

AIDS AND THE BLOOD SUPPLY: AN ANALYSIS OF LAW, REGULATION, AND PUBLIC POLICY

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I. INTRODUCTION

Acquired Immune Deficiency Syndrome (“AIDS”) is among the greatest challenges to modern epidemiology.¹ As the number of diagnosed cases and predicted future infections mounts,² the need to stem the transmission of the Human Immunodeficiency Virus (“HIV”)³ becomes an increasingly crucial public health issue. Since scientists first diagnosed AIDS and began to understand its viral source in the early 1980s, lawmakers and policymakers

1. The numbers of cases of HIV infection and AIDS throughout the world are staggering. See Jonathan Mann et al., *Toward a New Health Strategy to Control the HIV/AIDS Pandemic*, 22 J.L. MED. & ETHICS 41 (1994) (discussing estimates of the extent of the HIV/AIDS pandemic).

2. The Centers for Disease Control and Prevention (“CDC”) have issued a status report stating that one million Americans, or one out of every 250, was infected with HIV as of mid-1994. *HIV Infection and AIDS—A Status Report*, in SURGEON GENERAL’S REPORT TO THE AMERICAN PUBLIC ON HIV INFECTION AND AIDS 1,1 (1994). For further discussion of recent numbers of AIDS cases and predicted rates of HIV infection, see Richard M. Selik et al., *HIV Infection as Leading Cause of Death Among Young Adults in U.S. Cities and States*, 269 JAMA 2991, modified, Correction, 270 JAMA 710 (1993); Ann Rochell, *AIDS Deaths in U.S. Top 200,000: Next 14 Months to Claim at Least 130,000 More*, ATL. J. & CONST., Oct. 29, 1993, at A1; *AIDS Deaths to Mount More Slowly*, WASH. TIMES, Jan. 15, 1993, at A2; and *AIDS is Top Killer Among Young Men*, N.Y. TIMES, Oct. 31, 1993, § 1 at 19.

3. HIV is the virus believed by most authorities to cause AIDS. See generally *WHO’s Primer on AIDS*, 111 PUB. HEALTH REP. 7 (1996). For a discussion of a contrarian perspective that HIV does not cause AIDS, see William Booth, *A Rebel Without a Cause of AIDS*, 239 SCIENCE 1485 (1988), available in LEXIS, News Library, Asapii file. The contrarian perspective loses credibility as protease inhibitors of HIV replication achieve unprecedented success in the treatment of AIDS. For a discussion of the success of protease inhibitors in treating HIV-infected populations, see *Expert Discusses Impact of Treatments on Healthcare*, AIDS WKLY. PLUS, Mar. 18, 1996, at 11, available in Westlaw, HWD Database.

have sought responses to eliminate or retard the spread of HIV. As the quest for a vaccination or a cure has proven frustratingly elusive,⁴ managing AIDS in the short term has come to depend largely on measures that control its contagion.⁵

Some measures focus on reducing the instance of voluntary, high-risk activities, such as unsafe sexual practices⁶ and the sharing of hypodermic needles.⁷ Other measures attempt to lower the risk of unavoidable activities, such as blood transfusion.⁸ This Article focuses on the latter challenge—the development of laws, regulations, and policies to reduce the presence of HIV in the blood supply. Section II briefly discusses the problem of blood supply purity throughout the world. Section III distinguishes liability-based approaches from rule-based approaches to improving blood purity. Section IV examines and analyzes various rule-based options. Section V summarizes the recommendations made throughout the Article.

II. A GLOBAL PERSPECTIVE OF TRANSFUSION-ASSOCIATED HIV TRANSMISSION

For several years following identification of the earliest cases of AIDS,⁹ health officials had little reliable information about the relationship between blood transfusions and the transmission of the disease.¹⁰ After health officials

4. See Lawrence K. Altman, *Little Progress Seen in Effort to Crack AIDS Puzzle*, N.Y. TIMES, June 12, 1993, at 5.

5. See Steven R. Salbu, *HIV Home Testing and the FDA: The Case for Regulatory Restraint*, 46 HASTINGS L.J. 403, 434-35 (1995) (discussing avoidance of HIV infection as the most promising means of averting the suffering and death associated with AIDS).

6. In this regard, the use of condoms has been widely adopted as a measure against the spread of HIV. David L. Chambers, *Gay Men, AIDS, and the Code of the Condom*, 29 HARV. C.R.-C.L. L. REV. 353, 353 (1994).

7. For a discussion of public policy solutions to HIV infection via needle sharing, see Steven R. Salbu, *Needle Exchange, HIV Transmission, and Illegal Drug Use: Informing Law and Public Policy with Science and Rational Discourse*, 33 HARV. J. ON LEGIS. 105 (1996).

8. As of May 31, 1993, approximately 5500 cases of transfusion-induced AIDS were reported in the United States. Richard M. Selik et al., *Demographic Differences in Cumulative Incidence Rates of Transfusion-Associated Acquired Immunodeficiency Syndrome*, 140 AM. J. EPIDEMIOLOGY 105, 106 (1994). In many developing countries, the incidence of transfusion-induced AIDS is far higher. See *infra* notes 20-30 and accompanying text.

9. Scientists identified the first cases of AIDS-related Kaposi's sarcoma in 1979 and later identified AIDS as the cause. See Steven R. Salbu, *Regulation of Drug Treatments for HIV and AIDS: A Contractarian Model of Access*, 11 YALE J. ON REG. 401, 402 n.1 (1994).

10. A very early report on the topic of possible blood-borne transmission of AIDS was issued by the CDC in December of 1982. *Possible Transfusion-Associated Acquired Immune Deficiency Syndrome (AIDS)—California*, 31 MORBIDITY & MORTALITY WKLY. REP. 652 (1982). A 1983 joint

confirmed that the AIDS virus was blood-borne¹¹ but prior to the development of HIV antibody testing procedures,¹² transmission of HIV by transfusion was a daunting problem. Without a means of testing for contamination, blood supplies were vulnerable, and transfusion of blood from anonymous sources was tantamount to Russian roulette.¹³ Products derived from human blood, such as blood-clotting medicines for hemophiliacs, were also highly susceptible to HIV contamination.¹⁴ Because of widespread contamination of blood factor concentrate prior to 1985, HIV infection rates in the early years of the AIDS epidemic were higher among hemophiliacs than among any other group.¹⁵

While innovative products and processes of the future may eliminate transmission of HIV by transfusion,¹⁶ contraction of AIDS through exposure

statement made by the American Red Cross, the American Association of Blood Banks, and the Council of Community Blood Centers, characterized the spread of AIDS by transfusion as possible but unproven. David Stevens, *Negligence Liability for Transfusion-Associated AIDS Transmission: An Update and Proposal*, 12 J. LEGAL MED. 221, 222 (1991).

11. In 1984, scientists first verified that AIDS was caused by HIV, a blood-borne virus. See *Kirkendall v. Harbor Ins. Co.*, 698 F. Supp. 768, 772 (W.D. Ark. 1988); *Kozup v. Georgetown Univ.*, 663 F. Supp. 1048, 1052 (D.D.C. 1987), *aff'd in part and vacated in part*, 851 F.2d 437 (D.C. Cir. 1988). At that time, HIV was known as the human T-lymphotropic virus type III (HTLV-III). See *Kirkendall*, 698 F. Supp. at 772; *Kozup*, 663 F. Supp. at 1052.

12. The first license to manufacture an HIV-antibody test kit in the United States was granted on March 2, 1985, to Abbott Laboratories. Karen S. Lipton, *Blood Donor Services and Liability Issues Relating to Acquired Immune Deficiency Syndrome*, 7 J. LEGAL MED. 131, 131 (1986). Further approvals for other manufacturers, as well as a movement by blood banks to incorporate routine HIV-antibody testing into their procedures, followed within a few weeks. *Id.*

13. Because of this threat, the practice of autologous transfusion—the stockpiling of one's own blood in anticipation of surgery—has become a common hedge against the uncertainties of transfusion from blood supplies derived from anonymous sources. See *infra* notes 323-41 and accompanying text. Even though HIV-antibody testing has reduced the risk of contamination by transfusion, autologous transfusion has remained a popular alternative. See Martin R. Howard et al., *Regional Transfusion Centre Preoperative Autologous Blood Donation Programme: The First Two Years*, 305 BRIT. MED. J. 1470, 1470 (1992) (noting the recent increased interest in autologous blood donation as an alternative to voluntary blood donation).

14. Nine thousand hemophiliacs purportedly contracted AIDS in this manner. David Dishneau, *Hemophiliacs Live with Deadly Irony*, ROCKY MOUNTAIN NEWS, Mar. 5, 1995, at 13A. More recently, clotting factor concentrates for hemophiliacs have been rendered safer through a series of processes used to inactivate viral contaminants, including solvent detergent treatment, pasteurization, and dry heat treatment. Duncan P. Thomas, *Viral Contamination of Blood Products*, 343 LANCET 1583, 1583 (1994).

15. See Ron J. Perey, *Hemophiliacs, Transfusions, and AIDS: Liability for AIDS Contracted by Hemophiliacs and Others from Blood Factor Concentrate and Blood Transfusions*, 14 TRIAL DIPL. J. 137, 140 (1991).

16. See, e.g., *Hemolink Phase II Trials to Begin in 1996*, AIDS WKLY., Jan. 1, 1996, at 11 (reporting development of a red blood cell substitute that shows some promise of reducing or eliminating transfusion-related transmission of HIV). But see Rhonda L. Rundle, *Analyst Pans Blood-*

to blood products remains a serious problem in many parts of the world.¹⁷ The recent phenomenon of blood screening for HIV¹⁸ has reduced, but not eradicated, transfusion-associated infection. Credible estimates indicate that HIV has been transmitted to about 3000 people in the United States through exposure to blood or blood products since the adoption of blood screening tests in 1985.¹⁹ In many other countries, the risk of infection by transfusion is far greater. Risks are especially high in some developing nations²⁰ where

Substitute Firms, DENVER POST, Dec. 11, 1995, at E3 (reporting one securities analyst's observation that blood substitutes degrade quickly after transfusion, and that surgeons therefore may be reluctant to use them).

17. See, e.g., Chris Bull & Scott R. Akin, *Bloody Shame*, THE ADVOCATE, Dec. 14, 1993, at 24, 25 illus. (noting known exposure of hemophiliacs to HIV through tainted blood supplies in Canada, the United States, Colombia, Nigeria, Spain, Britain, Zaire, France, Switzerland, Italy, Kenya, Uganda, Japan, and China); Steven Dickman, *One Finger in the Romanian Dike*, 345 NATURE 379, 379 (1990) (documenting a massive infection of malnourished infants through microtransfusions employing contaminated blood, needles, and syringes).

Most studies indicate extremely low probabilities that HIV-infected blood will pass present screening processes and enter the U.S. blood supply. See, e.g., Michael P. Busch et al., *Evaluation of Screened Blood Donations For Human Immunodeficiency Virus Type 1 Infection by Culture and DNA Amplification of Pooled Cells*, 325 NEW ENG. J. MED. 1, 1 (1991) (indicating the probability that a screened donor in San Francisco will be positive for HIV-1 to be 1 in 61,171). However, while blood testing and other prophylactic procedures have reduced the risk that tainted blood will enter the U.S. blood supply, the separation of donated blood into component parts can allow more than one person to become exposed to a single contaminated donation. Kate Bohner, *Blood Strategies*, FORBES, Sept. 27, 1993, at 152, 152.

While findings suggest that transfusion-related HIV infections are extremely rare and well controlled in the United States, important questions remain. Researchers need to examine which components of current U.S. policy are responsible for impressive safety levels of the national blood supply and which aspects may be superfluous and inefficient. Unnecessary procedures for ensuring blood safety may waste scarce financial resources and result in the undue curtailment of blood supplies through excessive screening.

18. The earliest blood screening tests for HIV antibodies were implemented in 1985. See *AIDS Cases from Transfusions Give Rise to Suits*, N.Y. TIMES, July 26, 1991, at B16. Canada, for example, began screening its blood supply for HIV antibodies in 1985, several years after the first AIDS diagnoses. Accordingly, a number of Canadian provinces are adopting or considering policies to encourage the HIV testing of individuals who received blood transfusions between 1978 and 1985. Rebecca Wigod, *Blood Transfusions: HIV Testing Considered in B.C. as Ontario Takes Action*, VANCOUVER SUN, July 23, 1993, at C11, available in 1993 WL 7614212.

Likewise, the screening of blood for HIV antibodies in the United States began in 1985. Given an average period of ten years from time of infection to the development of AIDS, the number of persons potentially infected via transfusion during the 1970s and the first half of the 1980s is large. Laurie Garrett, *Young People and AIDS*, NEWSDAY, Aug. 4, 1992, available in 1992 WL 7548591.

For a discussion of the different types of screening tests and how they function, see John C. Petricciani & Jay S. Epstein, *The Effects of the AIDS Epidemic on the Safety of the Nation's Blood Supply*, 103 PUB. HEALTH REP. 236, 238-240 (1988).

19. Michael Chapman, *How Safe is the Blood Supply?*, CONSUMERS' RES., Apr. 1994, at 10, 14-15.

20. See, e.g., P. Binda ki Muaka et al., *Malaria, Anaemia, and HIV-1 Transmission in Central*

adoption and use of blood screening processes often lag.²¹ It has been estimated that as many as ninety percent of those infected with HIV reside in developing nations today.²²

In some countries, transfusion still accounts for as much as ten percent of all HIV infections.²³ One recent study reveals a poor understanding among blood donors in India regarding how AIDS is transmitted.²⁴ An uninformed public cannot effectively screen itself from attempting ill-advised donations. Ignorance may partially explain the high levels of HIV contamination in India's blood supply in the early 1990s,²⁵ which led the Indian government to suspend domestic manufacture of blood products.²⁶

Africa has been especially susceptible to problems associated with the contamination of blood supplies.²⁷ Because health care budgets can be severely constrained in developing nations, some governments have been unable to implement policies that effectively mandate consistent HIV testing of blood donations.²⁸ Moreover, the earliest HIV tests detected antibodies to HIV-1 and not the African HIV-2 strain,²⁹ which had not arrived in the United

Africa, 346 LANCET 1294, 1294 (1995) (noting that transfusion of HIV is a serious concern in a number of Central African countries, particularly in conjunction with the management of childhood anemia in regions where malaria is holoendemic).

The situation in some developing countries is such that the European Community has proposed a Council Regulation to implement a program to assist developing countries in their efforts to combat AIDS. Commission Proposal for a Council Regulation (EC) on HIV/AIDS-Related Operations in Developing Countries, 1995 O.J. (C252) 4, available in Westlaw, CELEX Database.

21. Delays in the consistent implementation of blood testing in developing countries are often a function of economic limitations. More consistent implementation of blood testing in cash-constrained countries may be fostered by the recent development of relatively inexpensive tests for HIV-1 and HIV-2. See *HIV Test Saves Lives in the Developing World*, AIDS WKLY., Dec. 11, 1995, available in 1995 WL 13702505 (discussing a dipstick test developed in Seattle, which permits HIV testing without support of elaborate laboratory facilities, at a cost of fifty cents per test).

22. *AIDS Now Challenging Every Aspect of Third World Development*, Canada Newswire, Feb. 11, 1994, available in Westlaw, CANWIREPLUS Database.

23. Sharon Kingman, *The Cost of Clean Blood*, NEW SCIENTIST, Sept. 5, 1992, at 20, 20.

24. N. Choudhury et al., *AIDS Awareness in Blood Donors in North India*, 5 TRANSFUSION MED. 267 (1995).

25. See Peter Kandela, *India: HIV Banks*, 338 LANCET 436, 437 (1991) (citing estimates that as much as 95% of donated blood in India remained unsafe).

26. *Id.*

27. Charles W. Hunt, *Africa and AIDS: Dependent Development, Sexism, and Racism*, MONTHLY REV., Feb. 1988, at 10, 10.

28. See Kingman, *supra* note 23, at 24.

29. For a discussion of the HIV-2 strain of the AIDS virus, see Francois Clavel et al., *Human Immunodeficiency Virus Type 2 Infection Associated with AIDS in West Africa*, 316 NEW ENG. J. MED. 1180 (1987).

States until the late 1980s.³⁰

Blood contamination scandals have arisen periodically in Europe, Asia, and North America.³¹ Levels of blood supply safety vary substantially from one country to the next,³² and while transfusion-associated HIV infections are declining in most industrialized nations,³³ they continue to rise in others. Often, blood contamination incidents are associated with the purported negligent failure of officials to mandate or implement policies that ensure consistent blood screening.

French government officials and advisors, for example, were criticized in the late 1980s for a 1985 contaminated blood scandal³⁴ that allegedly resulted from a failure to implement blood testing and screening procedures soon after they became available.³⁵ While many of the facts associated with the transfusion of contaminated blood in France over a decade ago remain to be determined, current charges include the provision of HIV-infected clotting factors to hemophiliacs despite the existence of heat-inactivated alternatives, the rejection of existing U.S. blood screening processes pending the availability of French tests, and the common use of blood donations from prisoners despite knowledge of the relatively high risk of AIDS among prison populations.³⁶ To avert future incidents of this nature, the Commission of the European Communities introduced a system of controls in 1995, intended to guarantee the quality and safety of blood and blood products.³⁷

30. See *infra* note 205 and accompanying text; see also Kathryn G. Lotfi, Note, *Suppliers of AIDS-Contaminated Blood Now Face Liability*, 34 HOW. L.J. 183, 191 (1991). More recently, tests have been developed to detect the presence of HIV-2 antibodies. These tests are mandated in the United States by the Food and Drug Administration (FDA). Monica Revelle, *Progress In Blood Supply Safety*, FDA CONSUMER, Apr. 1995, at 21, 24 sidebar "Testing Blood."

31. For an overview of recent incidents related to HIV-contamination of blood in some European and North American countries, see Richard L. Worsnop, *Blood Supply Safety*, 4 CQ RESEARCHER 987, 997-99 (1994). For discussion of a recent blood scandal in Japan, see *infra* notes 40-45 and accompanying text.

32. See S. Franceschi et al., *Trends in Incidence of AIDS Associated with Transfusion of Blood and Blood Products in Europe and the United States, 1985-93*, 311 BRIT. MED. J. 1534, 1534-35 & tbls.1&2 (1995) (examination of bloodborne AIDS rates in fourteen European countries and the United States).

33. *Transfusion-Associated AIDS Cases in U.S. and Most of Europe Declining*, AIDS WKLY., Jan. 29, 1996, available in 1996 WL 2093074.

34. Of 3000 French hemophilia patients, at least 1200 were estimated to have been infected with HIV as of 1991. Jean-Yves Nau, *France: HIV and Blood Testing*, 338 LANCET 809, 809 (1991).

35. For a discussion of the contaminated blood scandal in France, see *Are There Tragedies Without Villains?*, 371 NATURE 543 (1994).

36. Declan Butler, *Blood Scandal Raises Spectre of Dreyfus Case*, 371 NATURE 548, 548 (1994).

37. Commission of the European Communities, Pub. Health Law 15.18, Medicinal Products Derived from Human Blood or Plasma, available in LEXIS, World Library, Law File.

Allegations of similar incidents arise periodically throughout the industrialized world. Following initial inquiries in the early 1990s concerning blood contamination in Canada,³⁸ a high-level Red Cross official was investigated for purported negligence in administering Canadian blood donation and transfusion programs, which allegedly have been responsible for thousands of new HIV infections.³⁹ Likewise, critics have suggested that the Japanese government has understated or ignored incidents of transfusion-related HIV transmission.⁴⁰ Such charges recently led the Japanese government to issue a formal apology⁴¹ and to create a Ministry of Health and Welfare team to investigate the government's response to AIDS information in the early 1980s.⁴² The team's early findings suggest that the Japanese government suppressed a 1983 Ministry of Health and Welfare report that identified, among other things, the high risk of HIV contamination in blood products used by hemophiliacs.⁴³ Commentators contend that the failure of Japanese authorities to respond quickly to the information in the 1983 report, particularly regarding the need for heat treatment of some blood products,⁴⁴ resulted in avoidable infections.⁴⁵

Throughout the world, the risk of transfusion-related HIV transmission remains a serious problem. The following Section briefly discusses the two generic approaches that have been adopted to address this issue—liability-based and rule-based approaches. The latter are the main focus of this Article and are explained in detail in Section IV.

38. See Tom Fennell, *Voice of the Victims: An Inquiry Reveals How the Blood System Failed*, MACLEAN'S, Sept. 19, 1994, at 28, available in 1994 WL 6706577.

39. *International Red Cross Boss May Face Misconduct Charge in Canada*, AGENCE FRANCE-PRESSE, Jan. 29, 1996, available in Westlaw, EURONEWS Database. For a general discussion of Canada's problems regarding blood transfusions, see Wayne Kondro, *Canada: Blood Transfusion Inquiry*, 341 LANCET 1465 (1993).

40. *Lawmaker: Gov't Not Addressing AIDS Issue*, MAINICHI DAILY NEWS, Feb. 1, 1996, at 12, available in LEXIS, World Library, Mainws File.

41. Miho Yoshikawa, *Japan Reports Change in Pattern of Contracting AIDS*, Reuters North American Wire, Jan. 31, 1996, available in LEXIS, News Library, Curnws File.

42. *Health Minister Kan Announces HIV Infection Study Team*, Japan Econ. Newswire, Jan. 22, 1996, available in Westlaw, JWIREPLUS Database.

43. *Ministry Shelved Report on Risk of Transfusions in '83*, MAINICHI DAILY NEWS, Feb. 24, 1996, at 12, available in LEXIS, World Library, Mainws File.

44. Whereas heat-treated products were sold in the United States as early as March 1983, the sale of heat-treated products was not approved in Japan until July 1985. Thomas M. Burton, *Baxter, Bayer Join Japanese Settlement for Hemophiliacs Who Got AIDS Virus*, WALL ST. J., Mar. 15, 1996, at B5 (citing information provided by Bob Hurley, president of the Japanese unit of Baxter Int'l, Inc.).

45. See *Government Aware of HIV Infection Risk Via Blood Products*, Japan Econ. Newswire, Feb. 21, 1996, available in Westlaw, JWIREPLUS Database.

III. LEGAL, REGULATORY, AND PUBLIC POLICY CHALLENGES OF TRANSFUSION-ASSOCIATED HIV TRANSMISSION

Experts estimate that between ninety⁴⁶ and ninety-five percent⁴⁷ of persons transfused with blood infected by HIV-1 become seropositive⁴⁸ themselves as a result. Susceptibility to transfused HIV may be even higher among some classes of patients, such as cancer patients, whose immune systems are often already compromised at the time of surgery.⁴⁹ Accordingly, ensuring the integrity of blood supplies plays a critical role in the containment of AIDS.⁵⁰ Furthermore, because blood frequently crosses international borders,⁵¹ the consistent adoption of policies that protect blood supplies and respect human rights⁵² will be crucial to any effective global AIDS prevention policy.

46. Elizabeth M. Donegan et al., *Infection with Human Immunodeficiency Virus Type 1 (HIV-1) Among Recipients of Antibody-Positive Blood Donations*, 113 ANNALS INTERNAL MED. 733, 737 (1990) (reporting a 90% incidence of infection following transfusion of HIV-contaminated blood).

47. See J.W. Ward et al., Correspondence, *Transfusion Associated HIV Infection*, 322 NEW ENG. J. MED. 775 (1990); see also Declan Butler, *Concern over "Invisible Problem" of HIV Blood in Developing Countries*, 369 NATURE 429, 429 (1994) ("Receiving a transfusion of HIV-contaminated blood carries a roughly 95 percent risk of HIV infection . . .").

48. Seropositivity refers to blood test results indicating infection with HIV.

49. See Peggy Easton, *Cancer Patients at Low Risk from Blood Transfusions*, 87 J. NAT'L CANCER INST. 250, 250 (1995).

50. Possible HIV contamination of blood supplies has caused concern at various times in many countries. See, e.g., Bhupesh Mangla, *India: Disquiet About AIDS Control*, 340 LANCET 1533 (1992) (discussing blood safety policy in India in the wake of discovery of HIV antibodies in indigenously produced blood products); Alan Cowell, *4 Germans Convicted of Selling HIV Blood*, INT'L HERALD TRIB., Dec. 2, 1995, available in LEXIS, News Library, Curnws File (reporting the criminal conviction of three German executives and a German lab technician for knowing distribution of tainted blood); Stephen Kinzer, *German Official Denies Starting an AIDS Panic*, N.Y. TIMES, Nov. 6, 1993, at 5 (documenting the alleged distribution of HIV-tainted blood at numerous health centers in Germany); Alan Riding, *France Approved Use of AIDS-Tainted Blood*, N.Y. TIMES, Oct. 20, 1991, § 1, at 7 (citing an official report that charged the French government with authorizing transfusions of contaminated blood); Marlise Simons, *France Convicts 3 in Case of H.I.V.-Tainted Blood*, N.Y. TIMES, Oct. 24, 1992, at 1 (reporting the conviction of former health officials whose alleged distribution of HIV-tainted blood purportedly caused the infection of over a thousand hemophiliacs).

51. For example, blood products not tested for HIV antibodies by a company in Germany were exported to countries in Europe and the Middle East. Bull & Akin, *supra* note 17, at 24 *illus.*

52. Although human rights issues may not seem highly relevant to blood supply issues at first, actions such as the 1990 FDA ban on blood donations from all Haitian immigrants have sparked considerable ire among concerned groups and activists. See generally Janice Somerville, *FDA Position Banning Haitian Blood Donation Stirs Protest*, AM. MED. NEWS, June 15, 1990, at 3, available in Westlaw, HWD Database. The FDA ban was lifted shortly after it was adopted. Janice Somerville, *FDA Reverses Policy, Drops Ban on Haitian Blood Donors*, AM. MED. NEWS, Dec. 28, 1990, at 2, available in Westlaw, HWD Database; *Safer Blood, Fairer Policy*, N.Y. TIMES, Dec. 7, 1990, at A34.

More recently, furor arose among Ethiopian immigrants in Israel in response to allegations that their blood donations were being destroyed because officials believed the donations bore a high risk of

A. Liability-Based Approaches

Liability for the provision or transfusion of contaminated blood can help to ensure a pure blood supply by encouraging safe, responsible behavior.⁵³ In the United States,⁵⁴ such liability is usually grounded in negligence,⁵⁵ not strict liability or warranty theory. A number of decisions in the early 1980s protected blood banks from negligence liability, reasoning that because the risk of transfusion-associated AIDS was not commonly understood at the time, HIV transmission could not have been avoided through the exercise of reasonable care.⁵⁶ The Supreme Court of Colorado departed from this position in *United Blood Services v. Quintana*,⁵⁷ suggesting that blood banks could be held liable for negligence prior to the development of HIV blood tests if they failed to employ “available and proven scientific safeguards” in acquiring, preparing, or transferring human blood or its components for use in medical treatment.⁵⁸

HIV infection. See generally *AJ Congress Says Decision in Israel to Discard Ethiopian Blood Donations Was Taken “In Good Faith” and Is Not Racist, but Method Used Was “An Appalling Mistake”*, PR Newswire, Jan. 31, 1996, available in Westlaw, PRWIREPLUS Database; Patrick Cockburn, *Black Israelis Riot Over Insult to Their Blood*, INDEPENDENT (London), Jan. 29, 1996, at 9, available in Westlaw, INDEPENDENT Database; Judy Siegel, *MDA Accuses TV of Inciting Ethiopians*, JERUSALEM POST, Feb. 1, 1996, available in 1996 WL 4068559.

53. The threat of liability creates an incentive for parties to exercise care in the processing, handling, and distribution of blood and blood products.

54. Scholars in other nations also grapple with the appropriate sphere of liability for blood-related injuries in the era of AIDS. See, e.g., Sanda Rodgers, *The Canadian Blood Delivery System: Liability for Blood Related Injuries*, 21 OTTAWA L. REV. 311 (1989).

55. Juries have recently held blood collection and distribution centers liable for negligence in collecting and screening blood and blood products prior to the development of blood screening tests. See, e.g., George James, *Blood Center Liable in H.I.V.-Infected Transfusion*, N.Y. TIMES, Dec. 20, 1995, at B1. Negligence applies most obviously to those instances in which professionals failed to screen blood or were careless in executing screening procedures after 1985, when the technology for blood screening became widely available. However, courts differ on whether negligence is a viable claim in connection with blood transfusions given prior to the availability of blood screening technologies. Compare *Doe v. University Hosp. of the N.Y. Univ. Med. Ctr.*, 561 N.Y.S.2d 326, 328 (N.Y. Sup. Ct. 1990) (stating that negligence claims for acts committed in 1984 are not foreclosed by the pre-1985 unavailability of blood screening technologies) with *Doe v. University of Cincinnati*, 538 N.E.2d 419, 425 (Ohio Ct. App. 1988) (denying request of plaintiff for discovery because the contaminated blood in question was donated prior to the development of tests for HIV antibodies). For a general discussion of transfusion-related negligence, see Roger Parloff, *Tainted Tort*, AM. LAW., Sept. 1992, at 76.

56. See, e.g., *McKee v. Miles Lab., Inc.*, 675 Supp. 1060, 1063-64 (E.D. Ky. 1987), *aff’d sub nom.*, *McKee v. Cutter Lab., Inc.*, 866 F.2d 219 (6th Cir. 1989).

57. 827 P.2d 509 (Colo. 1992).

58. *Id.* at 523 (discussing COLO. REV. STAT. ANN. § 13-22-104(1) (West 1989)). For a detailed discussion of the case, see Jessamine R. Talavera, *Quintana v. United Blood Services: Examining*

Strict liability and warranty actions have been less successful.⁵⁹ Most states define the distribution of blood and blood components as a provision of services rather than a sale of products,⁶⁰ effectively removing them from the scope of strict liability and warranty actions,⁶¹ particularly when the provider is a hospital.⁶² This majority approach has been codified in many states through "blood shield statutes" that expressly label the provision of blood as a service, exempt blood donations from strict liability, or both.⁶³

Industry Practice in Transfusion-Related AIDS Cases, 2 CORNELL J.L. & PUB. POL'Y 475, 477 (1993).

59. See, e.g., *Kozup v. Georgetown Univ.*, 663 F. Supp. 1048, 1058-60 (D.D.C. 1987) (granting summary judgment to hospital and blood bank in regard to warranty and strict liability claims), *vacated in part on other grounds*, 851 F.2d 437 (D.C. Cir. 1988); *Howell v. Spokane & Inland Empire Blood Bank*, 785 P.2d 815, 821-22 (Wash. 1990) (en banc) (declining to extend strict liability to the collection and distribution of blood and blood products).

60. This characterization has been challenged by critics who contend that the conveyance of products like clotting agents for home storage and self-administration more closely resembles a sale than the provision of a service. See, e.g., J.M. Bielan, *Bad Blood: What is a Blood Bank's Duty to Prevent the Spread of AIDS?*, CAL. LAW., Apr. 1985, at 28, 31 (citing the reasoning of one lawyer who has represented plaintiffs in litigation against blood banks).

61. Lipton, *supra* note 12, at 135-36. The statutory definition of blood as a "service" and not a product has essentially enhanced the protection blood banks receive under their liability insurance policies. See *American Red Cross v. Travelers Indem. Co. of R.I.*, 816 F. Supp. 755 (D.D.C. 1993). By relying on the statutory definition of blood rather than the contractual definition of "product" found in the insurance policy, the *Red Cross* court effectively brought the liability within the scope of the policy. *Id.* at 759. Furthermore, the *Red Cross* court defined each decision "to screen the donor, . . . to test the blood, . . . [or] to provide warnings" as a separate occurrence under the policy. *Id.* at 761. This application of the policy's occurrence definition greatly increased the total insurance coverage available to the *Red Cross* under the policy because "each act of distribution of contaminated blood constitutes an 'occurrence' for purposes of applying the \$1 million occurrence limit." *Id.*

62. See *Perlmutter v. Beth David Hosp.*, 123 N.E.2d 792, 793-96 (N.Y. 1954) (establishing the doctrine that a hospital's provision of blood is part of a service contract rather than a sales contract with patients).

63. See ALA. CODE § 7-2-314(4) (1993); ALASKA STAT. § 45.02.316(e) (1994); ARIZ. REV. STAT. ANN. §§ 32-1481, 36-1151 (1993); ARK. CODE ANN. § 20-9-802 (Michie 1991); CAL. HEALTH & SAFETY CODE § 1606 (West 1990); COLO. REV. STAT. ANN. § 13-22-104(2) (West 1989); CONN. GEN. STAT. ANN. § 19a-280 (West 1986); DEL. CODE ANN. tit. 6, § 2-316(5) (1993); FLA. STAT. ANN. § 672.316(5), (6) (West 1993); GA. CODE ANN. § 51-1-28 (1982); HAW. REV. STAT. § 327-51 (1985); IDAHO CODE § 39-3702 (1993); 745 ILL. COMP. STAT. ANN. 40/2-2 (West 1993); IND. CODE ANN. § 16-8-7-2(a) (West 1992); KAN. STAT. ANN. § 65-3701 (1992); KY. REV. STAT. ANN. § 139.125 (Michie 1991); LA. REV. STAT. ANN. § 9:2797 (West 1991); ME. REV. STAT. ANN. tit. 11, § 2-108 (West 1995); MD. CODE ANN. CTS. & JUD. PROC. § 5-373 (1995); MASS. GEN. LAWS ANN. ch. 106, § 2-316(5) (West 1990); MICH. COMP. LAWS ANN. § 333.9121(2),(3) (West 1992); MISS. CODE ANN. § 41-41-1 (1993); MO. ANN. STAT. § 431.069 (Vernon 1992); MONT. CODE ANN. §§ 50-33-102 to -104 (1995); NEB. REV. STAT. § 71-4001 (1990); NEV. REV. STAT. § 460.010 (1995); N.H. REV. STAT. ANN. § 507:8-b (1983); N.M. STAT. ANN. § 24-10-5 (Michie 1994); N.D. CENT. CODE § 43-17-40 (1993); OHIO REV. CODE ANN. § 2108.11 (Baldwin 1993); OR. REV. STAT. § 97.968 (1995); S.C. CODE ANN. § 44-43-10 (Law. Co-op. 1985); S.D. CODIFIED LAWS ANN. § 57A-2-315.1 (1988); TENN. CODE ANN. § 47-2-316(5) (1992); TEX. CIV. PRAC. & REM. CODE ANN. § 77.003(a) (West 1986); UTAH CODE ANN. § 26-31-1 (1995); VA. CODE ANN. § 32.1-297 (Michie 1992); WASH. REV. CODE

While blood shield statutes historically have provided broad protection against strict liability to blood providers, some signals suggest a movement towards more expansive accountability.⁶⁴ For example, the Indiana Court of Appeals has recently held that the state's blood shield statute protects only blood banks and hospitals, not manufacturers of blood products.⁶⁵ The ruling is the first to deny pharmaceutical companies protection under a blood shield statute.⁶⁶ Whether it represents a movement towards greater transfusion-related liability in the future remains to be seen. Likewise, Federal Drug Administration ("FDA") Commissioner David Kessler's assertion that blood banks should be held to similar standards as private pharmaceutical companies⁶⁷ suggests that a wider array of institutions, both public and private, may be held accountable for the transfusion of tainted blood in the future. Nations throughout the world are grappling with these same issues, developing policies that will determine the appropriate bases of liability with respect to the transfusion of HIV.⁶⁸

B. Rule-Based Approaches

Rule-based means of protecting the public from blood-borne HIV contamination are the focus of this Article. Statutes, regulations, and institutional policies aimed at protecting the blood supply are all rule-based approaches, reflecting an attempt to thwart HIV contamination by applying mandatory, standardized practices and procedures to the processing and handling of blood.⁶⁹ Whereas liability-based approaches seek to discourage

ANN. § 70.54.120 (West 1992); WIS. STAT. ANN. § 146.31(2) (West 1989); WYO. STAT. § 34.1-2-316(c)(iv) (Michie 1991).

64. For arguments in favor of enhanced liability for impure blood products, including the expansion of strict liability, see Michael J. Miller, Note, *Strict Liability, Negligence and the Standard of Care for Transfusion-Transmitted Disease*, 36 ARIZ. L. REV. 473 (1994).

65. See JKB, Sr. v. Armour Pharm. Co., 660 N.E.2d 602, 604-06 (Ind. Ct. App. 1996).

For a discussion of the arguments for excluding manufacturers of blood products from strict liability immunity, see Pamela T. Westfall, Note, *Hepatitis, AIDS and the Blood Product Exemption from Strict Products Liability in California: A Reassessment*, 37 HASTINGS L.J. 1101 (1986).

66. *Blood Shield Law Does Not Insulate Factor VIII Maker from Liability Suit*, Health Care Daily (BNA), Feb. 2, 1996, available in LEXIS, Bna Library, Bnahcd file.

67. See Philip J. Hilts, *F.D.A. Seeks Tighter Rules on Safety of Blood Supply*, N.Y. TIMES, July 2, 1993, at A11 (quoting FDA Commissioner).

68. See, e.g., M.P. Bastianon, *Aids and the Blood Bank: The Argument for Strict Liability Exemption*, 11 U. TASMANIA L. REV. 191 (1992) (discussing bases of liability for the transfusion of HIV under Australian law).

69. A good example of a regulatory approach towards ensuring the purity of the blood supply is the FDA's five "layers of safeguards," which consist of donor screening, donor lists, blood testing,

risky or negligent practices through the threat of punishment subsequent to infraction, rule-based approaches establish barriers to eliminate opportunities for contamination. The adoption of statutes, regulations, and policies that set standards to prevent blood contamination will likely expand in the future, given the threat of government liability for transfusion-related infections.⁷⁰

In the United States, rule-based approaches have yielded remarkable improvements in the safety of blood transfusions.⁷¹ These improvements are the result of a multitiered strategy that employs purportedly mutually reinforcing policies⁷² to protect blood from exposure to contaminants and individuals from exposure to contaminated blood. Many of these policies have been adopted in various combinations in other parts of the world as well. Donor interviewing and donor self-deferral are two similar, front-end methods⁷³ of screening out risky donations.⁷⁴ In donor interviews, potential donors are questioned to determine whether they fall within high-risk categories and should therefore be prohibited from making donations. Under self-deferral programs, officials inform prospective donors of the qualifications to donate. Donors are required to disqualify themselves if they fail to meet all qualifications.⁷⁵ The United States has also adopted an all-volunteer blood donor policy,⁷⁶ reasoning that sellers of blood face a conflict of interest which encourages them to lie during the interview.⁷⁷ After

quarantine of untested blood, and investigation of problems related to the processing of blood and blood products. *See generally* Revelle, *supra* note 30, at 22-24.

70. For example, the province of Ontario, Canada, was sued in 1992 in regard to transfusion-related infections. *See* Tony Wong, *Ontario Faces 50 Lawsuits Over AIDS-Tainted Blood*, TORONTO STAR, Mar. 18, 1992, at E8.

71. The incidence of transfusion-related contraction of hepatitis, for instance, has declined from approximately 30% three decades ago to approximately 1% today. Bradford W. Stone, *How FDA Safeguards the Blood Supply*, FDA CONSUMER, June 1991, at 13, 15. Likewise, the risk of being infected with HIV through a transfusion in the United States has fallen from approximately 0.04% before screening was available, to around 0.0004% subsequent to the implementation of routine screening. Worsnop, *supra* note 31, at 988.

72. Although the purported mutual reinforcement of policies is the ideal, it may not always be the reality. A crucial question in assessing the effectiveness of the multitiered strategy focuses on the marginal contributions of each tier. As discussed in Section IV, *infra*, some tiers add negligible effectiveness to the overall strategy at a substantial and unjustifiable cost.

73. The term "front-end method" refers to means of preventing risky blood donations from ever being made. In contrast, a "back-end method" discourages risky or infected donations that have already been made from being incorporated into public blood supplies.

74. *See infra* Section IV.C.

75. Obviously, donor interviewing and donor self-deferral can be combined at a single site for mutual reinforcement.

76. *See infra* Section IV.B.

77. *U.S. Blood Supply Safe, Researchers Say*, Reuters North American Wire, Nov. 6, 1994,

voluntary donors have been qualified on the basis of interview responses and self-deferral procedures, their donations are tested, and if contaminated with HIV, quarantined from the blood supply.⁷⁸

To reinforce these policies, the United States and other countries have promulgated regulations governing the operating procedures of organizations that collect or distribute blood or blood products.⁷⁹ Some local authorities, as well as national organizations like the American Red Cross, maintain registries listing the names of persons who have attempted to donate blood, but tested seropositive at the time of the attempted donation.⁸⁰ The registries are used to disqualify rejected donors who try to make subsequent donations.⁸¹ Registration processes have also been used to trace donations originally believed to be uninfected but later found to be contaminated.⁸² Finally, some commentators have encouraged autologous transfusion,⁸³ directed transfusion,⁸⁴ and so-called "bloodless surgery"⁸⁵ as means of averting new HIV infections.⁸⁶

Despite these potential safeguards, individuals continue to become infected with HIV through the transfusion of blood and the use of blood products.⁸⁷ Even in the United States, where safety of the blood supply has improved dramatically, critics suggest that the risk of transfusion-related HIV infection remains a serious problem.⁸⁸ Nonetheless, responsible policies must account for both the costs and the benefits of potential marginal

available in LEXIS, News Library, Allnws File.

78. See Elisabeth Rosenthal, *Blood Banks Vigilant But Vouch for Safety*, N.Y. TIMES, July 27, 1992, at B2 (writing that "[t]he safety of the blood supply is maintained by questioning potential donors . . . as well as by testing donated blood").

79. See, e.g., 1989 O.J. (L 181) 44 (procedures for screening blood supplies in European Community), available in Westlaw, CELEX Database; 1991 O.J. (L 175) 26 (establishing "Europe Against AIDS Program," which includes provision for ensuring safety of blood transfusions), available in Westlaw, CELEX Database; *infra* Section IV.D.

80. See *infra* Section IV.E.

81. See *infra* notes 276-78 and accompanying text.

82. See *infra* Section IV.F.

83. See *infra* notes 323-41 and accompanying text.

84. See *infra* notes 342-53 and accompanying text.

85. See *infra* notes 354-64 and accompanying text.

86. See *infra* Section IV.G.

87. See Revelle, *supra* note 30, at 22 (noting that despite improvements in protecting the blood supply, some risk of HIV infection still exists).

88. For point-counterpoint arguments regarding the safety of the U.S. blood supply today, see *At Issue: Is the Blood Supply in the United States Safe?*, 4 CQ RESEARCHER 1001 (1994) (summarizing the conflicting positions of the American Red Cross and Michael Chapman, former associate editor of a consumer research publication).

improvements to the integrity of blood supplies. Whereas some of the policies examined in this Article are fairly uncontroversial, others have been the subject of heated debate. The following Section examines and assesses the most significant rule-based approaches.

IV. AN ANALYSIS OF BLOOD POLICY OPTIONS

This Section examines the most promising rule-based approaches to reducing the incidence of transfusion-associated HIV transmission. The proposed policies are examined in subsequent subsections and include (A) mandatory testing of donated blood and rejection of contaminated donations; (B) prohibition of the sale of blood through a mandatory all-volunteer policy; (C) predonation questioning and disqualification of donations from persons in high-risk categories; (D) regulations requiring improvements in information transmission, operating procedures, and the maintenance of blood supplies; (E) development and maintenance of information registries; (F) ex post facto procedures to trace recipients of blood identified as high-risk or tainted subsequent to transfusion; and (G) encouragement of autologous transfusion, directed donation, and bloodless surgery.

A. Mandatory Testing of Donated Blood and Rejection of Contaminated Donations

Among the less controversial regulatory measures is mandatory post-collection screening prior to incorporating donations into the public blood supply.⁸⁹ Since the first widely respected blood test for HIV antibodies became available in 1985,⁹⁰ the screening of specimens has become a fairly

89. While the concept of post-collection screening of blood donations is not controversial, the degree of rigor associated with blood testing has been the subject of some debate. Because existing tests serve as highly effective screens when properly and consistently administered, supplemental tests often yield negligible benefits at substantial cost. For a specific example of this problem, see *infra* notes 121-34 and accompanying text.

While the costs of blood screening procedures vary, the literature clearly suggests that some form of blood screening is cost effective. See, e.g., Richard S. Eisenstaedt & Thomas E. Getzen, *Screening Blood Donors for Human Immunodeficiency Virus Antibody: Cost-Benefit Analysis*, 78 AM. J. PUB. HEALTH 450, 453 (1988) (concluding that "current testing procedures generate net economic benefits in aggregate").

90. See *supra* note 12. Unfortunately, transfusion-associated HIV contamination was not uncommon prior to the availability of reliable blood screening technology. According to National Hemophilia Foundation estimates, approximately 10,000 people in the United States were infected from blood-clotting products prior to the implementation of safeguards. Larry MacIntyre,

common worldwide practice.⁹¹ After routine blood donation testing was implemented in the United States, the risk of being infected with HIV through a transfusion fell from approximately 1 in 2500 to around 1 in 225,000.⁹² In addition to protecting blood supplies, donor testing can also provide unique kinds of data that can improve our understanding of how HIV is transmitted.⁹³

Given the high incidence of HIV infection throughout many parts of the world, failure to implement specimen testing and screening procedures would be disastrous.⁹⁴ The only factors that might reduce the desirability of a

Pharmaceuticals Lose Lawsuit Protection, INDIANAPOLIS STAR, Jan. 25, 1996, available in 1996 WL 3119163.

91. The screening of blood donations has been more effectively implemented in some countries than in others. For example, transfusion-related infections remain alarmingly high in communist or formerly communist countries, where officials have been slow to adopt fundamental safety procedures that are standard in most industrialized nations. See, e.g., *Risks of AIDS Largely Ignored in Romania*, AIDS WKLY., Jan. 8, 1996, available in 1996 WL 2092936.

Transfusion of HIV-contaminated blood is also relatively common in some developing countries that have access to, and purportedly employ, blood screening technologies. The failure of pretransfusion testing to reduce the transmission of HIV effectively in these countries has been attributed to the inconsistency of testing, as well as high levels of donor seropositivity. Accordingly, transfusion remains the source of between 5% and 10% of all HIV infections worldwide. Butler, *supra* note 47, at 429.

92. Worsnop, *supra* note 31, at 988.

93. Self-screening and disqualification criteria render blood bank donors a uniquely valuable population from whom investigators can discover previously unidentified modes of HIV transmission. See Lyle R. Petersen et al., *Methodologic Approaches to Surveillance of HIV Infection Among Blood Donors*, 105 PUB. HEALTH REP. 153, 153 (1990). Assuming that disqualification based on behavioral patterns or donor status is reasonably effective, blood donations given by those originally qualified to donate but later discovered to be infected will provide researchers with a pool of persons whose infection cannot be easily or immediately explained by known causes. See *id.* at 155-56. While some cases will reflect error in donor self-assessment, personnel's assessment of donors, or false reporting, other cases may reflect high-risk behaviors that have yet to be identified as common means of transmitting HIV. See *id.* at 153-56. Presuming ethical issues regarding donor confidentiality are addressed carefully and conscientiously, scientists can and should study disqualified donor groups to understand more about how HIV is spread. The resulting findings have the potential to inform the public further about risky behaviors and to enable blood collection centers to establish more accurate criteria for donor self-deferral. See *id.* at 157.

94. The risk of not screening blood donations obviously increases proportionately with the prevalence of HIV infection in any given donor population. The prevalence of HIV infection and the attendant risk from failing to screen blood donations differ considerably by region. For example, the World Health Organization estimates that at least five million African adults have been infected with HIV as of 1991, and health care workers have reported that AIDS cases have doubled among certain populations in Africa every eight months. Louis W. Sullivan, *A Presidential Health Mission to Africa*, 106 PUB. HEALTH REP. 105, 108-09 (1991). These disproportionately high infection rates in Africa vary by geographic area. The proportion of the population believed to carry the AIDS virus in South Africa has recently been estimated at 2.1%. In contrast, infection rates in urban areas of Zimbabwe, Zambia, and Uganda have been estimated at between 20% and 30%. Hugh Pope, *AIDS Set to Engulf South Africa*, INDEPENDENT (London), Mar. 8, 1995, at International 13 available in Westlaw,

particular specimen screening procedure are inaccuracy or prohibitive cost. As is demonstrated in the following subsections, the kinds of blood tests that are routinely employed in the United States today—ELISA and Western Blot—are both accurate⁹⁵ and reasonably cost effective.⁹⁶ These tests are discussed in Section IV.A.1. In addition, the FDA is requiring blood banks to administer supplemental HIV-antigen tests beginning in 1996.⁹⁷ As we shall see in Section IV.A.2, these tests do not withstand a reasonable social cost-benefit analysis. Section IV.A.3 discusses an important post-screening issue that various countries address in divergent ways: whether donors whose specimens test seropositive should be informed of their HIV status.

1. ELISA and Western Blot Blood Tests

The FDA first approved an HIV-antibody blood test in early 1985.⁹⁸ The test most commonly used to detect HIV antibodies in blood donations is called ELISA, an acronym for “enzyme-linked immunosorbent assay.”⁹⁹

INDEPENDENT Database.

In the United States, concentrated drug use has contributed to disproportionately high infection rates in some inner-city neighborhoods. See MARY ELLEN HOMBS, AIDS CRISIS IN AMERICA: A REFERENCE HANDBOOK 11 (1992) (“Epidemiological evidence has shown that the geographic concentration of drug use in certain parts of the inner city results in geographic concentration of HIV and very high rates of infection in the population of these neighborhoods.”). Without blood testing and screening, the proportion of the blood supply containing HIV in such areas could approach the frighteningly high infection rates of the donor populations. While measures like the refusal to accept donations from persons in high-risk classes could reduce the proportion of donated blood infected with HIV, such measures would likely be of limited effectiveness without blood testing and screening due to such constraints as faulty donor reporting.

95. See *infra* notes 100-01.

96. See *infra* notes 104-05 and accompanying text.

97. See Memorandum from Kathryn C. Zoon, Ph.D., Director, Center for Biologics Evaluation and Research, Public Health Service, FDA, to All Registered Blood and Plasma Establishments, Recommendations for Donor Screening with a Licensed Test for HIV-1 Antigen 4 (Aug. 8, 1995), available at (visited on Nov. 15, 1995) <<http://www.fda.gov/cber/cberftp>> [hereinafter Antigen Memorandum]; see also *New AIDS Screening Test Detects Virus Earlier; Now Available to Blood and Plasma Collection Centers*, PR Newswire, Mar. 14, 1996, available in Westlaw, PRWIREPLUS Database; Sally Squires, *Blood Banks Adopt Stricter AIDS Test*, WASH. POST, Apr. 2, 1996, Health Mag., at 6.

98. The test was developed by Abbott Laboratories. See Della De Lafuente, *After 10 Yrs. Abbott Still AIDS Test Leader*, CHI. SUN-TIMES, Mar. 2, 1995, available in 1995 WL 6647044; see also *supra* note 12. Abbott Laboratories has since developed and marketed four refined versions that incorporate technological advances, yielding improved accuracy and reliability. *Id.*

99. After the development of blood ELISA tests, companies began experimenting to develop saliva ELISA tests. In early 1995, the FDA approved a product called “OraSure,” a saliva ELISA test for HIV antibodies manufactured by Epitepe Corporation. *Statement on FDA Approval of AIDS Virus Test System Based on Oral Fluid Samples*, PR Newswire, Dec. 23, 1994, available in Westlaw,

ELISA results, fairly reliable in their own right, can be confirmed using the more specific, and more expensive, Western Blot test.¹⁰⁰ In tandem with Western Blot confirmation, ELISA yields high levels of diagnostic accuracy.¹⁰¹ While the Centers for Disease Control and Prevention ("CDC") have recommended the use of Western Blot testing for the confirmation of positive ELISA results,¹⁰² critics contend that Western Blot confirmation is expensive, laborious, subjective, and indeterminate.¹⁰³

Evidence suggests that mandating ELISA testing with Western Blot confirmation is prudent. Professor Gregory Gelles has studied blood screening costs and the numbers of transfusion-related HIV infections that are directly averted as a result of ELISA and Western Blot confirmation.¹⁰⁴ He estimates that the cost of preventing each direct infection ranges from \$36,300 to \$128,833.¹⁰⁵ Even at the higher end, these costs are low compared to the costs of failing to prevent an infection, which include (i) treating the patient for life, (ii) the patient's pain and suffering, (iii) life-years lost to

PRWIREPLUS Database [hereinafter *Statement on FDA Approval*].

The potential use of saliva ELISA tests to screen prospective blood donors for HIV is controversial. Although it approved the saliva ELISA test, the FDA contends that OraSure is less accurate than the blood-based ELISA tests currently in use. According to the FDA, OraSure fails to detect one or two infected persons for every hundred infected persons tested and gives false positive diagnoses of approximately two people for every hundred uninfected persons tested. Joyce Price, *FDA Approves Saliva Test for HIV but Agency, Maker Differ a Little on OraSure's Accuracy*, WASH. TIMES, Dec. 24, 1994, available in 1994 WL 10986511; *Statement on FDA Approval*, supra. Epitope Corporation contends that the difference is more minute—99.6% accuracy for blood ELISA tests versus 99.2% accuracy for Orasure. Price, supra, at A1. For further study of the saliva ELISA test's reliability, see A.J. Hunt et al., *The Testing of Saliva Samples for HIV-1 Antibodies: Reliability in a Non-Clinic Setting*, 69 GENITOURINARY MED. 29 (Feb. 1993).

Under present FDA policy, OraSure has been approved for professional diagnostic use, but not for the screening of blood donors. *Statement on FDA Approval*, supra.

100. Robert N. Husson et al., *Diagnosis of Human Immunodeficiency Virus Infection in Infants and Children*, 86 PEDIATRICS 1, 3 (1990). For a discussion of the sensitivity and specificity of both tests, see Evelyne T. Lennette et al., *Indirect Immunofluorescence Assay for Antibodies to Human Immunodeficiency Virus*, 25 J. CLINICAL MICROBIOLOGY 199 (1987).

101. See P. Kimmig, *Sensitivität und Spezifität von Untersuchungsverfahren bei HIV [Sensitivity and Specificity of HIV Tests]*, 52 DAS ÖFFENTLICHE GESUNDHEITSWESEN 419 (1990) (stating the sensitivity of HIV blood tests to be approximately 99 to 100%, and the specificity to be 1 false positive per 50,000 to 100,000).

102. CENTERS FOR DISEASE CONTROL, AIDS PROTOTYPE GUIDELINES (1988).

103. V. Soriano et al., *Evaluación de diferentes criterios de interpretación del Western blot para el diagnóstico de la infección por el virus de la inmunodeficiencia humana [Evaluation of Different Criteria of Interpretation of the Western Blot for the Diagnosis of Infection by the Human Immunodeficiency Virus]*, 100 MEDICINA CLÍNICA 561 (1993).

104. See Gregory M. Gelles, *Costs and Benefits of HIV-1 Antibody Testing of Donated Blood*, 12 J. POL'Y ANALYSIS & MGMT. 512 (1993).

105. *Id.* at 520.

AIDS, and (iv) potential infection of others through the recipient of unscreened blood.¹⁰⁶

Moreover, because of technological improvements in ELISA testing, HIV-antibody screening processes are becoming increasingly effective at preserving the purity of the blood supply. Whereas experts estimated that assays used in the late 1980s identified HIV antibodies an average of forty-five days after infection,¹⁰⁷ improved assays now detect recombinant, protein-based HIV antibodies an average of twenty-five days after infection.¹⁰⁸ In effect, technological improvements have nearly halved estimates of the period of "serolateness"—the span of time after infection but prior to the production of antibodies, during which tests will yield false negative results.¹⁰⁹ Because false negative results are a troublesome source of error that may permit contaminated blood to enter the blood supply,¹¹⁰ the downward adjustment of the window period suggests that ELISA testing and Western Blot confirmation are becoming increasingly effective.

2. Antigen Testing

The difficult questions associated with mandatory testing of blood donations concern the rigor with which specimens should be tested, rather than whether they should be tested at all. Given that the development and

106. Screening of blood avoids this final cost in at least two ways. First, some prospective donors, upon discovering through screening that they carry HIV, will alter their behavior and avoid high-risk contacts with other parties. Second, those whose transfusion with HIV-contaminated blood is averted by screening avoid infection themselves, thereby eliminating the possibility of passing the virus on to secondary parties. *See id.* at 521.

107. *See generally* L.R. Petersen et al., *Duration of Time from Onset of Human Immunodeficiency Virus Type 1 Infectiousness to Development of Detectable Antibody*, 34 *TRANSFUSION* 283 (1994).

108. *See* M.P. Busch et al., *Time Course of Detection of Viral and Serologic Markers Preceding Human Immunodeficiency Virus Type 1 Seroconversion: Implications for Screening of Blood and Tissue Donors*, 35 *TRANSFUSION* 91 (1995).

109. The period between HIV infection and the development of identifiable HIV antibodies is also commonly referred to as the "window period."

110. Although the window period provides an opportunity for HIV-contaminated blood to enter the public blood supply undetected by routine testing, the estimated incidence of such cases is surprisingly infrequent. Recent CDC estimates suggest that one in 360,000 donations occurs during the window period of antibody undetectability. *Study Finds Risk of HIV Transmission Small*, *AIDS WKLY.*, Jan. 15, 1996, available in 1995 WL 2092974. Nevertheless, the window period is considered to be responsible for most cases of transfusion-associated HIV transmission today. *See Use of Seroconversion Panels to Estimate the Reduction in the "Window" Period Between the Appearance of Nucleic Acid and Serological Markers in HIV, HBV and HCV Infected Blood*, *AIDS WKLY.*, Dec. 18, 1995 (printing an abstract of a study by M. Manak et al., presented at a 1996 meeting of the Am. Ass'n of Clinical Chemistry), available in 1995 WL 13702256.

adoption of effective new blood screens has already raised the cost of collecting and distributing blood substantially since the mid-1980s,¹¹¹ authorities must decide the point at which a new test's incremental protection cannot justify its direct and indirect incremental costs.¹¹² The recent debate over requiring supplemental antigen testing brings this discussion into focus.

Recently, for example, a panel from the National Institutes of Health ("NIH") reviewed a series of tests presently used to screen HIV, syphilis, and hepatitis.¹¹³ The findings suggest that a point exists where adding a new test provides negligible screening benefits, by rendering enough false positive results to cause blood banks to dump hundreds of thousands of units of untainted blood.¹¹⁴

False positives associated with supplemental screening can exacerbate blood shortages at a time when blood donations are already down significantly.¹¹⁵ In countries that operate under blood deficits, such as the United States¹¹⁶ and Canada,¹¹⁷ reductions in the blood supply can be both costly and dangerous. The social cost of this waste depends upon a number of factors, including the prevalence of false positive results from the supplemental screening under consideration, the scarcity of blood supplies, and the concomitant degree to which disposal of uninfected blood will affect morbidity and mortality rates.

The trade-off between rigor in finding tainted blood and the increased

111. Whereas blood centers typically administered two tests on each donation sample in 1985, they now administer eight tests. Robert Mullins, *Blood Center Looking for a New Transfusion*, BUS. J.-MILWAUKEE, Feb. 3, 1996, available in 1996 WL 8800178.

112. Direct costs refer here to the laboratory bills that mount with each supplemental screening test. Indirect costs refer to social costs, such as the loss of untainted blood due to error from each new screening test that is administered. Sources of testing error include imperfections in a screening test's ability to detect antibodies or antigens accurately, the inability of screening tests to detect the presence of HIV antibodies during serolateness, the incidence of false positive test results, and human error in administering all forms of safeguards against blood contamination. The more tests that are employed to keep tainted blood from slipping through the cracks, the more opportunities there are for false positive diagnoses, and the more good blood that will be discarded.

113. See Tina Adler, *Debugging Blood: Protecting People from Tainted Blood*, 147 SCI. NEWS, 92, 92 (1995).

114. See *id.*; see also Elizabeth Corcoran, *The Burden of Proof: Donated Blood Runs a Costly Gauntlet of Tests*, SCI. AM., Apr. 1989, at 79, 79-80.

115. Blood donations in the United States are 6% lower than they were 10 years ago. Eric Lax, *Blood Ties: One Gift: Two Lives Forever Changed*, LIFE, Mar. 1996, at 60, 65 sidebar "Donating Blood: A Primer."

116. In 1989, the United States imported approximately 2% of its blood supply. Jeffrey McCullough, *The Nation's Changing Blood Supply System*, 269 JAMA 2239, 2239 (1993).

117. Cf. Wayne Kondro, *Canada: Blood Self-Sufficiency*, 340 LANCET 1341, 1341 (1992) (discussing one strategy in Canada for achieving self-sufficiency in blood and blood products).

likelihood of rejecting good blood will be unavoidable as long as error remains associated with blood screening processes. The task for lawmakers and policymakers is to determine the point at which the enhancements provided by a new procedure are outweighed by (i) the social cost of the incremental units of untainted blood discarded as a result of adopting the procedure and (ii) the direct expense of administering the additional tests.¹¹⁸

The most prominent recent controversy over a proposed supplemental screening test concerns antigen testing. Antigen testing's potential advantage is its ability to detect the presence of antigens after infection faster than ELISA can detect antibodies, thereby reducing both the period of serolateness and the window of opportunity during which the virus will be undetectable.¹¹⁹ The challenge to regulatory authorities has been to weigh the costs and benefits of antigen testing, given the relative success of ELISA screening with Western Blot confirmation.¹²⁰

Investigators who have assessed the use of antigen testing to supplement HIV-antibody tests have found the process ineffectual and expensive.¹²¹ In a comprehensive field study that tested hundreds of thousands of donors in a variety of geopolitical settings, no donations found positive for antigens were found negative for HIV-1 antibodies.¹²² In other words, supplementing existing antibody screens with antigen testing conferred no added diagnostic value.¹²³ Some medical researchers concede that antigen testing could

118. This balancing test applies to any new safeguards that lawmakers or policymakers consider adding to existing protections, regardless of whether the safeguard being considered is a supplemental screening test or another mechanism aimed at reducing transfusion-related HIV infections. For example, researchers have recently assessed the marginal value of the solvent-detergent treatment of plasma, a process in which plasma donations are treated rather than screened. See James P. AuBuchon & John D. Birkmeyer, *Safety and Cost-Effectiveness of Solvent-Detergent-Treated Plasma*, 272 JAMA 1210 (1994). The investigators determined that although the treatment of plasma process may save some life-years, its adoption is probably unjustifiable in terms of the marginal life-years saved and the costs of implementation. *Id.* at 1212-13.

119. See Gelles, *supra* note 104, at 523.

120. See *supra* Section IV.A.1.

121. See Michael P. Busch et al., *Screening of Selected Male Blood Donors for p24 Antigen of Human Immunodeficiency Virus Type 1*, 323 NEW ENG. J. MED. 1308, 1308-11 (1990); Daniel N. Mendelson & S. Gerald Sandler, *A Model for Estimating Incremental Benefits and Costs of Testing Donated Blood for Human Immunodeficiency Virus Antigen (HIV-Ag)*, 30 TRANSFUSION 73 (1990).

122. See Harvey J. Alter et al., *Prevalence of Human Immunodeficiency Virus Type 1 p24 Antigen in U.S. Blood Donors—An Assessment of the Efficacy of Testing in Donor Screening*, 323 NEW ENG. J. MED. 1312, 1312-17 (1990).

123. The possibility remains, however, that supplementary antigen testing could be justifiable in some geographic areas with very high HIV infection rates. Proponents of decision support systems, which are used to make difficult decisions under conditions of complexity and informational uncertainty, have observed that hard decisions regarding optimal blood screening policies may be

negligibly reduce the number of infected units of blood that enter the blood supply.¹²⁴ Out of twelve million units of blood donated annually, they estimate that presently around eighteen to twenty-seven units are contaminated with HIV and that antigen testing might reduce these numbers by approximately four to six units.¹²⁵ However, one-quarter to one-half of all transfusion recipients die within a year of transfusion from the medical complications for which they received the transfusion,¹²⁶ thereby reducing further the number of AIDS cases likely to be diverted by adding an antigen test.

Other studies that focus on the costs of supplemental antigen testing indicate that this duplicative process is enormously expensive. Using estimates for the cost of an HIV-Ag antigen test, the number of blood donations to be screened, and the number of AIDS cases that would be averted by adding HIV-Ag testing to existing protocols, Professor Gelles suggests an astounding cost of \$24 million per AIDS case prevented.¹²⁷ More recent estimates confirm Professor Gelles's finding that mandatory supplemental antigen testing is financially unrealistic. Because all blood donations would have to undergo the antigen test in order to achieve what are presently small gains,¹²⁸ it is likely that the costs of supplementary antigen

facilitated by examining the varying dynamics that govern distinct population groups. Some researchers, for example, have examined the costs of transfusing units of HIV-infected blood and discarding units of uninfected blood associated with particular screening strategies. *See* J. Sanford Schwartz et al., *Strategies for Screening Blood for Human Immunodeficiency Virus Antibody*, 264 JAMA 1704 (1990). Their findings suggest that different blood screening strategies should be adopted according to "local differences in disease prevalence and incidence." *Id.* at 1707. The basic logic behind this suggestion is sound: the costs associated with error in blood testing procedures are likely to change as the risks of particular types of error change. Perhaps most importantly, the risk of false-negatives increases for those populations at high risk for HIV. Accordingly, retesting or second-method testing procedures that cannot be justified for lower risk populations may be good policy if the procedures can be directly targeted to higher risk groups. This reasoning suggests that decision support systems can reduce the errors inherent in the transfusion of infected blood and the disposal of good blood. The challenge in this regard is for investigators to develop more elaborate, precise models of the risk postures of various donor populations, for which optimal screening policies can be tailored.

124. Eve M. Lackritz et al., *Estimated Risk of Transmission of the Human Immunodeficiency Virus by Screened Blood in the United States*, 333 NEW ENG. J. MED. 1721, 1725 (1995).

125. *Id.*

126. *Id.* at 1724.

127. Gelles, *supra* note 104, at 523-24.

128. *See supra* notes 121-27 and accompanying text. While it is difficult to imagine conditions under which antigen testing might be improved sufficiently to justify its supplemental adoption in industrialized nations, policymakers should consider technological improvements that could indicate a need to revisit the question. One company, for example, has recently announced that it is near the completion of machinery that could identify antigens within four days of HIV infection. Rebecca

testing, like most forms of supplementary testing,¹²⁹ will prove financially prohibitive.¹³⁰

For these reasons, antigen testing was justly deemed inadvisable by an FDA advisory committee.¹³¹ Notwithstanding the committee's recommendation, the FDA advised blood banks in the summer of 1995 to adopt supplementary antigen testing within three months of its commercial availability.¹³² The FDA's decision to mandate supplementary antigen testing either ignores or neglects the cost side of prudent blood safety policy. Given competing claims to scarce public resources, there must be a point at which minimal numbers of diverted infections are considered an imprudent use of vast amounts of tax dollars. Although the citizenry will never be brought to concur on the precise location of that point, how many would fix it at \$24 million per averted case of AIDS,¹³³ as estimated by Professor Gelles in

Rolwing, *High-Tech Machine Speeds HIV Detection*, BUS. J.-PHOENIX & THE VALLEY OF THE SUN, Jan. 5, 1996, at 29, available in 1996 WL 8561084. This innovation could dramatically reduce the opportunities for tainted blood to get into the blood supply during the serolateness window. While sound policy will depend not only on the technology's effectiveness but also on cost considerations, major improvements in antigen testing would certainly justify reexamination of otherwise rational policies.

129. Given the effectiveness of the screening processes presently in place, assessments of the supplemental value of antigen testing are likely to be representative of the cost-benefit structure of other proposed supplemental tests, even the most effective ones. Existing procedures permit few tainted units of blood to slip through the cracks. Accordingly, even screening processes that seem relatively inexpensive per unit are unlikely to survive cost-benefit analysis, given the large volume of units to be screened and the small number of incremental new infections that can be averted.

130. Because some readers will always object to the purported exchange of lives for money, even few lives for much money, I emphasize here that difficult resource allocation decisions cannot be avoided. At some point, dollars allocated for AIDS research, prevention, and treatment must be distributed among competing claims and therefore must be assessed on the bases of effectiveness and efficiency. My observation that supplementary antigen testing is likely to prove onerously and intolerably expensive merely suggests that the large sums of money that would be consumed by the test would probably save more lives if diverted to a more efficient use.

Drawing lines between acceptable and unacceptable costs for detecting tainted blood donations certainly will be difficult. While most would likely agree that \$36,300 is a reasonable social cost to save one person from HIV infection, most would probably consider \$24,000,000 too much, given competing claims on public moneys. Although determining methods for establishing such precise cost-benefit cut-off points is troublesome and goes beyond the purview of this Article, it is clear that existing protocols for blood screening are advisable. As technology provides us with new methods of improving blood screening effectiveness, we must assess each method to determine whether the incremental costs are acceptable or whether the moneys should be diverted to other more productive social ends.

131. See Antigen Memorandum, *supra* note 97. The committee disfavored antigen testing by a nine-to-six margin. *Id.*

132. *Id.*; see also *Man with AIDS Tests Negative for HIV; New Screening Plan Nears Approval*, L.A. DAILY NEWS, Mar. 8, 1996, at 16.

133. The relevant question for the citizenry to ask is whether 24 million dollars spent on

regard to antigen testing?¹³⁴

3. *Informing Donors Whose Specimens Test Seropositive of Their HIV Status*

Once blood screening procedures are adopted, policymakers must decide whether to inform contributors of infected specimens that they carry the AIDS virus. From the inception of screening, the approach in the United States has been to notify donors of seropositivity.¹³⁵ This approach enables infected donors to seek treatment and avoid engaging in high-risk behaviors, such as future blood donation attempts.

Conversely, India's policy has been to dispose of HIV-positive blood without informing donors of their HIV status.¹³⁶ Commentators note that this policy is attributable to concerns of maintaining confidentiality, avoiding stigmatization, and avoiding communication of seropositivity in the absence of counseling facilities.¹³⁷ India's approach also deters those who suspect they are infected from donating as an indirect means of HIV testing. As one World Health Organization ("WHO") representative has suggested, donors motivated even in part by diagnostic considerations are particularly likely to be high-risk candidates whose infected blood can pass into the supply during the window period.¹³⁸ Should this be the case, a policy of informing donors that their blood has tested seropositive could increase transfusion-associated transmissions of AIDS.

None of the arguments on either side of the issue is patently spurious. Choosing the optimal policy will depend on our ability to separate the relevant arguments from the tangential or disposable ones, and then assess the gains and losses associated with each option. The remainder of this subsection addresses whether the benefits of informing donors of HIV status

educational and media abstinence campaigns, condom campaigns, needle exchanges, or AIDS research can avert more than the single case of AIDS averted by spending those same dollars on supplemental antigen testing.

134. See *supra* note 127 and accompanying text.

135. See Marlene Cimon, *Notices of Positive AIDS Tests Urged; Panel Would Tell Blood Donors of Unconfirmed Results*, L.A. TIMES, July 10, 1986, § 1, at 4 (discussing a federal advisory panel's 1986 determination that there is a "clear ethical responsibility" to inform individuals of any positive test results, even those not confirmed by subsequent testing), available in 1986 WL 2182386.

136. Bhupesh Mangla, *India: HIV-Positive Blood Donors*, 341 LANCET 1527, 1527 (1993).

137. *Id.*

138. *Id.* (referring to the comments of Dr. Jai Narain, team leader of the New Delhi regional office of the WHO Global Programme on AIDS).

can be realized without incurring the losses that India's approach has sought to avoid.

Concerns regarding stigmatization, breach of confidentiality, and lack of counseling services are all manageable. Policymakers should not allow these considerations to derail a choice that otherwise maximizes blood supply purity. Stigmatization and confidentiality issues can be inexpensively and effectively minimized through the adoption of protective procedures.¹³⁹ As long as authorities provide effective, reliable assurances that test results will remain strictly confidential,¹⁴⁰ donors will be protected from both publication of their health status and any stigmatization that might subsequently result. Confidentiality and concomitant protection from any stigmatization that would result from a breach of confidentiality¹⁴¹ are routinely and effectively preserved by HIV testing clinics.¹⁴² The procedures, rules, and other safeguards adopted by these clinics to ensure privacy can easily be replicated in blood collection centers.

Similarly, blood collection organizations can address counseling concerns in the same way as HIV testing clinics.¹⁴³ At least three options can be

139. Protective procedures are inexpensive to maintain. Confidentiality and the protection it provides against stigmatization simply require self-monitoring by personnel in regard to (a) what information they divulge to others, and under what conditions; and (b) the protection they use in securing records. These procedures reflect care and responsibility in executing blood-collection tasks, and need not exact significant implementation costs.

140. Confidentiality rather than anonymity is probably the best option here. Confidentiality presumes that the donor will give his or her real name when donating blood, but that identification of blood test results will be used only to protect the blood supply from immediate or future donations by donors identified as seropositive. Anonymity would permit donors to give blood without identifying themselves. While anonymity obviously provides more reliable assurances that the donor's identity will remain secret, it is inconsistent with the utility of maintaining records that might screen out future donations by a person whose blood tests positive.

141. For discussion of confidentiality and protection from stigmatization in regard to HIV status generally, see Harold Edgar & Hazel Sandomire, *Medical Privacy Issues in the Age of AIDS: Legislative Options*, 16 AM. J.L. & MED. 155 (1990); Paul M. Schwartz, *The Protection of Privacy in Health Care Reform*, 48 VAND. L. REV. 295 (1995); and Peter J. Nanula, Comment, *Protecting Confidentiality in the Effort to Control AIDS*, 24 HARV. J. ON LEGIS. 315 (1987).

142. See Roger Doughty, Comment, *The Confidentiality of HIV-Related Information: Responding to the Resurgence of Aggressive Public Health Interventions in the AIDS Epidemic*, 82 CAL. L. REV. 111, 140 n.121 (noting that hospital and health clinic protocols often govern the handling of information to protect confidentiality regarding HIV status).

143. The provision of effective counseling opportunities in conjunction with blood donation requires special attention to the needs of donors. Blood donation centers are focused on the social end of increasing the public blood supply. Unlike HIV-antibody testing clinics, they exist primarily to serve society, not to serve the individual whose blood is being taken. Steve Connor & Sharon Kingman, *The Trouble with Testing*, NEW SCIENTIST, Jan. 1988, at 60, 60. Accordingly, blood collection centers will need to make concerted efforts if their attention is to be diverted to the needs of

considered regarding the provision of counseling to donors informed that their blood has tested seropositive: (i) mandatory counseling; (ii) counseling available at the option of the donor; or (iii) no availability of counseling, provided donors are informed prior to donation that no counseling is available and that they will be informed of the seropositivity, if any, of their blood. Because donors who arrive at blood collection sites may not expect to receive information regarding their HIV status, many likely have not considered their own capacity to process the life-altering knowledge that they are infected with HIV. For this reason, counseling certainly should be available at blood collection sites if a policy of informing infected donors of their serostatus is adopted.¹⁴⁴ The costs of maintaining this counseling function must be incorporated into any calculation of whether to notify infected donors that they are HIV-positive. Whether such costs are minimal or substantial may depend on whether the personnel who currently collect blood already possess some or all of the professional training needed to engage in such counseling and the degree to which one member of a collection team can specialize in counseling, thereby minimizing the number of professionals who need supplemental training.

A policy of informing donors of test results could have a more troublesome effect: the encouragement of high-risk persons to donate blood in order to learn whether they are infected with HIV. While this concern is important, the history of public health policy in the United States suggests that it is manageable. When blood screening practices were developed in 1985 to include a provision for informing infected donors of seropositivity, policymakers concerned with the possible effects on blood supply safety adopted an "alternative testing site program" that established a network of clinics designated for HIV-antibody testing.¹⁴⁵ Initiated before treatments for HIV infection and AIDS were available, the alternative testing sites were opened primarily to provide those anxious about their HIV status with a place

donors. Informing seropositive donors of their HIV status and counseling them demands a substantial shift in orientation.

144. Out of respect for the autonomy of individuals, blood centers should never coerce donors into receiving counseling that they do not want, simply because a paternalistic authority has decided that counseling is in their best interests. For a related discussion of mandatory versus optional counseling, see Salbu, *supra* note 5, at 421-25.

145. See Public Health Service; Program Announcement; Alternative Testing Sites to Perform Human T-Lymphotropic Virus-Type III (HTLV-III) Antibody Testing; Availability of Funds for Fiscal Year 1985, 50 Fed. Reg. 9909-10 (1985).

to be tested without the subterfuge of an attempted blood donation.¹⁴⁶

From its inception, the alternative testing site program has been highly effective. In its first year, percentages of specimens found positive for HIV antibodies were 432 times higher at alternative testing sites than at blood banks.¹⁴⁷ Of the relatively small 0.04% of blood bank donations that tested positive for HIV antibodies,¹⁴⁸ we can assume that some portion came from people who had no suspicion that they were infected and who did not choose blood donation as a method of indirect testing. Of the remainder who do abuse blood donation procedures to discover their HIV status, blood screening tests remain a highly effective safety measure that protects against contaminated blood entering the supply.¹⁴⁹

Of course, despite these impressive statistics, some nominal margin of contaminated blood units might be averted by adopting a policy against informing donors of their seropositive status. However, the residual cost is outweighed by the substantial benefits of notifying donors of their seropositivity. First, a notified donor has the information necessary to "select out" of attempting to make future donations. Left ignorant, a donor may try to donate again, potentially contributing contaminated units of blood to the supply. Second, a notified donor can avoid risky behaviors, such as unsafe sexual practices or the sharing of injection paraphernalia, thereby averting new infections. Third, given recent improvements in treatment for HIV infection and AIDS,¹⁵⁰ the donor informed of seropositivity can begin treatments that may avert suffering and extend life. The weight of these benefits suggests that donor notification of HIV status is sound policy, provided that convenient and affordable alternatives exist to discourage using blood collection centers merely to learn one's serostatus.¹⁵¹

146. Marvin E. Bailey, *Developing a National HIV/AIDS Prevention Program Through State Health Departments*, 106 PUB. HEALTH REP. 695, 695-96 (1991).

147. *Id.* at 696.

148. *Id.*

149. For further discussion of the effectiveness of blood screening tests in keeping HIV-infected blood from entering the blood supply, see *supra* Section IV.A.

150. Protease inhibitors, for example, have shown promise for the treatment of HIV-1 infection. See, e.g., Sven A. Danner et al., *A Short-Term Study of the Safety, Pharmacokinetics, and Efficacy of Ritonavir, an Inhibitor of HIV-1 Protease*, 333 NEW ENG. J. MED. 1528 (1995); Martin Markowitz et al., *A Preliminary Study of Ritonavir, an Inhibitor of HIV-1 Protease, to Treat HIV-1 Infection*, 333 NEW ENG. J. MED. 1534 (1995).

151. Affordable, convenient alternatives are becoming increasingly available with the creation of new technologies. For example, the development of HIV home-testing products improves the accessibility of HIV-related health information. This convenient new method of learning one's HIV status should further reduce the temptation to use blood banks as HIV testing facilities. See Salbu,

B. Prohibition of the Sale of Blood Through a Mandatory All-Volunteer Policy

Some health policy commentators recommend prohibiting the sale of blood by individuals. This subsection addresses (1) the logic and history of the prohibition of blood sales, (2) criticism of the prohibition of blood sales, and (3) recommendations regarding the prohibition of blood sales.

1. Logic and History of the Prohibition of Blood Sales

Policy distinctions made between sales and gratuitous donations of blood are based on differences in motives. Whereas sellers may be motivated by a desire or need for money, gratuitous donors are presumably¹⁵² motivated by altruistic impulses.¹⁵³ If sales are permitted, the greedy and the desperate may sell blood that they know to be tainted.¹⁵⁴ Conversely, the generosity of gratuitous donors encourages only those who believe their blood is pure to contribute to the supply. Dramatic differences in seropositivity among paid and unpaid donors tend to support this hypothesis.¹⁵⁵

The movement towards all-volunteer blood donation policies predates AIDS. It was predicated on evidence that transfusion recipients developed

supra note 5, at 428-29 (discussing the increased accessibility of information regarding HIV status conferred by home tests).

152. The presumption that altruism motivates voluntary blood donation may be somewhat simplistic. In one bizarre instance, the Atlanta-Area Red Cross purportedly lost a number of donors when it stopped giving Nutter Butter cookies out at donation sites. Eleena de Lisser, *With a Cookie Gone, Some Donors Threaten to Go, Too*, WALL ST. J., Jan. 17, 1996, at A1. This seemingly absurd reaction may indicate that the motivation to donate blood is affected by a number of factors that comprise the whole experience of donating blood, some of which may be self-serving even in the absence of actual payment. For example, if the receipt of food and the opportunity to interact with others motivate some donors, then altruism may not cause self-deferral by high-risk donation candidates.

153. For a detailed examination of the altruistic nature of blood donation and a discussion of the system in which blood is provided by gift rather than sale in the era of AIDS, see Thomas H. Murray, *The Poisoned Gift: AIDS and Blood*, 68 MILBANK Q. 205 (Supp. 2, 1990).

154. See Larry Gostin, *The Politics of AIDS: Compulsory State Powers, Public Health, and Civil Liberties*, 49 OHIO ST. L.J. 1017, 1046 (1989) (noting that most intentional donations of HIV-tainted blood involve payments).

155. Purchased blood is substantially more likely to be seropositive than donated blood. For example, seropositivity among paid blood donors in India is as high as 75%, whereas seropositivity among voluntary donors in India is 0.34%. Rachana M. Kumar et al., Letter to the Editor, *HIV-1 Infection in Multi-Transfused Thalassaemic Indian Children*, 7 J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES 1211, 1211 (1994).

hepatitis more frequently from sold blood than from donated blood.¹⁵⁶ As early as the 1950s, the hepatitis attack rate among recipients of sold blood averaged 4.1 per 100 cases, whereas the hepatitis attack rate among recipients of donated blood averaged 0.7 per 100 cases.¹⁵⁷ A number of subsequent research findings have confirmed a higher hepatitis contagion risk associated with the transfusion of commercial blood.¹⁵⁸

By the early 1970s, a movement was formed against the use of "cash blood," supported in large part by the work of the influential British professor Richard M. Titmuss,¹⁵⁹ who contended that market forces yield blood products of a lower net quality than altruistic forces.¹⁶⁰ Professor Titmuss argued that the sale of blood creates incentives for blood sellers to lie about medical conditions and histories,¹⁶¹ thereby increasing the presence of hepatitis in the blood supply. He also suggested that blood sales could cause altruistic blood donations to decline, resulting in potential blood shortages.¹⁶² In the wake of the hepatitis studies, Titmuss's book, and concerns that arose decades later regarding HIV transmission, the United States gradually moved

156. J. Garrott Allen et al., *Blood Transfusions and Serum Hepatitis: Use of Monochloroacetate as an Antibacterial Agent in Plasma*, 150 ANNALS SURGERY 455, 458 tbl.3 (1959).

157. *Id.* at 457 tbl.2.

158. This higher risk has been associated with many types of hepatitis, including types B, non-A, and non-B. *See, e.g.*, Harvey J. Alter et al., *Posttransfusion Hepatitis After Exclusion of Commercial and Hepatitis-B Antigen-Positive Donors*, 77 ANNALS INTERNAL MED. 691 (1972); John H. Walsh et al., *Posttransfusion Hepatitis After Open-Heart Operations: Incidence After the Administration of Blood from Commercial and Volunteer Donor Populations*, 211 JAMA 261 (1970). For a good review of the research in this area, see Richard D. Aach & Richard A. Kahn, *Post-transfusion Hepatitis: Current Perspectives*, 92 ANNALS INTERNAL MED. 539 (1980). *But see Hepatitis from Blood Transfusions: Evaluation of Methods to Reduce the Problem, Report to the Congress by the Comptroller General of the United States*, MND-75-82 (1976) (study refuting the relationship between the sale of blood and the risk of hepatitis to transfusion recipients and suggesting that the socioeconomic characteristics of donors are better predictors of hepatitis B antigen frequency rates than the payment/nonpayment factor), *cited in* ALVIN W. DRAKE ET AL., THE AMERICAN BLOOD SUPPLY 33-35 (1982).

159. *See* RICHARD M. TITMUSS, THE GIFT RELATIONSHIP: FROM HUMAN BLOOD TO SOCIAL POLICY (1971).

160. *See id.* at 150-52.

161. *Id.* at 151. This logic can be extended from hepatitis in the 1960s and 1970s to AIDS today. Persons in some high-risk categories, such as intravenous drug users, may be more likely to sell blood than the general population due to the financial exigencies associated with drug purchase and use. For a discussion about seropositivity among HIV drug users who donate or sell blood, see Dale D. Chitwood et al., *The Donation and Sale of Blood by Intravenous Drug Users*, 81 AM. J. PUB. HEALTH 631 (1991).

162. *See* TITMUSS, *supra* note 159, at 151 (suggesting that altruistic donors will increasingly be unwilling to give blood as the number of profit-making blood hospitals increases).

to an exclusively gratuitous donor policy.¹⁶³

2. Criticism of the Prohibition of Blood Sales

Detractors have criticized the policy of prohibiting blood sales since its inception. Some contend that banning blood sales can cause blood shortages¹⁶⁴ at a time when supplies are especially vulnerable.¹⁶⁵ Other critics

163. In 1975, the Department of Health, Education, and Welfare established the American Blood Commission ("ABC"), an association of private organizations engaged in blood banking and related activities. ROSS D. ECKERT & EDWARD L. WALLACE, *SECURING A SAFER BLOOD SUPPLY: TWO VIEWS* 9 (1985). The ABC supported the concept of a noncash blood supply. *Id.*

Likewise, the FDA proposed regulations in 1975 to increase the proportion of noncash blood in the overall blood supply. Whole Blood and Red Blood Cells: Label Statement to Distinguish Volunteer From Paid Blood Donors, 40 Fed. Reg. 53,040 (1975) (proposed Nov. 14, 1975). As promulgated, the regulations required blood products to be labeled according to donation source—either volunteer or paid. *Id.*

Under present policy, all blood stored in blood banks comes from volunteer donors. Although some plasma centers continue to purchase blood today, the products in which plasma is used are treated to kill HIV and other contaminants. See *Protecting the Nation's Blood Supply from Infectious Agents: New Standards to Meet New Threats: Hearings Before the Subcomm. on Human Resources and Intergovernmental Relations of the House Comm. on Gov't Reform and Oversight*, 104th Cong., 1st Sess. 157 (1995) (statement of Michael A. Fournel, Vice-President, Research and Dev., Bayer Corp.) ("[P]lasma products . . . are distinct from whole blood or blood components, especially because technologies applied in the processing of plasma products involve multiple inactivation or clearance steps that markedly enhance the safety of the final product relative to the starting material.").

164. Critical blood shortages have occurred periodically since all-voluntary blood donor policies were adopted in the United States. See, e.g., Eileen Dempsey, *Blood Donors Urged to Help Make Up Shortage*, COLUMBUS DISPATCH, Jan. 6, 1996, at 4B (reporting critical shortages in Ohio of O-negative blood, with less than one day's supply available); Linda Helser, *Type "O" Blood Supply Drops: Agency Sounds Alarm to Find Donors*, ARIZ. REPUBLIC, Jan. 5, 1996, at B1 (reporting inability of a non-profit blood provider to fill orders for types O-negative and O-positive blood); *New York Blood Center Declares Emergency Over*, PR Newswire, Mar. 1, 1995, available in Westlaw, PRWIREPLUS Database (citing the declaration of a blood emergency in New York City on January 23, 1995, which was exacerbated by national shortages, such that less than one day's reserves of O-positive blood were available).

Other countries have experienced similar blood shortages in recent years. See, e.g., Wendy Moore, *Health Changes: Blood Shed in the Service of the Nation*, GUARDIAN (London), Oct. 26, 1994, at 6 (discussing recent blood shortages in Great Britain and offering various explanations), available in Westlaw, GRDN Database; Adam Morawski, *Blood Donor Scarcity*, WARSAW VOICE, Dec. 11, 1994 (referring to recent blood shortages in Poland), available in LEXIS, News Library, Papers File; Deborah Stone, *Australia: Blood Bank is Bled White*, SUNDAY AGE (Melbourne), Nov. 8, 1992, at 8 (reporting critical blood shortage in Australia), available in LEXIS, World Library, Txtlne File; Alison Wiseman, *Blood Donor "Red Alert"*, S. CHINA MORNING POST, Apr. 12, 1994, at 4 (reporting acute blood shortage in Hong Kong and a plea made by the chief executive of one transfusion center requesting blood donations), available in Westlaw, CHINAPOST Database; *Blood Donors Ease Shortage*, TORONTO STAR, Dec. 29, 1994, at A6 (reporting critical blood shortage in central Ontario and Toronto); *Blood Shortage at KL Hospital Worst in 8 Years*, STRAITS TIMES (Singapore), Feb. 23, 1995, at 18 (discussing a blood shortage in Kuala Lumpur).

have suggested that Professor Titmuss neglects basic tenets of supply and demand and that payment for blood should be expected to increase rather than diminish blood supplies.¹⁶⁶ Likewise, Russell Roberts and Michael Wolkoff suggest that by distancing blood collection from the forces of supply and demand, the all-volunteer policy impedes the market mechanism that helps moderate overall quantity.¹⁶⁷ According to this suggestion, payment for blood may be desirable as a means of maintaining adequate blood supplies in the future.¹⁶⁸

Another group of commentators, some of whom concede the potential public health benefits of an all-volunteer policy, have nonetheless observed countervailing costs in the form of impaired property rights.¹⁶⁹ In this respect, an all-volunteer policy imposes a "blood inalienability" rule—a property-based rule that restricts "the [economic] transferability, ownership, or use"¹⁷⁰ of one's own blood. Some have couched their critique of the blood inalienability rule more specifically in terms of its disproportionate effect on the poor,¹⁷¹ many of whom lose an especially important economic option when restricted from selling their blood.

Others have questioned the accuracy of distinguishing between so-called gratuitous blood and paid blood. Professor Ross Eckert notes that numerous forms of non-cash compensation are frequently given in exchange for blood, including tickets to theatrical or athletic events, food, wallets, tool kits,

165. Several factors may exacerbate blood supply shortages in the future. Significant numbers of potential uninfected donors are disqualified from blood donation based on their personal histories. According to one study, between 10% and 14% of adult males and 1% of adult females who are otherwise suitable donors are disqualified on the basis of their personal histories. David I. Gregorio & Jeanne V. Linden, *Screening Prospective Blood Donors for AIDS Risk Factors: Will Sufficient Donors Be Found?*, 78 AM. J. PUB. HEALTH 1468, 1469 (1988).

Moreover, irrational fears associating blood donation with the risk of contracting AIDS are likely to diminish donor pools. According to a 1989 survey, 20% of United States residents associate the likelihood of contracting AIDS with blood donation. Diane M. Gianelli, *Fewer People Link AIDS with Giving*, *Getting Blood*, AM. MED. NEWS, Aug. 25, 1989, at 11.

166. See Hamish Stewart, *Rationality and the Market for Human Blood*, 19 J. ECON. BEHAV. & ORG. 125, 127 (1992) (discussing reactions of economists to Professor Titmuss's influential work).

167. Russell D. Roberts & Michael J. Wolkoff, *Improving the Quality and Quantity of Whole Blood Supply: Limits to Voluntary Arrangements*, 13 J. HEALTH POL. POL'Y & L. 167, 168-69 (1988).

168. *Id.* at 177.

169. See Susan Rose-Ackerman, *Inalienability and the Theory of Property Rights*, 85 COLUM. L. REV. 931, 941 (1985) (suggesting that while "the use of a modified inalienability rule . . . assure[s] high quality blood supplies," it may impose high distributive costs on blood donors due to the lack of compensation for blood donations).

170. *Id.* at 931.

171. See Madeline Morris, *The Structure of Entitlements*, 78 CORNELL L. REV. 822, 886 n.149 (1993) (stating that an inalienability rule "distribute[s] wealth away from the poor").

photograph albums, leave time, credit, insurance, medals, and media recognition.¹⁷² Because these rewards have dollar-value equivalents, Professor Eckert suggests that the prohibition of cash payments is inconsistent with the legality of providing non-cash premiums.¹⁷³

3. *Recommendations Regarding the Prohibition of Blood Sales*

The policy that prohibits cash payments for blood is sound. Purchased blood is consistently documented as bearing a particularly high risk of HIV contamination.¹⁷⁴ If we can maintain acceptable blood supply levels under a no-cash policy, then the policy is rational. The desirability of the policy decreases, however, to the degree that it contributes to dangerous supply shortfalls across the globe.¹⁷⁵ The more frequently that blood supplies become inadequate, and the more severe the period of inadequacy, the greater the social cost of the donor policies that contribute to the shortage.¹⁷⁶

Nonetheless, the sale of blood can be justified by compelling shortages only if adequate supplies cannot be raised using less costly alternative means. Should blood shortages become a serious problem, analysts should consider ways of increasing the blood supply without resorting to payment for blood. These might include, for example, increased budgets for the promotion of gratuitous donations and the marketing of altruistic reasons to give blood.¹⁷⁷

172. ECKERT & WALLACE, *supra* note 163, at 12. For anecdotal verification that blood donors are sometimes remunerated in kind, see Patricia Nealon, *They Give by the Gallon So That Others May Thrive*, BOSTON GLOBE, Feb. 21, 1996, (Metro), at 1 (quoting a former bank president who offered to give employees a day off if they donated blood).

173. See ECKERT & WALLACE, *supra* note 163, at 13 ("The knowledge of having had hepatitis or the incentive to conceal it might be no greater for someone who wanted to sell blood than for someone who wanted time off from work, a turkey, or credit for a portion of a hospital bill.") (citing Reuben A. Kessel, *Transfused Blood, Serum Hepatitis, and the Coase Theorem*, 17 J.L. & ECON. 265, 289 (1974)).

174. *Cf. supra* notes 156-58 and accompanying text.

175. See *supra* note 164.

176. Blood availability may be an increasingly important concern in years to come, as more contributors are disqualified from donating or select themselves out of the donor pool based on advancing age. Indeed, blood donations have dropped since the late 1980s. For example, 6.2 million pints of blood were donated in the United States in 1987; by 1994, the figure had dropped to 5.4 million. Dan Wascoe, Jr., *Blood Donation: High Profile May Mean High Turnout*, STAR TRIB. (Minneapolis), Jan. 22, 1996, at 3B.

177. Convincing the public to donate blood gratuitously is like any other marketing challenge. While financial considerations are important, they are not the only way to recruit gratuitous donors. Just as the seller of a product can compete on the basis of price or non-price characteristics, so public policy can encourage blood donation using financial or nonfinancial inducements. Given that payments increase the intentional provision of infected blood, it is reasonable to rely on nonfinancial

Of course, should future technological and procedural improvements in blood screening reduce the risk of error to virtually zero,¹⁷⁸ policymakers will need to revisit the question of cash payments for blood.

Whether to treat paid blood differently from blood given for noncash premiums should depend on the relative risks of each. If blood collected in exchange for indirect or nonmonetary benefits is found to be as safe as gratuitous blood, then the concerns of Professor Eckert¹⁷⁹ are academic rather than pragmatic and should not be evoked to alter our present noncash blood policy. If the conferral of perquisites yields blood that is safer than paid blood but riskier than unpaid blood, we must weigh the incremental risk of awarding perquisites against the benefit of augmented blood supplies.¹⁸⁰ If blood given for benefits in kind is as dangerous as blood given for cash, then the two should be treated identically. In general, any similarities between cash and noncash payments in encouraging the knowing donation of tainted blood suggest that we may need to move away from all forms of compensation, including compensation in kind.

Finally, the property rights of the population generally, and the poor specifically, do not provide a compelling reason to permit cash payments for blood. From a theoretical perspective, property rights are a social construct—one's rights of ownership and alienation are not limitless, but rather depend upon legal sanction.¹⁸¹ Just as the state can prohibit the sale of drug products

inducements to market gratuitous blood donation to the public.

178. The elimination of errors requires not only ubiquitous adoption of effective procedures, but also consistent implementation of effective procedures across all blood banks. Eradicating all sloppy or negligent implementation of otherwise highly effective procedures will be an extremely difficult task, given the limited budgets and ultimately autonomous operations of blood collection and distribution centers. A recent blood scandal in Germany provides an example of that difficulty: a financially strapped company economized on testing kits by pooling units of blood prior to actual testing, thereby reducing the kits' effectiveness in detecting HIV antibodies. James O. Jackson, *Very Bad Blood: The Discovery of HIV-Tainted Plasma in Germany Raises Alarm About the Ability to Ensure Safe Supplies Worldwide*, TIME, Nov. 15, 1993, at 65.

179. See *supra* notes 172-73 and accompanying text.

180. The logic attributing special danger to cash blood is less compelling in regard to noncash premiums. The provision of cash creates a difficult moral peril for those who face financial exigency, such as hungry people who are desperate to get food and addicted people who are desperate to get drugs. This kind of desperation is far more likely to override moral qualms about selling tainted blood for cash than a person's desire for time off the job or participation in insurance plans. Of course, under this reasoning, the more liquid the noncash perquisite, the greater the chance that despair will override ethical considerations. In this respect, items like easily scalped tickets to athletic events are likely to be more dangerous donation premiums than medals or media recognition. These theoretical postulates should be tested by data analysis that compares actual risks associated with various forms of noncash incentives.

181. See Dorothy E. Roberts, *Rust v. Sullivan and the Control of Knowledge*, 61 GEO. WASH. L.

that grow on an individual's land,¹⁸² it can legitimately prohibit blood sales that pose a serious public health threat. Intransigent as the problem of poverty has proven, it is reasonable to exclude one small alternative from the sphere of possible solutions, particularly when that alternative is potentially life-threatening to others.

C. Predonation Questioning and Disqualification of Donations from Persons in High-Risk Categories

Since scientists first noted a disproportionately high incidence of AIDS among several groups,¹⁸³ predonation questioning and donation disqualification procedures have become accepted practice in some countries. This Section includes (1) a brief introduction to questioning and disqualification procedures, (2) a history of the development of disqualification criteria in the United States, and (3) an evaluation of the use of questioning and disqualification procedures as a means of ensuring the safety of the blood supply.

1. Questioning and Donation Disqualification Procedures

In the United States, blood collection centers and public health authorities shield the blood supply from high-risk donations by educating the public about groups that should not donate blood and by requiring people to "self-defer" if they fall into any of the high-risk categories about which they are informed prior to donation.¹⁸⁴ Furthermore, under federal law, the failure of persons who have tested positive for HIV to defer from donating blood is a crime punishable by fine, imprisonment, or both.¹⁸⁵

The self-deferral approach can be supplemented by prospective donor questionnaires or interviews that disqualify those at high risk who fail to

REV. 587, 650 (1993) ("Property is a social construct . . . that serves societal interests and its meaning can be revised to accommodate changing views of justice.").

182. See 21 U.S.C. § 841(a) (1994) (prohibiting the manufacturing, distribution, or dispensation of illegal drugs).

183. These groups include gay men, bisexual men, users of intravenous drugs, and their sexual contacts. Daniel C. Berrios et al., *HIV Antibody Testing Among Those at Risk for Infection: The National AIDS Behavioral Surveys*, 270 JAMA 1576, 1576 (1993).

184. Edward H. Kaplan & Alvin Novick, *Self-Deferral, HIV Infection, and the Blood Supply: Evaluating an AIDS Intervention*, 14 EVALUATION REV. 686, 686-89 (1990).

185. 18 U.S.C. § 1118 (1994) (Protection against the human immunodeficiency virus, follows § 1121 and is the second of two sections 1118 in title 18 of the U.S. Code).

select themselves out of the pool.¹⁸⁶ Statistics suggest that these procedures create a pool of relatively safe donors. In the United States, HIV antibodies have been found in the blood of active donors only one-fortieth to one-eightieth as frequently as in random population samples.¹⁸⁷ Moreover, the discovery in the early 1990s of persons who appear to have AIDS but test negative for HIV antibodies indicates the prudence of supplementing blood tests with other forms of effective screening.¹⁸⁸ Because approximately three-fourths of such persons fall within high AIDS-risk classes,¹⁸⁹ a policy of self-deferral could substantially improve the quality of blood supplies.¹⁹⁰

Over the years, individuals have been categorically disqualified from donating blood on the basis of two types of potential high-risk profiles—those based on status and those based on behaviors. Disqualification based on status rejects donations from persons describing themselves as belonging to purportedly high-risk demographic groups. Disqualification based on high-risk behaviors rejects donations from persons who report having engaged in such risky activities as intravenous drug use or sexual intercourse with prostitutes.¹⁹¹

2. *The Development of Disqualification Criteria in the United States*

In the United States, blood restrictions have evolved through years of developing AIDS policy. In 1983, the Office of Biologics of the National Center for Drugs and Biologics (“Office of Biologics”)¹⁹² recommended in a

186. This supplementary step appears to be necessary because potential donors are not highly reliable at screening themselves. As one study found, “a small number of persons infected with the AIDS virus continue[] to donate blood in spite of attempts to stop them, including giving them literature explaining risks and recommending voluntary self-exclusion.” *Blood Supply Grows Safer*, FDA CONSUMER, Feb. 1990, at 5.

187. Roger Y. Dodd, *The Risk of Transfusion-Transmitted Infection*, 327 NEW ENG. J. MED. 419, 419 (1992).

188. Rosenthal, *supra* note 78, at B2.

189. *Cf. id.* (stating that about one-fourth of those with antibody-free AIDS-like symptoms fall outside high-risk categories).

190. Because cases of antibody-free AIDS-like symptoms appear to occur infrequently, *see id.*, the magnitude of this improvement may be small.

191. *See* Revelle, *supra* note 30, at 23 (briefly discussing various high-risk behaviors that result in permanent disqualification from donating blood).

192. The National Center for Drug and Biologics and its Office of Biologics were established as part of the FDA in 1982. *See* 47 Fed. Reg. 26,913, at 26,913 & 26,919 (1982). Both were reorganized two years later into the Center for Drug and Biologics (“CDB”) and the Office of Biologics Research and Review, respectively. *See* 49 Fed. Reg. 10,168, at 10,168 & 10,172-73 (1984). In 1987, the FDA established two centers to replace the CDB: the Center for Drug Evaluation and Research (“CDER”)

memorandum ("1983 Memorandum") that blood collection establishments institute educational programs to inform certain "increased risk" groups that they should refrain from donating blood "until the AIDS problem is resolved or definitive tests become available."¹⁹³ Under the 1983 Memorandum's guidelines, the "increased risk" groups were defined as "persons with symptoms and signs suggestive of AIDS, sexually active homosexual or bisexual men with multiple partners, Haitian entrants to the United States, present or past users of intravenous drugs, and sexual partners of individuals at increased risk of AIDS."¹⁹⁴ The Office of Biologics expressly designated its 1983 Memorandum as "an interim measure to protect recipients of blood and blood products until specific laboratory tests [become] available."¹⁹⁵

Since 1984, the Office of Biologics has issued biannual revisions of the exclusion categories, originally set forth in the 1983 Memorandum. Under the 1984 Revised Recommendations,¹⁹⁶ the 1983 principles of donor screening remained intact, but the list of persons to be instructed to refrain from donating blood was modified. Persons with "signs or symptoms" of AIDS remained excluded, and a list of indicia was attached.¹⁹⁷ While the exclusion of intravenous drug users remained unaltered, the 1983 exclusion of "sexually active homosexual or bisexual men with multiple partners" was changed to "[m]ales who have had sex with more than one male since 1979, and males

and the Center for Biologics Evaluation and Research ("CBER"). See 52 Fed. Reg. 38,275 (1987). Under CBER, the Office of Biologics Research and Review became the Office of Biologics Research. See 53 Fed. Reg. 8978, 8979-80 (1988). For the sake of simplicity, this Article will use the term "Office of Biologics" to refer to the Office of Biologics and its successors. The office is under the umbrella of the Department of Health and Human Services ("HHS") and sends its memoranda out under the HHS heading of "Public Health Service, Food and Drug Administration."

193. Memorandum from John C. Petricciani, M.D., Director, Office of Biologics, Nat'l Center for Drugs and Biologics, Public Health Service, FDA, to All Establishments Collecting Human Blood for Transfusion, Recommendations to Decrease the Risk of Transmitting Acquired Immune Deficiency Syndrome (AIDS) from Blood Donors 1 (Mar. 24, 1983) [hereinafter 1983 Memorandum].

194. *Id.* at 1 (footnote omitted).

195. *Id.* at 2.

196. Memorandum from Elaine C. Esber, M.D., Acting Director, Office of Biologics Research and Review ("OBRR"), Public Health Service, FDA, to All Establishments Collecting Blood, Blood Components or Source Plasma and All Licensed Manufacturers of Plasma Derivatives, Revised Recommendations to Decrease the Risk of Transmitting Acquired Immune Deficiency Syndrome (AIDS) from Blood and Plasma Donors (Dec. 14, 1984) [hereinafter 1984 Memorandum].

197. *Id.* at 2. The signs and symptoms of AIDS were listed as unexplained weight loss; night sweats; blue or purple spots typical of Kaposi's sarcoma on or under the skin, or on the mucous membranes; swollen lymph nodes lasting more than one month; persistent white spots or unusual blemishes in the mouth; fever [greater than] 99°F for more than 10 days; persistent cough and shortness of breath; persistent diarrhea.

Id.

whose male partner has had sex with more than one male since 1979.”¹⁹⁸ “Patients with hemophilia” was added as a new excluded category, and Haitians were restricted from donating only if they entered the United States after 1977.¹⁹⁹ The 1984 Revised Recommendations contained a list of appropriate medical screening questions²⁰⁰ and emphasized the importance of providing assurances of confidentiality in order to “increase the effectiveness of voluntary self-exclusion procedures.”²⁰¹

In 1986, the list of exclusions was revised to include

- persons with clinical or laboratory evidence of HTLV-III/LAV infection;
- men who have had sex with another man one or more times since 1977;
- past or present intravenous drug abusers;
- persons emigrating since 1977 from countries where heterosexual activity is thought to play a major role in transmission of HTLV-III/LAV infection [e.g., Haiti, Central Africa];
- persons with hemophilia who have received clotting factor concentrates;
- sexual partners of any of the above; and,
- men and women who have engaged in prostitution since 1977 and persons who have been their heterosexual partners within six months.²⁰²

The 1986 revision contained procedures for maintaining the confidentiality of exclusion,²⁰³ as well as a recommendation for written and

198. *Id.*

199. *See id.*

200. *See id.* at 2-3.

201. *Id.* at 3.

202. Memorandum from the Director of the OBRR, Center for Drugs and Biologics, Food and Drug Administration, to All Registered Blood Establishments, Additional Recommendations for Reducing Further the Number of Units of Blood and Plasma Donated for Transfusion or for Further Manufacture by Persons at Increased Risk of HTLV-III/LAV Infection 1-2 (Oct. 30, 1986) [hereinafter 1986 Memorandum].

203. *See id.* at 2-3.

These procedures should provide at a minimum:

- that units designated not for transfusion to others be removed from inventories and not made available for transfusion or for further manufacture unless under a specific exception granted in writing by the Director of the OBRR;
- strict confidentiality of donors' decisions and a confidential environment in which to make the decisions;

signed attestation by donors of their qualification under the revised guidelines.²⁰⁴

The 1988 revision made only one change to the 1986 guidelines. In recognition of the first case of HIV-2 infection reported in the United States,²⁰⁵ the list of emigrants disqualified from donating blood was expanded to include “persons emigrating since 1977 from countries where heterosexual activity is thought to play a major role in [the] transmission of HIV-1 or HIV-2 infection (e.g., Haiti, sub-Saharan Africa and islands located near these areas of Africa).”²⁰⁶ Donations from otherwise qualified donors of stipulated African nations were expressly authorized.²⁰⁷

In 1990, in a major reassessment of the bases for excluding blood donors, the Office of Biologics made several significant modifications.²⁰⁸ Its revised memorandum for that year limited the existing exclusion of potential donors on the basis of national or geographical origin²⁰⁹ to “blood establishments that have not implemented an FDA-licensed screening test for antibodies to HIV-

- HTLV-III/LAV antibody testing of all donated units;
- notification of all donors of the results of HTLV-III/LAV antibody tests considered positive by the criteria defined in the procedure manual for that establishment, without regard to whether they designated their units as acceptable for transfusion to others or excluded them from transfusion to others;
- assurances to donors that units confidentially excluded will be used for laboratory testing.

Id.

204. *See id.* at 2. The memorandum recommended a provision like the following:

I have reviewed and understand the information provided to me regarding the spread of the AIDS virus by donated blood or plasma and, if I consider myself to be a person at risk for spreading the virus known to cause AIDS, I agree not to donate blood or plasma for transfusion to another person or for further manufacture.

Id.

205. The first documented case of HIV-2 infection in the United States occurred in December 1987. *AIDS Due to HIV-2 Infection—New Jersey*, 37 MORBIDITY & MORTALITY WKLY. REP. 33, 33 (1988).

206. Memorandum from Elaine C. Esber, M.D., Director, OBRR, Public Health Service, FDA, to All Registered Blood Establishments, Recommendations Concerning Persons at Increased Risk of HIV-1 and HIV-2 Infection 1 (Apr. 6, 1988) [hereinafter 1988 Memorandum].

207. These nations included Morocco, Mauritania, Algeria, Libya, Egypt, Tunisia, Sudan, Somalia, and Western Sahara. *Id.*

208. *See* Memorandum from Gerald V. Quinnan, Jr., M.D., Acting Director, Center for Biologics Evaluation and Research, Public Health Service, FDA, to All Registered Blood Establishments, Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products—Section I, Parts A & B Only (Dec. 5, 1990) [hereinafter 1990 Memorandum].

209. For the 1988 Memorandum’s version of this type of exclusion, see *supra* text accompanying note 206.

2.”²¹⁰ Given the prevalence of HIV-2 antibody testing, the change has served to virtually remove the national/geographic origin exclusions that existed in previous memoranda. The change was purportedly predicated on findings that better assurances of blood safety would result from “specific improvements in donor education, including oral communication and direct questions about risk behavior,”²¹¹ without use of geographic deferrals. The 1990 memorandum emphasized risky behaviors over status under the theory that the former provide a more accurate basis for excluding those at high risk. As the author of the memorandum observed, “[t]he focus [of communications with potential donors] 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’).”²¹²

The remaining changes in the 1990 memorandum’s list of exclusions included the addition of one new category and the alteration of two existing categories. The memorandum added as a new excluded group “[p]ersons who have had, or have been treated for, syphilis or gonorrhea during the preceding 12 months.”²¹³ Two deferrals that existed in previous policy were extended from six to twelve months—those who “engaged in sex with . . . [prostitutes] during the preceding 12 months”²¹⁴ and “[p]ersons who have received a transfusion of whole blood or a blood component within the past 12 months.”²¹⁵

As the Office of Biologics refines its recommendations, it should address the continued need for categorical exclusions, given the trade-offs between blood safety and the sufficiency of the blood supply. Once sound criteria for exclusion are established, authorities should consider the effectiveness of various procedures that can be adopted to optimize the effective implementation of exclusions.

3. Evaluation of the Use of Questioning and Disqualification Procedures as a Means of Ensuring Blood Supply Safety

Several critical issues must be addressed in assessing the value of

210. 1990 Memorandum, *supra* note 208, app. at 2 (Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood Products).

211. *Id.* at 1.

212. *Id.* at 2.

213. *Id.* app. at 2.

214. *Id.*

215. *Id.* app. at 2a.

categorical exclusion policies. These issues include the need for categorical exclusion in light of other safety shields, the optimal types of categorical exclusions, and the optimal procedures for implementing these exclusions.

The value of categorical exclusions depends upon the extent to which other methods of protecting blood, such as post-collection screening, leave gaps in ensuring safety. The more accurate post-collection blood screening becomes, the lower the incremental benefit of categorical exclusion, which reduces the pool of prospective donors, thereby leading to potential shortages. If blood screening becomes sufficiently accurate and blood supplies become seriously impaired, categorical exclusion of high-risk donors could become poor policy, imposing substantial costs while conferring negligible benefits.

Related to this analysis is a layer of issues that affect the value of all categorical exclusion policies. These issues concern the degree of legitimacy associated with characterizing particular statuses and behaviors as "high-risk." Specifically, categorical exclusion policies should not be implemented without consideration of the degree to which the risk of any targeted group exceeds the risk of the population at large. The greater the degree of incremental risk associated with a given status or behavior, the greater the potential value of categorical rejection of blood originating from the class. Small, nominal, or illusory differences in risk may not justify the elimination of potentially large classes of blood contributors, particularly under conditions of substantial blood scarcity and effective post-collection blood screening. Accordingly, the 1983 categorical exclusion of blood from Haitian immigrants in the United States²¹⁶ was restricted in 1984 to Haitian immigrants who entered the United States after 1977,²¹⁷ based on a more refined assessment of the risk associated with that particular status. Likewise, the banning of blood donations by male homosexuals becomes less rational as the incidence of HIV among all other groups continues to increase more quickly than the incidence of HIV among male homosexuals.²¹⁸

A different form of error may be associated with dangerously underinclusive definitions of excluded groups. Two early examples, the 1983 and 1984 exclusions which focused on gay men, provide cases in point. Both

216. See 1983 Memorandum, *supra* note 193, at 1.

217. See 1984 Memorandum, *supra* note 196, at 2.

218. See Mark E. Wojcik, *AIDS in the World*, 16 HOUS. J. INT'L L. 713, 713 (1994) (book review) (citing "declining infection rates among gay men and increasing rates among heterosexuals"). For a discussion of increasing HIV infection rates among heterosexuals, see Ed Susman, *AIDS Epidemic Spread in Heterosexuals*, U.P.I., Jan. 31, 1996, available in LEXIS, News Library, Allnews File.

exclusions are arguably arbitrary and irrational. The 1983 language, which excluded "sexually active homosexual or bisexual men with multiple partners,"²¹⁹ appears to reflect either extreme naïveté or unconscionable carelessness. In acknowledgement of the fact that monogamous donors sometimes sleep with promiscuous mates, the exclusion was changed in 1984 to read as follows: "Males who have had sex with more than one male partner since 1979, and males whose male partner has had sex with more than one male since 1979."²²⁰ This language contains two sources of error that could impair the value of the exclusion. These are (i) the failure to exclude anyone based on activities prior to 1979²²¹ and (ii) the presumption that donors have accurate knowledge of the outside sexual activities of their partners. Presumably in light of these gaps, the exclusion was altered again in 1986 to prohibit more broadly donations by "men who have had sex with another man one or more times since 1977."²²²

While potential error associated with class generalizations will invariably undermine the utility of categorical screening, the exclusion of particular groups of prospective donors can be effective if the groups are substantially more likely to carry HIV than the donor population at large. In other words, the potential benefits of categorical exclusion increase as the correlation between class membership and HIV infection increases. This means that highly accurate stereotypes can be an efficient and effective means of making disqualification decisions regarding blood donations, whereas highly inaccurate stereotypes are inefficient and ineffective.²²³

219. 1983 Memorandum, *supra* note 193, at 1.

220. 1984 Memorandum, *supra* note 196, at 2.

221. This omission left a gap whereby persons infected with HIV through male homosexual activities prior to 1979 were permitted to donate blood.

222. 1986 Memorandum, *supra* note 202, at 1.

223. On a continuum, consider perfect positive correlation between class membership and HIV infection at one extreme, no correlation between class membership and HIV infection in the middle, and perfect negative correlation between class membership and HIV infection at the other extreme.

When a perfect positive correlation exists, disqualification of all class members from blood donation is efficient and effective. It is efficient because it permits accurate disqualification without individual testing or assessment; it is effective because it disqualifies only infected prospective donors, with no error. Accordingly, each categorical disqualification results in an avoidance of blood supply contamination, and no categorical disqualification results in the rejection of a pure blood donation.

When no correlation exists, disqualification of all class members from blood donation is neither efficient nor effective, as class membership is entirely unrelated to a donor's HIV status. Class membership thus becomes irrelevant to the goal of protecting the blood supply and provides an irrational basis for making decisions.

Finally, when a perfect negative correlation exists between class membership and seropositivity, disqualification of all class members from blood donation is most inefficient and ineffective.

Accordingly, the primary criterion for scrutinizing any categorical exclusion of donors should be the accuracy of the underlying stereotype. Because HIV is frequently transmitted through high-risk practices,²²⁴ behavior-oriented classes are likely to provide more accurate bases for exclusion than status-oriented classes.²²⁵ Banning donations by male homosexuals, for example, is subject to error associated with imperfect or erroneous presumptions. *Ceteris paribus*, heterosexual females who engage in unsafe sexual practices are at higher risk than homosexual males who are, and have been, celibate.²²⁶ While such specific cases erode the reliability of status-based classifications for excluding donors, the prudence of these classifications ultimately depends upon the strength of the relationship between status and behavior. For instance, the more likely male homosexuals are to carry HIV relative to the population at large, the smaller the error associated with the status-based classification.

An additional source of potential error associated with predonation questioning and screening processes is the error related to response inaccuracies. Even if a status-based classification is so highly correlated to HIV infection as to render class membership an effective and efficient screen, error can be attributed to both unintentional and intentional false reporting. Such error can erode the effectiveness of categorical exclusions.

Both unintentional and intentional reporting errors can impair the value of interrogation and categorical exclusion. Unintentional errors associated with any self-reporting process can arise as a result of misunderstandings or misinterpretations.²²⁷ Moreover, unintentional errors in the self-reporting of

Disqualification of class members under such conditions is counterproductive, increasingly deterring uncontaminated donations as the correlation approaches -1. Of course, policies of this sort are inconceivable, and there is little need to worry about them in reality. They are mentioned here in order to place the entire continuum of possible stereotypes in conceptual perspective. At some point, as we move from a perfect positive correlation to a perfect negative correlation, the use of categorical disqualification becomes sufficiently inefficient and ineffective that it is no longer a viable policy consideration.

224. See generally MARK VARGO, *THE HIV TEST: WHAT YOU NEED TO KNOW TO MAKE AN INFORMED DECISION* 18-34 (1992).

225. Status-based stereotypes entail the unavoidable inaccuracy that accompanies all stereotyping. Even close correlation between a status and a behavior is attenuated by inevitable exceptions to status-based generalizations.

226. Moreover, in some areas of the United States, heterosexual transmission has become the predominant method of HIV transmission. See, e.g., Laurie Garrett, "*Hetero*" Sex Gaining as AIDS Cause, *NEWSDAY*, Feb. 1, 1995, at A17 (noting that heterosexual transmission of AIDS has become the leading method of transmission in the South Bronx).

227. Accordingly, experts emphasize the importance of clear, unambiguous questions in the

class membership are likely to be exacerbated by the effects of cognitive dissonance. Faced with the painful implications of high-risk activities, some respondents may distort their perceptions of the severity of the risks that they have taken. Likewise, some men may resist identifying themselves as homosexual or acknowledging the hazards of sporadic unsafe sexual relations. Accordingly, some who would objectively be considered as intravenous drug users or homosexuals by virtue of their behavioral histories might subjectively determine that they should not be so categorized. Arguably, questions that seek behavioral rather than status information could mitigate some of this inaccuracy by taking the responsibility of classification away from the interested party (i.e., the prospective donor) and lodging it in the hands of a more disinterested professional. Nonetheless, some degree of error may still occur if respondents blur the characterization of what they have done in the past or underestimate the quantity or severity of past activities.

Error associated with inadvertent reporting inaccuracy is exacerbated by some prospective donors' intentional misrepresentations. Given the stigmatization of AIDS,²²⁸ homosexuality,²²⁹ and illegal intravenous drug use,²³⁰ some respondents feel pressure to lie when confronted with predonation questioning.²³¹ Such pressure can accrue at a number of stages during various screening procedures. Respondents may be embarrassed to answer truthfully either to a human questioner or on a form which will be processed by a human questioner.²³² Moreover, respondents may be concerned that the information sought will not be kept confidential or will be

development of survey instruments. *See, e.g.*, EARL R. BABBIE, *SURVEY RESEARCH METHODS* 128 (2d ed. 1990).

228. *See Doe v. Borough of Barrington*, 729 F. Supp. 376, 385 (D.N.J. 1990) ("Revealing that one's family or household member has AIDS causes the entire family to be ostracized.").

229. *Borquez v. Ozer*, No. 93CA1805, 1995 WL 656871, at *5 (Colo. App. Nov. 9, 1995) ("[A] strong stigma still attaches to both homosexuality and AIDS.").

230. *See Note, The Constitutional Rights of AIDS Carriers*, 99 HARV. L. REV. 1274, 1280 (1986) (mentioning the stigma attached to AIDS as a result of "the disease's close association with both homosexuality and intravenous drug use").

231. *See Red Cross Had No Duty to Question Blood Donors*, NAT'L L.J., Nov. 28, 1994, at B14 (observing adverse effect of the fear of stigmatization on accurate reporting by gay men regarding sexual histories or partners).

232. The latter form of interrogation may be preferable to the former under the theory that deception will be more frequent the more direct the human contact is in the questioning process. Arguably, some persons who would lie to a human interrogator would tell the truth on a less immediately confrontational form.

used later in harmful or discriminatory ways.²³³ Inevitably, a proportion of respondents will respond to these fears by answering the screening questions deceptively. The resulting error, combined with the potential error associated with inadvertent false responses, may undermine the utility of status-based classification as an accurate and useful screening tool.

Because of this potential pitfall, categorical exclusion policies should be fashioned with an understanding of how certain procedures can reduce inaccuracy and distortion.²³⁴ Generally, computerized questionnaires are superior to written questionnaires, and written questionnaires are superior to face-to-face interviews. The logic behind this preference ordering is as follows: Some false denials are given by self-aware respondents who admit their engagement in high-risk activities to themselves, but are uncomfortable admitting it to others. For these respondents, the more personalized the method of information solicitation, the greater the potential discomfort. Accordingly, relatively depersonalized written questionnaires should elicit fewer lies than relatively personalized face-to-face questioning.²³⁵ Likewise,

233. This hypothesis is reasonable, given the high incidence of perceived discrimination based on HIV-status. For example, during one six-month period in 1991, 104 cases of alleged HIV-status discrimination were filed in Massachusetts alone. Laura Pincus, *The Americans With Disabilities Act: Employers' New Responsibilities to HIV-Positive Employees*, 21 HOFSTRA L. REV. 561, 566 n.31 (1993).

234. While the procedures to be discussed may be helpful, they will not reduce all types of false denials. Some false denials of high-risk behavior may be a projection of self-denial. When a respondent is fooling not only the questioner but also himself or herself, the questioner cannot reasonably be expected to identify false reporting in the interview process. We can only hope that these cases are caught by ancillary nets, such as the blood specimen screening procedures discussed in Section IV.A.

235. At least two possible explanations support this reasoning. First, even under conditions of apparent privacy, the respondent who is speaking with a questioner is asked to identify risky behaviors to someone who not only knows the respondent's name, but also can identify the respondent by appearance. Second, if conditions of total privacy are compromised for any reason, whether it be carelessness or expediency related to spacial limitations, the respondent may reasonably believe that bystanders can hear his or her answers to the questions posed. I have witnessed, for example, blood collection procedures that utilize one open room. The only privacy is that which is created through the use of movable screens, which are of dubious value in obscuring view and of almost no value in obscuring sound. This scenario is probably common, given that blood collection procedures frequently occur in institutions that host blood drives using rooms that are only temporarily rearranged for blood collection purposes.

Ironically, critics have cited Canadian procedures that use written questionnaires as less rigorous than U.S. procedures, which require men to be asked face-to-face, "Have you had sex with a man since 1977?" See Mark Nichols & William Lowther, *Setting Standards: How U.S. Rules on Blood Are Tougher than Canada's*, MACLEAN'S, Sept. 19, 1994, at 26 (discussing an FDA inspector's report evaluating blood center practices in Toronto). Given the stigma attached by many to homosexual behaviors, the use of written questionnaires as opposed to face-to-face interviews to elicit potentially

computerized interview techniques are more highly depersonalized than written questionnaires²³⁶ and face-to-face interviews, and are therefore superior in encouraging honest responses.²³⁷

D. Regulations Requiring Improvements in Information Transmission, Operating Procedures, and the Maintenance of Blood Supplies

The quality of procedures adopted for the routine handling of blood can affect levels of blood impurity and transfusion-associated contamination.²³⁸ Likewise, human error in the implementation of procedures threatens the safety of blood supplies.²³⁹ To address these problems, the U.S. Department of Health, Education, and Welfare proposed a "National Blood Policy" in 1974 to centralize and standardize the collection and processing of blood for distribution through regional blood banks.²⁴⁰ A variant of that proposed policy was adopted later that same year.²⁴¹

Since 1974, the National Blood Policy has evolved in the United States through a series of standards, rules, and approved manufacturing practices. This Section examines the federal regulations that have been proposed or

sensitive or embarrassing information seems prudent.

236. Filling out written questionnaires entails a physical embodiment of information that can be avoided through the use of computers. Donors may place greater confidence in the confidentiality of the information they provide when they are asked to respond to questions on a computer terminal located in a private setting, where onlookers are precluded from seeing their answers. This process obviously avoids the personal contact of face-to-face questioning. It also avoids any passing of tangible information on to blood bank personnel, who will presumably read the information immediately and associate it with the person who has submitted it. When a respondent enters the same information into a computer located in a private setting, he or she can see the questionnaire process end and witness the computer resetting itself for another user without any tangible manifestation of information. If these dynamics are indeed comforting to prospective donors, computerized donor screening may be more effective than the use of written questionnaires.

237. See Steven E. Locke et al., *Computer-Based Interview for Screening Blood Donors for Risk of HIV Transmission*, 268 JAMA 1301, 1304-05 (1992) (finding that computer-based interviewing procedures elicited more self-reporting of high-risk behavior than Red Cross interviewing procedures and that respondents exhibited a high degree of faith in the confidentiality of answers entered into computers).

238. Cf. Revelle, *supra* note 30 (discussing FDA regulation of the routine handling of blood to ensure blood safety).

239. Ann Marie LoGerfo, Note, *Protecting Donor Privacy in AIDS Related Blood Bank Litigation—Doe v. Puget Blood Center*, 117 Wash. 2d 772, 819 P.2d 370 (1991), 67 WASH. L. REV. 981, 996 (1992).

240. See National Blood Policy: Request for Comments Regarding Proposed Implementation Plan, 39 Fed. Reg. 9329 (1974) (proposed Mar. 8, 1974).

241. See National Blood Policy: Department Response to Private Sector Implementation Plan, 39 Fed. Reg. 32,702 (1974).

promulgated to improve operating procedures, the maintenance of blood supplies, and the transmission of information. These regulations include (1) labeling requirements, (2) required maintenance and filing of error and accident reports, and (3) a proposed federal preemption of blood supply regulation.

1. Labeling Requirements

In 1980, the FDA proposed extensive amended labeling requirements for both blood and blood components as part of its revised "Current Good Manufacturing Practices."²⁴² The proposed labeling requirements were intended to simplify label information and to improve readability.²⁴³ They also provided for computer coding of critical information as a means of supporting the National Blood Policy goals of national coordination, centralization, and regional interdependency among blood banks.²⁴⁴ The ultimate aim was to develop and implement an automated data processing system for the rapid, accurate distribution of blood products and to encourage uniform labeling practices among all establishments that collect, process, or label blood or blood components.²⁴⁵

The proposal to require machine-readable codification of labels was rejected.²⁴⁶ Maintaining that computers could improve blood bank practices and reduce error, the FDA nonetheless concluded that mandated bar coding would impose an unjustifiable expense and burden on blood establishments that were not yet computerized.²⁴⁷ Consequently, the FDA established a voluntary adoption policy for the computer coding of labels, requiring only that those who do use bar coding employ a system approved by the Director of the Office of Biologics.²⁴⁸

242. See Current Good Manufacturing Practice for Blood and Blood Components; Uniform Blood Labeling, 45 Fed. Reg. 72,416 (1980) (proposed Oct. 31, 1980) (later approved and codified at 21 C.F.R. pts. 606, 640 (1996)).

243. *Id.*

244. See *id.* at 72,416-17 (codified at 21 C.F.R. §§ 606.121-.122 (1996)) (describing the computer coding of labels as part of the implementation of the National Blood Policy).

245. See *id.* (stating that "interregional resource-sharing" among blood banks and "centralization of blood collection" practices "predispose toward . . . implementation of an automated data processing system . . . [and] the uniform placement of . . . encoded information").

246. 50 Fed. Reg. 35,458, at 35,461 ("FDA agrees it is unnecessary to require encoding.").

247. Cf. *id.* ("[F]or those establishments that are not yet computerized . . . , the direct benefit of including encoded information on the container label would be minimal.").

248. See *id.* at 35,461-62.

Although it rejected a mandatory computerized coding system, the FDA approved labeling guidelines in 1985.²⁴⁹ The guidelines prescribe uniform practices for the development and handling of blood labels and require uniformity of information.²⁵⁰ The guidelines also require the physical or spatial separation of labeling operations from other operations in order to prevent mix-ups²⁵¹ and mandate that labels “be held upon receipt, pending review and proofing against an approved final copy, to ensure accuracy regarding identity, content, and conformity with the approved copy.”²⁵² In addition, the guidelines require the storage and maintenance of each type of label “in a manner to prevent mix-ups” and the destruction of “stocks of obsolete labels.”²⁵³

The FDA labeling guidelines apply to all “blood products shipped in interstate commerce.”²⁵⁴ Information required under the guidelines includes identification of the unit’s donor,²⁵⁵ designation of whether the product is intended for transfusion,²⁵⁶ and a “donor classification statement”²⁵⁷ identifying the source either as a “paid donor”²⁵⁸ or a “volunteer donor.”²⁵⁹ The guidelines also require that blood not intended for transfusion be labeled accordingly²⁶⁰ and include the reason for its unsuitability.²⁶¹

The FDA labeling guidelines are sensible, cost-efficient mechanisms for improving blood safety and avoiding unnecessary error. Blood products obviously must be designated in terms of the presence of contaminants, and

249. See Final Rule, Current Good Manufacturing Practice for Blood and Blood Components; Uniform Blood Labeling, 50 Fed. Reg. 35,458 (1985) (codified at 21 C.F.R. pts. 606, 640 (1996)).

250. See generally 21 C.F.R. pts. 606, 640 (1996).

251. *Id.* § 606.120(a).

252. *Id.* § 606.120(b)(1).

253. *Id.* § 606.120(b)(2).

254. 50 Fed. Reg. 35,458, at 35,460 (1985).

255. 21 C.F.R. § 606.121(c)(3) (1996).

256. *Id.* § 606.121(c)(5).

257. *Id.*

258. A “paid donor” is defined as “a person who receives monetary payment for a blood donation.” *Id.* § 606.121(c)(5)(i).

259. A “volunteer donor” is defined as “a person who does not receive monetary payment for a blood donation.” *Id.* § 606.121(c)(5)(ii). Persons who receive nonmonetary benefits are considered voluntary donors. See *id.* § 606.121(c)(5)(iii). The FDA reasons that (1) “the higher risk of posttransfusion hepatitis associated with blood from paid donors results primarily because direct monetary payment for blood attracts donations from persons from socioeconomic groups with prevalent transmissible hepatitis” and (2) nonmonetary incentives are “not as likely to attract persons from groups with a high risk of hepatitis.” 50 Fed. Reg. 35,458, at 35,460 (1985).

260. See 21 C.F.R. § 606.121(f) (1996). This requirement applies only to products not labeled “for noninjectable use only.” See 50 Fed. Reg. 35,458, at 35,464 (1985).

261. See 21 C.F.R. § 606.121(f) (1996).

federal regulation of labeling provides a consistency that helps to reduce errors, careless practices, and misinterpretations of designations. While the FDA's approach to labeling has been sound, the agency should revisit the question of mandatory machine-readable labels. Given the rapid diffusion of technology since the FDA rejected the proposed requirement in the early 1980s, the benefits of requiring computer bar coding are likely to have increased substantially, particularly over the past five years. Accordingly, it is time to calculate anew the costs and benefits of requiring the use of blood and blood product labels that can be read using automated processes.

2. *Required Maintenance and Filing of Error and Accident Reports*

Errors and accidents reported annually to the FDA by blood banks have risen from approximately one thousand in 1989 to approximately ten thousand per year in the early 1990s.²⁶² These numbers may understate the incidence of errors and accidents, given alleged deficiencies in the FDA's blood supply monitoring processes.²⁶³ A recent government audit, conducted by the Inspector General of the Department of Health and Human Services, concluded that the FDA is lax in the timely collection of hospital and blood bank "error reports."²⁶⁴ The audit report requested the promulgation of FDA regulations that would require blood suppliers to account for, and control damage quickly in the event of, accidents and mistakes.²⁶⁵ An FDA spokesperson agreed that gaps existed with respect to accountability for blood safety and stated that the agency was working on "proposals to require all facilities to submit error and accident reports."²⁶⁶

This endeavor is critically important to maintaining the safety of the blood supply. Error and accident reports help blood banks to identify persons at risk and to recall tainted blood as quickly as possible.²⁶⁷ Such reports also help the FDA to monitor blood bank operations.²⁶⁸ Finally, the accumulation of

262. See Richard J. Newman et al., *Bad Blood*, U.S. NEWS & WORLD REP., June 27, 1994, at 68, 70.

263. See generally Linda M. Dorney, Comment, *Culpable Conduct with Impunity: The Blood Industry and the FDA's Responsibility for the Spread of AIDS Through Blood Products*, 3 J. PHARMACY & L. 129 (1994).

264. See G. Pascal Zachary, *FDA Can Improve Safety of Blood with Better Data*, WALL ST. J., June 5, 1995, at B3.

265. See *id.*

266. *Id.* (quoting FDA spokesperson).

267. See *id.*

268. In 1993, for example, the American Red Cross entered a consent decree with the FDA in

reports over time is essential to the development of a history and collective memory of the kinds of errors that are made. Aggregating data from a wide variety of blood supply situations over an extended period of time permits detailed analysis and understanding of the sources of blood processing mistakes, as well as their potential avoidance or rectification.

3. *Proposed Federal Preemption of Blood Supply Regulation*

Recently, a number of influential blood suppliers²⁶⁹ have petitioned the FDA to consider preempting state and local regulations concerning donor suitability and other issues.²⁷⁰ The petition notes that blood today moves “extensively and continuously in interstate commerce.”²⁷¹ It further contends that FDA regulation of the collection, processing, labeling, and distribution of blood and blood components is extensive and overlaps a patchwork of state regulations that purportedly threatens the adequacy and safety of the blood supply.²⁷² In terms of adequacy, the petitioners suggest that “without a uniform regulatory scheme, the nation’s vital interest in the free flow of blood components and derivatives across State and local borders, as well as between the United States and its foreign trading partners, is in jeopardy.”²⁷³ In regard to safety, the petitioners argue that “[s]tate action can actually decrease blood

response to allegations that it had violated blood safety laws. John Schwartz, *Red Cross, FDA Agree on Blood Safety Regulations*, WASH. POST, May 8, 1993, at A5. The allegations included inadvertent distribution of hepatitis-contaminated blood, failure to follow safety precautions, and failure to report accidents and errors to the FDA. *Id.* Among the measures required by the consent decree, which strengthened FDA authority over Red Cross blood banks, were improved quality assurance and training of personnel, and stronger policies for the investigation and reporting of accidents and errors. *Id.*

The FDA has also threatened to close local blood banks for failure to comply with safety standards. One blood bank in San Francisco was cited in 1993 for purported violations in record keeping, blood testing, and blood labeling. Charles Petit, *FDA Threatens to Close Irwin Blood Bank*, S.F. CHRON., July 21, 1993, at A1. The FDA suspended the licenses of a Spokane blood center that same year, effectively barring the center from the interstate shipment of blood and blood products. *Blood Center Licenses Suspended*, FDA CONSUMER, July-Aug. 1993, at 6.

269. The group included the American Blood Resources Association, the American National Red Cross, the American Association of Blood Banks, and the Council of Community Blood Centers. Notice of Citizen Petition Requesting Federal Preemption of Certain State and Local Standards Affecting Blood, Blood Components, and Blood Derivatives, 58 Fed. Reg. 45,341 (1993).

270. *Id.* In addition to preemption of state and local regulations regarding donor suitability, the petition also requests preemption of state and local regulations on testing and labeling of blood, blood components, and blood derivatives. *Id.*

271. *Id.*

272. See *id.* at 45,342.

273. *Id.*

safety by mandating poorly thought-out schemes that may overwhelm the limited resources available to blood establishments and cause paradoxical outcomes.²⁷⁴

Federal preemption of blood supply regulation is long overdue. Any reason for maintaining state and local control, such as regional epidemiological variations, becomes decreasingly compelling as AIDS becomes increasingly pandemic. Likewise, the benefits of uniformity in labeling and other procedures, as discussed in Section IV.D.1, would be supported by the implementation of a single, consistent federal blood policy. Finally, the ongoing threat of blood shortages,²⁷⁵ exacerbated by the heightened screening and disqualification of donors recommended in this Article, suggests a growing need to shift blood between regions. The emerging nationalization of the blood supply suggests that blood safety is becoming more a federal issue and less a local one.

E. Development and Maintenance of Information Registries

The establishment of information registries can help blood collection and distribution authorities to monitor and control potential sources of impure blood. This Section addresses (1) the potential benefits of information registries and (2) the potential abuses and related costs associated with information registries.

1. Potential Benefits of Information Registries

In a number of countries, including the United States, registration mechanisms called "donor deferral registries" ("DDR's") have been adopted to screen out potential donors who previously have been disqualified from giving blood.²⁷⁶ Varieties of DDRs differ primarily according to the scope and degree of centralization. Many blood banks maintain local records of prospective donors whose blood has been rejected for seropositivity.²⁷⁷ These

274. *Id.*

275. *See supra* notes 164-65 and accompanying text.

276. Venezuela, the Philippines, Germany, and Canada are other countries that maintain such registries. D. Reviron et al., *Prevention of HIV Infection by Transfusion: Comparative Analysis of Systems Adopted in Developed Countries*, 6 AIDS & PUB. POL'Y J. 25, 26 (1991).

277. In the early 1990s, the Red Cross began implementing a national computer system to centralize records and information regarding those who donate blood at any of its centers in the United States. *See* Christine Woolsey, *Proposals Target Safety of Blood, Tissues*, BUS. INS., May 27, 1991, at 3, 3. The system allows any center to retrieve health histories and test results of donors who have been

localized DDRs can be made more comprehensive and inclusive through participation in computerized databases that provide access to the identity of large numbers of rejected donors across blood banks, states, or nations.²⁷⁸

The potential benefits of DDRs are a function of the degree to which collected information results in the accurate rejection of tainted blood that otherwise would have entered the blood supply.²⁷⁹ Reference to DDRs averts blood-supply contamination primarily when a seropositive donor tests falsely negative but is traced to a prior disqualification for having tested positive. Yet under today's screening technologies, the probability of a false negative test result is low.²⁸⁰ Moreover, in countries where the sale of blood is banned, donors presumably act out of charitable impulses and are therefore unlikely to attempt second donations after a previous disqualification.²⁸¹ As voluntary abstention practices approach ubiquity, the risk of contaminated donations by persons previously disqualified for seropositivity approaches zero.²⁸² For these reasons, the incremental protection of the blood supply provided by DDRs may be insubstantial.

Although they may avert only a small number of contaminations, registries have the potential to serve other useful functions. For example, accurate recordkeeping is an essential precursor to the *ex post facto* tracing procedures discussed in Section IV.F. Unfortunately, the sources of the blood

deemed unsuitable. *Id.*

278. Local blood banks that are unaffiliated with the Red Cross sometimes operate local DDRs whose effectiveness is limited because they are not connected to large, nationwide networks. *See* McCullough, *supra* note 116, at 2241. Presently, the American Red Cross operates a single, centralized DDR that provides any location with access to information obtained at any other location. *Id.*

279. As McCullough observes, these benefits have not yet been established. *Id.* Prudent policy therefore depends on studies that indicate marginal effectiveness and assess countervailing costs.

280. *See* Kimmig, *supra* note 101.

281. Conversely, in places where blood sale is permitted, greed and desperation might motivate some to attempt to sell their blood despite knowledge of infection. Self-serving motives may be particularly compelling when combined with drug addiction, which can increase both the desperation and the irrationality of prospective blood sellers. Because needle sharing among intravenous drug users is a significant means of HIV transmission, these risks will not be insignificant.

282. Of course, voluntary abstention by those who know themselves to be seropositive will never be ubiquitous. Whereas the optimistic might expect all donors rejected for seropositivity to screen themselves out as future donors, not all persons are rational, mentally stable, and virtuous. While rare, cases of purportedly intentional transmission of HIV do exist. *See, e.g., State v. Stark*, 832 P.2d 109 (Wash. Ct. App. 1992).

In addition, we cannot discount instances in which rejected, seropositive donors attempt to make second donations, either because they are not of sound mind or because they lack the rationality or intelligence to understand the ramifications of such an act.

transfused to a donee are not consistently and routinely recorded.²⁸³ Records might easily be maintained to identify the sources of blood associated with individual transfusions.²⁸⁴ Such records would permit authorities to investigate the history of blood units determined after transfusion to have been seropositive.²⁸⁵ The identified recipients of tainted blood could then be informed of their exposure in order to be tested for HIV and to modify behaviors that risk new transmissions.

The existence of records and procedures for informing recipients of tainted blood may also alleviate the fears of transfusion donees who have received untainted blood concurrent with any tainted blood incidents. This may be beneficial not only in reducing anxiety among the affected donees, but also in reducing public fears regarding the risks of transfusion in general.²⁸⁶

2. Potential Costs of Information Registries

The potential benefits of maintaining information registries must be balanced against potential costs. In addition to the obvious implementation costs,²⁸⁷ plausible social costs fall into three general categories: (a) invasion of privacy, (b) risk of discrimination, and (c) chilling effect on blood donation.

a. Invasion of Privacy. Information regarding HIV status is private information.²⁸⁸ The privacy concerns of individuals regarding HIV and AIDS

283. Ralph R. Frerichs & Eugene Seymour, Letter to the Editor, *HIV Testing and Blood Recipients*, 342 LANCET 1549, 1549 (1993).

284. Some commentators have recommended mandatory notation of a blood unit's source on all patient casenote records. See James J. McMenamin et al., Letter to the Editor, *HIV Testing and Blood Recipients*, 343 LANCET 478 (1994).

285. For an example of a laboratory in the United Kingdom that has adopted this process, see Patricia E. Hewitt, Letter to the Editor, *HIV Testing and Blood Recipients*, 343 LANCET 797 (1994).

286. Of course, post-transfusion information regarding contaminated blood sources cannot undo the potential exposure to HIV. Such information, however, may increase public trust by demonstrating that the relevant professionals behave responsibly and handle errors openly and honestly.

287. These costs include personnel hours and overhead expenses dedicated to the maintenance of records, hard-copy records and storage space, computer facilities, and computer programs.

288. Facts concerning a person's infection or illness, especially with respect to a stigmatized disease like AIDS, are fundamentally personal. See *Urbaniak v. Newton*, 277 Cal. Rptr. 354, 360 (Cal. Ct. App. 1991) (describing seropositive status as "a private fact" to persons "of ordinary sensibilities") (quoting *Forsher v. Bugliosi*, 163 Cal. Rptr. 628, 637 (Cal. 1980)); see also Carol A. Tauer, *AIDS and Human Rights: An Intercontinental Perspective*, in *AIDS: ETHICS AND PUBLIC POLICY* 154, 159 (Christine Pierce & Donald Vandever eds., 1988) (listing "the right of personal privacy and confidentiality regarding medical and sexual information" as a right that AIDS control measures can threaten).

are heightened by potential misunderstanding of the virus and the disease, as well as by ostracism, stigmatization, and discrimination.²⁸⁹

Any use of HIV-status information evokes privacy concerns.²⁹⁰ The degree of concern will vary according to the nature and extent of potential publication and associated risks. At one extreme, publication of the identities of those exposed to HIV would raise serious objections because the announcement of personal information would be far-reaching and the risks to the individual would be high. At the other extreme, a central registry which employs substantial privacy safeguards might be maintained. The safeguards might include legal or regulatory assurances of confidentiality, as well as structural protections to discourage any breach of the legal and regulatory constraints. Structural protections typically take the form of rules and procedures limiting access to registry information, maintaining high levels of security for computerized database information, training personnel with regard to the legal and ethical issues associated with privacy, and penalizing with adequate severity those who violate the privacy rights of others. Unless implementation of such precautions should prove ineffectual in preserving privacy interests,²⁹¹ lawmakers and policymakers should not presume that privacy concerns are unmanageable. Given the benefits of recordkeeping, authorities must consider and test administrative controls that are potentially powerful tools for the maintenance of privacy.

As we shall see in Section IV.E.2.b, the information kept in central registries can be used for discriminatory purposes if privacy protections are suboptimal. Moreover, the fear of privacy infractions and the negative results of publication can reasonably be expected to have a chilling effect on donor activity, even if those fears are exaggerated or irrational.

289. See INSTITUTE OF MED., NAT'L ACADEMY OF SCIENCES, *CONFRONTING AIDS: DIRECTIONS FOR PUBLIC HEALTH, HEALTH CARE, AND RESEARCH* 133-35 (1986); see also INSTITUTE OF MED., NAT'L ACADEMY OF SCIENCES, *CONFRONTING AIDS: UPDATE 1988*, at 62-64 (1988) (discussing studies and cases illustrating AIDS-based discrimination).

290. See Doughty, *supra* note 142, at 163-77 (suggesting that AIDS patient confidentiality is inadequately protected in relation to some public health policies).

291. While the listed precautions will mitigate both potential privacy violations and individual fears of such violations, they can never guarantee total compliance with regulatory or legal edict. Use of centralized registries requires the identification of individuals in order to serve the screening functions for which they are established, and some human beings will ultimately have access to that information as data are entered, processed, and used. While the potential for lapses decreases when extreme care is exercised, it is impossible to eliminate entirely the potential for abuse. Moreover, not all laws, regulations, and structural implementation systems will employ meticulous care in considering individual privacy rights. Use of central registries without powerful safeguards will inevitably create serious risks of breach of privacy.

b. Risk of Discrimination. Discrimination against persons with HIV or AIDS is well documented.²⁹² As observed in the previous discussion, the potential for discrimination heightens the individual's privacy stakes. Whereas some choose to reveal their HIV status to the world, others treat this information as purely personal. An important aspect of one's privacy interest in HIV-status information is the freedom to choose whether to risk public disclosure and possible exposure to discrimination.

While statutory protection against discrimination applies to people with AIDS ("PWAs") under the Americans with Disabilities Act ("ADA"),²⁹³ the potential for insidious discrimination remains high. Like all anti-discrimination laws, laws prohibiting discrimination against PWAs protect only against patent or ill-concealed abuses.²⁹⁴ Because motives exist in the mind of the individual, they are subject to degrees of concealment and subterfuge.²⁹⁵ A prospective discriminator who is clever and reasonably well versed in the law can achieve a discriminatory goal while leaving no evidence of discriminatory motives.²⁹⁶

These observations are made in order to emphasize a crucial consideration with respect to centralized registries: if lapses in privacy occur and the information contained in centralized registries is publicized, recipients can use the information for easily veiled discriminatory purposes. The difficulty in enforcing anti-discrimination laws arguably heightens the importance of curbing the flow of private information. Obviously, the ultimate method of ensuring complete privacy would be to maintain donor anonymity and decline to keep records of donor status.

Such a potent safeguard against discrimination must be weighed against the potential benefits of central registries, to determine the net utility of

292. See Michael Clozen et al., *Mandatory Premarital HIV Testing: Political Exploitation of the AIDS Epidemic*, 69 TUL. L. REV. 71, 72 n.3 (1994) (citing sources that discuss the stigmatization of, and discrimination against, persons with HIV and AIDS).

293. See Adrienne L. Hiegel, Note, *Sexual Exclusions: The Americans With Disabilities Act as a Moral Code*, 94 COLUM. L. REV. 1451, 1472 (1994) ("AIDS is clearly intended to be a per se disability under the ADA . . .").

294. Accordingly, pretext has become a prominent issue in discrimination cases. See generally Catherine J. Lanctot, *The Defendant Lies and the Plaintiff Loses: The Fallacy of the "Pretext-Plus" Rule in Employment Discrimination Cases*, 43 HASTINGS L.J. 57 (1991).

295. "[M]otives are seldom apparent or vocalized." Charles G. Burgess, *Recent Decision, Ex Parte Scarbrough*, 46 ALA. L. REV. 211, 223 (1994) (quoting *State v. Bruzzese*, 463 A.2d 320, 326 (N.J. 1983)).

296. By thoroughly documenting pretextual motives, for example, the discriminator may be able to present a plausible legal basis for what is actually an act of illegal discrimination.

elaborate recordkeeping. Because increased opportunities for discrimination attributable to the maintenance of information registries ultimately depend on some breach of privacy, the arguments raised in the preceding subsection apply in this subsection as well. If administrative safeguards can be developed to maintain privacy interests effectively, then marginal instances of discrimination enabled by registries will be negligible or nonexistent. Various promising combinations of procedures, rules, regulations, and penalties can and should be tested and evaluated to determine the unavoidable costs of maintaining information registries.

c. Chilling Effect on Blood Donation. The maintenance of records identifying persons who have tested seropositive could have a chilling effect on blood donations.²⁹⁷ This observation is the logical extension of the phenomena identified in the preceding two subsections. Both incursions upon privacy and misuse of information are negative factors in an individual's decision to donate blood.

A potent fear for donors under information registration systems is fear of litigation—that the recipient will sue the donor should the donated unit prove seropositive, or that the donor will be subpoenaed for discovery in connection with a suit by the recipient against the blood bank. Sufficiently escalated, such fears could chill blood donation and exacerbate blood supply shortages.

One court has suggested that the identification of donors for discovery procedures can facilitate the administration of justice without undue social or personal cost. In *Watson v. Lowcountry Red Cross*,²⁹⁸ the Fourth Circuit Court of Appeals upheld the district court's limited discovery procedures, under which a deposed donor's identity was disclosed only to the court and the donor's court-appointed attorney.²⁹⁹ Discovery took the form of written

297. It is also conceivable, albeit less likely, that the use of centralized registries could dissuade some persons from being tested for HIV. This situation would certainly be true if centralized registries were expanded to include the identities of all who test seropositive, whether blood donors or not. But a similar situation could occur under a more limited scheme being addressed herein—the registration only of those who test positive after donating blood. This kind of chilling effect on HIV testing could be a function of mistrust, ignorance, or both. Persons considering HIV testing might not believe that registries are limited to blood donors, or they may have imprecise information that registries exist in some contexts, the specific boundaries of which are unclear. As the public gains accurate or inaccurate information about the existence of some kind of registry of persons who have tested positive for HIV, suspicion of testing in general might well arise. Whereas a chilling effect on blood donation among members of high-risk groups arguably could be beneficial, a chilling effect on HIV testing among members of high-risk groups is detrimental. Those considered most at risk are also among those most likely to benefit from early medical intervention resulting from diagnostic HIV testing.

298. 974 F.2d 482 (4th Cir. 1992).

299. *Id.* at 489.

questions given to the donor by the donor's lawyer and returned to the district court.³⁰⁰ The Red Cross contended that permitting even limited identification and shielded deposition of donors would jeopardize the blood supply by discouraging donations and that the discovery violated the donor's privacy rights.³⁰¹ The Fourth Circuit supported the district court's finding that such limited discovery would have no appreciable negative impact on the blood supply and noted that the questions to be asked during deposition were no more intrusive than those which the Red Cross is required by law to ask prior to donation.³⁰²

It has been suggested that in light of *Watson*, suppliers should reassure donors that the "decision does not condone public disclosure of a donor's identity and background" and that "[o]nly in the event of a lawsuit will a blood supplier be required to reveal a donor's identity, and then only to a court."³⁰³ While this advice may encourage donations, it is misleading and could convey a false sense of security to prospective donors. First, the *Watson* decision is not binding in jurisdictions outside the Fourth Circuit. Second, even in the Fourth Circuit, the decision does not require that donor identification be shielded during donor discovery. Rather, it affirms that one trial court's approval of such procedures was not erroneous.³⁰⁴ In the wake of *Watson*, future Fourth Circuit courts could consistently approve more intrusive donor identification procedures that fail to protect donor identity.

Given the holding in *Watson*, prospective donors may indeed worry about being sued or subpoenaed as a result of donating blood. While such a threat could chill donation activity, donor dissuasion might be a positive rather than a negative side-effect. Those most fearful of future litigation will be those most fearful that their blood is contaminated. These are precisely the people that modern blood policy seeks to discourage from attempting donation. In balancing the costs and benefits of donor registration, chilling effects on donations by persons infected with HIV should be calculated as benefits. Accordingly, some proponents of donor identification procedures defend the process as a way of discouraging high-risk persons from making donations.³⁰⁵

300. *Id.* at 484.

301. *Id.* at 485-88.

302. *Id.* at 486, 488.

303. Selected Recent Court Decisions, *Blood Industry: Discovery from Anonymous Donors—Watson v. Lowcountry Red Cross*, 18 AM. J.L. & MED. 280, 281 (1992).

304. See *Watson*, 974 F.2d 482.

305. Robert K. Jenner, *Identifying HIV-Infected Blood Donors*, TRIAL, June 1989, at 47, 50.

Prudent policy must consider the predicted magnitude of both positive and negative chilling effects,³⁰⁶ as well as the possible utility of central registries discussed in Section IV.E.1. This analysis should entail a number of considerations, including the degree to which the chilling effect impairs pure blood donations; the value of the marginal loss of pure blood donations, considering the adequacy of supply levels; and the degree to which the chilling effect impairs impure blood donations. The more that persons at high risk for HIV are disproportionately dissuaded from donating by the maintenance of registries, the more likely that chilling effects will confer a net benefit rather than a net cost.

Finally, all these considerations must be added to the balancing of considerations in Sections IV.E.2.a and IV.E.2.b, which generally favored the implementation of information registries. The resulting analysis suggests that without evidence that chilling effects will precipitate dangerous blood shortages, the balance of interests favors policies that encourage donor registration.

F. Ex Post Facto Procedures to Trace Recipients of Blood Identified as High-Risk or Tainted Subsequent to Transfusion

Following transfusion, authorities sometimes suspect or learn that recipients may have been exposed to HIV. Such a situation can arise as a result of transfusions received before the development of reliable blood tests³⁰⁷ or before the widespread adoption of such tests at different times in different parts of the world.³⁰⁸ In addition, technicians may fail to detect HIV antibodies even when specimens are tested and screened due to laboratory error³⁰⁹ or the window period of serolateness that exists for a brief time following infection.³¹⁰

Several procedures can help identify blood recipients whose risk of HIV infection is discovered only after they have received transfusions. These procedures include trace-back programs, look-back programs, and archival

306. Positive chilling effects refer to the avoidance of blood donation by persons infected with HIV. Negative chilling effects refer to the avoidance of blood donation by persons not infected with HIV.

307. Reliable blood tests were not developed and widely implemented before 1985. *See supra* note 12.

308. *See supra* notes 20-21 and accompanying text.

309. *See supra* notes 262-64 and accompanying text.

310. *See supra* notes 109-10 and accompanying text.

searches.³¹¹ Under trace-back programs, physicians help blood banks locate potentially tainted blood by reporting the identities of HIV or AIDS patients whose only purported exposure to high-risk activity was blood transfusion.³¹² If appropriate records are kept, blood banks receiving this information can trace the transfusion to a particular blood unit, which is the “best-guess” source of the patient’s otherwise inexplicable infection.

The blood bank can then apply look-back programs, which identify other recipients of the same potentially contaminated blood and notify them that they may have been exposed to HIV.³¹³ How and when a blood bank should initiate look-back procedures after tracing contaminated blood may depend upon situational variables. For instance, if the donee through whom a unit was traced has never received any transfusions from other sources and reports no engagement in high-risk behaviors, policymakers must consider whether the blood bank should immediately use look-back procedures to identify other donees of blood derived from the same potentially contaminated source or whether the blood bank should first investigate in order to verify its suspicions of contamination prior to notification. The trade-off here is between speed of notification and quality of the information transmitted to those who may be affected. Whereas early notification gives relevant parties the most leverage in deciding what measures to take and when to take them, it can also cause undue alarm should the suspicions of contamination be false.³¹⁴

Archival searches entail the examination of institutional records to identify persons who may have been exposed to tainted blood.³¹⁵ For example, officials searched the records of the Hospital for Sick Children in Toronto to find those children who had received open-heart surgery at the hospital between 1980 and 1985,³¹⁶ the period immediately prior to the widespread

311. See M. John Gill et al., *Use of Blood Donation History of People with HIV Infection to Identify Recipients at Risk*, 151 CAN. MED. ASS’N J. 1147, 1148 (1994) (describing trace-back programs, look-back programs, and archival searches).

312. *Id.*

313. *Id.*

314. False suspicions may arise frequently if fearful or embarrassed donees deny participation in high-risk activities such as homosexual anal intercourse or intravenous drug use. These donees may seek to avoid the stigma associated in many societies with these practices by falsely attesting that transfusion is the only high-risk activity in which they have engaged. Such misrepresentation could result in a proliferation of false alarms associated with trace-back procedures. If so, authorities may determine that it is prudent to verify suspicions of tainted blood prior to notifying donees through look-back programs.

315. *See id.*

316. *Id.* (citing S.M. King et al., *HIV Information Project for Transfusion Recipients*, 5 PUB. HEALTH EPIDEMIOLOGY REP. ONT. 25 (1994)).

availability and adoption of effective HIV antibody testing. Once identified, those children were located and examined for symptoms related to HIV.³¹⁷

Archival searches are a specific variety of look-back program in which officials peruse records to identify broad classes of persons at risk, such as those who received blood prior to the development and implementation of screening procedures.³¹⁸ Whereas look-back programs often trace specific individuals who have received blood from very particular, highly suspect sources, archival searches generally identify larger groups of persons considered to be at risk.³¹⁹

The similarities between look-back programs and archival searches suggest that prudent adoption may depend on like considerations, such as (i) their ability to identify an acceptable number of unwitting donees of tainted blood, given the costs of implementing the programs, and (ii) the value to both the identified donees and the public at large of notifying the donees so they can seek treatment and alter behavior patterns that might otherwise contribute to the spread of HIV.³²⁰ The differences between most look-back programs and most archival searches suggest that look-back programs are likely to fare at least somewhat better under a cost-benefit analysis than archival searches. Because look-back programs generally seek to identify recipients of specific units of blood believed to have been exposed to HIV, they are more likely to identify larger percentages of persons who actually received contaminated blood than less closely targeted archival searches.³²¹ Moreover, because they usually focus their search on small, precise groups of individuals, look-back programs are less expensive than searches that scan

317. *Id.*

318. *See id.*

319. The nomenclature designating some programs as "look-backs" and others as "archival searches" is imprecise, and the terms are not always consistently used. Further confusion may result when look-back programs use archival information to locate those persons who received blood from a single suspected source. Nonetheless, as presently used, look-back programs and archival searches often differ in terms of the focus of the search.

320. The value of identifying donees so that they can seek treatment and alter their behavior will be contingent, of course, upon the quality of treatments available for persons with HIV and with AIDS, as well as the likely effects of knowledge of one's seropositivity on one's propensity to engage in high-risk activities. As researchers have made significant advances in the treatment of HIV and AIDS in the middle 1990s, particularly through the development of protease inhibitors, the potential to treat HIV effectively upon early diagnosis has become more meaningful. For an example of developments in the treatment of HIV and AIDS in 1995, see *supra* note 151.

321. This statement is true because the risk of exposure to HIV is much greater if one has been exposed to a specific unit of blood believed to be tainted than if one has been exposed to a random unit of blood, even if that random unit was donated before screening procedures were adopted.

archives for broad classes of potentially vulnerable blood recipients.³²² Accordingly, the efficiency and effectiveness of look-back programs are likely to be superior to the efficiency and effectiveness of archival searches.

G. Encouragement of Autologous Transfusion, Directed Donation, and Bloodless Surgery

Some transfusion recipients avert the risk of receiving contaminated blood by arranging to receive autologous transfusion—i.e., transfusion of their own blood.³²³ Autologous transfusion is safer than transfusion from anonymous sources because it exposes the recipient of blood only to contaminants that are already present in his or her bloodstream.³²⁴ While they cannot avoid some risks, such as the possibility that blood units will be confused and the patient will receive another person's blood, recipients of autologous transfusions do avert other risks, such as the possible failure of a blood collection center to test the blood units to be transfused.³²⁵

Opportunities to receive autologous transfusions are limited by a number of practical considerations. First, because donors of blood need time to replenish circulatory blood supplies before undergoing surgery and autologous transfusion, and because they may need to make several donations before enough blood is collected for surgical transfusion purposes, lead time of over a month is usually required to ensure receipt of one's own blood.³²⁶ As a result, autologous transfusion is ordinarily limited to elective procedures that can be scheduled well in advance of surgery.³²⁷ Second, a number of categories of patients are disqualified from autologous transfusion because of anemia or other conditions that may render the procedure unsafe or inappropriate.³²⁸ Third, hemophiliacs cannot use autologous products because

322. Tracing records to find those who received transfusions from one unit of blood constitutes a search on a smaller scale and hence is less expensive than locating all transfusion recipients over a particular span of time.

323. For a fuller explanation of autologous transfusion and related processes, see Michael Chapman, *The Safest Blood is Your Own*, CONSUMERS' RES., Apr. 1994, at 16.

324. Worsnop, *supra* note 31, at 988 sidebar "Some Donors Give to Themselves."

325. Omissions in the care and consistency of blood testing have resulted in scandals throughout the era of AIDS. For example, failure to test all collected and processed blood led to a recent blood scandal in Germany. See Debora MacKenzie, *How Safe is Europe's Blood?*, NEW SCIENTIST, Jan. 15, 1994, at 12, 12; see also *supra* note 31.

326. S. Gerald Sandler & Mark A. Popovsky, *New Technologies for a Safer Blood Supply*, TECH. REV., July 1990, at 23, 26.

327. *Id.* at 25-26.

328. *Id.*

they must receive clotting factors that their own bodies do not produce.³²⁹

Detractors have criticized autologous transfusion as inefficient and expensive for both individuals and society. The patient who donates blood for autologous transfusion ordinarily pays between \$100 and \$200 per pint, a range that exceeds the prices typically charged for non-autologous blood.³³⁰ Costs to the individual can be exacerbated further by insurance policies that exclude coverage of autologous transfusion.³³¹

More importantly, the social costs of autologous transfusion are considerable. Because blood for autologous transfusion is earmarked for receipt by the donor, it may not be subjected to the rigorous testing of anonymous blood.³³² Accordingly, much of the forty-four percent of autologous blood that is not used by the donor is discarded³³³ rather than redirected to other persons.³³⁴ In itself, this waste is not a compelling argument against encouraging autologous transfusion. The pool of blood designated for autologous transfusion is separate from the pool of blood donated for anonymous transfusion. In most instances, blood donated for autologous transfusion simply would not have been donated at all but for the anticipation of the donor's own elective surgery. This means that the volume of blood donated for autologous transfusion largely augments, rather than replaces, the non-dedicated blood supply. Accordingly, the practice of autologous transfusion is unlikely to deplete public blood supplies. Some have suggested that predepositing one's own blood in anticipation of elective surgery reduces the demand for blood from the community supply,³³⁵ potentially increasing the blood available for nonautologous transfusion.

That autologous transfusion is highly cost-ineffective may be a more

329. See Worsnop, *supra* note 31, at 994 sidebar "Screening Test Gives Hemophiliacs a Brighter Future" (observing that the plasma that is the source of blood clotting factors for hemophiliacs comes from many pooled donations, so that hemophiliacs are exposed by transfusion to thousands of donors at once).

330. *Banking Your Own Blood Not Worth Cost or Effort*, TIMES UNION (Albany), Feb. 2, 1996, at C4, available in Westlaw, TIMESUNION Database.

331. *Id.*

332. See Worsnop, *supra* note 31, at 988 cmt. (*Some Donors Give to Themselves*).

333. *Id.*

334. Some researchers have begun to investigate opportunities to diminish waste by redirecting unused autologous blood donations. See, e.g., Jane M. Starkey et al., *Markers for Transfusion-Transmitted Disease in Different Groups of Blood Donors*, 262 JAMA 3452 (1989).

335. See Pearl T.C.Y. Toy et al., *Predeposited Autologous Blood for Elective Surgery: A National Multicenter Study*, 316 NEW ENG. J. MED. 517, 519 (1987); Roslyn Yomtovian et al., *A Blood Drive Enlisting Past Autologous Donors*, MED. LABORATORY OBSERVER, Aug. 1988, at 65.

compelling argument against the procedure.³³⁶ Assessing cost-effectiveness requires several pieces of information. First, how many new cases of HIV contamination, hepatitis contamination, and other contaminations are avoided by autologous transfusion? Second, what is the net benefit of these averted infections? Finally, what is the cost of processing all blood for autologous transfusion? The literature in this area suggests that each life-year saved through preoperative autologous donation is extremely expensive, ranging anywhere from \$200,000 to \$2 million.³³⁷

Research posits a number of reasons why autologous blood donations are more expensive than anonymous donations, including the logistical costs related to scheduling and inventory management, as well as practice-related costs such as patient counseling.³³⁸ Moreover, because the risk of contracting HIV and hepatitis through an anonymous donation in the United States has been minimized via the policies previously discussed,³³⁹ the numbers of infections averted by the expensive process of autologous transfusion will be small. These factors likely contribute to findings that the incremental costs of autologous blood donation are very high relative to the incremental benefits associated with reductions in the transmission of disease.³⁴⁰ Accordingly, until the cost per life-year saved through autologous transfusion can be reduced, regulations and policies to encourage autologous blood donation should not

336. Whether encouragement of autologous transfusion is a cost-effective policy differs from whether an individual will want to incur the costs of pre donating his or her own blood in anticipation of elective surgery. Even if the social costs of autologous transfusion exceed the social benefits, it is likely that many individuals would still be willing to pre donate as an insurance policy against even a small possibility of contracting HIV.

337. See J.D. Birkmeyer et al., *The Cost-Effectiveness of Preoperative Autologous Blood Donation for Total Hip and Knee Replacement*, 33 *TRANSFUSION* 544, 549 tbl.4 (1993); John D. Birkmeyer et al., *Cost-Effectiveness of Preoperative Autologous Donation in Coronary Artery Bypass Grafting*, 57 *ANNALS THORACIC SURGERY* 161, 165 tbl.3 (1994).

338. See Cynthia J. Rutherford & Harold S. Kaplan, *Autologous Blood Donation—Can We Bank on It?*, 332 *NEW ENG. J. MED.* 740, 741 (1995).

339. See *supra* notes 71-86 and accompanying text.

340. See generally Jeff Etchason et al., *The Cost Effectiveness of Preoperative Autologous Blood Donations*, 332 *NEW ENG. J. MED.* 719 (1995). It should be remembered, however, that the results of any cost-benefit analysis incorporate and reflect a researcher's own valuation scheme. Consider, for example, the valuation of averted infections in terms of medical expenses, lost wages, and pain and suffering. Whereas determining the value of avoiding medical expenses is relatively objectively quantifiable, determining the value of avoiding pain and suffering is obviously more troublesome.

Moreover, not all researchers are in agreement regarding the cost-effectiveness of autologous transfusions. According to some, "[t]he most effective and least costly strategies to reduce HIV infection transmitted by transfusion of blood and blood products involve decreasing the use of homologous blood transfusions." Schwartz et al., *supra* note 123, at 1709.

be adopted.³⁴¹

Related to autologous transfusion is the practice of directed donation,³⁴² in which a donor of blood designates the recipient, usually a friend or relative.³⁴³ While those who arrange to receive a directed donation presume the process will reduce the chance of contracting HIV, some blood bankers and researchers suggest that directed donations may in fact be riskier than anonymous donations.³⁴⁴ They reason that people feel pressure to hide high-

341. Should autologous transfusion ever become so marginally effective and cost efficient that it should be encouraged by sound public policy, a secondary question will arise: whether autologous transfusion should be made available to all patients anticipating elective surgery. Patients known to be infected with HIV, for example, may wish to donate their own blood for future transfusion to avoid exposure to threatening viruses. Autologous transfusion by HIV-infected patients may eliminate or reduce a number of risks associated with transfusion of anonymously donated blood, including immunosuppression, viral infection, and activation of HIV replication. See Paul D. Mintz, Commentary, *Participation of HIV-Infected Patients in Autologous Blood Programs*, 269 JAMA 2892, 2893 (1993).

Although autologous transfusion can reduce the danger to HIV-positive recipients, risks of error or inadvertent contamination may be associated with the collection and storage of infected blood. See, e.g., *A Deadly Mistake in a Troubled Hospital: HIV-Contaminated Transfusion Underscores the Need for Reforms at King*, L.A. TIMES, Dec. 21, 1995, at B8 (reporting transfusion of contaminated blood that had been directed for quarantine). The interests of prospective HIV-infected autologous donors potentially conflict with the interests of other patients, particularly uninfected autologous donees who may bear the risk of oversights that could result in their exposure to contaminated blood. Mintz, *supra*, at 2893.

As soon as HIV-infected blood enters the supply, it is available for erroneous transfusion. According to one study done in New York, allogeneic blood is transfused into the wrong patient once for every 12,000 units of blood. J.V. Linden et al., *A Report of 104 Transfusion Errors in New York State*, 32 TRANSFUSION 601, 601, 603 & tbl.3 (1992). The risk of even infrequent infusion of infected blood into previously uninfected patients raises serious concerns, especially given that over 90% of those transfused with seropositive blood become infected with HIV themselves as a result. See *supra* notes 46-47 and accompanying text.

In calculating the magnitude of these risks, policymakers should consider whether special labeling and handling provisions for contaminated blood, as well as other administrative provisions, have the potential to lower misdirected transfusion rates. For example, regulations that require the clear labeling of seropositive units as "autologous use only" and "biohazard" may be a reasonable means of attempting to monitor HIV-infected autologous donations. Nonetheless, even if labeling error can be eliminated, correctly labeled units can still be given to the wrong patient. Because anaesthetized patients can do nothing to rectify errors in identity, the problem of patient mix-ups is potentially daunting. See generally W.H. Dzik & S. Devarajan, *Should Autologous Blood That Tests Positive for Infectious Diseases Be Used or Discarded?*, 29 TRANSFUSION 743 (1989).

342. Directed donation is also referred to as "recipient-selected transfusion."

343. For more detailed discussion of directed donation, see Margot S. Kruskall & Joel Umlas, *Acquired Immunodeficiency Syndrome and Directed Blood Donations*, 123 ARCHIVES SURGERY 23 (1988).

344. See P. Toy et al., Abstract S52, *Higher Non-A, Non-B Hepatitis Surrogate Marker Rates in Designated Donor Units*, 28 TRANSFUSION 17S (1988); Harvey M. Sapolsky, *AIDS, Blood Banking, and the Bonds of Community*, DAEDALUS, Summer 1989, at 145, 154-55 (noting blood bankers' concerns regarding the safety of directed donation).

risk behaviors when approached by friends or relatives requesting a directed donation.³⁴⁵ Survey data support this concern, reporting that twenty-two percent of directed donors would consider altering their responses to questions concerning their health in order to make a directed donation.³⁴⁶ Under these conditions, the voluntary nature of directed donation may be compromised, yielding a potentially heightened risk of HIV contamination.³⁴⁷

Proponents of directed blood donations suggest an alternative hypothesis—that directed donations should be safer than the blood supply at large. This hypothesis reasons that donors who know their recipients and agree to direct blood to them will be more concerned about the recipients' safety than donors who give blood to anonymous donees.³⁴⁸ Under such reasoning, individuals who know their blood is high-risk will be less likely to donate to those they know and care about than to those they do not know.³⁴⁹

Other supporters of directed donation have suggested that the pressure to provide blood without disclosing high-risk behavioral history can be greater in anonymous donation settings than in the more personal process of soliciting a directed donation.³⁵⁰ One commentator, for example, describes employer blood drives in which "Blood Captains" are designated to encourage employee donations.³⁵¹ As employees frequently move en masse to donate blood, the expectation that a high-risk donor will divulge his or her unsuitability to donate may be very unrealistic.³⁵² These observations suggest that disturbing pressures to lie may exist in regard to both directed and anonymous donation.³⁵³

Concern that directed donors feel pressured to hide high-risk histories is exacerbated by negative cost factors. Directed donations require the same individual processing as autologous blood donations and are subject to the same degree of waste. The relatively high costs of autologous blood

345. Sapolsky, *supra* note 344, at 155.

346. See B. Newman, Abstract A86, *Directed Donations—A Look at Various Issues*, 27 TRANSFUSION 574, 574 (1987).

347. For a very brief discussion of the idea that directed donations are not truly voluntary, see D.R. Parsons & D.T. Miller, Abstract A90, *A Proposal to Classify Directed Donors as Non-Voluntary*, 27 TRANSFUSION 575 (1987).

348. Roberts & Wolkoff, *supra* note 167, at 175.

349. *Id.*

350. See Sapolsky, *supra* note 344, at 154-55.

351. Linda J. Anderson, *The AIDS Crisis and Directed Donations*, 37 MED. TRIAL TECH. Q. 451, 463 (1991 Annual).

352. *Cf. id.*

353. *Id.*

donations are therefore associated with directed donations as well. Because directed donations are subject to both risk factors and cost factors, their net social desirability is lower than that of autologous transfusion. Accordingly, while directed donations should be permitted in the interests of individual free choice, they should not be supported or encouraged by legal or regulatory inducements.

An alternative to both autologous transfusion and directed donations is the adoption of so-called "bloodless" surgery techniques. Bloodless surgery is a transfusion-free procedure originally developed in response to the objections of Jehovah's Witnesses to blood transfusion.³⁵⁴ The process entails recycling a patient's own blood during an operation through the use of a machine called a "cell saver."³⁵⁵

While it is more suitable for some forms of surgery than for others,³⁵⁶ bloodless surgery is quickly gaining support within the medical community. In early 1996, for example, the Good Samaritan Hospital in Los Angeles adopted a surgical program featuring bloodless surgery to eliminate opportunities for the transmission of HIV.³⁵⁷ Similar programs have been developed recently by hospitals in Ohio,³⁵⁸ Nevada,³⁵⁹ New Jersey,³⁶⁰ New York,³⁶¹ and Florida.³⁶² As of late 1995, approximately fifty blood centers around the country offered some form of bloodless surgery.³⁶³

According to the coordinator of the Good Samaritan hospital's surgical program, bloodless surgery not only averts infection opportunities, but also

354. *Doctors Meet on Bloodless Surgery*, UPI, Oct. 6, 1995, available in LEXIS, News Library, Curnws File.

355. See Marty Munson, *Bloodless Surgery*, PREVENTION, Jan. 1996, at 48.

356. The recycling of blood is not suitable for cancer surgery or bowel surgery because the patient's blood may contain tumor cells or bacteria. Geoffrey Cowley et al., *In Search of Safer Blood*, NEWSWEEK, Aug. 10, 1992, at 44, 44. The process is more suitable for orthopedic and cardiovascular surgery. See *id.*

357. "Bloodless" Surgery Going Mainstream at L.A. Hospital, MOD. HEALTH CARE, Jan. 29, 1996, at 52.

358. Joan Whitely, *Options Cut Blood Loss in Surgery*, LAS VEGAS REV.-J., Jan. 16, 1996, at 1E (noting the bloodless surgery program at St. Vincent Charity Hospital in Cleveland, Ohio), available in 1996 WL 2333213.

359. *Id.*

360. Bob Groves, *Bloodless Surgery Gaining Wider Use: Englewood Hospital to Offer Option*, RECORD (N.N.J.), Sept. 19, 1994, available in 1994 WL 7770790.

361. Randi Glatzer, *Science Meets Religion: Doctor Tailors Treatment for Jehovah's Witnesses by Performing Surgery Without Transfusions*, NEWSDAY, Feb. 20, 1994, available in 1994 WL 7425073.

362. Sandra Jacobs, "Bloodless Surgery" Steps up to the Operating Table, MIAMI HERALD, Feb. 22, 1995, at 1E, available in Westlaw, MIA-HRLD Database.

363. See Whitely, *supra* note 358; *Doctors Meet on Bloodless Surgery*, *supra* note 354.

hastens patient recovery and reduces medical costs.³⁶⁴ These observations suggest that bloodless surgery is an inexpensive, effective way to avert contamination by reducing reliance on blood transfusions. Public financial support for the implementation of cost-efficient bloodless surgery programs compares favorably with more expensive and dubiously effective policies, such as the financing of autologous blood donation programs.

V. CONCLUSION

This Article has examined rule-based methods of promoting the safety of blood supplies in the form of laws, regulations, and public policies. All the observations and recommendations in the preceding section incorporate the fundamental economic axiom that decisions bear opportunity costs.³⁶⁵ For some policies, the high costs of saving incremental life-years cannot be justified, given the alternative social benefits of more efficient, effective employment of funds.

Given these assumptions, the discussion in Section IV yields several recommendations and observations. In general, the federal government is justified in requiring testing of donated blood and the rejection of HIV-contaminated donations. The present method—ELISA with Western Blot confirmation—is a highly effective screening process, the cost of which is far exceeded by its benefits. Conversely, supplemental antigen testing, soon to be mandated by the FDA, is exorbitantly expensive. This requirement cannot be justified under any reasonable cost-benefit analysis and should be abolished.

When a blood donation tests positive, the donor should be informed of his or her exposure to HIV. This policy requires the implementation of reliable safeguards that ensure confidentiality and prohibit discrimination against persons infected with HIV. Convenient and affordable testing sites must be provided to discourage the use of blood collection centers to learn one's serostatus.

Because evidence suggests that sold blood is significantly more likely to be contaminated than donated blood, the sale of blood should be strictly prohibited. Should this measure precipitate severe blood shortages in some locations, officials must investigate methods to increase the blood supply

364. See "Bloodless" Surgery Going Mainstream in L.A. Hospital, *supra* note 357.

365. For further explanation and discussion of the inevitability of opportunity costs in decisionmaking, see E.V. BOWDEN, *ECONOMICS: THE SCIENCE OF COMMON SENSE* 32 (5th abr. ed. 1986).

other than payment for blood. Such methods might include increasing budgets for the promotion of gratuitous donations and marketing altruistic reasons for giving blood. The question of cash payments for blood may need revisiting should future technological and procedural improvements in blood testing eliminate the possibility of contaminated blood entering the blood supply.

Predonation questioning and exclusion procedures are effective tools that can help to minimize the entry of contaminated blood into public supplies. Behavioral classifications that are associated with known means of HIV transmission are more effective categories for exclusion than status-based classifications, which incorporate the error that is inevitably associated with all forms of stereotyping. The greater the error, the more good blood is needlessly discarded, potentially resulting in blood supply shortages. Moreover, as HIV and AIDS spread throughout the population, status-based exclusions, such as the exclusion of gay men, become increasingly irrational. More useful behavior-linked classifications must continually be reassessed, as the means of HIV transmission and our knowledge of those means continue to evolve. Finally, federal and state agencies should consider encouraging or mandating the use of computerized questionnaire methods to maximize privacy and minimize respondent misrepresentations.

The regulations that govern and monitor information transmission, operating procedures, and the maintenance of blood supplies play an important role in blood supply safety. Labeling requirements mandating uniformity in the development and handling of blood labels discourage errors in interpretation by providing consistent information across states and regions. As computerization becomes increasingly prevalent, the FDA should consider promulgating regulations mandating blood collection centers and blood banks to adopt a uniform computerized coding system. A uniform system can prevent mix-ups and increase consistency in the designation and interpretation of labels.

Federal preemption of state regulation of blood centers' operating procedures and monitoring mechanisms is long overdue. Given the nationalization of the market for blood, public health would be served best by one set of carefully considered rules and standards applied consistently to all aspects of U.S. blood regulation.

The development and maintenance of blood registries play an important role in locating recipients of blood that is identified after transfusion as potentially contaminated. The ability to identify persons who may have received tainted blood bears a number of benefits: it allows those infected to

seek treatment; it enables officials to notify those infected not to donate blood; and it ensures the public that the blood industry is committed to acting responsibly and accountably at all stages of blood collection and distribution. While registered donor information is subject to abuse, such as discrimination and breach of privacy, lawmakers and administrators can implement both regulatory and procedural safeguards to protect donors while preserving vital sources of information.

Finally, three alternatives to the transfusion of blood from anonymous donors have some potential to reduce the risk of HIV transmission—these are autologous transfusion, directed donation, and bloodless surgery. Although an autologous transfusion can reduce a patient's chances of contracting AIDS, most studies indicate that the social cost of the procedure exceeds its social benefits. Accordingly, while autologous transfusion should remain an option for patients, it should not be encouraged as a policy through the development of subsidies or other incentives. Because directed donation shares the cost disadvantages of autologous transfusion and may also encourage donors to lie about high-risk behaviors, public policy should likewise permit but not encourage the practice. A more promising alternative to transfusions from the public blood supply is bloodless surgery, a procedure that confers many benefits while exacting few costs. Tax incentives, subsidies, or other governmental dispensations encouraging hospitals to develop bloodless surgery programs can hasten patient recovery and reduce HIV transmissions and medical expenditures.

The foregoing analysis has addressed exclusively those strategies for reducing the incidence of transfusion-based HIV infection that are widely considered by lawmakers and policymakers to be promising in the immediate future. The list of possibilities is ever changing, and innovative or controversial technologies require an ongoing assessment of continually emerging policy candidates and their impact on the portfolio of techniques that protect the public blood supply.³⁶⁶

366. Controversy exists, for instance, regarding the process of solvent-detergent treatment of frozen plasma, adopted in some European countries to reduce the risk of transmitting HIV and other viruses. AuBuchon & Birkmeyer, *supra* note 118, at 1210. The costs and benefits of this treatment have been called into question by researchers in the United States. *See id.* at 1212-13.