

Ethical & Legal Issues in the Supply of Blood Products

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The views expressed in this document are those of the author and do not necessarily reflect those of the Bayer Advisory Council on Bioethics

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Introduction

For the last few decades Canada has relied on the donation of human blood to meet modern therapeutic medical demand. It is a system of donation that satisfies many health needs. The system is said to be based on a “gift-of-life-ethic” that involves non-paid donors. Unfortunately, the system does not meet all the demand for blood products. Indeed, for decades Canada has largely relied on US collected or processed plasma to satisfy Canadian health needs. Plasma, the liquid part of blood, is processed into a range of therapeutic plasma derivatives: anti-clotting agents for treating haemophilia, albumin for treating trauma and burn patients, immune globins for immunization against hepatitis, tetanus, rabies, etc. Today most plasma is obtained by plasmapheresis, a procedure that involves the donation of blood, the separation of plasma from the red and white blood cells of blood, and the re-infusion of the red and white blood cells into the donor. In the US, the plasma supply is based on a paid-donor system. Canadian reliance on paid-donor plasma from the US, and the strengths and weaknesses of this long-term dependency, were recently laid bare in the Krever inquiry¹ on the blood system in the wake of the HIV/AIDS contamination of the blood supply.

While these circumstances are not unique to Canada, they do raise important questions for the development of national blood policy. Should Canada embark on its own system of paid plasma donation to boost supplies and enhance self-sufficiency? The newly-created Canadian Blood Service recently indicated that it would not rule out this consideration. On the one hand, there is historical precedent for the practice in Canada. Indeed, at different times in history many countries have had recourse to paid donations in the effort to provide adequate supplies of blood plasma for life-saving treatments. On the other hand, in the last few years Mexico, China, and much of Europe, have either banned or discouraged the sale of blood.² This latter trend is consistent with the long-standing policy of the World Health Organization (WHO). For decades, the WHO has urged nations to develop a national blood policy based on unpaid donations.³ Yet, in India following a recent Supreme Court ban on the 50-year-old practice of

¹ Krever H. *Commission of Inquiry on the Blood System in Canada. Final Report*. Ottawa, 1997,[www.hc-sc.gc.ca/main/hc/web/english/krever/index.html].

² Poole T. China Bans Sale of Blood. *The Independent [London]* 1 Oct. 1998, p. 14. See also Section III.C, below.

³ See Section III.B, below.

selling and buying donor blood, acute blood shortages have been reported.⁴ Thus, like many nations grappling with supply and safety issues, Canada now faces important moral choices.

The following, then, explores the arguments for and against the sale of blood plasma, as a window on some of the major ethical and legal considerations at issue in developing blood policy to confront national shortages. We begin with a brief retrospective on the history of transfusion medicine in Section I. It highlights some of the elements in the disequilibrium between supply and demand. Section II then outlines leading arguments for and against sales. Section III explores how some of the arguments have influenced blood policy, law and ethics in selected countries. Section IV concludes the analysis.

I. Supply & Demand Disequilibria

A. The Relevance of Transfusion History

For much of human history, there has been little concern about shortages of blood or blood products. The concern for blood shortages is, indeed, a notably modern one of the 20th Century. After exploring some of the highlights in the history of transfusion medicine, we shall sample some of the leading determinants of blood shortages.

⁴ Jayaraman KS. Ban on Sale May Cause Indian Blood Shortage. *Nature Med.* 1998;4:139.

Table A:

Glimpses of Transfusion Medicine History

1628: Dr. William Harvey of England discovers the circulation of blood.

1665: Dr. Richard Lower of England conducts the first transfusion of blood between animals.

1667: Professor Jean Baptiste Denis of Montpellier, France is credited with performing the first blood transfusion to a human. Denis bleeds a boy of about three ounces and gives him in exchange about nine ounces from a lamb. Denis' subsequent experiments have mixed success, lead to an unsuccessful manslaughter charge against him, and prompt the so-called edict of Chatelet. The edict forbids further transfusions without the approval of the Faculty of Medicine of Paris.

1818: Dr. James Blundell performs the first transfusion between humans, and demonstrates that the passage of blood through instruments does not damage blood.

1900-1902: Karl Landsteiner, a Viennese scientist, discovers the clumping of red blood cells, categorizes blood into A, B, and O groups and proves that patients may die from shock if they receive incompatible blood. Shortly after, another research team adds a fourth blood group, AB.

1915: Belgium and US researchers discover the anticoagulant action of sodium citrate. Other researchers discover that red cells in citrated blood stored at four degrees preserve longer if dextrose (glucose) is added.

1918: During World War I (WWI) the usefulness of whole blood transfusion is documented and the use of blood preserved for 20+ days proves effective. After WWI public enthusiasm for donating declines. Many Canadian hospitals resort to paying "professional donors" and asking transfused patients for payments or for blood replacement by relatives. Those who can afford the service pay up to 25\$/bottle, plus administration fees. Donor shortages also lead to the use of placental blood.

1921-1922: Dr. Bruce Robertson, of Toronto, conducts first exchange transfusion in the treatment of severe burns with children. British National Red Cross Society involves itself in a successful volunteer blood program.

1930: A Moscow physician demonstrates that blood promptly collected from the recently dead may be tested and distributed for clinical use.

1936-1939: During the Spanish Civil War, a Canadian thoracic surgeon demonstrates that blood can be stored and transfused safely from bottle to patient. In Chicago, a US physician innovates the idea of a 'blood bank'. In Ottawa, the first Red Cross Donor Service is established.

1939/40: After years of debate in the international scientific community, the ABO system is made the standard blood classification scheme, a technical step toward developing a civilian blood bank.

1940: London, England - Blood depots receive greater responsibility for supply and storing of blood, plasma and sterile transfusion equipment to a larger number of hospitals.

1940: C.H. Best, of Toronto, dries blood plasma and restores it to its original constituency with distilled water in experiments financed by the Canadian Red Cross. As WWII begins to escalate, the Department of National Defense seeks to support Britain and appoints committees to examine technical constraints and options. Best proposes the following: the Canadian Red Cross (CRC) will collect blood, Connaught Laboratories will receive government funding to produce dried serum, and the Canadian military will transport the product to Britain. A commercial based effort is rejected in part as too costly. A strictly government-run supply system, as in Britain, is judged not financially or politically viable, given recent debates over introducing a tax-supported universal health care system.

The exigencies of war help to create nationwide blood transfusion services. The Medical Research Council oversees schemes to organize blood depots to supply blood from across the country to forces overseas. The recognition that week-old blood may be used to prepare stable cell-free plasma provides an important therapy for the treatment of shock. The CRC will supply every hospital free of charge with whole blood collected from voluntary donors. National Campaign of 'Blood for the Wounded' corresponds with the Blood for Britain program in the US. Cultural and social views initially lead the US Red Cross to reject blood donations from Negroes. After national tumult, the US Red Cross modifies its policy so as to segregate blood.

1941: Canadian hospitals still require a patient's family and friends to donate twice the amount of blood transfused as repayment, if the patient does not purchase the blood from the bank (25\$/bottle) or resort to a professional donor. Because of the cost of commercially produced plasma, many hospitals process their own blood products. Random samples show many bottles to be contaminated with molds and bacteria. To address such issues, it is suggested that a national blood transfusion service should be administered by the Canadian Red Cross.

1943: Canadians make two million donations of blood in wartime through 662 blood clinics established by the Red Cross.

1944: War time transfusion therapy is so successful that a committee of the Canadian Hospital council, National Research Council and Canadian Red Cross Society study the possibility of providing transfusion service to civilians in peacetime. 'Blood Banking' remains in its infancy, and most hospitals depend on 'walking donors'. Patients pay as much as 40\$ per bottle for whole blood.

1947: CRC establishes a free national blood service. Its first Blood Transfusion Service (BTS) is established in British Columbia.

1954-55: The Canadian government, provincial health departments, Connaught Medical Research Laboratories, and the CRCBTS produce *immune globulin* from 100,000+ blood donations to reduce the effects of an outbreak of polio.

1959: Provincial governments with a hospital insurance plan contribute to Red Cross Transfusion Service. Blood Transfusion Services are available to more than 90% of all active hospital beds in Canada.

1961: With the opening of a blood transfusion depot in Quebec City, national coverage is complete. At clinics, blood is tested and grouped; donors are questioned for evidence of communicable diseases. Those with a history of malaria or jaundice are excluded. Laboratory analysis determines Rh, antibody and syphilis status.

1965: The 5th edition of the Red Cross Laboratory Manual is published as an international textbook of blood banking methods.

1960/70's: Closed system of plastic bags begins to replace glass bottles. The change means that blood may be safely processed more rapidly in larger amounts into packed red cells, platelets, cryoprecipitated factor VIII or fresh frozen plasma.

1972: Hepatitis B antigen screen is introduced, but its 35-45% sensitivity leaves undetected hepatitis carriers in the donor population. The introduction of the test means donor files must be updated, as donations have grown to more than a million annually in Canada.

1977: Radioimmune assays (RIA), with improved sensitivity, become the method of choice for detecting hepatitis.

1982: Three Canadian haemophiliacs are discovered to have developed AIDS, possibly from blood products.

1982: Licensing of Hepatitis B vaccine.

1983: A statement on AIDS and blood transfusion is issued by the American Association of Blood Banks, the American Red Cross and the Council of Community Blood Centers, with the assistance of the American Haemophilia Foundation and others. The statement acknowledges that AIDS may be transmitted through blood, but deems the evidence inconclusive. The Canadian Haemophilia Society offers recommendations for the prevention of AIDS in haemophiliacs. The US Center for Disease Control (CDC) and Red Cross advise that anyone at risk of developing AIDS should exclude themselves from donating blood.

1984: CRC prints donor brochures identifying individuals and groups at high risk for AIDS. Canadian federal health authorities circulate pamphlets to alert the public to the risk of AIDS transmission through blood. After the AIDS virus is experimentally added to Factor VIII concentrate and is found to be inactivated through heat treatment, the Canadian Bureau of Biologics (BOB) licenses Cutter Laboratories in the US to produce heat treated antihaemophilic factor VIII for Canada. Scientists also announce the discovery of the gene that causes haemophilia.

1985: The first supply of heat treated Factor VIII from Cutter is released for sale in Canada. Hundreds of haemophiliacs, who have been treated with antihaemophilic blood products, have been infected by HIV contaminated blood products. The U.S FDA approves the first commercial HIV test for screening donated blood.

1989: The Principles for the Canadian Blood System, dating from the 1970s, are revised to include voluntarism, self-sufficiency, adequacy, safety, gratuity, cost-effectiveness, and a national blood program.

1990: A screening test for Hepatitis C is developed, though this strain of the virus has been known for years to be transmissible by blood.

1993: Canadian and European authorities license the first genetically-engineered agent for treating hemophilia, recombinant DNA Factor VIII. The approvals follow licensure in the US a year earlier.

1994: Months after its creation by the Federal and Provincial Governments, a Commission of Inquiry on the Blood System of Canada begins its first of 250 hearings.

1997: Justice H. Krever, Chairman of the Commission of Inquiry on the Blood System in Canada, makes public his 1100-page final report that contains some 50 recommendations. In partial response, the federal government immediately announces the creation of a National Blood Safety Council to advise on matters of blood safety.

1998: A newly-created entity, the Canadian Blood Services assumes responsibility for operations of the Canadian blood system from the Canadian Red Cross. Hema Quebec assumes parallel responsibilities in Quebec.

Sources:

Cooter R. Medicine and the Goodness of War. *Can. Bull. Med. Hist.* 1990;7:147-159; Greenwalt TJ. A Short History of Transfusion Medicine. *Transfusion* 1997;37:550-563; Kapp RW. Charles H. Bat. The Canadian Red Cross Society, and Canada's First National Blood Donation Program. *Can. Bull. Med. Hist.* 1995;12:27-46; National Research Council of Canada. *Proceedings of the First Meeting of the Subcommittee on Blood Storage.* Montreal, 1939; Drees TC. *Blood Plasma: The Promise & the Politics.* Ashley Books: New York, 1983; Spencie L. *One Blood: The Death &*

B. Determinants of Supply & Demand: A Sampling

The foregoing chronology highlights a range of factors that may well contribute to shortages of human blood. Closer examination of some of factors shows how formidable are the challenges to confronting shortages.

Basic principles of economics hold that, whether for the short or long-term, shortages fundamentally result from disequilibria between supply and demand. This would seem self-evident. The simplicity of the insight fades, however, when policy-makers must decide how precisely to address shortages. Should they invoke supply-side initiatives, demand-side initiatives, or some combination of the two? Demand may be curtailed. Supplies might be increased. Factors affecting the balance between the two might be stressed. In short, if we take seriously the relation between supply and demand, it may help to structure more effective or at least more coherent approaches to plasma shortages. Otherwise, the policy intervention may prove erratic or incoherent. If emphasis is placed on supply-side “solutions”, when the leading or most influential factors lie on the demand side, the approach seems less likely to be effective. Ideally, then, a coherent approach to structuring national blood policy on shortages would be based on a clear understanding of the leading factors that contribute to demand, the factors that determine supply, and the factors that largely determine the dynamics and disequilibria between the two. Of the multiple factors that contribute to disequilibria between supply and demand, the following explores the influence of standards of practice, the state-of-the-art of science, cost, safety and socio-ethical attitudes.

1. Standards of Practice: The standards of practices for the treatment of classic haemophilia (haemophilia A) have long been a leading element in the medical demand for plasma. This was recently made clear in the Krever report. The report noted the evolution in the Canadian standard of medical care for the treatment of haemophilia from reliance on whole blood in the 1950s, to the use of high

purity concentrates in the 1970s, to the use of preventive home care in the 1980s, to the use of genetically-engineered factor concentrates in the 1990s.⁵ The history suggests that the discovery of, or gradual consensus on, effective plasma-based therapy may shift medical demand for human plasma. If the standard of medical practice requires more or less plasma-based therapeutics, and practitioners largely conform to the standard, then the standard may increase or decrease demand. When there is no standard or when the standard is largely ignored, medically-induced demand for a particular treatment is likely to prove erratic. Recent trends in the standards of practice for treating haemophilia illustrate the dynamic. Preventive or prophylactic therapy involving the use of the plasma-derivative Factor VIII (F VIII) has now been deemed the treatment of choice for haemophilia A in the UK, Sweden and other countries. Questions remain, however, over the precise amount of F VIII per capita that is needed for optimal therapy. Standards range from roughly 2 units/capita across many European countries⁶ to over 4.5 units/capita in countries such as Sweden.⁷ The high demand for plasma-based antihemophilic products in Sweden stems in part from its historic standards of practice. For some 40 years Sweden has distinguished itself by prophylactic treatment of haemophilia,⁸ with current therapy involving 25-40 international units (IU) per kilogram (kg), "usually three times weekly in haemophilia A."⁹ Such therapy is aimed at keeping the level of Factor VIII at optimal levels to prevent spontaneous bleeding, joint problems and like disabling conditions that compromise the lives of those with haemophilia.¹⁰ If the standard of medical practice in other countries shifts towards the Swedish model in the search for optimal therapy,¹¹ then plasma use may shift as well. Obviously, a two-fold difference in medical use of

⁵ Krever H, op. cited, pp. 164-177.

⁶ Schimpf K. Should Clinical Freedom be Constrained in the Pursuit of Self-Sufficiency? *Blood Coagulation & Fibrinolysis* 1994;5(4 Supp):S47-S49.

⁷ Leikola J. Can the Supply and Demand for Plasma-Derived Products Ever Be Reconciled? Self-Sufficiency from the Viewpoint of a Blood Transfusion Service. *Blood Coagulation & Fibrinolysis* 1994;5(4 Supp): S15-S17.

⁸ Nilsson IM, Berntop E, Löfqvist et al. 25 Years Experience of Prophylactic Treatment in Severe Haemophilia A & B. *J. Intern. Med.* 1992;232:25-32.

⁹ Nilsson IM. Is Haemophilia Prophylaxis Achievable in the Context of Self-Sufficiency? *Blood Coagulation & Fibrinolysis* 1994;5(4 Supp):S71-S75.

¹⁰ Liesner R. Prophylaxis in Haemophilic Children. *Blood Coagulation & Fibrinolysis* 1997;8(1 Supp):S57-S10.

¹¹ Schimpf, op. cited.

plasma derivatives may significantly influence national demand for human plasma. These examples suggest that national blood policy in countries with chronic shortages of plasma can ill afford to ignore or slight the role of the standards of medical practice.

2. Science & Technology: Shifts in the standard of medical practice relate directly to another leading determinant of supply and demand: scientific knowledge and technology. The chronology in Table A, above, demonstrates that the history of transfusion medicine is primarily a 20th century phenomenon largely due to advances in the state-of-the-art of medical sciences that finally permitted safe blood replacement therapies. As scientific knowledge and technological innovations move from discovery and into clinical practice, they may radically influence supply or demand. The discussion of standards of practice has suggested that therapies requiring more use of human plasma may increase medical demand. On the other hand, new technology will sometimes help to boost supplies or reduce demand. The discovery and introduction of the four blood groups, the shift from glass bottles to plastic blood collection bags, advances in blood preservation and banking, the introduction of plasmapheresis technology -- all, are supply-side examples noted in the chronology. On the demand side, recent studies of the use of blood transfusions for critically ill patients suggest that restrictive uses of blood have no negative impact on patient health.¹² If the finding is documented and replicated, it suggests that the optimal use of blood in some medical domains has not been attained. Such optimal use may reduce demand.

Similarly, the invention of viral screening tests or vaccines that minimize the risks of disease in donors are technological advances that enhance the quality of the blood supply. In this vein, technological optimism would suggest that the new genetic biotechnology era holds great promise for supply-side solutions to plasma shortages. The promise is illustrated by the discovery of cloning of the F VIII

¹² Hebert PC et al. A Multi-centre, Randomized Controlled Clinical Trial of Transfusion Requirements in Critical Care. *New Eng. J. Med.* 1999; 340: 409-417.

protein in the 1980s: the research laid the foundation for the development in the 1990s of genetically-engineered F VIII.^{13,14} It has become the standard of practice for treating Haemophilia A in North American and many European countries. Enabling technology thus resulted in a paradigm shift: from natural to genetically-engineered plasma replacement therapies. Similarly, gene therapy for haemophilia — an hereditary disorder that is transmitted to males¹⁵— may soon move from theory, to testing and into clinical therapy.^{16,17} Safe and effective gene therapy for haemophilia would likely reduce the demand for plasma-based therapies. Other potentials include the use of gene technology to clone and modify animals¹⁸ or human stem cells¹⁹, so as to generate new, safe and effective plasma-replacement therapies. These examples suggest the powerful therapeutic promise of scientific innovation for meeting medical needs and for balancing the demand for and supply of blood products. They further suggest that national blood policy in countries with chronic shortages of plasma can ill afford to ignore or slight the role of scientific research and technological development.

3. Cost & Finances: Cost and finances define another important factor in the supply and demand for plasma replacement therapies and technologies. When a new and effective plasma replacement technology emerges, for instance, who shall have access to the technology and at what cost? This question has recently arisen in the UK, where recent medical guidelines deem rDNA F VIII the treatment of choice for haemophilia A. Recombinant F VIII may cost a third more at the whole sale price than high-purity plasma-derived F VIII (\$.85/IU versus \$1.18/IU).²⁰ Indeed, it has been estimated that to shift from high-purity plasma-derived products to genetically-engineered FVIII to treat

¹³ Schwartz RS et al. Human Recombinant DNA - Derived Antihemophilic Factor (Factor VIII) in the Treatment of Hemophilia. *New Eng. J. Med.* 1990;323:1800-1805.

¹⁴ Grove GH. Recombinant Blood Components: Clinical Administration Today and Tomorrow. *World J. Surg.* 1996;20:1194-1199.

¹⁵ Hoyer, LM. Hemophilia A. *New Eng. J Med.* 1994;330: 38-47.

¹⁶ Fields PA, Pasi KJ. Gene Therapy for Hemophilia: How Far Have We Come? *Haemophilia* 1998;4:699-703.

¹⁷ Lozier JN, Brinkhous KM. Gene Therapy and the Hemophilias. *J Amer. Med Assoc.* 1994;271:47-51.

¹⁸ Zehr L. Nexia Produces Genetically Altered Goat. *Globe & Mail*, 1 Sept. 1998.

¹⁹ Geron Ethics Advisory Board. Symposium: Human Primordial Stem Cells. *Hastings Cntr. Rpt.* 1999; 29:30-48.

²⁰ Grupp RA. Prophylaxis for Hemophilia: State of Art or State of Confusion? *J. Pediatrics* 1998;132:915-917.

haemophilia, will cost 1.5²¹ to two times the estimated £40,000,000²² currently spent on FVIII in the UK. Such a cost differential may prove so prohibitive for the national health systems of some nations that the shift is unlikely to occur soon.²³ Recognition of cost as an important element of national blood policy may thus foster the development of strategies for cost-effectiveness. It may implicitly acknowledge the role of allocation of resources issues and related ethical implications. It may also enlarge the pool of analysts to include health economists and like interdisciplinary expertise for broader, coherent blood policy formulation.²⁴

4. Safety: Safety is another leading factor that contributes to supply and demand imbalances. As the chronology suggests, safety has been a moving force in the history of transfusion medicine. From the early days in the development of transfusions as an acceptable therapy, safety considerations today affect who and how we transfuse, donate, process, screen and even receive blood products. Some of the diverse medical, legal, professional and industrial standards of safety and quality control will be elaborated below. For now, it is important to note some of the less conspicuous dimensions of safety that prove challenging for national blood policy.

Safety is not an absolute concept, for example. Because we may agree that the protection of human life and health ranks high in our hierarchy of public values, we may readily agree that safety should be a cornerstone of national blood policy. Because implementation of the safety of the blood supply depends on range of other factors, however, we may not readily agree on how much safety to make a priority at a particular time in history. Suppose the purchase of a blood screening test costs tens of

²¹ Liesner, op. cited.

²² Giangrande PLF. Who Should Receive Recombinant Factor VIII? *Blood Coagulation & Fibrinolysis*, 1997;8(1 Supp): 525-527.

²³ Srivasta A, Chuansumrit A, Chandy G et al. Management of Haemophilia in the Developing World. *Haemophilia* 1998;4:474-480.

²⁴ See, e.g., Schramm W & Szucs TD. State-of-the-Art Principles and Practices of Medical Economics. *Haemophilia* 1998;4:491-497.

millions of dollars to detect 5 cases of viral infection in the blood supply annually. Do we all agree to invest in the new test? In the throes of a national blood products shortage, is it ever justifiable to use blood products that carry a small risk of contamination by a chronic but potentially lethal virus; or, is it preferable to maintain higher purity, but risk losing lives now for want of blood? While such stark situations may seldom arise, some would still argue that as a matter of policy and ethics the urgency of saving lives now should prevail over concerns about the longer term safety of the blood supply.

Whether one agrees with that judgment, the dilemma suggests basic insights. To make the underlying safety calculus, for instance, requires competent risks-benefit analysis. The collision of different judgments reveals, as well, that blood safety policy sometimes involves value conflicts. Coherent policy needs to recognize the relevant value conflicts, analyze them, and have in place the means to manage them. Finally, the scenarios suggest that a commitment to the protection of human health and life in national blood policy requires implementing means. The concept of and commitment to safety needs to be made concrete. Like other aspects of coherent blood policy, safety policy requires a search for both reasonable standards and for mechanisms of effective implementation.

5. *Socio-Ethical Attitudes:* Ethical and social attitudes may also influence the demand for and supply of blood products. A few examples illustrate the interplay.

The chronology in Table A above, for example, indicates how racial attitudes in the US during WWII led to the segregation of blood. In the absence of any medical basis for such segregation, the policy likely required human resources and monies that otherwise might more optimally have been allocated. Social attitudes thus helped to determine the structure and perhaps even the quantity of some of the US blood supply in that era. Such attitudes are based on particular values. For instance, the value of equality likely has more resonance in public policy and law today in North America than half a century ago. This helps explain why we may look askance at the blood segregation policy as insidious or counterproductive.

Still, the public value of equality wears many faces. A commitment to equality likely means that society has a general duty to accommodate equally the diverse religious beliefs of its members. If the dictates of some religious beliefs collide with practices designed to enhance the blood supply, which prevails? Inquiry about the therapeutic use of cadaver blood,^{25,26} might generate objections on the basis of religious beliefs, for instance. Other values and beliefs may come into play if society were to impose an obligation on its members to donate a pint of blood annually. A duty to donate might be based on grounds that human solidarity and the general welfare require it. Such a requirement may transgress individual or religious autonomy, however. As a result, society may opt more for a general policy of voluntarism and strongly-encouraged giving. Similarly, some may view the recourse to natural or genetically-engineered animal sources for blood replacement therapy as justified, depending on how the purpose, manner and results of the enterprise affect animal welfare.²⁷ Others may object to the use of animals, regardless of the purpose or manner, because the intervention is thought to abridge what might be viewed as intrinsic animal rights. Finally, as will be explored below, a society that judges the sale of blood as ethically abhorrent, when sales may well boost therapeutic supplies, makes a judgment about the relative good or ills and the implicated values. These examples indicate that ethical and social views may influence societal acceptance of different sources or strategies for addressing imbalances between the demand for and supply of blood. They further suggest that national blood policy in countries with chronic shortages of blood products can ill afford to ignore the role of underlying ethical considerations and associated values in defining national strategies to address blood scarcity.

²⁵ Yudin SS. Transfusion of Cadaver Blood. *JAMA* 1936;109:997-999.

²⁶ National Research Council of Canada. *Proceedings of the First Meeting of the Subcommittee on Blood Storage of the Associate Committee on Research*. Montreal, 2 Dec. 1939.

²⁷ Nuffield Council on Bioethics. *Animal to Human Transplants: The Ethics of Xenotransplantation*. London, 1996;37-45.

C. Sales & Disequilibria

The foregoing sampling of factors that influence blood shortages provides important context for the question of should we sell blood. First, assuming basic economic theory applies, blood shortages likely result from imbalances between demand and supply. Secondly, then, to focus on sales is to focus on a supply-side strategy to correct the disequilibria. Thirdly, without more information about other supply-side or demand-side factors, it is difficult to judge the comparative merits or the value of alternative strategies. A decision to focus exclusively on sales risks ignoring other legitimate factors and strategies that may ease imbalances. Some of those strategies may evoke greater or fewer ethical concerns. Some may prove more corrective of disequilibria. Indeed, if we acknowledge that evolving health needs, standards of medical practice, technological constraints and advances, costs, safety factors, and socio-ethical attitudes influence the supply of and demand for blood, then we also acknowledge that the question of sales/donor incentives is but one of many that needs to be asked to develop coherent blood policy. It is a dynamic web of factors. Nevertheless, the sales question has for decades been a major policy issue. It continues to be one that raises diverse considerations. Thus, it is against this broader context and in the absence of full comparative analysis that we turn to arguments for and against the sale of blood.

II. Sales: Arguments For & Against

This section outlines some of the leading arguments for and against the sale of human plasma as a means of increasing therapeutic supplies. Because the arguments also parallel or resonate through policy debates over the sale of other human bodily substances, broader arguments over the sales of human tissues are also canvassed.

A. Altruism: Gifts of Life for Strangers

Altruism, a term coined by a 19th century French philosopher Auguste Comte, has come to signify a principle of action and concern for the welfare of others. In 1970, Richard Titmuss, a British sociologist at the London School of Economics, argued in his book *The Gift Relationship*,²⁸ that altruism should be a foundational element of national blood policy. The argument is based on relationships and on communitarianism, in that how we relate to others defines our moral core as humans and communities. As a social welfare analyst, Titmuss argued that some corners of society should be defined and structured by giving, not trading. He chose blood policy in part because, for him, anonymously donated blood to strangers symbolizes the virtue of gift relations: motivated by no formal contract, no legal bond, no situation of power, domination, constraint or compulsion, no sense of shame or guilt, no gratitude imperative, no need for penitence, no money, no explicit guarantee or wish for a reward or a return gift.²⁹ In a policy choice between gift-based or commercial-based relations, society should opt for and cultivate the former. His work condemned the reliance of the US blood system on paid donors, as contrary to altruism, wasteful, exploitive of the poor, and unsafe. The arguments underlying the gift to strangers ethic have since been applied in policy debates over the transfer of human tissues and organs:

Impersonal gifts such as blood or body parts for charity may not regulate relationships between specific individuals, but they serve other functions by regulating larger relationships and honouring important values... Gifts to strangers affirm the solidarity of the community over and above the depersonalizing, alienating portions of mass society and market relations. They signal that self-interest is not the only significant human motivation. And they express the moral belief that it is good to minister to fundamental human needs...³⁰

While such views may well inspire or ennoble, several arguments may be invoked against them. First, for instance, to cast the debate and choice in terms of altruism versus paid donation is to construct a

²⁸ Titmuss R. *The Gift Relationship: From Human Blood to Social Policy*. London: George Allen & Unwin Ltd, 1970.

²⁹ *Ibid.*

³⁰ Murray TH. Gifts of the Body and the Needs of Strangers. *Hastings Center Rpt.* 1987;17:30-38, 35.

false dichotomy.³¹ All that is altruistically motivated is not necessarily moral. All that involves payment is not amoral. If this is accurate, then altruism cannot be an absolute and determinative social value even in such matters as national blood or tissue policy. Secondly, then, it not clear in either theory or practice that altruism need be the exclusive policy to ensure due regard for the welfare of others.³² Such a claim otherwise runs contrary to ethical pluralism. Thirdly, the precise basis of altruism is unclear: social contract or communitarianism, solidarity, good samaritanism. Fourthly, the philosophy reifies social relations by abstracting people and their diverse circumstances from reality. Would be donors are not universally the same, but live at all strata of society. They thus face varying barriers to the expression of their caring and regard for the welfare of others. Paying some donors may help them express their altruism. Finally, exclusive altruism may fail to supply sufficient blood or tissue for health needs. Systems based on altruistic and market components may yield a greater supply of scarce tissues like plasma.³³ Such mixed systems thus may be more responsive to the protection of health and life.

B. Commodification of the Human Body

A commodity is an object of commerce, usually a good that can be bought or sold in the market for particular value. Because the market does not inhabit all corners of life, however, all is not regarded or treated as commodities. At different epochs in the west, religious, ethical, and legal sensibilities have sought to keep the human body out of commerce as a non-commodity. At least since the 17th century, for instance, the common law has held that there is no property in the body.³⁴ The principle has not

³¹ McLachlan HV. The Unpaid Donation of Blood & Altruism: A Comment on Keown. *J. Med. Ethics* 1998;24:252-254.

³² American Medical Association, Council on Ethical & Judicial Affairs. Financial Incentives for Organ Procurement. *Arch. Intern. Med.* 1995;155:581-589.

³³ von Schubert. Donated Blood -- Gift or Commodity? Some Economic & Ethical Considerations on Voluntary vs. Commercial Donation of Blood. *Soc. Sci. & Med.* 1994;39:201-206.

³⁴ Law Reform Commission of Canada. *Procurement & Transfer of Human Tissues & Organs*, 1992:66.

governed all contexts, however, as illustrated by the history of slavery. Still, modern society can make choices:

By making something nonsalable we proclaim that it should not be treated as a commodity. When something is noncommodifiable, market trading is a disallowed form of social organisation and allocation....What are some of the things whose commodification is contested? Infants and children, human reproduction, sperm, eggs, embryos, blood, human organs, human sexuality, human pain, human labor.... These issues inhabit the domain of contested commodification, the arena of struggle over what things are suitable for markets, both literally and metaphorically.³⁵

Associated with such choices, is a long established philosophical theory of moral personhood, and the many provocative questions it raises. The theory distinguishes “persons” from “things”: things, as objects should never be bought and sold; persons, as subjects of free will, are entitled to respect, and should never be treated as things or as means towards an end. To regard a donor as a perpetually renewable blood resource tends to reduce a human to an object, for example.

If the person/subject-thing/object distinction seems persuasive or tenable, then it still raises important questions. How do we categorize human bodily substances or tissue? Are they property³⁶ that may be exchanged as part of ones exercise of free will? Some have argued this view on the basis of a personhood theory of property, consonant with the need to protect individuals in a biotechnological age.³⁷ On the other hand, some would argue that bodily substances like blood are so associated with our integrity as persons that they are tantamount to, or are elements and symbols of, human dignity or personhood.³⁸ What is the precise basis of categorizing a bodily substance or tissue as non-commodifiable or commodifiable? Is the context determinative? Some have argued that the answers depend on the bodily part or substance, meaning that we should regard and treat differently waste products like perspiration, renewable substances like sperm and blood products and non-renewable

³⁵ Radin MJ. *Contested Commodities*. Harvard Univ. Press, Cambridge: 1996:20-21.

³⁶ Andrews L. My Body My Property. *Hastings Center Rep.* 1986;16:28.

³⁷ See Law Reform Commission of Canada, op. cited., p. 43.

³⁸ See, e.g., Murray, op. cited.

tissues like kidneys.³⁹ If answers to such questions are not clear, it will be shown below that the uncertainty has not dissuaded some countries from grounding their laws and public policies on commodification theories.

C. Life Saving Necessity

One of the more forceful arguments invoked for justifying the sale of tissue is a public necessity claim. Typically, the argument is that sales or financial incentives are necessary to avert the greater and avoidable harms of human suffering, illness or death, which arise from acute, persistent tissue scarcity: “I believe in a higher morality: first, take care of all patients' needs, and then worry about the morality of paying donors”.⁴⁰ The argument is often cast as the most reasonable path in a choice of evils, whence the value of saving life or health emerges as paramount. It is an argument that relies in part on empirical evidence, meaning that examples of unpaid donor systems achieving adequate supply may tend to rebut the claim of necessity.⁴¹ The necessity argument has been relied on both historically and recently in arguments for the sale of human plasma and organs. Since it is a recurrent and powerful argument, it would seem prudent to understand the particular elements and showings essential for establishing a reasonable claim of necessity.

D. Language, Ethics & Public Discourse

Related to the commodification argument is a concern that flows from the growing scholarship on the relation between language, ethics, law and public policy. A major focus of the concern is on how words powerfully express values, how language shapes ethical deliberation, and how choice of words and discourse are critical in matters of public debate and policy. The word “donor”, for example, has

³⁹ Keown J. The Gift of Blood in Europe: An Ethical Defence of EC Directive 89/381. *J. Med. Ethics* 1997;23:96-100.

⁴⁰ McAulley C. Plasma Exchange & the Paid Donor System. *Lancet*, 18 October 1980:855.

⁴¹ Keown, op. cited.

two meanings in public policy debates on blood collection. To donate in the non-medical context often connotes giving or conveying as a gift. What, then, is the meaning of the phrase “paid donor”, since one is not usually paid for donations? The question may be partially answered by the second meaning of donor. In a medical context the word “donor” may simply mean one who serves as a source of biological materials. To avoid the confusion generated by the term “paid donor” one analyst has recently suggested the word “contributor” for those “donors” paid for plasma “donations”.⁴² Another potentially confusing term is the word “volunteer”. Voluntary usually connotes one's free will, meaning that a volunteer donor is one who gives without coercion. Yet, voluntary may also connote “gratis”. In the literature we therefore find “paid” donation juxtaposed against “voluntary” donations⁴³ -- the subliminal message being that a paid donation is not uncoerced. The choice of words conveys different messages. From this perspective, there are also significant differences in characterizing those who transfer blood as “donors” or “vendors”. To some, the use of commercial language tends to devalue the human body, corrode the gift ethic, and thus undermine morality. Proponents of sales are likely to contest these claims. They appeal to the virtues of free, vigorous and pluralistic discourses. Ethical pluralism, after all, supports a range of ethical discourses about markets of both a non-profit and profit nature.

E. Paid Donors: Expenses, Profits & Sales

The policy debates over paying donors also reflect differing views of the purposes and function of remunerating those who become sources of tissue. The debates may be guided by some basic questions. First, for instance, what is a tissue sale? Does all money exchanged surrounding the collection and transfer of tissue constitute a “sale”? Secondly, what is payment for -- tissue, services, expenses? The distinction between paying for services and paying for tissues, for example, has been

⁴² Bayer Advisory Council on Bioethics. *Creutzfeldt Jacob Disease, Blood & Blood Products: A Bioethics Framework*, s. 2.3. Ottawa, 1998 [www.bayer-bioethics.org].

⁴³ Titmuss, op. cited, pp. 75-89.

recognized by the courts in North America for decades in analogous tainted blood litigation.⁴⁴ If the payment is for tissue its quantity, its quality, and amount relative to demand would seem to determine price. As noted above, payment for tissue raises commodification concerns. If the payment is a fee-for-service, then the actual fee may well depend on the frequency, risks assumed and inconvenience. Thus, in the non-blood domain of reproductive tissue sales, part of the rationale for the huge differential in payments for human eggs and sperm in the US is the higher risk, inconvenience, pain and time required of egg “donors” (e.g. \$50 v. \$2500 per donation).⁴⁵ If the payment is to reimburse expenses, then the question becomes what expenses are to be covered. These differences suggest that payments associated with the transfer of human tissue need not necessarily be regarded as sales.

Thirdly, beyond the functional question of payment for what, is the question of the broader purpose of payment. For example, advancing a financial neutrality principle is one of the leading arguments for the payment of some expenses -- that is, payments are intended to remove the financial barriers to donation that might be erected by travelling and meal expenses or even by foregone income. Such payment effects the rational “that the donor should neither gain nor lose financially by the donation”.⁴⁶ A flat prohibition on any payments contravenes this neutrality principle by technically banning reimbursement of expenses. It so discourages those whose donations will incur prohibitive expenses in exercising their altruism. In the extreme, it effectively imposes a tax on some donations. By contrast, full or partial implementation of the neutrality principle, practically, would spell the difference between partial or full cost recovery for the donors. The setting of reasonable and uniform reimbursement fees for tissue collection centers across a region may eliminate the administrative burden of calculating donor expenses in every instance, and may minimize the risk of donors seeking to recover fees from the most generous

⁴⁴ See the *Pearlmutter* case from the 1950s in the US, discussed in Section II.A.1, below, and *Ter Keuzen v. Korn*, [1995] 3 S.C.R.674 from Canada.

⁴⁵ Mead R. *Annals of Reproduction: Eggs for Sale*. *New Yorker*, 9 Aug. 1999:56-65.

⁴⁶ Law Reform Commission of Canada, op. cited, pp. 84-85, citing the *Report of the Working Group on Vital Organ Transplantation to the Deputy Ministers of Health* (Sept. 1985).

of centres. As such, the rationale and implementation of payment of reasonable donor expenses is not without its difficulties. Unreasonable, excessive or unregulated payments for expenses may function as or be seen as payments for tissue. Payments that are intended to, or do, remunerate beyond actual or reasonably predicted costs or expenses are payments for profit. In theory, the monies gained in such profit circumstances might be taxable under income tax law.⁴⁷

Finally, it should be noted that many of the questions of tissue sales, the rationale and function of payment, and like considerations apply as well to debates over payments for processing, storing, and distributing tissue for therapeutic use. For instance, some generally maintain that it is ethically preferable for tissue banks not profit from human tissue -- that is, to receive payments beyond reasonable costs or expenses.⁴⁸ Some also question the equity and rationale of prohibiting donor sales from human sources while allowing them between processors, tissue banks, or hospitals. Thus, clarifying and distinguishing the function and purpose of payments enables public policy and law to discriminate between monetary transfers associated with the collection, processing and distribution of human tissue. As will be shown, the Council of Europe, the US, Canada, France, and Australia have incorporated such distinctions into prohibitions and policies on tissue sales.

F. A Duty to Rescue

Though not always framed as such, proponents and opponents of sales also seem to differ over the force and application of an ethical duty to rescue. In this instance, the duty would extend to those whose life or health is imperiled by the want of blood. The duty holds that we have responsibilities to render assistance to others in need of it, if doing so does not place us in peril. The duty has received

⁴⁷ Compare *United States v. Garber*, 607 F.2d 52 (5th Cir. 1979) (questioning the taxability of \$80,000+ of donor income from plasma sales) with Finnish Law which renders income from donated breast milk non-taxable.

⁴⁸ See, e.g., European Commission, European Group on Ethics in Science and New Technologies. *Opinion No. 11: Ethical Aspects of Human Tissue Banking*. Brussels, 1998.

some general legal recognition.⁴⁹ Arguably, the duty to rescue infuses tissue transfer law in some countries. Those that authorize post-mortem procurement of organs or tissues -- absent one's express or registered objection during life -- do so on a presumption that the recently deceased either intended,⁵⁰ or has a duty, to rescue fellow living beings who are desperately ill, by sharing bodily substances no longer needed upon death. Overall, those disposed towards strong notions of community might favor a duty to rescue. Those disposed towards strong notions of autonomy might favor such a duty less. Under some versions of the duty, it applies most forcefully when those in peril are specifically identifiable or when the would-be rescuer has a "special relation"⁵¹ with the person in need. Both conditions make the case more psychologically compelling. The duty has also been long debated in the transplantation literature.⁵² Indeed, it has even been litigated unsuccessfully in the context of alleged familial duties to provide bone marrow to relatives. In those instances, concerns over the inviolability, bodily integrity and autonomy of would-be donors were deemed paramount such that there was no duty to rescue by donation.^{53,54} Whether any such duty is grounded on social contract, solidarity, or good samaritanism, it raises questions on the specific contours of our duties to others in the face of chronic plasma shortages.

⁴⁹ See, e.g., Quebec. *Charter of Human Rights & Freedoms*, 1975, as amended, s. 2; RSQ, c. C-12.

⁵⁰ Jonssen L. The Swedish Transplantation Law. *Intl Dig. Hlth Legis.* 1997; 48: 237-239. See also Table D, below.

⁵¹ See, e.g., s. 215 of the *Criminal Code of Canada* which imposes familial duties to provide "necessaries for life". Under *R. v. Tutton*, [1989] 1 S.C.R. 1392, "necessaries for life" includes such routine tissue replacement therapy as insulin.

⁵² Law Reform Commission, op. cited, pp. 89-91.

⁵³ *Curran v. Bosze*, 566 N.E. 2d 1319 (Ill., 1990).

⁵⁴ *McFall v. Schimp*, 10 Pa. D. & C. 3d 90 (Penn. Cnty Ct., 1978).

G. Paid Blood = Contaminated Blood?

Even since it was argued in the 1950s that paid blood has a higher incidence of contamination,⁵⁵ blood products from paid donors have been associated with poorer quality, if not, unsafe blood. This was one of the arguments of Titmuss.⁵⁶ The claim has clear public health implications. As will be shown, it has prompted major statements and policy reforms in several nations historically and recently. Thus, it is among the most powerful of tissue sales issues. Opponents of paying donors tend to invoke the historic refrain; proponents of payments tend to refute it. The validity of the claim is a function in part of the historic legacy, in part of the force of any cause-effect relation and in part a question of empirical evidence.

Consider some of the historic legacy and modern empirical evidence. In terms of the legacy, for instance, while many accounts emphasize that paid blood is often less safe, the history also includes evidence that some paid blood was equal, or superior, to the quality of unpaid blood.⁵⁷ If this is accurate, it indicates that the history is not uniform but consists of varied stories. It further suggests that factors beyond money help to explain so-called tainted blood. One important factor would seem to be the state-of-the-art of infectious screening technology as applied to tissue procurement standards. Today, many developed nations do have relatively sophisticated infectious disease tests, modern screening technologies, viral inactivation processes, broad regulations and rigorous standards, which did not characterize blood collection some 30 years ago.⁵⁸ Yet, the saga of HIV and hepatitis C infection of the blood supply in recent years reminds us that screening and processing tests “are not 100%

⁵⁵ Domen RE. Paid - Versus - Volunteer Blood Donation in the United States: A Historical Review. *Transfus. Med. Rev.* 1995;9:53-59.

⁵⁶ Titmuss, op. cited, pp. 142-158.

⁵⁷ Domen, op. cited.

⁵⁸ Westphal RG. International Aspects of Blood Services in *Principles of Transfusion Medicine* (Rossi et al., eds). Williams & Wilkins, Baltimore, 1996:917-922.

effective”,⁵⁹ that rigorous standards are not uniformly applied, and that administration and organizational structure remain critical issues in national blood policy. Indeed, as will be shown, below, these factors have continued to prompt major policy debate in the late 1990s in such countries as Canada and the US. Some of the historic legacy continues.

In terms of the current evidence that paid blood is of poorer quality, the data seems to support differing views, in part because it does not necessarily meet the modern standards of evidence-based science. Some US studies have found disquieting HIV infection rates in those addicted to drugs and who have sold blood plasma.^{60,61} Broader recent medical reviews have found that the preponderance of such studies demonstrates that paid blood remains associated with a greater prevalence of transmissible disease.⁶² Other recent studies, however, support the view that it is neither payment nor nonpayment but the donor population that is most indicative of the quality of blood.⁶³ Many studies agree that reliable or definitive evaluation of the evidence is made difficult due to the paucity of well-controlled studies that test directly the relation between quality and payment, and control for confounding factors.^{64,65,66} Absent evidence from rigorous and scientifically-controlled inquiry, policy is based on data from uncontrolled studies, reported and historic experience, presumptions and bias.

⁵⁹ Barker LF, Westphal RG. Voluntary, Non-Remunerated Blood Donation: Still a World Health Goal? *Transfusion* 1998;38:803-806 (editorial).

⁶⁰ Chitwood et al. The Donation and Sale of Blood by Intravenous Drug Users. *Am. J. Pub. Hlth* 1991;81:631-633.

⁶¹ Nelson KE. Blood and Plasma Donations Among a Cohort of Intravenous Drug Users. *J. Am. Med. Assoc.* 1990;263:2194-2197.

⁶² Eastlund T. Monetary Blood Donations and the Risk of Transfusion - Transmitted Infection. *Transfusion* 1998;38:874-882.

⁶³ Strauss RG, Ludwig GA, Smith MV et al. Concurrent Comparison of the Safety of Paid Cytapheresis and Volunteer Whole - Blood Donors. *Transfusion* 1994;34:116-21.

⁶⁴ Domen RE. Paid - Versus - Volunteer Blood Donation in the United States: A Historical Review. *Transfus. Med. Rev.* 1995;9:53-59.

⁶⁵ Simon TL. Monetary Compensation for Plasma Donors: A Record of Safety. *Transfusion* 1998;38:883-886.

⁶⁶ Strauss RG, Ludwig GA, Smith MV et al. Concurrent Comparison of the Safety of Paid Cytapheresis and Volunteer Whole - Blood Donors. *Transfusion* 1994;34:116-21.

H. Financial Incentives & Health Disclosure

Part of the view that paid donors are more likely to yield tainted blood is that money provides an incentive not to disclose diseases or like health information that would disqualify donors from receiving payment. Honesty and truth-telling, as moral virtues, are infringed. Payment, moreover, compromises veracity to the public detriment:

As freedoms are lost in the blood marketplace truth is an accompanying victim. ... The paid seller of blood is confronted and, moreover, usually knows that he is confronted with a personal conflict of interests. To tell the truth about himself, his way of life and his relationships may limit his freedom to sell his blood in the market. Because he desires money and is not seeking in this particular act to affirm a sense of belonging he thinks primarily of his own freedom.... The social costs of untruthfulness are now clear and ... they fall randomly on rich and poor alike. The dishonesty of donors can result in the death of strangers.⁶⁷

The argument is powerful. It has echoed in many forums, including tainted blood litigation.⁶⁸ Its premises need not hold, however. Payment policy, for instance, need not silence donors about relevant health information. Payment policy may include advising donors that their blood or plasma may be used preferentially for therapy, but that it also may be used for research. Alternatively, it has been suggested that payment may be tied directly to quality donations, and that payment be delayed until laboratory tests have confirmed non-infectious blood.⁶⁹ In either instance, donor responsibilities should include a full, accurate and confidential disclosure of their health background to ensure medical suitability. Donor veracity may be supplemented by declarations that attach legal liability for fraudulently, purposively or knowingly transmitting disease through tissue donation.⁷⁰ Whilst one may question whether the risk of donor liability would deter unsuitable donors, others⁷¹ would characterize the invocation of donor-

⁶⁷ Titmuss, op. cited, p. 240.

⁶⁸ See, e.g., *Jones v. Miles Laboratories Inc.*, 700 F. Supp. 1127 at 1129, 1131 (N.D. Georgia, 1988).

⁶⁹ Del Pozo PR. Paying Donors and the Ethics of Blood Supply. *J. Med. Ethics* 1994;20:31-35.

⁷⁰ Kessel RA. Transfused Blood, Serum Hepatitis and the Coase Theorem. *J.L. & Econ.* 1974;17:265.

⁷¹ See, e.g., Titmuss, op. cited, pp. 158-172.

recipient liability over blood as a policy approach that reduces human tissue to a commodity to which commercial laws rationally apply.

I. Professional Duties or Mercantilism?

How does commerce in tissue affect provider-patient relations? Opponents of sales may fear that money will change, or in the least taint, the fiduciary relation between doctors and patients -- that is, the doctor's special duties of loyalty, trust and good faith to the patient.⁷² These concerns are not new in the paid blood debate.⁷³ Proponents of sales acknowledge the special duties that health professionals owe patients, even if they query how such duties specifically apply to blood donors. Still, they may argue that the ethical obligations and standards of professionals work to diminish the risks of conflicts of interests or even the appearance thereof. Some of this debate arises from evolving notions of professional ethics. For example, modern professional norms admit increasingly of commercial practices like advertising, while in the past such practices were condemned as unbecoming of professionals.

J. Autonomy-Paternalism: Economic Enhancement or Exploitation?

Another central issue in the debate centres on how to accord the respect due to the choices of those who would sell human tissue for pure economic enhancement. Opponents of sales deem it unethical to exploit the vulnerability of the economically-disadvantaged. The argument has a strong underlying current of unconscionability: that is, autonomy is not entitled to respect in this instance because it is compromised by duress; its exercise is not free and informed. Proponents of sales dispute the claim as

⁷² See Law Reform Commission of Canada, *op. cited.*, pp. 188-189.

⁷³ See Rugaber W. Prison Drug & Plasma Projects Leave Fatal Trail. *NY Times*, 29 July 1969, p.1. See also Section III.E.6.c, below.

unjustified paternalism that leaves the poor worse off.⁷⁴ It may thus be seen as unreasonable to deny the economically disadvantaged an opportunity to advance their economic plight⁷⁵ and so "enhance their autonomy".⁷⁶ Proponents of sales or a mixed system add that systemic oversight and effective regulation minimizes the risks of exploitation. Some have even suggested imposing generous wage and rigorous hour regulations on plasma collection, to minimize the risk of exploiting paid plasma "donors", to attract a larger and healthier donor population, and so increase the therapeutic supply of plasma.⁷⁷ The discourse echoes arguments over the legitimate role of money offered to potentially vulnerable populations in other areas of medical ethics, such as payment of those who participate in human research.⁷⁸

K. Equity or the Highest Bidder?

Another concern about sales is that allocation and distribution of blood or tissue might be determined by price mechanisms and not medical need. The scarcity value of the tissue will determine the price; blood will flow to the highest bidder. In the extreme, if the price in distant locales is greater, then even initially sold tissue may be resold, through brokers, to more distant or international markets with better prices and contracts, to the detriment of local or national health needs. Medical need, it is argued, should not be addressed by the vagaries of the market. The dispute echoes a deeper quarrel about how fair market mechanisms are. Again, the force of some of these arguments depends on whether the price and allocations would operate in a free or regulated market. France, for instance, regulates the amounts

⁷⁴ Hansmann H. The Economic and Ethics of Markets for Human Organs. *J. Health Politics, Pol'y & L.* 1989;14:57-85.

⁷⁵ Radcliffe-Richards J, et al. The Case for Allowing Kidney Sales. *Lancet* 1998;352:1950-52.

⁷⁶ Gillon R. Commerce & Medical Ethics. *J. Med. Ethics* 1997;23:67-68.

⁷⁷ Del Pozo, op cited.

⁷⁸ Dickert N, Grady C. What's the Price of a Research Subject? Approaches to Payment for Research Participation. *N.E.J.M.* 1999;341:198-203.

that donors receive for payment of expenses.⁷⁹ Health insurance regimes in countries like Canada also tend to control the price of medical inputs like biologicals.

L. Bodily Integrity & the Assumption of Risk

Concerns over sales are also animated by divergent views over whether sales unduly invite the compromising of one's bodily integrity or health. Advocates of sales may note that blood is a renewable tissue, and is transferred for therapeutic use with minimally invasive procedures and low risks, in contrast to nonrenewable organs like kidneys. Any such health risks should be further minimized by rigorous and competent professional and regulatory standards for blood collection. Opponents of sales may note that blood collection is a medical procedure that poses risks to donors; sometimes the risks result in serious illness or injury. Underlying the concern is that a commercial market encourages donors to sell to the highest bidder, and thus invites them to assume undue risks and compromise their physical integrity by over-donating, especially when they are desperate for money or when blood shortages would command a premium price. What is clear, is that the quarrel centers on risk assessments that will differ, unless analysts can agree on rigorous standards to govern the volume, frequency and tracking of donors giving to the blood system. As will be shown, volume and frequency norms and restrictions for plasma donors have resurfaced as an issue in North America and Europe. Again, then, the force of some of the considerations varies depending on whether the market is free or effectively regulated.

⁷⁹ See Section III.D.1, below.

M. Criminality

Would allowing tissue to be priced by the market forces invite or restrain heinous and criminal acts?

The question reveals two concerns. One concern is that placing a commercial value on human bodily substances or parts may induce criminality of the vulnerable by those desperate for money. The claim is extreme and has been raised in international concerns over tissue and organ trafficking.⁸⁰ It conjures up the body snatching days of the 19th century which resulted in anatomy acts in many countries.⁸¹ Such conduct has seldom,⁸² been associated with blood collection. Others express concern that by keeping bodily parts or substances priceless, especially by placing criminal bans on tissue sales, so-called black market prices may flourish with all their attendant abuses. From this perspective, it may be argued that it would be better to regulate sales and so minimize criminal elements.

N. De Facto Sales: Who Buys, Who Sells?

Is it more acceptable to pay someone to do a morally reprehensible deed, than to do the deed itself?

The question applies to the practice of paying to import and use plasma processed from paid donors, when the importing country itself has public policy or even laws against the sale of blood. The de facto dependence of many countries -- including such countries as Canada, the UK, Australia, and much of Europe -- on plasma imported from US companies that pay donors, strikes many as an apparent inconsistency in sales prohibitions. Some defend the practice as a practical necessity. The want of sufficient domestic supply or functional plasma processing infrastructure obliges the importation of plasma to treat illness or injury. Detractors consider the practice ethically suspect or repugnant.⁸³ The

⁸⁰ Rothman DJ, et al. The Bellagio Task Force Report on Transplantation, Bodily Integrity, and the International Traffic on Organs. *Transplantation Proceedings* 1997;29:2739-2745.

⁸¹ Jones DJ. Restrospective on the Future: Brain Death and Evolving Legal Regimes for Tissue Replacement Technology. *McGill L.J.* 1993;38:394-415.

⁸² Starr, op. cited.

⁸³ Del Pozo, op. cited.

practice risks abdicating control over the ethics of procurement and safety standards by delegating the deed (condemned at home) to an agent through whom the nation arguably has vicarious ethical responsibility. When the imported plasma has been procured from vulnerable, infected and paid donors abroad, then it may be forcefully argued that it would be ethically less objectionable to remunerate donors in the importing country to help boost national supplies, especially if the importing country may control the quality and ethics of blood collection by rigorous standards. Otherwise, the de facto purchase of human tissue through an agent also would seem to undermine the process value of transparency and so abuse the public trust,⁸⁴ if it is not done with full and open candor. Not to do so is to misrepresent⁸⁵ the ethics of national blood collection policy by veiling it with a veneer of virtue.

O. Tissue Sequel: Blood Policy as Precedent

Because blood is considered the first transplantable tissue, public policies surrounding the procurement and transfer of it promise to influence policy regarding the transfer of other bodily substances and tissues like organs. Some US analysts, for example, recently asked “on what grounds may blood and bone be traded on the open market but not cadaveric kidneys.”⁸⁶ In a recent report recommending regulated future markets in cadaveric kidneys, a committee of the American Medical Association claimed that “blood, reproductive materials and other tissues are allowed to be sold”.⁸⁷ In contrast, British and Canadian reports earlier this decade invoked the altruistic foundation of national blood policy to propound altruism and legal prohibitions against organ sales.⁸⁸ The recourse to the national blood

⁸⁴ Jones DJ. *Towards a Coherent Ethics Framework for Biotechnology in Canada*. Government of Canada, Ottawa: in press (transparency as a process value that builds public trust and public participation).

⁸⁵ See Drake AW, Finkelstein SN, Sapolsky HM. *The American Blood Supply*. Boston: Massachusetts Institute of Technology Press, 1982:125.

⁸⁶ Rothman, op. cited, p. 2741.

⁸⁷ American Medical Association, Council on Ethical and Judicial Affairs. Financial Incentives for Organ Procurement: Ethical Aspects of Future Contracts for Cadaveric Donors. *Arch. Intern. Med.* 1995;155:581-589.

⁸⁸ Nuffield Council on Bioethics. *Human Tissue: Ethical & Legal Issues*, London, UK, 1994; Law Reform Commission of Canada. *Procurement & Transfer of Human Tissues & Organs*, 1992.

model by both proponents and opponents of sales suggests the precedential effect that blood policy, ethics and law may have on national tissue policy. That relation casts the deliberations on or changes in national blood policy in broader light.

III. Arguments Applied

How do these varying issues and arguments apply in the national policies or laws of selected countries? The question is important, in part, because the clash of some of the arguments reveals a clash of value conflicts. The identified values, their conflicts, and how they are balanced or allocated may well inspire different policy or laws designed to address supply and demand issues. Thus, in the following section, the question of how the foregoing arguments apply in practice is explored through review of the national blood policies, relevant pronouncements and legal regulation of blood in the United States, the international community, Europe.

A. United States: A Mixed System

Table B: Sales as Public Necessity

Colloquy Between a Non-Profit Blood Bank Official & Chief Counsel to the Subcommittee on Antitrust & Monopoly of the U.S. Senate Judiciary Committee: Washington, 1964.

Q: "Would you be in the business of selling blood if you thought it was immoral?"

A: "I think it is immoral. I also think it is immoral to allow patients to die if they don't have blood..."

Q: "In balancing these two immoralities, you think the lesser immorality is selling blood? Is that right?"

A: "That is exactly right..."⁸⁹

From an international perspective, the system for the procurement and provision of blood in the United States is distinguished by at least three features. First, it is a mixed blood system, meaning that national policy and laws govern a system based on both paid and unpaid donors. Whole blood in the United States is largely provided by unpaid donors through the National Red Cross blood collection and distribution centres. The collection and manufacture of plasma derivatives is largely based on paid plasma donors. The mixed system has significant implications for the second and third distinguishing features. Secondly, then, the United States is largely self-sufficient in the supply of its national blood needs. Moreover, its plasmapheresis industry has for years supplied some 60% of the world demand

⁸⁹ Starr D. *Blood : An Epic History of Medicine & Commerce*. New York: Alfred Knopf, 1998:204, citing the US Congress, Subcommittee on Antitrust & Monopoly of the Senate Judiciary Committee Hearings. USGP: Washington, DC, 1964.

for plasma derivatives.⁹⁰ The US system helps to meet the medical needs of some European countries, Canada, Latin America and other underdeveloped and developing countries. Thirdly, the US government has promulgated an extensive series of regulations to address payments for and the procurement, testing and processing of plasma and other blood products. The standards imposed by the regulations are important both to those in the US and those in other countries that import US blood products.

The mixed system of blood procurement and collection of the US has evolved through some three phases of evolution.

1. Circa 1950 - 1970: The first phase began in the period of post-World War II to circa 1970. As in Canada and other nations that emerged from World War II, the National Red Cross assumed major responsibilities for the collection and processing of the nation's blood supply in the US. The humanitarian mission of the international Red Cross Society reflected in the US through its national chapter in the form of a national and non-profit organization that was granted a special Charter by the US Congress to collect and manage the national blood supply. Blood donation in the US in the period 1940 to 1970 was characterized by both paid and unpaid donors and adequacy and safety concerns. For instance, post-transfusion hepatitis was a significant issue in the medical literature for organizations collecting blood in the 1940s and 50s. While the literature in the early 50s expressed concerns about donor backgrounds, by the late 50s it contained several reports that associated a higher incidence of post-transfusion hepatitis with blood from paid donors.⁹¹ This trend in the literature continued in the 1960s with more regular and emphatic admonishments about the dangers of paid blood donors and the need for national concerted initiatives.

⁹⁰ Britten AF. Worldwide Supply of Blood & Blood Products. *World J. Surg.*, 1987;11:82-85.

⁹¹ Domen, op. cited.

Indeed, local and national reliance on paid blood sometimes divided US communities, and prompted vigorous ethico-legal debates and formal congressional hearings. The hearings resulted from a federal government ruling in 1964 against a non-profit Kansas City community blood bank for unfair trade practices.⁹² In essence, the government had ruled that by colluding and agreeing with local hospitals and doctors about securing blood only from non-commercial sources, the community blood bank had unlawfully interfered with the free trade of blood products to the detriment of the local blood service market and for-profit blood banks. The federal government ordered a cessation of the practices. If the ruling was welcomed by the for-profit sector, it revolted and galvanized many in the non-profit sector.⁹³ The latter condemned it as relegating human tissue to an economic commodity and as a perverse application of antitrust laws to non-profit health services. In the US Congressional hearings that subsequently explored the issue, the physician-director of the non-profit Kansas city blood bank, who was morally opposed to for-profit blood banking, invoked the paid blood = contaminated blood argument against for-profit blood banks. Under questioning by the US Committee, however, the director unwittingly endorsed the sales as a public necessity when he was obliged to concede that his bank, too, relied of necessity on paid donors. His colloquy with the committee is excerpted in the quote in Table B, above. The initial ruling of the federal government was later annulled in court.⁹⁴ The court did not address the issue of blood as a commodity, but based its reversal partly on the profit versus non-profit distinctions discussed in Section II.E above. The court held that the federal agency had exceeded its jurisdiction by imposing antitrust laws on a non-profit medical entity. Ultimately, the case reflects the search of US society in the 1960s for ethico-legal rules to govern blood products in a mixed blood system. While some may regard the case as symptomatic of the subjection of blood to the laws of the market place,⁹⁵ the legal outcome of the case suggests the contrary. Moreover, the specific proposition that US law ought to regard blood as a general commodity would be further rejected a

⁹² Starr, op. cited.

⁹³ *Ibid.*

⁹⁴ *Community Blood Bank of Kansas City v. FTC*, 405 F.2d 1011 (8th Cir. 1969).

⁹⁵ See, e.g., Titmuss, op. cited, pp. 158-172.

decade later in legislative and public policy responses to post-transfusion hepatitis law suits against hospitals, blood banks and physicians.

2. The 1970s -- Defining National Blood & Regulatory Policy: The 1970s became a marker decade in the history of US blood policy. It largely defined the contours and elements of the US blood policy as it exists today. There were changes and reforms in several respects. First, for example, administrative and structural changes were undertaken that resulted in centralizing the oversight of blood policy at the federal level. The US Federal Drug Administration (FDA) assumed regulatory responsibility for the safety of the nation's blood supply. Oversight of biologicals was transferred from the research culture of the US National Institutes of Health to a newly created Bureau of Biologicals in the regulatory culture of the FDA. Moreover, prior legislative uncertainty as to the scope and ambit of the FDA's regulatory authority was removed such that the organization had a firmer legal basis under federal law to impose conditions and standards for the collection and processing of blood products in the US.⁹⁶

Secondly, the paid versus unpaid blood debate directly influenced the defining of a new National Blood Policy. The examples of some states, like New Mexico⁹⁷ which had moved from a paid to an unpaid donor system without sacrificing blood supplies, helped fuel movement towards a national unpaid donor system. Following a federal governmental task force, the US government announced a National Blood Policy in 1973/74. The Policy has not been officially replaced, updated or repealed. It is based on four principle goals: supply, quality, accessibility, efficiency. The supply of blood, the Policy argued, should (a) be adequate for therapeutic needs, (b) meet the highest standards of transfusion therapy, (c) be accessible to all regardless of economic status, and (d) be collected processed, stored and utilized efficiently. On the basis of these four goals, the pronouncement outlined several implementing policies,

⁹⁶ Pub. L. 91-515, 84 Stat. 1297, 1308 (1970).

⁹⁷ Surgenor DM, Cerveny JF. A Study of the Conversion from Paid to Altruistic Blood Donors in New Mexico. *Transfusion* 1987;18:54-63.

such as enhancing resource sharing, exercising fuller regulatory authority, health education initiatives to ameliorate the optimal use of blood, and encouraging scientific research to address existing technical impediments, safety issues, and enhanced blood preservation. Though the Policy did not announce “safety,” as a principal goal, safety and ethical considerations were clearly contemplated and subsumed in the Policy goal of “quality”:

...[I]t is the Policy of the US government: (1) To encourage, foster and support efforts designed to bring into being an all voluntary blood donation system and to eliminate commercialism in the acquisition of whole blood and blood components for transfusion purposes. The ultimate aims of this policy are improvement in the quality of the supply of blood and blood products and development of an appropriate ethical climate for increasing use of human tissues for therapeutic medical purposes. In this context, the term commercialism applies to the relationship between the donor and the blood bank and focuses primarily on those commercial relationships which have encouraged reliance on blood from sectors of society in which transmissible hepatitis is particularly prevalent.⁹⁸ ...

The Policy applies or addresses some of the leading arguments noted in Section II, above. It uses the term “voluntary” not to mean uncoerced but to mean “gratis” or unpaid. In doing so, it conveys the subliminal message that a paid donor may not be uncoerced. (See Section II.D, above). The Policy seems intent on limiting some commercial aspects while tolerating others. It adopts the tainted commercial blood argument identified in Section II.G as a basis for curtailing commercialism. Yet, by limiting its definition of commercialism, it intended to leave untouched “the commercial acquisition of plasma and the marketing of plasma derivatives in recognition that commercial acquisition may still be necessary.”⁹⁹ Thus, the Policy did not seek to eliminate reasonable service-processing fees for the service aspects of processing blood, blood products and other tissues.

Blood Products Regulations: Thirdly, to increase oversight and implement the new National Blood Policy, the FDA promulgated regulations to govern biological and blood product matters,

⁹⁸ Office of the Secretary of Health, Education & Welfare. National Blood Policy. *Fed. Register*, 10 Sept. 1974;39:32702-32711.

⁹⁹ *Ibid.*, pp.32702-32703.

including plasmapheresis, whole blood, banking, donor screening, the labelling of blood and payments. The paid blood debate thus reflected in the regulations that would develop over the decade to transform the US into a federally-regulated mixed blood system. Under the labelling regulations, for example, blood procured for transfusion must be labeled as having been procured from either paid or unpaid donors.¹⁰⁰ In theory, such labelling enables hospitals, blood banks, and physicians to make an informed judgment about using paid or unpaid blood. The rationale behind the labelling reiterates the view that paid blood is more likely contaminated blood:

"... The high risk of post-transfusion hepatitis associated with blood and paid donors primarily reflects the fact that direct monetary payment attracts and motivates donations from individuals in unfortunate socio-economic circumstances in whom transmissible hepatitis is particularly prevalent, including drug addicts who were in desperate need of money to purchase drugs."¹⁰¹

Even accepting the rationale, it still leaves open the question of what is meant by a "paid" or "unpaid" donor? Do non-monetary incentives or credits qualify as payments? The regulations define payment as follows:

A paid donor is a person who receives monetary payment for a blood donation. A volunteer donor is a person who does not receive monetary payment for a blood donation. Benefits, such as time off from work, membership in blood insurance programs, and cancellation of non-replacement fees that are not readily convertible to cash, do not constitute monetary payment...¹⁰²

The regulations distinguish cash from non-cash incentives on the view that benefits that are not readily convertible to money are less likely to attract groups in which transmissible disease is prevalent.¹⁰³

Again, the regulations regarding labelling and the definition of paid and non-paid donors apply to whole blood products intended for transfusion. Plasma intended as source material for further manufacturing,

¹⁰⁰ 21 C. Fed. Register (CFR) 606.121.

¹⁰¹ US Department of Health Education & Welfare, Food & Drug Administration. Blood and Blood Products: Donor Classification Labelling Requirements. *Fed. Register*, 13 Jan. 1978;43:2142-2148 (final rule), superseding the rule proposal in *Fed. Register*, 14 Nov. 1975;40:53040.

¹⁰² *Ibid.*; codified, as amended, at 21 CFR 606.121(5).

¹⁰³ US Federal Drug Administration. Blood and Blood Products: Donor Classification Labelling Requirements. *Fed. Register*, 13 Jan. 1978;43:2142-2148.

“source plasma”, is exempted from the paid donor labelling requirements.¹⁰⁴ Instead, regulations governing the manufacturing process and the state of the viral inactivation procedures target the safety of plasma products derivatives.

Hence, the standards and norms, promulgated by the US FDA in the 1970s came to govern the US blood supply, as well as a significant portion of the world supply of plasma products. The plasma regulations specify such matters as the informed consent of the donor, medical supervision, medical screening of the donor, the processing and pooling of plasma, the volume and frequency of donation, the plasmapheresis process, reporting of fatal donor reactions, and medical record responsibilities. Parallel specifications were later developed to govern whole blood and other human blood products.¹⁰⁵

It should be noted from this retrospective that, while bioethics was in its infancy in the 1970s, many of the values underlying modern bioethics analyses both animated and were imported into these regulations. The ethical principle of autonomy and informed decision-making, for instance, is given legal effect through the informed consent provisions of the regulations. Values that animate the protection of bodily integrity are illustrated in the specifications and limitations regarding the frequency and volume of plasma that donors may lawfully give. The concern for recipient and public health safety is given legal effect by the standards governing the labelling of blood intended for transfusion and by requirements for donor screening and blood processing. Whether such standards remain adequate is a valid question. But functionally, the regulations represent an important and early instance of the interface between bioethics, law and public policy.

Serum Hepatitis Litigation & Blood Shield Statutes: If US governmental regulation of blood products in the 1970s revealed one role of the law in addressing supply and demand issues, serum

¹⁰⁴ *Fed. Register*, 26 Aug. 1972;37:17419, as amended and codified at 21 *CFR* 640.60 - 640.70.

¹⁰⁵ See, e.g., *Fed. Register*, 23 Dec. 1984;50:52602, as amended and codified at 21 *CFR* 640.1 - 640.56.

hepatitis litigation in the 1960s and 70s revealed other important roles. The issue was a harbinger of current blood litigation, and its resolution outlined many of the principles that remain dominant today. Many patients in the era received contaminated blood following surgery, in part because medical science had not invented an effective screening test for hepatitis. The state of the art of hepatitis screening technology would remain much the same from the 1940s to the 70s, when effective screening tests were developed. In the meantime, the question of who should bear responsibility for donor contaminated blood, and on what grounds, raised issues of the role of the law and the associated rights, duties, immunities and liabilities in the collection of blood. For those injured or diseased by contaminated blood products, it raises issues of the compensatory role of the law.

Three cases and the resulting legislative responses in the US suggested different answers to such questions. In the landmark 1954 case of *Perlmutter*,¹⁰⁶ the highest court of New York held that the distribution of blood to a patient constituted the provision of a hospital “service” and not the “sale of a product”. The Court rejected the application of a state statute, which would have made the hospital vulnerable to implied claims of warranty of fitness of the blood for its intended purposes. Noting that the viral infection in the blood was undetectable by existing standards of the day, and that application of the Sales Act would subject the hospital to broad liability, the Court concluded that the furnishing of blood was only incidental to the general services of a hospital providing medical care. When a similar issue subsequently arose in litigation between a patient and a blood bank, the Florida Supreme Court declined to extend *Perlmutter* reasoning to a blood bank.¹⁰⁷ The Court found that while a hospital performs a service in the provision of medical care, a blood bank functions largely to collect and distribute blood as a “commodity”. Shortly thereafter, in 1970, an Illinois court rejected the *Perlmutter* view and concluded that, indeed, hospitals should be as subject to strict liability for blood as they are for other defective therapeutic agents. The Court also intimated that regardless of whether the entity

¹⁰⁶ *Perlmutter v. Beth David Hospital*, 123 NE 2d 792 (NY 1954).

¹⁰⁷ *Community Blood Bank, Inc. v. Russell*, 196 SO 2d 15 (Fla. 1967).

involved in such activities was profit or non-profit, it should be held responsible.¹⁰⁸ Such differing views over the application of warranty and strict liability law to serum hepatitis contaminated blood in the US was largely resolved by the end of the 1970s with the widespread enactment of state blood shield statutes. In essence, the statutes codify the reasoning of *Perlmutter*, designate the provision of blood to be a service -- not the sale of a product -- and thus provide immunity from warranty and products liability theories. The statutes in many jurisdictions have been extended to blood banks and to the manufacturers of blood products. Arguably, the statutes serve a public policy function of protecting an important part of the national blood service infrastructure from undue litigation.

The role of the law in compensating those wronged by deviation from professional standards of care has not been entirely limited by the statutes, however. The blood shield statutes do not immunize providers of blood from liability for ordinary negligence. In this respect, it is noteworthy that negligence litigation in the US in the 1970s reflected the debate over paid and unpaid blood in terms of donor selection. In one case, which the Supreme Court of Oklahoma remanded for trial, the issue was whether it was negligence for a blood bank and hospital to use paid donors who were known to be at a higher risk of providing blood tainted with hepatitis.¹⁰⁹ In another case, the Supreme Court of Montana dismissed a hepatitis law suit with the following finding:

It may be that prisoners, bums and addicts who sell their blood are high risk donors, but it does not follow that everyone who sells his blood is a high risk donor. It is not negligence to offer to buy blood, when a blood bank finds that it is the only way to meet its obligations.¹¹⁰

The court specifically found that a donor who had been paid \$5 for her blood did not fall into such categories of “dangerous donors”. The suggestion that sales may be the only way for a blood supplier to meet its obligations again evokes the choice of evils argument or public necessity defence of sales

¹⁰⁸ *Cunningham v. MacNeal Memorial Hospital*, 266 NE 2d 897 (Ill. 1970).

¹⁰⁹ *Gilmore v. St. Anthony Hospital*, 598 P 2d 1200 (Okla. 1979).

¹¹⁰ *Hutchins v. Blood Services of Montana*, 506 P.2d 449 (Mont. 1973).

identified in Section II above. The words of the court thus echo the tension that arises between an adequate and safe supply of blood. The tension between adequacy and safety is difficult because both directly implicate the protection of human health and life.

3. 1980-1990s: Safety, Innovation & Regulation: A third stage in the development of the US blood system and policy unfolded in the 1980s and 1990s. Many of the issues that had already marked the development of US blood policy in the 1970s evolved significantly over the next two decades. While details of the scope and magnitude of the changes transcend the focus of this paper, four particular issues prove relevant: safety, technological innovation, regulatory or policy reforms, and the paid-donor debate. First, the discovery of HIV in the US blood system marked one of the defining issues of this era.¹¹¹ It began the first of several waves of bloodborne pathogens to contaminate the US blood supply. It created public health and government crises, generated research, litigation, and blood system restructuring. In the US, it effectively made safety an explicit policy (*de facto* goal) of national blood policy.

Secondly, the era of 1980-1990s in the US has been marked by striking technological developments for both the safety and supply. Research and development to detect viral and infectious agents in the blood supply generated new, more precise, and expensive blood screening technologies. For example, by the mid-eighties six additional donor laboratory screening tests had been introduced.¹¹² As well, more effective chemical and heating techniques have been introduced to remove or inactivate blood-borne viruses in the manufacturing process for plasma derivatives. Biotechnological research and development also enhanced both blood safety and supply in important respects. A genetically-engineered hepatitis vaccine became available in the 1980s. Its availability helps to immunize donors

¹¹¹ See, Institute of Medicine. *Blood Donors & the Supply of Blood & Blood Products*. Washington: National Academy Press, 1996. Institute of Medicine. *Blood & Blood Products: Safety & Risk*. Washington: National Academy Press, 1996.

¹¹² McClough J. The Nation's Changing Blood Supply System. *JAMA*, 1993;269:2239-2245.

and thus enhances blood safety. In 1989, recombinant erythropoietin (EPO) was approved for licensing in the US.¹¹³ When EPO corrects anemia, it helps to reduce the need for blood transfusions and thus demand for blood. The shift from natural to recombinant F VIII in this era has been described in Section I.B., above. To boost plasma supplies further by technological innovation, a US government advisory committee recently called for steps to accelerate the shift towards genetically-engineered plasma derivatives.¹¹⁴

Thirdly, the safety needs and technological innovation spawned diverse reforms. In 1995, the Institute of Medicine, as the Krever report has noted, criticized the US governmental process, structure and authority of decision-making during the AIDS blood crises.¹¹⁵ The US Department of Health and the FDA have been restructuring its regulatory authority and norms. Congressional oversight combined with critical US General Accounting Office (GAO) reports¹¹⁶ on regulation of the blood supply helped to generate new federal inspection initiatives,¹¹⁷ more rigorous quality control programs and new standards for blood banks.¹¹⁸ Such initiatives also apparently prompted plasma industry reforms, such as a voluntary reduction in the size of the plasma donor pools from which plasma derivatives are processed.¹¹⁹

¹¹³ US Congress. *Office of Technology Assessment. Recombinant Erythropoietin: Payment Options for Medicine*, Washington, 1990.

¹¹⁴ US Department of Health & Human Services. *Recommendations of the Advisory Committee on Blood Safety & Availability*. Washington, Aug. 1998.

¹¹⁵ Institute of Medicine. *HIV & the Blood Supply: An Analysis of Crisis Decisionmaking*. National Academy Press, Washington, 1995.

¹¹⁶ US General Accounting Office (GAO). *Blood Supply: FDA Oversight & Remaining Issues of Safety*. Washington, 1997; GAO. *Transfusion-Associated Risks*. Washington, 1997.

¹¹⁷ US Office of Inspector General. *Review of the Food & Drug Administration's Inspection Process of Plasma Fractionators*. Washington, 1997.

¹¹⁸ McCullough, op. cited. McCullough J. The Continuing Evolution of the Nation's Blood Supply System. *Amer. J. Clin. Path.* 1996;105:689-695.

¹¹⁹ US General Accounting Office. *Blood Safety: Recalls & Withdrawals of Plasma Products*. Washington, DC, 1998.

Finally, the GAO reports also offered new data relevant to the paid-donor debate. In particular, in the 1998 report entitled *Blood Plasma Safety*,¹²⁰ the GAO studied safety issues both in the manufacturing of plasma derivatives and in the collection of plasma from donor-paid and unpaid donors. The report noted that 85% of the US plasma supply comes from 370 licensed, commercial plasma collection centers; 15% comes from non-paid donors largely through the American Red Cross. Overall, the report reveals important findings on the relationship between donor payment, infected blood, regulatory norms and safety. If the evidence in the report is accurate, it casts doubt on major arguments that have developed over the last decade in the paid-blood-tainted-blood debate.

As noted above, effective process to inactivate viruses in donated blood and plasma have emerged since the 1980s as a major defense against contamination of the plasma supply. To be sure, viral removal and inactivation procedures have become a major manufacturing and policy norm for good reason. The development of such techniques and processes enables industry, experts and government to define blood processing standards to enhance the safety of the blood supply. In this context, even if one assumes that paid donors are associated with a higher incidence of viral transmission, viral inactivation standards and processes provide a safety shield or net. When effective, they thus minimize associated safety risks of the paid donor, and help to maximize the supply of therapeutic plasma derivatives.

The findings of the GOA report both confirm and challenge some of this logic. On the one hand, the report found that paid plasma donors¹²¹ carry over 1.5 times the risk of donating infected blood than non-paid donors. The finding adds weight to the historic claims of Titmuss and his progeny. On the other hand, the report agreed that the industry and government initiatives to improve plasma safety -- by

¹²⁰ US General Accounting Office. *Blood Plasma Safety: Plasma Product Risks Are Low If Good Manufacturing Practices Are Followed*. Washington, DC, 1998.

¹²¹ The GAO found that paid donors typically receive some \$15-20 for the two hours time required for plasma donation. *Ibid.* p. 4.

smaller donor pools, viral inactivation and manufacturing processes, etc. -- significantly reduce the risk of infection for most blood products manufactured from plasma. The report emphasized that this safety net depends on strict adherence to effective quality control norms, known as FDA mandated “good manufacturing practices”.¹²² The report found, however, that there have been major deficiencies in the manufacturing processes of major plasma producers in the US. These deficiencies prompted the FDA to secure court orders against two of the four major US commercial plasma producers. The court orders seek production changes or the cessation of plasma processing. The GAO findings are compounded by the shortcomings that the GAO and other analysts had already found in FDA inspections and regulations. Ultimately, the report underscores the critical and fragile nexus between defining, implementing and enforcing national plasma safety standards. Compromises or laxity in quality control norms may compromise safety and supply. The report suggests as well that paid-blood concerns cannot be dismissed, even in societies laden with resources, sophisticated technology and extensive regulations.

B. World Health Organization & International Red Cross

As some of arguments for and against sales have animated debate and policy information in the US, they have done so as well in the international community. One of the most influential policy statements emanated from the World Health Organization (WHO). In a 1975 resolution adopted by the World Health Assembly, the WHO urged the promotion and development of “national blood services based on voluntary and non-remunerated donation of blood.”¹²³ The resolution targeted three main concerns. One concern involved “the extensive and increasing activity of private firms in trying to establish commercial blood collection and plasmapheresis projects in developing countries.”¹²⁴ Such practices,

¹²² See 21 CFR 606; Zuck TF. Current Good Manufacturing Practices. *Transfusion*, 1995;35:955-966.

¹²³ WHO. World Medical Assembly Resolution 28.72: *Utilization and Supply of Human Blood and Blood Products*. May 1975.

¹²⁴ *Ibid.*

the resolution suggested, might interfere with the non-commercial development of national blood services in developing countries, especially those that lacked effective legislation to govern the operation of blood services, protect donors and recipients. The concerns echo the arguments about unregulated blood markets identified in Section II, above. The resolution was also based on the paid blood argument, both in terms of the impact on donor health and the “higher risk of disease being transmitted when blood products have been obtained from paid rather than volunteer donors.”¹²⁵ A report prepared in anticipation of the resolution indicates concern that payments might invite the compromising of donor health and become the principal source of income for certain people. These reflect the bodily integrity and exploitation issues noted above.

The silence of the resolution on what “non-remunerated” donation means is striking in important respects. The resolution was adopted six months after the US proposed its definition of paid and non-paid donors, which at least raised the definitional issue for the international community. The silence of the WHO may thus suggest that non-remunerated simply means no transfer of money, even to recompense donors for donation. If so, that meaning runs contrary to the financial neutrality principle identified in Section II.E, above. Whatever the basis for the silence, it cast some organizations or nations into a dilemma. Those that supported or had a practice of offering modest fees to plasma donors for their time and inconvenience might change their practice in conformity with the resolution, disagree with the resolution, or agree with its general thrust but nuance or define some payments as non-remuneration.

The international Red Cross, for instance, is one international organization that has endorsed and extended the WHO resolution. That the Red Cross formally pronounced in support of the WHO Resolution is not surprising. The background report for the 1975 WHO resolution had relied partially

¹²⁵ *Ibid*

on reports from the League of Red Cross for information concerning paid plasma practices in developing countries. Moreover, the Red Cross had already formally resolved, in 1973, that blood donation should be voluntary, non-remunerated and motivated by humanitarian principles. In 1981, the Red Cross endorsed the WHO resolution. In a 1990 reaffirmation of its position, the Red Cross declared that “voluntary non-remunerated blood donation is considered among the safest kind of blood donation in terms of security to the recipients”. The 1990 statement also argued that donors have “ethical responsibilities” towards recipients and should communicate without hesitation any contra-indication that could have potential harmful effects on a recipient.¹²⁶ The 1990 statement from the Red Cross helps explain and extend the rationale of the WHO 1975 resolution with an explicit appeal to ethics.

The progeny and substance of the 1970s resolutions of the WHO and Red Cross thus demonstrate the consensus and influence of thought of two leading international health organizations. They continue to reflect the official policy position of the International Red Cross and WHO some 25 years later. Despite a 1997 WHO declaration¹²⁷ outlining a partnership approach to government and private sector development of health policy, the WHO resolution continues to guide policy in both developing and developed countries. For example, in 1998 the WHO Blood Safety Unit included voluntary non-remunerated blood donation amongst its objectives in assisting countries in developing national blood programs.¹²⁸ As will be shown, the WHO resolution has been also influential on blood policy in Europe.

¹²⁶ *Intl Dig. Hlth Legis.* 1991; 42:175-176.

¹²⁷ See, e.g., WHO. *The Jakarta Declaration on Leading Health Promotion into the 21st Century.* (1997).

¹²⁸ See [www.who.int/pht/blood_safety/index.html].

C. Europe

Since the close of World War II, inter-European governmental organizations have been articulating governmental policies that influence the supply, demand and exchange of blood products in Europe. The two principal actors have been the Council of Europe (COE) and the European Economic Community. The former is a European intergovernmental human rights organization. The latter has long been the lead organization for governing the common economic market of Europe. It is now called the European Union (EU). The organizations have different mandates. Both were founded by treaties after World War II. Both have issued pronouncements that have shaped policy, law and ethics of blood supply in their member states. Together, they have articulated the norms that guide both the debates on, and substantive content of, European blood policy. The norms are summarized in Table C.

Table C: European Blood Policy: Leading Principles

C	Solidarity
C	Respect for Human Dignity
C	Duty-Free Transfers
C	Confidentiality of Health Data
C	Tissue Sharing
C	Health Protection & Safety
C	Voluntary, Unpaid, Anonymous Donations
C	Recompense Reasonable Donor Expenses
C	Non-Profit Tissue Banks
C	Self-Sufficiency
C	Optimal Use & Non-Wastage of Blood

To understand these principles in the European context, we first review the activities and statements of the COE followed by those of the EU.

1. Council of Europe

"The human body and its parts shall not, as such, give rise to financial gain."¹²⁹

Over the last 40 years, the COE has issued more than a dozen formal pronouncements on blood policy matters. Highlights of the more pertinent statements follow.

a. Agreement on the Exchange of Human Substances, 1958:¹³⁰ In 1958, the COE opened for signature an agreement on the sharing of human blood and its derivatives. The provisions make clear the intent of the treaty. Appealing to humanitarian principles of European solidarity, the treaty outlines labelling, documentation, and delivery procedures to facilitate and speed the transit of blood from countries with "sufficient stock for their own needs" to fellow member countries "in urgent need of them" (art. 2). This would seem to function along the duty to rescue principle, outlined in Section II above, whereby one should act to help those in peril if doing so does not seriously imperil oneself. The treaty also speaks to the financial conditions of exchange. One article requires parties to take necessary measures to exempt therapeutic substances from all import duties (art. 5). Another provides that blood and blood derivatives shall be made available "subject to the express condition that no profit is made on them" (art. 3). While the duty-free provision may well speed the transfer of blood derivatives, the non-profit provision as likely reflects a substantive ethical position. The text itself offers no elaboration of the injunction on profits.

b. Harmonization of Transplant & Tissue Exchange Legislation, 1978-79: Twenty years later, as Europe and much of the developed world began to respond to the legal challenges of the modern transplant era, the COE offered a fuller explanation of the non-profit rationale. In a 1978

¹²⁹ Council of Europe. *Convention on Human Rights & Medicine*, 1997, art. 21.

¹³⁰ Council of Europe. *European Agreement on the Exchange of Therapeutic Substance of Human Origin*. ETS No. 26, Paris, 1958.

resolution, it recommended a common set of provisions designed to harmonize transplants legislation.¹³¹ The provisions of Resolution 78(29) parallel the transplant laws of many countries. Amongst other things, they address donations from living and deceased donors, informed consent, medical examinations, conditions to protect the donor. The Resolution applies to blood and addresses payment for tissues. It provides that “no tissue may be offered for profit;” however, it allows the donor to be refunded for expenses incurred in making the donation (arts. 9, 14). Resolution 78(29) thus adopts the financial neutrality principle, discussed in Section II.E above, that the donor should neither gain nor lose financially:

... the article does not bring any obstacle to the refunding of expenses, in accordance with the provisions of the national law, caused by the removal operation and the preceding examination. It is fair and logical that, even though he is not allowed to get any profit from his donation, the donor should not carry the financial burdens of removal operations and preceding examinations. These refundable expenses include: loss of earnings, travelling expenses and any expenses caused by the removal operation as well as preceding examinations.¹³²

Perhaps because it could not achieve consensus on the question, the Resolution leaves the question of non-donor profits from processing fees for resolution under national law. While the specific rationale for the prohibition on donor profit is not elaborated in the document, the COE revealed its underlying concerns a year later in a further pronouncement on the exchange of therapeutic substances:

Articles 9 and 14 ... of Resolution (78) 29 establish the gratuitous nature of human substances donation, a principle which finds its roots in the practice of almost all member states which treat human substances as *res extra commercium*. Therefore, no price, however large or small, should be put upon these substances. This Recommendation therefore recommends member states to exempt human substances, having regard also to their humanitarian purpose, from all import and export duties and taxes ...¹³³

¹³¹ Council of Europe, Committee of Ministers. *Resolution (78) 29 of 11 May 1978: Harmonisation of Legislations of Member States Relating to Removal, Grafting & Transplantation of Human Substances*.

¹³² *Ibid.*

¹³³ Council of Europe, Committee of Ministers. *Recommendation No. R (79) 5 of 14 March 1979: International Exchange and Transportation of Human Substances*.

The Council of Europe policy that the human body is out of, or not an object of, commerce thus applies one of leading arguments against bio-commerce, as identified in Section I.N, above. It is also consistent with the traditions of European civil law. A policy that human bodily substances should not be priced accords with this tradition. Moreover, it accords with some of the moral philosophy of the 19th century German philosopher Immanuel Kant. Kant maintained that to price something is to make it replaceable, and that whatever remains above price has no equivalent and has dignity.¹³⁴ Under this view, duty-free and nonprofit policies on human tissue transfers may be seen as affirming the intrinsic respect for human dignity that we owe each other.

c. Blood Products for Haemophilia, 1980: A year later, in 1980, the COE elaborated further ethical underpinnings of European blood policy. In a recommendation on blood products for haemophilia, the COE outlined detailed technical procedures on factor concentrates and policy on the collection and labelling of blood products.¹³⁵ In doing so it advanced four important positions. First, it endorsed the WHO position on unpaid donations: “From an ethical point of view, with respect to the health of the donor and the recipient, the recommendations of the WHO and the league of Red Cross Societies concerning the promotion of voluntary non-remunerated blood and plasma donations should be followed.” Secondly, it adopted the US regulatory practice of labelling some blood products as having come from paid or unpaid donors. Thirdly, it urged a policy of optimal use and non-wastage of blood, as it said, for “economic and ethical reasons.” The ethical reasons were not elaborated. Finally, it encouraged member states to strive for “self-sufficiency”. The 1980 COE recommendation marks the first time that the COE used the term “ethical” in its blood policy pronouncements. Henceforth, it would invoke ethical argumentation to elaborate basic elements of its evolving policy.

¹³⁴ LRC, op. cited, pp. 57-61 quoting Kant.

¹³⁵ Council of Europe, Council of Ministers. Recommendation No. R(80)5 of 30 April 1980 Concerning Blood Products for the Treatment of Haemophiliacs. *Intl Dig. Hlth Legis.* 1982;33:17-20.

d. Blood Transfusion, Plasma & Donor Protection, 1980-1995: Indeed, over the next 15 years, the COE would draw on the principles that it had developed since 1958 to address such issues as blood safety and HIV, infrastructure and administration of blood services, quality assurance, plasma. Four of the pronouncements from the 1980-1995 era prove particularly germane. First, in 1983, two years after the identification in the scientific literature of the virus that causes AIDS, the COE offered recommendations to prevent its transmission through the international exchange of blood. The recommendation could offer no counsel on the testing of blood, because the safety and efficacy of HIV screening tests would not be established sufficient for licensure until 1985. Instead, the AIDS recommendation, inter alia, (a) urged the avoidance of coagulation factors prepared from large plasma pools; (b) reiterated the call to achieve national self-sufficiency “in the production and coagulation of factor products from voluntary, non-remunerated donors;” and, (c) urged countries to avoid importing “blood plasma and coagulation factor products from countries with risky populations and from paid donors.”¹³⁶ The urging of selective international quarantining of plasma and coagulation factors from paid donor countries is thus grounded on the paid blood means contaminated blood argument discussed in Section II, above.

Three years later the COE broadened its focus beyond AIDS and safety to issues concerning the structure of national blood services. It applied the principles of self-sufficiency, optimal use, and donor protection, to a 1988 recommendation on the administration and structure of national transfusion services.¹³⁷ The recommendation extends two of its oldest principles. It refers to human solidarity as “the basis of blood donation,” to recommend that health authorities have in place a system of rapid and adequate compensation for those injured by donated blood. The recommendation also reiterates

¹³⁶ Council of Europe, Committee of Ministers. Recommendation No. R(83) of 23 June 1983 on Prevention Possible Transmission of Acquired Immune Deficiency Syndrome (AIDS) from Affected Blood Donors to Patients Receiving Blood or Blood Products. *Intl Dig. Hlth Legis.* 1984;35:51-52.

¹³⁷ Council of Europe, Council of Ministers. Recommendation No. R (88) 4 of 7 March 1988 on the Responsibilities of Health Authorities in the Field of Blood Transfusion. *Intl Dig. Hlth Legis.* 1989;40:69-73.

support of non-remunerated donation, and extends the COE view on money into a call for a non profit infrastructure for the collection of blood.

Thirdly, in 1990, the COE outlined methods to establish a coordinated plasma programme.¹³⁸ The Recommendation notes the increasing demand for source plasma, acknowledges the reliance of many European countries on imports, and notes that other European countries are free from such reliance. It then calls on member countries to achieve self-sufficiency for plasma products on the basis of voluntary non-remunerated donation. It offers four reasons for doing so:

For the collection of source plasma a country should rely *exclusively* on voluntary, non-remunerated donation for:

- ethical reasons, in order to guarantee full respect of the health of the donor;
- clinical reasons, in order to avoid as much as possible the risk of transmission of infection;
- social justice reasons, in order to ensure participation in donation by all social strata of the population, irrespective of economic status;
- reasons of independence from importation and hence stability in the supply of products and their pricing. (Emphasis added)

The language is suggestive: imported source plasma from paid donors may be collected under ethically suspect and exploitative circumstances and may be more infectious than blood collected from non-paid donor systems. The Recommendation seems largely animated largely by some of the consequentialist arguments against tissue sales outlined in Section II, above. By its emphasis on “exclusive”, the Recommendation leaves little room for the option that European member states enhance their supply of source plasma by further developing a domestic mixed system. Instead, the Recommendation

¹³⁸ Council of Europe, Committee of Ministers. Recommendation No. R (90) 9 of 29 March 1990 on Plasma Products and European Self-Sufficiency. *Intl Dig. Hlth Legis.* 1991;42:27-30.

encourages the cessation of imports and movement away from even reliance on mixed systems for source plasma.

Fourthly, in 1995, the COE offered its first formal statement of blood policy in which it used the term “ethical principles”. It did so in a pronouncement on the protection of donors.¹³⁹ The ethical principles generally consolidate its prior statements on optimal use and non-wastage (art. 4), donor and recipient protection (art. 3), voluntary and non-remunerated donations (art. 1). The principles endorse the need to protect confidentiality (art. 5). The Recommendation also offers important details for the payment debate. For though the COE had endorsed and used the term “non-remunerated” for over a decade, its statements had offered little explanation of what constitutes remuneration. Close observers of COE policy might invoke the non-profit principle from the first two decades of COE tissue policy statements, to argue convincingly that “unethical” remuneration means payments beyond reasonable expenses. On the other hand, the WHO statement that the COE endorsed in 1980 makes no such distinctions. Hence, it is arguable that in adopting the WHO position the COE repudiated the distinctions and nuances it drew in the late 70s. Into this policy ambiguity, the COE offered an ethical principle to define “non-remunerated donation:”

Article 2

Donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components of his/her own free will and receives no payment for it, either in the form of cash or in kind which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation.

The definition of “voluntary” addresses the distinctions outlined in Section II.D, above, regarding the absence of coercion and payments. The definition of “non-remunerated” continues to adopt the

¹³⁹ Council of Europe, Committee of Ministers. Recommendation of No. 95(14) of 12 October 1995 on the Protection of the Health of Donors & Recipients in the Area of Blood Transfusion. *Intl Dig. Hlth Legis.* 1996;47:164-167.

neutrality principle discussed in Section II.E, above. It also responds to concerns that there is little ethical difference between cash or in kind payment in some circumstances: some payments made, in kind or in cash, are ethically equivalent. This differs from the US policy approach. Finally, the definition of paid donors seems to narrow prior COE policy. The 1995 principle would seem to permit only reimbursement for direct travel expenses; the 1978 Resolution would seem to permit reimbursement for reasonable travel expenses and loss of earnings.

*e. COE Convention on Human Rights & Biomedicine, 1997:*¹⁴⁰ The payment debate may also be informed by a recent and innovative COE treaty. In 1997, the COE opened for signature the Convention on Human Rights & Biomedicine. Though the Treaty does not refer to blood per se, it is relevant to the donation and transfer of human tissues by virtue of the general principles it announces. It identifies the protection of human dignity as the underlying value of the treaty. It addresses confidentiality, informed consent for medical interventions, and research ethics. As regards permissible financial transactions around the transfer of human tissue, it proclaims that “the human body and its parts shall not, as such, give rise to financial gain.”¹⁴¹ It thus adopts the principle of financial neutrality identified in Section II, above, and adopted into most COE blood policy statements before 1995. Since an interpretative document for the Treaty suggests that tissues like blood are considered “body parts”,¹⁴² the treaty gives legal effect to long-established COE blood policy. Indeed, it echoes the non-profit principle initially stated in the 1958 COE agreement on the exchange of human substances. As a regional instrument of public international law the 1997 Treaty will, after formal ratification, become binding on the 20+ European countries that had signed it by 1998.

¹⁴⁰ Council of Europe. *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights & Medicine*. Oviedo, 1997.

¹⁴¹ *Ibid.*, art. 21.

¹⁴² Council of Europe. *Explanatory Report to the Convention on Human Rights & Biomedicine*. Strasbourg, 1996 [www.coe.fr/oviedo/rapporte.htm].

2. European Union

The European Union has until recently played a narrower role than the COE in the articulation of European blood policy. Founded as the European Economic Community in the 1950s under the Treaty of Rome, it has since been responsible for the cultivation and regulation of the common market of Europe. Its focus for the last decades has been on its economic mandate, and the harmonization of national laws to facilitate the functioning of the European market. Because trade, research and scientific development have economic import, the EC has exerted some influence over scientific and health policy. Changes in European law in recent years, however, have enabled it to play at least four important roles in European blood policy: pharmaceutical regulator, partner with the COE, enforcer of blood policy and public health norms, and forum for reflection on ethics issues.

a. European Medicines Evaluation Agency (EMA): First, the EU influences the development of drug policy through its regulation of blood related biologicals and drugs. The common goal of developing standard procedures and norms for the testing and marketing of therapeutic products in Europe led decades ago to the development of European common market law on pharmaceuticals and medical devices. Today, the European Medicines Evaluation Agency plays a role parallel to the Canadian Bureau of Biologics or the US FDA. Amongst other things, it has recently been involved in evaluating PCR testing for Hepatitis C in the blood¹⁴³ and in issuing guidances on such matters as pre- and post-marketing requirements for human plasma derived F VIII.

b. EU/COE Partnership on Blood Policy: Secondly, for over a decade the EU has worked with the COE in developing European blood policy. Part of the partnership was cast by the different mandates of the organizations. For instance, one of the first major pronouncements of the

¹⁴³ See Seitz R, Burger R. Science, Lawyers and the Europeans: Testing Requirements in Transfusion Medicine. *Transfusion* 1998;38:506-507 (letter).

COE -- the 1958 COE treaty on the exchange of therapeutic substances -- implicates the mandate of the EU. If the provision in the treaty that therapeutic substances cross borders duty-free expresses a substantive ethical position, it is also a trade matter. In recognition of this and apparently to support the substantive provisions of the text, the EU formally became a party to the agreement in 1983.¹⁴⁴ The COE/EU partnership has since been given further legal and practical impetus. Recent amendments to the Treaty of the European Community (*Treaty of Maastricht, art 129; Treaty of Amsterdam, art. 125*), for instance, confer explicit public health responsibilities to the EU. Those EU duties directly implicate COE recommendations on the collection, processing and safety of blood. Given the historic role and work of the COE in European blood policy, would the EU endorse, modify or reject the blood policy and ethical reasoning of the COE?

c. 1989 & 1998 EU Standards on Plasma & Plasma Donors: Two plasma policy statements that the EU has issued in the last decade answer the question. They indicate that the EU affirms the policies of the COE. In a 1989 Directive,¹⁴⁵ the EU extended, with special provisions, some of its 1975 requirements regarding pharmaceutical products.¹⁴⁶ Directive 89/381 applies to “medicinal products derived from human blood or plasma”, such as albumin, coagulating factors and immunoglobulins. The Directive briefly addresses some technical, quality assurance and infectious disease control matters, and declares the following:

“Member States shall take the necessary measures to promote Community self-sufficiency in human blood or human plasma. For this purpose they shall encourage the voluntary unpaid donation of blood and plasma and shall take the necessary measures to develop the production and use of products derived from human blood or human plasma coming from voluntary unpaid donations. They shall notify the Commission of such measures.”

¹⁴⁴ Council of Europe, European Treaty Series 26. *Additional Protocol to the European Agreement on the Exchange of Therapeutic Substances of Human Origin*. Strasbourg, 1983.

¹⁴⁵ European Union. Council Directive 89/381/EEC of 14 June 1989.

¹⁴⁶ Brunko P. The Regulation of Medical Products Derived from Human Blood or Plasma in the European Community. *Dev. Biol. Standards* 1993;88:269-271.

The Directive thus affirms the COE recommendations on self-sufficiency and unpaid donors. Moreover, it gives legal effect to the COE the recommendations, since directives under EU law are binding on member states as to the result to be achieved (EC Treaty, art. 189).

The tendency of the EU to endorse COE pronouncements on blood policy has continued since 1989. It is illustrated in a 1998 Council Recommendation on the safety and suitability of plasma and blood donors.¹⁴⁷ Recommendation 98/463 advances some of the work that the EU has undertaken through the 90s on HIV, the public health and the blood system.¹⁴⁸ The recommendation includes important technical standards that have ethical and blood policy implications, such as donor testing, and volume and frequency limitations on plasma donations.¹⁴⁹ It urges member states to pursue self-sufficiency, proper donor selection, and optimal use of blood. In the Recommendation, the EU also endorses the definition of “voluntary and unremunerated” donations that the COE outlined in 1995. It encourages member states to “take all necessary measures to encourage the voluntary and unpaid donations of blood and plasma, and entirely support the efforts of the Council of Europe in this area ...”. The EU thus continues to affirm and enforce the blood policy positions that the COE has advanced over the years.

d. EU Reflection on Ethical Issues in Blood Policy: The COE/EU position on European blood policy recently received formal ethical support. In 1991, the EU created an independent, interdisciplinary advisory committee to provide advice on some of the ethical riddles posed in part by modern biotechnology. This formal structure for bioethical reflection is called the Group of Expert

¹⁴⁷ European Union. *Council Recommendation 98/463/EEC of 29 June 1998 on the Suitability of Blood and Plasma Donors and the Screening of Donated Blood in the European Community*. Off. J. Eur. Comm. L-203, 21 July 1998;4:14-26.

¹⁴⁸ See, e.g, European Community. *European Parliament and Council Decision 1729/95/EC of 19 June 1995 on the Extension of the Europe Against AIDS Programme*.

¹⁴⁹ For a comparison of European and Canadian norms restricting the frequency and volume of plasma donation, see the discussion in II.E.6 & Table E, below.

Advisers on Ethical Issues in Biotechnology (GAIEB). In a 1993 opinion on blood products, GAIEB addressed issues raised by the EU Directive of 1989.¹⁵⁰ The opinion identifies the supply and safety of blood, human dignity and the body in commerce as relevant ethical issues. Though brief, the opinion indicates that GAIEB regards donor payments as a threat to the dignity of the donor. The opinion does not define payment. Yet, it does endorse the COE and EU policy of voluntary unpaid donation. It argues that “Respect for the individual (right to life, to physical integrity and to human dignity), whether as a donor or as donee, is the foundation of the ethical principle that the human body in general and human blood in particular are not marketable.” This policy thus adopts the commodification argument of Section II.B., above.

e. European Consensus & the Ethics Discourse: The GAIEB opinion offers at least two important insights. First, it reveals a broad policy consensus on the leading substantive norms and principles of European blood policy, at least as they have been articulated in formal statements from inter-European governments. The principles are summarized in Table C, above.

Secondly, the opinion reveals a major shift in the European ethics discourse on blood policy. The shift has occurred in terms of both the voices in and the languages of the discourse. Consider the voice of the COE. The commitment to “solidarity” announced in the 1958 COE treaty on the exchange of therapeutic substances involves a moral statement about human and even state relations. An identifiable value is thus imbedded in this public policy and law, though there is no mention of ethics. The ethics discourse is implied or latent. In the 1980s, COE policies began to use the word “ethical,” and then “ethical principles.” Non-remunerated voluntary donations eventually became an explicit ethical principle. This illustrates the relation between language, ethics and public discourse on blood policy, noted in Section II.D, above. In the 1990s, the COE discourse resonates, in part, through declared

¹⁵⁰ European Union. Group of Advisers on the Ethical Implications of Biotechnology of the European Commission. *Opinion No. 2 on Products Derived from Human Blood & Human Plasma*. Brussels, 1993.

ethical principles and in part through a formal treaty on human rights and biomedicine. That the treaty was drafted by an expert ethics advisory committee of the COE means that the structure and process of ethics deliberations have shifted. Both inter-European governmental organizations have thus introduced formal ethical deliberations into their policy and law-making process. As such, the formal ethical opinion on blood products by GAIEB epitomizes a shift in the structure of ethical deliberations. The shift raises important issues about accountability and transparency in government decision-making. Because it offers new process and structure, it represents a new model of ethical deliberation on blood policy.

D. Selected European Country Profiles

How do the European blood policy principles that have been refined over the last decade actually apply in practice? Some general points are not in doubt. While Europe has achieved self-sufficiency in fresh blood products through unpaid donations, for instance, it has not done so in plasma products.¹⁵¹ Much of the European imbalance between demand and supply in plasma products over the years has largely been met with annual “imports of plasma and finished plasma-derivatives of a value of \$640,000,000 from the United States”.¹⁵² Beyond such generalities, clear responses to the question are hampered by the difficulty in securing current, detailed and accurate information regarding the different countries. Some recent government reports offer retrospectives. The Krever report of the Canadian Blood Inquiry, for instance, reviews how some European nations responded to the HIV/AIDS blood crisis. Most other reports on national supply and demand for European blood products date, or have data, from the early 1990s¹⁵³ or 1980s.¹⁵⁴ They tend to illustrate practices before AIDS reforms and before

¹⁵¹ Council of Europe & Commission of the European Communities (COE/EU). *The Collection & Use of Human Blood & Plasma in Europe*. Strasbourg, 1993:5.

¹⁵² Westphal RG. International Aspects of Blood Services in *Principles of Transfusion Medicine* (Rossi et al., eds). Williams & Wilkins, Baltimore, 1996:917-922.

¹⁵³ COE/EU, op. cited.

¹⁵⁴ US Congress, Office of Technology Assessment. *Blood Policy & Technology*. Washington: GPO, 1985.

rDNA F VIII became generally available. Again, few scrutinize comparative practices of EU/COE member states in terms of their adherence to European norms. Despite such limits, relevant portraits have begun to emerge. Accordingly, the following profiles the practices of a few European countries. Those chosen illustrate relevant issues on donor payment, sales prohibitions, and paths towards self sufficiency.

1. France

France has a tradition on payments that preceded formal articulation of European blood policy. It has long been expressed in public laws. It has more recently been voiced in formal ethics opinions. Indeed, at least since 1952 when the organization of blood services became a governmental responsibility France has formally excluded “profits” from the working fees involved in the processing of blood and blood components. In 1952, legislation on the therapeutic use of blood established the public control, a licensing scheme and standards for blood and plasma.¹⁵⁵ The law specifically empowered the government to set non-profit fees for the processing of human plasma. Even French legal analysts in this era distinguished donor indemnification fees for cost recovery or reimbursement from remuneration for profit.¹⁵⁶

These traditions continue, and are reflected in a recent convergence of ethical and legal thought. In a 1991 ethics opinion on blood products and commercialisation of the body, the French National Bioethics Committee (CCNE) identified gratuity, respect for the donor, and non-profit principles as fundamental values that have long inspired the French blood system.¹⁵⁷ Its analysis was based less on consequentialist concerns for safety and more on formalist ethical views about the human person. The Committee argued that gratuity and non-commercialisation of the human body are principles that flow

¹⁵⁵ Loi No. 52-354 du 21 juillet 1952, J.O. 22 juillet 1952:357.

¹⁵⁶ See, e.g., Savatier J. *De Sanguine Jus. Rec. Dalloz* 1954; 35 (Chronique 25):141-146.

¹⁵⁷ CCNE. *Avis no 28 sur la transfusion sanguine au regard de la non-commercialisation du corps humain*, Paris, 1991 [www.ccne-ethique.org/ccne/avis].

from a basic respect for human dignity. This is a concrete instance of the commodification argument, noted in Section II.B., above. Indeed, the Committee emphatically cautioned that if society begins to regard and treat blood components as matters of economic trade, “tomorrow, after blood, it will be all tissues and organs that become objects of commerce.” The caution was heeded in law. In 1993-94, France enacted blood transfusion¹⁵⁸ and bioethics legislation.¹⁵⁹ The laws codified a range of principles into the French *Code of Public Health*, including (a) the inviolability of the human person; (b) that the donation of blood, tissue and organs shall be voluntary, anonymous, and gratuitous,¹⁶⁰ and (c) that donors shall not be paid, other than for exceptional reimbursements of expenses in conformity with government regulations.¹⁶¹

The longstanding reliance of France both on unpaid donors and legal prohibitions on the sale of blood did not stop it from achieving self-sufficiency¹⁶² by the early 1990s. The path to self-sufficiency has been marked by significant plasma safety and quality control difficulties, however, particularly in the 1980s. France has had one of the highest European rates of HIV infection of those with haemophilia. Such difficulties contributed to a national blood scandal,¹⁶³ and helped to prompt structural and legislative reforms. In 1993, a national laboratory for fractionation was established.¹⁶⁴ It centralized the former regional fractionation centres. A national blood agency, the Agence Française du Sang (AFS)¹⁶⁵ was also established to coordinate the blood system, license and inspect transfusion centres, advise the government, train transfusion personnel, etc.. AFS is a non-profit public entity created by public law. It has a specific statutory mandate to maximize the safety and supply of blood, in accordance with advances in medical science and the ethical principles noted above.¹⁶⁶

¹⁵⁸ Loi n° 93-5 du 4 janvier 1994, codified in *Code de la Santé Publique* (Dalloz, Paris, 1997), art. L.666-1 et seq.

¹⁵⁹ Loi n° 94-654 du 29 juillet 1994.

¹⁶⁰ *Code de la Santé Publique*, art. L.666-1.

¹⁶¹ *Ibid.*, arts. L.665.13, L.666-3.

¹⁶² Council of Europe.

¹⁶³ Krever, op. cited, 807.

¹⁶⁴ Cazenave JP, Fellea G. Management of Plasmapheresis in France. *Hematol. & Cell Therapy* 1996;38:S25-S33.

¹⁶⁵ *Code de la Santé Publique*, art. L. 667-4.

¹⁶⁶ *Ibid.*, art. L.667-5.

Three other dimensions of France are noteworthy beyond its conformity with major European blood policy principles and goals. First, it is clear that both ethically and legally the early treatment of blood donation in France in the 50s inspired and served as precedent for more broader approaches to the therapeutic transfer of other human tissues in the 1990s. This dynamic illustrates the precedential momentum of tissue policy noted in Section II.O, above. Secondly, the historic ethico-legal principles of France have likely influenced the substantive ethical underpinnings of European blood and tissue policy. Thirdly, France has influenced the process of ethical reflection on European blood policy. Its 1991 ethical opinion on blood products stands amongst the first of a national bioethics body. If the opinion helped to inspire the 1993 opinion of the EU ethics group, the very process of formal ethical deliberations on such matters demonstrated a novel approach to reflecting on and building national blood policy.

2. Germany

Donor payments, demand for plasma, and self-sufficiency in Germany contrast decidedly with France. Germany is regarded in Europe as amongst the most generous in the amount of money provided to blood or plasma donors: some 50 DM (Cdn\$ 38) per donation. In the mid-nineties, the level of payment occasioned European debate over its rationale and effect. Some have argued that such monies contravene EU Directive 89/381 and threaten blood safety.¹⁶⁷ Of course, the safety claim is based on the paid blood = contaminated blood argument.

Germany has sought to refute suggestions that the money provided donors contravenes European blood policy. It has done so in at least two respects. First, in European debates, Germany has argued that a “differentiated system of reimbursing” donor travel and time expenses is consistent with the COE definition of “voluntary, unpaid donation”; instead, it argues that rigorous donor selection is the

¹⁶⁷ Cash JD. Payment Proposed for Blood Donations in Germany. *Br. Med.J.* 1994;309: 1160.

determinative factor for safety.¹⁶⁸ Austria and Sweden have also expressed reservations about a narrow definition of “unpaid donor”.¹⁶⁹ The debate over the scope of the meaning of the term “paid/unpaid-donor” reflects the ethics, language and commerce discourse noted in Section II.D, above. Still, the scope of the debate is not broad. That few if any voices in the European debate have suggested that the payments for plasma donors are unreasonably low and potentially exploitive, means that arguments for payments as professional fees have not entered the discourse. Rather, concerns on both sides resonate with fear of slipping down the slope towards undue inducements or disguised payments that go beyond reasonable reimbursement of donor expenses towards, payment for plasma or payment as fees for service. Thus, the tenor of the debate is to maintain the financial neutrality principle that animates reimbursement. (See Section II.E, above.) Indeed, even the official German position maintains that the risks associated with paid blood become greater with payments above 50DM¹⁷⁰ -- a practice that has occasionally been reported.¹⁷¹

Secondly, recent German legislation has been enacted consistent with European blood law. In 1998, the German Parliament adopted a *Transfusion Act*.¹⁷² The legislation, *inter alia*, requires the informed consent of donors, outlines provisions for medical documentation and confidentiality, provides for the establishment of an Advisory Working Group on Blood, and provides that donated blood or blood components “shall be non-remunerated”,¹⁷³ though the “donor may be granted a reimbursement.” The prohibition on the sale of blood would seem to advance the “voluntary-unpaid donor” position of the EU. Arguably, however, the provision is written broadly. For instance, the Act does not define key terms of the blood sales prohibition like “non-remunerated” and “reimbursement”. In the absence of regulations or directives that precisely define such terms, their meaning is left to the informed judgments

¹⁶⁸ Von Auer F. Germany (Donor Payments). *Br. Med.J.* 1995; 310: 399 (letter from German Ministry of Health).

¹⁶⁹ Council of Europe, European Health Committee. *Committee of Experts on Blood Transfusion & ImmunoHaematology, Meeting Report*: Strasbourg, 3-5 Oct. 1994: 13-16.

¹⁷⁰ Von Auer, op cited.

¹⁷¹ See, e.g., Peerenboom E. Germany Still Pays Donors. *Nat. Med.* 1998;4:139.

¹⁷² Germany. *Act on Regulating Transfusion Practice (Transfusion Act)* of 1 July 1998.

¹⁷³ *Ibid.*, s. 10.

of transfusion centres. In the context of continuing debate over the meaning of the term paid/unpaid donor, broad definitions leave the terms open to broad interpretations. This would seem to reflect the German position on broadly defining such terms in European public policy debates on blood supply. This breadth is further illustrated by its contrast with the prohibition on organ sales in the *German Transplantation Act*; it permits “appropriate compensation” for reasonably-associated expenses.¹⁷⁴ Whether such word as “appropriate” or “reasonable” expenses actually reduce the risk of undue payments, such explicit qualifying language is intended to keep the exception for payment of expenses narrow. Also in contrast to the *Transplant Act*, the *Transfusion Act* provides no penalties for violation of the sales prohibition¹⁷⁵.

If the scope of the legislation and magnitude of reimbursement for expenses in Germany seem exceptional by European standards, the country also differs from France in other respects. Unlike France, Germany has yet to achieve self-sufficiency in plasma. It thus shares the company of many other European countries. By both French and European standards, Germany also has higher demand for plasma products (e.g., EU = 2.65 I.U. of F VIII; GDR = 4.1 I.U. of F VIII).¹⁷⁶ If its relatively high demand for plasma products raises questions about the role of standards of therapeutic practice in national plasma shortages, it still means that the country must supply a comparatively higher volume of plasma if it does not reduce demand. To address the dynamic, Germany has long imported most of its plasma supplies from the US.¹⁷⁷

¹⁷⁴ See Table D, below.

¹⁷⁵ Compare s. 31 of the *Transfusion Act* with ss. 17-18 of the *Transplant Act*, both noted in Table D ?, below.

¹⁷⁶ COE/EU, op cited, pp. 22-23. See also, Delaney FM. *The Collection and Use of Human Blood and Plasma in the European Community*. Brussels. European Commission, 1995:32.

¹⁷⁷ Krever, op cited, p. 842.

3. Netherlands

Blood policy in the Netherlands has more parallels to France than to Germany. Like the French, the Dutch have relied on unpaid-donors, under national legislation, since before EU Directive 89/381. Legislation adopted in 1988 directly addresses financial exchanges in the collection of blood. It provides that (a) donors “may only receive compensation for reasonable costs” incurred and (b) that blood products “may be supplied only in return for reimbursement that may not exceed the cost incurred in order to acquire, prepare or supply such products.”¹⁷⁸ The provisions give legal force to a policy of non-profit operation of the blood system. By specifying non-profit operations in the supply of blood products, Dutch law conforms to European and transcends US blood policy.

In terms of the national demand for and supply of plasma, important factors seem to have influenced the Dutch ability to harmonize the two towards self-sufficiency. Like many of its neighbours, for years the Netherlands has depended on plasma imports from the US -- a fact that became an issue in the tainted blood scandal of the 1980s and 1990s.¹⁷⁹ Its reliance on US imports, however, has been dramatically less than its neighbours.¹⁸⁰ That reliance has largely ceased, because in recent years the introduction of recombinant VIII has helped the country achieve self-sufficiency.¹⁸¹

4. Nordic Insights -- Sweden, Norway & Finland

Northern Europe offers insights on the relation between donor status, safety and self sufficiency. In terms of the latter, the region is noteworthy. By the late 1990s, Sweden, Norway and Finland had

¹⁷⁸ Netherlands. Law of 8 Nov.1988 Prescribing Rules Governing Blood Transfusion, ss. 23, 28. *Intl Dig. Hlth Leg.* 1990; 41: 613-614.

¹⁷⁹ Krever, op cited, pp.912-920.

¹⁸⁰ COE / EU, op cited, p. 15.

¹⁸¹ Personal communication with Dr. WG van Aken , April 1999.

become self-sufficient in plasma products. The different paths of these countries towards an adequate plasma supply both parallel and differ from Germany and France.

Finland¹⁸² and Norway¹⁸³ have been self-sufficient in F VIII for more than 15 years using exclusively unpaid donors.¹⁸⁴ Partially because both Norway and Finland have had little reliance on imported plasma products, the rates of HIV infection amongst those afflicted with haemophilia are said to be “among the lowest in Western Europe”.¹⁸⁵ The self-sufficiency of these countries has been realized in part through reliance on national fractionation plants (Finland) or on contracts for fractionation (Norway).¹⁸⁶

Sweden differs from Finland and Norway in important respects. Its longstanding prophylactic treatment for haemophilia A, for instance, requires a national demand for F VIII that is amongst the highest in Europe and roughly twice that of Finland and Norway.¹⁸⁷ In terms of donors, Sweden has a decade-long tradition of paying blood donors 25-30 krona/donation (\$4-5 Canadian) and twice that for plasma donors.¹⁸⁸ The philosophy and effect of payment have reportedly changed in recent years. Inflation has devalued the amount that donors receive. When local hospitals stopped using payment as a recruitment message in the 1980s and intensified recruitment initiatives, altruistic donations significantly increased. Though national legislation¹⁸⁹ has helped establish donor protection, labelling and transfusion norms, the law is said not to prohibit payment. Blood donors continue to receive 30 Krona per donation as

¹⁸² Leikola J. Can the Supply & Demand for Plasma-Derived Products Ever Be Reconciled? *Blood Coagulation & Fibrinolysis*, 1994 Suppl. 4.

¹⁸³ Solheim BG et al. Self-Sufficiency for Blood & Plasma Products in Norway. *Biol. Clin. Hematol.* 1992;14:103-105.

¹⁸⁴ COE/EU, op. cited.

¹⁸⁵ Glomstein A. Self-Sufficiency & Blood Transmitted Diseases. *Blood Coagulation & Fibrinolysis*, 1995 Suppl 2;6:S23-S26.

¹⁸⁶ *Ibid.*

¹⁸⁷ See Section I.B, above.

¹⁸⁸ Personal Communication with Dr. O. Akerblom, University Hospital, Sweden, April 1999. See also Oldinger E. Skilda vagar for god blodförsörjning: Norden (Various Methods for Good Blood Supply in Scandinavia). *Nord. Med.*, 1996;111:212-8.

¹⁸⁹ Sweden, National Board of Health & Welfare. Compare *Regulations No. 27 of 12 July 1984 on blood donation, Int. Dig. Hlth. Legis.* 1985;36:481-S1 and *Regulations No. 38 of 15 Dec. 1989 on blood donation, Int. Dig. Hlth. Legis.* 1990;41:262-264.

reimbursement for expense. Plasma donors continue to receive 60 Krona, up to a maximum of 1560 annually (\$271.00 Cdn). While the payments to blood donors are considered consistent with European policy on “unpaid donors”, debate continues on the plasma payments.¹⁹⁰ In terms of self-sufficiency, while Sweden has tended to rely on imported F VIII more than Finland and Norway, it achieved self-sufficiency in plasma products by the mid-1990s.^{191,192} It has done so apparently through combined reliance of national fractioning and European fractionation contracts.¹⁹³ Though Sweden apparently has never had a formally defined national blood policy or program,¹⁹⁴ the government is studying the potential for long-term self-sufficiency.

In all, the experiences of these selected European countries offer a few lessons. Some of the countries are moving towards fulfillment of the stated European blood policy principles and goals. A minority have a tradition of paying donors; most do not. A growing number of countries are moving towards self-sufficiency in plasma products without donor payments, by fractionation contracts, national plants, increased use of rDNA F VIII. The experiences further indicate that an adequate plasma supply of F VIII depends on various supply and demand factors. The experiences show that an adequate supply may be achieved with or without donor payment.

E. Canada

The practices and policies of Canada share both likenesses to, and differences from, the US and Europe. In the context of the historic debates about paid donors and the evolution of the national plasma supply, Canada is characterized by at least six distinguishing features. First, it has a mixed history regarding payment to donors. Secondly, since the 1970s altruism has been a cornerstone of

¹⁹⁰ Personal communication with Dr. Akerblom, op. cited.

¹⁹¹ Oldinger, op. cited.

¹⁹² McCullough (national programs), op. cited:1023.

¹⁹³ See Nilsson, op. cited.

¹⁹⁴ McCullough, op. cited.

public policy regarding blood and tissue procurement. Thirdly, a public policy of altruism has enabled Canada to become largely self-sufficient for whole blood but not for plasma and its derivatives. Thus, fourthly, Canada has for years relied on US plasma supplied largely from paid donors. This indirect reliance on paid plasma donors raises important questions of ethics in the formal and de facto Canadian national blood policy. Fifthly, our indirect reliance, to date, on a paid plasma donor system arguably acknowledges plasma sales as an historic de facto necessity for ensuring an adequate plasma supply for Canadian health purposes. Finally, such reliance in practice has had the effect of eroding some of the elements and protections on which Canadian plasma regulations are based.

1. Mixed History of Payments

Like many European nations and the US, Canada has enjoyed a checkered history regarding the payment of blood donors since World War II. The chronology in Table A in Section I, above, indicates that as the Canadian blood system has matured over the last four decades, it has had to rely on occasion on paid, professional and unpaid Canadian donors. This mixed history results in part from the humanitarian principles surrounding the donation and collection of blood by international and national Red Cross Societies during the immediate post-war years, and in part from the perceived or practical necessity of sometimes resorting to pay people to provide incentives sufficient to ensure an adequate supply of blood and blood products. Thus, even if non-payment for donated blood and blood products has emerged as the general norm in Canada over the last quarter century, payments associated with regularly donating some rare blood products continue today. For instance, decades ago the Rh Institute of Winnipeg began paying modest honorariums to compensate the time, effort and expenses of donors of specialty plasma.¹⁹⁵ Such specialty plasma has been used over the years to produce immune globin for the successful prevention and treatment of potentially fatal newborn “blue baby” or hemolytic

¹⁹⁵ Personal Communication, Cangene Corporation (formerly Rh Institute of Winnipeg), June 1999.

disease.¹⁹⁶ The need, the donor practice and the production of these specialty plasma products continue.¹⁹⁷

2. Altruism in Canadian Tissue Laws

Even as the mixed history of donor payments in Canada has evolved, legal and public policy developments over the last decades have evidenced a formal commitment to altruism. Two measures of that commitment began some 30 years ago. Then, the development of national blood principles and the passage of tissue donation laws combined to entrench altruism as a preferred public policy on the procurement of tissue for therapeutic use in Canada. The national blood principles will be discussed below.

The 1970s began with deliberations on a proposed national model law to govern the transfer and procurement of tissue for transplantation. In 1971, the Uniform Law Conference of Canada formally proposed the *Uniform Human Tissue Gift Act*.¹⁹⁸ The model law adopted the terminology of “donors” and referred to donated tissues as “gifts.” The Act was proposed to afford the provinces model legislation to address such issues as consent and the legal transfer of organs and tissues from a deceased or living person for transplantation into another. Following the enactment of *Anatomy Acts* in the early part of the century and cornea transplant legislation in the 1950s, the *Uniform Gift Tissue Act* of the 1970s symbolizes the third wave of legislation to facilitate the transfer of human body parts for therapeutic purposes to medicine¹⁹⁹. The Canadian approach in this domain had long been influenced by the approaches of Britain and other countries. For example, in the early 1960s Ontario adopted a

¹⁹⁶ Bowman JM. Rh Immunization in Manitoba: Progress in Prevention and Management. *Can Med. Assoc. J.* 1983;129: 343-345.

¹⁹⁷ See the Cangene Corporation Donor Program at www.cangene.com.

¹⁹⁸ Uniform Law Conference of Canada, *1971 Proceedings of the Conference of Commissioners for Uniformity of Legislation in Canada*: 76, 152.

¹⁹⁹ Jones D., op. cited.

Human Tissue Act, shortly after Britain had enacted tissue legislation.²⁰⁰ The 1963 Ontario *Tissue Act* helped shape a proposed model Canadian *Tissue Act* in 1965.²⁰¹ In 1968, a *Uniform Anatomical Gift* was proposed as model transplant legislation in the US.²⁰² It used the word “gift”, but did not ban the sale of tissue. In 1971, Ontario introduced the word “gift” into its revised tissue legislation. The Ontario *Human Tissue Gift Act*²⁰³ was also novel in that it generally prohibited the sale of human tissue. This approach would influence the laws of Canada. For when the model *Tissue Act* of 1965 was replaced by the *Uniform Human Gift Tissue Act* of 1971,²⁰⁴ the new model law drew on the Ontario approach. The 1971 *Uniform Human Gift Tissue Act* was widely adopted in many provinces through the 1970s and 80s, in the form of provincial gift tissue legislation.²⁰⁵ Such laws give legal effect to the notion that tissue transferred for therapeutic purposes should be a “gift,” since they generally prohibit the sale of organs and tissues.

Do Canadian tissue laws forbid the sale of blood or plasma? With some exceptions, they generally do not because the Acts typically exclude blood and blood constituents from the sales prohibition or definition of “tissue.” The Ontario *Gift Tissue Act*, for instance, subjects individuals to a risk of fine and imprisonment for violating the following:

No person shall buy, sell or otherwise deal in, directly or indirectly, for valuable consideration, any tissue for a transplant or any body or parts thereof other than *blood or a blood constituent* for therapeutic purposes, medical education, or scientific research, and any such dealing is invalid as being contrary to public policy.²⁰⁶ (emphasis added)

²⁰⁰ Castel J-G. Some Legal Aspects of Human Organ Transplantation in Canada. *Can. Bar Rev.* 1968;46:345 at 395.

²⁰¹ *Ibid.*

²⁰² United States, Commissioners on Uniform State Laws, 30 July 1968.

²⁰³ The Act was proposed in 1970 and enacted in 1971 into the *Statutes of Ontario*, 1971, c. 83, s. 10.

²⁰⁴ Uniform Law Conference of Canada, op. cited. In 1989, the Uniform Law Conference of Canada adopted and proposed to the provinces a revised tissue transfer act, the *Uniform Human Tissue Donation Act*. Though few provinces have yet to adopt it, the Act strengthens the prohibition on tissue sales and retains the tissue sales exemption for blood.

²⁰⁵ See Table F in Section III.F, below.

²⁰⁶ *Human Gift Tissue Act*, RSO 1990, c. H.20, s.10. See also ss. 12,1. See generally, Table F, in Section III.F., below.

Several reasons might explain the exemption of blood. It may be based on the view that the transfer of regenerative tissue raises fewer physical risks to the donor. This consequentialist donor protection view is supported in part by the definition of “tissue” in many provincial tissue acts. Like the 1971 *Uniform Gift Tissue Act*,²⁰⁷ the definitions often exclude skin, bone, and blood or other regenerative tissues from the scope of the acts.²⁰⁸ The drafters of the Uniform Act intended not to prohibit the sale of blood, but offered no apparent rationale for the exemption.²⁰⁹ The exemption of blood may also be based on a historic view that blood has occasionally been sold in Canada with few, if any, untoward effects and that this relatively harmless practice should not be prohibited. This view is supported by provisions of some provincial laws that state that dealings that were lawful before the enactment of the tissue laws remain lawful.²¹⁰ The exemption of blood may also be based on a view that the role of the law should be limited in this domain. In other words, even if the sale of blood raises ethical and public policy issues, they may be of a magnitude that does not warrant formal prohibition, especially if regulation or other societal instruments may curb abuse and promote ethical conduct. The exemption may also be based on a view that the sale of blood, even if rare, may sometimes prove necessary. As this sampling of views illustrates, the sales exemptions and prohibitions in Canadian tissue laws raise many of the arguments about sales identified in Section II, above. The particulars of the tissue sales prohibitions are important nationally and internationally²¹¹. However, the particulars should not obscure insights about how the laws more broadly relate to altruism. For despite the exclusion of blood from Canadian tissue transplant laws, the widespread passage of laws that generally prohibit the sale of human tissue helped to enunciate and entrench altruism as a major element of formal tissue procurement policy in Canada.

²⁰⁷ See *Uniform Gift Tissue Act*, 1971, op cited, s. 1(c) (“tissue includes an organ, but does not include any skin, bone, blood, blood constituent or other tissue that is replaceable by natural process of repair”).

²⁰⁸ See, e.g., s.1 of the Ontario *Human Gift Tissue Act*.

²⁰⁹ Uniform Law Conference of Canada, op. cited, p. 76.

²¹⁰ See, e.g., *Human Gift Tissue Act* of Nova Scotia, s. 13 (“Nothing in this Act makes unlawful any dealing with a body or parts thereof of a person that would be lawful if this Act had not been passed.”).

²¹¹ See Table F in Section III. F, below.

3. Principles of the Canadian Blood System

Altruism, the “gift of life” ethic, would also become a formal part of the national blood system of Canada in the 1970s. We have already seen that in 1975 the WHO adopted its resolution urging the development of national blood systems based on voluntary, unpaid donations. Did the WHO resolution influence Canadian policy approaches? It is an open question, even if it may seem so chronologically. The Krever Report indicates that in 1976 correspondence with the Red Cross the federal government outlined three governing principles for the national blood supply: voluntary donations, national self-sufficiency, and the gratuity of blood products to recipients.²¹² These principles would evolve and expand. In the period 1979- 81, for instance, the federal, provincial, and territorial ministers of health of Canada (a) approved four principles²¹³ for the Canadian blood system and (b) created the Canadian Blood Committee (CBC), to develop a range of implementing initiatives and to direct the Canadian blood system in accordance with the 1979 guiding principles.²¹⁴ Table E, below, summarizes these principles.

²¹² Krever, op. cited, p. 102.

²¹³ Canadian Blood Committee. *New Principles for the Canadian Blood System: A Report of the Canadian Blood Committee*. Ottawa: Sept 1989: Appendix A.[hereinafter Canadian Blood Committee].

²¹⁴ US Congress, Office of Technology Assessment. *Blood Technologies, Services and Issue*. Washington, US GPO, 1985:177.

**Table D:
Principles of the National Blood System of Canada**

Guiding Principles, 1979 ²¹⁵	Revised Principles, 1989/1996 ²¹⁶
(1) <i>Voluntarism</i> : To protect the voluntary donor system by enhancing the opportunities of Canadians to voluntarily donate a gift for society's general benefit and by responsively managing that resource;	(i) <i>Voluntarism</i> : The voluntary system should be maintained and protected;
(2) <i>Self-sufficiency</i> : To ensure self-sufficiency of blood products by reducing Canada's dependence on foreign sources of blood products supply, particularly those that rely on purchase of plasma for raw material;	(ii) <i>Self-Sufficiency</i> : National self-sufficiency in blood and plasma collection should be encouraged;
(3) <i>Gratuity</i> : To ensure gratuity of blood products by reinforcing the Canadian tradition whereby no payment is made for a donation of blood and/or plasma and no specific charges are made to recipients of blood and blood products; and	(iii) <i>Adequate Supply</i> : Adequacy and security of supply of all needed blood, components and plasma fractions for Canadians should be encouraged;
(4) <i>Non-profit</i> : That a Canadian non-profit policy be maintained and that any charge to recover more than the real cost of producing blood fractionation products for Canadians in Canada should be considered profit.	(iv) <i>Safety</i> : Safety of all blood, components and plasma fractions should be paramount;
	(v) <i>Gratuity</i> : Gratuity of all blood, components and plasma fractions to recipients within the insured health services of Canada should be maintained;
	(vi) <i>Cost-Effective</i> : A cost-effective and cost-efficient blood system for Canadians should be encouraged; and
	(vii) <i>National Program</i> : A national blood program should be maintained.

Though the term altruism is not found in the guiding principles of 1979, the reference to a “voluntary donor system” and the suggestion that blood is “a gift for society’s general benefit” connotes altruistic policy within the voluntarism principle. The “self-sufficiency” principle from 1979-81 also specifically

²¹⁵ Canadian Blood Committee, *op cited*.

²¹⁶ For the 1989 principles see Canadian Blood Committee, *op cited*, and Krever, *op. cited*, pp. 103-104. For the 1996 affirmation of the 1989 principles, see the *Federal/ Provincial/Territorial Memorandum of Understanding (Regarding Respective Roles & Responsibilities in a Renewed National Blood System)*, 1997 [hereinafter FPTMOM], (on file with the Canadian Blood Services). These sources express the voluntarism principle with subtle differences. Under the Canadian Blood committee and Krever report version, “the voluntary donor system should be maintained and protected”... Under the FPTMOM, “voluntary donations should be maintained and protected...”

states an intent to reduce Canadian reliance on paid donor systems for national plasma supplies. The “gratuity principle” refers to non-payment of donors. The “non-profit principle” adopts some of the distinctions noted in Section II.E above regarding expenses, profits and sales. Taken together, the guiding principles of 1979 seem directly targeted at grounding Canadian national blood policy on elements of altruism.

In 1989, the guiding principles of the Canadian blood system were streamlined, expanded and revised. As indicated in Table E, the revised principles reiterate some of the founding principles and reveal an evolution. New principles were added to bring the number to seven. A principle of a national blood program was added, for instance. A new principle of “adequacy” was added, even if it was implied within the founding principle of “self-sufficiency.” As well, though quality control and safety matters had long been emphasized in the national blood supply policy, the arrival of the HIV/AIDS pandemic in the 1980s, made an explicit reference to “safety” a paramount concern. Beyond these additions the three founding principles of voluntarism, self-sufficiency and gratuity were maintained with some modification. For example, the definition of “gratuity” no longer refers to “paid donations.” Instead, it refers to free access to blood components, presumably as part of the national health system. Similarly, the principle of voluntarism is maintained, though any explicit reference to a “gift for society’s benefit” was deleted in the revision, to place emphasis on protection and maintenance of the voluntary system. The changes in wording raise concerns -- noted in Section II.B, above -- about the relation between language, ethics and public discourse on blood supply policy. The founding principle of “non-profitism” for blood fractionation products has been replaced by a principle of “cost-effectiveness.” The change would seem to acknowledge a legitimate role for for-profit fractionation of plasma and blood products in the national blood strategy. If the addition of “cost-efficiency,” the elimination of “non-profitism” and the redefinition of “gratuity” were intended to facilitate steps to ensure the adequacy of plasma supplies, then such accommodation still did not yield a rejection of altruism and the “gift of life” ethic. Rather, the scope and practicalities of implementing altruism have been modified; some might say diluted. Any such dilution reflects evolving thought on competing values. Indeed, when the revised principles were

proposed in 1989, it was noted that “it is sometimes difficult to develop policy that achieve all these principles” and “strike a balance” between them.²¹⁷ The tension between and evolution of some of the principles of national blood policy reflect the inherent value conflicts that underlie national policy on the collection and supply of blood products for therapeutic uses.

In recent years, the evolution of the national blood principles of Canada has been marked by at least three developments. First, in 1997 the Krever Report advanced recommendations that both reiterated and suggested modifications of the principles. Recommendation 2 of the Report proposes five principles to govern the blood supply system: (a) blood, as a public resource; (b) general non-payment of donors; (c) sufficient collection in Canada to meet domestic needs; (d) free and universal access to blood products/components; (e) safety of supply as paramount. The report thus echoes the adequacy, self-sufficiency, safety, gratuity and voluntarism principles of 1989. In arguing that blood is a public resource, the report explicitly endorses the gift-of-life ethic of altruism: “A fundamental value that must guide the blood supply system in Canada is that blood is a public resource, given altruistically by persons in Canada for the benefit of other persons in this country.”²¹⁸ The report refers to the 1975 WHO position and argues that unpaid donation is preferable because unpaid blood is safer, in part because paid donors may not always be truthful about their illness out of fear of losing payment. The report thus adopts two of the consequentialist arguments against paid blood noted above.²¹⁹ The report indicates that altruism may not be an absolute value, however. In rare instances, it continues “the collection of blood for specialized blood products may require an offer of compensation.”²²⁰ The invocation of altruism as a general principle that may admit of limited exceptions thus parallels the official US blood policy adopted some 25 years ago.²²¹ Even so, the general affirmation of altruism in the

²¹⁷ Canadian Blood Committee, *op cited*, p. 3.

²¹⁸ Krever, *op. cited*, p. 1047, 1062.

²¹⁹ *Ibid.* The assertions rely on paid = contaminated blood and veracity arguments noted in Sections II.G & II.H, above.

²²⁰ Krever, *op. cited*, p. 1047.

²²¹ See Section III.A.2, above.

Krever report adds another voice to those public analysts²²² in the 1990s who have explicitly advocated it as a general element of national policy on the procurement of human blood or tissue.

Secondly, in 1998, when the newly-created Canadian Blood Services Corporation (CBS) assumed operations of the Canadian blood system, it did so on the basis of the revised principles of 1989 and new operating principles.²²³ In reviewing reforms of the blood system in the wake of the AIDS crisis in 1996, the federal, provincial and territorial ministers of health had affirmed the 1989 principles as those that would still guide the national blood system. In the transfer of responsibilities for operating the national blood system from the Red Cross to the new CBS, four new CBS operating principles were also defined: safety as paramount, transparency, accountability, and a fully integrated system.²²⁴ These operating principles do many things. They echo some of the principles of the Krever report. They share an overlap with the 1989 national principles on such matters as safety. Even so, they espouse more administrative or governance principles, like transparency and accountability. In doing so, they reflect institutional process values that are consistent with the role of public institutions in democratic society. In complementing the 1989 principles, they arguably express elements of national blood policy. While Canada has not formally defined and declared a “national blood policy,” its articulation of guiding principles over the last decades strongly parallels those core elements of the policy principles of the United States in the 1970s and those that emerged from Europe over the last fifteen years.²²⁵ The continuing affirmation of elements of altruism in national blood principles since the 1970s, indicates that it remains a major element of thought and policy on the national blood supply in Canada.

Within this context, a third development has recently brought into fuller public light the basic tensions and value conflicts between guiding principles of the national blood system. In the autumn of 1998, the CBS indicated that part of its new responsibilities for the blood system involves working towards

²²² See, e.g., Law Reform Commission of Canada, *op cited*, Recommendation 2, pp.170-171.

²²³ See FTPMOM, *op cited*.

²²⁴ *Ibid*.

²²⁵ See Sections II.A and II.C, above.

national self-sufficiency. The CBS emphasized its general commitment to “gratuity” or non-payment of donors as the preferred means of achieving an adequate supply. It noted however, that “if a situation arose in which patients were at risk for want of blood products”, its supply responsibilities meant that it would not “rule out” the option of remunerating plasma donors.²²⁶ It is interesting that instead of invoking the “voluntarism” principle to mean unpaid donors, the CBS invoked the “gratuity” principle. This is noteworthy because the 1989 definition of voluntary refers to unpaid donors; the 1989 definition of “gratuity” does not, although the original 1979 definition did. (See Table E) Whatever term is used, the declaration makes clear that legitimate questions are being raised over whether altruism and unpaid donations continue to satisfy all of the national blood needs of Canada.

4. Altruism & Self-sufficiency

The historic commitment to altruism in Canadian national blood policy has yielded mixed results in terms of national self-sufficiency. The Canadian system based on unpaid donors generally provides an adequate supply of whole blood for Canadian therapeutic needs. Self-sufficiency in the general blood supply does not mean that Canada is immune from occasional disequilibria between supply and demand. For spot shortages occur even in countries that are self-sufficient. By contrast, altruism and unpaid donations for plasma in Canada have not yielded equivalent results or self-sufficiency. Like many European nations, Canada has for years been obliged to rely on imported US plasma that is generally procured from paid donors. Canada typically imports from the US over 55% of its annual plasma needs.²²⁷ Moreover, a want of domestic fractionation plants²²⁸ has obliged Canada to rely on US fractionation processes for the making of plasma derivatives. In contrast to many European nations, then, Canada faces double reliance and barriers to self-sufficiency: insufficient donated plasma and

²²⁶ Canadian Blood Services. *New Blood System will Continue to Rely on Unpaid Donations*. 19 Aug. 1998 Press release, [www.bloodservices.ca/english/news/aug2098a.html].

²²⁷ Personal Communication with Canadian Blood Services, July 1999. See also Siblal B. Does Canada Face a Crisis? US Considers Ending Plasma Exports. *CMAJ* 1998; 158:1639-1641.

²²⁸ See Krever, *op cited*, pp. 526-532.

insufficient technological/industrial capacity in Canada to convert whole plasma to therapeutic plasma-derivatives.

5. Altruism & De facto Reliance on Plasma Sales

The commitment to altruism in Canadian national blood policy and the continuing practice of Canadian reliance on paid plasma donations from the US raise important questions. First, is the apparent divergence between altruism and reliance on paid plasma consistent with the principles of national blood policy? On the one hand, the voluntary system appears to be generally maintained in Canada. Recourse to US plasma supplies would also seem to satisfy the principles of adequacy and cost-effectiveness, especially if it is shown that it is not economically or technically feasible for Canada to generate and fraction its own plasma products. From this view, the reliance on paid plasma may be seen as a justified exception to the voluntarism/altruism principle of national blood policy. On the other hand, such reliance may be seen as a contradiction of the substance and spirit of national blood principles. Indeed, upon what ethical basis is the practice justified? Some might deem it ethically incongruous on substantive and process grounds. As noted in Section II.N, above, unless there is clear and consistent openness about the causes, conditions and consequences of the reliance, silence on the issue amounts to a lack of candor and transparency to Canadians. Such silence offends the ethical virtue of truthfulness and the process value of transparency for modern governance. The practice, as well, raises important questions as to whether there is a difference between contracting to have done a deed that is ethically suspect, rather than doing the deed itself. (See Section II.N, above). If not, one might argue that it would be more prudent for Canada to offer and regulate reasonable remuneration to donors in Canada, to increase the national plasma supply and to maintain closer control over donor populations and donated plasma.

6. Regulating Plasma Sales: Federal Regulations

Adopted under the federal *Food and Drug Act*, Canadian plasma regulations recently celebrated their 20th anniversary. Like many public health norms from the past, the regulations have largely remained obscured from public attention until crisis strikes. In this instance, the tainted blood crisis and the subsequent Krever Report focussed scrutiny on federal regulation of blood practices. The formal public law regulation of plasma donation, collection and processing for blood products to meet the therapeutic needs of Canadians is intended to advance certain goals, interests and values. This subsection explores those interests and values. It also examines why and how decades ago Canadians and like societies moved towards formal plasma regulation of the plasma industry: the decision involved a choice not to allow strictly market forces to govern issues of national plasma supply. It then explores how some of the resulting standards and limits of the regulations relate directly to the paid-plasma debate.

a. Underlying Interests & Values: The development of norms to govern the procurement and processing of human plasma for therapeutic needs implicates at least five societal interests. First, it implicates the protection and promotion of the public health. In blood policy matters the health of the public, as we have seen, depends both on a safe and adequate supply. Secondly, the process implicates the health of individual recipients: patients. Patients may have short or long-term need of plasma products. Thirdly, it implicates the standards and integrity of relevant health professionals. Doctors, nurses, hospitals, blood banks and blood services have expertise and professional duties that involve them in the collection, distribution and use of plasma. Fourthly, it implicates plasma processors and manufacturers. Manufacturers have an interest in having generally, uniform clear and effective norms to enable them to discharge their responsibilities. Finally, plasmapheresis implicates the health of the person from whom plasma is given: the donor.

Given the range of implicated interests, are they all equal? Should one or more be paramount? Such questions raise the issue of potential conflicts between the implicated interests and associated value choices. For instance, if one takes the view that maximizing the welfare of all those implicated should take priority, one might conclude that the protection of the public health should be paramount. This view may be based on a series of integrated concerns : namely (a) that the common good of the public health takes precedence as a paramount duty, (b) that individual, potential recipients and the public are least able to protect themselves under the circumstances and thus require positive societal action, and (c) and that such initiatives advance the transcendent value of protecting human health and preserving human life. Such claims may parallel and compete with other values. If recipients or donors respectively receive or give plasma without knowing the associated health risks, for example, they undertake the uninformed assumption of risk. The uninformed assumption of risk may seriously compromise autonomy and bodily integrity. One's autonomy and bodily integrity implicate fundamental values. Such examples may not necessarily reveal a hierarchy, but they do highlight a range of interests and values implicated by the norms that govern the plasmapheresis process. The range of interests and values begs a further question: from a societal perspective, which mechanism(s) may best allocate, balance or harmonize them towards an optimal societal allocation?

b. From Self-Regulation to Federal Regulation: Plasmapheresis regulations stem from an affirmative decision to protect and promote the national public health through force of public law. The decision in the 1970s by the Canadian Government to regulate plasmapheresis was consistent with a growing perception that plasma donation, collection and processing could not be left strictly to market forces. The sentiment was expressed formally in North America, first in the United States. It was fed by a collage of reports, events, and realizations. The publication of Titmus' book that condemned US commerce in blood in the early 1970s, for instance, coincided with reports and Congressional hearings

targeted at reforming the US blood system.²²⁹ The reports exposed some of the limits of sole reliance on private actors to maximize and balance the interests noted above. Of course, reliance on professional and commercial standards of practice in plasmapheresis does help establish norms largely through self-regulation. The ethics norms to which many health professionals subscribe, for instance, impose duties that clearly advance some of the public values and interests noted above. The ethical duties of health professionals are neither comprehensive nor absolute, however. Their interaction with commercial forces may also dilute their relevance and effect. Moreover, in a fiercely competitive entrepreneurial environment, norms or standards that impose time demands and significant administrative, personnel or financial costs, with few immediate economic returns, may provide insufficient incentive for the standards to be rigorously honoured and respected. Before the regulation of plasma in the US, for example, over 25% of those plasma collection centres surveyed reported having no doctor present during plasmapheresis.²³⁰ Health expertise and oversight that screens for disease-free donors protects the health and well-being of the public, future recipients and donors. Failure to observe rigorous health norms heightens risks. Such concerns increased from 1971-1976 in the US, and resulted in increasingly broader federal regulation of plasmapheresis.²³¹ In Canada, the arrival of commercial plasma centres in the early 1970s prompted a government review, whereupon an expert committee subsequently recommended federal regulations, partially on the view that if plasmapheresis is practised unscrupulously it poses risks to donors and recipients of plasma.²³²

Concern about such practices was not restricted to North America. It was international. One analyst has described this era “as the wild cat days” of the developing international plasma industry.²³³ One news report from the era described how an American company operating in Haiti every day payed

²²⁹ See Section III.A.2, above.

²³⁰ Hartney JB & the American Medical Association Committee on Transfusion & Transplantation. *Plasmapheresis Operations in the United States -- 1968*. *JAMA*. 1970;213:1023-1025.

²³¹ In 1972, the US proposed to license plasmapheresis entities. The proposed regulations were “finalized” in 1973. In 1974, the US proposed to broaden its plasma regulations. In the 1976, those were finalized.

²³² Krever, *op cited*, p. 125.

²³³ See Starr, *op. cited*, pp. 231-249.

some 350 largely unemployed, illiterate donors \$3-5/ litre of plasma -- sometimes up to 50 times per year per individual -- which was exported for sale to pharmaceutical companies in the US, Germany and Sweden for processing.²³⁴ The “donations” netted the company \$2-5/litre in profit. The owner argued that the plasma was cleaner than that from donors in inner cities of the US, and that his operations helped individual Haitians, their economy and US patients. Such arguments proved unpersuasive to some in the international community. In 1975, the World Health Organization noted “the extensive and increasing activities of private firms in trying to establish commercial blood collection and plasma projects in developing countries”; the World Health Assembly Resolution of 1975 accordingly urged Member States to “enact effective legislation ... and to take other actions necessary to protect and promote the health of blood donors and recipients...”²³⁵ Canada thus adopted federal plasma regulations in 1978²³⁶ consistent with the WHO recommendation. The regulations were enacted on the view that an unregulated commercial market increases health risks both to potential plasma donors and recipients.²³⁷ Hence, they were partially premised on the unregulated commercial blood markets arguments noted in Sections II.G and II.K, above.

c. Regulatory Standards & Limits -- Importing Paid Plasma: By prohibiting the sale, collection, or processing of plasma not in accordance with its requirements,²³⁸ Canadian plasma regulations effectively impose uniform standards on both non-profit and profit plasma entities. The regulations, *inter alia*, (a) require the licensure of plasmapheresis centres (not the licensure of plasma donors); (b) require medical/health professionals to monitor plasma donation; (c) specify medical examinations, laboratory tests and other norms to ensure healthy donor selection; (d) impose storage, shipping, handling and labelling norms on collected plasma; (e) require manufacturers of plasma

²³⁴ Severo R. Impoverished Haitians Sell Plasma for Use in the U.S. *N.Y. Times*, 28 Jan. 1972, p. 2.

²³⁵ See Section III.b, above and Appendix 1, below.

²³⁶ Canada, Minister of National Health & Welfare. Food & Drug Regulations Amendment: Human Plasma Collected By Plasma Plasmapheresis, 22 June 1978. *Canada Gazette*, Part II, 12 July 1978;112(13):2895-2902.

²³⁷ See Krever, *op. cited*, p. 125.

²³⁸ *Food & Drug Act Regulations*, C.04.402.

derivatives to observe specific health and technical standards; and (f) impose documentation and reporting duties for collectors and processors of plasma.²³⁹

To be effective health protection regulations should, amongst other things, be based on accurate scientific standards, sufficiently comprehensive to achieve their purpose, regularly revised to accommodate new technological and health developments, consistently adhered to by the regulated entities, and implemented and enforced with sufficient resources. The Canadian Blood Inquiry report concludes that the federal government was tentative, without sufficient expertise, and under-resourced regarding the assertion and implementation of its regulatory authority on blood matters.²⁴⁰ A review of such issues deserves separate and thorough analysis that is beyond the scope of our study. Two matters do warrant comment in passing, however.

First, the findings of the Inquiry along with the recent findings of the US GAO, regarding FDA regulatory lapses, parallel conclusions drawn by independent bodies in other countries in the wake of national tainted blood scandals. Together, they indicate that effective health protection regulations in the blood product domain depend on a range of important factors, and that government regulation is an imperfect means for maximizing the implicated interests of the public, recipients, health professionals, donors, etc. Nevertheless, public regulation is a distinct societal mechanism that derives its legitimacy from the formal delegation to government of special duties, powers and monies from the public whom it serves. As such, amid crisis that make conspicuous the voids and limits of regulation, government has a duty to study the lessons and exercise leadership to cast reforms.

In this respect, secondly, the recent revelations about the inadvertent use by the Canadian Red Cross of plasma from US prisons would seem to highlight some limits of the Canadian plasma regulations. Apparently unbeknownst to the CRC in the early and mid-eighties, it distributed blood products

²³⁹ Canada. *Food & Drug Act Regulations*, as amended C.04.400 *et seq.* See also C.04-230-C.04.240.

²⁴⁰ Krever, *op. cited*, pp. 146-147, 999-1001.

manufactured from plasma that was originally procured by US plasma collection entities from paid prison donors.²⁴¹ According to the Krever report, the US plasma collectors sold the plasma to international plasma brokers, including one in Montreal. The brokers, in turn, shipped and sold some of the plasma to Europe and some to a Canadian pharmaceutical entity, Connaught Laboratories. Connaught fractionated the plasma into blood products under contract with the Canadian Red Cross. The Red Cross provided the therapeutic agents to Canadian hospitals and doctors, who transfused them into patients. The derivatives were later found to have been contaminated with hepatitis. Canadian patients infected by the plasma products have recently filed law suits against several of the parties involved in these transactions.^{242, 243}

The revelations and allegations have provoked legal and ethical angst. Part of the angst flows from medical and ethical concerns that may justify a general public policy norm against procuring plasma from prisoners. First, health data has for decades indicated that prisons have relatively high populations of those infected with transmissible blood-borne pathogens like hepatitis.^{244,245,246,247,248} In the early 1970s, such data persuaded the Canadian Red Cross to discontinue the collection of prisoner blood.²⁴⁹ The US FDA 1983²⁵⁰ recommendation against using higher risk donors -- e.g., drug abusers and homosexual men with multiple sex partners -- may be interpreted as including prison blood donors, but

²⁴¹ See generally Krever, op. cited, pp.389-395.

²⁴² De Palma A. Suit Says Canada Imported Tainted Blood from US Inmates. *N.Y. Times*, 29 Jan. 1999, p. A_____.

²⁴³ Picard A, McIlroy A. Hemophiliacs Launch \$1-Billion Law Suit. *Globe & Mail* [Toronto], 25 Feb. 1999, p. A5.

²⁴⁴ Schafer IA, Mosley JW. A Study of Viral Hepatitis in Penal Institutions. *Ann. Int. Med.* 1958;49:1162.

²⁴⁵ Koff RS et al. Prisoner Blood Donors and Post Transfusion (icteric) Viral Hepatitis. *Transfusion* 1967;7:436-439.

²⁴⁶ Kliman A, Reid NR, Lilly C. et al. Hepatitis-Associated Antigen (Australia antigen) in Massachusetts Blood Donors. *N. Eng. J. Med.* 1971;285:783-787.

²⁴⁷ Cohen, RL. Imprisoned Plasma Donors: Medical-Ethical Case & Comment. *J. Prison & Jail Health* 1982;2:41-46.

²⁴⁸ Decker MD, Vaughn NW, Brodie JS et al. Seroepidemiology of Hepatitis B in Tennessee Prisoners. *J. Infect. Dis.* 1984;150:450-459.

²⁴⁹ Wrobel DM, Feinman V, Berris B, Sinclair J. Frequency of Hepatitis B Antigen in Blood Donors. *C.M.A.J.* 1973;108:570-572. See also Krever, op. cited, p. 618.

²⁵⁰ United States, Food & Drug Administration. National Center for Drugs & Biologics. Intravenous Drug Abusers & Homo-Sexual Men With Multiple Sex Partners. *Recommendations to Decrease the Risk of Transmitting Acquired Immune Deficiency Syndrome (AIDS) from Blood Donors*. Washington, DC, 23 March 1983.

any lingering doubts were laid to rest in 1995²⁵¹ when the FDA explicitly excluded prisoners from the eligible blood donor population. Indeed, duties to the health of potential recipients and the public mean that a decision likely to visit higher risks on them should only be justified on the most compelling grounds, such as a medical urgency or want of other sources. Secondly, procuring plasma from US prisons raises issues about the ethics and effects of paying for blood. Paying “donors” for blood in a prison context may have perverse effects. As noted in Section II.H above, to structure payment on the condition that donors must avow that they are free of transmissible diseases, for example, means that donors who are most in need of, or desperate for, monies have a high incentive either not to know their health status or not to be truthful. Whether the payment is cash or an incentive like five days off one’s prison sentence for each donation,²⁵² the result may have the equivalent effect on veracity. For such reasons, since 1978 Canadian regulations have indicated that those whose word, reliability or veracity is in question should not be considered eligible plasma donors.²⁵³ When veracity is compromised and the results of disease screening tests are neither readily available, nor accurate or readily shared, then the health of potential recipients and the public may be compromised. The Krever Report indicates that some of the prisoners who apparently infected some of the plasma sold to Canada were not truthful about their medical past.²⁵⁴ Subsequent reports have indicated that the US prisoners received \$10 per donation,²⁵⁵ and that plasma payments were the sole source of income in some of the prisons that provided blood revenue or credits for sales. Thirdly, beyond the public health and truthfulness issues, paying prisoners for blood raises concerns about the voluntariness and exploitation of a captive population. Obviously, prisons are not autonomous settings. Prisoners are necessarily captive of institutional power and control. Other areas of law and ethics thus strictly limit medical interventions on prison populations²⁵⁶ to maximize the likelihood of uncoerced, informed and relatively autonomous

²⁵¹ United States, Food & Drug Administration, National Center for Biologics Evaluations and Research. *Recommendations for the Deferral of Current and Recent Inmates of Correctional Institutions as Donors of Whole Blood, Blood Components, Source Leukocytes and Source Plasma*. Washington, DC, 8 June 1995.

²⁵² Kiliman A. Australia Antigen in Volunteer & Paid Blood Donors. *N.E.J.M.* 1971;284:109.

²⁵³ *Food & Drug Act Regulations*, s. C.04.407.

²⁵⁴ Krever, op. cited, p. 392.

²⁵⁵ De Palma, op. cited.

²⁵⁶ See, e.g., 45 U.S. *Code of Federal Register* 46.301-46.306 (limited medical research on prisoners).

choice. This is a concrete instance where the requirement of independent and competent medical professionals, with their associated ethico-legal duties to the donor and future recipients, may help balance the inherent discrepancy of power between the institutional forces that pay for blood and potential prison donors. (See Section II.I, above).

While the truthfulness, captive population and hepatitis risks may combine to make compelling ethical arguments for a general policy against the use of plasma from prison donors, it should also be noted that the very prevalence of hepatitis in prisons has long attracted manufacturers of therapeutic plasma derivatives. As ironic as it may seem, previously infected or infected plasma is sometimes desirable. An elevated level of hepatitis antibodies in plasma, for instance, facilitates the production of the medications (immunoglobins) that are used to immunize individuals against hepatitis. Theoretically, if prisons concentrate higher populations of those with hepatitis, then prisons may serve as a fertile source for cultivating “infected plasma” into plasma-derived medications. Such a source may prove attractive to plasma suppliers and manufactures. Indeed, in practice, as early as the 1960s -- years before either Canada or the US adopted federal plasma regulations -- reports emerged that US procurers of plasma had begun operations at Arkansas and other US prisons to secure and generate plasma with hepatitis antibodies.²⁵⁷

The paid prison plasma saga may well revive -- or perhaps in the eyes of some, confirm -- Titmussian arguments against the sale of blood: that is, to sell it is to reduce human tissue to an object of commerce that is bought and sold according to the vagaries of the market, which includes paying donors, that compromises truthfulness to public detriment, and results in paid-blood being contaminated and directly harmful to unsuspecting recipients.²⁵⁸ It may be added that the importation of paid prison plasma circumvents basic elements and standards of Canadian public policy on blood. In response, one may argue that importing US plasma had been a de facto component of Canadian blood policy for decades,

²⁵⁷ Rugaber W. Prison Drug & Plasma Projects Leave Fatal Trail. *NY Times*, 29 July 1969, p.1.

²⁵⁸ See Sections II. A.B.G.H., above.

that the prison saga exemplifies a tragic aberration, and that like excesses are generally curbed by applicable regulations. Of course, the claims, issues and facts of this saga will unfold in policy forums or be contested in court in the coming years. One dimension of the saga that makes the Titmussian arguments so unsettling, however, is that they are a refrain from the pre-regulatory days heard today in a post-regulatory era. In other words, if regulating the plasma industry decades ago was partially intended to establish enforceable safety norms on a unregulated market, Canadian society may legitimately ask whether the preventive health and protection role of government regulation has been fulfilled in this saga? Or, have there been regulatory shortfalls? The preventive regulatory role might be partially fulfilled, for instance, by imposing on pertinent parties a general regulatory duty to obtain contaminant-free tissues from donors, meaning that plasma contaminated with infectious agents shall generally not be procured, distributed or manufactured for therapeutic use.²⁵⁹ To minimize further the risk of patients receiving contaminated plasma, government may require the licensing of all collectors, brokers, and manufacturers of source plasma and plasma derivatives, and to oblige them to adhere to uniform quality assurance and procurement standards. Such possibilities in the context of the prison plasma saga provoke important questions on the role, scope and effectiveness of Canadian plasma regulations:

- Did, or do, applicable Canadian regulations require that all plasma for use in Canada -- even that from abroad -- be collected in an establishment licensed by Health Canada?²⁶⁰

²⁵⁹ Since the 1940s, Canadian drug regulations have strived towards this goal by regulating the safety of human tissue procured for the development of biological products. See, e.g., Canada. Provisions Applicable to Biological Products as Included in Section I of these Regulations and Prepared from Human Resources. *Canada Gazette*, 31 Oct. 1942. The regulations have done so by requiring that donors be medically certified as free from transmissible diseases, as part of the duties of those manufacturing biological blood products. Over time, the precise wording of the regulatory requirements has changed and raised interpretive issues. The version in effect from 1978-1996 provided that (a) "A manufacturer shall obtain human sera, or human plasma, only from a person certified by a qualified medical practitioner to be healthy", and (b) required that a "manufacturer shall not use a person to serve as a donor of blood, placenta, or cord who has a history of disease transmissible by blood transfusion including syphilis, infectious hepatitis or malaria." *Food & Drug Regulations*, as amended, C.04.231-232. Query: does the term "manufacturer" directly or indirectly include plasma "suppliers" and international plasma "brokers?"

²⁶⁰ See section C.04.427 of the plasma regulations. "*Manufacturing Responsibility*:

(1) Subject to subsection (2), all steps in the manufacture of human plasma, including plasmapheresis, laboratory testing, labelling, storage and issuing, shall be performed in an establishment licensed to

- If so, were such norms adhered to or enforced in the saga involving the importation of contaminated plasma drawn from US prisoners?
- Indeed, should Canadian law require the licensure of foreign and national plasma collectors, brokers, suppliers, and manufacturers that provide plasma or its derivatives for therapeutic use in Canada?
- Moreover, if it does not clearly do so now, should the law make it generally unlawful to procure or donate plasma that is known, or likely, to be infectious?

Reasonable minds may well differ over the optimal level and mechanism for plasma regulation, particularly in light of some of value conflicts that inhere in the commitment to safety and adequacy of supply in Canadian blood principles. Yet, those principles express the paramountcy of safety. Because Canada continues to rely on largely US-procured paid plasma for much of its therapeutic needs, such public safety questions are not academic. They seem pertinent to ongoing initiatives to reform the Canadian plasma regulations.

d. Donor Volume & Frequency Norms -- Canadian & International Reforms?:

Proposed reforms of the Canadian plasma regulations also revisit a question that has long been central to, but often obscured in, the plasma supply and sales debates: how often and how much should a plasma donor donate? The question and its ethical implications helped to prompt plasma regulations decades ago. They continue to be debated internationally today.

manufacture human plasma under this Division.

(2) The test required by paragraph C.04.410(2)(b) [immunoglobulin composition] and section C.04.418 [hepatitis B] may be performed by an outside clinical laboratory.”

A provision of the original 1978 plasma regulations, this section was revoked in 1996, as part of an overhaul of the Food & Drug Regulations. See P.C. 1996 of 19 Dec. 1996, SOR/97-12, s. 50, *Canada Gazette*, 1997;II:4528.

Historically, the failure of unregulated commercial plasma entities to offer adequate health protections of plasma donors helped to prompt North American government regulation. US regulators, for example, premised their regulations in part on the need to take action to curb “abusive practices”:

These abuses include taking excessive quantities of plasma from donors on a frequent basis, poor arm preparation prior to plasmapheresis which creates a potential for infection, and inadequate procedures which increase the risk of returning to the donor red blood cells of another donor which can lead to hemolytic-transfusion reaction and death.²⁶¹

The regulations followed a call for improved standards in a study by a US National Academy of Sciences committee on plasmapheresis.²⁶² Headed by a Canadian scholar, the committee both recognized the contribution of plasmapheresis to meeting national therapeutic demand for plasma, and had recommended guidelines to address inadequate safeguards for donors. Hence, US regulations intentionally targeted preventing the possible “exploitation” of the donors and more broadly ensuring “that there will be a continuous and healthy donor population”.²⁶³ The regulatory purpose behind Canadian plasma regulations were similar,²⁶⁴ if less explicit.²⁶⁵ Such concerns speak to our sense of justice: both about risks that may compromise the health of donors, and about the fairness of visiting such risks, disproportionately or without fair benefit, on individuals or segments of society whose economic straits may make them particularly vulnerable to economic inducement. (See Section II.J, above). Accordingly, public regulations that require the informed consent of plasma donors, the medical examination and periodic surveillance of them, the reporting of fatal donor reactions, and norms on the volume and frequency of plasma donation, are designed to minimize the potential for abuse, partially by attempting to establish minimum, coherent and uniform donor protection standards.

²⁶¹ US Food & Drug Administration. License Source Plasma. *Fed. Register*, 17 July 1974;39:26161-26165.

²⁶² US National Academy of Sciences, Ad hoc Committee on Plasmapheresis. Safeguards for Plasma Donors in Plasmapheresis Programs. *JAMA* 1970;213:743-747.(hereinafter NAS Plasma Committee).

²⁶³ US Food & Drug Administration. Source Plasma. *Fed. Register*, 12 March 1976;50:10762-10771.

²⁶⁴ Personal communication with Professor Robert Painter of the University of Toronto, former US National Academy of Sciences Chair of the Ad Hoc Committee on Plasmapheresis, November 1999.

²⁶⁵ See Krever, *op. cited.*, p. 125.

Unfortunately, the goal of offering coherent plasmapheresis standards has long been clouded by medical uncertainty on how often and how much plasma may be safely procured from donors. Before the regulation of plasmapheresis in the late 1960s, for example, a team of Canadian and US experts had determined that “plasmapheresis is a safe procedure when practised under close medical supervision and when reasonable limits of size and frequency of donation are set”; however, the same experts could not agree on a single index that would ensure the health of the donor.²⁶⁶ At the time, US donors typically gave ½-1 litre of plasma one to four times a week.²⁶⁷ This would translate into dozens of litres per year. By contrast, a 1967 French law restricted plasma donations to a maximum of a ½ litre/week, 2 litres/month and 10 litres/year; Council of Europe norms of the day similarly translated into a maximum of some 12-15 litres annually.²⁶⁸ When US regulations took effect in the early 1970s, the standards curtailed some of the pre-regulatory practices but still permitted the procurement of over 50 litres per year. When Canadian regulations took effect in the late 1970s, they assumed a position between Europe and the US. The current Canadian maximum of 23-37 litres annually has changed little over the decades. A 1997 draft of proposed revision of plasma regulations -- that are generally intended to harmonize with US pharmaceutical standards -- largely maintains the existing Canadian norms on volume and frequency. (See Table E, below). This has raised debate over whether the Canadian volume and frequency norms should be raised to harmonize with US norms.²⁶⁹ While the debate might be reduced to a choice between status quo donor protection norms and modern reforms to increase the plasma productivity and self-sufficiency of Canada, the choice really is how to balance and weigh interests in the face of scientific uncertainty. In Europe, 1998 recommendations on plasma donation affirm the historic European standard of some 15 litres annually. The report candidly notes, however, that “there is no scientific evidence of whether or not adverse health effects may result from

²⁶⁶ NAS Plasma Committee, *op cited*.

²⁶⁷ *Ibid*.

²⁶⁸ Lundsgaard-Hansen P. Volume Limitations of Plasmapheresis. *Vox Sang* 1977; 32:21-25.

²⁶⁹ Personal communication with Health Canada, July 1999.

higher volume collections;” it urges scientific study of the issue as a matter of priority.²⁷⁰ The finding echos those from the literature 30 years ago.

Whether revisions to the Canadian plasma regulations shall ultimately affirm or revise the maximums on the volume and frequency of plasma donations,²⁷¹ the standards that have prevailed in North America and Europe over the last quarter century stand as an important relic of the plasma supply and paid donor debate. US norms -- which for decades have authorized plasma procurement from individuals at a volume three-five times that of Canada and Europe -- have been central to the US supply of plasma largely from paid donors. On a volume per donor basis and all other things being equal, the amounts of plasma procured under US standards would seem more productive and efficient. But would even the most altruistic individual offer plasma 30-50 times per year without some recompense for the time, inconvenience, expense and minimal risks of “donation?” The US plasmapheresis industry has long maintained that the public would not. Does such frequency compromise the health of donors? In the absence of scientific certainty for a universally acknowledged standard, countries have obviously chosen to answer the question differently by choosing varied allocations of the risks and benefits of potential maximums. From an international perspective, the US seems to have erred on the side of procurement efficacy, but with theoretically higher health risks per donor. The European standard has erred on the side of theoretically lower donor risks, but with lower plasma returns per donor. Canada has split the difference in its plasma regulations. Still, by the decades of use and purchase of US plasma and plasma derivatives Canada, Europe, and other nations have, de facto, significantly relied on the less protective, more productive US standards to meet national therapeutic plasma needs. In essence, Canada has long been operating on two different regulatory standards.

²⁷⁰ European Union. Council Recommendation 98/643/EC of 29 June 1998, op. cited.

²⁷¹ New data or reports on the health status of long-term, frequent plasma donors in the US may contribute to Canadian deliberations on revising the Canadian standards. See Rodell MB, Lee ML. Determination of Reasons for Cessation of Participation in Serial Plasmapheresis Programs. *Transfusion* 1999;39:900-903.

**Table E:
 Regulating Plasma Donations -- Maximum Volume & Frequency Norms**

	Maximum Volume Per Donation	Minimum Time Between 2 Donations	Maximum Donations Per Week (7 days)	Maximum Volume Per Year
Canada				
Current Regulations	360-600 ml (WB) ¹ = 216-360 ml (PL)	48 hours ²	4 ³	38-62 L (WB) ⁴ = 23-37 L (PL)
Proposed	----- 625-800 ml ⁵	----- 48 hours ⁶	----- 2 ⁷	----- 23-37 L ⁸
Europe	500 ml ⁹	48 hours ¹⁰	211	15 L ¹²
United States				
Frequent Donors	625-800ml ¹³ -----	48 hours ¹⁴ -----	2 ¹⁵ -----	65-83 L ¹⁶ -----
Infrequent Donors	625-800 ml ¹⁷	1/month	1/month ¹⁸	12-14.4L ¹⁹

Key: ml = milliliters, L = Liters, WB = Whole Blood, PL = Plasma

1. Canada. *Food and Drug Regulations*, as amended (*Human Plasma Collected by Plasmapheresis*), SOR/85-1022, C.04.416.(1).
2. *Ibid.* C.04.416.(4).
3. *Ibid.* C.04.416.(5).
4. *Ibid.* Based on a 6-month limit of 19-31 liters, as per C.04.416.(6).
5. Health Canada. *Proposed Changes to Canadian Plasmapheresis Regulations*, 14 March 1997, C.04.416.(4).
6. *Ibid.* C.04.416.(6)(a).
7. *Ibid.* C.04.416.(6)(b).
8. *Ibid.* Based on a 6-month limit of 11.5-18.5, as per the proposed C.04.416.(6)(7).
9. European Union (EU). *Council Recommendation 98/463/EEC of 29 June 1998 on the Suitability of Blood & Plasma Donors & the Screening of Donated Blood in the European Community*. *Off. J. Europ. Commun.* (L-203), 21 July 1998;41:14-26.
10. *Ibid.*
11. *Ibid.*
12. *Ibid.* While not formally recommended as an EU standard, the EU refers to 15 liters as the international guideline.
13. United States. 21 *Code Federal Regulations* (CFR) 640.65(b)(6) limit the amount of whole blood per donation to 500-600 milliliters, an amount seldom approached by modern automated plasmapheresis. An early 1990's review of the safety of donating plasma by automated processes led the FDA to establish a per donation limit of 625-800 milliliters of plasma. United States. Food & Drug Administration (FDA), Center for Biologics & Evaluation & Research. *Volume Limits for Automated Collection of Source Plasma*. 4 November 1992 [hereinafter "US FDA, 4 Nov. 1992 memo"].
14. 21 CFR 640.65(b)(4).

15. 21 CFR 640.65(b)(5).
16. US regulations indicate no annual limit. If one donates 625-800 ml twice/week for 52 weeks (104 times), it yields 65-83 liters/year.
17. US FDA, 4 Nov. 1992 memo, op. cited.
18. United States. FDA, Center for Biologics & Evaluation & Research. *Revision of FDA Memorandum of August 27, 1982: Requirements for Infrequent Plasmapheresis Donors*. 10 March 1995.
19. *Ibid.*

F. Legal & Policy Bans on the Sale of Blood

Do the ethical objections that some countries or organizations have to paid donors translate into formal legal prohibitions on the sale of donor blood? Table F, below, summarizes some of the legal and policy prohibitions in the international community. We have examined many of them. For purposes of contrast, Table F also includes a few countries not detailed in this study. Some of the findings are noteworthy. It would seem, for instance, that the home of Titmuss, the UK, has no formal statutory prohibition on the sale of donor blood. This stands in direct contrast to such jurisdictions as Australia and France. North America generally has enacted limited prohibitions, though policy pronouncements against the general sale of blood are in clear evidence. Many of the sampled jurisdictions also provide exceptions from policy or legal bans for payments of “reasonable” donor expenses. This is the modern trend. As well, almost all have formal legal prohibitions against the sale of organs, including the UK. That some jurisdictions have enacted no statutory bans on blood sales but have done so for organs might be explained by three perceptions or rationales: (a) that organs sales are a grave problem in need of clear legal rules, as the UN has championed over the last decade; (b) that regenerative tissues like blood raise fewer ethical or like objections; and (c) that legal prohibitions on the sale of donor blood are unneeded in part because policy prohibitions and de facto bans prove sufficient. Given evolving and divergent views on such contested issues, it is unsurprising to find that they may be given different weight in different societies at different times. Table F, below, for instance indicates that some jurisdictions tend to reject the above arguments that favour the exemption of blood from tissue/organ sales prohibition. Thus, Quebec and Australia have included blood in laws prohibiting tissue sales. Quebec is noteworthy because while it formerly exempted regenerative tissue from its tissue sales prohibition, it no longer does so since the mid-1990s.

**Table F:
 Legal & Policy Prohibitions on the Sale* of Human Donor Blood --
 An International Sampling**

	Law Against Sale of Blood	Policy Against Sale of Blood	Law Against Sale of Tissue/Organ	Permits Reimbursement of Reasonable Donor Expenses
Australia	X ¹	X	X ²	X
Canada	R ³	X ⁴	X ⁵	X ⁶
Council of Europe	X ⁷	X ⁸	X ⁹	X
European Union	X ¹⁰	X ¹¹		X
France	X ¹²	X ¹³	X ¹⁴	X
Germany	X ¹⁵	X ¹⁶	X ¹⁷	X
Sweden			X ¹⁸	X
United Kingdom		X	X ¹⁹	
United States	R ²⁰	X ²¹	X ²²	X
WHO		X ²³		

R = Limited or Regulatory Prohibition

* Formal definitions of “sales”, if defined in the relevant policies or laws of a jurisdiction, range from broad definitions that target exchanges “for valuable consideration” to narrow definitions that target only “for-profit” exchanges. See Section II.E, above.

1. Australia Capital Territory. *Transplantation & Anatomy Act*, 1978, s. 44.1; New South Wales. *Human Tissue Act*, 1983 (as amended), ss. 4, 32.1; Northern Territory. *Human Tissue Transplant Act*, 1995, ss. 4, 24.1; Queensland. *Transplantation & Anatomy Act*, 1979, as amended, ss. 4, 40-44; South Australia. *Transplantation & Anatomy Act*, 1983, ss. 5, 7, 35.1; Tasmania. *Human Tissue Act*, 1985, ss. 3, 27(1); Victoria. *Human Tissue Act*, 1982, ss. 38-40; Western Australia. *Human Tissue & Transplant Act*, 1982, ss. 3, 29.1.
2. *Ibid.*
3. Canada. *Food & Drug Act Regulations*, as amended, C.04.402 (prohibiting sale of plasma not in conformity with federal requirements). Article 25 of the *Civil Code of Quebec* requires that transfers of bodily parts or products be “gratuitous”. Effective January 1994, article 25 replaced article 20(3) of the former Civil Code of Lower Canada, which required gratuitous alienation except for regenerative substances. The former provision thus did not forbid payments for the transfer of blood. See also LRCC, *Procurement & Transfer of Human Tissues & Organs*. Ottawa, 1992:132. All other Canadian provincial tissue statutes exempt blood from their prohibitions on tissue sales. See references in note 5, below.
4. Canadian Blood Committee (1981-91), Canadian Blood Agency (1991-1998). *National blood policy principles: “voluntary” donations & preferred “non-profit” infrastructures*. See Law Reform Commission of Canada. *Procurement & Transfer of Human Tissues & Organs*. Ottawa, 1992:10; Krever H. *Commission of Inquiry on the Blood System: Final Report*. Ottawa, 1997:102-104.

5. Alberta. *Human Tissue Gift Act*, R.S.A. 1980, as amended, c. H-12, ss. 1, 10; British Columbia. *Human Tissue Gift Act*, 1996, c. 211, s. 10; Manitoba. *Human Tissue Act*, 1987, ss. 1, 15.2; New Brunswick. *Human Tissue Act*, R.S.N.B. 1973, as amended, c. H-12, s. 8(3); Newfoundland. *Human Tissue Act*, R.S.N., c. H-15, ss. 1, 18; Northwest Territories, *Human Tissue Act*, R.S.N.W.T. 1988, c. H-6 (silent on sales); Nova Scotia. *Human Tissue Gift Act*, R.S.N.S. 1989, as amended, c. 215, s. 11; Ontario. *Human Tissue Gift Act*, R.S.O. 1990, as amended, c. H-20, ss. 1, 10; Prince Edward Island. *Human Tissue Donation Act*, P.E.I. Acts, 1992, c. 34, ss. 1, 15; Quebec. *Civil Code of Quebec*, art. 25; Saskatchewan. *Human Tissue Gift Act*, R.R.S. c. H-15, s. 11; Yukon. *Human Tissue Gift Act*, R.S.Y. c. 89, s. 10.
6. Perhaps because so few of the Canadian provinces have overhauled their tissue laws in recent years, few of the laws explicitly exclude from their tissue sale prohibitions reasonable payments for the reimbursement of expenses associated with the procurement of tissue. Technically, this may affect payments for expenses incurred in procuring organs and other non-regenerative tissues governed by the laws. The clear modern international trend of explicitly authorizing reasonable procurement and donor expenses has thus yet to find broad expression in Canada. Analysts have noted this potentially dysfunctional dimension of Canadian tissue donation laws and have urged reform. See LRCC, *op cited*, pp. 135-36, 184-185.
7. Council of Europe (COE). *Convention on Human Rights & Bioethics in Medicine*, art. 21. Oviedo, 1997. The COE includes Albania, Andorra, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Moldova, Netherlands, Norway, Poland, Portugal, Romania, Russian Federation, San Marino, Slovakia, Slovenia, Spain, Sweden, Switzerland, the "former Yugoslav Republic of Macedonia", Turkey, Ukraine, United Kingdom.
8. Council of Europe, Committee of Ministers. *Recommendation No. 95(14) on the Protection of the Health of Donors & Recipients in the Areas of Blood Transfusion*.
9. Convention, *op. cited*.
10. European Union (EU). *Council Directive 89/381/EEC of 14 June 1989 (Products Derived from Human Blood or Human Plasma)*, s. 3.4. The EU includes Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, United Kingdom.
11. European Union. Group of Advisors on the Ethical Implications of Biotechnology of the European Commission. *Opinion No. 2 of 12 March 1993 on Products Derived from Human Blood & Human Plasma*. Brussels, 1993.
12. France. *C. Santé Publique*. Dalloz: Paris, 1997, arts. L.665-13, L.666-1; art. D.666-3-1-666-5-4; *Décret no. 94-611 du 30 juillet 1994*, art. 1.
13. France. Comité consultatif national d'éthique pour la science de la vie et de la santé. *Avis no 28 sur la transfusion sanguine au regard de la non-commercialisation du corps humain*. Paris, 1991 [www.ccne-ethique.org/ccne/avis].
14. France. *C. Santé Publique*. Dalloz: Paris, 1997, art. L.665-12, 665-13.
15. Germany. *Act Regulating Transfusion Practice*, 1 July 1998, s. 10.
16. Von Auer F. Germany (Donor Payments). *Br. Med. J.* 1995;310:399 (letter).
17. Germany. Transplantation Act of 5 November 1997, ss. 17-18, *Int'l Dig. Hlth Legis.* 1998;49:316-325.
18. Sweden. Regulations of 4 March 1997 on the Removal of Organs & Tissues for Transplantation and other Medical Purposes, s. 12, *Int'l Dig. Hlth Legis.* 1997;48:318, adopted under *Law No. 831 of 8 June 1995 on Transplantation*, ss.15,16. *Intl Dig. Hlth Legis.* 1996;47: 28-30.
19. United Kingdom. *Human Organ Transplant Act*, 1989, s. 1.1.
20. United States. *Public Health Service Act*, 42 USCA 262 (prohibiting sales of blood products not in conformity with federal requirements).
21. United States, Office of Health Education & Welfare. National Blood Policy. Fed. Reg., 10 Sept. 1974:32702-32711 (exempting plasma sales from voluntarism policy).
22. United States. *National Organ Transplant Act of 1984*. 42 USCA s. 274(e).
23. World Health Organization. *World Health Assembly Resolution 28.72: Utilization & Supply of Human Blood & Blood Products*. 1975.

IV. Conclusion

A. The Question & Arguments Revisited

This study began by asking a simple question: to overcome its chronic dearth of plasma, should Canada embark on a program of paying plasma donors? The question has afforded a window on ethical, legal and policy dimensions of prominent issues in the national and international supply of blood.

Section I, above, sampled some leading factors that contribute to disequilibria between the national demand for and supply of blood plasma: including, evolving standards of medical practice that help define demand, safety and cost, socio-ethical attitudes, and the state-of-the-art of transfusion medicine and technology. It is a dynamic web of factors. Even this limited sampling has revealed that paying donors is a “supply-side” option whose efficacy and ethics should, ideally, be evaluated against other supply inputs, demand inputs and major causes of disequilibria.

In this imperfect context, Section II advanced some 15 theoretical arguments for and against the sale of blood. The analysis in Section III has shown that many of the arguments have been formally adopted in national and international policy and laws. The experience of other nations also indicates that while there are diverse paths to self-sufficiency, Canada faces a double burden by its want of domestic fractionation capacity and want of domestically donated plasma. Thus, Scandinavian countries have achieved self-sufficiency with and without paying plasma donors. Germany, with one of the highest per capita demands for some plasma derivatives, continues to seek self-sufficiency. It offers amongst the highest of European payments to plasma donors -- despite a national law that prohibits the sale of blood -- on the rationale that the payments are for expenses incurred in the services of donation not for the sale of tissue. Its neighbour France -- which has recently achieved self-sufficiency -- has adopted formal ethics opinions and laws against the sale of blood. It has done so on the view that the sale of

human tissue commodifies the body and erodes intrinsic human dignity. Since the 1970s, the WHO has emphasized a more consequentialist view. Its official position espouses a paid blood = contaminated blood argument for unpaid donation, on the belief that paying donors gives them high incentives to be less than truthful about transmissible diseases. The argument has been at issue in some of the historic and recent tainted blood litigation in North America. The Council of Europe and the European Community have adopted the reasoning of many of these arguments in their official policies and laws. The inter-European policies of these organizations also regard some ranges of unpaid donor incentives as unethical. That many countries have invoked public law to set standards for the collection and processing of plasma into therapeutics has transformed what once was often an unregulated plasma market into a regulated market of both a profit and non-profit character.

What emerges from the arguments and the experiences of selected foreign nations surveyed? The analysis reveals that there are strong points of agreement regarding two of the leading arguments in the debate. Most nations sampled in this study have resolved the pros and cons of such arguments in favour of adopting formal blood policy and laws that enshrine altruism: transfers of blood/tissue as gifts of life to strangers. Hence, Canada, Europe and the US generally respond no to the question of should we sell blood.

The response of nations to the question of whether we should pay plasma donors is more contentious, but still reveals lines of agreement. Indeed, there seems to have emerged a *de facto* consensus. For years, the countries surveyed have either directly paid plasma donors or have heavily depended on supplies from countries that do so. This broad international practice maybe explained through different discourses. In the language of economics, recourse to the international plasma markets has been thought essential to balancing national therapeutic supplies relative to demand. In the language of health professionals, it has become a standard of national blood practice essential to the needs of patients and modern transfusion medicine. In terms of ethics and public policy, it has been consistent with the

values of preserving human health and life. Hence, a clear line of argument has emerged over the last quarter century: paying plasma donors may sometimes prove necessary to meet national health needs. The argument was formally aired in US blood policy in 1974. Ever since in the US it has been a reality, meaning that formal policy and the actual practice in the US stand in accord. Since the 1970s in much of Europe and Canada, the *de facto* practice has been one of regular and substantial purchasing of paid plasma from the US, in spite of formal national policies or principles that espouse altruistic blood policy. Increasing numbers of European countries have recently stopped or decreased their reliance on this practice. But like others that have yet to achieve self sufficiency in plasma, Canada continues its indirect reliance on the paid donor system of the US. This historic reliance has extended to differing US regulatory standards for plasma collection. The reliance would seem to concede the necessity of plasma donor payments. Perhaps in recognition of this in 1997 and in 1998, respectively, the Krever report and the newly created CBS suggested that paying Canadian plasma donors may need to be considered. The possibility was advanced even as both analysts affirmed altruism as the prevailing and preferred public policy for blood procurement.

B. A New Plasma Policy Era?

Do pronouncements about paying plasma donors in Canada signify the beginning of the end of gifted-based relations for tissue procurement? Does it move society towards a slippery slope away from altruism towards encroaching commercialism? Will it erode the ethics of national blood policy? Such questions should not be taken lightly. Precisely because of the kind of concerns they raise, I would submit that arguments about paying Canadian plasma donors, and the questioning that such proposals generate, should be welcomed as the start of a new era in national blood policy. They may mark a new era for several reasons.

1. Words, Deeds & Accountability in National Blood Policy

Questions about paying Canadian plasma donors may help to open an important national dialogue about coherence in and accountability for blood policy. This would seem particularly so regarding written blood principles and actual blood practices for the national supply of plasma. Indeed, for a fair understanding and evaluation of national blood policy, both words and conduct would seem to matter. To focus uniquely on formal policy, and ignore conduct that may be consonant or dissonant with written policy, is to elevate form over substance in an area where the substantive reality involves human health and life. From a problem-solving perspective, moreover, conduct aimed at maintaining a safe and adequate blood supply may show the true scope of the challenges. Both words and deeds are also important to ethical analysis and for broader purposes of public accountability. Both seem essential to a coherent national blood policy.

From this perspective, the disjuncture in Canada between the formal principles of the blood system and our actual practice seems no longer tenable. The disjuncture has been chronic for decades. It is doubtful that the public, on whom altruism depends and for whom it is supposed to work, has been aware of the nature, scope and implications of actual practice. This seems odd. Workable public altruism depends critically on public participation in, and a moral commitment to, solving the challenges of the national blood supply. Public commitment, in turn, resides on a public trust that has been shattered in many nations by the revelations, deaths, and uncertainties of tainted blood scandals. The public trust must be rebuilt. Policymakers have an obligation to engage the public in responsibility for addressing and resolving national blood dilemmas. For purposes of public accountability, then, the disjuncture needs to be publically scrutinized, explained and preferably resolved. Public education, deliberation and problem solving are thus in order. The recently announced commitment of the CBS to transparency in the governance of the blood supply is a welcome democratic process value that needs to flourish practically. If the commitment to transparency in blood governance means anything, it means

being open and engaging about formidable challenges that implicate the public health. As such, transparency by all major players may become a component of good ethics governance towards blood policy reform.

2. *(De)(Re)fining National Blood Policy*

Principled public discussion about whether it is in the best interests of Canada to pay plasma donors, directly or indirectly, may also begin dialogue on what should be the national blood policy of Canada. While principles to guide the blood system have been declared over the years, Canada has never officially defined a national blood policy. This is a broader challenge that requires, amongst other matters, good process, an innovative partnership initiative, democratic deliberation and participation, and ethical reflection. A national blood policy may ultimately reconcile the stated principles of the blood system with actual practice regarding plasma. It may introduce needed clarity into national blood functions and roles. It may meld the historic principles of the Canadian blood system, the newer ones of the Canadian Blood Service, those that emerged from the Blood Inquiry, and others, into a set of foundational principles that both enshrine high public values and suggest implementing programs for a reformed blood system.

3. *From Pure to Pragmatic Altruism*

Principled discussion about paying donors may also signal an open, public policy shift from pure to pragmatic altruism. The Canadian history of buying paid plasma from the US indicates that the limits of pure altruism present dilemmas that warrant resolution. Indeed, unless altruism is absolute and determinative in national blood policy, then it is justifiable to pursue reasonable policies that seek to advance other relevant, important values. Such pursuits acknowledge that value conflicts are inherent in the ethics of blood policy. If this is true, it would be dereliction of duty for responsible policymakers

not to explore and pursue a range of policy options. Arguably, such considerations illustrate a shift from pure to pragmatic altruism. Pragmatic altruism involves scrutinizing the theory, context and practical consequences of the commitment to it, so as to best harness its strengths and minimize its limits. If a practical consequence of altruism is that it yields an insufficient supply of plasma -- to the detriment of the public values of preserving health and protecting life -- then the limitation needs to be acknowledged and addressed. As will be elaborated below, a pragmatic approach also recognizes that justifying precise, narrow exceptions to altruism need not signal its abandonment as a general and preferred public policy for tissue procurement.

4. *Partnered Problem-Solving & Evidence-Based Policy Options*

Effective dialogue on paid plasma donors may also help to strike an innovative, partnered approach to developing evidence-based policy options for the Canadian plasma shortage. No doubt, calls for innovation and collaboration have been sounded before. Yet, the aftermath of national blood inquiry, the recent creation of the CBS and implementation of national blood reforms, pending revision of federal plasma regulations, and more open discussion of the plasma dilemma -- all combine to make for a unique opportunity for forging a concerted, innovative partnership to address the plasma shortage. The partnership may be built by a range of players, including managers of the blood system, regulators, the public, non-governmental organizations, the plasma industry, transfusion professionals, researchers, etc. The function of the partnership would be to engage in problem-solving the plasma dilemma on the merits, by generating evidence-based policy options. Such an initiative may require the suspension of traditional positions, in a rigorous search for evidence-based solutions. For example, if it can be shown that plasma will be regularly, effectively and safely supplied regardless of donor payment, then those who favour payment largely as a means of securing an effective and regular supply, would seem to have their interests satisfied such that they may abandon their traditional position. By the same token, if it may be documented -- by the modern standards of evidence-based medicine -- that payments to

plasma donors increase the supply and raise no or minimal risks of safety, then those holding safety-based objection to payments have little logical basis for the position. If the objection to payments is that they tend to exploit the down-trodden or economically disadvantaged, then the arguments of economic exploitation or liberation and appropriate regulations should be debated and scrutinized, as they are starting to be done in other areas of bioethics. To generate empirical evidence where it is scant or needed, the health research councils of Canada, the CBS, provincial health councils might invite funding proposals for clinical studies and pilot projects on some of the controverted issues in the paid donor debate -- e.g., donor safety of high volume and high frequency donation; disease markers in paid and unpaid donor populations; trials that might seek to recruit plasma donors, who would undergo rigorous screening, monitoring and would receive non-exploitative, reasonable, uniform fees. Such data may help to answer specific questions where current evidence is lacking. The data may also help refine norms for a safe, effective and coherent regulatory regime.

C. The (Im)Morality of Blood Sales?: A Public Necessity Test/Doctrine

Absent current or definitive evidence that other policy options will mitigate or remedy the national plasma shortage of Canada, a policy of indirect or direct payment of plasma donors seems likely to attract support or serious consideration. Even if other promising policy options emerge, they too may raise important ethical issues, infringe other public values and have to be weighed against the paying donors option. Arguments of public necessity in the blood domain have resounded over the last decades. They are likely to be heard again.

Society needs mechanisms to evaluate arguments of public necessity, especially since the argument is usually invoked to justify infringing cherished public principles, norms or values. Accordingly, to test such claims as the necessity of paying plasma donors, it is proposed that policymakers scrutinize them under a “public necessity doctrine”. The proposed doctrine consists of three elements.

1. *Exigent Circumstances: Urgency & Harms = Compelling Public Purpose*

First, to invoke the doctrine of public necessity, proponents seeking to justify an initiative should show that exigent circumstances have arisen that present a public urgency and significant risk of harms. In essence, the showing requires proponents to articulate a compelling public purpose or objective for the proposed initiative. In the blood context, this showing should not be difficult. That Canada has for decades had a shortfall of plasma evidences a chronic blood supply problem that imperils public health. A program that is designed to preserve health and human life likely satisfies the requirement of defining a compelling public purpose. Ensuring a safe and adequate supply of plasma also likely defines a precise and compelling public objective.

2. *Necessity: Choice of Evils*

Secondly, the urgency of the situation must compel a choice of evils. As in the classic necessity scenario, the choice will often be between avoiding competing harms or risks that implicate esteemed public values. In the blood sales context, one may argue that the choice is between a chronically inadequate supply of blood plasma with no sales, or an adequate supply of plasma with limited sales. The choice may be cast as between preserving pure altruism and preserving public health and human life.

3. *Reasonable, Proportionate Means Towards the Lesser Harm*

Thirdly, the means chosen should, objectively, be shown to be a reasonable and proportionate means towards achieving the compelling public purpose. To make the showing, the choice should (a) bear a real and substantial relation to the goal; (b) be amongst the few effective alternatives of choice; (c) and be narrowly tailored to effect the purpose.

< ***Real & Substantial Relation.*** The method chosen should bear a real and substantial relation to advancing the stated purpose of the program. Applied to plasma sales, proponents of paying plasma donors would need to show that payment has a real and substantial relation to boosting the supply of plasma. The evidence for doing so would largely come from US and international practice over the last decades.

< ***Few Effective Alternatives.*** The method chosen need not be the only mechanism for achieving the programmatic goal, but it should be amongst the few that are likely to prove effective. The programmatic goal would be to boost the supply of plasma. The effective alternative test would thus oblige proponents of sales to consider seriously, and perhaps test, other reasonable initiatives that may effectively harmonize the therapeutic supply of and demand for plasma. Will national practice standards for physicians on the use of plasma reduce, or more reasonably constrain, national therapeutic demand? Have we sufficient data to conclude that plasma supplies are used optimally, or are waste reduction measures warranted? What of research and development of plasma or blood substitutes, as happened in the Factor VIII story? Shall consistent appeals to a Canadian public fully informed about the national peril from our plasma shortages, yield sufficient supply?

< ***Narrowly Tailored & Proportionate Means.*** The means chosen should be tailored narrowly, so as to advance the stated purposes and be less violative of competing public values. For example, to minimize infringement of the public value of altruism, exceptions to it should be narrow and well-defined. Hence, the scope of the program, its elements and its duration should be narrowly structured in a manner proportionate to the need. Since whole blood is not in chronic short supply, a program that broadly targets the sale of blood would unduly infringe the public value of altruism. Global blood sales would thus be unlikely to pass a test of public necessity in Canada. The likelihood that competing public values will come into play suggests that formal ethics analysis of policy options may help sharpen the understanding and skills of the public and policymakers in properly tailoring ethical blood policy initiatives.

APPENDIX 1

World Health Organization, World Health Assembly Resolution 28.72 of May 1975: Utilization & Supply of Human Blood & Blood Products

The Twenty-eighth World Health Assembly,

Conscious of the increasing use of blood and blood products;

Having considered the information provided by the Director-General on the utilization and supply of human blood and blood products;

Bearing in mind resolution XVIII of the XXII International Conference of the Red Cross;

Noting the extensive and increasing activities of private firms in trying to establish commercial blood collection and plasmapheresis projects in developing countries;

Expressing serious concern that such activities may interfere with efforts to establish efficient national blood transfusion services based on voluntary nonremunerated donations;

Being aware of the higher risk of transmitting diseases when blood products have been obtained from paid rather than from voluntary donors, and of the harmful consequences to the health of donors of too frequent blood donations (one of the causes being remuneration),

1. THANKS the Director-General for the actions taken to study the problems related to commercial plasmapheresis in developing countries;
2. URGES Member States:
 - (1) to promote the development of national blood services based on voluntary nonremunerated donation of blood;
 - (2) to enact effective legislation governing the operation of blood services and to take other actions necessary to protect and promote the health of blood donors and of recipients of blood and blood products;
3. REQUESTS the Director-General:
 - (1) to increase assistance to Member States in the development of national blood services based on voluntary donations, when appropriate in collaboration with the League of Red Cross Societies;

- (2) to assist in establishing cooperation between countries to secure adequate supply of blood products based on voluntary donations;
- (3) to further study the practice of commercial plasmapheresis including the health hazards and ethical implications, particularly in developing countries;
- (4) to take steps to develop good manufacturing practices specifically for blood and blood components in order to protect the health of both donors and recipients; and
- (5) to report to the World Health Assembly on developments in these matters.