

Chapter 5

Public Health Techniques and Technologies

CONTENTS

	<i>P a g e</i>
American Public Health Law, 1787-1887	62
The Police Power in the Twentieth Century	62
Due Process and Police Power	62
Privacy and State Police Power	64
Modern Public Health Techniques and Technologies	66
Prevention: Innoculation and Vaccination	65
Reporting Morbidity Data	67
Screening and Testing Techniques	68
Contact Tracing	76
Social Controls: Full or Partial Quarantine	77
Treatment	82
Blood Banking	83
Public Education and Statistical Forecasting	85

Chapter 5

Public Health

Techniques and Technologies

The public health is a significant part of "the general Welfare," which the Constitution was intended to better secure. Enormous strides have been made in the medical sciences in the last two decades, in large part as a result of development of the "new biology." Medical capabilities increasingly present us, as individuals and as a society, with options far beyond our traditional understanding of rights and duties, choice and necessity, consent and obligation. This chapter deals with the use of medical science and associated technologies in government programs to protect the health of Americans. The next chapter discusses some specific medical interventions as they apply to individuals.

In public health, it is not so much new technologies and techniques that promise to raise future constitutional issues, but rather the use of old (and historically accepted) techniques and technologies that appear newly controversial in the context of modern expectations of privacy and civil liberties and modern attitudes about risk and exposure. Another factor is new scientific capability to identify risks and exposure pertaining to people who are not yet ill, or pertaining to licit behaviors such as smoking or overeating.

In some areas public expectations outstrip the ability to solve urgent problems. A high expectation of good health and an unrealistic optimism about medical capabilities may contribute to the growing problem of liability or malpractice suits against physicians and hospitals. Not all medical interventions are successful. All of the effort thrown into the study of cancer, with enormously promising results,

cannot yet assure anyone that he or she will be cured.

In public health, we are faced with a terrible epidemic at a time when people had become almost complacent about the ability of vaccines and antibiotics to deal with infectious disease. The capability to identify risks, predict the spread of disease, screen for exposure, and test for infectiousness is much greater than in historical epidemics; yet in the case of AIDS we cannot cure the disease, nor prevent it once exposure has occurred. The social frustration that this incurs may challenge us to define the limits of individual rights and the scope of our mutual obligations to society.

In dealing with such health provisions as mandatory vaccination, quarantine, housing inspections, school health, and mandatory seat belts, one is nearly always operating under State laws, based on State police power. Police power is the inherent power of governments to exercise within their jurisdictions reasonable control over persons and property in the interest of the general security, health, safety, morals, and welfare.

In public health, the Federal Government has only necessary and implied powers derived from its powers to tax and spend for the general welfare, to regulate interstate commerce, and to provide for the national defense. The States retain primary responsibility for public health policies and programs through their inherent police power. But both State and Federal Government are subject to the Bill of Rights limitations on governmental power.

AMERICAN PUBLIC HEALTH LAW, 1787-1887¹

In the colonial period, epidemics could devastate a community. Smallpox and yellow fever sometimes sickened from 30 to 50 percent of a town's population within a short time, and might kill 10 percent. Even measles could be a major disaster; Cotton Mather in 1713 lost his wife, three of his children, and a servant to measles. The effects of such infection on the Indians, who had no resistance from past exposure, were often even more cataclysmic.

Public health programs in the 17th and 18th centuries consisted of emergency measures to meet these crises. When epidemics threatened, towns often declared quarantines, posting guards at the docks and on roads leading into town. Sick people were cared for in their homes or the pest house. Town funds were provided for medical care and to feed and shelter orphans or the children of sick parents. No one questioned the right of the authorities to take whatever measures were necessary.

After the Civil War there was somewhat more disposition to question the scope and limits of police power. In 1894, the terms of

States' public health authority were laid out one by one in a Supreme Court decision:²

- The police power is very broad, and the State legislature has wide discretion to determine when and how it is used.
- Public interests must require such interference by the State; there must be a serious threat.
- The means used by the State must be "reasonably necessary" and not "unduly oppressive."
- The State must not impose "unusual and unnecessary" or "arbitrary" restrictions on persons or occupations.
- The courts will examine or supervise the legislature's exercise of police power to ensure that these conditions are met.

Until well into the twentieth century judicial decisions about public health law and practices seldom emphasized individual rights as such. They turned on questions of how the State exercised its authority, whether or not the Court perceived that the State was dealing with a serious problem, how great an intrusion the State action would be, and how strictly the authorizing statute was read. Courts generally permitted public health authorities great leeway in infringing on the freedom of an individual.

¹Dr John Duffy, Professor Emeritus of Medical History, University of Maryland, assisted in the preparation of this section of the chapter.

²*Lawton v. Steele*, 152 U.S. 133, 136-7 (1893).

THE POLICE POWER IN THE TWENTIETH CENTURY

Due Process and Police Power

The tension between the State's police power and the constitutional right to due process is central to discussions of modern public health practice. One of the most cited Supreme Court cases on public health and police power is a 1905 case, *Jacobson v. Massachusetts*.³ It involved the constitutionality of a State statute that provided a fine of \$5 for any adult refus-

ing to be vaccinated when a city board of health had decided vaccination was "necessary for the public health." The Cambridge board of health did so when a smallpox epidemic threatened in 1902. Jacobson, refusing to be vaccinated on the grounds that it was dangerous and ineffective, was tried and fined \$5. He appealed first to the Massachusetts Supreme Judicial Court and then to the U.S. Supreme Court, arguing that the vaccination law violated his Fourteenth Amendment rights to due process and equal protection of laws (the latter because

³197 U.S. 11.

under the law physicians could declare some children “unfit subjects for vaccination”).

The Supreme Court confirmed that the State legislature can enact “reasonable regulations” to protect public health and safety, and may vest this authority in local bodies like boards of health. The Court said that constitutional rights must be preserved, but it found that the Fourteenth Amendment right to “liberty” does not mean absolute freedom, and the State may restrain personal and property rights in order to secure the “general comfort, health, and prosperity of the State.” Under the “principle of self-defense, of paramount necessity, a community has the right to protect itself against an epidemic of disease.” Further, the Supreme Court would be “usurping the functions of another branch of government” if it judged the method chosen by the legislature to be unreasonable, arbitrary, or unnecessary. Vaccination was a well recognized, generally accepted means of preventing smallpox; the legislature accepted it as such, and the courts had no superior knowledge. Judicial review of a general welfare enactment, according to the Court, should be very narrow, and such a statute would be invalid only when it is “. . . beyond all question, a plain, palpable invasion of rights secured by the fundamental law. . . .”

This case is a starting point for the discussion of future cases of constitutional limitations on police power because it confirms that the legislature need not be “right” in its public health decisions; its acts need only have some “real or substantial relation” to the preservation of the public’s health—not the “best” way but a “reasonable” way. Courts are not to be the arbiters of scientific disputes.

Underlying the Court opinion was the concept of a social contract between individual and community and between State and Federal Governments. The Court said:

We are unwilling to hold it to be an element in the liberty secured by the Constitution . . . that one person . . . residing in any community and enjoying the benefits of local government, should have the power thus to dominate the majority when supported in their action by the authority of the State.

And it also said:

The safety and health of the people of Massachusetts are, in the first instance, for that Commonwealth to guard and protect. They are matters that do not ordinarily concern the Federal government.

Jacobson dealt with a real, identifiable, and familiar public health problem. But in the same 1905 term, the Supreme Court dealt with the constitutionality of a State statute concerned with occupational health and safety, in the case of *Lochner v. New York*.⁴ The statute prohibited bakery and confectionery employees from working more than 60 hours in 1 week. The Court framed the issue in this way:

Is this a fair, reasonable, and appropriate exercise of the police power of the State, or is it an unreasonable, unnecessary, and arbitrary interference with the right of the individual to his personal liberty or to enter into those contracts in relation to labor which may seem to him appropriate or necessary for the support of himself and his family?

This decision came less than 2 months after deciding *Jacobson*. The Court again recognized that it may not merely substitute its judgment for that of the legislature and strike down a law. Nevertheless the Court did not view limitation of the work day as a health or welfare issue, but as State regulation of economic relationships between two competent adults. It denied that this law was within the police power of the State, because bakers are no less able “to assert their rights and to care for themselves than members of other occupations. . . .” The “welfare, safety, and morals of the general public (were) not protected by the law” since there was no evidence that clean and wholesome bread is related to the number of hours the baker works.⁵ This case was contrasted by the Court with an earlier one upholding a law limiting the working day of underground miners and shelterers, because

⁴198 U.S. 45 (1905).

⁵The New York court in upholding the statute had concluded that there was sufficient evidence to demonstrate that the occupation of baker or confectioner was unhealthy and tended to result in diseases of the respiratory organs.

working underground was “clearly unhealthy.”⁶

These two cases, within a few months of each other, demonstrate the significance of the standards which courts use in evaluating the legislature’s exercise of the police power. Had the Court actually applied the Jacobson standard of minimal rationality and the presumption of constitutionality, *Lochner* would have been decided differently. But the vaccination law was indisputably a health law, aimed at reducing contagious disease; while in the *Lochner* case the law was not perceived as enforcing a well-recognized medical procedure. *Lochner* signaled the beginning of an era in which the Court struck down as economic regulations many statutes framed around public health goals.’

Ultimately, however, the Jacobson standard prevailed. In 1934 the Supreme Court returned to the more restrictive standard of judicial review, saying that the Due Process Clause only requires that “the law not be unreasonable, arbitrary, or capricious and that the means selected shall have a real and substantial relation to the object sought to be attained.”⁸

⁶*Holden v. Hardy*, 169 U.S. 366 (1898); the Court found ‘that given the dangers of working underground, the deprivation of fresh air and sunlight, and being frequently subjected to foul air, the law was a proper exercise of police power, designed to protect the health of miners. It also recognized that the State could reasonably conclude that workers needed protection because the owners and workers do not have equal bargaining power.’

⁷In *Adkins v. Children’s Hospital*, 261 U.S. 525 (1923), ‘the Court struck down a law which established a minimum wage for women and children, the explicit purpose of which was to protect them from “conditions detrimental to their health and morals, resulting from wages which are inadequate to maintain decent standards of living.” The Court claimed the law was arbitrary, that the “relationship between earning and morals is not capable of standardization,” and that the law did not take into account the fact that different people need different amounts of money to maintain a minimum acceptable standard of living.’

⁸*Nebbia v. New York*, 291 U.S. 505 (1934). The Court upheld a New York statute establishing a board to determine the maximum and minimum prices retailers could charge for milk. Three years later the Court upheld a minimum wage law for women. The judicial policy of examining the substance of the law under the umbrella of the Constitution’s Due Process Clause, and “second guessing” the legislature as to its efficacy, is called “substantive due process.” It is to be distinguished from “procedural due process,” in which the Court asks whether a law affects people in an arbitrary, discriminatory, or irrational manner. In recent years, the Court has returned to the doctrine of substantive due process in emphasizing fundamental individual rights.

A modern court in a police power case still will not generally evaluate arguments as to the scientific soundness of the exercise of police power. For example, the Court ruled in 1955 on the constitutionality of State laws regulating the fitting and sale of eyeglasses.⁹ Opticians were prohibited from placing an old lens in a new frame or from reproducing a broken lens without a prescription. A trial court struck down this law, holding that the requirements were not ‘reasonably and rationally related to the health and welfare of the people.’ But the Supreme Court reversed, on the grounds that the legislature might have concluded that eye examinations were so important “for the detection of latent ailments” as to justify their requirement on all possible occasions. Said the Court:

The day is gone when this Court uses the Due Process Clause of the Fourteenth Amendment to strike down State laws, regulatory of business and industrial conditions, because they may be unwise, improvident, or out of harmony with a particular school of thought.

In summary, the courts will generally be inclined to accept as constitutional public health actions that appear to be reasonably related to preservation of the health of the population without attempting to determine independently the scientific validity and efficacy of the measures taken. Nevertheless, this remains an area where the scope of individual rights and presumed limitations on state power appear to be constantly subject to challenge.

Privacy and State Police Power

The evolution of the concept of privacy as a constitutional right was traced in the first chapter. The case of *Buck v. Bell*, the 1926 case upholding the right of the State to sterilize inmates of State mental institutions, was described in chapter 3 and illustrates both the deference to State interests and the lack of acknowledgment for privacy rights that were the rule until recent decades. Fifteen years after that case, the Court struck down a State statute providing for compulsory sterilization of

⁹*Williamson v. Lee Optical* (70, 348 U.S. 483 (1955).

"habitual criminals," using the Equal Protection Clause of the Fourteenth Amendment, but also affirming that marriage and procreation were fundamental rights.¹⁰

The right of privacy has repeatedly been used by the Courts since 1965 to protect the individual's right to make decisions about marital, reproductive, and family matters. State supreme courts have extended this right to cover individuals refusing life-sustaining medical care,¹¹ refusal to take anti-psychotic medi-

cation,¹² and obtaining acupuncture treatments." But the Supreme Court specifically refused to extend this right to cover consensual sodomy.¹⁴ It is thus uncertain how this right might be applied in future issues related to public health techniques and technologies.

¹⁰*Skinner v. Oklahoma*, 316 U.S. 535 (1942).

¹¹*In re Karen Quinlan*, 355 A.2d 647 (N. J., 1976); *Superintendent of Belchertown v. Saikewicz*, 373 Mass. 728 (1977).

¹²*Rogers v. Okin*, 821 F.2d 22 (Neb., 1987).

¹³*Andrews v. Ballard*, 498 F. Supp. (S.D. Texas, 1980).

¹⁴*Bowers v. Hardwick*, 106 S.Ct. 2841 (1986). Although the challenge was brought by a homosexual male, the challenged statute was written to apply to heterosexual or homosexual behavior, by married or single persons.

MODERN PUBLIC HEALTH TECHNIQUES AND TECHNOLOGIES

In the extended discussion that follows, frequent reference will be made to the current epidemic of acquired immunodeficiency syndrome (AIDS). Many of the traditional public health techniques are being used in this epidemic, but in a social, political, and legal framework that has radically changed in recent decades. New scientific knowledge and capabilities are also providing new approaches—although not as many or as rapidly as society had hoped—and these by definition may raise new constitutional issues.

AIDS is not like most of the severe epidemics associated with the origins of public health programs in the United States. It appeared suddenly, but it is not episodic as were yellow fever, Asiatic cholera, or influenza. It can have a very long incubation, it has a very low infectivity, and it cannot spread by casual contact. There do not appear to be any factors calling for engineering or environmental remedies, which have been major factors in control of past epidemics.

Yet AIDS does represent the working of some traditional Public Health techniques and technologies that need to be examined further for their constitutional implications; and more pertinently, AIDS also demonstrates the public health applications of some new developments in biology.

The problems raised by the AIDS epidemic are not intrinsically new. Larger numbers of people die every year from other single causes, including the effects of smoking.¹⁵ But the problems raised by AIDS are so severe and acute as to revive old and neglected issues of public health and civil liberties, to emphasize structural problems in the capability to respond to civil emergencies, and to stress weak points in our social fabric. The problems throw into sharp relief the potential conflict between constitutional principles of individual rights and protection of the general welfare. The resolution of AIDS problems, if done humanely and with full attention to both fundamental freedoms and the protection of the general welfare, may stand us in good stead in the future in other contexts.

Prevention: Inoculation and Vaccination

The major medical innovation during the colonial period was smallpox inoculation, introduced in Boston in 1721, but already an old practice.¹⁶ In the colonies it was denounced

¹⁵Smoking was officially blamed for 350,000 deaths in 1985, 100 times the number of AIDS deaths in the same year, as pointed out by William Pollin, "Drug Abuse, U. S.A.," *Issues in Science and Technology*, Winter 1987, p. 24.

¹⁶In inoculation, matter from pustules in an active smallpox case was inserted under the skin of a healthy person who thereby,

(continued on next page)

by some physicians as too dangerous, and by many ministers as an attempt to evade God's punishment for immorality. But because of its obvious value, inoculation was an accepted practice by the time of the Revolution.

The success of inoculation in reducing the toll from smallpox prepared the way for vaccination, introduced by Jenner in 1798.¹⁷ Vaccination won immediate acceptance, and the incidence of smallpox fell sharply during the next 30 years. By the 1830s, a generation that had never known a smallpox epidemic saw little reason to be vaccinated, and there was a steady rise in smallpox until about the 1870s. After the Civil War, health officials began urging compulsory vaccination of school children and mass vaccination of adults during outbreaks. In spite of a strong anti-vaccination movement, joined by a few doctors alarmed by infections arising from vaccination within-needles, the movement succeeded in most States.¹⁸

When there is strong public awareness of the possibility of epidemics, most people can compare the risk of taking the vaccine against the clear and present risk of the disease, and can thus appreciate the value of vaccination. As immunization programs succeed and the acute disease threat disappears, the benefit to the individual is less well perceived. The benefit accrues to the community at large. Any risks or undesirable side-effects of a vaccine which become known are therefore apt to stimulate resistance.

Of all infectious human diseases for which a vaccine has been developed, only smallpox has been eradicated; the rest are merely held at bay. In Britain and in Japan, whooping

cough reemerged as an epidemic disease when the use of pertussis vaccine diminished during the 1970s because of public alarm about rare side-effects.

Nevertheless, vaccination remains a primary tool of public health. Because it was one of the earliest tools for protecting public health, its use is well established in law and judicial precedents. At present, there is no vaccine against AIDS, although several are being tested. Should a vaccine be developed, there would almost certainly not be a mandatory program of vaccination for the general population, since the risk of AIDS is concentrated in certain age groups and even more narrowly in specific behavior-defined populations.

Mandatory vaccination laws for more general infectious diseases would however almost certainly be sustained. The presumption on the part of the courts would continue to be that vaccine programs are a "reasonable" public health strategy.

Although physicians have generally welcomed vaccines, local medical societies have often opposed free vaccination for lower income groups by public health departments, unless there is a life-threatening epidemic or the threat of one.¹⁹ A possible constitutional issue is the assertion of the right to a vaccine when one is available for a disease perceived as highly threatening. But as discussed in the following chapter, courts have so far consistently maintained that there is no constitutional right to medical treatment and government has no constitutional obligation to make it available.

(continued from previous page)

usually, acquired immunity. The immunity came from antibodies produced in response to this small scale invasion of disease organisms, but the response was not understood at the time.

¹⁷Vaccination is the use of dead or attenuated viruses from cows inoculated with cowpox to produce immunity to smallpox in humans.

¹⁸Such waves of popular opposition have been associated with other public health innovations, such as fluoridation of water supplies; they are sometimes attacked as hazardous or even as plots by internal or external enemies to poison the citizenry.

¹⁹Despite the great attention to vaccines as a result of AIDS, the U.S. capability to develop vaccines for new or newly epidemic diseases is in general weak. Almost all vaccines have a sole manufacturer or a very few possible manufacturers. There is no governmental capability for vaccine production. Vaccines are relatively unprofitable and product liability is a strong disincentive to potential developers. The United States is the only country in the industrialized world where vaccine manufacture is unprotected from litigation regardless of compliance with manufacturing regulations, according to Dr. June Osborn, Dean of the School of Public Health, University of Michigan.

Reporting Morbidity Data

The first necessity in controlling epidemics is to recognize them early. Thus it is mandatory for physicians to report certain infectious diseases. Historically, there has been little connection between the diseases which cause the greatest morbidity and mortality and those which arouse the greatest public fear or attention. The two diseases that most worried the public in the 19th century were yellow fever and Asiatic cholera—deadly, erratic and unfamiliar. To Americans these epidemics seemed to be malignant forces that struck mysteriously and vanished almost as strangely. Such diseases always awaken more public fear and stronger public actions than diseases that may exact a far higher toll but do so consistently rather than episodically, and hence become familiar conditions of life. The disorders that were steadily and consistently responsible for the most sickness were malaria and respiratory infections. They were regarded as inevitable, much as we tend to regard high death rates from automobile accidents.

The chief killer disease of the 19th century was tuberculosis. Yet in the early 19th century it was regarded as a romantic disease, as pictured in *La Boheme* or *Camille*. Later in the century it was considered a natural disorder about which little could be done. Most insurance policies did not insure against death from tuberculosis; hence the family received no burial money and the doctor might not get paid. Therefore tuberculosis deaths were often recorded under other headings. When health departments at the end of the century began ordering physicians to report cases of tuberculosis, the medical profession rose up in arms. The New York City Health Department, making tuberculosis a reportable disease in 1897, found itself opposed by the New York Academy of Medicine, the County Medical Society, and most medical journals. The medical societies went to the State legislature in an attempt to limit the powers of the board of health.

Venereal disease has always been under-reported by physicians. In 1882 the American Public Health Association rejected a resolu-

tion to make venereal disease reportable on the grounds that it would bring disapprobation on the association. In 1892 the New York Academy of Medicine dismissed a similar resolution on the same grounds. A New Orleans physician writing in a medical journal in 1920 called proposals to require reporting of venereal disease “socialist tommy-rot” that would “undermine the morals of the American people.”

Since then, a wide array of mandatory reporting statutes, such as for venereal disease, have been considered necessary and permissible. Laws requiring mandatory reporting by physicians or health care facilities of the names and other information about people who have been infected receive great impetus from advances in the ability to acquire, store, and disseminate such information using computers.²⁰ In this decade, however, mandatory reporting laws have again become highly controversial in regard to abortion, drug use, and AIDS.

The Supreme Court has addressed the issue of mandated release of medical information to the State by the physician on several recent occasions. One example concerns New York State’s Controlled Substances Act of 1972, which requires reporting by physicians of prescriptions for certain drugs.” Public disclosure of the identity of the patients is prohibited and punishable by one year imprisonment and a \$2000 fine. In spite of this, the Federal District Court found the law to be unconstitutional, as intruding too broadly into the doctor-patient relationship, part of the “zone of privacy” accorded constitutional protection. But the Supreme Court reversed, finding the requirement was a reasonable exercise of police powers, and that there was no violation of privacy interests.²²

²⁰ Material in this section is drawn largely from “Constitutional Implications of Scientific and Technological Advances in Public Health,” prepared for OTA by Dr. Leonard H. Glantz, Professor of Health Law, Boston University Schools of Medicine and Public Health.

²¹ Information about the physician, the drug and dosage, and the name, address, and age of the patient is sent to the computer of the State Department of Public Health. Only 17 departmental employees have access to the information.

²² *Whalen v. Roe*, 429 U.S. 589 (1977).

It had been argued without avail that the constitutional right of privacy encompasses two distinct interests; the individual interest in avoiding disclosure of personal information, and the freedom to make certain kinds of important decisions without State interference; and that both interests were violated by the law. Knowing that the State would receive this information would make doctors reluctant to prescribe, and patients reluctant to use, certain medication.

Justice Brennan, in his concurring opinion, specifically recognized that new technology may require the Court to address this issue again:

The central storage and easy accessibility of computerized data vastly increase the potential for abuse of that information, and I am not prepared to say that future developments will not demonstrate the necessity of some curb on such technology.

Another case in 1976 involved the reporting requirement of a State abortion law,

... the purpose of which shall be the preservation of maternal health and life by adding to the sum of medical knowledge through the compilation of relevant maternal health and life data. ... 23

The statute stated that the information must be confidential, must be used only for statistical purposes, but must be available for inspection by local, State, or national health officers. The Court also upheld the constitutionality of this provision, finding that it is useful in protecting the health of female citizens, and may be a resource for future medical decisions. Given these realistic goals, the guarantee of confidentiality, and the fact that the reporting has no legally significant impact on the abortion decision or on the physician-patient relationship, the Court found no constitutional violation, but it did suggest that the law approaches "impermissible limits." This decision was especially significant because of the close scrutiny that the Court gives all legislation regulating abortion.

²³*Planned Parenthood of Missouri v. Danforth*, 428 U.S. 52, 70 (1976).

Ten years later the Supreme Court invalidated a Pennsylvania abortion reporting requirement which called for very detailed reporting,²⁴ available for public inspection and copying (in a form that would not bear the identification of the person filing the report). The Court struck this down on the grounds that: 1) many of the details were unrelated to health interests, 2) the records could be inspected by anyone, which indicated to the Court that the legislature had some purpose in mind other than protecting the public's health; 3) even though the woman's name was not listed there were enough data that identification became "likely," and may have been the "obvious purpose of these extreme reporting requirements." The Court said that the law would have a chilling effect on the exercise of a constitutional right.

Given the fact that public disclosure about having AIDS or being an AIDS carrier could have a devastating effect on an individual, it is reasonable to surmise that the Court may give as much scrutiny to State AIDS reporting requirements, if challenged, as to an abortion reporting requirement. The State would have the burden of proving the public health need and showing adequate privacy safeguards. In such circumstances the interests of the State in learning the extent and distribution of the disease would have to be balanced against the individual's concern for privacy. However, the balance could be struck differently in the case of AIDS than in the abortion example, because of the risk to the population at large.

Screening and Testing Techniques²⁵

Mandatory testing or screening of large populations or specific categories of people has

²⁴*Thornburgh v. American College of Obstetricians* 106 S. Ct. 2169 (1986). Reporting requirements included the identification of the referring and primary physicians and the name of the facility or agency; the woman's political subdivision, age, residence, race, marital status, number of previous pregnancies; the basis for determination that the fetus was not viable; the method of payment; and other information. The report was to be signed by the attending physician.

²⁵Material in this section was prepared for OTA by: Dr. Sheila Jasanoff, Cornell University Program in Science, Technology, and Society; Dr. June Osborn, Dean of the School of

(continued on next page)

been done or has been considered for purposes of detecting hereditary disease (primarily in the case of newborn infants, where early treatment is effective), for control of infectious disease, and for detecting drug abuse.

The constitutionality of data collection will depend on a variety of factors, including the purpose for which information is obtained. Thus questions of obtaining information cannot be wholly separated from questions of use, which might be, for example, to document the spread of the disease. Courts have not been reluctant to sustain a requirement that public school students undergo an annual physical examination²⁶ or that couples seeking marriage licenses submit to tests for venereal disease.²⁷ Nevertheless, some features of the testing process, whether for hereditary disease, infectious disease, or law enforcement, may raise constitutional problems regardless of the uses to which the State puts the information being collected.

Screening for Hereditary Disease

Mass screening has been undertaken in this country in the past primarily for the purpose of identifying individuals at special risk of producing genetically damaged offspring. Such programs were initiated during the 1970s for Tay-Sachs disease and sickle cell anemia. Both programs focused on ethnic minorities with which those diseases are uniquely associated. The former aroused less concern because it was carried out largely without legislative requirements.²⁸ By contrast, laws mandating screening for sickle cell disease (associated with people of African descent) were passed in many States in the early 1970s. In 1972 Congress enacted the National Sickle Cell Anemia Control Act, which allocated \$115 million over 3

years for a program of screening, counseling and education.²⁹

Following initial support from the Black community, these sickle cell initiatives later came under fire. Black leaders questioned the propriety of the legislative focus on sickle cell anemia when there are so many other important causes of illness among Blacks.³⁰ Some critics said that sickle cell screening increased the potential for stigmatizing a particular minority group and could reinforce latent feelings of racism. A few saw the overt tie-in between screening and marriage-licensing laws in several States as particularly sinister. In the words of one Black activist, such a connection represented "the entering wedge for governmental involvement in genetic criteria for procreation."³¹

Similar concerns are reported to have troubled some leaders of the gay community in the early days of the AIDS epidemic; fearing that association of gays with an epidemic disease would intensify discrimination against them, some leaders resisted early efforts at public education about the ways in which the disease was transmitted.³² Such concerns suggest that whenever mandatory screening programs are limited to identifiable minorities, there may be perceptions of conflicts between the State's interest in public health and the constitutional goal of equal protection. If testing is limited to discrete subgroups, then the burden on the State to justify it should be especially high.

Mandatory screening for heritable traits or biological susceptibilities thus raises issues of due process, unreasonable search and seizure, and privacy. The legitimacy of such programs

(continued from previous page)

Public Health, University of Michigan; and Dr. Leonard Glantz, Professor of Health Law, Boston University Schools of Medicine and Public Health.

²⁶*Streich v. Board of Education*, 34 S.D.169 (1914).

²⁷*Peterson v. Widule*, 157 Wis. 641 (1914).

²⁸Madeleine J. Goodman and Lenn E. Goodman, "The Overselling of Genetic Anxiety," *Hastings Center Report*, October 1982, pp. 20-21.

²⁹Aubrey Milunsky and George J. Annas, *Genetics and the Law* (New York, NY: Plenum Press, 1976), p. 174.

³⁰Lawrence E. Gary, "The Sickle Cell Controversy," in Adela S. Baer (ed.), *Heredity and Society*, 2nd ed. (New York, NY: Macmillan), pp. 363-364. Sickle cell anemia is almost exclusively found in those of Black African ancestry. About 10 to 13 percent of American Blacks carry the trait (which is recessive); about 3 percent have the disease.

³¹*Ibid.*, p. 366.

³²Randy Shilts, *And the Band Played On: Politics, People, and the AIDS Epidemic* (New York, NY: St. Martin's Press, 1987), pp. 52-103.

will turn to a large extent on the nature of the State's interest in acquiring information.

Mandatory Drug Testing

Drug testing programs have been adopted by numerous State and Federal agencies, and have given rise to a number of court cases. In regard to the constitutionality of various forms or programs of drug testing, very little is certain and challenges are likely to continue, at least until the Supreme Court decides two cases scheduled to come before it in the 1988-89 term. One of these cases involves Federal workers, and one involves railroad employees.

In the future, the "new biology" is likely to lead to development of many drugs that are related to, and closely resemble, naturally occurring bodily substances such as opiates in the brain. Some of these new drugs maybe subject to abuse; that is, may have socially undesirable effects. It maybe particularly hard to test for such drugs; and to distinguish them from the naturally occurring substances that people may have in widely varying quantities. Their detection might require tests that are even more intrusive than urine analysis, which many people find highly objectionable. Thus drug testing issues are unlikely to be resolved completely and for all time.

In considering the constitutional implications of drug testing it is necessary to distinguish carefully between what can be done by government with regard to the public or some categories of the public; what can be done by government with regard to its employees; and what can be done by non-government employers with regard to their employees.

In terms of government drug testing in the interest of general law enforcement—testing members of the general public to detect violations of the laws limiting use of controlled substances—the constitutional question is whether or when drug testing by government officials is "an unreasonable search and seizure," under the Fourth Amendment. At least one judge has argued that one "cannot retain a privacy interest in a waste product . . . "3³ but the

³³Judge Nebeker, concurring, *Turner v. Fraternal Order of Police*, 500 A.2d.1000 (D.C.App.1985).

weight of authority runs counter to this. Courts have held that one does have an interest in avoiding the mandatory testing of urine or blood and also in the information contained in bodily fluids,³⁴ although that individual interest may be inferior to a State interest. One court has said,

Drug testing is a form of surveillance, albeit a technological one. Nonetheless, it reports on a person's activities just as surely as if someone had been present and watching. It is George Orwell's "Big Brother" society come to life.³⁵

But the Constitution has been found in general not to prohibit such bodily intrusions as compelled vaccination, blood tests or urinalysis where the government provides sufficient justification and evidence of procedural regularity. For example, in *Schmerber v. California* in 1966,³⁶ the Supreme Court upheld the performance in a hospital of a blood test for alcohol content performed on an automobile crash victim, without a warrant. It has long been established that a State interest in health and safety may justify testing programs that intrude to some degree on individual liberty and privacy. The use of roadblocks and alcohol tests to deter drunk driving has been ruled constitutional.³⁷ Courts have traditionally considered that here the gravity of the public interest outweighs the intrusion into personal liberty, particularly in view of the effectiveness of the testing program.

And in *Shoemaker v. Handle* (1986)³⁸ breathalyzer and urinalysis tests of race horse jockeys were deemed constitutional in view of the procedural safeguards built into the process and the fact that testing occurred in the context of a closely regulated industry.

The ordinary individual as citizen (rather than employee) enjoys a significantly higher expectation of privacy. Courts are certain to be cautious in assessing the legitimacy of gen-

³⁴*McDonell v. Hunter*, 612 F. Supp. 1122 (D. Iowa 1985); *Capua v. City of Plainfield*, 1 IER Cases 625 (U.S. Dist. Ct., N.J. 1986).

³⁵*Capua v. City of Plainfield*, at 626.

³⁶384 U.S. 757 (1966).

³⁷*State v. Superior Court in and for County of Pima*, 691 P.2d 1073 (Ariz., 1984).

³⁸795 F.2d 1136 (3 Cir.1986).

eralized screening programs. In order to overcome these barriers, the government would have to present an extremely strong showing of need.

When government *as employer* proposes to test its employees for drug use, it must still observe constitutional safeguards. Here one must distinguish between drug testing when there is probable cause for suspicion, completely random testing, and mass testing of all employees.

Recent cases have struck down the mass testing of both Federal and municipal employees for drug abuse on the ground that the circumstances did not justify dispensing with the Fourth Amendment's requirement that searches and seizures should be based on individualized suspicion. The most recent Federal precedent is a permanent injunction granted by a U.S. District Court judge in July 1988 to prevent random urine testing of employees of the U.S. Department of Justice. The judge said that because there was no evidence of a drug problem in the Department there was no justification for infringing on the constitutional rights of "trusted and apparently law-abiding employees." ³⁹ In a case involving municipal workers, another court noted that the city's testing program for fire fighters was overly broad in that it would collect information that bore no relation to the government's interest in preventing illegal drug abuse. ⁴⁰

Courts have also stressed the need for appropriate procedures to protect the employees' legitimate expectation of privacy against such administrative searches. One court has even held that a public employee who at the time he is hired signs a consent to be tested cannot be held to that consent because "advance consent to future unreasonable searches is not a reasonable condition of employment." ⁴¹

On the other hand, there is much disagreement among courts on these points. In June

1988, the Third Circuit U.S. Court of Appeals upheld a program subjecting municipal police officers to random urinalysis done in the course of an annual physical examination, yet a month earlier the Sixth Circuit U.S. Court of Appeals struck down a program of compulsory drug testing of firefighters and police officers, saying the intrusion on their privacy was not justified. ⁴²

The courts have banned only "random" drug testing programs. The courts agree that if a public employer has "reasonable cause" or "reasonable suspicion" that a person's job performance is presently impaired by the use of drugs, a drug test maybe required. Thus when public employees were discovered smoking marijuana on the job, it was held that the employer could require testing. ⁴³ Certain public employees such as police have been held to have a lesser expectation of privacy due to their "paramilitary nature"; and a search may be conducted without a warrant, or "probable cause" if there is some objective basis for the search. ⁴⁴

The U.S. Supreme Court has held that "facilitative searches" such as those conducted by fire marshals and building inspectors can be done without the need for "probable cause" or "reasonable suspicion, if they comply with a reasonable administrative plan and are based on neutral criteria. Thus some experts believe that random drug testing will be upheld if governments use a plan that does not discriminate and if there is legislation authorizing such testing, with appropriate safeguards. ⁴⁵

³⁹*Policeman's Benevolent Association of New Jersey v. Washington Township*, CA 3, No. 87-5793, June 21, 1988; *Lovorn v. Chattanooga*, CA 6, No. 86-6281, May 23, 1988.

⁴⁰*Allen v. City of Marietta*, 601 F. Supp. 482 (M = N.D. GA. 1985).

⁴¹*Turner*, p.10008. The Fourth Amendment and the Due Process Clause are flexibly applied. The strictness which both are applied is related to the reasonable expectations of the person claiming protection and the nature of the interest at stake. Thus one court held that jockeys may be subjected to random drug testing because of the long history of testing in that occupation and because of the pervasive way the racing industry is regulated. (*Shoemaker v. Handel*, 795 F.2nd 1136 (3rd Cir. 1986).

⁴²See, for example, a letter to the Editor of the *New York Times*, June 18, 1987, from John F. Banzhaf, 3rd, Professor of Law and Legal Activism, The George Washington University.

³⁹Ruth Marcus, "Drug Tests Blocked for Justice Workers," *Washington Post*, July 30, 1988, p. A1.

⁴⁰*Capua v. City of Plainfield*, ITER Cases 625 (U.S. Dist. Ct., N. J., 1986).

⁴¹*McDonell v. Hunter*, 612 F. Supp.1 122, (D. Iowa 1985).

Another issue was raised in a recent case before the U.S. Court of Appeals for the District of Columbia, involving the testing of school bus drivers and attendants as part of an annual required physical examination. The Court said that such tests were permissible, but also said that the test must detect current impairment, not merely past use, in order to justify occupational restriction.⁴⁶

The use of illicit drugs in the workplace has prompted private sector employers to begin or to consider urine screening programs. They may be motivated by concern for safety in the workplace, safety in facilities and transportation systems used by the public, the productivity of workers, or the general health and welfare of workers. The question is often raised as to whether employers have a right to know or to restrict what is done in the employee's off-the-job time, so long as it has not been shown to affect their performance.

Debate about drug testing is complicated by the multiplicity of drugs at issue, the complication of cross-reacting innocent compounds that can trigger false-positive test results, the practical problem of ascertaining whose urine is being tested, and questions about the frequency of testing. The cost of testing is fairly high, especially if confirmatory testing is used, as it should be. How frequently testing should be done is another question that can be decided only arbitrarily.

Questions about scientific validity play a significant part in decisions concerning the permissibility of mass screening programs. The more accurate and reliable the test, and the lower the degree of unavoidable error, the more likely it is to pass judicial scrutiny. The false positive rates associated with some widely used drug screening tests, for example, are unacceptably high to many experts. For example, the radio-immunoassay screening of blood may yield a false positive rate of as much as 43 percent for cocaine, while the enzyme multiplied immunoassay technique of urinalysis may have a false positive rate as high as 10

percent." Because of the potential for stigmatization and legal misuse, such error rates are likely to make judges wary about declaring mass testing programs to be lawful.

Use of drugs is clearly a health hazard. Health professionals treat addicts as sick people, and the Supreme Court has held that drug addiction is a disease or "status" for which people cannot be punished, as opposed to an act or behavior (e.g., possessing or selling drugs) for which they could be punished.⁴⁸ Advocates of mandatory drug testing use public health language ("an epidemic of drug abuse"). They also cite the danger to others, for example, coworkers in factories or passengers on trains and airplanes, to justify strong public health measures. However, mandatory drug testing is aimed at detecting only illegal drugs, although the use of some legal drugs, such as tranquilizers, might also result in some impairment of performance. In fact, drug testing does not determine whether one is presently *impaired* but detects past use of a drug. Effects of the drug may not have overlapped the workday at all. Because of these factors, courts have looked closely at random drug testing—i.e., testing where there is no probable cause to suspect illegal behavior on the part of a given person—and for the most part have struck down such provisions.

People not trained in law often forget that the Constitution provides limitations on government only; that constitutional provisions do not protect them against actions by private citizens; and that only when Congress has passed laws embodying those constitutional principles do they have an effect in the private sector.

Thus it surprises some citizens to learn that public employees may, because the government is their employer, have some constitutional rights in the workplace that private company employees do not enjoy. Private sector employees must depend on State or Federal

⁴⁶ *Jones v. McKenzie*, 85-01624, Nov. 17, 1987.

⁴⁷ Morris J. Panner and Nicholas A. Christakis, "The Limits of Science in On-the-Job Drug Screening," *Hastings Center Report*, December 1986, n. 8.

⁴⁸ *Robinson v. California*, 380 U.S. 660 (1962).

privacy statutes or individual contractual bargaining agreements with employers; they have no constitutional rights to their job or to privacy as a condition of employment.

Diagnostic Testing for Infectious Disease

Diagnostic testing to determine who has a disease is usually looked on as beneficial for the patient, who can then begin treatment, and for the community, since steps can be taken to reduce the transmission of a disease. The exception comes when there is no curative treatment to be given, when available control measures may infringe on the patient's freedom, and when the testing creates an information file that is viewed as a threat of further infringement or discriminatory actions in the future.

Within less than 3 years of the first reported description of the clinical disease AIDS in 1981, three laboratories had independently isolated and identified the virus, HIV, that is the causative agent of AIDS.⁴⁹ This gave immediate hope of developing a test to identify infected individuals. Laboratory work then established the usefulness of a particular cell line to grow the virus to high concentrations in tissue culture and allow it to be purified and concentrated. That in turn facilitated the production of the large quantities of virus needed to serve as diagnostic antigen,⁵⁰ suitable for

⁴⁹Some critics maintain that this could have been accomplished as much as 2 years earlier had there been appropriate funding and attention when the existence of the epidemic was first discovered. For a critical account of the process, see Randy Shilts, *And the Band Played On* (New York: St. Martin's Press, 1987). There was competition between research scientists to discover the infectious agent, and acrimonious dispute over the allocation of credit for the discovery. Three groups of scientists used their own terminology in naming the virus. This contributed to serious confusions in discussion even within the scientific community. The terminologic dispute created problems for persons concerned with the critical task of educating the public about the new virus and its risks. For that reason an international committee of virologist was assembled and proposed a uniform nomenclature. The virus was named *human immunodeficiency virus* or HIV. As new relatives of that virus are uncovered by further research, they are referred to as HIV-2, HIV-3, etc. J. Coffin, A. Haase, J.A. Levy, et al., "Human Immunodeficiency Viruses," *Science* 232: 697, 1986.

⁵⁰An *antigen* is a protein or carbohydrate substance—a toxin, enzyme, or the jacket of a virus—that when introduced into the human body stimulates that body to produce *antibodies*, or substances whose function is to combine with the antigen and neu-

recognition of human antibody responses to HIV.

All viruses contain a number of different proteins or antigens that can stimulate the immune response. Antibodies to HIV usually appear during the first 4 to 8 weeks after infection and nearly always within 3 months, and usually persist indefinitely. There are several variations of the screening test for HIV.

The development of diagnostic AIDS tests was accomplished within a few months by several U.S. firms. Most of the tests are variations of what is called an ELISA test. The initials stand for enzyme-linked immunosorbent assay. The virtue of the test lies in its easy readability, using techniques and equipment thoroughly familiar to blood banks and clinical laboratories. Other variations such as indirect immunofluorescence or radioimmuno-precipitation have been developed, but their principles are similar. All blood and plasma donations to U.S. blood banks have since 1985 been routinely screened for AIDS. Testing of individuals can be done by private physicians or in special or general clinics and laboratories. Protection of the confidentiality and integrity of this data, most of which is probably computerized, has raised many concerns.

Media coverage of the race to develop an antibody test was extensive. Nevertheless public confusion over the terms sensitivity and specificity led to a widespread false impression that the tests were not reliable. This residual public unease is confounded with very different problems of the uncertainty of clinical diagnosis and prognosis.⁵¹

Any biological phenomenon has "outliers"—i.e., variations extend across a broad range, with some unusual examples that are far from the mean or average. When a disease detection test is developed, it can be made highly *sensitive*, in order to pick up even the outliers

tralize, agglutinate, or precipitate it, rendering it harmless. This is the primary means by which the body protects itself from disease.

⁵¹*Diagnosis* is identifying a disease from its signs or symptoms. *Prognosis* is predicting the course of the disease, the likelihood of recovery, or the duration of survival in a specific case.

or unusual cases, but then it will also pick up some false signals. If the goal is accuracy, or specificity—i.e., no false positives—then the outlier cases or signals must be ignored or allowed to escape. The majority of cases, falling near the mean, will be clearly recognized, but there will be some false negatives.

When the antibody test for HIV was developed, it was purposely designed to provide maximum protection of the blood bank supply, and therefore was made especially sensitive. Here, it was clearly best to err on the side of being too careful, at the cost of a substantial number of false positives. Unfortunately, some press reporters interpreted this as a sign of a poor test, when in fact it was a necessary accompaniment of appropriate caution.

The false positives made it necessary to have a confirmatory test, or supplemental procedure, to be sure that a positive reaction in the ELISA test was in fact an indication of infection with HIV. The first supplemental test was called the “Western Blot,” and identified antibodies to specific proteins of HIV, thus giving a detailed picture of the immune response reflected in the patient’s blood serum. This has been replaced in some laboratories by other supplemental tests, but they operate on the same general principle. At present, the state of the art allows both sensitivity and specificity of greater than 99 percent for the ELISA test, which already compares favorably with any clinical laboratory test in medical use, and supplemental tests permit very reliable identification of infected individuals when done properly. Recently, questions have been raised about the accuracy of the Western Blot. Many commercial laboratories are apparently unfamiliar with and possibly unskilled in using it, and there is no standard for its interpretation.

Some experts hope for a generically different supplementary diagnostic test: one that would allow recognition of the antigen rather than the antibody in test material. The hope is that it might be possible chemically to identify virus proteins in blood and tissue samples with a greater sensitivity than that of antibody

detection.⁵² This would be of great merit chiefly because in the interval early in infection, the antibody has not had time to develop, and a person tested during that time may be falsely reassured, and may inadvertently infect other people as a result. However, the benefit of an antigen test maybe counterbalanced by a large number of false negatives, since HIV can exist solely as integrated DNA in host cells, without any antigen expression. Thus failure to detect viral antigen would not necessarily mean the absence of infection.

Present AIDS tests are moderately expensive and time-consuming, and require trained laboratory personnel. Confidential testing is offered by many physicians and clinics, but there may be long waits, and there is much variability in the adequacy of the counseling that is offered. There have been no “home test kits,” or tests that give fast results, but a home test kit is expected to be on the market within a few months. If fast, inexpensive, and highly accurate tests are developed, some of the purely technical restraints on mass screening will fade. However, medical and public health experts, persons with AIDS, and care-givers stress the importance of linking testing to supportive counseling. This is important both for the good of the infected, and to maximize the likelihood that these people will take care to avoid infecting others. The possibility of “on-the-spot” or home testing is likely to further erode that link to counseling. In the meanwhile, the question is whether large scale mandatory testing programs should be undertaken now.

In early 1988 researchers at CDC announced a technique called PCR (for polymerase chain reaction) or DNA amplification, which identifies proviral sequences of HIV-I in the DNA of blood cells of people who are infected. This method may make it possible to obtain test results within 3 days. CDC currently speaks cautiously of the “potential utility of the PCR

⁵²It is already possible in specialized laboratories to grow HIV itself from white blood cells of persons with HIV antibody, with a success of over 60 percent on a single try, but this is unwieldy and expensive. Also, antigen is usually not recoverable from Ab-positive persons.

technique in complementation or replacing virus isolation as a routine means of determining the presence of HIV-I.⁵³

Debate over the desirability of systematically screening large populations—e.g., prisoners, Federal employees, marriage license applicants, hospital patients—seems to be growing. In March, 1988, the U.S. District Court for the District of Nebraska refused to allow a multicounty mental retardation agency to require some of its employees to submit to testing for HIV infection, on the grounds that this violated employees' Fourth Amendment (search and seizure) rights.⁵⁴ The agency had acted on the grounds that employees might transmit AIDS to clients who bit or scratched them.

In part the impetus for mandatory testing may come from the fact that there is little else to be done, and mandatory screening seems more activist than reliance on voluntary testing. In some limited populations, mandatory testing would provide the opportunity for some control; for example, screening of prisoners allows authorities to isolate those who are infected or to take strong measures to prevent other prisoners being subjected to risk through sexual activity.⁵⁵

Testing of marriage license applicants could allow an uninfected partner to be warned and possibly reduce the number of infants born infected with AIDS, but heterosexual couples other than IV drug users are not a high risk group at present. Some States routinely require testing for syphilis in connection with

a marriage license application.⁵⁶ Louisiana and Illinois both passed laws requiring AIDS testing for applicants for a marriage license; Texas passed a similar statute that will go into effect only when the state incident rate reaches 0.83 (when the law was passed, the rate was 0.01). But in July 1988, Louisiana repealed the premarital test law after only 6 months, and in Illinois there is also a strong movement for repeal. Of 75,000 people tested under the Illinois law, only 10 tested positive (the prediction had been for 80 to 100 positives) and the cumulative costs for testing were reported to exceed \$6 million (paid for by the applicants for a marriage license, at costs of \$30 to \$200 per couple).⁵⁷

Mandatory testing for health-care professionals themselves has been proposed, but there has been little public or professional discussion of the pros and cons of this measure.

Many people, including many public health and medical experts, conclude that any benefits from mandatory screening programs are more than counterbalanced by the separating of testing from counseling and the likelihood of driving persons at risk "underground." The National Academy of Sciences/Institute of Medicine reached that conclusion, as did a preliminary consultation at the World Health Organization in March 1986.

The issue of how to balance these costs against the benefits of testing programs has not yet been fully resolved. The conclusion that mandatory screening is unwarranted is greatly affected by the lack of treatment, the clear need for counseling in the event of a positive test, and the uncertainty that confidentiality can

⁵³Chin-Yih Ou et al., "DNA Application for Direct Detection of HIV- I in DNA of Peripheral Blood Mononuclear Cells," *Science*, Jan. 15, 1988, pp. 295-297.

⁵⁴*Glover v. Eastern Nebraska Community Office of Retardation*, DC Neb, No. CV. 87-0-830, Mar. 29, 1988.

⁵⁵According to Professor Wayne Welch of The George Washington University's Intergovernmental Health Project staff, there is already mandatory testing for members of the Armed Services, the Foreign Service, and the Job Corps, and for Federal prison inmates. Prisoners are being screened in seven states. Utah has passed a law prohibiting a person diagnosed as having AIDS from marrying. Florida requires pregnant women with "high risk characteristics" to be tested.

Nevada, where prostitution is legal, requires that prostitutes be screened for AIDS. *Government Executive*, July-August 1987, p. 13.

⁵⁶This is becoming a serious problem in prisons, and the rights of prisoners in this regard are a matter of debate and uncertainty. A Massachusetts trial judge said in September that a prisoner could not be forced to take an AIDS test merely because he had scratched and injured a guard. On the same day, a Federal judge in Minnesota upheld the conviction of an infected prisoner for assault with a dangerous weapon after he bit two judges, noting that the human mouth and teeth do not ordinarily constitute a deadly or dangerous weapon. Associated Press, "AIDS Decisions Diverge in Cases Against Prisoners," *The National Law Journal*, Sept. 28, 1987, p. 4.

⁵⁷Sandra G. Boodman, "Premarital Testing Annoying Many in Illinois," *The Washington Post*, July 30, 1988, p. A1.

be maintained. Screening at least spares those who are unknowingly infectious from the additional grief of finding too late that they have passed on the infection, perhaps to spouses or offspring. If a cure or effective treatment were possible, past precedents argue that the State interest in saving lives and preventing the spread of the threat would almost certainly override concern about individual privacy rights.

Voluntary testing, as compared to mandatory testing, is likely to involve those who are: 1) already well informed about AIDS, 2) socially responsible about the risks of infecting others, 3) comparatively well off financially, and 4) relatively sophisticated about medical procedures. Two high risk groups are probably least likely to ask for testing: IV drug users and prostitutes, who are already at risk both of incurring other life-threatening diseases and of arrest for illegal activities; who are likely to have little access to health services and little money; and who are hardest to reach with public education.

The cost of screenings also a significant factor. The screening of a unit of blood by the ELISA test costs at least \$2 and more commonly approaches \$5. When a positive ELISA test occurs, repeat and supplemental testing are required, adding at least another \$50 to the cost. These figures do not include the need for skilled counselors and for procedures to assure confidentiality of test results. Thus the economic and social costs of mass screening for AIDS, both for those who have been exposed and for the public at large, are significant.

Contact Tracing

Still another traditional Public Health technique, contact tracing, has also again become controversial because of the AIDS epidemic. Public health management of sexually transmitted diseases has long history. Mandatory contact tracing-i. e., tracking down and warning people who have had sexual relations with an infected partner-is a technique that has usually been closely associated with reporting and testing strategies. Contact tracing in the

case of AIDS has become attractive to some Federal officials and State legislatures because that strategy is perceived to have been useful in the control of syphilis and gonorrhea. Such action also seems indicated by fairness to people who have unknowingly been put at direct risk, and may consequently unknowingly put others at risk.

To the surprise of many observers, the American Medical Association (AMA) in June 1988 recommended that its members warn sexual partners of patients with AIDS and of AIDS carriers. This is an exception to the strong tradition of physician-patient confidentiality, on which the AMA has always insisted.⁵⁸

There are however two problems with mandatory contact tracing as a strategy for AIDS control. First, some experts question the assumption that it was effective in the past. Syphilis came under control primarily because of the discovery of penicillin rather than because of contact tracing; and gonorrhea is at present out of control in spite of contact tracing.

Second, in those epidemics the impetus for contact tracing was the knowledge that treatment could be offered to the contact. The patient had a strong ethical reason for reporting, and the contact a highly practical reason for welcoming the news. Both benefits tended to compensate for the sacrifice of privacy. With AIDS there is no therapeutic help to be offered. The only benefit to contacts would be that of counseling if their tests prove positive. But 2 or 3 months are usually required for antibodies to appear, so there may be an interval of uncertainty, distress, and disruption of relationships even if the tests are ultimately negative. For public health officials and physicians, sustained infectiousness of the patient over many months makes it difficult to be sure of complete contact identification, especially since many sexual partners may be involved. The need for reiterative testing becomes a ma-

⁵⁸Isabel Wilkerson, "A.M.A. Urges Breach of Privacy To Warn Potential AIDS Victims," *New York Times*, July 1, 1988, p. A1.

major difficulty. Techniques for assuring the confidentiality of data are available but may be demanding and expensive, and may still not be trusted by those supplying the information.

These problems must however again be weighed against the great benefit of warning those who have been exposed, so that in turn he or she will not unknowingly expose others. Some public health officials are swinging toward support of contact tracing. New York health officials for example recently asked physicians to warn sex partners of AIDS patients of the risk.⁵⁹ The City Health Commissioner said, however, that there is no way to force patients to disclose the names of contacts, and that under current rules governing professional behavior in New York, physicians and hospitals that breach patient confidentiality would be subject to civil penalties, such as lawsuits. Current New York laws do allow health officials to notify people who have been in intimate contact with patients with venereal disease or tuberculosis, and some states have already authorized contact tracing for AIDS cases. California and Texas allow but do not require physicians or surgeons to disclose positive test results to a patient's spouse, and provide confidentiality safeguards for patients who voluntarily consent and list names for contact tracing. Illinois provides immunity from civil liability for those willing to provide names for contact tracing.

Some people urge that people who know they are infected should be legally required to warn sex partners. An army sergeant in San Antonio was recently sentenced to 5 months in stockade and a dishonorable discharge for ignoring orders from officers and having sex without telling his partners he was infected with AIDS, or taking protective measures.⁶⁰ In June 1988, a military trial was beginning of an Army private accused of having sexual

relations with male and female soldiers without warning them that he was infected.

On June 24, 1988, the Presidential Commission on the Human Immunodeficiency Virus Epidemic recommended that State health officials be required to contact and notify sex partners of persons infected with AIDS.

Social Controls: Full or Partial Quarantine

The strategies of final resort for control of most epidemics are: 1) infrastructure or environmental reform, when there is believed to be an environmental factor such as an animal vector, and 2) failing all else, social control measures including quarantine or isolation.

There are no known environmental factors in the AIDS epidemic, in the sense of sanitation factors, industrial contaminants, or animal vectors for the disease agent. One factor in the urban environment proved to be important: the "bathhouses" in some large cities that were a primary focus of promiscuous homosexual behavior that facilitated the transmission of the disease. Action by public health authorities to close these commercial establishments in San Francisco and New York was delayed by the protest and political and legal resistance of proprietors and clients, on the grounds of civil liberties, but once the fact of an infectious disease and a mode of transmission had been established, there was little doubt that the closure fell within the long established scope of State police power.

Three further social control measures, beyond those already discussed, have been suggested or proposed in the context of the AIDS epidemic: full quarantine, excluding children with AIDS from public schools, and prohibiting persons with AIDS (or carrying the infection) from engaging in certain occupations. These potential control measures have very significant constitutional implications.

Quarantine would impose a harsh burden on those infected with AIDS, particularly those who as yet suffer no symptoms of the disease, because the quarantine would be life-long. In

⁵⁹ Ronald Sullivan, "Warn AIDS Patients' partners, Health Official Urges," *The New York Times*, Oct. 15, 1987, p. R1.

⁶⁰ He was found guilty of disobeying officers, of adultery, and of sodomy, but not guilty of aggravated assault and reckless endangerment. "Soldier Guilty of Concealing AIDS Infection from Partners," *The Washington Post*, Dec. 3, 1987, p. A20.

spite of this, newspaper polls have shown many Americans (one poll said 51 percent) favor quarantines, and legislatures in 5 States are said to be considering, or to have considered, such legislation. Florida health authorities have quarantined one prostitute to her home, wearing an electronic anklet.⁶¹ Social attitudes and judicial decisions regarding quarantines may have changed significantly in the last few decades, but this conclusion is somewhat hypothetical, as the use of traditional quarantines has become relatively rare and unfamiliar.

In the early national period, quarantines were often imposed. The major infectious disease problem was yellow fever. The disease reappeared in 1793 after a long absence, and a devastating epidemic struck along the entire coast from Boston to New Orleans. Philadelphia, New York, and other cities established temporary health boards with broad authority, and began quarantines. They isolated yellow fever victims and began massive programs to cleanup the foul streets and privies. As the epidemic increased in intensity, temporary hospitals were established, and funds were provided to care for the sick and those left orphaned.

The disease was spread by water transport and generally struck hardest in the low-lying crowded dock areas occupied by the poor. The rich fled. Philadelphia and New York City in 1797 began a policy of evacuating entire sections of the city. New York, for example, provided temporary housing out in the country, in Greenwich Village. The city authorities assumed full responsibility in this way for epidemics of yellow fever for another century, through the final large outbreak in 1905 in New Orleans, when Federal, State, and local officials joined together to cut short the epidemic.

Courts have since often struggled with the issue of quarantine as an ultimate social control measure, and have generally dealt with it according to: 1) the nature of the disease and

2) the length of time for which a person is infectious and would need to be isolated. Until recent decades, courts gave great weight to the inherent power of government to protect the general welfare by whatever means were considered to be appropriate, by the public and their legislators even if not by experts.

For example, a 1909 case involved the quarantine in South Carolina of an elderly woman, who had contracted leprosy many years earlier as a missionary in Brazil.⁶² Subsequently she mingled freely in the society of a small town for years, even teaching Sunday School, until the city board of health decided that she should be isolated. She had infected no one, medical authorities testified that she was only slightly if at all contagious, and the woman frantically offered to remain isolated in her own home. Nevertheless, the court permitted her involuntary removal to and confinement in a cottage built for her outside the city limits. The court held that even though the disease was only "slightly contagious" the board of health was justified because of the "distressing nature of the malady."

By contrast, public health officials in San Francisco and elsewhere made no move to quarantine persons with AIDS who continued to frequent commercial bathhouses for reasons of anonymous sexual activity, in spite of the repeated warnings of their physicians that they were likely to be transmitting the infectious disease.⁶³ In the intervening half century, attitudes toward individual rights had changed significantly.

Even at the turn of the century when quarantine was more often applied than now, courts did intervene in quarantine programs where the exercise of police power was extreme and arbitrary. In 1900 San Francisco's board of health quarantined a 12 block district inhabited by 10,000 to 15,000 people, because bubonic plague was thought to exist in the area. This was challenged on the grounds that it was differentially enforced against Chinese but not non-Chinese (most of the residents in the area

⁶¹Deborah Jones Merritt, "Communicable Disease and Constitutional Law: Controlling AIDS," *New York University Law Review*, vol. 61, No. 5, 1986, p. 775. The *Los Angeles Times* poll cited by Merritt was published Dec. 19, 1985, p. 1.

⁶²*Kirk v. Wyman*, 65 S.E. 387 (S.C.1909).

⁶³Shilts, *op. cit.*, footnote 49.

were Chinese); there was insufficient evidence of bubonic plague;⁶⁴ and in many blocks there was no evidence of any illness at all. A Federal judge terminated the quarantine on the grounds that it was “unreasonable, unjust, and oppressive.”⁶⁵

In 1922, the Supreme Court of Illinois upheld the isolation of a boarding house operator who was not ill but was a carrier of typhoid bacillus.⁶⁶ She could, the court said, be quarantined for as long as she presented a danger to the public, even though this would likely be for the rest of her life. The court noted several requirements: the person must be known to be ill or infectious (“mere suspicion” was not sufficient); State authorities must have reasonable ground to believe that public health would be endangered; the action must cease when the necessity for it ceases; and the emergency or necessity must exist, not merely be anticipated. However, public authorities need not wait until the disease has already been transmitted to take action. “One of the important elements in the administration of health and quarantine regulations is a full measure of common sense.”

Some courts were less concerned about the principles governing exercise of police power. The Supreme Court of Ohio, also in 1922, allowed city health commissions to make examinations of all persons suspected of having venereal disease, and “all known prostitutes” were considered to be, per se, reasonably suspected. Another regulation allowed the quarantine of one who had or was reasonably suspected of having venereal disease when in the opinion of the health commissioner such quarantine was necessary to protect the public health. A woman was arrested as a prostitute; charges were dismissed but she was then in-

voluntarily institutionalized by the commissioner of health for 2 months’ treatment. In refusing a writ of habeas corpus, the State Supreme Court said:

There is perhaps no provision of the Federal Constitution that is more overworked than the Fourteenth Amendment . . . It has been so many times decided that the Fourteenth Amendment does not limit the states in the proper exercise of the police power that the citation of authority seems needless.⁶⁷

A generation later, in 1944, there was a similar case in which two women arrested for having “unlawfully solicited for prostitution” were held without bail until examined for venereal disease, pursuant to a State statute. The Supreme Court of Illinois upheld their detention on the sole grounds of the *charge* of prostitution, saying that:

It has been almost universally held in this country that constitutional guarantees must yield to the enforcement of the statutes and ordinances designed to promote the public health. . . .⁶⁸

The court also cited with approval another authority, that “whenever a police regulation is reasonably demonstrated to be a promoter of public health, all constitutionally guaranteed rights must give way. . . .”

Even in recent years, courts have upheld statutes that permitted involuntary testing of women arrested for prostitution.⁶⁹ Public health measures may be less likely to be limited by courts under constitutional principles when they are aimed at venereal disease, or when applied to prostitutes who are by definition engaged in criminal activity, than in more general cases of infectious disease.

But most of these statutes and court decisions occurred during wartime; Dr. Allan M. Brandt, in his book *No Magic Bullet*,⁷⁰ dis-

⁶⁴There had been 11 deaths in which some symptoms of bubonic plague appeared on autopsy, but no case in which a living person was diagnosed as having the disease and no evidence of any transmission of disease by the deceased.

⁶⁵*Jew Ho v. Williamson*, 103 F. 10 (N.D. Cal 1900).

⁶⁶*People Ex Rel. Barmore v. Robertson*, 134 N.E. 815 (111.1922). The court said that it would not evaluate the wisdom of the State legislature and board of health, and would not interfere with a particular action so long as it did not appear to be, on its face, “arbitrary, oppressive, and unreasonable.”

⁶⁷*Ex Parte Company* 139 N.E. 204 (Ohio 1922).

⁶⁸*People ex rel. Baker v. Strautz*, 54 N.E. 2nd 41 (1944).

⁶⁹For example, *People v. Superior Court* (Hartway) 562 P.2d 1315 (Cal. 1977).

⁷⁰Allan M. Brandt, *No Magic Bullet* (Oxford: Oxford University Press, 1985).

cussed the impact of wartime preparedness initiatives on the creation and enforcement of laws aimed at reducing the prevalence of venereal disease. In the past, quarantines for venereal disease have been limited in duration since those who were infected could be rendered non-infectious by medical treatment.

The courts have upheld quarantines for many other infectious diseases including scarlet fever⁷¹ and tuberculosis;⁷² and have upheld lifelong quarantines for typhoid. But quarantine has come to be used less and less as vaccines or cures were developed for many infectious diseases.

On the one hand, the pattern of court decisions about quarantine shows an ever broadening tolerance for the exercise of police powers. This tolerance has expanded from quarantine based on demonstrated necessity to quarantine based on suspicion of disease, to quarantine based not on disease symptoms but on accusation of sexual activities. On the other hand, some constitutional authorities believe that courts would now be very reluctant to uphold the broad use of long quarantines, because concern for individual rights has increased. Deborah Jones Merritt, for example, suggests that:

Recent developments in constitutional law suggest that courts would no longer uphold such broad quarantine orders. Although the courts might still approve the isolation of individuals who either knowingly engage in activities threatening a high-risk of infection to others or lack the mental competence to avoid those activities, judges would be unlikely to sustain the quarantine of individuals who are willing to modify their activities to avoid such risks.⁷³

Not all authorities concur in that judgment, on the grounds that courts have in general given wide discretion to governments in exercising their police power when the public perceives a serious risk. In particular, some people warn, any evidence that AIDS has been

transmitted through non-sexual, non-drug related contact in even a very few cases would be likely to increase both political demands for and judicial acceptability of quarantine. This occurrence seems highly unlikely.

The constitutional acceptability of some lesser forms of social control is also still unclear. For example, continued admission of children with AIDS to public school has brought about conflict in many communities. The Centers for Disease Control (CDC) in August 1985 reassured parents about the "apparent non-existent risk of transmission" of the virus to other school children and recommended that schools decide how to handle children with AIDS on a case-by-case basis.⁷⁴ Some school districts have adopted CDC's guidelines, some have refused to admit AIDS children, some have segregated them within schools.⁷⁵ Both parents and school boards have resorted to the courts. State and Federal legislators have introduced bills to ban AIDS sufferers from schools. These struggles are so far unresolved except on a case-by-case local basis.

In the first decades of this century courts allowed school boards almost unlimited authority to exclude students with communicable diseases." Not only children who were ill, but those who had been exposed to infectious diseases at home or elsewhere could be excluded. In recent decades, while declining to recognize education as a fundamental right," the Court has nevertheless scrutinized any law or policy that excludes children from public schools.

The State was not allowed to exclude undocumented alien children, on the grounds that this would relegate the children to a permanent 'subclass,' that the children were not re-

⁷¹*Stone v. Racjowski*, 86 A 606 (1913).

⁷²*Moore v. Draper*, 57 So.2d 618 (1952 '1a')

⁷³Merritt, op. cit., footnote 61, p. 778.

⁷⁴CDC discounted most means of "casual transmission," but recognized parents' fears that body fluids may be exchanged among children by biting, scratching, uncontrolled urination, casual injuries, etc. 'Education and Foster Care of Children Infected with Human T-Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus,' 34 *Morbidity & Mortality Weekly Rept.* 517, 519 (1985).

⁷⁵Merritt, op. cit., footnote 61, pp. 756 ff.

⁷⁶*Ibid.* The remainder of this section draws heavily on Merritt, op. cit., unless otherwise referenced.

⁷⁷*Papasan v. Allain*, 106 S. Ct. 2932, 2943-45 (1986); *Plyler v. Doe*, 457 U.S. 202, 223 (1982).

sponsible for their alien status, and that the cost of educating these children was insubstantial in the light of the costs of lack of education for the children, the State, and the Nation. These reasons could apply to children with AIDS, except that they are unfortunately unlikely to live to constitute a permanent subclass. The likelihood of transmission through schoolroom contact is generally regarded by experts, although perhaps not by all members of the public, as extremely small or nonexistent. A New York trial judge recently followed this reasoning in ruling that automatic exclusion of all AIDS patients from public schools would violate the Equal Protection Clause.⁷⁸

In 1979 the New York City Board of Education began to exclude from regular classrooms mentally retarded children who were also carriers of the hepatitis B virus. Hepatitis B is communicable in a similar fashion to AIDS—through the use of contaminated needles, blood-to-blood contact, and sexual contact (usually homosexual contact). While the virus has been isolated in saliva, there is no evidence that it has been transmitted through this route.” The New York City policy was challenged on the grounds that it violated the Rehabilitation Act of 1973, the Education of the Handicapped Act, the New York Education Law, and the Due Process and Equal Protection Clauses of the Fourteenth Amendment.⁸⁰

The Board of Health argued that it was making traditional use of the police power to protect the health, safety, and welfare of its citizens and that its actions were “rationally related” to this purpose. The Court nevertheless struck down the Board’s policy. It cited the Fourteenth Amendment, although it relied primarily on antidiscrimination laws.⁸¹ A Cali-

⁷⁸*District 27*, 130 Misc. 2d 398, 502 N. Y.S.2d 325; cited by Merritt, op. cit., footnote 61, p. 762.

⁷⁹According to Dr. Leonard Glantz, Prof. of Health Law, Schools of Medicine and Public Health, Boston University, some authorities think that there is a greater likelihood that hepatitis B could endanger others in a classroom or household than that AIDS could do so. The material on school admission in this section relies heavily on analysis by Dr. Glantz as well as Dr. Merritt.

⁸⁰*New York State Association for Retarded Children v. Carey*, 612 F. 2d. 644 (2nd Cir. 1979).

“The court said that since the policy excluded only mentally retarded children and made no effort to find or exclude other

fornia court ordered a school district to readmit a child with AIDS to kindergarten on the grounds that AIDS is a handicap under Section 504 of the Rehabilitation Act.⁸²

In a similar case a New York court invalidated a school board policy excluding children with AIDS. Again recognizing that public education is not a fundamental right, the court said that when a State does provide it, it must be available to all on equal terms. The courts will give any denial of schooling close scrutiny because of the significant negative impact this could have on children.⁸³

The Public Health Service (PHS) has officially urged that AIDS sufferers or carriers not be excluded from work, saying that “No known risk of transmission . . . exists” for workers in offices, schools, factories, construction sites, food service jobs, health service delivery, etc.⁸⁴ The Public Health Service recommended only routine disinfection of equipment contaminated by anybody fluids, regardless of known infection.

Some school districts decide on a case-by-case basis whether public school teachers and associated workers with AIDS may continue to work. Several cities have barred persons with AIDS or AIDS-Related Complex from working as food servers or as teachers. Judicial precedents could support these restrictions. Under the rational basis test, as long as the courts perceive that there is even remote risk of infection,⁸⁵ they would be obliged to uphold such regulations. The Supreme Court held, in 1978, that New York City could con-

children who were carriers, the Board evidently recognized that carriers presented only a “remote possibility” of infecting others.

⁸²*Thomas v. Atascadero Unified School District*, No. 886-609 AHS(BY) (C. D. Calif. Nov. 17, 1986).

⁸³*District 27 Community School Board v. Board of Education*, 502 N. Y. S.2d. 325,337 (Sup.1986).

“recommendations for Preventing Transmission of Infection with Human T- Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus in the Workplace, 34 *Morbidity & Mortality Rept.* 681,682 (1985), hereafter cited as PHS Workplace Recommendations.

⁸⁵The Public Health Service holds that there is some possibility of such transmission, for example, by direct transfer of blood through the injury of one person and an open lesion on another person’s skin, but says that this kind of transmission is highly unlikely.

stitutionally bar all methadone users from working for its transit authority even though the bar was "broader than necessary to exclude those methadone users who were not actually qualified to work."⁸⁶ Thus if the courts found sufficient grounds to exclude some AIDS victims from health care, personal service, or food handling occupations, they would be likely to uphold broad rules barring AIDS victims rather than insist on individualized determinations of the threat posed by a particular employee. But those "sufficient grounds" do not appear to exist, and the Supreme Court has said that the protection given to the handicapped by recent legislation extends to people with infectious disease.

None of these judgments are at all conclusive; they represent possibilities rather than predictions of how courts would decide in future situations. Constitutional lawyers and scholars differ strongly on these points. Clearly, scientific knowledge about risks and exposures, in this case, has not been sufficient to prevent or resolve challenges to public policy on the basis of constitutional principles; it may only have complicated those challenges.

In June 1988, the President's Commission on AIDS and the National Academy of Sciences both recommended tough new Federal laws to prohibit discrimination against the 28,000 Americans with AIDS and the more than 1 million other Americans estimated to be infected. The Presidential commission, with a divided vote, recommended that the Federal law against discrimination against the handicapped be extended to apply to private sector employees.

Treatment

Health care in the United States is primarily provided through the private sector, but the public health system is an important developer of new drugs and other health care regimes and techniques. In addition, Medicare and Medicaid do provide payment for health

care for many Americans. As discussed in the next chapter, there is a growing concern about the availability of adequate medical care for Americans who may not be able to pay for increasingly expensive care, or who do not have access to health insurance: "A(n). . . issue confronting society and its political elements is the question of whether health is a universal human right."⁸⁷

Neither Congress nor the Supreme Court has in any way recognized such a "human right" as a constitutional right. But the AIDS epidemic may fuel pressure for new health care delivery mechanisms or programs because of the high costs of treatment, because those with AIDS are young and more likely than the average worker not to have health insurance, because they may lose their jobs when their illness becomes known, and because health insurance providers try to avoid enrolling those in high-risk categories.

The projected costs of health care for AIDS patients in the next few years are enormous. While AIDS is uniformly lethal, it entails many weeks or months of progressive debilitation, including neurologic deterioration. Since this is a disease of young adults whose health insurance is usually dependent on their employment status, early termination of employment has abroad impact. Home care, day care, long-term care in skilled nursing facilities, and hospice care can improve the quality of remaining life for many patients, while reducing costs. The range of lifetime health care cost estimates per case range from \$29,000 to \$157,000, reflecting in part the variation in availability of such options.

Health care will become still more costly and difficult as drug addicts become an increasingly large proportion of the patients. Many of the innovations in patient care so far have relied heavily on the volunteerism characteristic of some gay communities, which has no parallel in some of the other high risk groups.

⁸⁶*New York City Transit Authority v. Beazer*, 440 U.S. 568 (1979), as cited by Merritt, op. cit., footnote 61, p. 771.

⁸⁷J.C. Snyder, "Public Health in the U. S.A.," in John Walton, Paul B. Beeson, Ronald Bodley Scott (eds.), *The Oxford Companion to Medicine*, vol. ii, p. 172.

The appearance of the first anti-HIV drug, AZT, raised some thorny issues likely to recur with other candidate treatments. The handful of drugs that have been developed for treatment of virus infections of any sort are usually very toxic. Antiviral drugs present very different problems from those of antibiotics for bacterial infections. Most bacteria are distinctive, self-contained organisms, subject to attack through their specialized mechanisms of multiplication. Viruses act as "fifth columns," taking over the host cell so completely that it is difficult to kill the virus without seriously damaging the host.

AZT, for example, has a serious suppressive effect on the patient's bone marrow, usually necessitating regular blood transfusions. It has other toxic properties, often so severe that treatment must be stopped. Its cost is nearly \$10,000 yearly per patient. This is not a promising solution even in the affluent United States, where over a quarter of a million cases of AIDS are anticipated by 1991; it certainly will not work for developing countries. But so desperate are AIDS patients that even at that cost, the demand for AZT exceeds the supply.

The urgent need for some treatment prompted creation of an unusual mechanism for early licensing of AZT and an even more unusual system to try to get more equitable distribution of the drug. The intense pressures that prompted these actions will worsen tenfold in the next 5 years if there are no other effective treatments. A large number of unauthorized treatments, ranging from health food diets to drugs authorized for other medical purposes, are being widely used by those with AIDS who can afford their often high costs. Many people are highly critical of government agencies for what they view as foot-dragging in testing these "treatments."

Yet other people are concerned that the rapidity of licensure of AZT seems to herald more rapid deployment of new drugs in general—not just for AIDS—and they fear that the slow but cautious approach which has assured drug safety in the past maybe replaced with a faster but more hazardous approach. Few hazards,

however, appear prohibitive compared to a disease that is probably 100 percent fatal.

In the meantime, in response to the growing demand from the AIDS community, the FDA announced in July 1988 that it would allow Americans to import unapproved drugs from abroad in small quantities for personal use in treating or preventing AIDS.⁸⁸

Blood Banking

Blood supply and transfusion was a primitive process until World War II. Blood groups were recognized only in the 1930s. Until the need for close matching of blood types was recognized it was not uncommon for hemorrhage to be dealt with by direct arm-to-arm transfer of untested blood.

Blood transfer for medical purposes increased dramatically with expansion of surgical capabilities and other therapeutic interventions. It prolonged the lives of cancer patients and many others who needed transfusions for maintenance. By 1983, an average of 13 million voluntary blood donations were made per year. Most donations were divided into two or three components (i.e., red cells, plasma, platelets). There were over 3 million recipients per year, many receiving multiple infusions.⁸⁹

The transmission of the disease hepatitis as a complication of blood transfusion was recognized in the early 1940s. By misadventure the newly developed live-virus vaccine for yellow fever was stabilized using human serum that was infected with hepatitis viruses. Over 50,000 cases of hepatitis resulted. Blood screening for the disease agent then began.

⁸⁸Philip M. Boffrey, "F.D.A. Will Allow Patients To Import AIDS Medicines," *New York Times*, July 25, 1988. One example of such a drug is dextran sulfate, which the Federal Government is now beginning to test in human trials, but which is already in use in some countries.

⁸⁹J.R. Allen, "Scientific and Public Health Rationales for Screening Donated Blood and Plasma for Antibody to LAV/HTLV-III," Chapter 15 in *AIDS: The Safety of Blood and Blood Products*, J.C. Petricciani et al. (eds.), The World Health Organization. New York: John Wiley and Sons Ltd. Also J.C. Petricciani, "Licensed Tests for Antibody to Human T-Lymphotropic Virus Type III," *Ann. intern. med.* 102: 726-729, 1985.

The identification of hepatitis B virus and development of a means of screening had been expected to eliminate most of the hepatitis contamination. But as it turned out, only a small proportion of the transfusion-associated hepatitis was eliminated. Clearly at least one other virus was involved. The remaining blood transmitted hepatitis was subsequently referred to as "non-A, non-B hepatitis."⁹⁰ Later immunologic evidence strongly suggests that there are at least two other hepatitis viruses.

The risk of hepatitis is still significant; blood-transfusion hepatitis continues to threaten 7 to 10 percent of those getting transfusions. Additional "surrogate" screening tests have recently been added in an effort to prevent these infections, and they add several dollars to the cost of each unit of blood.

Besides blood donation there is a large "industry" of plasmapheresis growing from extensive demand for gamma globulin and from the recent capability to fractionate blood plasma and prepare concentrated materials (e.g., clotting factors to substitute for genetically lacking proteins in hemophiliacs). The pooling and concentrating of donated plasma has allowed the life expectancy of severe hemophilia A patients to rise from about 14 years in the early 1960s to 42 years in the early 1980s. Unfortunately the same technical feat made them early victims of the spread of AIDS.⁹¹

This was the second great disaster to hit bloodbanking. By 1982 it was suspected that AIDS was infectious, and that the unknown agent might be transmitted through blood exchange, and several cases of AIDS in hemophiliacs had been reported.⁹² In March 1983, the FDA after consultation with the major blood banking organizations, the National Institutes of Health, and the National Gay Task Force, recommended that persons "at in-

creased risk of AIDS" (specifically homosexual males) be asked to refrain from donating blood; that there be expanded medical screening of donors to detect early symptoms of AIDS, and that this screening include examination for lymph node enlargement and weighing to detect early weight loss.

Critics have since charged that this action was delayed by resistance from both blood banks and gay organizations.⁹³ The Centers for Disease Control officially reported only in January 1984 that there were cases of AIDS associated with transfusions, and later in 1984 some blood banks began using surrogate tests. Many lots of blood thought to be infected were withdrawn and destroyed. In April 1984, the AIDS virus was identified, and a specific AIDS blood screening test became available in mid-1985. Screening for AIDS now adds about \$5 per unit to the cost of blood transfusions.

By the end of 1987, according to the Centers for Disease Control, 1,608 cases of AIDS acquired through blood transfusion had been reported in the United States. Of all persons with hemophilia A (12,400 persons), approximately 70 percent maybe infected with AIDS; of those with hemophilia B (3,100), about 35 percent may be infected.⁹⁴ The number of cases of transfusion-related AIDS will thus increase for some time even if the risk of infection through blood transfusions has ended.

Public anxiety about the safety of the blood supply has led to the demand that "directed donations" be allowed, in which one chooses one's own blood donors from personal friends and relatives. The costs of such a program, i.e., subdividing blood units and allowing special storage, is potentially very high. It also creates a "two-class" blood system, and so has been opposed by many professionals in transfusion medicine.

Autologous donation is the process by which one donates one's own blood for anticipated future use. In planned, elective surgery this

⁹⁰Hepatitis A is caused by still another virus which is physiochemically similar to polio virus and is rarely a factor in blood transfusions.

⁹¹J. F. Desforges, "AIDS and Preventive Treatment in Hemophilia," *New Eng. J. Med.* 308: 94-95, 1983.

⁹²U.S. Congress, Office of Technology Assessment, *Blood Policy & Technology, OTA-H-260* (Washington, DC: U.S. Government Printing Office, January 1985), p. 13.

⁹³Shi, *supra* cit., footnote 32, Parts IV and V.

⁹⁴U.S. Public Health Service, Centers for Disease Control, *Morbidity and Mortality Weekly Report*, vol. 36, Supplement No.S-6, Dec. 18, 1987, table 14, p. 40.

can be a wise precaution. It is not generally useful for emergencies.

Blood supply system professionals generally insisted that would-be donors must be informed that tests will be done on the blood and a donor who tests positive will be informed of the results; and most have strongly supported the position of many other health professionals that counseling must be offered in conjunction with blood testing for HIV antibodies. An elaborate process has been set up for obtaining donor consent, notification of results, and follow up counseling. The burden on blood banks is very large. Strong pleas have been made for persons whose behavior puts them at risk of AIDS not to donate. But in communities without alternative testing sites, access to the AIDS test through blood banks means that some people will donate in order to find out if they are infected.

The American Red Cross in 1986 instituted a look-back procedure, in which infected donors who are identified through a current donation have their prior donations traced. Stored samples are tested; recipients of prior positive donations are contacted and told of their possible contamination.

Public Education and Statistical Forecasting

Epidemics are usually attacked through preventive education, prevention by vaccine, drug treatments, and sometimes social control measures such as quarantines. Only the first has yet shown real promise for the AIDS epidemic in the next decade. Education is now the major public health strategy, other than research and the screening of blood and organ donors. This means a combination of strategies to inform the general public about the disease in a way that will be effective yet minimize diffuse fear, that will alert adolescents to the lethal hazard implicit in certain behaviors, and that will urge people to avoid behaviors that put them at high risk. The NAS/IOM panel proposed that for every dollar invested in research an equal sum should be invested in education for prevention.

There are however strong political constraints on this strategy because some people perceive any information about avoidance strategies (other than abstinence or heterosexual monogamous marriage) as equivalent to condoning homosexuality or promiscuity. The Public Health Service and Centers for Disease Control had planned to mail an AIDS information brochure to every U.S. household in October 1987. But because of political resistance from those who feared it would offend some religious groups, the President's Commission on AIDS delayed the mailing until late spring 1988.⁹⁵

There is some evidence that public education about AIDS has brought about behavior change within the group so far at highest risk, homosexual males. Most observers report, although there is probably no real quantitative data, that extreme promiscuity has strongly declined and the use of condoms has risen. Most experts believe however that other high risk behavior, i.e., intravenous drug use, is much less likely to change, since its practitioners are already accepting very high legal and health risks.

Public education is also regarded as the best strategy for dealing with some newly identified behavioral or environmental risks, and for some that have been recognized for several decades, such as smoking. There will soon be increasing non-genetic predictive power concerning the likelihood of a variety of pathologic states such as coronary artery disease and adult-onset diabetes. Medical science is leading toward a refined definition of desirable "health behaviors" to reduce the likelihood of or severity of such outcomes, so much so that some have been codified in a fully sanctioned set of Federal objectives.⁹⁶ Increasingly, public health programs emphasize lifestyle change and preventive health measures.

The first strongly documented scientific warnings that smoking was deleterious to

⁹⁵William Booth, "The Odyssey of a Brochure on AIDS," *Science*, vol. 237, Sept. 18, 1987, p. 1410.

⁹⁶Public Health Service, U.S. Department of Health and Human Services, *The 1990 Health Objectives for the Nation: A Mid-Course Review* (Washington, DC: Public Health Service, 1986).

health came from epidemiologic studies in the 1950s, when epidemiologic methods were not well accepted except when dealing with infectious diseases. The data are now well-established; smoking contributes directly and materially to over 350,000 deaths a year in the United States, and "passive smoking" (indirect inhalation of tobacco fumes from others' smoking) has been found to be physiologically real and pathologically significant.⁹⁷

This raises a social/ethical, and ultimately perhaps a constitutional issue, "how much personal liberty can be tolerated in self-damaging behavior?" Society has debated this issue before in terms of motorcycle helmets, seat belts, and alcohol; and will increasingly face it in terms of other lifestyle, nutrition, or environmental factors. Increasingly accurate predictive power concerning adverse health behavior brings us closer to the zone in which society claims an interest in the individual's assumption of risk. Complicating this is the question raised earlier with regard to occupational genetic screening: should some people, who are genetically sensitive to some environmental factors, be legally prevented from entering occupations, jobs, workplaces, or general locations that are accessible to less susceptible people?

Public education and social pressure—even without laws and regulations seeking to control behavior—is considered excessively intrusive by some people, when it pertains to eating habits, weight control, recreational pursuits

⁹⁷U.S. Department of Health and Human Services, *The Health Consequences of Smoking: Cancer*, A Report of the Surgeon General, 1982 (PHS 82-50179); *The Health Consequences of Smoking: Cardiovascular Disease*, A Report of the Surgeon General, 1983 (PHS 84-50204); *The Health Consequences of Smoking: Chronic Obstructive Lung Disease*, A Report of the Surgeon General, 1984 (PHS 84-50205).

and other matters that they regard as highly personal. Some social observers see the possibility of a backlash against such pressures, such as occurred against "Blue Laws" and obscenity and pornography laws, raising new demands for protection of personal privacy and choice.

On the other hand, to the extent that forecasting carries a useful personal message, issues of cost, access, and equity arise. Affluent people may have full benefit of forewarning and preventive care, and others may not, even when much of the predictive capability results from knowledge and technology developed with public funding. It is in fact only recently that government-funded health programs countenanced reimbursement for any prevention or health maintenance costs.⁹⁸

Public health professionals increasingly argue for a national goal of comprehensive health care for all⁹⁹ based on the statement in the Preamble to the Constitution of the World Health Organization, which the United States formally endorsed, that

The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic, or social condition. ... 100

The fundamental public health issue of the next generation may be the question of whether this goal can implicitly be found in the constitutional language of a right to life, liberty, and property.

⁹⁸C.J. Schramm, "Can We Solve the Hospital-Cost Problem in Our Democracy," *New Eng. J. Med.* 311: 729-732, 1984.

⁹⁹Snyder, *op. cit.*, footnote 87, p. 1170.

¹⁰⁰Preamble to the Constitution, *World Health Organization Basic Documents* (Geneva, Switzerland, 1963), p. 1.