

HIV/AIDS AND BLOOD DONATION POLICIES: A COMPARATIVE STUDY OF PUBLIC HEALTH POLICIES AND INDIVIDUAL RIGHTS NORMS*

I. INTRODUCTION

This paper presents a comparative study of blood donation policies in force in the United States, Canada, Denmark, Australia, Uganda, and Singapore which demonstrate the balance between effective health policy and individual rights norms. This study examines national public health policy formulation and implementation, specifically focusing on how the paradigms of law and epidemiology are reconciled to create effective public health policies. This analysis highlights policy differences between states like the United States and Canada, where the national governments have limited power and confer comparatively strong individual rights guarantees, and those like Denmark and Singapore, which assume a “duty ‘to do right for the people’” and in which, in certain circumstances, collective rights subordinate individual rights.¹

Especially since the diagnosis and identification of human immunodeficiency virus (HIV) and its end-stage disease acquired immune deficiency syndrome (AIDS), national governments, often in concert with non-governmental organizations, have sought to guarantee safe blood supplies.² Governments are compelled by national and interna-

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1. Thio Li-ann, *The Constitutional Framework of Powers*, in *THE SINGAPORE LEGAL SYSTEM* 67, 73 (Kevin Y.L. Tan ed., 2d ed. 1999).

2. See Timothy S. Rothermel, *AIDS: Its Impact on Development Programmes*, in *THE GLOBAL IMPACT OF AIDS* 163 (Alan F. Fleming et al. eds., 1988); see also *GLOBAL BLOOD SAFETY INITIATIVE, CONSENSUS STATEMENT ON ACCELERATED STRATEGIES TO REDUCE THE RISK OF TRANSMISSION OF HIV BY BLOOD TRANSFUSION WHO/GPA/INF/89.13, WHO/LAB/89.6* (Mar. 20–22, 1989) [hereinafter *GBSI*]; *WORLD HEALTH ORGANIZATION, GUIDELINES FOR QUALITY ASSURANCE PROGRAMMES FOR BLOOD TRANSFUSION SERVICES* (1993). For a discussion of the blood donation policies enacted to reduce blood transfusion re-

tional interests to guarantee safe blood supplies.³ Many critics, however, view the terms of blood donation and screening policies in the United States and other countries as unreasonably burdening individual rights, though these policies were conceived to comply with international recommendations, like those promulgated by the World Health Organization (WHO).⁴

This paper takes as its point of departure concerns that the exclusionary criteria for blood donation used in the countries studied may be viewed as discriminatory. The prohibition of blood donations by groups considered at high risk for HIV, including men who have sexual relations with other men (MSM), is an example of a potentially problematic exclusionary criterion. This paper discusses whether these criteria, including the prohibition on blood donations by MSM, may be regarded as justifiable to prevent transfusion-related transmission of HIV and other blood-borne pathogens, and to protect the public health and the rights of individuals receiving blood transfusions. Ultimately this paper concludes that the policy determination that exclusionary criteria are justifiable depends upon the reconciliation of the differing concepts of right and risk in law and epidemiology. In the context of blood donation policies in the countries discussed, exclusionary criteria that effectively target individuals in high risk groups and prevent them from donating blood are justifiable because they reduce the risk of contaminated blood entering the blood supply.

lated transmission of HIV in the United States, Canada, Denmark, Singapore, Uganda, and Australia, see *infra* section III.A–F.

3. The specific sources of international law and relevant international and multi-national policies pertaining to this issue are beyond the scope of this paper. The World Health Organization (WHO), the World Health Organization's Global Programme on AIDS, the Global Blood Safety Initiative (GBSI), the United Nations Development Programme (UNDP), and the League of Red Cross and Red Crescent Societies have worked extensively on this issue and have promulgated several nonbinding consensus statements and models for reducing transmission of HIV by blood transfusion. See generally GBSI, *supra* note 2. These statements and recommendations do not constitute binding international law. DAVID P. FIDLER, INTERNATIONAL LAW AND INFECTIOUS DISEASES 58 (1999). The only "international health agreement on communicable diseases [that is] binding on [WHO] Member States" is the International Health Regulations. *Id.* Sexually Transmitted Diseases—communicable diseases—like AIDS/HIV are not included in the IHR and may not be included in the revised regulations set to be released in 2002. Michelle Forrest, Note, *Using the Power of the World Health Organization: The International Health Regulations and the Future of International Health Law*, 33 COLUM. J.L. & SOC. PROBS. 153, 172 (2000).

4. *FDA Panel Rejects Bid to Ease Ban on Blood Donations by Gays*, N.Y. TIMES, Sept. 15, 2000, at A29 [hereinafter *FDA Panel*]; Marjolein Harvey, *Gay Rights Pitted Against Patient Rights in Blood Bank Debacle* (Mar. 28, 2000) (on file with the Duke Journal of Comparative and International Law).

Because public health interventions, such as those described in the six case studies, are concerned with maximizing community health, individual interests or rights often are not the primary focus of public health policy makers. Public health analysis, specifically that undertaken by epidemiologists, is concerned predominately with the health of populations or communities. The individual is considered as a part of the community, not as an individual per se. A public health policy thus might appear to be overbroad, or an exclusion unjustifiable, when considered from a legal perspective concerned with protecting individual rights. However, such apparent overbreadth may be, and often is, acceptable and even necessary in cases in which the public health policy is proven effective. In a legal analysis, even broad exclusions may be viewed as sufficiently narrowly tailored when the exclusion is strictly drawn epidemiologically. For example, where HIV seroprevalence is high in a given population—as it is among MSM or injection drug users in several of the countries studied—the prohibition of blood donations by individuals within those populations is considered an acceptable and effective measure to prevent transfusion-related transmission of HIV.⁵ Exclusionary criteria thus are justifiable so long as they effectively reduce the risk of transmissibility of HIV or other blood-borne pathogens, advancing the goal of the public health measure.

This paper arrives at the above conclusion after presenting a background of HIV/AIDS, the blood supply, and donor self-exclusion. The six comparative studies of national public health policies illustrate how states have sought to balance the apparently competing interests of protecting the blood supply and the health of donees with the rights and interests of donors. This paper ultimately considers the extent to which limitations imposed by national public health policies, specifically blood donation policies, may be regarded as necessary and justifiable limitations on individual rights to promote public health.

II. HIV/AIDS AND THE BLOOD SUPPLY

Since their emergence and identification, HIV and its end-stage disease AIDS have had a profound and devastating impact not only on human health and population, but also on human society, eco-

5. See discussion *infra* section III.A–F.

nomics, and politics.⁶ HIV/AIDS is responsible for more deaths globally than is any other virus.⁷ Since the outset of the epidemic in the late 1970s and early 1980s, 21.8 million people have died from HIV/AIDS and related causes; as of December 2000, 36.1 million people were living with the disease.⁸ These figures are more than 50% higher than those projected in 1991 by the WHO's Global Programme on AIDS.⁹

Most of the prevention strategies recommended for reducing HIV transmission in both developed and developing countries have focused on behavior-change interventions.¹⁰ These primarily aim to reduce the sexual transmission of HIV. Such a focus is well-founded, as HIV is transmitted primarily through sexual activity: heterosexual transmission accounts for up to 80% of adult HIV infections in sub-Saharan Africa.¹¹ In the United States, sexual transmission, both homosexual and heterosexual, accounted for 57% of AIDS cases reported through 2000.¹² HIV, however, is also "acquired through perinatal and parenteral transmission."¹³ Perinatal transmission of HIV (women transmitting the virus to their children either in pregnancy or in childbirth) has been estimated to cause up to 15% to 20% of HIV

6. See LAWRENCE O. GOSTIN & ZITA LAZZARINI, HUMAN RIGHTS AND PUBLIC HEALTH IN THE AIDS PANDEMIC xiii (1997); cf. T. BARNETT & P. BLAIKIE, AIDS IN AFRICA: ITS PRESENT AND FUTURE IMPACT 102 (1992) (Researching 129 households in Rakai, Uganda, the authors find that "AIDS had not yet drawn adaptive responses in production and consumption [that differ significantly from] the many other adaptations households make . . . in response to other rapid processes of socioeconomic change. However, [the authors] believe that in certain localized areas, AIDS is beginning to be the major determinant of socioeconomic change.").

7. Mortality rates due to HIV/AIDS have far surpassed those due to both malaria and tuberculosis. STEPHANIE WASSERMAN, NATIONAL CONFERENCE OF STATE LEGISLATURES, HIV/AIDS FACTS TO CONSIDER: 1999 3 (1999).

8. UNAIDS, AIDS EPIDEMIC UPDATE: DECEMBER 2000, at 3, UNAIDS/00.44E-WHO/CDS/CSR/EDC 2000.9 (English Original, Dec. 2000), available at http://www.unaids.org/epidemic_update/report_dec00/index_dec.html (last visited Oct. 28, 2001) [hereinafter AIDS Epidemic Update].

9. *Id.* at 4.

10. See NATIONAL RESEARCH COUNCIL, PREVENTING AND MITIGATING AIDS IN SUB-SAHARAN AFRICA 157-93 (1996).

11. *Id.* at 83 (citing P. Piot et al., *AIDS: An International Perspective*, 239 SCIENCE 573-79 (1988)).

12. Centers for Disease Control, *HIV/AIDS—United States, 1981-2000*, 50 MORBIDITY AND MORTALITY WKLY. REP. 430, 430 (2001).

13. NATIONAL RESEARCH COUNCIL, *supra* note 10, at 83.

infections.¹⁴ Parenteral transmission (transmission through blood transfusion, injection, or scarification) has been found to account for over 10% of all HIV infections in sub-Saharan Africa,¹⁵ and approximately 25% of cases of AIDS in the United States.¹⁶ The substantial majority of cases of HIV caused by parenteral transmission in developing countries, especially those in sub-Saharan Africa, are caused by transfusion-related transmission, as opposed to in developed countries, where the majority of cases caused by parenteral transmission result from injection drug use.¹⁷

HIV is transmitted successfully through vaginal and anal intercourse at a rate of between 0.1% and 1%.¹⁸ By comparison, the success of HIV transmission is over 90% when infected blood is transfused to a formerly uninfected person.¹⁹ Direct blood contact is one of the most efficient, yet most preventable, forms of HIV transmission.²⁰ In fact, an internationally recognized AIDS researcher asserts that “the most successful single achievement in the prevention of HIV infection has been the drastic reduction in transfusion-acquired infection resulting mainly from effective screening of donated blood.”²¹ In developed countries, the rate of HIV infection resulting from blood transfusions with contaminated blood is virtually zero;²² the blood supplies in these countries are effectively free of HIV.²³ In developing countries, however, especially those in sub-Saharan Africa, the infec-

14. *Id.* at 94 (citing T.C. Quinn, et al. *Special Considerations For Developing Nations, in PEDIATRIC AIDS: THE CHALLENGE OF HIV INFECTION IN INFANTS, CHILDREN, AND ADOLESCENTS* 31–49 (P.A. Pizzo & C.M. Wilfert eds., 1994)).

15. *Id.* at 97; see also Eve M. Lackritz et al., *Blood Transfusion Practices and Blood-Banking Services in a Kenyan Hospital*, 7 *AIDS* 995, 995 (1993).

16. Centers for Disease Control, *supra* note 12, at 430.

17. See Lackritz et al., *supra* note 15, at 995; see also Centers for Disease Control, *supra* note 12, at 430. The percentages presented describing the proportions of HIV infections attributable to the different transmission mechanisms do not add up to 100% because they are estimates. Statistical estimations vary according to the representative populations studied.

18. EUROPEAN COMMISSION, *DEVELOPMENT: STUDIES AND RESEARCH, SAFE BLOOD IN DEVELOPING COUNTRIES* 17 (C. Gerard et al. eds., 1995) [hereinafter Gerard].

19. BARRY D. SCHUB, *AIDS AND HIV IN PERSPECTIVE: A GUIDE TO UNDERSTANDING THE VIRUS AND ITS CONSEQUENCES* 111, 114 (2d ed. 1999).

20. See *id.* at 110–11.

21. *Id.* at 114.

22. Gerard, *supra* note 18, at 17.

23. The blood supplies in developed countries such as Canada, Australia, Denmark, and the United States have been free of HIV only since the mid- to late-1980s. Prior to the implementation of effective screening programs there were significant numbers of transfusion-related HIV infections. See *infra* section II.A–D; see also Centers for Disease Control, *supra* note 12, at 433.

tion rate resulting from blood transfusions is still significant, approximately 10%.²⁴ Safe blood strategies therefore must be implemented and enforced to reduce the rate of HIV transmission by blood transfusions.

In addition to reducing the rate of HIV transmission, safe blood supplies reduce the risk of transmission of other blood-borne pathogens.²⁵ Safe blood supplies minimize the risk of transmitting “acute microbial infections,”²⁶ and generally increase public health: blood’s therapeutic and life-saving uses range from transfusions to pharmaceutical products made from blood components.²⁷

Various organizations, including the European Commission’s Directorate General for Development and the WHO/United Nation Development Programme (UNDP) Global Blood Safety Initiative (GBSI), have recommended strategies for maintaining a safe blood supply.²⁸ The GBSI recommendations state that blood should be obtained from voluntary, non-remunerated donors from low risk populations.²⁹ The recommendations also urge that donors be questioned about HIV-associated symptoms and risk factors, and given the opportunity to exclude themselves from donation (self-exclude) confidentially.³⁰ The emphasis on confidentiality and on individual rights

24. See Centers for Disease Control, *supra* note 12.

25. Blood borne agents transmissible by blood transfusion include viruses, such as hepatitis B (HBV) and C (HCV); human T-cell leukemia types one and two (HTLV-1, 2); bacteria, such as syphilis (*Treponema pallidum*), brucellosis (*Brucella abortus*) which causes undulant fever, and the spirochete that causes lyme disease (*Borrelia burgdorferi*); and parasites, such as those that cause malaria, Chagas’ disease, and trypanosomiasis. John A. J. Barbara, *Transfusion-Transmitted Infections: Epidemiology Relevant to Blood Safety*, in 1 QUALITY ASSURANCE IN TRANSFUSION MEDICINE 419, 423 (Gail Rock & M. J. Seghatchian eds., 1992). There has been extensive debate as to whether variant Creutzfeldt-Jakob disease (vCJD) is a blood borne disease. See *infra* text accompanying note 123.

26. Barbara, *supra* note 25, at 420.

27. Ronald Bayer & Eric Feldman, *Introduction: Understanding the Blood Feuds*, in BLOOD FEUDS: AIDS, BLOOD, AND THE POLITICS OF MEDICAL DISASTER 2 (Eric A. Feldman & Ronald Bayer eds., 1999).

28. See *supra* note 3.

29. Gerard, *supra* note 18, at 42.

30. See INSTITUTE OF MEDICINE, HIV AND THE BLOOD SUPPLY: AN ANALYSIS OF CRISIS DECISIONMAKING 128 (Lauren B. Leveton et al. eds., 1995).

A risk factor is a variable (demographic [e.g., age or gender], clinical [e.g., family history of disease or behavior], or laboratory [e.g., biological or physiological characteristic—for example, high cholesterol is considered a laboratory risk factor for heart disease]) associated with either an increased or decreased risk of developing the disease. In a prospective study, it is measured at baseline from which people are followed forward until they develop the disease; the risk relationship is called the relative risk. In a retrospective study, it is measured by questionnaire after identifying who is a case and who is a control; the risk relationship is called the odds ratio (odds

demonstrates the various organizations' commitments to balance public health strategies with human rights concerns.³¹

Even as blood-screening technologies improve and become increasingly available and required by law in many countries including South Africa,³² Canada,³³ and the United States,³⁴ obtaining blood donations from low risk donors is nevertheless still important because blood screening procedures are not 100% effective.³⁵ More importantly, use of low risk donors minimizes the possibility of blood donation by infected individuals who are in the window period during which HIV is "invisible to laboratory screening procedures."³⁶ The

of exposure in someone with the disease divided by the odds of exposure in someone without the disease). See generally JOHN M. LAST, A DICTIONARY OF EPIDEMIOLOGY (1988).

31. See GOSTIN & LAZZARINI, *supra* note 6, at 51–54. The London Declaration on AIDS prevention, endorsed by the World Health Assembly, emphasized "the need in AIDS prevention programmes to protect human rights and human dignity. Discrimination against, and stigmatization of, HIV-infected people and people with AIDS and populations groups undermine public health and must be avoided." *Id.*

32. Charles Ngwena, *Legal Responses to AIDS: South Africa*, in LEGAL RESPONSES TO AIDS IN COMPARATIVE PERSPECTIVES 117, 121 (Stanislaw Frankowski ed., 1998); see also STANDARDS FOR THE PRACTICE OF BLOOD TRANSFUSION IN SOUTH AFRICA (3rd ed. 1999); Human Tissue Act 1983, 6 BSRSA 2000 (S. Afr.).

33. See *infra* section III.A.

34. See *infra* section III.B.

35. The ELISA (enzyme-linked immunosorbent assay) test to detect HIV antibodies in blood is 99.7% effective, making it one of the most sensitive of all viral serological tests. SCHOUB, *supra* note 19, at 115. Rapid tests that can yield results in minutes, like the latex agglutination test, are also widely used. Both of these tests, however, can only confirm seropositivity when HIV antibodies are present in the patient's serum (blood). *Id.* at 130, 135. On average, antibodies are not present in blood until twenty-five days after infection; thus the average window period during which the ELISA and rapid tests are ineffective is twenty-five days. Ai Ee Ling et al., *Failure of Routine HIV-1 Tests in a Case Involving Transmission With Preseroconversion Blood Components During the Infectious Window Period*, 284 JAMA 210, 210 (2000). Theoretically, the p24 antigen detection ELISA test (looking for p24 antigen from the core of the virus) should shorten the window period, as p24 antigen on average can be detected "about 6 days before antibody tests become positive." *Id.* at 210–11. Researchers, however, have found that the test is too insensitive for widespread use. SCHOUB, *supra* note 19, at 139, 153; see also INSTITUTE OF MEDICINE, *supra* note 30, at 78; JP AuBuchon et al., *Cost-effectiveness of Expanded Human Immunodeficiency Virus-testing Protocols For Donated Blood*, 37 TRANSFUSION 45–51 (1997) ("Although expanding the donor HIV screening protocol with p24 antigen or RNA PCR testing will prevent rare cases of transfusion-associated HIV, the cost-effectiveness of such an addition is predicted to be far below that of most medical interventions. Thus, HIV test protocol additions are unlikely to provide cost-effective improvements to blood safety in the United States." (citations omitted)); cf. Eve M. Lackritz, *Prevention of HIV Transmission By Blood Transfusion in the Developing World: Achievements and Continuing Challenges*, 12 AIDS S81 (Supp. A 1998) ("HIV-1 p24 antigen testing was implemented in the USA in March 1996. In the first 18 months of p24 antigen testing, an estimated 18 million blood donations were tested at a cost of US\$90 million to detect three antigen-positive, antibody-negative donations.").

36. SCHOUB, *supra* note 19, at 115.

window period is the period of approximately six to eight weeks following infection. During this time, individuals infected with HIV have a large viral load but detectable antibodies are not yet present in the infected individual's blood.³⁷

Because of the risks associated with blood donors donating infected blood during the window period, thereby introducing HIV into the blood supply, "[e]xclusion of blood donors with an increased risk of HIV infection is considered an effective strategy to reduce the residual risk of HIV contamination [of the blood supply]."³⁸ However, as William McFarland, a noted epidemiologist, has written, the determination of such criteria is difficult; thus, "[t]he search for HIV risk factors to use as criteria for exclusion from blood donation has been the subject of much recent transfusion-related research."³⁹ As much current research shows, infected populations and risk factors vary extensively from country to country and even within countries.⁴⁰ In the United States, for example, the collection of blood from prisoners is prohibited because the incidence of HIV and other communicable diseases is higher among the prisoner population than among comparable populations.⁴¹ Thus, in order for the exclusion of blood donors to protect the blood supply effectively from viral contamination, the exclusionary criteria must be tailored to the specific epidemiological situation of the given country and in fact exclude individuals who are at an increased risk for both prevalent and incident HIV.⁴²

In developed countries, pre-donation screening to exclude high risk individuals, also referred to as behavior risk-factor screening or donor self-exclusion, used in combination with serological or biological screening has been highly effective in reducing both the number of

37. *See id.*

38. William McFarland et al., *Risk Factors for Prevalent and Incident HIV Infection in a Cohort of Volunteer Blood Donors in Harare, Zimbabwe: Implications for Blood Safety*, 11 AIDS S97, S98 (Supp. 1 1997); *see also infra* note 293.

39. *Id.*

40. *See generally* AIDS EPIDEMIC UPDATE, *supra* note 8.

41. Richard G. Cable, *Conducting the Blood Donor Medical Interview*, in 1 QUALITY ASSURANCE IN TRANSFUSION MEDICINE 105, 108 (Gail Rock & M. J. Seghatchian eds., 1992).

42. *See* McFarland et al., *supra* note 38, at S98. Incidence is a measure of the risk of developing the disease in the population. Incidence is defined for epidemiological purposes as the number of new cases of a disease that occur in a specific population at risk for developing the disease in a given time period divided by the number of such persons. People who have the disease at the beginning of that time interval are not at risk of becoming incident cases but do contribute to the prevalence of the disease. The prevalence is the number of cases of a disease divided by the number of individuals in the population at a specific time point. Prevalence is a measure of the burden of disease in the population. *See generally* LAST, *supra* note 30.

blood donations from people who are HIV-positive at the time of donation and the risk of infection by blood donated during the window period.⁴³ This high success rate is due to the fact that screening criteria have been closely linked to epidemiological risk factors for an extended period of time.⁴⁴ A minimal risk remains, however, as “blood collected from asymptomatic donors in the window period often is highly infectious and is considered the principle remaining reason why disease still can be transmitted by screened units of blood.”⁴⁵

In France, the risk of HIV transmission through blood transfusion has been reduced by the use of pre-donation interviews in combination with serological screening. In French blood donation centers, donors are screened by interview rather than by a strict questionnaire. At the Foundation Nationale de Transfusion Sanguine in Paris, France,

the doctors performing this interview are requested to ask questions regarding classical risk factors such as homosexuality, drug addiction, contacts with at risk partners, history of transfusion, rather than presenting donors with a rigid written questionnaire. The quality of this interview is important: the physical conditions and the questions asked must take into account the *latest epidemiological data on HIV infection in the country, in particular the risk factors of HIV infection, in order to frame suitable questions for the medical interview.*⁴⁶

In France, the United States, and other developed countries, the use of pre-donation donor self-exclusion, in combination with virological screening has successfully reduced transfusion transmitted HIV because the questions asked prior to donation effectively target at-risk

43. In the United States, because of the successful use of antibody tests for blood donor screening and the exclusion of high risk donors, the residual risk of HIV transmission by blood transfusion is approximately 0.0002%, or twenty per million. Eberhard Fiebig, *Safety of the Blood Supply*, 357 CLINICAL ORTHOPAEDICS & REL. RES. 6, 11 (1998); see also SCHOUB, *supra* note 19, at 153 (The combination of pre-donation and serological screening in the United States has reduced “the risk of infection from blood donated during the window period to [only on] the order of one in a million.”). “Of 12 million units of donated blood each year, 10 HIV infected units slip through, accounting for two to three cases of donor transmitted HIV infections a year.” Deborah Josefson, *FDA Declines To Lift Ban on Homosexual Men as Blood Donors*, 321 BRIT. MED. J. 722, 722 (2000).

44. See Fiebig, *supra* note 43, at 6, 11.

45. *Id.* at 12.

46. Jean-Jaques Lefrère et al., *Interviews with Anti-HIV-Positive Individuals Detected through the Systematic Screening of Blood Donations: Consequences on Predonation Medical Interview*, 62 VOX SANG 25, 26 (1992) (emphasis added).

populations.⁴⁷ Thus, even if the screening categories are overbroad and screen out many individuals who do not pose a high risk of transmitting HIV, they effectively screen out those individuals who pose a high risk of transmitting HIV.

In developing countries, the risk of transfusion-transmitted HIV infection is significantly higher than in developed countries.⁴⁸ The South African Law Commission found that even after pre-donation donor self-exclusion, 0.56% (5.6 in every 1000) of blood donations were HIV-positive.⁴⁹ The disparity in screening effectiveness between developed and developing countries is due in part to the fact that in developing countries, especially those in sub-Saharan Africa, it is often difficult to define low risk populations because “all sexually active persons” are effectively high risk individuals.⁵⁰ The disparity in screening effectiveness is also due to the increased seroprevalence in the countries’ overall populations.⁵¹ Thus, developing countries that seek to reduce the transmission of HIV by blood transfusion face the difficult task of setting parameters for self-exclusion (defining which groups are high and low risk) so that individuals who are HIV-positive at the time of donation or who are likely to seroconvert after donation are deterred from becoming blood donors. Because exclusionary criteria are intended to screen out individuals with a high risk of infection, the definition of what constitutes high risk may be broad and over-inclusive, necessarily excluding more individuals from donating blood than are infected.

The task of narrowly defining criteria for blood donation self-exclusion is conceptually challenging and often times legally problematic. For example, within the past year alone, public health policy makers in the United States and South Africa have come under scru-

47. See Fiebig, *supra* note 43, at 6, 11; see also L.S. Doll et al., *Human Immunodeficiency Virus Type-1 Infected Blood Donors: Behavioral Characteristics and Reasons for Donation*, 31 *TRANSFUSION* 704, 707 (1991).

48. SCHOUB, *supra* note 19, at 153; see also McFarland et al., *supra* note 38, at S98.

49. Out of 7,078,333 blood donations tested for HIV between 1985 and mid-1994, 39,777 blood donations were HIV positive. See Ngwena, *supra* note 32, at 159 (citing South African Law Commission, *Aspects of the Law Relating to AIDS*, Working Paper No. 171, 1995). Ngwena’s statistical analysis is incorrect: after providing the numbers of blood donations, he states 0.0056% rather than 0.56%. Ngwena did not report the epidemiology of HIV infection among infected blood donors. Information on the seroprevalence rates of HIV among infected donor populations would facilitate adoption of more effective exclusionary criteria, because questions could be asked to exclude groups among whom seroprevalence is high.

50. Gerard, *supra* note 18, at 48.

51. William McFarland et al., *Risk Factors for HIV Seropositivity Among First-Time Blood Donors in Zimbabwe*, 38 *TRANSFUSION* 279, 279 (1998).

tiny because of restrictions on blood donation by MSM.⁵² Opponents of the restrictions assert that any prohibition on blood donation by MSM constitutes discrimination on the basis of sexual orientation and, therefore, is unjustifiable.⁵³ Public health policy makers, however, counter that these restrictions are necessary to protect the safety of the blood supply and thus constitute a justifiable measure, albeit one which appears discriminatory.⁵⁴

This debate effectively highlights the fundamental conflict between the paradigmatic goals of public health and law. Public health, specifically epidemiology, is concerned predominately with populations and public welfare, whereas law and the clinical practice of medicine are concerned with individuals.⁵⁵ Because public health policies are adopted to maximize community health, they often do not privilege individual interests.⁵⁶ A public health policy thus may appear to be overbroad in a legal analysis, while epidemiologists view it as a reasonable preventive measure.

III. COMPARATIVE NATIONAL PRACTICE

The practices adopted by various countries to protect and maintain blood supplies free of HIV and other viral contaminants, such as hepatitis, arguably do not constitute customary international law because of a lack of *opinio juris*.⁵⁷ These practices thus are not binding

52. FDA Panel, *supra* note 4, at A29; Harvey, *supra* note 4.

53. FDA Panel, *supra* note 4, at A29.

54. *Id.*

55. See LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 13 (2000).

56. *Id.* at 14–15.

57. A full discussion of whether the practices adopted to protect and maintain clean and safe blood supplies constitute customary international law is beyond the scope of this paper. However, a brief outline of such an argument follows.

Article 38 of the Statute of the International Court of Justice defines customary international law as comprised of a state's acts, state practice, and a given state's intent and belief that those acts are obligatory acts under international law, *opinio juris*. PETER MALANCZUK, AKEHURST'S MODERN INTRODUCTION TO INTERNATIONAL LAW 39 (7th rev. ed. 1997); see also Military and Paramilitary Activities (Nicar. v. U.S.), 1986 I.C.J. 14, 97 (June 27). State practice refers not only to a state's conduct regarding foreign affairs, but also to its domestic affairs, for example national legislation, judicial decision, and policy. 1 OPPENHEIM'S INTERNATIONAL LAW 26 (Robert Jennings & Arthur Watts eds., 9th ed. 1992). A state's actions only become state practice or part of custom when they are committed "under the aegis of the conviction that these actions are, according to international law, obligatory or right." *Id.* at 27; see also North Sea Continental Shelf Cases (F.R.G. v. Den.; F.R.G. v. Neth.), 1969 I.C.J. 3, 44 (Feb. 20). The International Court of Justice in the *North Sea Continental Shelf Cases* emphasized that for a state's acts to be considered to have the requisite *opinio juris*, two necessary preconditions must be satisfied: "Not only must the acts concerned amount to a settled practice,

on other states. The legal and policy practices of other countries, however, are often instructive in developing and analyzing law and policy.

This section presents a comparative analysis of the policies of the United States, Canada, Denmark, Australia, Uganda, and Singapore, concerning blood donations, transfusions, and HIV-transmission prevention. The United States, Canada, Denmark, and Australia are categorized as Pattern One countries because the majority of sexually transmitted HIV infections in these countries result from homosexual contact.⁵⁸ Uganda and Singapore, on the other hand, are categorized as Pattern Two countries because the majority of sexually transmitted HIV infections result from heterosexual contact.⁵⁹

This section focuses on policies concerning pooled blood donations rather than autologous or directed donations. Autologous donation refers to an individual donating blood that he or she will use at a later date. Directed donation refers to an individual soliciting blood donations from friends or family. This policy is disfavored because of confidentiality concerns, and because individuals who would otherwise defer from blood donation because of high risk behavior might feel compelled to donate blood for a relative or friend.⁶⁰

Each section below chronicles the development of law and policy from the early identification of HIV/AIDS within the state's blood

but they must also be such, or be carried out in such a way, as to be evidence of a belief that this practice is rendered obligatory by the existence of a rule of law requiring it." *North Sea Continental Shelf*, at 44.

It is highly doubtful that national blood donation policies implemented to prevent the further transmission of HIV and the inclusion therein of specific exclusionary criteria could satisfy the preconditions of state practice and *opinio juris* sufficient to constitute customary international law. For the most part, states draft these policies with an eye towards the national public health. Furthermore, even if these policies are drafted in harmony with the policies of other countries, or international best-practice, it is unlikely that such practice alone could substantiate a claim of international law because of the marked lack of *opinio juris*.

58. Dr. Jonathan Mann described the pattern of HIV/AIDS in North America, Western Europe, Australia, and New Zealand as Pattern One. He wrote: "In these areas, the sexual transmission of the virus is predominantly homosexual although heterosexual transmission has been, and is continuing to occur. In these areas, HIV transmission by blood transfusion is prevented because blood transfusions are screened, but bloodborne spread is still occurring through sharing of needles and syringes among persons with self-injecting behaviours. Finally in these areas of the world there is transmission from mother to child but . . . there are relatively fewer instances of transmission to children." Jonathan Mann, *Worldwide Epidemiology of AIDS*, in *THE GLOBAL IMPACT OF AIDS* 4 (Alan F. Fleming et al. eds., 1988).

59. *Id.*

60. Ronald Bayer, *Blood and AIDS in America: Science, Politics, and the Making of an Iatrogenic Catastrophe*, in *BLOOD FEUDS: AIDS, BLOOD, AND THE POLITICS OF MEDICAL DISASTER* 20, 26 (Eric A. Feldman & Ronald Bayer eds., 1999).

supply to the establishment of comprehensive protocols for preventing transfusion-related transmission of HIV. Where available, the legal prescriptions that mandate specified policies are presented. These case studies provide examples of measures implemented to prevent the continued spread of HIV through blood and blood products, and the policy decisions that led to their formulation. The United States features prominently in this analysis and is a point of departure and reference because of the availability of information on the formation of blood donation policy and the availability of research on its efficacy.

A. United States

In July 1982, the U.S. Centers for Disease Control (CDC)⁶¹ issued a warning to blood bank agencies and hemophiliacs that the recently identified disease AIDS was caused by a blood-borne pathogen.⁶² By the end of 1982, over 400 cases of AIDS had been diagnosed in the United States predominately among homosexual men, Haitians, intravenous drug users, and hemophiliacs.⁶³ The CDC urged that precautionary measures be implemented to stave off further spread of the disease.⁶⁴

Throughout 1982, researchers found increasing evidence indicating that AIDS was blood-borne and could be transmitted by blood

61. The U.S. Public Health Service (USPHS), housed within the Department of Health and Human Services, is responsible for national public health. James G. Hodge, Jr., *The Role of New Federalism and Public Health Law*, 12 J.L. & HEALTH 309, 337 (1998). The USPHS was originally the Marine Hospital Service; it was renamed in 1912. Since that time, the USPHS has grown from administering health services to marines to administering many of the operative agencies of the United States Department of Health and Human Services (DHHS) including the CDC, the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Human Resources and Services Administration (HRSA). *Id.* The specific responsibility for developing policies to ensure the quality and safety of the blood supply was delegated under the United States Public Health Act of 1944 to the Center for Biologics Evaluation and Research. 42 U.S.C. § 241 (2001). The FDA implements policies drafted by the Center for Biologics Evaluation and Research through federal regulations.

62. ANDRÉ PICARD, *THE GIFT OF DEATH: CONFRONTING CANADA'S TAINTED-BLOOD TRAGEDY* 56 (1995).

63. *Id.* at 57.

64. "The CDC has no direct regulatory power. It provides epidemiologic information and technical support to other regulatory agencies and information to medical providers and the public, but relies on the FDA and other Public Health Service agencies to implement its recommendations. It issued regular surveillance reports and initiated meetings of blood banks, manufacturers, and the FDA during the early 1980s, but its recommendations were often ignored in the face of opposition from powerful interest groups, especially blood bankers and gay rights activists." Sherry Glied, *Markets Matter: U.S. Responses to the HIV-Infected Blood Tragedy*, 82 VA. L. REV. 1493, 1495-96 (1996).

transfusion. In July 1982, the CDC reported that three hemophiliacs had died of AIDS-related infections; none of the infected individuals had any risk factor other than that they had received blood transfusions.⁶⁵ In December 1982, the CDC reported that five more hemophiliacs had contracted AIDS, and that there were five other AIDS cases that might have resulted from blood transfusions.⁶⁶

The Hemophilia Foundation proposed in 1982 that blood banks proscribe donations by gay men.⁶⁷ However, because they did not want to foster an exclusionary policy, and because gay men were considered “crucial to the donor pool,”⁶⁸ blood banks did not implement this proposal immediately. Dr. James Curran, the director of AIDS activities at the CDC urged the gay community to seize the “political initiative with a call for voluntary withdrawal of all gay men from the donor pool.”⁶⁹ He stated, “The thing is, people are dying. The medical problem is more important than the civil rights issue.”⁷⁰ Despite Dr. Curran’s recommendations, however, the blood banking agencies in the United States (the American Association of Blood Banks, the American Red Cross, and the Council of Community Blood Banks) expressly rejected pre-donation screening on the basis of sexual orientation, so as not to discriminate against MSM.⁷¹

In March 1983, the U.S. Food and Drug Administration (FDA) issued recommendations that “members of groups at increased risk for AIDS should refrain from donating plasma and/or blood. This recommendation includes all individuals belonging to such groups, even though many individuals are at little risk of AIDS.”⁷² Groups that were excluded from blood donation included “men who had sex with men, members of the Haitian community, injection drug users,

65. Bayer, *supra* note 60, at 20–21.

66. *Id.* at 22.

67. *Id.* at 23.

68. *Id.* Gay men were crucial to the donor pool because “[p]rior to AIDS, gay people used to go in together to donate blood, as a community effort.” Melinda Tuhus, *Supplies of Blood Fall as Demand Increases*, N.Y. TIMES, Oct. 29, 2000, § 14CN (Conn. Ed.), at 3. Few other groups donated with the solidarity that gay men did prior to the mid-1980s.

69. THE ADVOCATE, Feb. 17, 1983, at 9, *quoted in* Bayer, *supra* note 60, at 23.

70. Bayer, *supra* note 60, at 23.

71. *Id.* at 24.

72. Food & Drug Administration, *Recommendations to Decrease the Risk of Transmitting Acquired Immune Deficiency Syndrome (AIDS) from Blood Donors*, Memorandum from the Director, Office of Biologics, National Center for Drugs and Biologics (Mar. 24, 1983), *quoted in* Inge B. Corless et al., *Perspectives in Conflict: The Response to Transfusion-Associated AIDS*, 14 AIDS & PUB. POL. J. 47, 59 (1999).

and the sexual partners of any of those individuals.”⁷³ All of these groups had high AIDS prevalence rates at the time.⁷⁴ The U.S. Public Health Service (USPHS) issued these recommendations to comply with federal regulations mandating that blood donors be “free[] from any disease transmissible by blood transfusion,”⁷⁵ and because there was “no alternative but to treat all members of groups at increased risk for AIDS as posing a threat of transmission.”⁷⁶

Diagnosis of AIDS prior to the onset of the symptomatic illness was almost impossible before the identification of HIV and the creation of screening tests. Furthermore, the latency or “window period” between exposure to the infection and illness was lengthy, necessitating other screening measures because “the pool of persons potentially capable of transmitting an AIDS agent may be considerably larger than the presently known number of cases.”⁷⁷ While status-based classifications to exclude donors generally are disfavored because of their lack of specificity, the utility of these classifications “ultimately depends upon the strength of the relationship between status and behavior.”⁷⁸ For example, if there is a high prevalence of HIV in a MSM population, the error associated with exclusionary criteria based on MSM behavior is less.⁷⁹ An exclusionary criteria based on MSM behavior, however, is functionally identical to a status-based classification. The use of exclusionary criteria closely resembling status-based classifications ultimately was validated by epidemiological data that showed the large prevalence of HIV/AIDS infection in MSM populations in the 1980s.⁸⁰

73. Norbert Gilmore & Margaret Sommerville, *From Trust to Tragedy: HIV/AIDS and the Canadian Blood System*, in BLOOD FEUDS: AIDS, BLOOD, AND THE POLITICS OF MEDICAL DISASTER 128, 134 (Eric A. Feldman & Ronald Bayer eds., 1999); *see also* Bayer, *supra* note 60, at 25.

74. *See infra* text accompanying notes 81, 85.

75. 21 C.F.R. § 640.3(a)(c) (2000); *see also* 21 C.F.R. § 640 (2000) (regulating donor suitability).

76. Bayer, *supra* note 60, at 25.

77. *Id.* (quoting Centers for Disease Control, *Prevention of Acquired Immune Deficiency Syndrome (AIDS) Report of Interagency Recommendations*, MORBIDITY AND MORTALITY WKLY. REP. 101-03 (Mar. 4, 1983)).

78. Steven R. Salbu, *AIDS and The Blood Supply: An Analysis of Law, Regulation, and Public Policy*, 74 WASH. U. L.Q. 913, 954 (1996).

79. *Id.*

80. *See infra* text accompanying notes 81-85.

After the identification of HIV in early 1984, testing of blood donations became widely available.⁸¹ The American Red Cross reported that soon after testing began, one in 500 U.S. donors tested positive for HIV.⁸² In New York City, “87% of intravenous drug users [at a drug clinic] tested positive.”⁸³ The infection rate in San Francisco among healthy, apparently uninfected gay men was 55%; among gay men tested in New York City, the infection rate was 38%.⁸⁴ HIV tests of apparently uninfected hemophiliacs “revealed that 72% were infected; among those who infused Factor VIII more than once a month, the infection rate was 90%.”⁸⁵

In 1985, blood banks initiated universal testing of blood donations.⁸⁶ Potential blood donors were informed that their blood would be tested for antibodies to HIV.⁸⁷ If donors tested HIV-positive, they were notified confidentially.⁸⁸ “Neither blood banks nor donors could elect to avoid such notification.”⁸⁹ After pre-donation blood donor screening was implemented in 1985, a study was done evaluating blood donors who tested HIV positive.⁹⁰ Of 818,629 blood donations included in the study, 450 (or 0.05%) donors were HIV positive.⁹¹ During 1985–1986, the year in which the study was conducted, sero-

81. Bayer, *supra* note 60, at 31–32. Serological screening of blood donations was not available prior to 1984 because although HIV, the virus that causes AIDS, was identified in 1983, the virus was not propagated in a cell culture until 1984. Only after propagation of HIV in the laboratory could diagnostic serological tests to specifically target HIV antibodies be developed. See SCHOUB, *supra* note 19, at 10. The first serological test kit to detect HIV antibodies was licensed by the FDA for use in March 1985. Corless et al., *supra* note 72, at 47; see also Lisa M. Korsten, Note, *The Global Market For Blood: A Proposal For Expansion and a Consistent System of International Regulation*, 11 B.U. INT’L L.J. 227, 238 n.74 (1993).

82. PICARD, *supra* note 62, at 66.

83. *Id.*

84. *Id.*

85. *Id.* Factor VIII is a protein extracted from blood products which promotes blood clotting and frequently is given to hemophiliacs. If blood products (i.e., lymphocytes or monocytes) containing HIV or other viral contaminants are used in the production of Factor VIII, the virus will be transmitted to all individuals receiving the product. SCHOUB, *supra* note 19, at 111–12. Factor VIII infusion by hemophiliacs compounded the incidence of HIV infection in the hemophiliac population because large numbers of individuals were exposed prior to knowledge of HIV contamination or the implementation of preventative measures. See Bayer, *supra* note 60, at 22, 29–31, 44.

86. Prior to 1985, the United States did not have any regulatory policy in place that addressed blood donation screening. See Glied, *supra* note 64, at 1506.

87. Bayer, *supra* note 60, at 32.

88. *Id.*

89. *Id.*

90. J. W. Ward et al., *Epidemiologic Characteristics of Blood Donors with Antibody to Human Immunodeficiency Virus*, 28 TRANSFUSION 298, 298 (1988).

91. *Id.*

prevalence among donors declined from 0.07% to 0.04%.⁹² Seventy-seven percent (77%) of the seropositive men interviewed reported sexual contact with men; of this 77%, 53% identified themselves as bisexual.⁹³ As a result of the coordinated use of antibody testing and pre-donation screening, the residual risk of HIV transmission by blood transfusion in the United States since 1985 has been reduced to virtually none.⁹⁴

A residual risk of transfusion-transmitted HIV still exists in the United States, albeit minimal. The risk remains because blood donated in the window period may not test positive for antibodies to the virus even while there is a high viral load present in the blood.⁹⁵ To ensure that the risk remains as low as possible, the United States continues to enforce strict pre-donation screening criteria.⁹⁶ Stringent criteria are also in place because of the extensive litigation that ensued after incidences of transfusion-related transmissions of HIV.⁹⁷ Pre-donation screening using donor self-exclusion questionnaires, while not required by law, is used in all blood donation programs in the United States.⁹⁸ The questionnaires are used in combination with serological screening of all blood donations for HIV and other blood borne pathogens; serological screening is mandatory in the United States.⁹⁹

The FDA further restricted the pre-donation blood donor exclusion system in 1990 by reducing the pool of potential donors. Dr. Louis W. Sullivan, then Secretary of the Department of Health and Human Services, said,

92. *Id.*

93. *Id.*

94. See Fiebig, *supra* note 43; see also George B. Schreiber et al., *The Risk of Transfusion-Transmitted Viral Infections*, 334 NEW ENG. J. MED. 1685 (1996).

95. Dr. Michael Busch of the University of California at San Francisco says that “of the nation’s 12 million units of donated blood, about 10 HIV-infected units are undetected each year, causing about two or three HIV infections annually.” *FDA Panel, supra* note 4.

96. See Bayer, *supra* note 60, at 53.

97. See generally *id.* at 34–52.

98. United States Blood Donation Questionnaire (on file with the Duke Journal of Comparative and International Law).

99. 21 C.F.R. § 610.45 (2000) ((a) *Testing Requirements.* (1) Each donation of human blood or blood components intended for use in preparing a product shall be tested for antibody to HIV by a test approved for such use by the FDA, except as otherwise approved in writing by the FDA. . . .); 21 C.F.R. § 640.3 (2000). As early as 1985, some individual states in the U.S., like Washington, had implemented legislation requiring systematic screening of blood donations, prior to the passing of a national law. D. Reviron et al., *Prevention of HIV Infection by Transfusion: Comparative Analysis of Systems Adopted in Developed Countries*, 6 AIDS & PUB. POL. J. 25, 25 (1991).

The strengthened program will enhance . . . the current procedures used to safeguard the blood supply. By shifting the focus of screening procedures to cover a broader range of risk factors, FDA will build upon the safety of the blood supply while providing all healthy and willing individuals the opportunity to donate blood.¹⁰⁰

The FDA continued to mandate that each blood donation be tested for HIV and other blood-borne infectious agents.¹⁰¹ In addition, the FDA urged blood donation centers to implement the following measures:

1. Blood establishment personnel should talk with each candidate donor to ensure comprehension concerning the risk of HIV infection, i.e., information about these risks is available in the language appropriate to each donor and is constructed to be culturally sensitive to promote comprehension. The focus should be *on behavior and not on stereotypes* (e.g., many men who have had male-to-male sexual experiences do not identify themselves as “homosexual,” “gay,” or “bisexual”).
2. The oral and/or written interaction between potential donors and blood establishment personnel should include direct questions about *risk behaviors* for HIV infection. . . .¹⁰²

Although these measures have proven effective in reducing the number of infected blood donors and thus the incidence of transfusion-related transmission of HIV,¹⁰³ many scientists and gay activists believe that the measures have not satisfied their goal of specifically targeting high risk behaviors rather than stereotypes.¹⁰⁴ The latter concern was addressed specifically when an FDA advisory panel reviewed whether or not to change the ban on blood donations by men who have sexual contact with other men.¹⁰⁵

Under the FDA's rules for blood donation, men who have had sexual contact with other men even just once since 1977 are prohibited from donating blood in the United States. This exclusionary cri-

100. Press Release, Brad Stone, Food and Drug Administration, New Blood Policy (Dec. 5, 1990) (on file with the Duke Journal of Comparative and International Law).

101. *Id.*

102. *Id.* (emphasis added.)

103. S. A. Glynn et al., *Trends in Incidence and Prevalence of Major Transfusion-Transmissible Viral Infections in US Blood Donors*, 284 JAMA 229 (2000) (finding that from 1992 to 1996 HIV prevalence declined in first-time donors from 0.030% to 0.015% (P=.006); this combined with “the decrease in HIV and HCV prevalence rates, [and] the . . . lower rates of infection in first-time donors compared with the general population, suggests the continued benefit of behavioral risk factor screening”).

104. Deborah Josefson, *FDA Declines to Lift Ban on Homosexual Men As Blood Donors*, 321 BRIT. MED. J. 722 (2000).

105. *Id.*; see also *FDA Panel*, *supra* note 4.

terion has been criticized as discriminatory and inapposite, especially since HIV seroprevalence among gay men has declined to approximately 8%.¹⁰⁶ Whether MSM should continue to be excluded from blood donation in the United States has generated extensive recent debate.

Scientists and gay activists urged the FDA to change the current restrictions to prohibit only blood donations from men who have engaged in homosexual activities within the past five years.¹⁰⁷ The proposed revised blood donation restrictions would not prohibit donations from “men who have had gay sex only once” or men who have not engaged in same sex activities in the past five years.¹⁰⁸ The revisions would enable approximately 62,300 gay males to qualify as donors. An FDA medical official estimates that should these individuals be allowed to donate blood, only approximately 1.7 units of HIV infected blood would enter the blood supply each year.¹⁰⁹

Scientists from the FDA and the CDC maintained, however, that the present ban should remain in force, and that it is justified by the epidemiology of HIV transmission in the United States.¹¹⁰ Despite a decline in seroprevalence among MSM, and projections that the easing of the restrictions would not significantly increase the incidence of transfusion-related HIV infection, an advisory panel of the FDA voted in 2000 to maintain the more restrictive ban.¹¹¹ The FDA and the CDC publicly stated, however, that they consider the exclusionary policy to be based on behavior and epidemiology rather than on sexual identity.¹¹²

The United States' blood donation policy embodies the compromises necessary between public health and individual rights, which are encountered frequently when formulating public health regulation or policy in a democratic political society.¹¹³ Public health focuses on the development of policies to protect individuals' health within the society through collective action.¹¹⁴ The government must have a

106. *FDA Panel*, *supra* note 4; *see also* U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, FOOD & DRUG ADMINISTRATION, CENTER FOR BIOLOGICS EVALUATION & RESEARCH, BLOOD DONOR SUITABILITY WORKSHOP 9 (Nov. 23, 1998).

107. *FDA Panel*, *supra* note 4; Harvey, *supra* note 4.

108. *See FDA Panel*, *supra* note 4.

109. *Id.*

110. Stone, *supra* note 100.

111. *FDA Panel*, *supra* note 4.

112. Josefson, *supra* note 104, at 722.

113. *See generally* GOSTIN, *supra* note 55, at 7–22, 85–109.

114. *Id.* at 12.

legitimate justification for the public health interventions that it implements.¹¹⁵ There is a general presumption, subject to judicial scrutiny, that these interventions are justified if they minimize the overall risk of harm to citizens' health.¹¹⁶ For example, the United States Supreme Court in *Jacobson v. Massachusetts*¹¹⁷ held that compulsory vaccination is a legitimate use of the state's police power.¹¹⁸ Jacobson's liberty interest was not violated by compulsory vaccination because in the United States' constitutional system, liberty is not absolute.¹¹⁹ As the Court stated, "There are manifold restraints to which every person is necessarily subject for the common good."¹²⁰ The Court held that the restraint in *Jacobson*, and the risk of a consequent "injury [to Jacobson's liberty interests was] too small to be seriously weighed as against the benefits coming from the discreet and proper use of the preventive."¹²¹ To public health policy makers in the United States, the risk of harm associated with HIV, of acquiring a fatal or potentially fatal disease from a blood transfusion, far outweighs the costs of pre- and post-donation screening or any consequent infringement on liberty interests or personal autonomy in denying someone the opportunity to donate blood.¹²²

Recent revisions in restrictions demonstrate the extent to which public health protections are favored over other interests, such as expanding the pool of potential blood donors, even when the exclusionary criteria are seemingly arbitrary or discriminatory. Responding to the threat of transfusion-related transmission of new variant

115. *Id.* at 72.

116. *See generally id.* at 77–82.

117. 197 U.S. 11 (1905).

118. *See* GOSTIN, *supra* note 55, at 66–70.

119. *Jacobson*, 197 U.S. at 26 ("The liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly free from restraint.").

120. *Id.*

121. *Id.* at 24.

122. *See generally* GOSTIN, *supra* note 55, at 86–100. A right to donate blood has not been recognized by courts or legislatures in the United States. *Raso v. Moran*, 551 F. Supp. 294, 297 (D.R.I. 1982) ("The plaintiff does not, and indeed could not, contend that he maintains a liberty interest in giving blood that is based on the Constitution itself."); *see also* *Bishop v. Ventetuolo*, C.A. No. 90-0497B, 1991 U.S. Dist. LEXIS 19307, at *9 (D.R.I. Dec. 5, 1991) (holding that where a prisoner participates in a blood donation program so that his sentence is reduced by ten days for each pint of blood donated, his "expectation [of continued participation] amounts to a protected liberty interest in the donation of blood. Before an inmate can be denied the opportunity to participate in the blood donation program, he must be provided notice, an opportunity to submit written evidence as to his health, status, and a statement of reasons for his disqualification from the program.").

Creutzfeldt-Jakob disease (nv-CJD), now referred to as variant-CJD (vCJD),¹²³ the FDA imposed restrictions on blood donation by individuals who spent more than six months in the United Kingdom between 1980 and 1997.¹²⁴ These restrictions have eliminated up to 4% of eligible blood donors in certain states.¹²⁵ The FDA imposed these restrictions despite a lack of evidence supporting them as an appropriate prevention: only ninety definite cases of vCJD have been diagnosed, eighty-seven of which were in the United Kingdom.¹²⁶ None of the reported cases resulted from exposure to blood products; in fact vCJD has been transmitted by blood only in experimental circumstances using animal subjects and direct injection.¹²⁷ Transmission was

123. Variant CJD is caused by the same infectious agent, prion protein, as that which causes bovine spongiform encephalopathy (BSE) or mad cow disease. See Litjen Tan et al., *Risk of Transmission of Bovine Spongiform Encephalopathy to Humans in the United States: Report of the Council on Scientific Affairs*, 281 JAMA 2330–39 (1999); see also Center for Biologics Evaluation and Research, *Draft Guidance: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products*, at 1 (Aug. 2000), available at <http://www.fda.gov/cber/gdlns/cjdvcjd.pdf> (last visited Oct. 8, 2001).

124. Scott Gottlieb, *FDA Bans Blood Donation By People Who Have Lived in UK*, 319 BRIT. MED. J. 535 (1999). Restrictions are in place to prevent against the spread of other blood borne diseases. See *supra* text accompanying notes 24–27. On August 27, 2001 the FDA issued revised draft guidance “intended to further reduce the risk of transmission of [vCJD] to recipients of blood and blood products.” Press Release, Food and Drug Administration, FDA Issues Draft Guidance to Further Reduce the Possible Risk of Transmission of Variant Creutzfeldt-Jakob Disease By Blood and Blood Products (Aug. 27, 2001), available at <http://www.fda.gov/bbs/topics/NEWS/2001/NEW00768.html> (last visited Oct. 8, 2001) [hereinafter Draft Guidance Press Release]. The revised guidance recommends changes to be implemented by May 31, 2002 to “expand the donor deferrals that have been recommended since August 1999 for donors who have lived or traveled in the U.K.” *Id.* The proposed changes include deferral of donors who (1) have spent three or more cumulative months in the U.K. from 1980 through the end of 1996; (2) were stationed at U.S. military bases in Europe from 1980 through 1996; (3) have lived for a cumulative period of five years or more in France since 1980; or (4) received a blood transfusion in the U.K. at any time since 1980. *Id.* at 1–3. The additional deferral of individuals who have lived for a cumulative period of five years or more in other countries in Europe since 1980, would take effect on October 31, 2002. *Id.* at 3. The FDA recommends implementation of the deferral criteria despite the fact that “vCJD is not known to have been transmitted by blood transfusion.” *Id.* at 1.

125. Tuhus, *supra* note 68.

126. Paul Brown et al., *Bovine Spongiform Encephalopathy and Variant Creutzfeldt-Jakob Disease: Background, Evolution, and Current Concerns*, 7 EMERGING INFECTIOUS DISEASE 6, 11 (2001) (Two cases of vCJD were confirmed in France and one case was confirmed in the Republic of Ireland.); see also Tan et al., *supra* note 123, at 2335 (“Although WHO and the EU state that transmission of CJD via blood cannot currently be confirmed and too few data on nv-CJD exist to make recommendations, they advocate exclusion of blood donation by people who have or are at risk for CJD.”).

127. See Draft Guidance Press Release, *supra* note 124, at 1; see also Gottlieb, *supra* note 124, at 535; F. Houston et al., *Transmission of BSE by Blood Transfusion in Sheep*, 356 THE LANCET 999, 1000 (2000).

reported when vCJD was injected into mice brains,¹²⁸ and when whole blood was transfused from an infected sheep to a previously uninfected sheep.¹²⁹

The FDA has adopted “an extremely conservative approach to guidelines on blood and blood products.”¹³⁰ Although no cases of transfusion-transmitted vCJD have been reported or are believed to have occurred, and there is a total “lack of data on vCJD transmission via plasma,” the FDA proscribed donation from people who might be at risk of acquiring vCJD.¹³¹ According to researchers, the limited threat posed by vCJD is “in public health terms . . . compelling enough to warrant action by relevant US authorities.”¹³²

The cautious approach to public health policy and regulation in the United States is unlikely to change as demonstrated by the recent campaign by scientists and gay activists to change the restrictions on blood donation by MSM. A scientific advisory panel of the FDA on September 15, 2000 voted seven to six against changing the rule banning blood donation from men who have had sex with another man since 1977, to a ban on MSM contact within the five years prior to donation.¹³³ The panelists who voted against the rule change, however, urged scientists to study any potential effects of the proposed changes in policy.¹³⁴ Although only an estimated 8% of MSM in the United States are HIV-positive, male-male sexual contact still is considered “a leading risk factor for HIV infection” in the United States.¹³⁵ MSM contact is considered a significant risk factor in part because “[d]espite the current questioning of donors and use of exclusion criteria, a study of nineteen large U.S. blood centers revealed that 43% of all donations discarded because they were HIV-positive came from men who reported a history of male-male sexual contact.”¹³⁶ Epidemiologists assert that these data “support the need to continue interviewing potential donors about behavior that presents a risk of HIV transmission.”¹³⁷ Scientific advisors to the FDA thus did

128. Gottlieb, *supra* note 124, at 535.

129. Houston et al., *supra* note 127, 1000.

130. Tan et al., *supra* note 123, at 2338.

131. *Id.* at 2335.

132. *Id.*

133. *FDA Panel, supra* note 4.

134. *Id.*

135. Eve M. Lackritz et al., *The Risk of HIV Transmission By Screened Blood*, 334 NEW ENG. J. MED. 992, 993 (1996).

136. *Id.*

137. *Id.*

not consider the risk of HIV transmission minimal enough to change policy. In the United States, to justify a public health regulation, the risk of harm may be quite limited so long as the consequence is significant. Because blood transfusion is a highly effective means of transmitting HIV, and MSM contact is a significant risk factor for HIV, blood donations by MSM are proscribed although the chance of such a transmission occurring is rare.¹³⁸

B. Canada

The AIDS epidemic emerged in Canada at roughly the same time as in the United States. In 1982, when over 400 cases of AIDS had been diagnosed in the United States, only eight cases had been identified in Canada, the majority of which resulted from homosexual transmission.¹³⁹ In subsequent years, the number of afflicted individuals dramatically increased, as did the number of individuals who were infected by blood transfusion.¹⁴⁰

In 1983, the Canadian Hemophilia Society's Medical and Scientific Advisory Committee (MSAC) issued recommendations to the Red Cross Blood Transfusion Service of Canada (CRCBTS) "to reduce the risk of AIDS in the blood supply."¹⁴¹ That same year, the Canadian Red Cross Society (CRCS), organized under the League of Red Cross Societies (League),¹⁴² publicly asked "homosexual and bisexual men with multiple partners to abstain from giving blood, along with newly arrived Haitian immigrants and intravenous drug users."¹⁴³ Although the CRCS's appeal was a targeted intervention following

138. See Gostin, *supra* note 55, at 94–95.

139. PICARD, *supra* note 62, at 57.

140. *Id.* at 57–60.

141. *Id.* at 72. The recommendations read as follows:

a) serious efforts should be made to exclude blood donors who might transmit AIDS, including: 1) an education campaign to promote self-exclusion by donors belonging to high-risk groups, such as male homosexuals and Haitian immigrants, with the cooperation of the leadership of these groups; 2) specific questions on the blood donor questionnaire to detect symptoms associated with AIDS, such as swollen lymph glands, night sweats or unexplained fever or weight loss; 3) evaluation and implementation of laboratory tests that would identify individuals at high risk of AIDS transmission.

Id.

In Canada at this time, and until 1987, the Canadian Red Cross Society and under its administration the CRCBTS were run as voluntary organizations independent of government regulation or intervention. 1 THE HONORABLE MR. JUSTICE HORACE KREVER, FINAL REPORT, COMMISSION OF INQUIRY ON THE BLOOD SYSTEM IN CANADA 51 (1997) [hereinafter KREVER REPORT].

142. *Id.*

143. PICARD, *supra* note 62, at 73.

MSAC protocol—the groups targeted were high risk: 61% of diagnosed AIDS cases were among homosexual men, and 37% were among Haitian immigrants—response to the CRCS was highly critical.¹⁴⁴ Gay and Haitian organizations filed discrimination complaints and boycotted clinics, emphasizing civil rights concerns rather than blood safety.¹⁴⁵ The CRCS ultimately withdrew from the donor self-exclusion questionnaires any question addressing whether a potential donor had engaged in high risk practices, or whether they suffered from any symptom resembling HIV or AIDS.¹⁴⁶ The only diagnostic question permitted was “Are you well?”¹⁴⁷ The CRCS withdrew its interventions to comply with the League’s principles of impartiality and neutrality. The principles proscribe discrimination “against individuals on the basis of their race or nationality or [causing] controversy about a group of people.”¹⁴⁸

Physicians and lawyers affiliated with the CRCS reacted strongly against the drafting of a questionnaire that ignored risk factors for the disease in order to conform with League anti-discrimination principles. Michael Worsoff, the lawyer for the CRCS, was asked at a March 29, 1983 meeting of the AIDS Working Group, “What would be the legal aspects if an issue is made of the right of donors to give blood?”¹⁴⁹ He responded:

It is not a matter of the donor having a right to donate blood. Rather, it is a case of the Red Cross having both a moral and legal obligation to assure the safety of the blood it accepts for processing and distribution. The evidence of possible unacceptability of the blood does not have to be conclusive, the decision can be made on a basis of ‘reasonable doubt’ as to its suitability. With reference to the AIDS problem in particular, the premise is not that the CRC has to justify beyond any scientific doubt that there is a link between designated ‘high risk groups’ and the development of AIDS since, if there is even a possibility of transmission via blood, the CRC has the moral and legal obligation to protect the recipient above all.¹⁵⁰

Despite Worsoff’s legal advice, which favored protecting the blood supply and using appropriate screening criteria, the CRCS ultimately decided to use questionnaires that did not mention AIDS, associated

144. *Id.*

145. *Id.* at 74.

146. *Id.* at 75.

147. *Id.*

148. KREVER REPORT, *supra* note 141, at 50–51.

149. PICARD, *supra* note 62, at 75.

150. *Id.*

symptoms, or known risk factors.¹⁵¹ Although doctors implemented screening measures independent of CRCS, it was not until 1985 that the CRCS implemented prevention mechanisms, including donor screening, and changed the questionnaires to “include symptom-specific questions.”¹⁵² Surrogate screening, using Hepatitis B test results to predict HIV positivity, was never among the measures implemented in Canada.¹⁵³ By this time, however, HIV had permeated the blood supply. HIV seroprevalence was 56% among hemophiliacs in Montreal; this number increased to 74% by 1988.¹⁵⁴ A study of blood donors in Toronto estimated HIV seropositivity at 0.37%—one out of every 370 donors may have been infected.¹⁵⁵ Because of the CRCS’s delay in implementing prevention strategies, between 900 and 1400 individuals who received blood transfusions were infected with HIV.¹⁵⁶

The measures implemented by the CRCS in 1985 were less stringent and direct than those adopted in the United States and the United Kingdom, countries to which the Canadian government refers for comparative practice.¹⁵⁷ Prospective donors were required to read a pamphlet that provided information about the risk factors and symptoms of HIV/AIDS.¹⁵⁸ They were then interviewed “to ensure that they read the information presented to them, were in good health, had no symptoms of AIDS or HIV infection, and had no reason to be excluded They were not asked expressly about their sexual and drug-using activities.”¹⁵⁹ These measures in combination with serological screening implemented in late 1985 have reduced the risk of transfusion-related transmission of HIV.¹⁶⁰

Prior to 1989, “standards of health and safety and of quality assurance in the collection, testing, processing, storage, and distribution of whole blood and its components were in the hands of the operator

151. *Id.*

152. *Id.* at 82; *see also* Gilmore & Sommerville, *supra* note 73, at 134.

153. Michael Trebilcock et al., *Do Institutions Matter? A Comparative Pathology of the HIV-Infected Blood Tragedy*, 82 VA. L. REV. 1407, 1446 (1996).

154. Gilmore & Sommerville, *supra* note 73, at 132; *see also* Kate Dunn, *HIV and Canada’s Hemophiliacs: Looking Back at a Tragedy*, 148 CAN. MED. ASSOC. J. 609 (1993).

155. Gilmore & Sommerville, *supra* note 73, at 133.

156. *Id.* at 141.

157. *Id.* at 134–35.

158. *Id.* at 135.

159. *Id.*

160. *Id.*

of the blood system,” the CRCS.¹⁶¹ In 1989, however, the Canadian government brought blood and its components under the jurisdiction of the Food and Drugs Act (FD Act) by labeling blood a Schedule D substance.¹⁶² Despite the incorporation of blood into Schedule D, regulations that had been in place since 1978 governing “human plasma collected by plasmapheresis” in Division 4 of the FD Act were not extended to cover whole blood.¹⁶³ Currently, “there are . . . no regulations that relate only to the collection, processing, and distribution of whole blood or . . . plasma.”¹⁶⁴ Whole blood products and plasma are subject only to the general requirements applicable to Schedule D substances and “drugs manufactured from ‘preparations from human sources.’”¹⁶⁵ Schedule D regulations require that raw material (blood) and the ultimate blood to be transfused be tested as specified, and be subject to “manufacturing and quality control; the institution of rapid recall procedures; and the maintenance of comprehensive records.”¹⁶⁶

Even as blood was brought under the jurisdiction of the FD Act in 1989, Canada lacked a national blood policy, and previous efforts to institute a national policy had been abandoned.¹⁶⁷ The position of the Red Cross in the Canadian blood system was ill defined, as were the relationships between the CRCS and the provincial governments, which contracted with the CRCS for blood service.¹⁶⁸ In 1991 the Canadian Blood Committee (CBC), which coordinated, monitored, evaluated, and administered the funding for the blood system on behalf of provincial and territorial governments, was replaced by the

161. KREVER REPORT, *supra* note 141, at 116. Schedule D status referred explicitly to blood derivatives or products created with or from plasma, as opposed to whole blood or blood components. *Id.* at 146.

162. *Id.* at 129.

163. *Id.* at 130. The requirements promulgated in Division Four on plasmapheresis carefully prescribe all aspects of the donation process, including donor eligibility requirements. Food and Drugs Act, C.R.C., ch. 870, §§ 04.404, 04.406 (2001) (Can.). Plasmapheresis is a process in which whole blood is taken from a donor through a cell separator. After the plasma is extracted from the blood donation by a centrifuge, the donor’s heme is reinjected. Trebilcock et al., *supra* note 153, at 1421.

164. KREVER REPORT, *supra* note 141, at 132.

165. *Id.*

166. *Id.* at 147.

167. 3 THE HONORABLE MR. JUSTICE HORACE KREVER, FINAL REPORT, COMMISSION OF INQUIRY ON THE BLOOD SYSTEM IN CANADA 1002 (1997) [hereinafter 3 KREVER REPORT].

168. *Id.* at 1003.

Canadian Blood Agency (CBA).¹⁶⁹ The CBA, a non-profit corporation, administers and oversees the Canadian blood program.

All of these changes in the institutional structure of the Canadian blood program were accompanied reluctantly by changes within the CRCS; standard operating procedures were developed and implemented for the recruitment of blood donors and manufacturing practices.¹⁷⁰ These changes might have been initiated in part in response to a U.S. FDA inspector's determination that "operation of the CRCS Toronto blood center fell short of [U.S.] FDA standards on nineteen counts [including] the failure to conduct complete searches for possible sources of HIV infection."¹⁷¹ CRCS facilities sought to comply with U.S. FDA standards in order to be eligible to export Canadian manufactured blood products to the United States.¹⁷² Despite the CRCS's reorganization, in 1997, the Canadian Ministers of Health decided "that the Red Cross [CRCS] should no longer have a role in Canada's blood system."¹⁷³ The decision was based ultimately on the fact that the "Red Cross's necessary adherence to the principles of the international Red Cross movement prevented it from subordinating itself to government policy and direction."¹⁷⁴

The Canadian donor self-exclusion questionnaire currently in use, the Record of Donation Questionnaire, adopts a conservative approach to constructing exclusionary criteria. Canada, like the United States, proscribes blood donation by individuals who have lived for six months or longer in the United Kingdom and in France, and proscribes donations by injection drug users, individuals from high endemic areas, individuals who have taken clotting factor concentrate for hemophilia or other blood disorders, and by men who have had "sex with a man, even once since 1977."¹⁷⁵ The Record of Donation Questionnaire also has several questions targeting female sexual practices that increase risk of infection. For example, females are prohibited from donating blood if they have had sex with men who have had sex with other men since 1977, or have had sex with an

169. *Id.* at 1004; *see also* Trebilcock et al., *supra* note 153, at 1426.

170. 3 KREVER REPORT, *supra* note 167, at 1005.

171. Trebilcock et al., *supra* note 153, at 1449.

172. U.S. federal regulations require that foreign entities seeking to export blood products to the United States comply with U.S. standards. *See* 21 C.F.R. § 607.40 (2000).

173. 3 KREVER REPORT, *supra* note 167, at 1021.

174. *Id.*

175. Record of Donation Questionnaire, *available at* http://www.bloodservices.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/9749ca80b75a038585256aa20060d703/ef7f6ef3dabf8d2785256ab9005caa3c?OpenDocument (last updated Sept. 26, 2001).

injection drug user, or an individual from a high endemic area.¹⁷⁶ These exclusionary criteria are tailored to the epidemiology of HIV transmission in Canada: 72% of all reported AIDS cases as of December 1998 were caused by homosexual infection.¹⁷⁷ Seventy-seven percent (77%) of HIV infections in men were caused by homosexual or bisexual transmission, while 4% were caused by injection drug use and 3% were caused by blood transfusions. Of HIV infections in women, 63% of cases were caused by heterosexual contact, 20% were caused by injection drug use, and 11% by blood transfusions.¹⁷⁸ By drafting exclusionary criteria that target the risk factors for HIV infections, the Canadian blood system effectively has reduced the risk of transfusion-transmitted HIV infection.

C. Denmark

Doctors in Denmark were aware as early as 1982 that AIDS could be transmitted by blood transfusion.¹⁷⁹ Because of the centralized nature of the health care administration and delivery system in Denmark, preventative measures were initiated and implemented quickly to minimize the risk of HIV/AIDS transmission.¹⁸⁰

Denmark, like most European Union countries, recognizes a right to health and health care, derived from both historical national practice and international law.¹⁸¹ Since 1892, Denmark has provided

176. *Id.*

177. JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS & WORLD HEALTH ORGANIZATION, EPIDEMIOLOGICAL FACT SHEET ON HIV/AIDS AND SEXUALLY TRANSMITTED INFECTIONS, 2000 UPDATE, CANADA, at 6 (2000), available at http://www.unaids.org/hivaidsinfo/statistics/june00/fact_sheets/pdfs/canada.pdf (last visited Oct. 5, 2001).

178. *Id.*

179. Erik Albæk, *The Never-Ending Story? The Political and Legal Controversies over HIV and the Blood Supply in Denmark*, in BLOOD FEUDS: AIDS, BLOOD, AND THE POLITICS OF MEDICAL DISASTER 162, 164 (Eric A. Feldman & Ronald Bayer eds., 1999).

180. Jason B. Saunders, Note, *International Health Care: Will the United States Ever Adopt Health Care For All? A Comparison Between Proposed United States Approaches to Health Care and the Single-Source Financing Systems of Denmark and the Netherlands*, 18 SUFFOLK TRANSNAT'L L. REV. 711, 716 (1995).

181. Several treaties recognize a general right to health. See generally U.N. CHARTER, art. 55; CONST. OF THE WORLD HEALTH ORG., opened for signature July 22, 1946, pmbl., 14 U.N.T.S. 185, 186; International Covenant on Economic, Social, and Cultural Rights, Sept. 19, 1966, art. 12, 993 U.N.T.S. 3, 8; Convention on the Rights of the Child, Sept. 2, 1990, art. 24, 1577 U.N.T.S. 3, 10. The Universal Declaration of Human Rights contains some of the strongest language expressing a right to health.

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness,

compulsory sickness insurance to citizens; by 1960, 75% of the Danish population was covered under national health insurance policy.¹⁸² In 1971, Denmark abolished independent service health care providers, consolidating insurance in a single national provider system. This reform “allowed municipal authorities to take over the administration of the system, which provided automatic membership for all inhabitants financed through a graduated tax system.”¹⁸³

In July 1983, the NBH officially recommended that men who engage in sexual activity with other men, or who identify themselves as homosexuals, not donate blood.¹⁸⁴ This recommendation was revised in September 1983; NBH requested that “people in high-risk groups and their sexual partners exclude themselves as donors.”¹⁸⁵ The limited pre-donation screening was supplemented by blood donation screening for hepatitis B, as a surrogate marker for AIDS.¹⁸⁶ In 1985, NBH implemented measures requiring donors to read an AIDS information pamphlet and to sign a statement that they did not belong to any of the enumerated risk groups.¹⁸⁷

Prior to 1985, only one case was reported of an HIV-positive individual donating blood in Denmark. The donor was a self-identified homosexual man who gave blood three times between June 1983 and May 1984.¹⁸⁸ All of the recipients of the infected blood died of primary diseases.¹⁸⁹ However, despite Denmark’s efforts to protect the

disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

Universal Declaration of Human Rights, Dec. 10, 1948, art. 25, G.A. Res. 217A(III), U.N. Doc. A/810, at 71.

182. Saunders, *supra* note 180, at 716.

183. *Id.* at 717.

Denmark’s national health care system is divided into nineteen ministries, as well as additional departments and subspecialty units. *Id.* at 726 n.63. The National Board of Health (NBH) advises the ministries on health matters. *Id.* This agency’s authority exceeds advisory status, as it exerts control over subspecialty and policy development. *Id.* Furthermore, its policy recommendations are compulsory. *Id.*

184. Albæk, *supra* note 179, at 164.

185. *Id.* at 165.

186. M.P. Busch et al., *Value and Cost-Effectiveness of Screening Blood Donors For Antibody To Hepatitis B Core Antigen as a Way of Detecting Window-Phase Human Immunodeficiency Virus Type 1 Infections*, 37 *TRANSFUSION* 1003, 1003 (1997) (finding that “the value of screening donors for antibody to hepatitis B core antigen (anti-HBc)” because of its “low yield and very poor cost-effectiveness . . . indicates that this test is not an effective screening test for HIV-1 . . . donations”).

187. Albæk, *supra* note 179, at 165.

188. *Id.* at 171.

189. The term primary disease refers to a cause of death independent of HIV, for example lung cancer or heart failure.

blood supply from transfusion-related HIV transmission, contaminated blood products imported from the United States and other countries had caused the infection of eighty-nine hemophiliacs.¹⁹⁰ A study published in the British journal *The Lancet* estimated that 64% of Danish hemophiliacs were HIV-positive by 1984.¹⁹¹ The prevalence of HIV among hemophiliacs, as well as reports of blood transfusions of infected blood, caused widespread discontent with Danish blood policy.¹⁹² In late 1985, the NBH mandated that HIV antibody screening of blood donations be implemented as a matter of urgency starting January 1, 1986.¹⁹³

Many hemophiliacs, physicians, and activist groups aver that the NBH should have introduced prevention measures, including screening and heat treatment of blood products for hemophiliacs, much earlier than 1986.¹⁹⁴ However, despite extensive litigation, the conduct of NBH and its ministers was not found to have been negligent by Denmark's High Court or Supreme Court.¹⁹⁵ As a result of the litigation, Denmark and its health system have implemented extensive measures with respect to the safety of blood and blood products. Since 1986, all blood, sperm, and organ donors have been screened.¹⁹⁶

Denmark has the highest rates per capita of HIV infection and AIDS in Scandinavia, and a moderate rate per capita compared to other European countries.¹⁹⁷ UNAIDS estimates that in 1999, 0.17% of the Danish population, or 4,300 individuals, were living with HIV/AIDS.¹⁹⁸ The measures implemented since 1986 have been successful in preventing HIV contamination of the blood supply and

190. *Id.* at 182.

191. *Id.* at 166.

192. *Id.*

193. *Id.* at 173.

194. *Id.*

195. *See id.* at 175–83. (Cases included *Gentofte Kriminalrets dom af 29.11.1989 i sag 443/1988* (Den.); *Case of A. and Others v. Denmark*, 22 Eur. Ct. H.R. 456 (1996) (60/1995)).

196. Annika Snare, *The Legal Treatment of AIDS in Denmark*, in *AIDS AND HUMAN RIGHTS: AN INTERNATIONAL PERSPECTIVE* 34, 36 (1988).

197. The rates per capita as estimated by Joint United Nations Programme on HIV/AIDS & World Health Organization are Sweden 0.09%; Norway 0.07%; Netherlands 0.19%; France 0.43%; and Spain 0.58%.

198. JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS & WORLD HEALTH ORGANIZATION, EPIDEMIOLOGICAL FACT SHEET ON HIV/AIDS AND SEXUALLY TRANSMITTED INFECTIONS, 2000 UPDATE, DENMARK, at 3 (2000), available at http://www.unaids.org/hiv/aidsinfo/statistics/june00/fact_sheets/pdfs/denmark.pdf (last visited Nov. 2, 2001) [hereinafter Denmark Fact Sheet].

transfusion-related transmissions. By 1988, the exclusionary criteria on the blood donor questionnaire had been expanded to include prohibitions on blood donations by MSM, bisexual men, intravenous drug users, prostitutes, individuals who have resided in “Africa, India, South-East Asia or South America,” or individuals who have had intercourse with any people within these categories, or suffered from various illnesses.¹⁹⁹ The use of this questionnaire significantly reduced the risk of transfusion-related transmission of HIV; by 1988, the transfusion-related transmission rate was less than one per 400,000.²⁰⁰

The risk of transfusion-related transmission was reduced by use of the pre-donation questionnaire in combination with HIV screening because the questionnaire was tailored to the epidemiological situation in Denmark.²⁰¹ In Denmark, 66% of men with HIV are infected through homosexual contact, 19% by heterosexual contact, and 9% through intravenous drug use.²⁰² Sixty-three percent (63%) of women are infected by heterosexual contact, 13% of whom are infected by bisexual men.²⁰³ A study conducted during 1986–1988, just after implementation of pre-donation and serological screening programs, found that out of 1,200,000 donations, only nineteen donors were HIV-positive.²⁰⁴ Nine of these nineteen donors, or 47%, had risk factors for HIV infection that should have precluded them from donat-

199. Denmark Blood Donor Questionnaire (Henrik Hensen, trans.), available at <http://www.bloddonor.dk> (last visited Nov. 2, 2001).

200. Kirsten W. Schmidt & Ebbe Dickmeiss, *Screening af donorblod for anti-HIV. Erfaringer fra bloddonorscreeningen 1986–1988* [Screening of donor blood for anti-HIV. Experiences from blood donor screening 1986–1988], 152 UGESKR LAEGER 2552 (1990) (Den.). More recent statistics were not available.

201. The Danish blood donation standards closely resemble “the standards laid down in the 7th edition of the Guidelines [for the selection of blood donors], produced by the Council of Europe.” E-mail from Niels Mikkelsen, Secretary General, Blood Donors in Denmark (Mar. 8, 2001, 03:23:28 EST) (on file with the Duke Journal of Comparative and International Law). Systematic screening of blood donations is practiced in all European Union Member States, and is required by law in Belgium, France, Germany, Norway, and other countries. Reviron et al., *supra* note 99, at 25.

202. Else Smith & Mads Melbye, *Det førsteårs erfaringer med et indberetningssystem for HIV-positive i Danmark* [First year experience with a system of mandatory reporting of HIV-positive cases in Denmark], 154 UGESKR LAEGER 2196 (1992) (Den.); see also Denmark Fact Sheet, *supra* note 198, at 6 (finding the rates of infection virtually unchanged: among men with AIDS, 66.2% were infected through homosexual contact, 17.7% through heterosexual contact, and 8.6% through injection drug use; among women with AIDS, 65.6% were infected through heterosexual contact, 21.3% through injection drug use, and 2.5% through perinatal transmission).

203. Denmark Fact Sheet, *supra* note 198, at 6.

204. Schmidt, *supra* note 200, at 2552.

ing.²⁰⁵ Denmark's pre-donation self-exclusion questionnaire is tailored to screen out individuals who pose a significant risk of transmitting HIV. As long as individuals self-exclude, the use of this questionnaire will continue to contribute to the reduced risk of transfusion-related transmission of HIV in Denmark.

D. Australia

AIDS was first diagnosed in Australia between 1981 and 1982.²⁰⁶ In Australia, as in Canada, the United States, and Denmark, the disease initially affected the homosexual population. By 1984, up to 50% of homosexual men in Sydney were seropositive.²⁰⁷ As is characteristic of a Pattern One country, HIV/AIDS only later spread among intravenous drug users and then minimally among the heterosexual population.²⁰⁸ Of the estimated 14,000 individuals currently living with HIV/AIDS in Australia, only 900 are women, 19.1% of whom acquired HIV through transfusions of blood or other blood products.²⁰⁹ Eighty-four percent (84%) of men diagnosed with AIDS through 1998 were homosexual or bisexual.²¹⁰ Since 1984-1985, HIV transmission and incidence have declined overall; even today, new infections continue to be diagnosed predominately among homosexual and bisexual males.²¹¹

Australia has been one of the most proactive of the developed countries in formulating legislative policies to address HIV/AIDS. Because Australian regulation occurs on both the provincial and state level, Australian policies concerning the control and prevention of HIV transmission and infection have been less uniform than those of

205. *Id.*

206. John Ballard, *HIV-Contaminated Blood and Australian Policy: The Limits of Success*, in *BLOOD FEUDS: AIDS, BLOOD, AND THE POLITICS OF MEDICAL DISASTER* 244, 244 (Eric A. Feldman & Ronald Bayer eds., 1999).

207. Geoffrey Walker, *Australia's Response to AIDS: The Law and the Policy Issues*, in *LEGAL RESPONSES TO AIDS IN COMPARATIVE PERSPECTIVE* 169, 169 (Stanislaw Frankowski ed., 1998).

208. JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS & WORLD HEALTH ORGANIZATION, EPIDEMIOLOGICAL FACT SHEET ON HIV/AIDS AND SEXUALLY TRANSMITTED INFECTIONS, 2000 UPDATE, AUSTRALIA, at 3 (2000), available at http://www.unaids.org/hiv/aidsinfo/statistics/june00/fact_sheets/pdfs/australia.pdf. (last visited Oct. 10, 2001).

209. *Id.* at 3.

210. *Id.* at 6.

211. Walker, *supra* note 207, at 170.

other countries, notably the United Kingdom.²¹² Australia is a Commonwealth comprised of states and territories. Thus, while a “Commonwealth statute . . . creates uniform law on its respective subject matter throughout Australia . . . the Commonwealth has had only limited involvement in public health law and a great deal of the relevant regulation exists at the State and Territory level.”²¹³ The division of legislative oversight “between the Commonwealth, States and Territories has been identified as a major barrier to achieving ‘best practice’ health care.”²¹⁴ Despite this division, there has been “a substantial amount of cooperation and collaboration between State and Commonwealth health officials” on HIV and related issues.²¹⁵ The cooperation between state and Commonwealth governments and the resulting rapid legislative action addressing HIV/AIDS is due in part to the fact that the government was largely responsible for managing and maintaining the blood supply in the 1980s.²¹⁶ The Australian Blood Transfusion Services (ABTS) was operated under the auspices of the Australian Red Cross Society, but was coordinated and maintained by the National Blood Transfusion Committee (NBTC).²¹⁷ Subsequent to 1976, Australian federal and state governments shared the capital costs of ABTS: “operating costs were met 60% by state governments, with the Red Cross contributing the lesser of 5% of costs . . . and the balance covered by the federal government.”²¹⁸ The Commonwealth or federal government is involved in health care finance, but the primary responsibility for providing health services in Australia rests with the six state and two territorial governments.²¹⁹ Thus, when the threat of HIV was found in the Australian blood supply and in Australian-manufactured blood products, the state governments quickly took action, testing blood and implementing prevention protocols.²²⁰

212. Marlene C. McGuirl & Robert N. Gee, *AIDS: An Overview of the British, Australian, and American Responses*, 14 HOFSTRA L. REV. 107, 113 (1985).

213. Brian R. Opeskin, *The Architecture of Public Health Law Reform: Harmonisation of Law in a Federal System*, 22 MELB. U. L. REV. 337, 338 (1998).

214. *Id.*

215. McGuirl & Gee, *supra* note 212, at 113.

216. Ballard, *supra* note 206, at 244.

217. *Id.* at 245.

218. *Id.* at 246.

219. *Id.*

220. *Id.* at 244. The first documented case of transfusion transmitted HIV was reported in July 1984. *See id.* at 250.

In May 1983, Dr. Gordon Archer, director of the Sydney Blood Transfusion Services, “called publicly for homosexual men to avoid donation.”²²¹ Archer’s statement was the first public announcement identifying high risk groups in Australia and was met with protest from homosexual interest groups in Sydney.²²² However, Archer’s recommendation was not unfounded; seroprevalence among homosexual men in Sydney had reached 50%.²²³ Through 1997, the majority of HIV cases in Australia had occurred amongst homosexual and bisexual men, accounting for 80.3% of infections; another 3.1% of infected homosexual and bisexual men have intravenous drug use as a possible risk factor.²²⁴ Because NBTC concluded that Archer’s recommendations were justified by the epidemiology of HIV transmission in Australia, it began to take steps towards creating a formal screening questionnaire in the form of “information sheets with similar wording . . . issued at donation centers asking for abstention by sexually active homosexual or bisexual men with multiple partners, intravenous drug users, and sexual partners of these people.”²²⁵ Rather than adopting a national protocol, however, each state’s blood transfusion services (BTS) accepted responsibility for implementing its own preventative measures.²²⁶ None of the BTS at that time “proceeded to introduce screening measures beyond the distribution of pamphlets to donors, relying on voluntary self-exclusion.”²²⁷ The delay in implementation among the state BTS was due partly to pressure from gay activists who alleged that the proposed measures were discriminatory.²²⁸ The delay in implementation, however, adversely affected blood supply protection: in the early 1980s, Australia had a rate of transfusion-transmitted HIV/AIDS up to five times higher than that of the United States.²²⁹

In July 1984, the first case of transfusion-transmitted HIV was reported in Australia.²³⁰ Almost immediately more stringent measures were implemented to protect blood supplies from HIV and other

221. *Id.* at 249.

222. *Id.*

223. Walker, *supra* note 207, at 169.

224. *Id.* at 169–70.

225. Ballard, *supra* note 206, at 249. In Victoria, the inclusion of the qualifier multiple partners led to litigation.

226. *Id.*

227. *Id.* at 250.

228. *Id.*

229. Walker, *supra* note 207, at 172. The actual numbers are not available.

230. Ballard, *supra* note 206, at 250.

virus contamination. The Sydney BTS mandated that donors sign a form declaring that “they were not a member of a high-risk group.”²³¹ Hepatitis B testing also was begun as a surrogate test for HIV, though this later was found to be ineffective.²³² At this time, few other states in Australia had adopted measures as extensive as those adopted in Sydney, although the categories of donors precluded from blood donation had been expanded.²³³

Three more cases of transfusion-transmitted HIV were reported in Queensland in mid-November 1984. All three of the cases involved infants who died after receiving infected blood donated by an HIV-positive homosexual.²³⁴ The Queensland government responded by passing legislation that imposed “criminal sanctions for false declarations by [blood] donors.”²³⁵ In reaction to this action by the Queensland government, the Australian Commonwealth Minister of Health decided to create a uniform national policy on blood donation so as to coordinate the various state practices.²³⁶

The policy measures adopted in Australia are enforced by criminal law. Legislation has been enacted that renders “false or misleading declarations by blood donors an offense punishable by fine or imprisonment.”²³⁷ Blood will not be accepted from blood donors unless they sign a statement concerning their involvement in “high risk” activities.²³⁸ This legislation and other preventative measures adopted in

231. *Id.*

232. *Id.* at 251 n.21. Dr. Ian Gust tested sera from 601 people who had tested positive to hepatitis B core antigen and found no evidence of HIV infection.

233. *Id.* at 251.

234. *Id.* at 252.

235. *Id.*; see also Walker, *supra* note 207, at 207. Although such legislation initially was widely criticized, it has gained increasing acceptance. In the United States, for example, between 1987 and 1989, twenty states enacted legislation criminalizing behaviors which constituted a significant risk for transmitting HIV.

236. Ballard, *supra* note 206, at 252.

237. *Id.* at 253–54. (“Although several HIV-positive donors were found to be aware of their risk status, there were no prosecutions [under the Australian legislation] until a case arose in 1993 in Victoria, leading to conviction, in which there was public evidence that the donor was aware of being HIV-positive.”).

238. See Human Tissue Act, 1983 (N.S.W.), as amended by Regulation No. 308 of 1986 (N.S.W.), reprinted in WORLD HEALTH ORGANIZATION, LEGISLATIVE RESPONSES TO AIDS 4–6 (1989). Form 3 (§ 21 c) states, “There are some people in the community who MUST NOT donate blood because their blood may transmit infection to patients who receive it. Prostitutes should not donate blood. The following certificate must be completed and signed by any person who wishes to donate blood. Please read it carefully as it is an offence knowingly to sign a certificate which contains any statement which is false or misleading and any person who does so is liable to a heavy penalty.” *Id.* Included among the statements on the certificate is the following: “3. I have not engaged in male to male sexual activity since 1980.” *Id.*; see also WORLD

Australia, such as the extensive pre-donation donor exclusion questionnaire, have proven highly effective in preventing transfusion-related transmission of HIV.²³⁹ From April 1985 to December 1996, “out of 11 million blood donations tested for HIV-1-antibody, [only] 87 were found to be positive.”²⁴⁰ The effectiveness of these measures is due in large part to the fact that the questionnaires are tailored to Australia’s epidemiological situation. The known residual risk of acquiring HIV through a blood transfusion in Australia is 7.9×10^{-6} (7.9 per million),²⁴¹ substantially less than the risk in the United States, in 1991, of less than 20 per million.²⁴² Since 1985, there have been no reported instances of transfusion associated HIV in Australia.²⁴³

E. Uganda

Uganda was one of the first sub-Saharan African countries in which AIDS was reported,²⁴⁴ and also has been one of the countries hardest hit by the epidemic.²⁴⁵ Because of the large numbers of deaths due to HIV/AIDS, “demographers project that [by the year 2010] life expectancy will fall from . . . 59 to 31 years in Uganda.”²⁴⁶

Although HIV/AIDS has taken a substantial social and economic toll on Uganda, Uganda “has been sited [sic] as the success story in Sub-Saharan Africa in its efforts to reduce HIV prevalence levels.”²⁴⁷

HEALTH ORGANIZATION, LEGISLATIVE RESPONSES TO AIDS 4-5 (1989) (reprinting Australian Capital Territory and province legislation concerning blood donation).

239. See Mary-Louise McLaws & Jennifer Learmont, *Heterosexually Acquired HIV Infection in Female Blood Donors: Case Series Between 1985-1990*, 7 AIDS CARE 631 (1995).

240. Ballard, *supra* note 206, at 253. For a discussion of HIV-1 see *infra* note 252.

241. See Gordon S. Whyte & Helen F. Savoia, *The Risk of Transmitting HCV, HBV, or HIV By Blood Transfusion in Victoria*, 167 MED. J. AUSTL. 142, 142, 146 (1997).

242. Fiebig, *supra* note 43, at 6, 14. The residual risk is estimated to be at least five to ten times lower than the rate in similar developed countries. Ballard, *supra* note 216, at 262. The only negative consequence of the extensive pre-donation interviews and consequent donor rejections has been the 25% decline in blood collection since 1984. *Id.* at 262-63. Australia has dealt with the decline in blood donations by reorganizing the blood system and reduction in consumption of blood products. *Id.* at 263.

243. *Id.* at 254.

244. NATIONAL RESEARCH COUNCIL, *supra* note 10, at 48.

245. *Id.* at 233; see also Ian M. Timæus, *Impact of the HIV Epidemic on Mortality in sub-Saharan Africa: Evidence from National Surveys and Censuses*, 12 AIDS S21-22 (Supp. 1 1998) (“In just 6 years in Uganda, men’s death rates nearly doubled and women’s death rate more than doubled. The probability of dying between ages of 15 and 60 rose from a moderate level to one of the highest levels documented in Africa since the 1960s.”).

246. NATIONAL RESEARCH COUNCIL, *supra* note 10, at 2.

247. JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS & WORLD HEALTH ORGANIZATION, EPIDEMIOLOGICAL FACT SHEET ON HIV/AIDS AND SEXUALLY TRANSMITTED INFECTIONS, 2000 UPDATE, UGANDA, at 3 (2000), available at <http://www.who.int>.

Uganda was one of the first African countries to acknowledge publicly HIV/AIDS and the extent to which it was impacting the country and to invite foreign assistance to improve the general health system and implement programs to address the epidemic.²⁴⁸ Unlike many HIV/AIDS interventions in other sub-Saharan countries, such as Kenya, Zambia, and Zimbabwe, Ugandan HIV/AIDS interventions have had a significant impact.²⁴⁹ In the late 1980s, HIV seroprevalence was 15–20%;²⁵⁰ in 1999, the HIV seroprevalence among adults was 8.3%.²⁵¹ This decline in seroprevalence is due in part to mortality and to reduced rates of new infections, and in part to HIV/AIDS intervention policies. The impact of HIV/AIDS interventions is also evidenced by the “recent reduction in the prevalence of HIV-1 infection among young males in rural Uganda,”²⁵² and a fall in infant and child mortality in the early 1990s.²⁵³

unaid.org/hivaidsinfo/statistics/june00/fact_sheets/pdfs/uganda.pdf (last visited Oct. 3, 2001) [hereinafter Uganda Fact Sheet].

248. EUROPEAN COMMISSION, DEVELOPMENT: STUDIES AND RESEARCH, SAFE BLOOD IN DEVELOPING COUNTRIES: LESSONS FROM UGANDA 50 (Rex Winsbury ed., 1995) [hereinafter LESSONS FROM UGANDA].

249. Compare HIV prevalence among antenatal women in four countries' urban and rural areas: In Kenya, HIV prevalence among antenatal women in one urban area increased from 2% in 1985 to 19% in 1995. In rural areas, it increased from less than 1% to 13% in 1997. JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS & WORLD HEALTH ORGANIZATION, EPIDEMIOLOGICAL FACT SHEET ON HIV/AIDS AND SEXUALLY TRANSMITTED INFECTIONS, 2000 UPDATE, KENYA, at 3 (2000), available at http://www.unaids.org/hivaidsinfo/statistics/june00/fact_sheets/pdfs/kenya.pdf (last visited Oct. 3, 2001). In Zambia, HIV prevalence had increased from 5% in 1985 to 27% in 1992 and it has since remained stable at that rate. JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS & WORLD HEALTH ORGANIZATION, EPIDEMIOLOGICAL FACT SHEET ON HIV/AIDS AND SEXUALLY TRANSMITTED INFECTIONS, 2000 UPDATE, ZAMBIA, at 3 (2000), available at http://www.unaids.org/hivaidsinfo/statistics/june00/fact_sheets/pdfs/zambia.pdf (last visited Oct. 3, 2001). In Zimbabwe, HIV prevalence increased from 10% in 1989 to 36% in 1994. JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS & WORLD HEALTH ORGANIZATION, EPIDEMIOLOGICAL FACT SHEET ON HIV/AIDS AND SEXUALLY TRANSMITTED INFECTIONS, 2000 UPDATE, ZIMBABWE, at 3 (2000), available at http://www.unaids.org/hivaidsinfo/statistics/june00/fact_sheets/pdfs/zimbabwe.pdf (last visited Oct. 3, 2001). In urban areas in Uganda, by comparison, HIV prevalence increased from 11% in 1985 to 31% in 1990, but then declined to 14% by 1998. In rural areas, HIV prevalence was 13% in 1992; it declined to 8% by 1998. Uganda Fact Sheet, *supra* note 247, at 3.

250. Uganda Fact Sheet, *supra* note 247, at 3.

251. *Id.*

252. NATIONAL RESEARCH COUNCIL, *supra* note 10, at 45. HIV-1 refers to the first strain of HIV independently isolated by Dr. Luc Montagnier and isolated and propagated by Dr. Robert Gallo. See SCHOUB, *supra* note 19, at 9–10. HIV-2 was isolated in 1986 by Dr. Montagnier and his colleagues from AIDS patients in Guinea Bissau and the Cape Verde Islands. *Id.* at 11.

253. Timæus, *supra* note 245, at S20.

The HIV/AIDS interventions undertaken by the Ugandan government have succeeded because of legal reform as well as reforms in health policy and delivery.²⁵⁴ This approach is stated explicitly in the government's multisectoral policy on HIV/AIDS:

All Ugandans have individual and collective responsibility to be actively involved in AIDS control activities in a coordinated way. The fight against AIDS is not only directed at the prevention of the spread of HIV, but also addresses the active response to, and management of, all perceived consequences of the epidemic.²⁵⁵

The Ugandan non-discrimination policies have not eliminated individual discrimination against, and stigmatization of, individuals with HIV/AIDS.²⁵⁶ The policies nonetheless demonstrate Uganda's commitment to caring for individuals with HIV/AIDS and preventing further spread of the virus.²⁵⁷

Among the most successful of the prevention policies implemented by the Ugandan government, with the assistance of foreign non-governmental organizations, has been the reorganization of the Uganda Blood Transfusion Service (UBTS). The UBTS "has been one of the major instruments of AIDS control in the country, rivaling if not exceeding in influence other . . . AIDS prevention strategies."²⁵⁸

In 1987, Lorenzo Natali, then vice-president of the European Commission, issued a memorandum to certain African, Caribbean, and Pacific countries.²⁵⁹ Natali's memorandum offered direct aid from the European Commission (EC) to countries to design and implement AIDS interventions and preventions.²⁶⁰ Uganda affirmatively responded to the EC's offer, and after extensive discussion with the Ugandan government, Dr. Lieve Franssen, an EC consultant, recommended that "EC support to Uganda could best be used for a safe blood initiative."²⁶¹ The program not only would prevent further spread of HIV/AIDS, but also would improve the quality of health care provided. Although HIV was transmitted predominately by het-

254. LESSONS FROM UGANDA, *supra* note 248, at 50–53.

255. UNAIDS, HIV AND AIDS—RELATED STIGMATIZATION, DISCRIMINATION, AND DENIAL: FORMS, CONTEXTS, AND DETERMINANTS: RESEARCH STUDIES FROM UGANDA AND INDIA 28 (2000), UNAIDS/00.16E (English Original, June 2000).

256. *Id.* at 28–30.

257. *See id.* at 34.

258. LESSONS FROM UGANDA, *supra* note 248, at 28.

259. Countries that received EC development funds were signatories to the Second Lomé Convention. Second ACP-EC Convention of Lomé, *opened for signature* Oct. 31, 1979, 1980 O.J. (L347) 2, 19 I.L.M. 327.

260. *Id.* at 59.

261. *Id.* at 34.

erosexual activity in Uganda, accounting for up to 80% of infections, a significant number of the remaining cases were caused by blood transfusions.²⁶² These cases were preventable and afflicted individuals, especially children, who might not otherwise have become infected.

The needs for and uses of blood in most African countries differ widely from those in Europe and North America. In the latter, blood is used primarily for emergency operations or other post-traumatic events,²⁶³ whereas in developing countries blood often is used to treat anemia. For example, at one hospital in Kinshasa, Zaire,²⁶⁴ 87% of blood transfusions were given to children for malaria-induced anemia.²⁶⁵ Furthermore, in many sub-Saharan African countries, like Uganda, "both the need and the circumstances are different, with children and maternity cases being the main recipients, and electricity supplies often unreliable."²⁶⁶ Dr. Fransen thus advised:

For several reasons the importance of transfusion as a mode of transmitting HIV infection is much greater in Uganda than in most industrialised countries. First, the seroprevalence of HIV infection in the general population is very high, transfusions are given much more frequently in Uganda than in industrialised countries, and more than 50 per cent of the transfusions go to children with malaria. . . . The prevention of this mode of transmission is technologically feasible and the high rate of seropositivity among blood donors makes this intervention more cost-effective than in Europe. In addition, the improved medical use of blood transfusions, and the greater availability of properly stored and screened blood, will have a positive effect on health and health systems in general.²⁶⁷

Fransen's ultimate recommendation was that the EC sponsor the rehabilitation of blood transfusion facilities in Kampala.²⁶⁸ After the creation of adequate facilities and the reorganization of the UBTS,

262. *Id.* at 60; see also R.D. Mugerwa et al., *Human Immunodeficiency Virus and AIDS in Uganda*, 73 E. AFR. MED. J. 20 (1996).

263. LESSONS FROM UGANDA, *supra* note 248, at 37.

264. On May 16, 1997, the name of Zaire was formerly changed to the Democratic Republic of the Congo. Because UNAIDS has not adopted this change, for the sake of consistency, the Democratic Republic of the Congo will be referred to as Zaire in this note. CENTRAL INTELLIGENCE AGENCY, THE WORLD FACTBOOK 111 (1999).

265. NATIONAL RESEARCH COUNCIL, *supra* note 10, at 97.

266. LESSONS FROM UGANDA, *supra* note 248, at 37.

267. *Id.* at 60-61. At the time, the rate of HIV seroprevalence in the general population was 15-20%. *Id.*

268. *Id.* at 61.

safe blood could be supplied to Kampala and surrounding areas, and then eventually to other regions of the country.²⁶⁹

In 1986, “9% of all blood donated at the main Mulago teaching hospital in Kampala was positive for HIV.”²⁷⁰ At this time, mission hospitals, notably Nsambya and the new Mulago hospital, implemented limited testing of blood donations.²⁷¹ These facilities were funded both by the EC and the WHO. However because “HIV testing was not available for the majority of hospitals in other towns in Uganda,” the testing had limited impact on reducing the transmission of HIV by transfusion.²⁷² Furthermore, few other preventative measures had been implemented fully.

The reorganization of the UBTS began with infrastructural development, specifically the rehabilitation of the former Kampala blood bank in Nakasero (NBB). By 1988, while the rehabilitation was underway, the Ugandan Red Cross had become ineffective largely because of a decline in funding and support from the middle class and business communities.²⁷³ NBB thus had to develop its own donor recruitment program. The Ugandan Red Cross lent its name and authority to the NBB program.²⁷⁴ In 1990, the blood bank facilities were completed and NBB had initiated its program to recruit safe blood donors.²⁷⁵

NBB requires that blood donor recruitment be limited to voluntary, altruistic blood donation.²⁷⁶ Donor recruitment focuses on secondary school and college students because of the epidemiology of HIV infection in Uganda: HIV prevalence is highest in both urban and rural populations in Uganda among 25 to 44 year old males, and 15 to 34 year old females.²⁷⁷ Once prospective donors are recruited, they are given pre-donation counseling. This counseling consists of giving potential donors “facts concerning the need for blood transfu-

269. *Id.* at 48.

270. *Id.*

271. *Id.*

272. *Id.*

273. *Id.* at 64.

274. *Id.* at 64–65.

275. *Id.* at 78.

276. *Id.* at 69, 113.

277. NATIONAL RESEARCH COUNCIL, *supra* note 10, at 76 (citing D. Serwadda et al., *HIV Risk Factors in Three Geographic Strata of Rural Rakai District, Uganda*, 6 AIDS 983–89 (1992)); Hans-Ulrich Wagner et al., *General and HIV-1 Associated Morbidity in a Rural Ugandan Community*, 7 AIDS 1461, 1463 (1993).

sion and the reasons why people should give blood to save lives.”²⁷⁸ The counseling is designed to facilitate a potential donor’s identification of his or her own risk factors and aid the donor in deciding whether to self-defer.

By 1989, seroprevalence among donated blood in Uganda had risen to 24%; thus demand for the screened blood from NBB rapidly increased.²⁷⁹ Within a year of opening, the majority of local hospitals and blood collection services sent blood to be processed at NBB.²⁸⁰ NBB’s decision to provide blood bank services to all hospitals was the first step towards formation of a national blood bank.²⁸¹ In 1990, NBB’s safe blood project was extended to the rest of Uganda.²⁸² In addition to creating regional blood banks, a plan to provide HIV testing was initiated and implemented in conjunction with NBB.²⁸³ Since national testing started in 1990, 200,000 individuals have been tested.²⁸⁴ The widespread implementation of HIV testing has reduced the number of infected individuals donating blood; this protects the blood supply, since people no longer need to resort to blood donation as a means by which to ascertain their HIV status.

A 1995 report on UBTS estimates that in 1994 alone, 7,200 people would have been infected with HIV by blood transfusions in Uganda had the UBTS protocols not been implemented.²⁸⁵ Other benefits include that about 60,000 people each year attend talks given by UBTS recruitment officers, thus gaining invaluable education about HIV/AIDS and the infection’s transmission.²⁸⁶ Furthermore, over 75,000 HIV tests are administered per year, increasing awareness and potentially further reducing transmission rates.²⁸⁷

The Blood Donation Questionnaire administered by the UBTS differs greatly from those administered in the United States, Canada, Denmark, and Australia. It is extremely short, proscribing donation if a donor affirms the following statements:

In the last six months you have had sex with someone you are unsure about.

278. LESSONS FROM UGANDA, *supra* note 248, at 113.

279. *Id.* at 48.

280. *Id.* at 63.

281. *Id.*

282. *Id.* at 79.

283. *Id.*

284. *Id.* at 84.

285. *Id.* at 92.

286. LESSONS FROM UGANDA, *supra* note 248, at 93.

287. *Id.*

In the last two months you have had an illness such as a bad cold.

In the last year you have had:

- i. An injection except at a hospital or clinic; or
- ii. Skin scarring or cutting by a traditional healer; or
- iii. A surgical operation.

You have ever had hepatitis (jaundice causing yellow coloration of the eyes).²⁸⁸

The self-exclusion questionnaire does not address explicitly the epidemiology of sexual HIV transmission in Uganda, although it does address the increased risk of infection associated with injections and transfusions.²⁸⁹ In Uganda, the strongest risk factor for HIV incidence is the number of sexual partners an individual has had in his or her lifetime. Both men and women who report five or more sexual partners have a significantly higher risk of HIV infection than those who report at most one partner.²⁹⁰ Men and women who are unmarried and in “steady” relationships have a higher risk of infection than do those who are married.²⁹¹ Similarly, men who are divorced, separated, or widowed have a higher risk of infection than do those who are married.²⁹² The Ugandan blood donation questionnaire does not question donors about these activities, instead asking only whether the potential donor has had sex with someone he or she is unsure about.

The donor self-exclusion questionnaire is not sufficiently narrowly tailored to address specific forms of sexual transmission of HIV, but rather is drafted broadly to encompass any sexual contact in which the partner is “unsure” about the other partner’s HIV status. This pre-donation donor exclusion likely has contributed to the reduction in transfusion-associated HIV in Uganda resulting from serological screening of donated blood. No studies have been done in Uganda on this point, however, and there is no information available on current levels of transfusion-transmitted infection. Research has shown that behavioral risk factor screening through donor self-exclusion questionnaires effectively contributes to a reduction in the

288. Uganda Blood Donation Questionnaire (on file with the Duke Journal of Comparative and International Law).

289. *Id.*

290. Maria A. Quigley et al., *Case-Control Study of Risk Factors for Incident HIV Infection in Rural Uganda*, 23 J. ACQUIRED IMMUNE DEFICIENCY SYNDROME 418, 422 (2000).

291. *Id.* at 420.

292. *Id.*

risk of transfusion-related transmission of HIV.²⁹³ Implementation of a more narrowly tailored questionnaire by the UBTS likely would contribute to a further decline in the incidence of transfusion-related HIV infections.

F. Singapore

Singapore became a fully independent state in 1965 when it separated from the Malaysian federation formed in 1959 at the end of British colonial rule.²⁹⁴ Singapore, though still a considered a developing country, has the world's largest trade surplus per capita and is the eleventh largest trading partner of the United States.²⁹⁵ Credit for much of Singapore's rapid economic development has been given to its system of governance. Singapore's government exercises extensive control over traditional areas of government regulation as well as over the country's economy.²⁹⁶ Known as "soft authoritarianism" or "Confucian capitalism," the Singaporean political system embodies the

concept of a government by honourable men (junzi), who have a duty to do right for the people, and who have the trust and respect of the population. [This concept directly contradicts the] Western idea that a government should be given as limited powers as possible, and should always be treated with suspicion unless proven otherwise.²⁹⁷

The government justifies its extensive legislative and economic regulatory powers as furthering a "communitarian adaptation of free market economics."²⁹⁸

293. See *supra* text accompanying note 39; see also Yupa Urwijitaroon et al., *Reducing the Risk of HIV Transmission Through Blood Transfusion By Donor Self-Deferral*, 27 SE. ASIA J. TROPICAL MED. & PUB. HEALTH 452 (1996). A self-deferral form was given to all blood donors that included "questions about HIV risk factors in the three month period prior to blood donation." Among general donors, the prevalence of anti-HIV antibodies was 0.61%, while among self-deferred high risk donors, it was 1.99%. "In comparison with the general donors, the high risk donors demonstrated statistically significant higher prevalence rates of HIV antigen (p <0.05. . .)."

294. Rafael X. Zahralddin-Aravena, *Chile and Singapore: The Individual and the Collective, a Comparison*, 12 EMORY INT'L L. REV. 739, 767 (1998).

295. *Id.*

296. Douglas L. Tookey, *Singapore's Environmental Management System: Strengths and Weaknesses and Recommendations for the Years Ahead*, 23 WM. & MARY ENVTL. L. & POL. REV. 169, 175 (1998).

297. Li-ann, *supra* note 1, at 73 (quoting *Shared Values White Paper*, ¶ 41, (Cmd 1, 1991) (Sing.)).

298. Zahralddin-Aravena, *supra* note 294, at 741-42.

Singapore's health regulations are based on the Constitutional premise that "individual concerns must sometimes be subordinated to collective interests."²⁹⁹ Part IV of the Singapore Constitution recognizes the "Individual as the primary normative unit which the state is supposed to serve."³⁰⁰ Individual rights, however, are not absolute: constitutionally defined individual "liberties are subject to derogating laws relating to such collective interests as 'public order, public health, or morality'."³⁰¹

The Singaporean health system, including the public health system, is highly regulated. Three different governmental Ministries, as well as the private sector, administer health services.³⁰² Singapore, through these agencies and their regulatory policies, aspires to realize "high standards of public health and a quality environment" for all citizens.³⁰³ Singapore's aspirations are evidenced in its multi-sectoral regulation, including that governing its blood policies.³⁰⁴

The Singapore Blood Transfusion Service (SBTS) was founded in 1946, prior to Singapore's independence, and has since supplied blood to all of Singapore's private and public hospitals.³⁰⁵ The Singapore Blood Transfusion Service, now the Center for Transfusion Medicine (CTM), is controlled by the Ministry of Health. Singaporean blood policy protocols are regulated by the government under the Infectious Diseases Act of 1976, and the Infectious Diseases (Amendment) Act of 1992.³⁰⁶ HIV was first identified and confirmed in Singapore in 1985;³⁰⁷ the first case of AIDS was reported in 1986.³⁰⁸

299. Li-ann, *supra* note 1, at 79.

300. *Id.*

301. *Id.* at 79 n.72.

302. The three Ministries overseeing health services in Singapore are the Ministry of Health (MOH), Ministry of the Environment (ENV), and Ministry of Manpower (MOM). Ministry of Health Singapore, Overview of the Singapore Healthcare System 2 (2001), available at http://www.gov.sg/moh/mohinfo/mohinfo_a.html (last visited Oct. 28, 2001).

303. Ministry of the Environment, The Singapore Green Plan—Towards a Model Green City 8 (1992) (Sing.), quoted in Tookey, *supra* note 296, at 172.

304. See *supra* note 302.

305. Ministry of Health, Overview of the Singapore Blood Transfusion Service, available at <http://www.gov.sg/moh/health/sbts/sbt2.html> (last visited Oct. 8, 2001).

306. CLB & Anor v. Public Prosecutor, 1993-1 SLR 589, 1993 SLR Lexis 434 (High Court, 1993) (Sing.); see also I. C. Boudville & S. Y. Wong, *Health Care Systems In Transition II. Singapore, Part II. The Current Status of HIV-AIDS*, 20 J. PUB. HEALTH MED. 23, 27 (1998).

307. FEDERAL RESEARCH DIVISION, LIBRARY OF CONGRESS, SINGAPORE: A COUNTRY STUDY 112 (Barbara Leitch LePoer ed., 2d ed. 1991) [hereinafter SINGAPORE: A COUNTRY STUDY]; see also Boudville & Wong, *supra* note 306, at 23.

308. Boudville & Wong, *supra* note 306, at 23.

By 1988, thirty-four cases of AIDS had been diagnosed.³⁰⁹ The incidence of HIV increased over the next decade; by the end of 1999, 2,600 adults, or 0.13% of the adult population of Singapore, were infected with HIV.³¹⁰ The “predominant mode” of HIV transmission in Singapore has been sexual contact, which was “responsible for 95% of the cases up to 1996.”³¹¹ Sixty-eight percent (68%) of HIV infections caused by sexual contact through 1996 resulted from heterosexual contact, and 25.2% resulted from homosexual contact.³¹² As of December 1999, 57.8% of HIV-positive Singaporean men had been infected through heterosexual contact, compared to 27.1% infected through bisexual or homosexual contact.³¹³ Of the remaining HIV infections diagnosed as of December 1999, 1% were caused by perinatal transmission, while 1.6% resulted from injection drug use.³¹⁴

After the diagnosis of HIV in two Singaporeans in 1985, the government immediately implemented legislation and adopted measures to prevent further spread of the disease.³¹⁵ The legislation mandated that SBTS screen all blood donations for antibodies to HIV.³¹⁶ Two years later, in 1987, the government enacted legislation requiring that all prospective donors complete a “compulsory questionnaire-cum-declaration” prior to donating blood.³¹⁷ Since the implementation of these screening procedures, no incidences of transfusion-transmitted HIV have been reported in Singapore.³¹⁸

309. SINGAPORE: A COUNTRY STUDY, *supra* note 307, at 112.

310. JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS & WORLD HEALTH ORGANIZATION, EPIDEMIOLOGICAL FACT SHEET ON HIV/AIDS AND SEXUALLY TRANSMITTED INFECTIONS, 2000 UPDATE, SINGAPORE, at 3 (2000), *available at* http://www.unaids.org/hivaidsinfo/statistics/june00/fact_sheets/pdfs/singapore.pdf (last visited Oct. 10, 2001) [hereinafter Singapore Fact Sheet].

311. Boudville & Wong, *supra* note 306, at 24.

312. Singapore Fact Sheet, *supra* note 310, at 6.

313. *Id.*

314. *Id.*

315. *See* The Infectious Diseases Act (Amendment of First Schedule) Notification 1985 No. S 98 (Apr. 17, 1985) (Sing.); *see also* The Infectious Diseases Act (Prescribed Form) Regulations 1985 No. S 354 (Dec. 23, 1985) (Sing.) (providing the form to be used to notify the government of incidences of infectious diseases including AIDS).

316. SINGAPORE: A COUNTRY STUDY, *supra* note 307, at 112. The questionnaire used in 1985 could not be obtained. This section will discuss the questionnaire currently in use.

317. Boudville & Wong, *supra* note 306, at 25.

318. Boudville & Wong, *supra* note 306, at 24 (“One case of infection occurred because of a contaminated blood transfusion received in the early 1980s while the individual was in the United States, whereas no cases have been attributable to transfusion of blood products in Singapore.”). Though HIV-positive individuals have donated blood in Singapore, and been prosecuted accordingly, HIV was detected in their blood by serological screening. Thus their blood was not introduced into the blood supply. *See infra* notes 319, 321.

In 1992, the Infectious Diseases Act was amended to create criminal offenses related to HIV/AIDS transmission. These include the offense created by Section 11(1): any false statement by a prospective blood donor in response to the pre-donation questionnaire can be prosecuted as a criminal offense.³¹⁹ A violation of Section 11(1) carries “a penalty, upon conviction, of imprisonment of up to two years or a fine of up to \$20,000 or both for making a false declaration.”³²⁰ Since 1992, there have been several prosecutions of individuals who provided false information in blood donor registration forms, under Section 11(1) as well as under §182 of the Penal Code, which proscribes giving false information to a public servant.³²¹ Two individuals, who were HIV-positive at the time of donation, were charged under Section 182, with “giving false information to a public servant, the Medical Director of the Singapore Blood Transfusion Service.”³²² Both were sentenced to “a week’s imprisonment and a fine of \$800.”³²³ Another person who donated blood on June 25, 2000 and whose blood tested positive for HIV has been charged under Section 11(1).³²⁴ According to Singaporean epidemiologists, the use of pre-donation questionnaires, to which one must respond honestly or face threat of prosecution, deters individuals at risk of HIV from donating blood to ascertain HIV status, and thus further contributes to a safe blood supply.³²⁵

The Singapore Blood Donation Questionnaire, also known as the blood donor registration form, prohibits individuals from donating blood for various reasons including low body weight, history of major illness, or travel to high endemic regions.³²⁶ The questionnaire also prohibits donation by any potential donor who may be at risk of having a disease transmissible by blood. A potential donor is excluded if he or she is in any of the following groups:

- 1) Persons with positive HIV test results or those with AIDS;

319. Press Release, Ministry of Health, HIV-Infected Blood Donor (Apr. 10, 2001), *available at* <http://www.gov.sg/moh/releases/2001/10%20Apr%202001.html> (last visited Oct. 28, 2001).

320. *Id.*; *see also* Boudville & Wong, *supra* note 306, at 25.

321. CLB & Anor v. Public Prosecutor, 1993-1 SLR 589, 1993 SLR Lexis 434, at *4 (High Court, 1993) (Sing.); *see also* Press Release, Ministry of Health, *supra* note 319.

322. CLB & Anor v. Public Prosecutor 1993-1 SLR 589, 1993 SLR Lexis 434, at *4.

323. *Id.*

324. Press Release, Ministry of Health, *supra* note 319.

325. Boudville & Wong, *supra* note 306, at 25.

326. Singapore National Blood Donation Recruitment Programme Information, *available at* http://www.redcross.org.sg/serv_bloodonorecruitprog_m_Info.htm (last visited Oct. 9, 2001).

- 2) Persons who have had multiple sex partners;
- 3) Persons who have engaged in casual sex;
- 4) Men who have had sex with other men;
- 5) Persons who have injected themselves with drugs;
- 6) Sex prostitutes;
- 7) Persons with symptoms suggestive of AIDS e.g. weight loss, swollen glands in the neck, armpits or groins, persistent diarrhoea or rare cancers;
- 8) Anyone have had [sic] sex with anyone in these groups.³²⁷

Although homosexual or bisexual contact is responsible for only 27.1% of the HIV infections affecting men in Singapore, SBTS prohibits blood donations by men who have had sex with another man.³²⁸ Similarly, although injection drug use is responsible for only 1.6% of HIV infections in Singapore,³²⁹ individuals who have injected drugs are prohibited from donating blood because the risk of such individuals donating seropositive blood is considered too high to be acceptable.³³⁰

Because HIV is transmitted predominately through heterosexual contact in Singapore, the questionnaire was constructed to deter individuals so infected from donating blood. In Singapore, as of 1996, 67% of HIV-positive individuals were single, 25% were married, and 8% widowed or divorced.³³¹ The “single most important risk factor for HIV infection in Singapore” is “contact with commercial sex workers during travel to other countries.”³³² Questions two, three, and eight effectively target individuals at risk from these transmission mechanisms, by excluding men and women from donation who have had sex with multiple partners or who have had sex with anyone who might be at risk of HIV infection, including commercial sex-workers.³³³

327. *Id.*

328. Singapore Fact Sheet, *supra* note 310, at 6.

329. *Id.*

330. The current seroprevalence of HIV in Singaporean populations of injection drug users and homosexual men has not been estimated. This information could be useful to determine whether the exclusionary criteria functions to exclude a population that poses a significant risk of introducing HIV into the blood supply, or whether the risk of introduction is minimal but still present.

331. Boudville & Wong, *supra* note 306, at 23.

332. *Id.* at 24.

333. Singapore Blood Donation Questionnaire, *supra* note 328, at 6.

The exclusionary criteria of Singapore's Blood Donation Questionnaire are extensive. Because the government privileges public health and welfare over individual rights, and donating blood is not considered such a right, neither the exclusionary criteria nor the attendant criminal penalties have been challenged. The combined use of pre-donation self-exclusion questionnaires and serological screening as well as legal enforcement have proven effective in maintaining the safety of the Singaporean blood supply: no incidence of transfusion-transmitted HIV infection have occurred since their implementation.

IV. CASE-STUDY SYNTHESIS/CONCLUSION

The above case studies present the legislative and public health policy concerns and actions that contributed to the formation of coherent blood donation policies in the countries studied: the United States, Canada, Denmark, Australia, Uganda, and Singapore. The overriding concerns of these countries in creating blood donation policies are protecting the safety of the blood supply and preventing further incidence of transfusion-transmitted HIV.³³⁴

All of the above countries, when forming their blood donation policies, considered which populations were at risk for developing HIV or had high seroprevalence. Countries thus sought to create policies that conformed to the available epidemiological information on patterns of HIV transmission and infection. In addition to formulating and implementing effective blood donation policies, the impact on individual interests and rights were also considered. These countries sought to balance public health protection and the governmental interest in creating blood donation policies that would prevent transfusion-related transmission of HIV with minimal infringement on individual rights. Furthermore, the questions asked in the pre-donation exclusion questionnaires were formulated so as to exclude those individuals and groups at high risk of HIV infection.

The initial diagnoses of AIDS in the four Pattern One countries discussed—the United States, Canada, Denmark, and Australia—oc-

334. Statistical information concerning the effectiveness of pre-donation donor self-exclusion questionnaires in combination with serological screening to prevent transfusion-related HIV infection is not available for all of the case-studies countries. The data from those countries for which this information is available suggests that this combination of measures has been successful. In the United States, the residual risk of transfusion-transmitted HIV infection is 20 per million. *See supra* note 43. In Australia, this risk is significantly lower, at 7.9 per million. *See supra* note 242. In Canada and Denmark, the risk is also quite low; however, data is not available. In Singapore, no incidences of transfusion-transmission HIV have been reported.

curred in these countries' homosexual populations. Early diagnoses of AIDS were also found in populations of Haitian immigrants and injection-drug users. Soon after the diagnoses of AIDS in these populations, AIDS began to occur in the hemophiliac populations, signaling not only that was AIDS transmissible by a blood borne agent, but also that this agent was in the respective nation's blood supplies and blood products. These countries were called upon to implement policies to prevent further transmission of the disease. At least in the United States, Canada, Denmark, and Australia, these early policies, which excluded MSM from donating blood because of the high seroprevalence in homosexual populations, pitted gay rights activists against public health policy makers. All of these countries eventually placed public health goals over individual civil rights concerns.³³⁵ This reflected the policy position that public health measures that effectively reduce the risk of disease transmission are justifiable if they reduce the risk even minimally, so long as they do not unduly restrict individual liberties. Despite the conflicts over exclusionary criteria, the policies implemented in the four countries were effective in reducing transfusion-related transmission to today's current low levels.

The requirement of proportionality evidenced by the four Pattern One countries' approaches to drafting public health policy, demonstrates the complexity of balancing public health priorities with individual rights. It also highlights tensions between science and public health, and law. The former, especially as illustrated by the discipline of epidemiology, considers groups over individuals, whereas the latter, at least as evidenced in representative and social democracies, is concerned with balancing the interests of stable governance with individual rights.

The spread of HIV/AIDS has been held by these four countries to be a sufficiently grave threat to citizens' health to justify the preventive measures implemented. Some of the measures adopted have been more restrictive than others. For example, Australian legislation making "false or misleading declarations by blood donors an offense punishable by fine or imprisonment"³³⁶ closely resembles legislation enacted in Singapore, a Pattern Two country that explicitly

335. None of these countries recognize an affirmative right to donate blood; thus none considered prohibitions on blood donations by high risk groups to compromise individual liberty interests.

336. *Supra* note 216.

defines public health as a governmental interest for which individual rights may be abrogated.

Conflict over balancing public health policies with individual rights was not as evident in either Uganda or Singapore, the two Pattern Two countries presented as case studies. In Uganda, this is because the blood donation questionnaire does not explicitly prohibit MSM from donating blood. In fact, its exclusionary criteria are far more general than those of any other country studied, only excluding individuals from donating blood who are “unsure” about their partners.³³⁷ In Singapore, this question did not explicitly arise because the Singaporean Constitution provides that individual “liberties are subject to derogating laws relating to such collective interests as ‘public order, public health, or morality.’”³³⁸ The Singaporean Constitution thus privileges public health protection, facilitating the easy drafting and implementation of such policies.

In all of these countries, the blood donation policies adopted combine the use of pre-donation and serological screening to reduce the risk of transfusion-transmitted HIV infection. All of the questionnaires exclude individuals considered to be at high risk for HIV infection, although some questionnaires, such as those used in Singapore, the United States, Canada, and Australia, are more tailored than are others, for example that used in Uganda. The questionnaires, however, screen out those groups with a high seroprevalence of HIV infection, as well as individuals with high risk behaviors.

Public health policy formation and enactment is never simple, especially when it concerns the development of blood policies to protect against transfusion-related transmission of a virus such as HIV. The case studies presented in this note illustrate successful models for drafting and enacting public health policies that ultimately achieved the goals to which they were intended—reduction in the incidence of transfusion-transmitted HIV without unduly compromising individual rights or interests.

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337. *See* Reunión De Consenso Sobre Selección De Donantes En Bancos De Sangre [Consensus Meeting Regarding the Selection of Blood Donors in Blood Banks] (Aug. 4, 1999) (Uru.) (on file with the Duke Journal of Comparative and International Law).

338. Li-ann, *supra* note 1, at 110–11 n.72.