infected sites. Modern blood therapy requires the separation of blood into its component parts and plasma. Plasma constitutes the liquid portion of whole blood, after the removal of the cellular elements, but with blood proteins still intact. Today the transfusion of whole blood is rarely indicated.

The separation of plasma into its component proteins is the key to modern transfusion therapy. This process is known as plasma fractionation. These parts may be further concentrated into plasma derivatives providing for concentrated proteins. The use of blood components is essential to modern transfusion therapy. Blood is a major body organ and the introduction of a foreign organ into a recipient has a major impact on that person. Certain blood components are antigenic and can cause immunization. Other components are

therapeutic, but exist in quantities such that their therapeutic effect can only be realized by providing concentrated specific components.

For example, haemophiliacs lack factor VIII. Sufficient factor VIII could be provided to allow for major surgery upon an individual suffering from haemophilia by transfusing approximately ten litres of fresh plasma for several days both pre- and post-operatively. The ability to provide only the blood component that the patient needs, in this case factor VIII, reduces the risks to the patient. It also allows for a significantly more efficient use of donated blood.

Plasma for fractionation can be obtained in several ways. Almost any plasma can be fractionated. Not all plasma can be processed so as to yield all blood fractions. Certain plasma fractions require that the plasma be specially treated prior to fractionation. Some require the introduction of special anti-coagulants prior to fractionation.

The plasma fractions most in demand include albumin, several forms and types of immunoglobulin and the antihaemophiliac factors (factors VIII and IX). Current technology allows whole blood for transfusion to be stored for a period of up to 35 days at +4 degrees Celsius. After expiry of its shelf life it can be fractionated to provide certain of the less labile factors such as albumin and non-specific immunoglobulins. Outdated blood cannot be used to produce factors such as factor VIII.

The more labile factors must be made from plasma that has been separated from cell components shortly after collection or which has been stored frozen and fractionated shortly after thawing. Stored plasma may be kept at +4 degrees Celsius for a maximum of 35 days or for 12 months at −20 degrees Celsius or 24 months at −30 degrees Celsius. Frozen plasma may be used for the preparation of the particularly labile factors. It may be kept at −30 degrees Celsius for twelve months or at −20 degrees Celsius for three months. Certain fractions require that the plasma be frozen as a first stage in the concentration process.

Plasma for fractionation must be processed in batches, therefore one contaminated donation will contaminate the entire batch. Plasma may be obtained through the traditional donation of whole blood or by the process of plasmapheresis, whereby the red cell concentrates are returned to the donor at the time of donation. The use of plasma fractions from pooled plasma raises the possibility of transmission of viral diseases, particularly hepatitis B, non-A non-B hepatitis and AIDS.

All plasma collected for preparation of factors by the Canadian Red Cross has been tested at the time of collection for hepatitis B through the use of enzyme-linked immunoassay and for AIDS antibodies by enzyme-linked immunoassay (ELISA test) and the Western Blot confirmatory test. Plasma will not be used unless it has been found negative for both hepatitis B and the HIV virus associated with AIDS. In addition, plasma fractions are heat-treated to inactivate the HIV virus, should it be present. Certain plasma fractions, particularly

albumin, can be treated for hepatitis and AIDS virus with greater certainty than can others. The Canadian Red Cross points out that certain plasma fractions supplied by it, particularly factor VIII, may be fractionated for the Canadian Red Cross from volunteer donor plasma that the Red Cross has collected or may be purchased commercially when the supply of Canadian plasma is insufficient to meet clinical needs.[33]

Regulatory control over blood and blood fractions is primarily provided by the *Food and Drugs Act*[34] under the jurisdiction of the federal Minister of National Health and Welfare. That *Act* defines a drug as including any substance manufactured, sold or represented for use in:

> (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or symptoms thereof, in man or animal,
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> (b) restoring, correcting or modifying organic functions in man or animal, or
>
> (c) disinfection in premises in which food is manufactured, prepared or kept. . . .[35]

The *Act* further provides that the term "sell" includes "offer for sale, expose for sale, have in possession for sale and distribute whether or not the distribution is made for consideration".[36] Clearly then, *all blood products fall within the definition of a drug*. Furthermore, any distribution of blood and blood products by the Canadian Red Cross will be characterized as a sale regardless of the gratuitous nature of the distribution. This latter point may have implications for the nature of the liability to be imposed where injury is caused by blood or a blood product under provincial Sale of Goods Acts. The issue as to whether the distribution of blood and blood products constitutes a sale or a service has been one of continuing controversy in the United States, where the impact of the characterization of the transaction, even when for consideration, has been highly contentious.

Section 2 defines a "device" as:

> any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in

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[33] CLINICAL GUIDE TO TRANSFUSION: PRODUCTS AND PRACTICES (Ottawa: Canadian Red Cross Society Blood Services, 1987) at 18.

[34] R.S.C. 1985, c. F-27, *as am.* S.C. 1985, c. 19, ss. 193-96; S.C. 1985, c. 26, s. 12; S.C. 1987, c. 33, ss. 1 & 2; S.C. 1988, c. 51, ss. 9-12.

[35] R.S.C. 1985, c. F-27, s. 2.

[36] R.S.C. 1985, c. F-27, s. 2.

> (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms thereof, in man or animal,
>
> (b) restoring, correcting or modifying a body function or the body structure of man or animal. . . .[37]

Mechanisms for the transfusion of blood are therefore governed as devices under the *Food and Drugs Act*. The *Act* itself is deceptively simple. The true scope and application of the *Act* can be found only in the schedules, tables and regulations attached to it.

Blood and blood products are regulated in a rather perplexing fashion under the *Act*. This is in part a result of the historically charitable nature of the Canadian blood distribution system, originating in the Canadian Red Cross. While all whole blood and blood products are governed by the general definition of "drug" found in the *Act*, only certain blood products ("blood derivatives") are subject to special regulation under Schedule D. An amendment[38] to the *Food and Drugs Act* has added "blood" to Schedule D in addition to "blood derivatives" which were there previously. This has resulted in the requirement that all blood and not only blood derivatives be prepared in licensed premises and governs the manufacturing process by which blood is prepared.

Because of the very close professional ties between the various actors in the Canadian blood delivery system, both in the public and private sector, but particularly within the public and quasi-public sector, some of the regulation appears to be extremely informal.

The general provisions that apply to all drugs, including whole blood, require that the drug be manufactured, prepared, preserved, packed and stored under sanitary conditions and cannot otherwise be sold.[39] All drugs must be manufactured in accordance with the manufacturing practices as set out in the *Food and Drug Regulations*, Part C[40] and elaborated in a government publication entitled GOOD MANUFACTURING PRACTICES FOR DRUG MANUFACTURERS AND IMPORTERS.[41] Detailed records must be kept.[42]

Part C of the *Regulations* also sets out the labelling requirements that apply to all blood products as to other drugs. Among the information that must be included is information sufficient to identify the lot of the drug, the manufacturer and the expiry date, as well as the

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[37] R.S.C. 1985, c. F-27, s. 2.
[38] SOR/89-177.
[39] R.S.C. 1985, c. F-27, s. 8.
[40] R.S.C. 1987, c. 870.
[41] Health and Welfare Canada, GOOD MANUFACTURING PRACTICES FOR DRUG MANUFACTURERS AND IMPORTERS, 2d ed. (Ottawa: Canadian Government Publishing Centre, 1985).
[42] C.R.C. 1978, c. 870, s. C.01.049.

net amount and any preservatives. Directions for administration must also be provided.[43] The schedule also makes provision for recall of a drug and for notification of the recall to the Director.[44]

Schedule D drugs include blood derivatives, human plasma collected by plasmapheresis, immunizing agents and drugs obtained by recombinant DNA procedures. Recombinant DNA procedures hold promise of synthetically produced blood fractions with a related increase in production, increased certainty that the product is neither contaminated nor infectious, impact on cost and a diminished need for human donor source plasma. Whole blood collection is not governed by Schedule D of the *Act*.[45] Schedule D drugs can be manufactured only in premises that have been licensed by the Minister, and may be manufactured only according to processes and conditions approved as a condition of the licence.[46] Licensing of biologicals, that is, those drugs prepared from tissues of animals, of human origin or from micro-organisms, is under the jurisdiction of the Bureau of Biologics of the Department of National Health and Welfare. Red Cross plasmapheresis collection centres have been licensed since 1978, as a necessary adjunct to the manufacture of Schedule D drugs. Red Cross collection of other blood, which usually occurs at the same location and on the same premises, is expected to be licensed in the near future, following informal discussion of the need for licensing between the Canadian Red Cross and the Bureau of Biologics. It should be noted that section 12 of the *Act* requires that all premises for the manufacture of human plasma must be licensed. The Canadian Red Cross has not yet met this requirement with regard to all plasma facilities, although all plasmapheresis centres are licensed. To the degree that any centres do not meet the standards that are required before a licence will be issued, and it must be assumed that not all centres do so, there is a violation of the *Act*. This violation has obvious implications with respect to the question of liability both of the Red Cross, the Bureau of Biologics and the Minister of National Health. The Bureau of Biologics and the Canadian Red Cross are cooperating to achieve the licensing of all Red Cross collection centres.

The licensing process implies regular inspection by the Bureau of Biologics. Every licence must be renewed annually. Many of the detailed provisions that apply to Schedule D drug production are similar to those required for drugs that do not require the manufacturer to be licensed. Thus, the requirements as to labelling are almost identical to those that apply to all other drugs. However, the requirements set out for the Schedule D drugs are more detailed because these drugs are

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[43] C.R.C. 1978, c. 870, s. C.01.004.

[44] C.R.C. 1978, c. 870, s. C.01.051.

[45] D.W. Boucher & J. Furesz, *Regulatory Control of Blood Products in Canada* (1987) 67 DEVELOP. BIOL. STANDARD 221.

[46] R.S.C. 1985, c. F-27, s. 12.

the product of human and animal components. They pose greater risks and include in particular various vaccines which, if not properly produced, would be greatly hazardous to the recipient. For this reason the potency of the Schedule D drugs is more closely regulated. In addition, the manufacturer is required to notify the Bureau of any changes in personnel, in quality control procedures and in the premises.[47] All products that require licences may be released only by lot. Samples of the lot must be submitted to the Bureau together with testing results when the Bureau so requires. The lot samples are retested in the Bureau's laboratories. When testing is satisfactory with regard to safety and purity the lot is released for sale.

Part C of the *Regulations* sets out two sets of specific requirements for blood products. The first apply to all preparations from human sources.[48] Section C.04.232 requires that no manufacturer may use as a blood donor any person who has a history of a disease transmissible by blood transfusion including syphilis, infectious hepatitis or malaria. The donation must be taken under the supervision of a medical practitioner.[49] More particularly, section C.04.237 requires that a manufacturer maintain complete records of all donors, which records include a medical certificate that the donor is healthy.

Part C also contains specific provisions with regard to plasmapheresis.[50] These are fairly detailed and are designed to ensure the health of the donor and that he or she is fully informed of the implications of the procedure for his or her health. Detailed identification procedures and records are required.

The Bureau sets the standards for testing of plasma products for human pathogens, particularly hepatitis B, hepatitis non-A non-B, and HIV (the AIDS virus). HIV testing was imposed as of October 1985. It should be noted that while Part C of the *Food and Drugs Regulations* refers to and requires testing for hepatitis B antigen,[51] there is no reference to testing for HIV to be found there. Rather, the need for, and date of commencement of testing for the AIDS virus was informally arranged by collaboration between the Canadian Red Cross, the Canadian Blood Committee and the Bureau of Biologics of the Department of National Health and Welfare. As is the standard practice, blood that reacts positively for HIV or hepatitis B using the ELISA test must be tested a second time and if repeatedly reactive must be discarded. Blood that twice tests positive using ELISA must be retested using the more sensitive and more expensive Western Blot assay. However, even where the blood tests negative on the Western Blot assay it is discarded, as the results of this test are not sufficiently

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[47] *Supra*, note 45 at 222.
[48] C.R.C. 1978, c. 870, s. C.04.230 *et seq.*
[49] C.R.C. 1978, c. 870, s. C.04.233.
[50] C.R.C. 1978, c. 870, s. C.04.400 *et seq.*
[51] C.R.C. 1978, c. 870, s. C.04.418.

sensitive to ensure that a negative reading is truly indicative of a lack of infection. In addition, coagulation products are heat-treated to inactivate any HIV virus that has not been screened out. This is particularly important in light of the long incubation period associated with the AIDS virus, during which time an infected person may not test positive despite the existing infection.

The Bureau of Biologics claims to have been the first in the Western world to require that all coagulation products be heat-treated, which it did as of November 1984, with a phase-in period of six months in order not to interrupt availability of supply.[52] As of June 1985, only heat-treated coagulation products were permitted for use in Canada.[53] Following a determination that certain lots of factor VIII were contaminated despite "dry" heat treatment, a newer method of "wet" heat treatment or treatment of the blood plasma prior to freezing, at greater temperatures and for longer periods, was required. There is some evidence that wet heat treatment of coagulation products may inactivate hepatitis B and non-A non-B viruses as well as the HIV virus.[54]

Equivalent regulation of United States blood products occurs through the Federal Food and Drug Administration.[55] The American blood market is organized in a manner which is significantly different from that in Canada, being partly voluntary and gratuitous and partly commercial in nature. The whole blood and components sector, including red cells, platelets, cryoprecipitate and fresh frozen single

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[52] *Supra*, note 45 at 226.

[53] The decision to recall three lots of factor VIII produced by Armour Pharmaceutical Company of Pennsylvania was announced by the Canadian Red Cross 17 December 1987.

[54] *Supra*, note 45 at 228. Current "wet" heat treatment, or pasteurization, requires heating the blood product at 60 degrees Celsius for a period of ten hours while in its liquid state. It is one form of inactivating the viruses found in coagulation factors. It is believed to be effective in eliminating viral transmission but has the disadvantage of denaturing larger amounts of protein more than other methods. It is consequently more expensive. The impact that this method of treatment has on the efficiency of yield may lead to world shortages of factor VIII.

An alternative method involves a vapour treatment of coagulation factors under an inert gas at increased atmospheric pressures. This method is used by only one company and is proprietary. It is relatively inefficient in yield of factor VIII.

The third form of viral inactivation involves the "dry" heat treatment of coagulation products. Dried lyophilized coagulation products are heated between 30 to 72 hours at 60 to 80 degrees centigrade. This form of inactivation has been associated with the appearance of the AIDS virus and of the non-A non-B hepatitis virus. It is a relatively efficient process and the machinery is less costly.

[55] *See generally* D. MacN. Surgenor, *Progress Toward a National Blood System* (1974) 291 NEW ENGL. J. OF MEDICINE 17; J. G. Allen, *Advantages of Volunteer Blood Donation* (1974) 291 NEW ENGL. J. OF MEDICINE 1365; D. MacN. Surgenor, *Progress Toward a National Blood System: The American Blood Commission* (1976) 294 NEW ENGL. J. OF MEDICINE 1367; D.M. Stewart, *The Battle Over Blood Collection* (1977) 3 AM. J. LAW AND MEDICINE 77; *Blood Policy and Technology*, Office of Technology Assessment, Washington, D.C., 1985.

donor plasma, is largely voluntary. The source plasma and plasma components sector, including albumin, factors VIII and IX and the immunoglobulins, is largely commercial and has two components. The first of these is the "for-profit" collectors or plasmapheresis centres. The second is the fractionators. The "not-for-profit" segment of the American blood industry uses the commercial fractionators as a market for salvaged plasma and to fractionate its own blood products. In 1983 approximately 1.3 million of the 6 million litres of American source plasma produced was exported. Additional export of plasma derivatives occurs.

Canadian blood products are, at this time, processed from Canadian source products by Cutter Industries, a California-based fractionator. Even when fractionation was conducted by Connaught Laboratories, American sourced and produced products were purchased to make up the Canadian shortfall when it occurred.

The American blood industry is divided between the American Red Cross (ARC) which, like its Canadian counterpart, expanded its wartime collection function into a permanent postwar operation, the American Association of Blood Banks (AABB), the Council of Community Blood Centres, United Blood Services and others. These groups, unlike the American Red Cross, are not only collectors but users of blood products.[56] The policy of the American Red Cross is to return collected blood to the community in direct proportion to its collection. The result of this policy is that urban users of blood are undersupplied. The American Red Cross charges a processing fee for blood. In 1983 the processing fee for whole blood varied from $28 to $59 depending on location. Additional fees are also charged to the hospital, and by the hospital to the patient. These include additional processing fees, non-replacement fees, laboratory charges, infusion charges and others. In 1984 the cost of factor VIII was estimated at $4,500 to $13,000 (U.S.) per year for the average haemophiliac. Some of this cost is absorbed by public programs.

The AABB has established a national clearing house for blood available to its members. Fees are charged to members for the privilege of deposit or withdrawal of blood products. There is also often competition among members for recruitment of the same donors. In the early 1970s each of the AABB and the ARC collected approximately forty percent of United States blood needs.

Regulation of blood at the federal level is through the Food and Drug Administration's Bureau of Biologics. Blood and blood products are regulated as a drug under the Federal *Food, Drug and Cosmetic Act (1938).*[57] Federal authority extends over interstate blood facilities

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[56] *See* Surgenor, *Progress Toward a National Blood System, ibid.* at 19 where the author argues that the AABB was created because blood banks perceived that the American Red Cross' policy of free blood constituted a "threat to the economic basis of bloodbanking practice in hospitals".

[57] 21 U.S.C. 321(g)(1) (1970).

and to intrastate operations for the purposes of registration. Because of resistance from the AABB, and because of a questionable jurisdiction to regulate intrastate facilities, the FDA restricted its intervention solely to registration. It stopped short of adopting a licensing function except for biologic products intended for sale, barter or exchange in the District of Columbia or in interstate commerce. Additional federal jurisdiction is based on the *Public Health Service Act*.[58] The Food and Drug Administration has produced a detailed set of regulations governing the production of blood products.[59]

V. Rules Governing Liability for Blood and Blood Products

Injury can be caused by blood and blood products. As with any other provision of a health care service or use of a device, technique or drug, the injury may be of a kind that is compensable through the tort system. Alternatively, the injury may be such that the injured party or that party's insurer must bear the loss, absent a compensatory scheme. The causes of injury by blood may be the result of a risk inherent in the therapy, human error in technique of production or of transfusion, or mislabelling, among others. Forms of action potentially include the remedies that result from the marketing and sale of defective products as well as those that sound in negligence.

The possibility of transmission of disease,[60] and in particular of the AIDS virus with its attendant fatal consequences, has refocussed attention on liability for injury caused by blood products as well as on the measures taken to ensure that blood products are free of contamination. It is important to note that the measures taken to ensure a secure, non-infectious blood product may have an impact on the willingness or reluctance of donors to provide gratuitous blood.

Persons who are uncertain of the security of the supply may decline to donate for fear that contamination can occur to them by association or through the instruments used to collect their donation.[61] Lack of confidence in the blood supply system can lead to parallel autologous or commercial systems claiming greater security.[62] A move towards commercialization not only jeopardizes the gratuitous system by potentially diverting donors, but raises important questions about the safety of blood sold by persons in financial need,[63] and about their

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[58] 42 U.S.C. 262 (1970).

[59] 21 CFR Ch. I, Parts 606, 607, 610 and 640.

[60] Diseases transmissible through blood and blood products include malaria, syphilis and hepatitis.

[61] *See* R.D. Edkert & E.L. Wallace, Securing a Safer Blood Supply (Washington, D.C.: American Enterprise Institute, 1985).

[62] Autologous blood transfusion (autotransfusion) involves the reinfusion of the patient's own red blood cells.

[63] The provincial *Human Tissue Gift Acts* allows the sale of blood. *See, e.g.*, R.S.O. 1980, c. 210, s. 10 (Ontario); R.S.B.C. 1979, c. 187, s. 10 (British Columbia); S.N.S. 1973, c. 9, s. 11 (Nova Scotia).

honesty in withholding their blood when they are members of a high-risk group.

These factors can have an impact on the level of supply of blood through donations and potentially on the provision of blood therapy to Canadians. The factors that have an impact on liability for injury caused by blood products differ from those that usually inform debate about defective products or services. Any move toward a paid system of donation would increase the costs of providing blood products to the Canadian health care system and raise concerns as to the quality of blood obtained through paid donations, as well as of the exploitation of vulnerable populations.

In the past there was surprisingly little litigation alleging injury from defective blood or blood products in Canada. The pace of litigation has increased following the alleged transmission of Acquired Immune Deficiency Syndrome to certain recipients of Canadian blood products.[64] In addition, one group in particular is at high risk for injury from blood products. Haemophiliacs use large quantities of blood products, specifically factor VIII. As factor VIII is produced from multiple donations of plasma, the risk of contamination of the product by transmissible viruses is significantly greater. It is estimated that there are between 2,500 and 3,000 haemophiliacs in Canada. There have been thirty-three cases of AIDS among haemophiliacs, eleven of whom have died. In November 1987, the Children's Hospital of Eastern Ontario reported that of thirty-three children being treated for haemophilia, sixteen have tested positive for the AIDS antibodies and are therefore likely to develop AIDS.

Presumably, the infection occurred prior to the identification of the AIDS virus and the realization that it is transmissible through the use of blood products, and prior to effective screening and treatment of blood products to deactivate the virus. In November 1987, the British Government offered an *ex gratia* payment to the British Haemophilia Society of $23 million. No similar payment was offered to others injured by infected blood products. The Canadian Haemophilia Society launched a campaign for similar compensation for its members in January 1988. In the literature that accompanies their campaign they point out that "[t]he number of cases will likely not increase since

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[64] Two cases have been identified through newspaper files and discussions with the Red Cross. An action has been filed against the Izaak Walton Killam Children's Hospital in Halifax and against the Canadian Red Cross and a number of doctors to recover on behalf of a child alleged to have contracted AIDS from a contaminated blood transfusion. The transfusion was given during surgery in 1985, prior to implementation of the Red Cross' screening program.

A second case concerns an Edmonton woman who died of AIDS after receiving blood transfusions in both 1981 and 1986. The 1986 transfusion occurred eight months after the implementation of screening. One of the issues is whether the AIDS infection was transmitted during the 1981 or the 1986 transfusion.

On 20 November 1985, *The [Ottawa] Citizen* reported that sixty Canadians have contracted AIDS through blood or blood products. Some of these are haemophiliacs and four were reported to be children.

product safety has been improved; thus we will not be creating a precedent."[65]

Theoretically, there are several parties who are potentially liable for any injury caused by defective blood products. These include the health care professional providing the service, the institution in which the service is provided (if any), the manufacturer or fractionator, the Canadian Red Cross, and the federal government as establishing the regulatory climate and conditions under which the Canadian Red Cross and its fractionators must operate.

AIDS is not the first serious disease to be subject to transmission through blood and blood products. As well, consideration of AIDS transmission through blood must take into account the relatively rapid growth in knowledge about this disease. Issues of liability for damage allegedly caused by blood relate specifically to the state of knowledge about the disease at the time of the injurious incident where the principles of negligence, rather than strict liability, are concerned. The understanding of AIDS as a phenomenon, and of its impact, mirrors an earlier concern over liability issues for blood products.

In the United States, concern over infectious, undetectable and serious disease transmission through blood and blood products focussed on the transmission of hepatitis. A number of cases, legislative responses and legal commentaries resulted. This debate appears to have found no echo in Canada. However, the questions raised and answers suggested are fertile ground for considering the implications of transmission of infection through Canadian-sourced blood products.

The original litigation and legislative response thereto involved transfusion transmission of hepatitis. The early leading case was decided by the New York Court of Appeal in 1954. Hepatitis contracted through transfusions continued to be a serious consequence of transfusion therapy into the 1970s and raised issues that presage those raised by transmission of AIDS. Serum hepatitis is transferred through blood therapy where the donation comes from someone infected with the disease. Like AIDS, hepatitis can have a long incubation period. In 1970, it was estimated that there were some 30,000 cases of serious hepatitis caused by transfusions of which approximately twenty percent were fatal. At that time there was no effective screening device, nor was immunization available.

Today, both testing of the donation for hepatitis contamination and immunization are available to counteract hepatitis B. No screening device nor immunization is yet available for non-A non-B hepatitis.[66]

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[65] Canadian Hemophilia Society, *Special Bulletin #1*, January 1988. As this article goes to press, the Canadian government has made an offer of compensation to hemophiliacs.

[66] The discovery of the virus believed to be responsible for transmission of non-A non-B hepatitis was reported in *The [Ottawa] Citizen* on 12 May 1988 at B-7. The report indicated that Chiron Co. of Emeryville, California would be applying to the American Food and Drug Administration for permission to test a blood screening kit that summer.

Hepatitis A is not usually transmitted by transfusion. Transfusion-transmitted hepatitis also shares certain high-risk groups with the AIDS virus. These include homosexuals with multiple partners and intravenous drug users. As with AIDS, haemophiliacs are at particularly high risk due to the quantities of blood products that they are obliged to use.

American litigation with regard to blood-transmitted hepatitis raised the issue of the nature of the liability to be imposed. While actions in negligence were clearly theoretically available to the injured plaintiff, the obvious preference was to allege that the injury gave rise to a strict manufacturer's liability or, in the alternative, that an action could be brought for breach of the implied warranties attendant on a contract of sale. A successful action of this nature would allow the plaintiff to avoid proving negligence and to recover for the injury suffered even where no testing or screening device was available to avoid offering a hepatitis-contaminated product. The analogy to AIDS-contaminated blood products is clear.

In the early case of *Perlmutter* v. *Beth David Hospital*,[67] the plaintiff alleged breach of the implied warranties attendant on a contract of sale. The New York Court of Appeal refused to characterize the delivery of blood to the plaintiff by the defendant hospital as a sale, despite the fact that the cost of the blood was specifically enumerated on the hospital bill to the plaintiff. The Court characterized the transfusion as a service, rather than a sale. While a similar argument was successful in *Hoder* v. *Sayet*,[68] cases that successfully apply the implied warranties of a contract of sale, or of the *Uniform Commercial Code*, have been the exception.

Other plaintiffs have attempted to rely on the strict liability doctrines available in tort. The blood supplier is described as the manufacturer of a defective product. This head of recovery is outlined in section 402A of the RESTATEMENT (SECOND) OF THE LAW OF TORTS which provides that:

> One who sells any product in a defective condition unreasonably dangerous to the user or consumer. . .is subject to liability for physical harm thereby caused to the ultimate user or consumer.[69]

In 1970, the judgment in *Cunningham* v. *MacNeal Memorial Hospital*[70] applied this theory of liability to hold the defendant hospital liable for the transmission of hepatitis through a transfusion. However, few courts followed the reasoning of the Illinois Court.

In addition, blood products may be characterized as falling within the "comment k" exception to section 402A, which refers to products

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[67] 308 N.Y. 100, 123 N.E. (2d) 792 (1954) [hereinafter *Perlmutter*].
[68] 196 So.2d 205 (1967) (Fla Dist Ct App.).
[69] (St Paul, Minn.: American Law Institute, 1965).
[70] 47 Ill.2d 443, 266 N.E.2d 897 (1970).

that are unavoidably unsafe. This would be applicable only during such time as no reliable test was available to determine whether a particular blood donation was infected by the virus at issue, whether that be hepatitis, AIDS or some other virus.[71]

The response of state legislatures to the possibility that liability would attach in the absence of negligence is astounding in uniformity and shows the strength of the medical and blood industry lobbies. State legislatures began to draft legislation to preclude liability in the absence of negligence immediately following the decision in *Perlmutter*. By 1986, forty-seven jurisdictions had passed statutes precluding the application of the principles of strict liability to blood and blood products or specifically identifying a negligence standard as the appropriate basis for allegations of injury due to blood products.

These statutes are of three kinds. The first explicitly rejects the application of doctrines of strict liability to blood and blood products, whether in tort or in sales law. The second group rejects the application of implied warranties of fitness or merchantability without referring to strict liability in tort or to negligence specifically. The third group speaks specifically of liability for hepatitis transmission for which it provides statutory protection. Other statutes define the use of blood and blood products as a service and not a sale.[72] Only four jurisdictions rely entirely on the principles of the common law. These are the District of Columbia, New Jersey, Rhode Island and Vermont.

American principles applying strict liability in tort to manufacturers under section 402A of the RESTATEMENT find no direct equivalent in Canadian products liability law. Rather, the potential heads for recovery of injury due to blood and blood products sound in negligence, sales law and in manufacturer's liability, which is based on negligence in Canadian tort law. I will comment briefly on issues arising out of obvious acts of negligence, as for example the mislabelling of blood or negligence in the techniques adopted in the transfusion itself, and concentrate on those that are relevant to viral transmission or more complex manufacturing failures.

Mislabelling of products is clearly negligent and injury caused thereby should be easily compensable through the tort system. The party responsible for the mislabelling, or that party's insurer, would bear the responsibility for compensation. Negligence in the techniques of transfusion would be the responsibility of the party providing the medical care service and, where appropriate, that party's employer under doctrines of vicarious liability.

Viral transmission raises more complex liability issues, both at the level of rules for recovery and at the level of compensation policies.

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[71] *See Belle Bonfils Memorial Blood Bank* v. *Hansen*, 665 P.2d 118 (1983).

[72] These statutes are collected in K.S. Lipton, *Blood Donor Services and Liability Issues Relating to Acquired Immune Deficiency Syndrome* (1986) 7 J. OF LEGAL MEDICINE 131 at 135, n.20 *et seq*. The categorization is Ms Lipton's.

If we turn first to principles of negligence in the collection and manufacture of blood and blood products, care must be taken to identify the appropriate date for assessment of liability. Two specific questions should be examined. The first of these involves donor assessment and exclusion prior to donation. The second involves issues of blood testing and manufacturing processes designed to destroy any viral infection that has not been identified through the blood screening process. The principles that apply to these medically sophisticated problems are, of course, the same principles that apply to questions of donor screening for syphilis.

Once it became clear[73] that one of the forms of transmission of the AIDS virus was, like hepatitis, through blood exchange (whether by the use of contaminated needles by intravenous drug users or through medical exposure to infected blood products), the first response of the North American blood community was to move toward self-exclusion of donors in high-risk groups, including Haitians, drug users and homosexuals. On 13 January 1983, the American Red Cross, the American Association of Blood Banks and the Council of Community Blood Centers issued a joint statement containing six recommendations designed to reduce the risk of transmission of AIDS through blood components. These included screening of donors, through specific questions designed to identify AIDS symptoms and avoidance of donor recruitment from high-risk groups.[74] On 2 March 1983, the American government issued similar recommendations, including education for self-exclusion of high-risk groups, re-education of screening and recruitment personnel to recognize the early symptoms of AIDS and safe disposal of contaminated blood.[75]

Both self-exclusion, and the instructions given to personnel at blood collecting locations to allow them to identify those donors who should be excluded are a component of the standard of care that is expected of the Canadian Red Cross. If the instructions given to Red Cross personnel or the information provided to potential donors fall

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[73] *See* R. Shilts, AND THE BAND PLAYED ON: POLITICS, PEOPLE AND THE AIDS EPIDEMIC (New York: St. Martin's Press, 1987). Mr Shilts argues that the information indicating blood-based transmission was available much earlier than was generally acknowledged. He states that the various blood distributors declined to recognize the clear impact of available information for fear of limiting their usual pool of donors, and because to do so would not be in their financial interest. He argues that the leaders of the American homosexual community did the same for a multitude of reasons including financial incentives not to admit that casual commercialized sex occurring in "bath houses" was a risk to the participants, and a fear of further ostracism by the general community.

[74] American Red Cross, American Association of Blood Banks, Council of Community Blood Centers, *Joint Statement on Acquired Immune Deficiency Syndrome Related to Transfusion*, 23 January 1983, cited in Lipton, *supra*, note 72 at 143.

[75] *Recommendations to Decrease the Risk of Transmitting Acquired Immune Deficiency Syndrome (AIDS) from Blood Donors*, Office of Biologics, National Center for Drugs and Biologics, FDA, 24 March 1983.

short of that provided by other blood collectors,[76] liability could attach in negligence. A current action against the Canadian Red Cross alleges that the self-exclusion information available to prospective donors was not effectively brought to the attention of those donors and resulted in the contamination of a donation. The donation occurred prior to the availability of the test for viral contamination of the blood.

Information designed to result in voluntary self-exclusion should have been made available in 1983, along with concurrent instruction to blood collection personnel. It should be noted that mechanisms to exclude potentially infectious donors had previously been adopted by blood collectors to reduce the incidence of hepatitis and malaria contamination.[77] Suggested points of inquiry concerning AIDS susceptibility included a history of intravenous drug abuse, hepatitis, unexplained weight loss exceeding ten pounds, persistent fever, night sweats or diarrhea, acute respiratory infection or skin nodules suggestive of Kaposi's sarcoma, a cancer affecting AIDS patients. Persons in high-risk groups were asked to self-exclude.[78]

It is worth noting that a decision was taken not to question directly donors about their sexual orientation. The basis of this decision was that the cooperation of high-risk groups was necessary to their exclusion.[79] American cases have recognized that the failure to screen effectively potential donors can constitute negligence.[80] Pamphlets currently available at Red Cross collection centres contain much the same information.[81]

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[76] The type of information required may include that which a court feels should have been provided. It is always open to a court to raise the level of behaviour required of the reasonable person in all of the circumstances.

[77] J. Pindyck *et al.*, *Measures to Decrease the Risk of Acquired Immunodeficiency Syndrome Transmission by Blood Transfusion* (1985) 25 TRANSFUSION 3.

[78] *Ibid.* at 9. *See also* S.G. Sandler & A.J. Katz, *Impact of AIDS on Blood Services in the United States* (1984) 46 VOX SANGUINIS 1; Centers for Disease Control, *Additional Recommendations to Reduce Sexual and Drug-Abuse-Related Transmission of Human T-Lymphotropic Virus Type III/Lymphedenopathy-Associated Virus* (1986) 35 MORBIDITY AND MORTALITY WEEKLY REP. 152 at 153-54.

[79] *See* Shilts, *supra*, note 73 and Lipton, *supra*, note 72 at 146.

[80] *See, e.g.*, *Klaus* v. *Alameda-Contra Costa Medical Ass'n Blood Bank Inc.*, 62 Cal. App. 3d 417 at 419 (1976); *Hoder* v. *Sayet*, *supra*, note 62; *Tufaro* v. *Methodist Hospital Inc.*, 368 So. 2d 1219 (La App. 1979).

[81] A Canadian Red Cross pamphlet indicates that the following persons must not give blood: "any male who has had sexual relations with another male since 1977, any person who has shared a needle to inject drugs, any person who has regularly received treatment with blood products, any man or woman who has had sexual relations with someone other than his or her usual partner, particularly with a prostitute, in areas where AIDS cases are known to occur especially Central Africa, Haiti, and major North American cities, sexual partners of any of these people". In addition, persons with the physical symptoms referred to in the sources listed in note 72, those with lumps in their armpits, neck or groin lasting more than one month, long-lasting white spots or unusual sores in the mouth or blue or purple spots on or under the skin are asked to self-exclude and to see a doctor.

Once testing mechanisms became available, the failure to test and later to treat blood for the presence of the virus constituted negligence. Prior to 1985, no testing device was available to screen blood donations for the presence of AIDS antibodies. Therefore, prior to that date no liability in negligence could attach for failure to test the donation itself.

Prior to the development of ELISA, numerous tests were considered. These included tests to detect antigens that were suspected to be involved with AIDS and tests to determine changes generally found in the serological or metabolic markers. Surrogate tests are those that do not directly detect the presence of the disease. None were licensed to screen blood for AIDS. Only one was considered sufficiently promising to be pursued on a research basis. The Food and Drug Administration Blood Products Advisory Committee rejected implementation of the anti-HBc test.[82] In March 1985, as the FDA Advisory Committee was concluding its study of the feasibility of anti-HBc testing, the American Food and Drug Administration licensed the ELISA test for screening blood for HIV antibodies.[83] From the date that those tests became widely available, the failure to test, or negligence in the testing procedure, would give rise to an action in negligence for damages caused.[84]

One interesting aspect of the implementation of the ELISA test involves the decision of the various blood services in the United States to delay notification of test results and of the Canadian Red Cross to delay implementation of testing for a six-month period. These decisions were made primarily to allow testing centres, other than blood collection centres, to make the necessary adjustments so as to be capable of offering testing services to those persons concerned about their health status. It was feared that without such a delay, persons wishing to have their blood tested for the presence of the AIDS antibody would utilize the services of blood collection agencies, as these were the only locations at which such testing was available. The potential impact for additional viral contamination of blood supplies was perceived as significant. Thus, a decision was taken by the Canadian Red Cross to delay testing for six months during which time facilities specifically dedicated to diagnostic testing could be identified. This decision was a clear, consultative decision of those professionals whose expertise became the measurement of a standard of care. The motives of those making the decision are not to be impugned. The concern was for the

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[82] Blood Products Advisory Committee, FDA, *Final Report of the Hepatitis B Core Antibody Testing Study Group*, 16 June 1984.

[83] 50 Fed. reg. 9909 (1985) announced in Health and Human Services News Release, 2 March 1985.

[84] A repeat test and confirmatory Western Blot test were recommended for positive results at a workshop sponsored by the National Institutes of Health. *See Experience with the HTLV-III Antibody Testing-Update On: Screening, Laboratory and Epidemiological Correlations*. Center for Drugs and Biologics, FDA, National Institutes of Health and CDC, 31 July 1985.

protection of the blood supply. Nonetheless, there are persons who may have been injured by infected blood during the six-month period when the implementation of testing was technologically feasible, but was not provided for reasons of a different order. The American Red Cross, to avoid this particular problem, chose to commence testing but to delay notification of positive antibody test results to donors until such time as at least one alternative site was established in the community.[85] The potential for damage from transmission of the disease is obvious.

Actions for damages for injuries due to blood products in Canada require proof of negligence. The rules of manufacturer's liability differ from those identified by the AMERICAN RESTATEMENT. Therefore, there is little to be gained by framing an action in manufacturer's liability rather than negligence. Canadian liability rules do, however, raise interesting questions about the possibility of an action for breach of provincial Sale of Goods Acts and the warranties therein. The *Food and Drugs Act* defines the term "sale" as it applies to a drug governed under that *Act* as including distribution whether or not for consideration. It is unlikely, however, that reliance on the non-consideration aspect of this definition and the definition from the federal *Act* could be used to supplement a provincial definition so as to allow access to the strict liability of the Sale of Goods Acts for breach of the warranties of fitness for purpose and merchantability.

In considering liability issues for blood products, some thought must also be given to the manufacturer's duty to warn the consumer of the dangers inherent in the use of the product. In traditional terms, the manufacturer is free to market or distribute an inherently dangerous product, only within certain parameters. The labelling requirements that apply to blood products are, to some extent, set out in the *Food and Drugs Act*. Additional information by way of a warning is provided by the Canadian Red Cross in its booklet entitled *Clinical Guide to Transfusion*, which it provides with distribution of blood products. This contains the additional warning information referred to earlier in this paper. This information is not provided to the ultimate recipient of the product in the ordinary course of events, but rather to the health care professional who provides the transfusion services. The only exception to this would be certain products provided for the home use of haemophiliacs. Therefore, it is unlikely that the information concerning the risks of blood transmitted infection would be communicated by manufacturers' warnings to the ultimate recipient of the product.

Communication of the various risks of blood products would lie with the physician or other appropriate health care professionals whose legal obligation it is to obtain the patient's consent to the health care

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[85] American Red Cross TWX from S.G. Sandler, M.D. to all responsible heads (27 June 1985) as referred to in Lipton, *supra*, note 72 at 155, n. 102.

treatment in all of its aspects and with all of the significant or material risks measured by an objective standard of disclosure.[86] In addition, the problems in establishing the causation element in the informed consent cases would be overwhelming in many instances of blood therapy. Even where the plaintiff could effectively establish professional negligence in a failure to disclose the risks of transfusion therapy, Canadian courts would likely find that the reasonable objective patient would have consented to the administration of medically necessary blood products, at least in the absence of a viable alternative.

In summary then, Canadians injured by blood and blood products are likely to have to establish negligence at some point in the manufacturing process. Available knowledge, and therefore the date at which the tortious act occurred, will be key where rapid advances have been made in the understanding and control of blood transmitted infection. The major areas of liability to be examined would include donor screening mechanisms for the purposes of exclusion of inappropriate donors, testing mechanisms used to test the blood for evidence of infection, treatment of the product to deactivate any otherwise undetected infection, the fractionation and labelling process itself, the information given to the recipient and the technical excellence of the transfusion process. In the absence of a viable theory of strict liability, injury caused in the absence of negligence will be borne by the victim him or herself.

Finally, even where negligence in the process can be identified, AIDS transmission raises serious issues of proof of causation. The long latency period and the transmission of the virus through both heterosexual and homosexual sexual intercourse may reduce the question of proof of causation to a review of the sexual history of the victim and the victim's sexual partners. These concerns would apply even where the infected victim suffers from haemophilia with the attendant increased use of blood products.

For these reasons compensation for injury due to blood products raises questions about the appropriateness of tort law as a solution to the problem of blood related injury.

VI. Compensation for Blood Related Injuries

> [T]he legal system does not ensure that the disabled are compensated unless negligence can be proved. As well, the tort system does not and cannot deal effectively with a health care professional who practices

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[86] *Hopp* v. *Lepp*, [1980] 2 S.C.R. 192, 112 D.L.R. (3d) 67; *Reibl* v. *Hughes*, [1980] 2 S.C.R. 880, 114 D.L.R. (3d) 1. It is unlikely that the rules established in *Buchan* v. *Ortho Pharmaceutical (Canada) Ltd* (1984), 46 O.R. (2d) 113, 8 D.L.R. (4th) 373 (H.C.), *aff'd* (1986), 54 O.R. (2d) 92, 25 D.L.R. (4th) 658 (C.A.) would be held to apply to the ordinary case of blood therapy. They might, however, apply to those haemophilia preparations that are used in the home.

> substandard care. Nor can it deal effectively with a negligent hospital or negligence in the health products industry.[87]

The literature on the failure of tort law to fulfill effectively the functions traditionally assigned to it is extensive.[88] If the primary functions of tort law include compensation of the injured person and deterrence of negligence in potential defendants, it is generally conceded that tort litigation fails to achieve these ends. Tort law results in uncompensated plaintiffs, inadequate coverage, provides liability for fault rather than compensation for injury, requires an individual to undertake costly litigation and results in significant delays.

As a mechanism to deter hazardous behaviour tort is equally unsatisfactory, often for the same reasons. The requirement of the litigious plaintiff results in only a very small percentage of potentially actionable injuries being pursued. Even where litigation is undertaken, courts prefer to compensate the plaintiff and are ill-equipped to implement principles of deterrence in their reasons for judgment. Furthermore, our ability to calculate damages remains much too imprecise to allow for the careful calculations required for principles of deterrence to be effective. In addition, compensable loss is calculated on the basis of injury and not on the basis of moral culpability or the nature of the behaviour and the need for future deterrence. Generally, the deterrent impact of tort law is moderated by the implications of available insurance coverage, and in the inability of that industry to calculate premiums in a way that would correlate to deterrence objectives. Finally, the defendant may prefer to pass on liability costs to the consumer, rather than to engage in loss minimization measures. The substitution of principles of strict liability has not been universally endorsed as an appropriate solution to the difficulties created by the tort system.

In the context of injury caused by blood and blood products certain additional factors should be taken into consideration in designing a mechanism to ensure the twin goals of compensation and deterrence. These factors arise out of the special nature of the original source of the raw material for the product — the human donor. They

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[87] J. Sellers, *The Potential Effect of Liability Claims on the Canadian Public Health Care System: A Need for Legal Reform and/or an Alternative to Litigation for the Compensation of Persons Disabled Because of Medical Misadventure*, reprinted in Ontario Task Force on Insurance, FINAL REPORT OF THE ONTARIO TASK FORCE ON INSURANCE (Toronto: Ministry of Financial Institutions, 1986).

[88] *See generally* W.P. Keeton, ed., PROSSER AND KEETON ON THE LAW OF TORTS, 5th ed. (St Paul, Minn.: West, 1984); J.G. Fleming, THE LAW OF TORTS, 6th ed. (Sydney: Law Book Co., 1983); S.M. Waddams, PRODUCTS LIABILITY, 2d ed. (Toronto: Carswell, 1980); Ontario Law Reform Commission, REPORT ON PRODUCTS LIABILITY (Toronto: Ministry of Attorney General, 1979); E.P. Belobaba, PRODUCTS LIABILITY AND PERSONAL INJURY COMPENSATION IN CANADA: TOWARDS INTEGRATION AND RATIONALIZATION (Ottawa: Consumer and Corporate Affairs Canada, 1983); T. Ison, THE FORENSIC LOTTERY (London: Staples, 1967).

arise out of the special character of the manufacturer of the finished product, the Canadian Red Cross. They are compounded by the use of fractionators who are subject to a non-profit requirement under the 1980 decision of the Ministers of Health, although at this moment "for-profit" American fractionators are being utilized by the Canadian Red Cross. The withdrawal of commercial insurers from the field and the undertaking of the Canadian Blood Committee to provide indemnification to the Red Cross also affects on our thinking with respect to the form that compensation for injury should take. The rapid changes in the nature of the viral contaminant responsible for Acquired Immune Deficiency Syndrome must be taken into account.[89] The existence of a particularly vulnerable population, Canada's haemophiliacs, also is of significance. Coagulation factors continue to be at greater risk for contamination of the product due to the large numbers of donors involved to produce those components.[90] Finally, the essential nature of blood therapy and its part in the delivery of health care to Canadians should be borne in mind in the assessment of mechanisms for compensation for blood injuries.

Why compensate persons injured by blood products beyond what the rules of tort liability would provide? In my view, persons injured by blood products have a particularly good case for entitlement to compensation by a mechanism other than private litigation. This entitlement goes beyond those arguments that are specific to the general failure of the tort system and includes the special considerations referred to above.

I am not persuaded by Connaught's claim that the failure of the Canadian Blood Committee to provide an acceptable indemnity for injury due to blood products was a compelling factor in its decision to leave the fractionation field. It appears that Connaught was equally concerned with its outdated processing plant and with the uncertain market conditions and technological future of blood component production. Nor is there evidence that the past level of claims was such as to trigger a need to withdraw from the market.

It should be borne in mind that the potential for injury, as distinct from liability, is significantly greater with AIDS than with hepatitis. In the interval between the recognition that AIDS could be transmitted through blood products and the licensing of the ELISA test procedure and implementation of heat treatment, the potential for injury through

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[89] *See* "Chameleon AIDS virus confounding vaccine quest" *The [Ottawa] Citizen* (12 May 1988) B7; "Invisible Enemy: AIDS virus dodges doctors' efforts to find vaccine or cure for victims" *The [Toronto] Globe and Mail* (23 May 1988) A3.

[90] Factor VIII concentrate contains a distillate of clotting factors obtained from between 2,000 and 20,000 blood or plasma donors. *See* P.H. Levine *et al.*, *The Acquired Immune-deficiency Syndrome in Persons with Haemophilia* (1985) 103 ANN. INTERN. MED. 723; S. Dietrich & D.C. Boone, *AIDS and Congenital Clotting Disorders* in J.C. Petricciani *et al.*, eds, AIDS: THE SAFETY OF BLOOD AND BLOOD PRODUCTS (Chichester: John Wiley & Sons, 1987) at 52.

blood products was clearly great. Nonetheless, the likelihood of liability in the absence of negligence was exceedingly small. Canadian awards for personal injury do not approach those offered in the United States in size. Nor, as we have seen above, is it likely that liability would attach in the absence of proof not only of negligence, but of causation.

The likelihood of a successful suit for injury caused by blood products does not answer the question of the appropriateness of compensation. It does not preclude the negative impact on the willingness of Canadians to volunteer as blood donors should there be significant concern about the safety of the Canadian blood supply, nor does it answer to the impact of such concerns on the ability of Canada to maintain a national, self-sufficient, gratuitous blood supply system. Concerns about safety would likely create a demand for an autologous system and possibly for a parallel free market system.

The literature on alternative means to ensure indemnification identifies those situations in which compensation schemes better serve public goals of compensation and deterrence. At issue is the means by which we choose to regulate individual responsibility for risks. A determination must be made as to those risks which we will spread or share among the collectivity. The answers to such questions reflect our views on social policy. Kenneth Abraham phrases the question as follows:

> On what bases shall we require individuals to bear risks? When is it legitimate to compel people to share risks that many of them would prefer to bear individually or to manage through other devices, such as investment in loss prevention? When should we use insurance to distribute risk, and when are other methods of risk management preferable?[91]

Professor Abraham argues that where our political and moral philosophy is such that the proper role of government is to redistribute resources among individuals, a philosophical analysis should be added to our economic analysis. In certain cases this approach suggests that compensation is best achieved through a system other than the traditional rules of tort liability supplemented by insurance.

Compensation funds provide a better method of ensuring that compensation reaches those who are actually injured by blood products. Deterrence is best achieved here by the use of regulatory mechanisms that are already in place and are available for strengthening. The *Food and Drugs Act* provides a key regulatory structure which should provide an effective alternative mechanism for deterring and controlling inappropriately risky activity. Inspection and licensing of facilities and determination of safety standards and manufacturing requirements, if

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[91] K.S. Abraham, DISTRIBUTING RISK: INSURANCE, LEGAL THEORY, AND PUBLIC POLICY (New Haven, Conn.: Yale University Press, 1986).

effectively implemented, should result in a more effective mechanism for deterring inappropriate behaviour than the tort liability model.[92]

Dr Sellers, in his report on liability issues in the Canadian health care system, identifies the objectives of legal regulation of health care as:

> (1) the social responsibility of Canadian society to compensate persons who have become disabled so that they may enjoy a quality of life which would not be attainable if no compensation were available;
>
> (2) the responsibility and accountability of health care professionals, health care institutions and the health products industries to maintain and improve their standards; and
>
> (3) the responsibility of the administrative structure of the health care system to ensure the efficient use of available resources.[93]

In the context of injury incurred by use of blood and blood products, these objectives can best be met by the use of a compensatory system and by sophisticated regulation of the blood industry.

In my view, compensation for those injured by blood products is compelled by our moral obligation towards the recipients of Canadian blood products, where regulation and funding for the production of these products is significantly government controlled. Compensation is further mandated by the public participation in the Canadian blood collection process and by the public benefit achieved by the maintenance of a volunteer based blood donor system. Such a system provides significant advantages to the maintenance of the fundamental principles of the Canadian health care system as evidenced in the *Canada Health Act*,[94] such as the benefits to be realized in achieving security of supply and the stabilizing effect that such a scheme should have on the blood distribution industry and network in Canada. Finally, should the Canadian Blood Committee continue to insist that the fractionation of blood products be done on a "not-for-profit" basis, protection of the fractionator from liability is perhaps an appropriate concomitant. The parameters here are not unlike those associated with vaccine injury and proposals for vaccine compensation schemes. It has been argued that the exit of commercial manufacturers from the production of vaccines is due in part to economics and in part to legal principles:

> The development and production of vaccines is expensive; the sale of vaccines is not profitable when compared to the sale of pharmaceuticals.[95]

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[92] *See ibid.* at 53; Ontario Task Force on Insurance, *supra*, note 87 at 63 which states that "[c]ompensation should be principled and prompt. Deterrence should be principled and precise." *See also* Ontario Law Reform Commission, *supra*, note 88.

[93] Sellers in Ontario Task Force on Insurance, *ibid.* at 363.

[94] R.S.C. 1985, c. C-6.

[95] W.K. Mariner & M.E. Clark, *Confronting the Immunization Problem: Proposals for Compsensation Reform* (1986) 76 AM. J. PUBLIC HEALTH 703 at 703.

It is far from clear that a completely safe blood supply is either an attainable or an appropriate goal. In a major editorial the editors of the journal TRANSFUSION asked some penetrating questions about the appropriateness of a zero-risk policy for blood. They argued that risk reduction rather then zero-risk should be the goal for the safety of the blood supply. They outlined the increases in other forms of risk that would attend upon an attempt to reduce the risk of AIDS transmission by using screening mechanisms. They added that the availability of a testing technology "does not necessarily mean the resources to implement such procedures should be expended".[96]

Evidence of this kind of benefit-to-risk assessment has been identified with regard to the implementation of screening mechanisms for purposes of protection of the blood supply and is apparent in the discussion about the implementation of screening for HIV-2 which is allegedly not yet a hazard in North America but has been identified in patients in West Africa. Cases in France and New Jersey have been identified recently.[97]

For all of these reasons it is suggested that the removal of blood injury from the purview of tort litigation is the appropriate mechanism to provide compensation to those hopefully few persons who are injured by blood products in Canada.

VII. THE IMPACT OF THE *FREE TRADE AGREEMENT* ON THE CANADIAN BLOOD DELIVERY SYSTEM

Concern has been raised in the media recently as to the potential impact of the *Free Trade Agreement* on the Canadian blood delivery system. The concern seems to focus on the possibility that "for-profit" American commercial firms will choose to operate in Canada as a result of the *Agreement* and that these firms will offer payment for blood donations where the Canadian Red Cross will not do so. There is some fear that this will have a negative impact on the number of Canadians who will continue to provide gratuitous donations of whole blood or plasma where payment is available from rival organizations. Questions might well also be raised as to the possibility that rival commercial organizations would offer alternative blood delivery possibilities for a price, thereby eroding the principles of universality that

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[96] F. Zuck, *Greetings — A Final Look Back with Comments About a Policy of a Zero-risk Blood Supply* (1987) 27 TRANSFUSION 447 at 448.

[97] *See* R. Milko, *Current Issues Review*, 85-15E, Library of Parliament; C.R. Horsburgh & S.D. Holmberg, *The Global Distribution of Human Immunodeficiency Virus Type 2 (HIV-2) Infection* (1988) 28 TRANSFUSION 192.

the Canadian health care system has embraced.[98] Questions as to the impact of the *Agreement* on the Canadian blood delivery system arise within the purview of the impact of the *Agreement* on Canadian social institutions in general.

The *Free Trade Agreement* potentially affects the provision of blood and blood products in several ways. Furthermore, *commercial* blood bank laboratories are specifically referred to as included services under Part IV of the *Agreement*.[99] The *Agreement* may potentially have an impact in the context of the sale of blood and blood products as a commodity, in the provision of blood services and with respect to investment in blood companies. Federal and provincial subsidization of blood collection and manufacturing may also be an issue under the *Agreement*.

The objective of the *Agreement* is to remove barriers to trade between Canada and the United States. This is to be accomplished in two ways. First, the *Agreement* is designed to ensure equal treatment of the goods and services of each of the parties in the other party's market place. Second, the *Agreement* purports to reduce existing barriers to free trade over a period of time which varies with the nature of the specific impediment and sector of industry.

It should be noted that blood and blood products are not at this time subject to an import tariff, nor are there impediments to the operation of American companies within Canada. In fact, Autologous Systems Incorporated operates a commercial autologous blood service in Montreal and has been licenced by the Canadian Bureau of Biologics to do so. Continental Pharma Cryosan Incorporated (CPCI) operates a plasma brokerage business out of Montreal. It owns North American Biologicals Incorporated of Florida. Thus, the possibility of market penetration by American companies exists even without the *Free Trade Agreement*. However, certain changes arising from the *Agreement* could hasten or enhance American occupation of the Canadian industry. Other changes, not inherent in the *Agreement* itself (specifically predicted changes in the production of blood products from a whole blood base to a biogenetic base), could have the same effect.

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[98] *See* "Red Cross Fears Trade Deal Will Ruin Blood-Donor Program" *The [Ottawa] Citizen* (18 July 1988) A12: "Some Opposition MPs are warning that free trade in this area will open the floodgates to competition from the U.S. with the bottom line to reap profits from selling high-cost blood to labs and hospitals." The article quoted Essex-Windsor MP Steven Langdon to the effect that our Red Cross system of donating blood would disappear and Lloyd Axworthy to the effect that "[w]ith a closer harmonization of the economic systems, you can't divorce that from our social and health systems. We'll end up adopting many of the same kind of practices they have."

[99] *See* Statistics Canada, STANDARD INDUSTRIAL CLASSIFICATION, 4th ed. (Ottawa: Dept of Supply and Services, 1980) under List of Divisions, Major Groups, Groups and Classes, Division D - Health and Social Service Industries, Major Group 86, no. 868 and 8685. In this sector the *Agreement* is restricted in its application to commercial services only.

The relevant provisions of the *Agreement* include those that apply to trade in goods, provision of services and foreign investment in the other party's industries. Trade in goods is covered by Part II of the *Agreement*. This Part applies to goods which originate in the territory of either of the parties, or which are sufficiently transformed within the territory of one of the parties so as to be characterized as meeting the terms of the agreement with regard to qualification as to origin. These goods are to be allowed entry into the other country without the imposition of a tariff. Included are goods that are classified according to the Harmonized Commodity Description and Coding System. Whole human blood as well as human blood sera, plasma and blood fractions are referred to specifically.[100]

Part II also refers to rules with regard to national treatment and technical standards. The sovereign right of each party to impose regulation for the purpose of protection of human life and for the purposes of health and safety is recognized as long as the objective of such regulation is not to impede trade. Where domestic and imported goods are subjected to the same health and safety requirements, no interference with free trade can have been intended.[101]

The provisions that refer to the service sector have a similar objective of ensuring equality of treatment. Only certain services are included, specifically, for our purposes, commercial medical and other health laboratories and blood bank laboratories. In addition to the limitation to "commercial services" in the laboratory sphere, with which we are concerned, the provisions of the *Agreement* with regard to services are prospective in application.[102]

Government procurement policies and subsidies are exempt from the application of Part IV.[103] Outside of the blood banking services referred to specifically, government provided services, including health services, are excluded.[104] Thus, if Canada maintains a "not-for-profit" blood policy and precludes the commercialization of blood donation, collection or processing, American firms can equally be precluded from operating commercial organizations in these matters. Only equality of treatment is mandated by the *Agreement*.

Similar conclusions may be drawn with regard to the provision of Part IV that deals with investment in Canadian entities by American

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[100] *Canada-United States Free Trade Agreement Implementation Act*, S.C. 1988, c. 65, Schedule - Part A, Annex 301.2, Schedule - Part B, Tariff Items 3002.90 and 3002.10.

[101] *Canada-United States Free Trade Agreement Implementation Act*, S.C. 1988, c. 65, Schedule - Part A, articles 603 and 609.

[102] *Canada-United States Free Trade Agreement Implementation Act*, S.C. 1988, c. 65, Schedule - Part A, article 1402.5.

[103] *Canada-United States Free Trade Agreement Implementation Act*, S.C. 1988, c. 65, Schedule - Part A, article 1402.9.

[104] *See* commentary to Part Four of *The Canada-U.S. Free Trade Agreement* (Ottawa: External Affairs, 10 December 1987) at 195.

institutions. Again, the *Agreement* requires "no less favourable treatment" with regard to the acquisition, operation and sale of existing business. Only if a commercial blood products market is developed will American investment be entitled to equality of treatment.

It is worth considering whether the federal government has constitutional jurisdiction to insist that Canadian blood policy continue to be based on the dual principles of gratuitous donation and non-profit collection. Canadian blood policy is, as we have seen, formulated by the federal and provincial Ministers of Health co-operatively and through the instrument of the Canadian Blood Committee. It is premature to conclude that the non-profit principle will be continued for fractionation, but it seems likely that the Canadian Blood Committee and the various governments will reaffirm the gratuitous donation system of which Canadians are justly proud.

Should the various provinces fail to prohibit the sale of blood, it is unlikely that the federal government will have the jurisdiction to do so. The sale of blood is not prohibited at this time at either the federal or provincial levels.[105] In the absence of such a prohibition, either Canadian or American firms are free to purchase blood in Canada. They simply have failed to do so. The *Free Trade Agreement* would have an impact only on a decision of the provincial governments to prohibit the sale of blood to American corporations while allowing Canadian corporations to engage in such activities.

Federal jurisdiction over blood and blood products is likely only found in the criminal law power that provides regulatory authority over blood products under the *Food and Drugs Act*. This jurisdiction would be limited to those purposes that legitimately fall within the scope of valid protection of health and safety interests. Where a compelling argument could be made that the sale of blood results in blood of a lesser quality and therefore involves legitimate quality concerns, federal jurisdiction could be maintained. While such an argument is not far-fetched, it is equally not *prima facie* evident. The debate as to the quality of paid blood has been extensive and complex since the publication of THE GIFT RELATIONSHIP.[106] It should be noted that the labelling requirements of the United States *Food and Drug Regulations* demand that blood be labelled as either paid or gratuitous.[107] The impact of this requirement has been to reduce the number of commercial collectors of blood. However, the labelling requirements do not apply to source plasma and as a result, plasma donors continue to be paid for the donation that is used for fractionation. While there are not similar jurisdictional impediments under American constitutional law, the American decision to require labelling might assist in an

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[105] *See* the *Human Tissue Gift Act* in various Canadian provinces, *supra*, note 63.

[106] *Supra*, note 5.

[107] 21 CFR Ch. I, Part 606 para. 121.

argument that prohibition of payment, or a similar labelling requirement, falls within the valid constitutional authority of the federal criminal law power.

VIII. "NOT-FOR-PROFIT", SELF-SUFFICIENCY, VOLUNTEER DONORS AND THE FUTURE DIRECTION OF THE CANADIAN BLOOD DELIVERY SYSTEM

The history of blood delivery and processing in Canada and the recent embargo on further investment in fractionation pending reconsideration by the Canadian Blood Committee indicate that a major rethinking of Canadian blood systems is necessary. The decision of Connaught Laboratories to withdraw from the fractionation field citing liability concerns is a further indication. The possibility that the public will demand certain additional services such as autologous blood transfusions as well as major changes in the production of blood products through the future use of biogenetic compounds, point in the same direction. AIDS testing and heat treatment of blood products has also had an impact on the economics of production of blood products. The original determination that the principles of Canadian self-sufficiency and non-profit based production should apply has helped to shape the Canadian blood delivery system. All of these elements continue to bear on liability and compensation issues in the context of the Canadian blood delivery system. Presumably, the same factors have an impact on the willingness of corporations to respond to liability issues. Certainly the *Free Trade Agreement* does preclude differential treatment of American corporations or service providers. It does not, however, dictate the shape that the Canadian blood system must assume.

It is not within the expertise of this author to draw a blueprint for a new Canadian blood industry. However, several additional factors seem worthy of note. Clearly, self-sufficiency comes at a cost. Canadians are not at this time self-sufficient for all blood products. Rather, some fifty percent of certain products are purchased on foreign markets, often from American commercial fractionators. Second, self-sufficiency in raw products may be of greater importance than self-sufficiency in manufacturing capability. Third, the requirement that fractionators operate on a non-profit basis is unusual in the context of health care services, devices and drugs. Health care providers and pharmaceutical companies are generally expected to operate on something other than a "break-even" basis. When Connaught pulled out of fractionation of Canadian blood products, considerable savings were achieved by allowing fractionation of that product by an American-based fractionator. Market size and economies of scale also are relevant. All of these factors impact on the liability implications of Canadian blood products, even if indirectly.

The non-profit principle has been expressed primarily in the refusal to allow Canadian corporations to make a profit from the fractionation of blood products, that is from the manufacturing process.

However, the real impetus is, I believe, to avoid making a profit from freely donated blood, as by selling surplus blood and blood by-products. It is possible that we need to clarify our thinking as to what we mean by a non-profit blood system, and that it is possible to find a way to provide a profit incentive to Canadian fractionators without exploiting blood donations that are freely and gratuitously provided by Canadians.

Finally, if the predictions as to the change in blood therapy from one based in human source products to one based in biogenetic products prove accurate, the structural parameters as well as the ethical dimensions of the blood supply system will change dramatically. The implications for safety and purity of the product, and therefore for liability issues, will also change. At that time, at least with regard to those products, the issues that inform production of blood products will vary little from those that impact on any Canadian manufacturing industry that provides an essential product in a small market. Presumably, the *Free Trade Agreement* would have a significant impact on the shape that such an industry takes. Until that time, however, and even then only with regard to those products that can be biogenetically produced, the future direction of Canadian blood products production must grapple with the problems posed by a small market, by a lack of technical capability, by the impediments posed by a non-profit requirement and by the special nature of the source product.

The sale of human blood has been of concern for some time. International prohibitions on that sale were referred to early in this study. Behind these references lies an international trade in blood and plasma of the most exploitative nature and proportions. Canada has avoided exploitation of the nature identified in developing countries through the absence of a paid donor base. The United States has not done so, although it has limited the degree of exploitation to some extent through labelling requirements. Nonetheless, blood and plasma are purchased for a pittance from exploited populations in that country and are used to produce blood products for the United States and for international markets. Canadian participation in these practices must be avoided at all costs.