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Taunya Lovell Banks

Roger R. McFadden

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RUSH TO JUDGMENT: HIV TEST RELIABILITY AND SCREENING

Taunya Lovell Banks*
and Roger R. McFadden**

I. INTRODUCTION

Acquired Immune Deficiency Syndrome (AIDS) has elicited more public hysteria, misinformation, and moral approbation than any other modern disease.¹ There is little public sympathy for persons with AIDS because the groups currently at highest risk (homosexual and bisexual males, intravenous drug users, and prostitutes)² are already socially stig-

* Professor of Law, University of Tulsa; B.A., 1965, Syracuse; J.D., 1968, Howard.

** Pathologist, Okmulgee Memorial Hospital Authority; B.A., 1966, Fort Hays State College; M.D., 1970, University of Kansas; Candidate for J.D., 1988, University of Tulsa. The authors would like to thank Professor Arthur S. Leonard and Attorney David L. Wing for their comments on an earlier version of this article. However, the views expressed herein are solely those of the authors.

1. *AIDS Hysteria Counterproductive*, AM. MED. NEWS, Jan. 17, 1986, at 4 (reprinting article by John F. Fennessey, M.D. from the *Detroit Medical News* which recounts that public hysteria from leprosy and other dread diseases is being repeated today regarding the AIDS epidemic). *See also AIDS Crises Especially Difficult for Religious Community*, Tulsa World, June 15, 1986 at B3, col. 1 (citing comments by Rev. Charles Stanley of the Southern Baptist Convention in which he said "...AIDS is God indicating his displeasure and his attitude toward that form of life style [homosexuality], which we in this country are about to accept."). *Ending Discrimination Against AIDS Patients*, AM. MED. NEWS, Nov. 21, 1986, at 4.

2. *Update: Acquired Immunodeficiency Syndrome—United States*, 257 J. A.M.A. 433 (1987). Sixty-six percent of all reported cases are homosexual or bisexual men who are not known intravenous (hereinafter IV) drug users; 17% were heterosexual IV drug users; and 8% were homosexual or bisexual men who have histories of IV drug use. Of the persons with AIDS not fitting within the aforementioned groups, 32% of those interviewed (59% of all the cases) have histories of gonorrhea

matized and viewed as engaging in illegal activity.³ Policy decisions regarding AIDS are apt to be colored by the underlying social disaffection with those groups, most of whom already are victims of discrimination.⁴

It is believed that AIDS is caused by the Human Immunodeficiency Virus (HIV).⁵ HIV is transmitted by transfusion of blood or blood products, sharing contaminated needles, or intimate sexual contact.⁶ The venereal connotation poses an additional burden in achieving a rational approach to the disease. Because of the likelihood of discrimination against those persons infected with the virus and those persons in high risk groups, the courts, the traditional buffer and only recourse from the temporary excesses of society, will be forced to take a more active role in this area.

As the number of AIDS cases increases, governments are beginning to consider more invasive action. For example, in February, 1987, the Centers for Disease Control (CDC) announced that it was considering a recommendation that the HIV antibody enzyme-linked immunosorbent

and/or syphilis, and 27% gave histories of sexual contact with female prostitutes. *Id.* Heterosexual transmission represents 4% of all cases (2% of males and 27% of females). *Id.*

3. See *Bowers v. Hardwick*, 106 S. Ct. 2841 (1986) (upholding GA. CODE ANN. § 16-6-6 (1984) which provides that consensual homosexual sodomy is illegal). Twenty-four states and the District of Columbia have laws prohibiting sodomy. *Id.* at 2845 (citing *Survey on the Constitutional Right to Privacy in the Context of Homosexual Activity*, 40 U. MIAMI L. REV. 521, 524 (1986)). For statutes discussing prostitution, see OKLA. STAT. tit. 21 § 1029 (1981); CAL. PENAL CODE § 647 (West Supp. 1986); White Slave Traffic Act, 18 U.S.C. §§ 2421-2424 (1982). See also *Cherry v. State*, 18 Md. App. 252, 306 A.2d 634, 677 (1973) (solicitation is an act and not speech protected by the First Amendment). See generally 63A AM. JUR. 2D *Prostitution* §§ 1-44 (1984). For statutes concerning drug abuse see OKLA. STAT. tit. 63 § 2-404 (1981); CAL. HEALTH & SAFETY CODE § 11350 et seq. (West Supp. 1987). See generally 25 AM. JUR. 2D *Drugs, Narcotics and Poisons* § 21, 37, 40-48 (1966).

4. "Fears concerning non-sexual transmission [of AIDS] have led not just to the isolation and rejection of AIDS patients but to renewed attacks on homosexuality as well. A psychologist testifying before the Texas legislature, argued for a bill to incarcerate homosexuals 'until and unless they can be cleansed of their medical problems.'" A. BRANDT, NO MAGIC BULLET 183 (1985).

5. Acquired Immunodeficiency Syndrome (AIDS) is a specific clinical syndrome consisting of immunodeficiency, and opportunistic infections or malignancy associated with the HTLV-III/LAV virus. The human T-lymphotropic virus type III (HTLV-III) or lymphadenopathy-associated virus (LAV) are apparently identical and cause a spectrum of disease. At one end is clinically overt AIDS which appears to be almost uniformly fatal. At the other end of the spectrum are seropositive individuals who are asymptomatic and are assumed to be infected with the HTLV-III/LAV virus. The AIDS Related Complex (ARC) is a form of disease with overt clinical manifestations (lymphadenopathy, fever, wasting, diarrhea, etc.) which are less severe than overt AIDS. See Slater, Kirk, & Fine, *Acquired Immunodeficiency Syndrome: Review of Clinical Aspects*, 79 J. OKLA. ST. MED. ASS'N 17, 17-19 (Jan. 1986). But see *Researchers Propose Alternative Viral Causes of AIDS*, 1 AIDS ALERT 73-76 (1986) (noting that some scientists question whether HTLV-III virus is the causative agent, and others suggest swine flu virus as a causative agent). Human immunodeficiency virus (HIV) is an alternative nomenclature for the virus.

6. *The Acquired Immunodeficiency Syndrome: Commentary, AIDS, FROM THE BEGINNING*, 392, 396 (H. Cole & G. Lundberg ed. 1986).

assay (ELISA) test be administered to all patients routinely admitted to hospitals, to couples applying for marriage licenses, and to pregnant women.⁷ This recommendation represented a dramatic departure from previous CDC recommendations which focused on mandatory screening of blood donors and voluntary screening of persons in high risk groups.⁸ Mere consideration of this recommendation stirred controversy and thus it was not adopted.⁹ A few weeks earlier, CDC disclosed that it had initiated anonymous blood testing in five undisclosed hospitals.¹⁰ The purpose of this testing was to better assess the prevalence of HIV infection in the general population.¹¹ Even this decision was hotly contested both inside and outside the CDC.¹²

Recently, President Reagan urged wide-spread "routine testing" of marriage license applicants, federal prisoners, patients at venereal disease and drug abuse clinics, entering immigrants and aliens, and patients in veterans' hospitals.¹³ A few days later, several large insurance companies announced their intention to severely limit the availability of life insurance coverage to anyone who refuses to be screened for the HIV infection.¹⁴

As HIV infection becomes more prevalent in the heterosexual population, there is increasing pressure on public health officials to take more stringent action to stem the spread of the virus. Many claim that the

7. Boffey, *Local Experts Doubt Value of Wide AIDS Testing*, N.Y. Times, Feb. 23, 1987, at 12Y, col. 1 (nat'l ed.).

8. *Id.*

9. Altman, *Mandatory Tests for AIDS Opposed At Health Parley*, N.Y. Times, Feb. 25, 1987, at A1, col. 4.

10. *CDC to Proceed with Anonymous AIDS Testing*, AM. MED. NEWS, Jan. 23/30, 1987, at 30.

11. *Id.*

12. *Id.* Ethical concerns arise when unidentified blood samples are used resulting in the inability to inform patients who tested positive. Additional problems arise in testing identified blood samples without advance permission from the patients.

13. *Reagan Urges Wide AIDS Testing But Does Not Call For Compulsion*, N.Y. Times, June 1, 1987 at 1, col. 2. The article noted that on May 31, President Reagan called for mandatory testing of immigrants and federal prisoners, and also called for "routine" testing of marriage license applicants, and people seeking treatment for drug abuse and sexually transmitted diseases. In April, Education Secretary William Bennett called for mandatory testing for hospital patients, immigrants, marriage license applicants, and prisoners. Davidson, *Secretary Bennett Advocates Making AIDS Tests Mandatory for Some People*, Wall St. J., May 1, 1987, at 5, col. 1. In June, Attorney General Edwin Meese suggested that prisoners with positive test results might be detained and denied parole. *Reagan Officials To Extend Reach of AIDS Testing*, N.Y. Times, June 14, 1987, at E4, col. 1. Secretary Bennett also approved of this possibility. *Bennett Would Detain Some Carriers of AIDS*, N.Y. Times, June 15, 1987, at Y14, col. 1 (nat'l ed.). Senator Jesse Helms added that "we are going to have to quarantine if we are really going to contain this disease." Otte, *Debate Rages Over AIDS-Test Policy: Opponents Cite Privacy Costs, Testing Errors*, Wall St. J., June 18, 1987, at 29, col. 5.

14. Sullivan, *Insurers To Limit Policies Of Buyers Refusing AIDS Test*, N.Y. Times, June 5, 1987, at 11, col. 4.

only way to determine the extent of the epidemic and to stop the spread of the virus is to identify all persons who are infected with HIV.¹⁵ To date, the only means available to determine who has been exposed to or infected with HIV is through one of a variety of blood tests.¹⁶

Since the vast majority of persons presumed to be infected with HIV are asymptomatic, the test or tests used to define this population becomes critical. The reliability of current HIV antibody tests must be examined because being labeled "seropositive" may result in social stigma and adverse economic sequelae. The issue of test reliability is a scientific determination. However, whether a scientific test is sufficiently reliable to use as a basis for restricting individual liberty is a legal matter. The current HIV antibody tests, while sufficiently reliable for donor screening, are scientifically insufficient for other purposes. Current efforts by governments to institute mass screening of targeted groups for nondonor purposes raise serious legal issues.

II. THE CURRENT HIV ANTIBODY TESTS

As defined by the Centers for Disease Control, AIDS is a specific syndrome.¹⁷ As of June 29, 1987, 37,867 AIDS cases had been reported nationwide.¹⁸ The AIDS virus has caused an estimated 50,000 to 100,000 cases of AIDS Related Complex (ARC), which is an intermediate form of the disease.¹⁹ By far, the largest group of persons thought to be infected with the virus are totally free of signs or symptoms of disease. This group is detected only by serological (blood) testing and is termed antibody positive or "seropositive."²⁰ An estimated one to five million Americans are thought to fall in this latter category.²¹ Thus, HIV infec-

15. *Widespread Test for AIDS Virus Favored by Most*, Gallup Reports, N.Y. Times, July 13, 1987, at Y11, col. 5 (nat'l ed.). See also *Wider AIDS Virus Testing Urged*, AM. MED. NEWS, March 13, 1987, at 1, 10; Wilentz, *Putting AIDS to the Test*, TIME, March 2, 1987, at 60.

16. Gostin & Curran, *AIDS Screening, Confidentiality, and the Duty To Warn*, 77 AM. J. PUB. HEALTH 361 (1987).

17. The Center for Disease Control defines AIDS as "a reliably diagnosed disease that is at least moderately indicative of an underlying cellular immunodeficiency in a person who has had no known underlying cause of cellular immunodeficiency nor any other cause of reduced resistance reported to be associated with that disease." *Acquired Immune Deficiency Syndrome (AIDS) Update—United States*, 250 J. A.M.A. 335 (1983).

18. OKLA. ST. HEALTH DEPT.: AIDS MONTHLY SURVEILLANCE REPORT (June 30, 1987).

19. Clark, *AIDS*, NEWSWEEK, August 12, 1985, at 24. See also *supra* note 5.

20. "Serologically positive: showing positive results on serological examination; showing a high level of antibody." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1192 (26th ed. 1974).

21. *Nation's Hospitals Awaken to Increasing AIDS Caseload*, 1 AIDS ALERT 117 (1986). See also *AIDS*, *supra* note 19, at 23 (estimating up to one million); *Fighting AIDS: Congress Looks for a Way to Help*, 45 CONG. Q. WEEKLY REP. 263 (1983) (estimating 1-2 million). But see Barry, Cleary & Fineberg, *Screening for HIV Infection: Risks, Benefits, and the Burden of Proof*, 14 LAW, MED. &

tion is responsible for a spectrum of disease ranging from full-blown clinical AIDS to a totally asymptomatic seropositive condition.

A. Determining Test Reliability

The evaluation and analysis of a laboratory test is a complex matter. However, this article will only address the reliability of the HIV (ELISA) test as a basis for diagnosis and the imposition of restrictive or prejudicial actions.

Two types of tests screen for infectious diseases: those that test directly for the etiological (causative) agent, and those that test indirectly for the effects of the disease. Because an indirect test merely infers the presence of disease, it is usually less meaningful and less specific than a direct test. Unfortunately, direct tests are either commercially unavailable, too expensive, or too complex to be of practicable routine use for many disease states.

The HIV antibody test is an indirect test.²² The etiological agent is HIV, which acts as an antigen and causes the host to produce antibodies to the virus.²³ The current HIV antibody tests detect this antibody. A person who tests positive is *presumed* to be infected with the virus.²⁴ It is further *presumed* that a person who tests positive is also capable of transmitting the virus to others.²⁵

Typically, the evaluation of a new laboratory test involves testing both a large population of people known to have the disease sought and a large population known to be disease free.²⁶ From these results, the sen-

HEALTH CARE 259 (1986) [hereinafter *Screening for HIV Infection*] (estimating 500,000 to 1,750,000); Morganthau, *Future Shock*, NEWSWEEK, Nov. 24, 1986, at 30 (estimating five million).

22. "There is still no *direct* simple immunologic test for the virus [HTLV-III virus]". . . .

. . . .

. . . "[ELISA tests] are tests for antibody to the virus, *not* tests for the virus or AIDS." 7 LAB REP. FOR PHYSICIANS, June, 1985, at 42, 43 (emphasis added); *Screening for HIV Infection*, *supra* note 21, at 260.

23. "There is still no direct simple immunologic test for the virus or its component antigens, but such tests are under development. Currently, it is possible to detect the presence of serum antibodies to several antigenic components of HTLV-III/LAV." LAB REP. FOR PHYSICIANS, *supra* note 22, at 41-43.

24. *Id.* "A positive test . . . could be due to subclinical infection, immunity, or cross-reactivity [or] false positive results due to laboratory error. . . . The Western blot test . . . may also vary from one lab to another. . . ." *Screening For AIDS*, 27 THE MEDICAL LETTER ON DRUGS AND THERAPEUTICS, March 29, 1985, at 29 [hereinafter THE MEDICAL LETTER]. See also Abbott Laboratories, *Human T-Lymphotropic Virus Type III, Abbott HTLV-III E.I.A.*, 11 (1985) [hereinafter *Abbott*] (instructing labs how to do an AIDS antibody test). "The implications of antibody to HTLV-III in an asymptomatic person are *not* known." *Id.* at 1 (emphasis added).

25. For a general discussion of the ELISA test, see *Screening for HIV Infection*, *supra* note 21, at 261. See also *infra* notes 32 and 35.

26. R. GALEN & S. GAMBINO, BEYOND NORMALITY: THE PREDICTIVE VALUE AND EFFI-

sitivity²⁷ and specificity²⁸ of the test can be calculated. The predictive value²⁹ of the test can be derived by using the prevalence³⁰ of the disease, the number of true positives (TP), true negatives (TN), false positives (FP), and false negatives (FN).³¹

The above process was not used in evaluating the HIV antibody tests. Since there are no signs or symptoms of the disease in asymptomatic seropositive persons, the test is used to define who has the disease. Persons who test positively are *presumed* to be infected and capable of transmitting the disease.³² Further, people who test negative are *presumed* to not have the virus.³³ Using such circular logic, the test defines itself. Any parameters derived from such an evaluation would seem to be open to serious question.³⁴

Using an indirect test to define its own parameters raises several unanswered questions: (1) Are all persons who test HIV antibody positive actually infected with the virus?³⁵; (2) Are all of these persons potentially

CIENCY OF MEDICAL DIAGNOSES 6 (1975) [hereinafter GALEN & GAMBINO]. "In order to obtain meaningful referent values for disease it is necessary to study and define meaningful reference populations, which should include: (1) Subjects who are free of any known disease. (2) Subjects who are free of the disease in question, *but who have other diseases*. (3) Subjects with the disease in question." *Id.* (emphasis in original).

27. Sensitivity is the "probability that a test or procedure result will be positive when the disease is present." Griner, Mayewski, Mushlin & Greenland, *Selection and Interpretation of Diagnostic Tests and Procedures*, 94 ANNALS OF INTERNAL MED. 553 (1981) [hereinafter Griner].

28. Specificity is the "probability that the test or procedure result will be negative when the disease is not present." *Id.* at 557. For example, a test with 95% sensitivity, when used on 100 people with the disease sought, will give 95 positive results (true positives), and 5 negative results (false negatives). Sensitivity does not apply to people free of the disease.

29. *See infra* note 41.

30. "The prevalence rate for a disease equals the number of patients per 100,000 population who have the disease at the time of the study." GALEN & GAMBINO, *supra* note 26, at 11. Prevalence is sometimes expressed as a percentage. For example, if there are 10 persons with the disease per 100,000 population, this can be expressed as 10/100,000 or as 0.01%. *See also infra* note 44.

31. *See infra* note 41.

32. "Much confusion reigns regarding the sensitivity and specificity of ELISA tests [for AIDS]. In fact, the situation could be characterized as 'out of hand'. . . all AIDS patients should be *assumed* to be positive for the antibody and all healthy blood donors should be *assumed* to be negative. . ." 7 LAB REP. FOR PHYSICIANS, June 1985, at 42 (emphasis added). *See also* THE MEDICAL LETTER, *supra* note 24, at 30 (noting that, "all seropositive patients must be considered potentially infective for an indefinite period."); Wilentz, *Putting AIDS to the Test*, TIME, March 2, 1987, at 60 (noting that, "[s]cientists assume . . . that those who test positive are still carrying the virus and can transmit it.") (emphasis added).

33. Wilentz, *supra* note 32.

34. "At the moment there is no standard reference antiserum ("gold standard") against which all test antisera may be measured. Therefore, the sensitivity and specificity of the ELISA test have been defined operationally." *Status Report on the Acquired Immunodeficiency Syndrome*, 254 J. A.M.A. 1342 (1985).

35. 7 LAB REP. FOR PHYSICIANS, *supra* note 22, at 42. *See also* S. Weiss, J. Goedert, M. Sarngadharan, A. Bodner, R. Gallo & W. Blattner, *Screening Test for HTLV-III (AIDS Agent) Antibodies*, 253 J. A.M.A. 225 (1985) ("the presence of HTLV-III antibodies does not necessarily

infectious?; (3) Are there other antibodies or substances in the blood that can cause a false positive test?³⁶ and, finally, (4) Do all persons who are infected test positive?³⁷

When viewed in the light of some of the proposed legislative uses for the antibody test, these questions pose serious legal and medical issues. If a significant proportion of HIV antibody positive persons are neither infected nor capable of transmitting the disease, then subjecting these persons to prejudicial sequelae would be a matter of serious concern. Likewise, if there are significant numbers of infected persons who are capable of transmitting the virus, but who test negative for the antibody, then a large population of undetected carriers would escape the restrictive measures and defeat the purpose of any proposal.³⁸

A final consideration in evaluating a test is the purpose for which it is to be used. Obviously, test results used as a basis for instituting therapeutic, prophylactic, or restrictive measures, which would be potentially harmful or prejudicial³⁹ to the person testing positive, must be more reliable than test results used solely to screen for a disease, without serious sequelae. In this context, it should be noted that the HIV (ELISA) antibody tests were specifically designed and licensed to be screening tests, rather than diagnostic tests, for blood and blood products.⁴⁰

B. Predictive Value Of The Current "AIDS" Tests

The predictive value of a test is defined by three parameters: sensi-

indicate active infection, as it is possible that some of the HTLV-III antibody specificities measured by this ELISA could have neutralizing or protective effects." *Id.* at 225. See also J. Ward, A. Grindon, P. Feorino, C. Schable, M. Parvin & J. Allen, *Laboratory and Epidemiologic Evaluation of an Enzyme Immunoassay for Antibodies to HTLV-III*, 256 J. A.M.A. 359 (1986) (reporting 63.9% virus culture positivity of Western Blot positive specimens).

36. See *False Positive Tests for HTLV-III Antibodies in Alcoholic Patients with Hepatitis*, 314 NEW ENG. J. MED. 921-22 (1986) (noting in letters to editor that there were 13% false positive ELISA results in this group).

37. *HTLV-III Virus Reportedly Spread By 'Negative' Blood*, AM. MED. NEWS, July 11, 1986, at 12 (transmission of virus from a 'negative' blood donor).

38. "Tests designed to screen blood for antibodies to the HTLV-III virus believed to cause AIDS vary in their ability to detect exposure to the infection in its very early stages, say researchers at the National Institutes of Health." *Some HTLV-III Tests Found Inaccurate*, AM. MED. NEWS, July 11, 1986, at 7.

39. See *infra* notes 124-31 and accompanying text.

40. Petricciani, *Licensed Tests for Antibody to Human T-Lymphotropic Virus Type III*, 103 ANNALS OF INTERNAL MED. 726, 726 (1985) "The recent licensing of commercial tests to detect antibodies to . . . HTLV-III marked the beginning of . . . efforts by government and the medical community to increase the safety of the blood and blood products in the United States." *Id.* See also Abbott, *supra* note 24. "It is inappropriate to use this test as a screen for AIDS or as a screen for members of groups at increased risk of AIDS in the general population. The presence of HTLV-III antibody is NOT a diagnosis of AIDS." *Id.* at 11 (emphasis in original).

tivity, specificity, and prevalence. The role of predictive value is to measure how accurately either a negative test value predicts the absence of disease, or a positive test value predicts the presence of disease.⁴¹ Positive predictive value is determined by dividing the number of true positives by the sum of the true positives and the false positives and multiplying by 100 to give a percentage ($TP/TP+FP \times 100=P$).⁴² A predictive value of 50% is the value expected from a random coin toss; half of the results will be correct, half will not.

Using the formula, the following hypothetical explains how the predictive value correlates to false positive and false negative test results. Assuming, *arguendo*, that there are 1,000,000 HIV virus-infected persons in a population of 200,000,000 (prevalence of 0.5%) and that the HIV (ELISA) antibody test is 98.3% sensitive and 99.8% specific, the following results would be obtained:

True Positives	983,000
False Positives	398,000
True Negatives	198,602,000
False Negatives	17,000
POSITIVE PREDICTIVE VALUE	71%

Thus, approximately 400,000 persons would be falsely labeled as "positive." One-fourth of all positive results would be false positives. Seventeen thousand (17,000) infected individuals would be undetected.

If the same assumptions are made in using the higher estimate of 3,000,000 infected persons (prevalence of 1.5%) with the same sensitivity and specificity of the test, the results would be:

True Positives	2,949,000
False Positives	394,000
True Negatives	196,606,000
False Negatives	51,000
POSITIVE PREDICTIVE VALUE	88%

The above results indicate how significantly the increased prevalence af-

41. Positive predictive value = true positives divided by the sum of the true positives + false positives ($TP/TP + FP = PV$). Griner, *supra* note 27, at 567. See also GALEN & GAMBINO, *supra* note 26, at 172, 177 (noting the effect of prevalence on predictive value. A test with 99% sensitivity and specificity at a prevalence of 0.1% has a positive predictive value of only 9% (i.e., for every 100 positive tests, only 9 would be true positives). But at a prevalence of 5%, of the same sensitivity and specificity with the same test, the positive predictive value is 83.9% (i.e., 16.1% of the positive results would be false positives)).

42. *Id.*

fects the predictive value.⁴³ There would still be the same number of persons falsely labeled as "positive," but now these represent 12% of all positives. The number of undetected infected persons rises to 51,000 (false negatives).

Finally, new antibody tests have been introduced which claim a sensitivity of 100% and a specificity of 99.8%.⁴⁴ Using the aforementioned assumptions, the results would be:

FOR A PREVALENCE OF 0.5%:

True Positives	1,000,000
False Positives	398,000
True Negatives	198,602,000
False Negatives	0
POSITIVE PREDICTIVE VALUE	72%

FOR A PREVALENCE OF 1.5%:

True Positives	3,000,000
False Positives	394,000
True Negatives	196,606,000
False Negatives	0
POSITIVE PREDICTIVE VALUE	88%

As demonstrated above, the new test would not decrease the number of persons who would be falsely labeled "positive." It does, however, eliminate any false negatives. The predictive values remain essentially unchanged.

Most testing for HIV antibody does not result in a diagnosis of "positive" without repeat testing.⁴⁵ The confirming tests usually consist of a repeat ELISA test which if again positive, is confirmed by the Western Blot test.⁴⁶ This additional testing should reduce the number of false

43. *Screening for HTLV-III Antibodies: The Relationship between Prevalence and Positive Predictive Value and its Social Consequences*, 253 J. A.M.A. 3395 (1985) (noting in letters to editor that where the ELISA cut-off level is set can drastically affect the results). A cut off at 3 results in 9,250 false positives for every true positive. A cut off at 6 results in 1,390 false positives for every true positive. A cut off at 12 results in no false positives, but would miss over 75% of the true positives. *Id.* at 3395. See also *Screening for HIV Infection*, *supra* note 21, at 262-63.

44. *Recombinant DNA May Provide Second Generation AIDS Test*, CLINICAL CHEM. NEWS, April, 1986, at 1 (predicting sensitivity of 96-100% and specificity of 99.8%). See generally Meyer & Pauker, *Screening for HIV: Can We Afford The False Positive Rate?*, 317 NEW ENG. J. MED. 238 (1987).

45. *But c.f. Update: Acquired Immunodeficiency Syndrome—Europe*, 255 J. A.M.A. 717, 719, 725 (1986) (noting follow-up practices on positive ELISA tests in 21 European countries). Portugal uses no follow-up tests. *Id.* Six others recommend follow-up, and the other nine required it. *Id.*

46. "The Western Blot is the most commonly used confirmatory method for detecting HIV antibody." Levinson & Denys, *AIDS Methods*, CLINICAL CHEM. NEWS, Dec., 1986, at 8. The

positives.⁴⁷ However, because the Western Blot test is also an indirect test to detect the antibody (not the virus), it is conceivable that there may be cross-reacting substances that give false positive results in both tests.⁴⁸

Certainly there are documented cases of false positive Western Blot tests.⁴⁹ Further, some authorities question the reliability of the Western Blot test, which is not licensed by the Food and Drug Administration.⁵⁰ In sum, despite medical claims about reliability, the current tests do not seem to be adequate bases on which to make decisions which restrict the legal rights of individuals.⁵¹ The current antibody test, if used for screen-

Western Blot, like the ELISA, tests for the HIV-specific antibodies produced by an infected person's immune system. *The Impact of Routine HTLV-III Antibody Testing of Blood and Plasma Donors on Public Health*, 256 J. A.M.A. 1778, 1779 (1986). See also *Another AIDS Virus, an Alternative Test*, 52 AM. SOC'Y FOR MICROBIOLOGY NEWS 283 (1986) (discussing current AIDS tests and quoting James Allen from The Centers for Disease Control that "the 'ideal' confirmatory test for the disease is yet to be developed and licensed.").

47. The additional testing would seem to have no effect on false negatives since these would not be retested. *Dementia Associated with Human Immuno-Deficiency Virus with a Negative ELISA*, 315 NEW ENG. J. MED. 891 (1986).

48. See *HTLV-III Seropositivity in 1971-72 Parenteral Drug Abusers—A Case of False Positives or Evidence of Viral Exposure?*, 314 J. A.M.A. 1387 (1986) (noting in letters to editor that "it appears possible that parenteral drug abusers may have been exposed. . . as early as 1971. An alternative and equally viable explanation is that the HTLV-III seropositivity . . . represents false positive or non-specific reactions. . . [a] false positive Western blot result has recently been reported. . ."). *Id.* at 1387. More recently, several physicians from Montreal, after retesting a 55-year-old asymptomatic woman who tested positive for HIV on both ELISA and Western Blot tests, found that she was not seropositive. The physicians cautioned that ". . . blood banks [should] use both HIV-infected and noninfected cell lines when confirming seropositivity by the Western Blot test and that the presence of bands on such tests not be automatically considered to indicate positive status." *Need for Caution In Interpretation of Western Blot Tests for HIV*, 257 J. A.M.A. 1047 (1987). There are cases of false positives on the ELISA among recipients of IV Immune Globulin. *HTLV-III Antibodies After Immune Globulin*, 257 J. A.M.A. 316 (1987) (letters to editor).

49. *San Francisco Health Labs Use IFA, Not Western Blot, as Confirmatory test*, 1 AIDS ALERT 85, 96 (1986) (quoting Judith Wilber, PhD., of the city's department of public health, that "[t]he Western Blot is so unstandardized and so different from laboratory to laboratory that we were really concerned about the interpretations. . . . We have seen some studies that say that the same [Western] Blots have been sent to different labs and been interpreted differently."). *Id.* at 96. See also *Asymptomatic Blood Donor with a False Positive HTLV-III Western Blot*, 314 NEW ENG. J. MED. 118 (1986) (noting in letters to editor that a patient who initially tested positive by both ELISA and Western Blot methods was later found to be a false positive).

50. *Status Report on the Acquired Immunodeficiency Syndrome*, 254 J. A.M.A. 1342 (1985). Doctors criticizing the Western Blot have stated, "Despite the high degree of specificity of the Western Blot and its correlation with viral culture results, it is not ideal since it is somewhat subjective and potentially less sensitive than the ELISA test." H. Kaplan & S. Kleinman, *Serologic Tests for Infection With Human Immunodeficiency Virus*, 17 LAB. MED. 690, 692 (1986).

51. Lundberg, *The Age of AIDS: A Great Time for Defensive Living*, 253 J. A.M.A. 3440 (1985). "The very low general prevalence of clinical AIDS (perhaps 4 per 100,000) means that with a test with a sensitivity of 95% and a specificity of 99.7% there will be 99 false-positive results for every one true-positive result." *Id.* (emphasis added). See also Sivak & Wormser, *Predictive Value of a Screening Test for Antibodies to HTLV-III*, 85 AM. J. CLINICAL PATHOLOGY 700 (1986) (The authors assume a very low prevalence in the general population and note that there is less than a 3% chance that a positive test result is a true positive (i.e., 97% false positives)).

ing or diagnosis and relied upon as the basis for restricting legal rights, will incorrectly identify large absolute numbers (although small relative numbers) of individuals with the HIV antibody. It will also fail to detect a significant number of seropositive persons.

C. *Related Problems — Laboratory Error*

The foregoing discussion of the predictive value of the HIV antibody test is based on the assumption that individuals who are positive on repeat testing, and confirmed by Western Blot testing, are infected with and can transmit the virus. Such an assumption may not be valid; if not, then there should be serious reservations about the use of the test for diagnosis.⁵²

Many factors contribute to the accuracy of laboratory tests. Recently, the *Wall Street Journal* published a two-part article on the fallibility of medical laboratory tests.⁵³ The article stated that human specimens are sometimes inadvertently switched,⁵⁴ machines can emit spurious results because of loss of calibration,⁵⁵ and testing chemicals can lose their potency or can be misused.⁵⁶ Another author reveals that reagent lots may be defective, and clerical errors in filing and reporting can occur.⁵⁷ The *Wall Street Journal* indicated that the general public has a false sense of confidence in laboratory test results and that physicians

52. See McCue, Sasgawa & Hein, *ELISA Test Kits for Detection of AIDS—Associated Antibodies*, AM. CLINICAL PRODUCT REV., May, 1987, at 20.

53. Bogdanich, *False Negative: Medical Labs, Trusted As Largely Error-free, Are Far From Infallible*, Wall St. J., Feb. 2, 1987, at 1, col. 6; Bogdanich, *Risk Factor: Inaccuracy in Testing Cholesterol Hampers War on Heart Disease*, Wall St. J., Feb. 3, 1987, at 1, col. 1.

54. Bogdanich, *False Negative*, *supra* note 53.

55. *Id.*

56. *Id.*

57. Griner, *supra* note 27, at 570. See also Banker & Polzynski, *Auditing Transcription Errors: A Spot Check for Lab Performance*, MED. LABORATORY OBSERVER, April, 1986, at 52-58. In a prospective study of transcription errors in test results, an error rate of 0.2% was found. *Id.* at 54. Note that this study did not focus on other areas of possible error: mislabeling of samples, machine errors, reagent variation, filing errors, etc. An error rate of 0.2% in our hypothetical sample of 200,000,000 results in 400,000 errors. An example of the problems encountered in mass screening situations is the U.S. military's effort to test urine samples for the presence of drugs. The test used (EMIT), had an error rate of up to five percent. Improper adjustment and failure to decontaminate equipment after processing positive samples increases the margin of error. Of the 1.8 million urine samples the Navy tested in 1984, 60,000 were positive, 27,581 were confirmed by second-stage analysis, 17,417 received nonjudicial punishment, 1,710 were court-martialed, and 6,596 were discharged. The military used both service and civilian labs to conduct the confirmatory tests. After the complaints about "false positives" continue to grow, the military conducted an investigation and found that " 'poor quality control records' made it impossible to provide scientifically and legally supportable documentation in many cases." Ensign, *Controlling Behavior Through Urine and Blood Testing*, PATHOLOGIST, March, 1986, at 29, 31.

"don't realize how difficult it is to consistently generate accurate data"⁵⁸ from these tests. Some of this confidence has been engendered by the dramatic advances in computerized diagnostic testing, but, as the article points out, "[e]very lab is producing some errors"⁵⁹

Despite numerous studies reporting a high frequency of laboratory errors and poorly-trained, over-worked technicians, heightened public awareness has not led to increased accountability.⁶⁰ Although there is some federal regulation of clinical laboratories, many laboratories and other facilities doing testing are not subject to any national regulation or licensure. In the absence of nationwide standards, there is a wide disparity in clinical laboratory test performance. In a well run laboratory, errors should be minimal. However, when contemplating the testing of several million persons, even a minute error rate can translate into very large absolute numbers.

The reality of laboratory error should cause policy makers to think carefully about imposing reporting requirements for persons found to be seropositive, especially when the laboratory is operated by the state. Persons falsely labeled seropositive as a result of negligence may have little or no legal recourse for any subsequent damage.⁶¹ It is doubtful that the rate of laboratory error would change with new, more precise tests for the antibody or antigen. Some rate of error is inherent in any laboratory, no matter what precautions are taken.

III. TEST ACCURACY AND RELIABILITY

At least one federal court has dealt with the issue of whether a scientifically reliable test may be reliable enough to be used as a basis for justifying punitive action against an individual.⁶² Over the past five years, numerous federal and state courts, in the context of challenges to mandatory drug testing, have grappled with the issue of how accurate and reliable a scientific test must be to satisfy constitutional standards.⁶³

58. Bogdanich, *False Negative*, *supra* note 53.

59. *Id.*

60. *Id.*

61. Sovereign immunity may preclude a remedy against the state and its instrumentalities unless the state has consented to such suits. While most states have consented to suit to some extent, the legislation is usually narrowly construed by the courts. In addition, official immunity may prevent recovery against a government employee.

62. *Peranzo v. Coughlin*, 608 F. Supp. 1504, 1507 (S.D.N.Y. 1985) (drug test of prison inmate).

63. For cases relating to prisons, see *Spence v. Farrier*, 807 F.2d 753 (8th Cir. 1986); *Harmon v. Auger*, 768 F.2d 270 (8th Cir. 1985); *Wycoff v. Resig*, 613 F. Supp. 1504 (N.D. Ind. 1985); *Peranzo*, 608 F. Supp. 1504; *Higgs v. Wilson*, 616 F. Supp. 226 (W.D. Ky. 1985), *vacated on other grounds*, 793 F.2d 1291 (6th Cir. 1986); *Jensen v. Lick*, 589 F. Supp. 35 (D.N.D. 1984); *Smith v. State*, 250

These courts have had little or no guidance from the United States Supreme Court on this issue. In *California v. Trombetta*,⁶⁴ a case cited by several lower courts, the United States Supreme Court concluded that the Intoxilyzer, a device that analyzes a suspect's breath to measure the concentration of alcohol in the blood, is accurate.⁶⁵ In so doing, the Court indicated that due process does not require a state to preserve breath samples as part of criminal defendants' constitutionally guaranteed access to exculpatory evidence.⁶⁶ One federal district court interpreted *Trombetta* to mean that the due process guarantee does not mandate absolute scientific accuracy in determining criminal culpability.⁶⁷ This interpretation is misleading.

While the Court in *Trombetta* addressed the issue of the Intoxilyzer's accuracy,⁶⁸ it never squarely addressed the issue of the underlying reliability of the device because this point was not raised by the parties.⁶⁹ Further, the Court indicated in a footnote that state courts and legislatures were "free to adopt more rigorous safeguards governing the admissibility of scientific evidence than those imposed by the Federal Constitution."⁷⁰ This footnote could be interpreted as evidence of the Court's discomfort with establishing any firm criteria governing the accuracy and reliability of scientific tests in the absence of greater discussion of this issue by the medical and legal community.

A. Test Accuracy

Without question, a scientific test with a predictive accuracy of 95% or better is acceptable for many routine decisions. However, these limits may not be accurate enough for decisions based on current antibody tests. The degree of accuracy legally required should depend upon the consequences of the test results. Where the antibody test is used to screen blood or blood products, a test with 95% accuracy is sufficient because the consequences of a false positive test result are insignificant.

Ga. 438, 298 S.E.2d 482 (1983). *Hoepfner v. State*, 379 N.W.2d 23 (Iowa Ct. App. 1985). For cases relating to public employees, see *National Treasury Employees Union v. Von Raab*, 649 F. Supp. 380 (E.D. La. 1986), *order vacated*, 816 F.2d 170 (5th Cir. 1987); *Rushton v. Nebraska Pub. Power Dist.*, 653 F. Supp. 1510 (D. Neb. 1987).

64. 467 U.S. 479 (1984).

65. *Id.* at 489.

66. *Id.*

67. *Peranzo*, 608 F. Supp. at 1508. This interpretation was noted by another court in *Wykoff*, 613 F. Supp. at 1511.

68. *Trombetta*, 467 U.S. at 489 n.9.

69. *Id.* at n.10.

70. *Id.* at 491 n.12.

However, when the consequence of a positive HIV test result is refusal to hire or loss of job,⁷¹ physical denial of schooling,⁷² segregation or quarantine,⁷³ refusal to insure or treat medically,⁷⁴ or denial of housing and other services,⁷⁵ 95% accuracy may not be legally sufficient and may violate the due process clauses of the fifth⁷⁶ and fourteenth amendments.⁷⁷

As mentioned previously, in *Trombetta*, the Supreme Court addressed the accuracy of the Intoxilyzer, a machine. In concluding that this machine was accurate, the Court relied on the certification of the State Department of Health⁷⁸ and the accuracy requirements developed by the National Highway Traffic Safety Administration of the Department of Transportation.⁷⁹ Also instrumental in the Court's decision was the fact that respondents had numerous other ways of challenging the accuracy of the Intoxilyzer.⁸⁰ Unlike the respondents in *Trombetta*, individuals subjected to adverse decisions due to positive HIV test results have no alternative means to refute a wrongful label. Thus, the accuracy of the antibody test is more crucial here than in *Trombetta*.

Trombetta is distinguishable on another basis. The Court in *Trombetta* was determining the legal sufficiency of a machine's accuracy as opposed to the accuracy of a scientific test. As the Court indicated in its discussion of the State Health Department certification process, there are two independent measurements that are part of a uniform test procedure⁸¹ and records of the machine's weekly calibrations are kept and are available to drunk driving defendants.⁸² No similar mechanism is available for persons labeled seropositive.

The recent challenges to mandatory drug testing are analogous to the legal issues raised by screening for HIV infection. The bulk of the cases challenging the accuracy of drug tests involve the EMIT (Enzyme

71. See *infra* note 206 and accompanying text.

72. See *infra* note 208.

73. See e.g., McFadden, *Boy Put In Psychiatric Ward as AIDS Suspect*, N.Y. Times, June 12, 1987, at Y11, col. 1 (nat'l ed.).

74. See *infra* notes 205 and 207 and accompanying text.

75. See *infra* notes 204, 208, 209 and accompanying text.

76. U.S. CONST. amend. V.

77. U.S. CONST. amend. XIV.

78. *California v. Trombetta*, 467 U.S. 479, 489 (1984).

79. *Id.* at 490 n.19.

80. Respondents could have inspected the machine used or checked its weekly calibration and the breath samples used in the calibrations. They also had the right to cross examine the operator of the machine. *Id.*

81. Two samples of the accused's breath are taken and each sample is tested independent of the other using the Intoxilyzer. *Trombetta*, 467 U.S. at 489.

82. *Trombetta*, 467 U.S. at 490.

Multiplied Immunoassay Technique) test. The EMIT test, like the ELISA test, does not directly measure the amount of drugs in a person's urine, but measures instead the reaction of an enzyme to the drug.⁸³ A single unconfirmed EMIT test has a predictive accuracy of 95+%.⁸⁴

Most of the drug testing cases involve due process challenges by prison inmates to the use of test results to support disciplinary sanctions.⁸⁵ A few cases have allowed the imposition of disciplinary sanctions based on a single EMIT test.⁸⁶ However, most scientific experts recommend⁸⁷ and many courts require a second confirming test; either a second EMIT test, the more sensitive TLC (Thin Layer Chromatography) test, or the GS/MS (Gas Chromatography/Mass Spectrometry) test.⁸⁸ The courts' attitude in the prison cases can perhaps best be summarized by the language of the Court of Appeals for the Eighth Circuit in *Spence v. Farrier*:⁸⁹

Although it is conceivable that an inmate could be unjustly disciplined as a result of EMIT tests, the margin of error is insignificant in light of institutional goals. States need not implement all possible procedural safeguards against erroneous deprivation of liberty when utilizing results of scientific testing devices in accusatory proceedings.⁹⁰

In contrast, the courts' attitude toward drug testing of public employees has been more conservative. Several federal district courts have refused, in the absence of probable cause, to uphold mandatory drug testing programs of civilians by the Department of Army,⁹¹ city firefighters and police,⁹² probationary school teachers,⁹³ and school bus drivers.⁹⁴ However, the Court of Appeals for the Eighth Circuit upheld mandatory

83. Dubowski, *Drug-Use Testing: Scientific Perspectives*, 11 NOVA L. REV. 415, 456-60 (1987).

84. Jaffe, *Drug Screening-The Provider's Perspective*, 79 J. OKLA. ST. MED. ASS'N. 760, 762 (1986).

85. See *supra* note 63.

86. See generally *Wykoff v. Resig*, 613 F. Supp. 1504 (N.D. Ind. 1985); *Jensen v. Lick*, 589 F. Supp. 35 (D.N.D. 1984); *Smith v. State*, 250 Ga. 438, 298 S.E.2d 482 (1983). The urine samples tested using the TLC method confirmed the results of the single EMIT test. *Wykoff*, 613 F. Supp. at 1510.

87. Hoyt, Finnegan, Nee, Shults & Butler, *Drug Testing in the Workplace—Are Methods Legally Defensible?*, 258 J. A.M.A. 504, 507 (1987).

88. See *Spence v. Farrier*, 807 F.2d 753 (8th Cir. 1986); *Peranzo v. Coughlin*, 608 F. Supp. 1504 (S.D.N.Y. 1985).

89. 807 F.2d 753 (8th Cir. 1986).

90. *Id.* at 756.

91. *American Fed'n of Gov't Employees v. Weinburger*, 651 F. Supp. 726 (S.D. Ga. 1986).

92. *Capua v. City of Plainfield*, 643 F. Supp. 1507 (D.N.J. 1986). See also *Lovvorn v. Chattanooga*, 647 F. Supp. 875 (E.D. Tenn. 1986) (all firefighters).

93. *Patchogue-Medford Cong. of Teachers v. Bd. of Educ.*, 119 A.D.2d 35, 505 N.Y.S.2d 888 (1986).

94. *Jones v. McKenzie*, 628 F. Supp. 1500 (D.D.C. 1986).

drug testing in limited situations. The Eighth Circuit upheld random drug testing of prison guards in *McDonell v. Hunter*.⁹⁵ In so doing, however, the court noted that there were extensive procedural protections in place to eliminate or check false-positive test results.⁹⁶ Thus, the court seemed reluctant to uphold an adverse employment decision based on scientific test results alone.

The prison and public employee drug testing cases, when viewed together, suggest that a scientific test with a 95% predictive accuracy may not, standing alone, be constitutionally sufficient to justify such extreme measures as long-term quarantine or segregation. Whether greater accuracy will be required before the government can prevent seropositive persons from marrying or before the government can deport seropositive resident aliens is unclear. The courts in the drug testing cases seem to apply a balancing test. They weigh the government's justification for testing against the rights of the individual, but take into account the trustworthiness and accuracy of the test when the balance favors the government.

As discussed above, the current test for the HIV antibody (ELISA) was licensed as a tool for screening blood and blood products.⁹⁷ The test, as designed, has a high sensitivity (resulting in a high false positive rate) to better assure the safety of the nation's blood supply. Therefore, the assay may not be useful to determine, for legal purposes, whether the virus has infected someone.⁹⁸ While the second generation of screening tests will undoubtedly be more reliable or medically precise than the current test, they may be too expensive for routine screening for the HIV antibody.⁹⁹ Even this new generation of tests would have a number of

95. 809 F.2d 1302 (8th Cir.1987).

96. *McDonell*, 809 F.2d at 1309.

97. See *supra* note 40 and accompanying text. Recently Mike Housh, administrative assistant to California Assemblyperson Art Agnos, said that insurance companies and the military are violating federal law by using the ELISA tests to identify AIDS-infected people, because they are misusing a specifically designed medical test. Violations of the law could result in fines from \$100,000 to \$500,000 and up to one year in prison. *Military, Insurance Use of ELISA Violates FDA Regulations, Says Legislative Aide*, 1 AIDS ALERT 142 (1986).

98. Because of interferences, the positive predictive value of the ELISA assay in the general population has been estimated to be about 0.6-2.7 percent, which means that about 97 percent of the positive tests will be false. . . .

. . . .

Presently, the high-risk groups are well defined, making true identification less tenuous. Yet, even within the high-risk groups uncertainty can arise.

Levinson & Denys, *AIDS Methods*, CLINICAL CHEM. NEWS, Dec. 1986, at 8.

99. Blakeslee, *Pressure for Wider AIDS Testing Fuels Search for Better Methods*, N.Y. Times, June 9, 1987, at Y22, col. 1 (nat'l ed.).

false positives and could not accurately identify all infected persons.¹⁰⁰ As James Allen from the Centers for Disease Control admits, "the 'ideal' confirmatory test for the disease is yet to be developed and licensed."¹⁰¹

Many questions still remain regarding the meaning of a positive test,¹⁰² false-negative tests results, and the incubation period for the virus.¹⁰³ Even the National Institutes of Health consensus noted that "the tests for infected blood are not yet optimately effective . . . no method of donor screening can totally eliminate risk of HIV infection through blood."¹⁰⁴ In light of the existing medical uncertainty, the government should exercise caution before enacting policies which may have grave social and economic consequences when other reasonable noninvasive alternatives, such as educating the public about AIDS, exist to reduce the spread of HIV infection.

B. Test Reliability

The Court of Appeals for the Fifth Circuit, in *National Treasury Employees Union v. Von Raab*,¹⁰⁵ held that the EMIT test was not so unreliable as to violate due process of law. In so ruling, the court vacated the decision of the district court, which found that all drug testing procedures result in false positives whether due to problems with the test, specimen storage, handling and preparation, and personnel qualifications.¹⁰⁶ After weighing the interests of the government against the intrusiveness and unreliability of the tests, the district court concluded that the testing plan was unreasonable and not rationally related to the achievement of the governmental interests.¹⁰⁷ Concerned about the possibility of laboratory error, the district judge, citing one instance where an employee alleged that his sample was mixed up with that of another Customs employee,¹⁰⁸ concluded, "[t]he entire process is fraught with the danger of mishaps and false-positive readings."¹⁰⁹ In rejecting the district court's conclusion that the EMIT test was unreliable, the Fifth

100. Blakeslee, *supra* note 99.

101. *Another AIDS Virus, an Alternative Test*, *supra* note 46, at 284.

102. Kaplan & Kleinman, *supra* note 50, at 692.

103. *Ethical Guidelines Proposed for HIV Antibody Tests*, AM. MED. NEWS, Oct. 10, 1986, at 26.

104. *Id.*

105. 816 F.2d 170, 181 (5th Cir. 1987).

106. *National Treasury Employees Union v. Von Raab*, 649 F. Supp. 380, 389-90 (E.D. La. 1986).

107. *Id.* at 390.

108. *Id.* at 389.

109. *Id.*

Circuit cited no supporting data.¹¹⁰ Rather, the appellate court justified its conclusion by citing the methods used by the Customs Service to insure greater accuracy of the testing procedures.¹¹¹ The court failed to draw a distinction between test reliability and test accuracy. Accuracy goes to the validity of the test's results, whereas reliability goes to what the test measures. The district court cited to the affidavit of a toxicologist which indicated the limited reliability of the EMIT test.¹¹² The affidavit noted that a retest using GC/MS does not necessarily cure the limited reliability.¹¹³ Both courts failed to address the issue of how reliable a test should be to satisfy due process requirements.

Although the parameters of due process have not been drawn with precision, at least one court has attempted to spell out in mathematical fashion the evidentiary percentages required by law for different standards of proof.¹¹⁴ However, few courts have seriously considered this formula. The existing confusion in the courts over the issue of the reliability and accuracy of drug tests will continue if HIV testing becomes widespread. As already discussed, the consequences of HIV testing are potentially more severe than drug testing in the workplace or prison. Therefore, the legal sufficiency of scientific tests demands more discussion.

IV. THE GOVERNMENT'S POWER OVER PUBLIC HEALTH

The existence of government authority to take measures to control the spread of communicable diseases dates back to Blackstone's *Commentaries*.¹¹⁵ Courts have long recognized the broad power of state and local governments to deal with communicable diseases.¹¹⁶ The federal government also has the power to promulgate regulations to control

110. *National Treasury Employees Union*, 816 F.2d at 181.

111. *Id.* at 181-82.

112. *National Treasury Employees Union*, 649 F. Supp. at 389-90.

113. *Id.* at 390.

114. *United States v. Fatico*, 458 F. Supp. 388, 402, (E.D.N.Y. 1978) *aff'd*, 603 F.2d 1053 (2d Cir. 1979), *cert. denied*, 444 U.S. 1073 (1980). The court in *Fatico* reduced the types of burdens to mathematical percentages: preponderance of the evidence 50+%; clear and convincing evidence 70%; clear, unequivocal and convincing evidence 80%; and proof beyond a reasonable doubt 95+%. *Id.* at 404-06. The appellate court affirmed the decision but failed to specifically endorse the lower court's percentage analysis of burden of proof. *Fatico*, 603 F.2d 1053 (2d Cir. 1979).

115. 4 W. BLACKSTONE, COMMENTARIES *161-62 (1769). "Measures to prevent the spread of dangerous communicable diseases . . . are practically as old as history." *Rock v. Carney*, 216 Mich. 280, 185 N.W. 798, 799 (1921) (Wiest, J., concurring).

116. *See generally* 39A C.J.S. *Health and Environment* § 18 (1976); 39 AM. JUR. 2D *Health* § 26 (1968). *See also infra* notes 138-44 and accompanying text.

communicable diseases.¹¹⁷ In all, three levels of government health officials have varying responsibility for dealing with the current AIDS crisis: local, state, and federal.

A. *State And Local Involvement In Public Health*

In 1796, Congress assigned the authority to quarantine to state governments.¹¹⁸ Subsequently, Chief Justice John Marshall in the seminal case, *Gibbons v. Ogden*,¹¹⁹ acknowledged that the tenth amendment of the United States Constitution¹²⁰ gives the states the power to enact inspection, quarantine and health laws.¹²¹ The Supreme Court more fully addressed the issue of the state's authority over public health in *Jacobson v. Massachusetts*.¹²² In *Jacobson*, a decision upholding a mandatory smallpox vaccination provision, the Court recognized that states under their police power have the authority to enact very broad health laws.¹²³ Today, states have an undisputed right to enact reasonable regulations to protect the health and safety of the public.

The due process and equal protection clauses of the fourteenth amendment have been interpreted to limit the state's police power.¹²⁴ Historically, the courts have construed the state's police power liberally to uphold measures taken when government acts rationally to alleviate actual threats to public health, even at the expense of individual rights.¹²⁵ In the past, public health measures were difficult to defeat because the courts presumed their validity and applied the minimal rationality

117. See *infra* notes 138-44 and accompanying text.

118. Act of May 27, 1796, ch. 31, 1 Stat. 474 (1845).

119. 22 U.S. (1 Wheat.) 1 (1824).

120. U.S. CONST. amend X.

121. *Gibbons*, 22 U.S. at 203.

122. 197 U.S. 11 (1905).

123. "Although this court has refrained from any attempt to define the limits of that power [police power], yet it has distinctly recognized the authority of a State to enact quarantine laws and 'health laws of every description'. . . ." *Id.* at 25.

124. The "liberty" guarantee of the due process clause encompasses freedom from bodily restraint, freedom to contract, engage in common occupations of life, raise children, etc. *Board of Regents v. Roth*, 408 U.S. 564, 572 (1972).

125. Damme, *Controlling Genetic Disease Through Law*, 15 U.C. DAVIS L. REV. 801, 804-05 (1982) [hereinafter *Controlling Genetic Disease*]. The deferential attitude of the courts toward state public health regulations is recognition that state government has an important interest in this area. R. ROEMER & G. MCKRAY, *LEGAL ASPECTS OF HEALTH POLICY: ISSUES AND TRENDS* 26 (1980). Thus, courts found that even where there is a threat to life, the rational basis standard is used to judge the regulation. *Id.* citing, *People v. Privitera*, 74 Cal. App. 3d 936, 141 Cal. Rptr. 764 (Cal. Dist. Ct. App. 1977) (a laetrile decision). In addition, the Supreme Court has rejected the use of the strict scrutiny standard in similar situations. *Whalen v. Roe*, 429 U.S. 589 (1977) (the right to privacy was asserted to challenge information regarding legitimate prescriptions for drugs).

test.¹²⁶

The Court of Appeals for the Second Circuit indicated in *New York State Association for Retarded Children v. Carey*¹²⁷ that even where the challenged action goes to the very essence of government's police power, like a public health matter, it is the responsibility of the courts "to ensure that the established legal standards, constitutional and statutory, are followed by government agencies. To permit the factual determination of these agencies to go unchallenged may be to neglect this task."¹²⁸ In *Carey*, the court of appeals held that public school officials could not justify isolating mentally retarded children who were carriers of hepatitis B (serum hepatitis, a blood-borne disease like AIDS). Considerable evidence showed that the threatened danger to other school children was only remote and that isolation would be detrimental to mentally retarded children.¹²⁹ The court refused to defer to the administrative findings, but upheld the district court's examination of the evidence submitted by the school board to justify the isolation.¹³⁰

The *Carey* decision indicates that courts today may not be deferential to public health regulations that have a detrimental impact on individual rights. Recall that most of the public health law cases cited by government officials in support of restrictive measures were decided in an era before the courts acknowledged that the fourteenth amendment provided broad protection of individual rights and before medical science matured.¹³¹

Public health officials traditionally use a variety of measures to control infectious diseases. As these health regulations become more restrictive and invasive, so does the scrutiny.¹³² The courts seem willing to use a flexible rationality standard which takes into account the restrictive

126. See, e.g., *City of New Orleans v. Dukes*, 427 U.S. 297 (1976) (ordinance prohibiting pushcart food sales in French Quarter upheld); *Massachusetts Bd. of Retirement v. Murgia*, 427 U.S. 307 (1976) (Massachusetts statute requiring uniformed police officers to retire at age fifty upheld). The state's authority over public health is usually delegated to local health departments. Thus, most measures to control infectious diseases are initiated by local health authorities pursuant to the state's police power. A presumption of validity attaches to local enactments and regulations adopted under the state's police power. Judicial review is limited to whether the regulation is related to and reasonably necessary and suitable for the protection of the public health, safety, welfare or morals. *ROEMER & MCKRAY*, *supra* note 125, at 13. The power to enact reasonable health measures applies even though communicable or epidemic diseases are not involved. *Id.* at 14.

127. 612 F.2d 644 (2nd Cir. 1979).

128. *Id.* at 648.

129. *Id.* at 650.

130. *Id.* at 651.

131. See *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

132. *Controlling Genetic Disease*, *supra* note 125, at 805.

nature of the public health measure, the efficacy of the measure, and the existence of other less restrictive alternatives. However, the courts still give great weight to health officials' claims of public need.

The state's power over public health is generally shared with local subdivisions. Although state systems vary, this division of functions usually takes one of two forms. The first is a highly centralized system in which the state legislature passes a law delegating the authority to a state board of health or state health commissioner to promulgate regulations.¹³³ Under this structure, the counties, cities, or towns may pass additional regulations in the area, but generally operate as enforcement agents for the state.¹³⁴ Under the second type of structure, there is considerable decentralization. The state public health agency functions largely in a supervisory capacity.¹³⁵ The local public health agencies are generally responsible for the detailed implementation of general state public health measures.¹³⁶ In those highly decentralized states, the counties and/or cities will have their own health codes.¹³⁷ Therefore, a hierarchy of laws and regulations results from the nature of the state-local relationship.

B. *Federal Involvement in Public Health*

Unlike the states, the constitutional basis for federal involvement in health matters is narrow. In 1796, Congress authorized the President to assist the states in the enforcement of their health laws.¹³⁸ In 1890, Congress gave the President permanent authority to supervise quarantines.¹³⁹ Today, the federal power to regulate public health is based on the commerce clause.¹⁴⁰

Prior to 1930, the federal government's role in the public health area was minimal because of restrictive constitutional interpretations by the Supreme Court and limited scientific knowledge.¹⁴¹ While the states tra-

133. F. GRAD, PUBLIC HEALTH LAW MANUAL 16-17 (2d printing 1970).

134. *Id.*

135. *Id.*

136. *Id.*

137. *Id.*

138. See Act of May 27, 1796, ch. 31, 1 Stat. 474 (1845).

139. For a general discussion of federal quarantine authority, see Chapman & Talmadge, *Historical And Political Background of Federal Health Care Legislation*, 35 LAW & CONTEMP. PROBS. 334 (1970).

140. U.S. CONST. art. I, § 8, cls. 1, 3. Morgenstern, *The Role of The Federal Government In Protecting Citizens From Communicable Diseases*, 47 U. CIN. L. REV. 537, 544-45 (1978) [hereinafter Morgenstern].

141. *Id.* at 543.

ditionally have been primarily responsible for public health, responsibility for interstate and international health questions rests on the federal government.

The federal government's power to regulate the spread of contagious diseases is vested in the Secretary of the Department of Health and Human Services.¹⁴² This authority includes the power to apprehend or detain persons to control the spread of certain diseases designated by the President.¹⁴³ Federal action manifests itself through direct regulation under the commerce clause and cooperation with or through the states.¹⁴⁴

V. METHODS OF CONTROLLING INFECTIOUS DISEASES

A. *Generally Used Methods*

At present, research, public education, and improved treatment are methods used to fight disease.¹⁴⁵ As a result, the public must increasingly rely on medical expertise to accurately assess the public health threat and response.¹⁴⁶ The public health decision-making process is two pronged. First, it requires an assessment of the risk posed by the disease and second, a choice of response.¹⁴⁷ When this decision-making process is challenged in the courts, the state must prove that medical evidence justifies its risk assessment.¹⁴⁸ However, the state's response to a proven

142. 42 U.S.C. §§ 243, 264 (Supp. 1983).

143. 42 U.S.C. § 264(b) (Supp. 1983). Present designated diseases include "Cholera or suspected Cholera, Diphtheria, infectious Tuberculosis, Plague, suspected Smallpox, Yellow Fever, and suspected Viral Hemorrhagic Fevers (LHASA, Marburg, Ebola, Congo-Crimean, and others not yet isolated or named)." Exec. Order No. 12,452, 3 C.F.R. 224 (1984), *reprinted in* 42 U.S.C. § 264 (Supp.1983).

144. Morgenstern, *supra* note 140, at 544-45.

145. Note, *Fear Itself: AIDS, Herpes and Public Health Decisions*, 3 YALE L. & POL'Y REV. 479, 480 (citing G. ROSEN, A HISTORY OF PUBLIC HEALTH 355-56, 393 (1953) and C. WINSLOW, THE CONQUEST OF EPIDEMIC DISEASE 364 (1943)).

146. *Id.*

147. *Id.* Other writers suggest a three step process: (1) evaluation of the scientific problem (nature of the viral entity and the ability of the scientific community to develop a safe and effective vaccine); (2) selecting a method to measure the objective results obtained in stage one (in some cases objective evidence is uncontroverted; in other cases the evaluation outcomes will be unclear or debatable and scientists may not be able to measure data until long-term analysis of the results is completed); (3) correlating the measurement obtained in stage two with designated government program options. It should be noted that stages one and two of this decision-making model involve only the scientific community. Morgenstern, *supra* note 140, at 547.

148. See, e.g., *New York State Ass'n. for Retarded Children v. Carey*, 466 F. Supp. 479 (E.D.N.Y. 1978), *aff'd*, 612 F.2d 644 (2d Cir. 1979) (admission of children who were carriers of Hepatitis B into regular public schools required); *Grube v. Bethlehem Area School Dist.*, 550 F. Supp. 418 (E.D. Pa. 1982) (pupil with only one kidney could not be barred from playing football); *LaRocca v. Dalsheim*, 120 Misc. 2d 697, 467 N.Y.S.2d 302 (1983) (upheld prison official's decision

risk is presumed valid unless the challenger proves that the response is medically unjustified or more restrictive than another choice of comparable medical effectiveness.¹⁴⁹

Public concern over the increasing number of AIDS cases has put pressure on federal, state, and local health authorities to take more definitive action to prevent the spread of the disease. In the past, public health officials relied on the following methods of controlling infectious diseases: mandatory screening,¹⁵⁰ reporting requirements,¹⁵¹ mandatory vaccinations, quarantine,¹⁵² isolation and removal, and compulsory physical examination and treatment.¹⁵³ Suggested proposals for controlling the AIDS epidemic have included: mandatory universal screening,¹⁵⁴ mandatory screening of selected groups,¹⁵⁵ quarantine or isolation of all HIV antibody positive persons,¹⁵⁶ tattooing seropositive persons in "private" areas,¹⁵⁷ issuance of public health identification cards to non-infected persons,¹⁵⁸ mandatory premarital screening,¹⁵⁹ and screening of persons in certain professions (typically food handlers and health care workers).¹⁶⁰

not to isolate prisoners with AIDS). See also Note, *Fear Itself: AIDS, Herpes and Public Health Decisions*, *supra* note 145, at 484-90 for a more complete discussion of the earlier case law.

149. See, e.g., *People ex rel. Barmore v. Robertson*, 302 Ill. 432, 134 N.E. 815 (1922) (upheld quarantine of boarding house for typhoid); *Rock v. Carney*, 216 Mich. 280, 185 N.W. 798 (1921) (examination for venereal disease); *Kirk v. Wyman*, 83 S.C. 372, 65 S.E. 387 (1909) (court refused to uphold an isolation order for person with leprosy).

. . . courts cannot invade the province of the legislative branch of the government. Inasmuch as it is the province of the legislative branch to determine what laws and regulations are necessary to the public health, . . . ; but the courts must determine whether there is any real relation between the preservation of the public health and the legislative enactment, or the regulations and proceedings of boards of health under authority of the statute.

Id. at 390.

150. See Closen, Connor, Kaufman & Wojcik, *AIDS: Testing Democracy—Irrational Responses To The Public Health Crisis And The Need For Privacy In Serologic Testing*, 19 J. MARSHALL L. REV. 835 (1986).

151. See Comment, *Reportability of Exposure To The AIDS Virus: An Equal Protection Analysis*, 7 CARDOZO L. REV. 1103 (1986).

152. See Parmet, *AIDS And Quarantine: The Revival of an Archaic Doctrine*, 14 HOFSTRA L. REV. 53 (1985); Elsberry, *AIDS Quarantine in England and the United States*, 10 HASTINGS INT'L & COMP. L. REV. 113 (1986).

153. *Controlling Genetic Disease*, *supra* note 125, at 806-13.

154. Comment, *Protecting the Public from AIDS: A New Challenge to Traditional Forms of Epidemic Control*, 2 J. CONTEMP. HEALTH L. & POL'Y. 191 (1986).

155. See *infra* notes 163-71 and accompanying text.

156. *Letters to the Editor*, Wall. St. J., Nov. 20, 1985, at 31, col. 1.

157. *Id.*

158. *Id.*

159. *Id.*

160. *Id.* See also California Congressman Considers Bill Restricting AIDS Patients From Work, 1 AIDS ALERT 107 (1986) (Congressman William Dannemeyer's bill would restrict employment of

B. *Mandatory Screening*

Mandatory mass screening for the HIV antibody is the measure mentioned most often by persons calling for stronger measures to protect the public from AIDS.¹⁶¹ Most states have mandatory screening laws.¹⁶² These laws typically require mandatory screening of newborns for genetic diseases,¹⁶³ screening of drivers to determine alcohol content,¹⁶⁴ and screening of couples as a precondition to marriage.¹⁶⁵ No state currently requires compulsory blood testing of the entire population (universal testing), although several states are considering mandatory pre-natal and pre-marital screening tests.¹⁶⁶

Some compulsory screening for HIV has already been initiated. Mandatory screening is required by the military for all recruits and enlisted personnel, and for all freshman at the Naval Academy.¹⁶⁷ The State Department has recently initiated mandatory screening programs for foreign service applicants, officers, and their dependents.¹⁶⁸ The city

persons with AIDS in health care, food service, teaching, hair styling and any other field involving direct contact with the public).

161. In 1987, thirty-two states considered bills on mandatory HIV testing. Breo, *States Swamped With AIDS Bills*, AM. MED. NEWS, June 26, 1987, at 1, 25. See also *supra* notes 7, 8, 10, 13-15 and accompanying text.

162. F. ROZOVSKY, CONSENT TO TREATMENT: A PRACTICAL GUIDE 105 (1984).

163. *Controlling Genetic Disease*, *supra* note 125, at 820.

Screening has been defined as the *presumptive identification* of unrecognized disease or defect by the application of tests, examination, or other procedures which can be applied rapidly. Screening tests sort out apparently well persons who probably have a disease from those who probably do not. A screening test is not intended to be diagnostic. Persons with positive or suspicious findings must be referred to their physicians for diagnosis and necessary treatment.

(emphasis in the original). Riskin & Reilly, *Remedies For Improper Disclosure of Genetic Data*, 8 RUT.-CAM. L.J. 480, 481 (1977) (citing Breslow & Roberts, 25 CHRONIC DISEASES 363, 365 (1955)).

164. Many states have laws requiring mandatory testing of persons suspected of driving under the influence of alcohol. Unlike the other compulsory tests, the courts in these states view the driver as consenting to the test by virtue of operating his vehicle on the highway.

165. GRAD, *supra* note 133, at 41.

166. ANDERSON, ARNSTEIN, & LESTER, COMMUNICABLE DISEASE CONTROL 94 (4th ed. 1962) (the authors state that one state has a "still untested" law providing for compulsory examination of the entire population). *Id.* The following states have considered state legislation on HIV pre-marital tests: Ala., Ark., Calif., Conn., Fla., Ga., Hawaii, Idaho, Ill., Ind., Iowa, Kan., Md., Mass., Mich., Minn., Miss., Mo., N.H., N.J., N.Y., N.C., Ohio, Okla., Pa., R.I., S.C., Tenn., Tex., Va., and Wash. In addition, Calif., Ga., Ill., R.I. & Wash., have considered similar legislation for pre-natal testing. Breo, *supra* note 161, at 25.

167. *Plebes To Be Tested For AIDS Antibody*, AM. MED. NEWS, March 14, 1986, at 42.

168. Berke, *State Department to Begin AIDS Testing*, N.Y. Times, Nov. 29, 1986, at 49, col. 1. On January 20, 1987, the American Federation of Government Employees filed suit in an attempt to halt HIV testing, alleging that the testing program is a violation of the right to privacy, due process, unreasonable search and seizure, and the Rehabilitation Act. A federal district judge denied a motion for a preliminary injunction in *Local 1812 v. United States Dept. of State #87-012*, 1987 LESBIAN/GAY L. NOTES 29 (May); Screening programs have also been proposed for the Peace Corps,

of Nashville requires screening of all potential massage parlor employees,¹⁶⁹ and the state of Nevada requires monthly screening of all prostitutes.¹⁷⁰ In addition, mass (as opposed to universal) screening has been suggested for prisoners,¹⁷¹ drug treatment centers participants,¹⁷² homosexual males,¹⁷³ and food handlers.¹⁷⁴ Screening has also been proposed for admission to hospitals or for obtaining medical insurance.¹⁷⁵

Screening laws are usually designed to apply to those persons who are likely to infect many others if their own infection is not discovered.¹⁷⁶ For example, these laws often apply to persons in certain occupations like school teachers and food handlers.¹⁷⁷ Most, if not all states require some compulsory testing of public school children.¹⁷⁸ Screening in these instances is used to prevent the spread of air-borne, highly contagious diseases. The AIDS virus does not fit within this category since it is transmitted primarily through blood and exposure to body fluids rather than by casual day-to-day contact.

Even the routine testing of only certain groups of the population is

requiring the applicant to present a doctor's certificate showing a negative HIV test result. 1987 LESBIAN/GAY L. NOTES 21 (Apr.). Screening programs have further been proposed for the job corps. *AIDS Screening Program Set for Job Corps*, BNA INDIVIDUAL EMPLOYMENT RIGHTS, Jan. 6, 1987, at 2.

169. *Illinois To Set Up Sites For AIDS Tests*, AM. MED. NEWS, Oct. 25, 1985, at 43.

170. *Prostitutes To Undergo HTLV-III Testing*, AM. MED. NEWS, Apr. 4, 1986, at 34.

171. Penal institutions contain two high risk groups, people with a history of intravenous drug abuse and males engaged in homosexual activities. In addition, tattooing with make-shift instruments poses another avenue for potential infection. Four states, Nevada, Colorado, Iowa, and Missouri, already screen all inmates for the antibody. *Prisons Confront Dilemma of Inmates With AIDS*, 255 J. A.M.A. 2399, 2400 (1986). See also *Doctors' Panel Suggests Limited AIDS Testing*, N.Y. Times, June 21, 1987, at Y19, col. 1 (nat'l ed.) (A.M.A. supports testing of prison inmates and immigrants).

172. Levine & Bayer, *Screening Blood: Public Health and Medical Uncertainty*, 15 Hastings Center Report 8, 11 (1985).

173. A bill drafted by an Illinois legislator would mandate screening of high-risk groups. *Quarantine Sought For AIDS Victims*, AM. MED. NEWS, Nov. 8, 1985, at 10.

174. See *supra* note 160 and accompanying text.

175. Levine & Bayer, *supra* note 172, at 11.

176. *Id.*

177. GRAD, *supra* note 133, at 41 (referring to food handlers, bakers, nurses, and teachers in contact with young children).

178. See *Cude v. State*, 237 Ark. 927, 377 S.W.2d 816 (1964); *Pierce v. Board of Educ.* 30 Misc.2d 1039, 219 N.Y.S.2d 519 (Sup. Ct. 1961); *Board of Educ. v. Maas*, 56 N.J. Super. 245, 152 A.2d 394 (Super. Ct. App. Div. 1959), *aff'd.*, 158 A.2d 330 (1960), *cert. denied*, 383 U.S. 843 (1960); *State ex rel. Dunham v. Board of Educ.* 154 Ohio St. 469, 96 N.E.2d 413, (1951), *cert. denied.*, 341 U.S. 915 (1951); *Barber v. School Bd. of Rochester*, 82 N.H. 426, 135 A. 159 (1926); *State ex rel. Lehman v. Partlow*, 119 Wash. 316, 205 P. 420 (1922); *Board of Trustees v. McMurtry*, 169 Ky. 457, 184 S.W. 390 (Ct. App. 1916). Georgia's Board of Education approved mandatory HIV testing of students and teachers suspected of being infected and proposing the possibility of excluding teachers who are seropositive. *Georgia AIDS Tests*, BNA INDIVIDUAL EMPLOYMENT RIGHTS, June 23, 1987, at 2.

not without controversy.¹⁷⁹ Opponents of mandatory screening question the value of such testing when little or nothing is done with the cases of disease found or when the connection between the targeted group and the spread of infection is nonexistent or tenuous at best.¹⁸⁰ Because compulsory blood tests involve potential invasions of individual liberty and privacy, the tests must be reasonably related to a specific public purpose,¹⁸¹ be expressly authorized by law;¹⁸² and be based on reasonable grounds or probable cause.¹⁸³

The American Medical Association and the United States Public Health Service have opposing views on compulsory HIV testing. The American Medical Association has rejected outright all efforts to require premarital testing for the HIV antibody, reasoning that this type of screening would be ineffective.¹⁸⁴ The United States Public Health Service, although initially suggesting only voluntary testing of high risk groups, now supports more widespread testing.¹⁸⁵ This change in position by the Public Health Service was due to its increased confidence in the reliability of the HIV (ELISA) test.¹⁸⁶

1. Potential for Discriminatory Use

Aside from the issue of test accuracy, there are two major problems with mandatory screening requirements. First, there is the potential for discrimination in the use of test results. Second, there are privacy concerns associated with required screening.

Traditionally, screening programs have been directed at those persons most likely to spread infection. Screening requirements are not suited to screen the entire population. The tests are often costly and, furthermore, universal screening does not necessarily result in the detec-

179. ANDERSON, ARNSTEIN & LESTER, *supra* note 166, at 478. See also Levine & Bayer, *supra* note 172, at 11. "Prior experience with mass screening that entails the risk of discrimination—for example, the screening of blacks for sickle cell trait in the early 1970s—should prove a cautionary note. That effort was eventually abandoned largely because of the negative social consequences to the people the test was supposed to help." *Id.*

180. ANDERSON, ARNSTEIN & LESTER, *supra* note 166, at 478.

181. *Huffman v. District of Columbia*, 39 A.2d 558, 561-62 (D.C. 1944).

182. *Ex Parte Arata*, 52 Cal. App. 380, 198 P. 814 (1921); *Wragg v. Griffin*, 185 Iowa 243, 170 N.W. 400, 403 (1919).

183. *Hill v. Hilbert*, 92 Okla. Crim. 169, 173, 222 P.2d 166, 169 (1950); *Welch v. Shepherd*, 165 Kan. 394, 196 P.2d 235 (1948); *In re King*, 128 Cal. App. 27, 16 P.2d 694 (1932).

184. *AMA Urges Physicians To Offer AIDS Information To Patients*, AM. MED. NEWS, Dec. 20, 1985, at 9. See also *Doctor's Panel Suggests Limited AIDS Testing*, *supra* note 171.

185. *PHS Urges Expanded Screening For AIDS*, AM. MED. NEWS, Mar. 28, 1986, at 8. Note that voluntary screening probably would not work because high risk groups do not want to be identified.

186. *Id.*

tion of a substantial number of infected or diseased persons. Repeat screening is often required since a negative test result only indicates a person's status at the moment of the test. The need for repeat tests of the same population further increases the cost, and limits the money and other resources that can be devoted to developing an effective treatment for the disease. Therefore, public health officials will probably focus on screening only targeted groups.

Due to the composition of the high risk groups frequently associated with AIDS (homosexual and bisexual men, intravenous drug users, and prostitutes), there are social and political factors that have not been present in most other disease outbreaks. At least one authority claims that "[t]o some extent, the AIDS epidemic is a unique experience in public health."¹⁸⁷ Fear of AIDS makes automatic lepers out of those persons identified as serologically positive. Because many people hold strong views about persons with AIDS, those subject to screening might well experience loss of employment as well as other discriminatory actions. Similar discrimination occurred less than twenty years ago with the disease of sickle cell trait.

In the 1970's, misunderstanding about the sickle cell trait, primarily found in blacks, caused temporary employment discrimination by New York City's Fire Department, the Transit Authority, the telephone company, and several major airlines.¹⁸⁸ In 1972, the Secretary of the Army stated that applicants for certain programs had to be screened for the trait, and carriers would be ineligible for admission.¹⁸⁹ Insurance companies without actuarial support temporarily raised rates or dropped coverage of sickle cell carriers.¹⁹⁰ As the sickle cell experience indicates, there is the real possibility that governments will use test results as a basis to prosecute or persecute members of the high risk groups.

The Hastings Center, a think tank on medical ethics, recommended

187. *Information, Consideration Needed—Brandt*, 253 J. A.M.A. 3376 (1985) (quoting Edward N. Brandt, Jr., Chancellor of the University of Maryland School of Medicine).

188. Riskin & Reilly, *supra* note 163, at 488-89.

Of perhaps even greater significance is the danger that improper release of genetic information may spark discrimination in such areas as employment and access to health or life insurance because of misunderstandings about the physical implications of certain genetic facts. . . . It was only after a dramatic political attack by black physicians and business leaders that this genetic discrimination ceased.

Id. See also *Drake v. Covington County Bd. of Educ.*, 371 F. Supp. 974 (M.D. Ala. 1974) (an unmarried public school teacher was dismissed when the school board learned from the teacher's physician that the teacher was pregnant. Held: disclosure of the medical records violated her right of privacy).

189. Riskin & Reilly, *supra* note 163, at 489.

190. *Id.*

in a recent report that mandatory screening only be initiated when "therapeutic intervention is available or when infectivity puts others at risk through casual contact."¹⁹¹ As the report points out, this is not the case with AIDS.¹⁹² The two reasons most commonly put forth to justify mandatory screening for the HIV virus are first, to collect statistical data to determine the scope of the epidemic and second, to motivate infected persons to change behavior that puts others at risk.¹⁹³ Neither of these reasons fit within the Hastings Center's recommended ethical guidelines for mandatory screening.

It is difficult to justify mandatory testing simply to collect statistical data. The testing is invasive. The prejudicial effects of possible disclosure of positive test results are severe. The value of collecting statistical data for a disease that is incurable under these circumstances should be outweighed by the need to protect the individual from discriminatory use of the data.

In addition to its invasiveness, the test's effectiveness for modifying behavior is questionable. In response to the argument that people need to know if they are infected in order to modify their behavior and minimize the risk of transmitting the virus to another, opponents of mandatory testing contend that behavior modification can be achieved effectively with or without actual knowledge of one's antibody status.¹⁹⁴ It cannot be assumed that mere knowledge of one's antibody status will produce the required behavior modification.¹⁹⁵ It may be more effective and certainly less invasive to urge all persons, whether infected or not, to modify behavior to minimize the chance of either transmitting or being infected with HIV.

The potential for discriminatory use of the test results is best illustrated by the military's response to seropositive persons in the armed service. Positive test results have been used to identify, harass, and discharge homosexuals in the military.¹⁹⁶ Clearly, these consequences are

191. Bayer, Levine & Wolf, *HIV Antibody Screening: An Ethical Framework for Evaluating Proposed Programs*, 256 J. A.M.A. 1768, 1770 (1986).

192. *Id.*

193. *Id.* at 1773.

194. Gostin & Curran, *The Case Against Compulsory Casefinding in Controlling AIDS—Testing, Screening and Reporting*, 12 AM. J.L. & MED. 7, 19-20 (1987).

195. *Antibody Testing Won't Cut Risky Behavior—Study*, AM. MED. NEWS, June 5, 1987, at 3, 33 (concluding that gay and bisexual men and pregnant women receiving treatment at a drug abuse clinic were unable to curb their high risk behavior).

196. Moore, *The Military Has an AIDS Crisis; Is There A Lawyer in the House?*, WASH. POST NAT. WEEKLY ED., Nov. 10, 1986, at 32-33. Recently, Congress amended a 1978 policy regulation on confidentiality. This change prohibits admission of homosexuality or drug use during the course

inconsistent with the stated purpose of these tests.¹⁹⁷ Even more troubling are the justifications given by the State Department for testing foreign service personnel and their dependents, namely the Department's inability to provide medical treatment for those infected personnel in foreign countries and its desire to prevent the spread of the disease to other countries.¹⁹⁸ The first reason seems to be an attempt to avoid the medical costs associated with treating persons with AIDS. The second reason ignores the difficulty in transmitting the disease. The above reasons are suspect when the consequence of a positive test result is discharge from the foreign service, even if the seropositive person is a family member.¹⁹⁹

2. Privacy Concerns

The courts recognize that one of the two constitutionally protected zones of privacy is that zone encompassing the interest in avoiding disclosure of personal matters.²⁰⁰ "This is essentially an interest in confidentiality."²⁰¹ When faced with an alleged invasion of this privacy right, the courts apply a balancing test, weighing the state's interest in disclosure against the interest infringed upon by the state's action.²⁰² Assuming the government's interest in stemming the spread of AIDS by mandatory mass screening outweighs any individual right to privacy, there is the problem of controlling access to the test results.

of HIV screening from being used as the sole ground for punitive action. *Military Reaffirms 0.15% 'Positive Rate'*, AM. MED. NEWS, Nov. 7, 1986, at 42. More recently, the Army attempted to court-martial an enlisted man for aggravated assault and other offenses arising from consensual sex acts between the soldier and other soldiers while he knew he had a positive HIV antibody test result. Turner, *The Military Battles A New 'Biological' Weapon: AIDS*, NAT'L L.J., May 11, 1987, at 6.

197. The Department of Defense justifies its policy on HIV antibody screening by saying that military personnel are exposed to a variety of infectious agents which would be harmful to an immunosuppressed person. Gostin & Curran, *supra* note 194, at 26.

198. Berke, *supra* note 168.

199. *Id.*

200. See *Plante v. Gonzalez*, 575 F.2d 1119, 1127-28 (5th Cir. 1978), *reh'g denied*, 580 F.2d 1052 (1978); *Florida Bd. of Bar Examiners Re: Applicant*, 443 So. 2d 71, 76 (Fla. 1983); *South Florida Blood Service, Inc. v. Rasmussen*, 467 So. 2d 798, 802 (Fla. Dist. Ct. App. 1985) (citing *Whalen v. Roe*, 429 U.S. 589, 598-600 (1977)). The Supreme Court has recognized that implicit in the substantive due process clause of the fourteenth amendment is a right of privacy. See *Griswold v. Connecticut*, 381 U.S. 479 (1965) (use of contraceptives in marital relationship falls within the zone of privacy protected by the Constitution); *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972) (right of privacy extends beyond marital relationship); *Doe v. Bolton*, 410 U.S. 179, 197-200 (1973) (The Court has specifically recognized both types of privacy interests in the medical area); *Whalen v. Roe*, 429 U.S. 589, 599-600 (1977) (includes an "individual interest in avoiding disclosure of personal matters" and "interest in independence in making certain kinds of important decisions.").

201. *South Florida Blood Service*, 467 So. 2d at 802 (the court refused to allow disclosure of donors to a blood bank).

202. *Id.* at 803 (citing *Nixon v. Administrator of General Services*, 433 U.S. 425 (1977)). See also *Florida Bd. of Bar Examiners*, 443 So. 2d at 76.

Disclosure of positive test results is of particular concern with the HIV virus because social stigma and adverse economic consequences may result. At least one state court has recognized this fact.²⁰³ Persons suspected of having the disease have been denied housing,²⁰⁴ medical care,²⁰⁵ employment,²⁰⁶ insurance,²⁰⁷ banned from public schools,²⁰⁸ and been shunned as social outcasts.²⁰⁹ Such treatment for those who are truly infected must be condemned and deemed deplorable when such prejudices are inflicted on one who falsely tests positive. Clearly, a breach of confidentiality can have tragic results for a person who merely tests positive.²¹⁰

Protection of identity is essential for people with confirmed seropositive results, who do not have AIDS. Several states recently enacted statutes covering disclosure of test results.²¹¹ California makes an

203. *South Florida Blood Service*, 467 So. 2d at 802. See generally Nanula, *Protecting Confidentiality In The Effort To Control AIDS*, 24 HARV. J. ON LEGIS. 315 (1987).

204. D. ALTMAN, AIDS IN THE MIND OF AMERICA 61 (1986) (citing the case of Dr. Jo Sonnabend, a New York City doctor, who treated a number of persons with AIDS and 1983 was threatened with eviction from his building and noting that the Lambda Legal Defense and Education Fund was receiving about five complaints per week). See also 1987 LESBIAN/GAY L. NOTES 29 (May) (citing Poff v. Caro, No. L-28516-87, in which a N.J. Superior Court ruled that a landlord who refused to rent to three healthy gay men because of fear of AIDS violated the state's disability law).

205. ALTMAN, *supra* note 204, at 60. See also *Surgeon Spurns AIDS-Infected Patients*, AM. MED. NEWS, Mar. 27, 1987, at 3, 32.

206. ALTMAN, *supra* note 204, at 61. See also *First AIDS Discrimination Charge Issued*, AM. MED. NEWS, Aug. 22/29, 1986, at 2, 23 (federal government charged a N.C. hospital with removing a registered nurse who had AIDS); *Baker & McKenzie Loses AIDS Round*, NAT'L. L.J., June 22, 1987, at 2 (associate fired because he had AIDS); *Shuttleworth v. Broward Co.*, 2 IER Cas. (BNA) 3 (1986) (county settled with a budget analyst who was fired after being diagnosed with AIDS).

207. *Insurance Discrimination*, LAMBDA UPDATE, Summer 1986, at 1 (noting the problem that single men in general and gay men in particular have in getting insurance without submitting to the HTLV-III antibody test); Shipp, *Insurance Concerns Seek AIDS Test*, N.Y. Times, Feb. 2, 1987, at Y19, col. 2 (nat'l ed.).

208. McFadden, *Schools in New York Will Admit An AIDS Pupil But Not 3 Others*, N.Y. Times, Sept. 8, 1985, at Y1, col. 1 (nat'l ed.). See also *District 27 Community School Bd. v. Board of Educ.*, 502 N.Y.S.2d 325 (Sup. Ct. 1986) (upholding New York City's policy of determining admissibility of children with AIDS on a case-by-case basis); *Georgia AIDS Tests*, *supra* note 178.

209. ALTMAN, *supra* note 204, at 65. "Thus not only people with AIDS but large numbers of people thought to be at risk for AIDS have experienced the pariah status that AIDS is reintroducing into modern society." *Id.* See also Johnson, *Anti-AIDS Bias By Undertakers Is Ruled Illegal*, N.Y. Times, Jan. 15, 1987, at Y15, col. 6 (nat'l ed.); *Nail Salon Charged in AIDS Bias*, Tulsa World, Dec. 21, 1986, at A24, col. 1. *AIDS Case Barred By Airlines*, N.Y. Times, July 19, 1987, at Y12, col. 3 (nat'l ed.).

210. *South Florida Blood Service, Inc. v. Rasmussen*, 467 So. 2d 798, 802 (Fla. Dist. Ct. App. 1985). "AIDS is the modern day equivalent of leprosy. AIDS or a suspicion of AIDS, can lead to discrimination in employment, education, housing, and even medical treatment. If the donors' names were disclosed outside the litigation, they would be subject to this discrimination and embarrassment, even though most, if not all of the donors, would not be AIDS victims in fact, but only innocent suspected victims." *Id.*

211. Knudson, *Coloradans Are Divided Over AIDS Law*, N.Y. Times, June 15, 1987, at Y14, col.

unconsented disclosure a misdemeanor.²¹² Massachusetts requires health care providers to obtain the informed consent of patients for each release of test results, rather than allowing them to rely on the standard blanket consent.²¹³ The consent form must indicate the reason for the disclosure.²¹⁴

The difficulty in maintaining confidentiality is due in part to inconsistencies among jurisdictions and government agencies in the manner of testing, monitoring, and data collection.²¹⁵ Further, "a number of different third parties such as insurers, state agencies, and investigators of billing fraud may be authorized to review confidential information . . . [m]oreover, as computer technology rapidly advances, the technical difficulties encountered in protecting confidentiality of electronic files increase as well."²¹⁶ One way to ensure privacy and protection against misuse of test information is to not identify persons with confirmed positive test results. This is called anonymous, as opposed to confidential, testing.

The public health services generally do not engage in anonymous testing, but attempt to protect the identity of test takers through a variety of means.²¹⁷ For example, Colorado, a state that requires reporting of positive antibody test results,²¹⁸ uses confidential testing. Public health officials believe that identification of the patient is needed so that follow-up care may be provided.²¹⁹ The state does take extra care to ensure confidentiality of test results and the identity of test-takers. Colorado uses a four part form with automatic carbons. The top sheet contains the patient's name, address, sexual preference, and lifestyle activities.²²⁰

1 (nat'l ed.) (tightening mandatory reporting requirements and strengthening confidentiality protections); See also CAL. HEALTH & SAFETY CODE § 199.21 (West 1987).

212. *Special Report: Acquired Immunodeficiency Syndrome—Infection Control and Public Health Law*, 314 NEW ENG. J. MED. 931, 932 (1986).

213. *Mass. Addresses Test Result Disclosure*, AM. MED. NEWS, Sept. 12, 1986, at 28.

214. *Id.*

215. *AIDS As A Handicapping Condition*, 9 MENTAL & PHYSICAL DISABILITY REP. 402, 404 (1985).

216. *Id.* See Gore, *Labs Grapple With Issue Of AIDS Confidentiality*, CLINICAL CHEM. NEWS, Apr. 1987, at 1, 2 (noting the potential for breach of confidentiality via hospital computers).

217. ANDERSON, ARNSTEIN & LESTER, *supra* note 166, at 468. For example, some states use a special blank with a key number, the physician keeps the stub showing the patient's name and number and sends the health department the number. The "Danish" system uses initials and date of birth. *Id.* Health officials in New York City will test up to 100,000 anonymous hospital specimens in October to more accurately measure the spread of AIDS in the State. Sullivan, *New York to Test 100,000 for AIDS Anonymously*, N.Y. TIMES, Aug. 5, 1987, at Y12, col. 1 (nat'l ed.).

218. *Confidentiality Or Anonymity? Debate Over Reporting Procedures Continues*, 1 AIDS ALERT 94-97 (1986).

219. *Id.* at 94.

220. *Id.* at 95.

This sheet remains at the test site. The next two sheets contain no patient information and are used for recording laboratory information.²²¹ The last form is presealed in an envelope and sent to the state department of health after the laboratory results are recorded.²²² The state also maintains very tight security in those places where the test records are stored.²²³

California has employed anonymous screening in San Francisco.²²⁴ Each blood sample is given a number and there is no identification of the patient.²²⁵ A test result is not disclosed unless the person can produce the corresponding identification number.²²⁶ The form, however, does allow nonspecific information to be recorded such as gender, marital status, and race.²²⁷

There are several reasons to support identification of seropositive persons. First, infected persons need to be informed of their medical condition so that proper action can be taken. Second, public health officials need to trace cases of seropositivity to better stem the spread of the disease and take proper precautions to protect the general public. Third, medical researchers, especially those engaged in longitudinal studies, need to link one set of data with other epidemiological studies. This linkage cannot be performed without maintenance of identifiers, at least for the time covered by the study.

On the other hand, a major problem with mandatory confidential mass screening is that the government would have the responsibility of collecting and storing the data. The potential for misuse of this information for nonhealth purposes is great.²²⁸ This information could be used

221. *Id.* at 96.

222. *Id.*

223. *Id.* at 96-97. Security guards are at the entrance to the building; two records clerks are in the room at all times; access to the room is limited; all signs identifying the room have been removed. *Id.* at 97. During the 1987 Legislative Session, Colorado amended existing law, tightening confidentiality provisions. Knudson, *Coloradans Are Divided Over AIDS Law*, *supra* note 207.

224. *Confidentiality or Anonymity?* *supra* note 218, at 97.

225. *Id.*

226. *Id.*

227. *Id.*

228. *See Drake v. Covington County Bd. of Educ.*, 371 F. Supp 974 (M.D. Ala. 1974).

Documented cases of breaches of confidentiality have occurred, as when the CDC turned over lists of AIDS patients to public health departments and the New York Blood Center, or when a list of people undergoing treatment for AIDS symptoms was circulated among Seattle policemen. (There has been considerable argument as to whether declaring AIDS a notifiable disease requires the provision of names as distinct from the incidences of cases to public health authorities).

ALTMAN, *supra* note 204, at 80. "As with other aspects of the epidemic, the problem of how much information should be made available for research and surveillance raises difficult questions about the balance between individual rights and the public good." *Id.* at 81.

to persecute homosexuals and prosecute suspected intravenous drug users and prostitutes. No doubt there are many who would be just as fearful of placing that information in private hands even though it would be easier to sue the private agency for any improper disclosure of information. The interest of both society and seropositive persons in confidential versus anonymous testing are clearly mixed.²²⁹

Non-donor screening, at this time, appears to be of little social value.²³⁰ The use of the HIV antibody (ELISA) test or the Western Blot as screening tests in other situations could be extremely prejudicial and misleading. Setting up an acceptable program of compulsory testing would be difficult because the usefulness of the HIV antibody test (ELISA) results for purposes other than protecting the nation's blood supply is unknown.²³¹ There appears to be no evidence that testing for purposes other than blood donation (this would include testing organs for transplants and semen for artificial insemination) has had any impact on the transmission of the disease. As the coordinators of the Hastings Center's project on AIDS: Public Health and Civil Liberties, noted: "[m]ore compelling evidence than presently exists would be needed to justify such encompassing policies, which would threaten the civil liberties of the individuals being tested."²³² Mandatory screening proposals require closer examination of the test and the usefulness of such screening, and the use of the test results.

If the test does not accurately determine who is infected with HIV, then mandatory mass screening will not necessarily stem the spread of the virus because it will identify persons who are not infected and will not detect all who are infected. Arguably, screening would not be rationally related to the articulated public health goal. The use of the test in blood donor screening is arguably a non-prejudicial use with a legitimate public interest.²³³ However, there appears to be no evidence that testing for other purposes has had any impact on the transmission of the

229. Gray & Melton, *The Law and Ethics of Psychosocial Research on AIDS*, 64 NEB. L. REV. 637, 655-59 (1985).

230. Levine & Bayer, *supra* note 172, at 11; *Special Report: The Acquired Immunodeficiency Syndrome—Infection Control And Public Health Law*, *supra* note 212, at 931.

231. *Special Report: Acquired Immunodeficiency Syndrome—Infection Control and Public Health Law*, *supra* note 212, at 931.

232. Levine & Bayer, *supra* note 172, at 11.

233. The test results have proved useful, as indicated by the drop in transfusion transmitted AIDS after institution of the HTLV-III/LAV antibody test by blood banks. Bennett, *Better AIDS Screen Needed*, CLINICAL CHEM. NEWS, August, 1986, at 1 (noting that a small but significant number of infected donors are not detected by the test).

disease.²³⁴

As the number of AIDS cases continues to rise and the disease spreads rapidly into the heterosexual community, some mandatory testing is inevitable. It will not be surprising if a number of states mandate pre-natal screening since there is a great risk of a seropositive mother transmitting the virus to her child.²³⁵ In addition, because pregnancy alters the body's immune system, pregnancy in seropositive women is believed to substantially increase the mother's chances of developing full-blown AIDS.²³⁶ However, any expanded testing cannot be carried out responsibly until state and federal authorities enact laws which better protect the civil and confidentiality rights of infected individuals.

V. CONCLUSION

Application of the HIV antibody test, as originally designed and used, seems to be justified for the purpose of screening blood products. The safety of the nation's blood supply has been improved with little or no prejudicial impact on those tested. Recent proposals to expand the use of the test as a diagnostic or mass screening tool, and to use such results as the basis for restrictive or prejudicial measures, raise serious questions about the reliability of the test for these purposes. Significant numbers of innocent people who are not infected with the virus could be falsely labeled as "positive".

Since AIDS is not transmitted by casual or day to day contact, most of the proposed measures (testing of teachers, food handlers, homosexual men, public school children, health care workers) seem unwarranted. Most of these proposals appear to be a response to public (and official) hysteria, bigotry, and misinformation. For example, measures such as mandatory testing of all food handlers or all medical personnel, or the discharge of all positive persons in these categories, may not actually prevent the spread of AIDS because there has never been a documented case of AIDS being transmitted by casual contact with persons in these professions.

Some so-called "health" proposals may really be attempts to regu-

234. This opinion is shared by many health officials. Altman, *Mandatory Tests For AIDS Opposed At Health Parley*, N.Y. Times, Feb. 25, 1987, at A1, col. 4.

235. Gunan & Hardy, *Epidemiology of AIDS in Women in the United States*, 257 J. A.M.A. 2039, 2042 (1987); Wofsy, *Human Immunodeficiency Virus in Women*, 257 J. A.M.A. 2074, 2075 (1987).

236. Altman, *Need to Widen AIDS Testing Seen as Health Forum Ends*, N.Y. Times, Feb. 26, 1987, at B7, col. 1.

late or punish groups for their lifestyles or to regulate or punish businesses that cater to high risk groups. Most authorities agree that the only effective way to control the spread of the disease is by education and safe sexual practices. Although many members of high risk groups will alter their lifestyles in response to the disease, there will remain a few recalcitrant individuals who refuse to alter their behavior, and who may intentionally place others at risk. For this small group, civil, or even criminal sanctions may be appropriate.

The courts traditionally have refused to scrutinize public health decisions. Persons harmed by testing and legislative proposals will possibly have no effective legal recourse. Because this issue is so heavily laden with emotion, any abdication of responsibility by the courts can only lead to unredressable and potentially harmful results. Therefore, the courts must take a more active role in closely reviewing public health measures aimed at controlling the spread of AIDS.

Author's Note: A vaccine against HIV has been approved for clinical trials by the FDA. Several other vaccines are in the development stage. Since a vaccine causes antibody production, and since both the ELISA and Western Blot tests are designed to detect antibody, this is another potential source of false positives. *HIV Vaccine Approved for Clinical Trials*, 258 J. A.M.A. 1433-34 (1987). The article notes, "The production of . . . antibodies after inoculation will render the volunteers . . . HIV-positive by the ELISA and Western Blot tests. Thus, the consent form indicates that discrimination based on antibody positivity to HIV is a possible hazard." *Id.* at 1434.

