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Mission Creep: Public Health Surveillance and Medical Privacy

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**MISSION CREEP: PUBLIC HEALTH SURVEILLANCE
AND MEDICAL PRIVACY**

WENDY K. MARINER*

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INTRODUCTION

The claim of “disease” in a domestic setting has the same kind of power as the claim of “national security” in matters relating to foreign policy. Both claims are very powerful arguments for executive action. Both claims are among those least likely to be questioned by any other branch of government and therefore subject to abuse.¹

In 2004, the Technology and Privacy Advisory Committee, appointed by the U.S. Department of Defense “to examine the Terrorism Information Awareness Program and to develop safeguards,” published its recommendations for ensuring that Department of Defense technologies respect U.S. law and privacy values.² The Committee stated:

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¹ *City of Newark v. J.S.*, 652 A.2d 265, 271 (N.J. Super. Ct. Law Div. 1993).

² TECH. & PRIVACY ADVISORY COMM., U.S. DEP’T OF DEF., SAFEGUARDING PRIVACY IN THE FIGHT AGAINST TERRORISM, at iii (2004) [hereinafter SAFEGUARDING PRIVACY], available at <http://www.cdt.org/security/usapatriot/20040300tapac.pdf>.

There are more than 650 million intelligence intercepts alone every day. One of the most immediate challenges facing U.S. anti-terrorist activities is separating out the “signal” of useful information from the “noise” of all those data. More data are available than there are – or ever could be – analysts to analyze it.

....

... If conducted without an adequate predicate, [data mining] has the potential to be a 21st-century equivalent of general searches, which the authors of the Bill of Rights were so concerned to protect against.³

The Committee was especially concerned that data legitimately collected with “particularized suspicion”⁴ to find a suspected terrorist might later be used for different purposes, such as ordinary law enforcement. This type of “mission creep,” as the Committee called it, might not be so legitimate or socially acceptable, and thus would require both specific regulation and careful monitoring to ensure the protection of privacy.⁵

September 11, 2001, catalyzed a vast surveillance industry of data collection, linkage, and mining.⁶ The expanded surveillance provoked complaints that this response overstepped the bounds of liberty and privacy.⁷ Yet outrage was hardly universal, perhaps because most voters believed that they were not under surveillance.⁸ When *The New York Times* reported on the National Security Agency’s monitoring of domestic telephone calls, however, public opinion began to change.⁹

³ *Id.* at 48-49 (footnote omitted).

⁴ *Id.* at 49.

⁵ *See id.* at 39-40.

⁶ For a description of the industry’s post-9/11 development, see generally ROBERT O’HARROW, JR., *NO PLACE TO HIDE* (2005); Chris Jay Hoofnagle, *Big Brother’s Little Helpers: How ChoicePoint and Other Commercial Data Brokers Collect and Package Your Data for Law Enforcement*, 29 N.C. J. INT’L L. & COM. REG. 595 (2004).

⁷ *See generally* DANIEL J. SOLOVE, *THE DIGITAL PERSON: TECHNOLOGY AND PRIVACY IN THE INFORMATION AGE* (2004); Marc Rotenberg, *Privacy and Secrecy After September 11*, 86 MINN. L. REV. 1115 (2002); Daniel J. Solove, *Digital Dossiers and the Dissipation of Fourth Amendment Privacy*, 75 S. CAL. L. REV. 1083 (2002); Kathleen M. Sullivan, *Under a Watchful Eye: Incursions on Personal Privacy*, in *THE WAR ON OUR FREEDOMS: CIVIL LIBERTIES IN AN AGE OF TERRORISM* 128 (Richard C. Leone & Greg Anrig, Jr. eds., 2003).

⁸ *See generally* DAVID COLE, *ENEMY ALIENS: DOUBLE STANDARDS AND CONSTITUTIONAL FREEDOMS IN THE WAR ON TERRORISM* (2003); David Luban, *Eight Fallacies About Liberty and Security*, in *HUMAN RIGHTS IN THE ‘WAR ON TERROR’* 242 (Richard Ashby Wilson ed., 2005).

⁹ *See* James Risen & Eric Lichtblau, *Bush Lets U.S. Spy on Callers Without Courts*, N.Y. TIMES, Dec. 16, 2005, at A1. The American Bar Association House of Delegates, reacting to the news story as well as an internal task force report, voted overwhelmingly to urge the Bush administration to comply with the Foreign Intelligence Surveillance Act (FISA), and called on Congress to investigate the domestic surveillance program. ABA TASK FORCE ON

Mission creep is also happening in the health sphere, and public attitudes toward what is now called public health surveillance may follow a similar trajectory.¹⁰ At the end of the nineteenth century, states began requiring physicians to report cases of smallpox and other contagious diseases that could cause epidemics.¹¹ Polite society believed (or wished to believe) that such diseases were concentrated in the disadvantaged classes, especially among immigrants and prostitutes.¹² The affluent classes could endorse compulsory reporting laws to gain protection from illnesses without suffering the indignity of having their own names reported.¹³

DOMESTIC SURVEILLANCE IN THE FIGHT AGAINST TERRORISM, REPORT WITH RECOMMENDATIONS 1-5 (2006), available at http://www.abanet.org/op/greco/memos/aba_house302-0206.pdf.

¹⁰ Public reaction may be primed by earlier reports that millions of records of identifiable data had been lost by or stolen from credit and background checking companies such as ChoicePoint and Bank of America, as well from educational institutions such as Boston College and Tufts University. See, e.g., Bruce Mohl, *Breach in Security Reaches 2d Credit Firm*, BOSTON GLOBE, Apr. 14, 2005, at E1 (reporting on security breaches at HSBC North America, Boston College, Tufts University, and Bank of America); Tom Zeller Jr., *Breach Points Up Flaws in Privacy Laws*, N.Y. TIMES, Feb. 24, 2005, at C1 (reporting on the ChoicePoint breach). Congress has introduced bills to impose stricter standards of privacy and security on such companies. See Mohl, *supra* (reporting on two pending bills that would create a notification requirement); Zeller, *supra* (reporting on bills submitted by Senator Dianne Feinstein (D-Cal.) that would create a nationwide notification requirement). In 2006, ChoicePoint settled Federal Trade Commission charges (of violating consumer rights and privacy laws) by paying a \$10 million civil fine and \$5 million for consumer redress. See Stipulated Final Judgment and Order for Civil Penalties, Permanent Injunction, and Other Equitable Relief at 4, 17, *United States v. ChoicePoint Inc.*, No. 1:06-CV-0198 (N.D. Ga. Feb. 15, 2006), available at <http://www.ftc.gov/os/caselist/choicepoint/choicepoint.htm>. ChoicePoint, which began by keeping insurance claim records, has introduced new privacy protections. Gary Rivlin, *Keeping Your Enemies Close*, N.Y. TIMES, Nov. 12, 2006, § 3, at 1. Additionally, the Department of Homeland Security plans to increase cooperation between federal intelligence operations and local law enforcement. Robert Block, *Fighting Terrorism by Sharing Data*, WALL ST. J., Oct. 16, 2006, at A6.

¹¹ Michigan adopted the first such compulsory reporting law in 1883. JAMES A. TOBEY, *PUBLIC HEALTH LAW* 133 (3d ed. 1947). By the mid-twentieth century, all states had adopted laws requiring physicians (and often hospitals, laboratories, and other health facilities) to report “notifiable,” “communicable,” or “dangerous” diseases to the state or local health department. *Id.*

¹² See generally JAMES A. MORONE, *HELLFIRE NATION: THE POLITICS OF SIN IN AMERICAN HISTORY* (2003) (describing how the same groups have been blamed for the spread of disease, violence, laziness (unwillingness to work), and sexual depravity throughout U.S. history).

¹³ Turn of the century physicians initially objected to reporting on their paying patients, believing it would violate physician-patient confidentiality or stigmatize their medical practice. However, most reported on charity patients. See C.-E.A. WINSLOW, *THE LIFE OF HERMANN M. BIGGS: PHYSICIAN AND STATESMAN OF THE PUBLIC HEALTH* 134 (1929).

Today, almost everyone, regardless of station, could be subject to public health surveillance. The scope of public health surveillance has grown significantly beyond its contagious disease origins. Public health organizations now recommend compulsory reporting of more than sixty infectious diseases, twenty-nine genetic conditions (for newborns), almost all types of cancer, and other chronic diseases like asthma and lupus.¹⁴ The Bush administration's National Strategy for Pandemic Influenza has given the Department of Homeland Security the task of developing a National Biosurveillance Integration System (NBIS) to integrate surveillance data about agriculture, food, environment, and human diseases.¹⁵ In January 2006, the New York City Department of Health and Mental Hygiene began requiring laboratories to submit electronic reports of the blood sugar test results of all patients with diabetes, by name and without patient consent.¹⁶ The Health Department intends to contact patients who are not controlling their blood sugar to encourage taking medications, better diet, and more exercise.¹⁷ Although there will always be a need to investigate disease outbreaks in order to prevent epidemics, the more prevalent use of disease surveillance data today is for statistical analysis, planning, budgeting, and general research.¹⁸

This new generation of reporting laws reflects a goal of many people in public health: to collect data about chronic diseases outside the context of a research study and without the need to obtain any individual patient's informed

¹⁴ See, e.g., MATERNAL & CHILD HEALTH BUREAU, U.S. DEP'T OF HEALTH & HUMAN SERVS., NEWBORN SCREENING: TOWARD A UNIFORM SCREENING PANEL AND SYSTEM 7-11 (2005), available at <http://mchb.hrsa.gov/screening>; CDC, Nationally Notifiable Diseases Surveillance System, <http://www.cdc.gov/epo/dphsi/nndsshis.htm> (last visited Apr. 1, 2007).

¹⁵ See generally HOMELAND SEC. COUNCIL, NATIONAL STRATEGY FOR PANDEMIC INFLUENZA: IMPLEMENTATION PLAN (2006), available at http://www.whitehouse.gov/homeland/nspi_implementation.pdf. The proposed Bioterrorism Act of 2005 (formally titled "Protecting America in the War on Terror Act of 2005") would "establish and maintain a national electronic surveillance program" that goes beyond detecting a bioterror attack to creating a general health database for studying health trends. S. 3, 109th Cong. § 172 (2005). The Centers for Disease Control and Prevention (CDC) has already developed the National Electronic Disease Surveillance System (NEDSS), intended to bring all kinds of reporting systems into one national integrated electronic database. See generally CDC, National Electronic Disease Surveillance System, <http://www.cdc.gov/nedss> (last visited Apr. 1, 2007).

¹⁶ N.Y., N.Y., HEALTH CODE art. 13, § 13.04 (Dec. 14, 2005) (effective Jan. 15, 2006).

¹⁷ For a discussion of the regulation, its rationale, and possible legal challenges, see generally Wendy K. Mariner, *Medicine and Public Health: Crossing Legal Boundaries*, 10 J. HEALTH CARE L. & POL'Y 121 (2007).

¹⁸ Stephen B. Thacker, *Historical Development*, in PRINCIPLES AND PRACTICE OF PUBLIC HEALTH SURVEILLANCE 1, 6 (Steven M. Teutsch & R. Elliott Churchill eds., 2d ed. 2000); see also TRUST FOR AMERICA'S HEALTH, IMPROVING CANCER TRACKING TODAY SAVES LIVES TOMORROW: DO STATES MAKE THE GRADE? 1-4 (2003), available at <http://healthyamericans.org/state/cancergrade/pdf/FullReport.pdf> (describing the value of cancer data for research).

consent. The question is whether these new surveillance programs should be able to compel the collection of personally identifiable data. Is it possible to reconcile individual interests in personal privacy with modern forms of public health surveillance? Are mandatory public health surveillance programs that focus on statistical analysis, research, or monitoring personal health status a reasonable exercise of the state's police power, or are they vulnerable to challenge as an invasion of privacy? Do they offer the promise of medical advances, or the threat of "general searches, which the authors of the Bill of Rights were so concerned to protect against"?¹⁹ This Article begins to answer these questions.

Part I summarizes the evolution of public health surveillance programs. Part II describes three major functions of surveillance programs: outbreak investigation, identifying newborns who need essential medical care, and research. It also highlights how the aim of those who collect medical information has shifted from preventing the spread of contagious diseases to the more general purposes of research, budget analysis, and policy planning.²⁰ This shift poses a challenge to the principles of liberty and privacy that underpin one's individual autonomy to decide whether to participate in research or to accept medical care.

Part III argues that the sparse case law on constitutional challenges to compulsory reporting laws offers only a fragile conceptual framework for modern public health statutes that compel the disclosure of personally identifiable information. The cases themselves offer little guidance, often ignoring how surveillance information is used and how valuable the right of privacy is to individuals. Modern health surveillance programs, with their focus on obtaining data accurate enough to use for statistical analysis and research, do not easily fit the legal constructs guiding earlier laws designed to prevent epidemics. At the same time, the general goal of improving public health fails to provide any principle for limiting government intrusions into medical privacy.

The Article concludes that modern public health surveillance needs defensible principles that define the scope and limits of state power to collect personally identifiable medical information. Part IV outlines a more robust approach to balancing the state's interest in public health and the individual's interest in the privacy of medical information. This approach weighs the present value of the actual use of the information (instead of speculative long-range goals) against the dignitary value of privacy. Although space precludes a fully developed argument, I hope this Article will inspire thoughtful efforts to retain the value of modern public health surveillance without sacrificing the value of patient privacy.

¹⁹ SAFEGUARDING PRIVACY, *supra* note 2, at 48.

²⁰ See generally Stephen B. Thacker & Joanna Buffington, *Applied Epidemiology for the 21st Century*, 30 INT'L J. EPIDEMIOLOGY 320 (2001) (arguing for the expanded application of epidemiological research to improve public health).

I. THE EVOLUTION OF PUBLIC HEALTH SURVEILLANCE

As the name implies, disease surveillance is the collection of data about diseases and the individuals who have them. Its original purpose was to identify people with communicable diseases²¹ so that public officials could take prompt action to prevent an epidemic.²² Classically, disease surveillance involved a public health official who would investigate an individual found to have a communicable disease in order to find out where she might have acquired the disease and who else might have been infected (an action known as contact tracing).²³ Individuals likely to transmit a communicable disease to others could be subject to isolation,²⁴ and geographic areas might also be quarantined to protect against exposure to disease.²⁵

²¹ Many statutes use the term “communicable” as a synonym for “contagious” to emphasize person-to-person transmission of infection and, by implication, to exclude application to other “infectious” diseases. “Infectious” diseases include any disease that can be transmitted to a human being from any source, whether human, animal, or environmental. Communicable or contagious diseases are a subcategory of infectious diseases that can only be transmitted from one human to another. David Heymann, *Infectious Agents*, in 1 OXFORD TEXTBOOK OF PUBLIC HEALTH 171 (Roger Detels et al. eds., 4th ed. 2002).

²² See CDC, 50 MORBIDITY & MORTALITY WKLY. REP., NO. RR-13, UPDATED GUIDELINES FOR EVALUATING PUBLIC HEALTH SURVEILLANCE SYSTEMS 2 (2001) [hereinafter CDC, UPDATED GUIDELINES], available at <http://www.cdc.gov/mmwr/PDF/rr/tr5013.pdf> (“Public health surveillance is the ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health action to reduce morbidity and mortality and to improve health.”). See generally Guthrie S. Birkhead & Christopher M. Maylahn, *State and Local Public Health Surveillance*, in PRINCIPLES AND PRACTICE OF PUBLIC HEALTH SURVEILLANCE, *supra* note 18, at 253.

²³ See generally Kumnuan Ungchusak, *Principles of Outbreak Investigation*, in 2 OXFORD TEXTBOOK OF PUBLIC HEALTH, *supra* note 21, at 529.

²⁴ See, e.g., *City of Newark v. J.S.*, 652 A.2d 265, 267-68 (N.J. Super. Ct. Law Div. 1993) (ordering involuntary hospitalization of a homeless man who could not avoid exposing the public to his active, contagious tuberculosis).

²⁵ See *Jew Ho v. Williamson*, 103 F. 10, 24 (C.C.N.D. Cal. 1900) (striking down a quarantine for plague in San Francisco on equal protection grounds because it confined only Chinese inhabitants and also because it arbitrarily confined exposed and non-exposed people in the same area); *Wong Wai v. Williamson*, 103 F. 1, 9-10 (C.C.N.D. Cal. 1900) (same). For a history of the epidemic, see generally MARILYN CHASE, *THE BARBARY PLAGUE: THE BLACK DEATH IN VICTORIAN SAN FRANCISCO* (2003). For a history of the quarantine of immigrants to New York City for cholera, see generally HOWARD MARKEL, *QUARANTINE!: EAST EUROPEAN JEWISH IMMIGRANTS AND THE NEW YORK CITY EPIDEMICS OF 1892* (1997). Quarantine of large populations has almost never prevented an epidemic, and is not generally recommended today. Joseph Barbera et al., *Large-Scale Quarantine Following Biological Terrorism in the United States*, 286 JAMA 2711, 2715-16 (2001). A contemporary example is China’s threat of quarantine to prevent the spread of SARS in 2003, where public fear of the quarantine led hundreds of thousands to flee Beijing. See Joseph Kahn, *Quarantine Set in Beijing Areas To Fight SARS*, N.Y. TIMES, Apr. 25, 2003, at

Around 1879, the Marine Hospital Service (predecessor to the Public Health Service) began to collect data on diseases like cholera and yellow fever in order to prepare for quarantine measures for ships arriving in U.S. ports.²⁶ Later, case reporting began on the state level.²⁷ The Council of State and Territorial Epidemiologists (CSTE), a private professional association of epidemiologists employed primarily by state and local health departments, was organized later to make periodic recommendations concerning which diseases states should track.²⁸

In the latter part of the twentieth century, disease surveillance expanded to monitor new disease trends, and the more comprehensive term “public health surveillance” increasingly replaced “disease surveillance” (at least among public health professionals).²⁹ As infectious diseases claimed fewer lives in

A1. See generally INST. FOR BIOETHICS, HEALTH POLICY & LAW, UNIV. OF LOUISVILLE SCH. OF MED., QUARANTINE AND ISOLATION: LESSONS LEARNED FROM SARS (2003), available at http://mmrs.fema.gov/PublicDocs/2003-11_SARS_Quarantine_Rpt.pdf.

²⁶ The Marine Hospital Service was originally created to care for merchant seaman. An Act for the Relief of Sick and Disabled Seamen, ch. 77, 1 Stat. 605 (1798). The Quarantine Act of 1878 gave the Marine Hospital Service the power to quarantine ships arriving in U.S. ports, to conduct medical examinations of immigrants, and to report the name and destinations of any ships leaving infected ports. An Act To Prevent the Introduction of Contagious or Infectious Diseases into the United States, ch. 66, 20 Stat. 37 (1878). By 1912, the year in which the Marine Hospital Service was renamed the Public Health Service, Congress had authorized field studies to investigate the “diseases of man and . . . the pollution of navigable streams.” RALPH C. WILLIAMS, THE UNITED STATES PUBLIC HEALTH SERVICE, 1798-1950, at 167 (1951); see also FITZHUGH MULLAN, PLAGUES AND POLITICS: THE STORY OF THE UNITED STATES PUBLIC HEALTH SERVICE 58 (1989). Executive orders still list quarantinable diseases in order to protect national ports from contagion. President Bush added anthrax to the list in 2001, then SARS in 2003, and then “[i]nfluenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic,” in 2005. Exec. Order No. 13,295, 3 C.F.R. 220 (2004), amended by Exec. Order No. 13,375, 3 C.F.R. 162 (2006) (relying on the authority granted to the President by the Public Health Service Act § 361, 42 U.S.C. § 264(b) (2000)).

²⁷ See, e.g., Michael A. Stoto, *Population Health Monitoring*, in HEALTH STATISTICS: SHAPING POLICY AND PRACTICE TO IMPROVE THE POPULATION’S HEALTH 317, 322-24 (Daniel J. Friedman et al. eds., 2005).

²⁸ See Sandra Roush et al., *Mandatory Reporting of Diseases and Conditions by Health Care Professionals and Laboratories*, 281 JAMA 164, 164 (1999).

²⁹ See Thacker, *supra* note 18, at 1-16; Steven B. Thacker & Donna F. Stroup, *Future Directions for Comprehensive Public Health Surveillance and Health Information Systems in the United States*, 140 AM. J. EPIDEMIOLOGY 383, 384 (1994). This shift to public health surveillance follows a shift away from communicable disease prevention to personal health promotion. Attention to health promotion may date from 1974, when Canada published the landmark Lalonde Report. See generally MARC LALONDE, A NEW PERSPECTIVE ON THE HEALTH OF CANADIANS (1974), available at http://www.hc-sc.gc.ca/hcs-sss/alt_formats/hpb-dgps/pdf/pubs/1974-lalonde/lalonde_e.pdf. U.S. Surgeon General Julius Richmond published a similar report, *Healthy People*, in 1979, initiating the periodic review of Americans’ overall health status and setting goals for improvement. See generally U.S.

the United States,³⁰ chronic diseases, such as heart disease and cancer, became the leading causes of death.³¹ Such diseases are influenced, if not caused, by a variety of social, environmental, genetic, and behavioral factors, and public health surveillance seeks to identify these factors.³² Today, surveillance programs exist for a variety of cancers, genetic conditions of newborns, and occupational diseases, as well as other health-related events like immunizations, injuries, and adverse drug reactions.³³ Unlike earlier reporting systems, chronic disease programs are not intended to intervene with individual cases.³⁴ People with cancer or diabetes, of course, pose no threat of contagion. Reducing the risk of chronic diseases is not as simple as shutting off a cholera-contaminated water supply, pasteurizing milk, or constructing sewers. It requires a far more complex set of programs.

As disease prevention has become more complex, data collection tools have become more sophisticated. Case reporting is only one method of data collection.³⁵ Other methods include population surveys, medical record reviews, and epidemiological and behavioral research studies aimed at

DEP'T OF HEALTH & HUMAN SERVS., HEALTHY PEOPLE 2010 (2d ed. 2000), available at <http://www.health.gov/healthypeople/document>.

³⁰ See COMM. ON EMERGING MICROBIAL THREATS TO HEALTH, INST. OF MED., EMERGING INFECTIONS: MICROBIAL THREATS TO HEALTH IN THE UNITED STATES 151-53 (1992) (commenting on the elimination of diseases like smallpox and the reduced risk of other contagious diseases like measles and tuberculosis in the twentieth century).

³¹ See Arialdi M. Miniño et al., *Deaths: Preliminary Data for 2004*, NAT'L VITAL STAT. REP., June 28, 2006, at 1, 4 (reporting data on the major causes of death in the United States, of which the top three are heart disease, cancers, and stroke).

³² ALAN PETERSEN & DEBORAH LUPTON, THE NEW PUBLIC HEALTH, at i (1996) ("The new public health takes as its foci the categories of 'population' and 'the environment,' conceived of in their widest sense to include psychological, social and physical elements."); Wendy K. Mariner, *Law and Public Health: Beyond Emergency Preparedness*, 38 J. HEALTH L. 247, 252-54 (2005) (arguing that the public health field may pay increasing attention to the "social determinants of health" in the future); see also Elizabeth Fee, *The Origins and Development of Public Health in the United States*, in 1 OXFORD TEXTBOOK OF PUBLIC HEALTH 35, 45-46 (Roger Detels et al. eds., 3d ed. 1997) (discussing the "epidemiological transition" of the postwar era).

³³ See Stephen B. Thacker et al., *Public Health Surveillance for Chronic Conditions: A Scientific Basis for Decisions*, 14 STAT. MED. 629, 629-30 (1995).

³⁴ A pilot study looking at surveillance programs in eight states (Arkansas, Colorado, Florida, Maine, Michigan, New York, Oregon, and Wisconsin) found that surveillance data was most commonly used to compile statistics for the CDC. Emilie Curry, *Public Health Surveillance Data Survey 13 & fig.7* (2004) (unpublished manuscript, on file with author).

³⁵ In case reporting, physicians (and others) report their diagnoses to a local or state health department. Reports were first made by sending a postcard; more detailed forms followed. Cases requiring urgent intervention are reported by telephone. Now, electronic transmission of diagnoses is beginning. Nevertheless, the basic structure of case reporting systems today differs little from the original design, even though details like reporting forms and available medications have evolved. See Stoto, *supra* note 27, at 321.

determining the distribution, incidence, and causation of diseases across locations and populations, as well as the effects of prevention and treatment interventions.³⁶ Such data allow statistical analyses and research in order to identify and recommend ways to avoid illnesses.³⁷ The data are also used to determine government funding for public and private programs, such as AIDS treatment under the Ryan White CARE Act.³⁸

While medical science has reduced the need for intervening with individuals to control disease, information technology has increased the ease and utility of obtaining and disseminating information.³⁹ The information revolution made it possible to collect large amounts of information about people, including medical information, combine it with different databases (record linkage) for various analyses,⁴⁰ and transmit it electronically all over the world.⁴¹ As one

³⁶ See generally Julie A. Pavlin et al., *Innovative Surveillance Methods for Rapid Detection of Disease Outbreaks and Bioterrorism: Results of an Interagency Workshop on Health Indicator Surveillance*, 93 AM. J. PUB. HEALTH 1230 (2003). The National Health Interview Survey has been conducted periodically since the mid-twentieth century, under the auspices of the National Center for Health Statistics. For an example of a more targeted study, see Edward H. Kaplan & Ron Brookmeyer, *Snapshot Estimators of Recent HIV Incidence Rates*, 47 OPERATIONS RES. 29, 31-35 (1999) (developing mathematical models of the incidence of HIV infection and then applying the models to data collected by government agencies).

³⁷ The information can also be used to identify specific populations in need of health services. Smallpox was eradicated in the United States by identifying areas where people had not been immunized and making concerted efforts to persuade them to get the vaccine. Ruth L. Berkelman et al., *Public Health Surveillance*, in 2 OXFORD TEXTBOOK OF PUBLIC HEALTH, *supra* note 21, at 759, 760.

³⁸ Ryan White Comprehensive AIDS Resources Emergency Act of 1990, Pub. L. No. 101-381, 104 Stat. 576 (codified as amended in scattered sections of 42 U.S.C.), *amended* by Ryan White HIV/AIDS Treatment Modernization Act of 2006, Pub. L. No. 109-415, 120 Stat. 2767.

³⁹ Public health surveillance programs might be analogized to fire departments. Although fires are rare events, firefighters must be ready to respond on a moment's notice to control the fires that do occur and to prevent a conflagration. Firefighters find other things to do while waiting for a fire, such as inspecting fire alarms and attending to emergencies other than fires. Epidemics of communicable disease are rare events in the United States, but those that do occur often require a large effort that could not be mounted from scratch. Public health programs provide a ready infrastructure. In down times, public health surveillance programs perform other tasks, such as statistical analyses of disease trends and research about the causes and consequences of diseases.

⁴⁰ U.S. GEN. ACCOUNTING OFFICE, NO. GAO-01-126SP, RECORD LINKAGE AND PRIVACY: ISSUES IN CREATING NEW FEDERAL RESEARCH AND STATISTICAL INFORMATION 1 (2001), *available at* <http://www.gao.gov/new.items/d01126sp.pdf> (defining record linkage as "a computer-based process that combines multiple sources of existing data").

⁴¹ The federal regulations on medical information privacy that resulted from the Health Insurance Portability and Accountability Act (HIPAA) were inspired by the federal government's desire to have all medical providers keep electronic medical records that

leading text explains, "Public health surveillance information is used to assess public health status, define public health priorities, evaluate programs, and conduct research."⁴² Nonetheless, before September 11, 2001, public health agencies had not persuaded the public to compel reporting of personally identifiable health information for all these purposes.

The five deaths from anthrax letters sent in October 2001 fueled fears that terrorists might use chemical or biological agents to attack the United States.⁴³ The SARS epidemic in 2003 revived fears of natural epidemics.⁴⁴ Both the possibility of bioterrorism and new natural epidemics like avian influenza⁴⁵ inspired new legislation to collect vast amounts of medical information in an attempt to detect cases in time to prevent the further spread of disease.⁴⁶

could be easily transmitted wherever they were needed and comparable across different institutions for purposes of federal benefit payment programs. See 45 C.F.R. pts. 160, 164 (2006). Recognizing that such ease of access to personal medical information might raise concern among the public, Congress required that either legislation or regulations be produced to protect the privacy of personal medical information. When Congress failed to act, the Department of Health and Human Services adopted regulations (the HIPAA Privacy Rule). Attempts to create a nationwide system of electronic medical records have stalled in Congress. Ricardo Alonso-Zaldivar, *Bill Seeks National Medical Records System*, L.A. TIMES, Aug. 13, 2006, at A22. Supporters believe that having records electronically accessible anywhere in the country would improve quality and prevent medical errors, but critics argue that current attempts to establish such a system contain too few privacy safeguards. See *id.*

⁴² Thacker, *supra* note 18, at 6.

⁴³ See John A. Jernigan et al., *Bioterrorism-Related Inhalational Anthrax: The First 10 Cases Reported in the United States*, 7 EMERGING INFECTIOUS DISEASES 933, 934 (2001) (describing the first ten reported cases, both fatal and non-fatal, in the anthrax outbreak).

⁴⁴ See generally LEARNING FROM SARS: PREPARING FOR THE NEXT DISEASE OUTBREAK (Stacey Knobler et al. eds., 2004) [hereinafter LEARNING FROM SARS], available at <http://books.nap.edu/html/SARS/0309091543.pdf>; WORLD HEALTH ORG., SEVERE ACUTE RESPIRATORY SYNDROME (SARS) (2003), available at http://www.who.int/csr/media/sars_wha.pdf; World Health Org., Summary of Probable SARS Cases with Onset of Illness from 1 November 2002 to 31 July 2003, http://www.who.int/csr/sars/country/table2004_04_21/en/index.html (last visited Apr. 1, 2007)

⁴⁵ See generally Arnold S. Monto, *The Threat of Avian Influenza Pandemic*, 352 NEW ENG. J. MED. 323 (2005); Klaus Stöhr, *Avian Influenza and Pandemics – Research Needs and Opportunities*, 352 NEW ENG. J. MED. 405 (2005); Kumnuan Ungchusak et al., *Probable Person-to-Person Transmission of Avian Influenza A (H5N1)*, 352 NEW ENG. J. MED. 333 (2005).

⁴⁶ On October 23, 2001, the CDC released a "model state law" on emergency powers that, among other things, would require physicians and hospitals to report patients with any infectious disease to the state health department and require drug stores to report sales of prescription and over-the-counter medications for respiratory illnesses. See MODEL STATE EMERGENCY HEALTH POWERS ACT § 301 (Ctr. for Law & the Public's Health 2001), revised version available at <http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf>; see also George J. Annas, *Bioterrorism, Public Health, and Civil Liberties*, 346 NEW ENG. J. MED. 1337, 1338-39 (2002) ("[T]he authority to respond to a bioterrorist attack or a new epidemic

Public health agencies welcomed federal bioterrorism grants to fund surveillance programs.⁴⁷ Put forth just as the Bush administration proposed to collect other personal information to find possible terrorists, the collection of information for purposes of analyzing disease outbreaks and trends appeared to further diminish personal privacy.⁴⁸ Soon thereafter came public reports that records held by private companies and public agencies had been lost or obtained by fraudulent means.⁴⁹ Public sentiment about providing personal information to the government or private companies has appeared to whipsaw between support in the name of preventing terrorism and opposition due to fears of government invasions of privacy.⁵⁰

So-called emergency preparedness programs might have returned disease surveillance to its contagious disease roots. But public health had already grown far beyond them, sweeping all health conditions into its sphere of interest. New information technology encourages both more surveillance and new uses for the data collected, from changing the environment to changing individual behavior. Surveillance programs have traditionally been disease-specific, but the present federal attention to terrorism has been encouraging

that the model act provides is much too broad, since it applies not just to real emergencies such as a smallpox attack but also to nonemergency conditions as diverse as annual influenza epidemics and the AIDS epidemic.”).

⁴⁷ The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594, authorized funding to improve public health surveillance and reporting at the state and local level, and to integrate federal, state, and local systems. See 42 U.S.C. §§ 247d-4(b), 300hh(b)(2) (Supp. IV 2004). Proponents argued that bioterrorism surveillance would have dual uses – detecting both terrorist attacks and disease outbreaks caused by nature or accident. Critics argued that such measures would be counterproductive and that the public would be better served by providing public health services. See generally Hillel W. Cohen et al., *The Pitfalls of Bioterrorism Preparedness: The Anthrax and Smallpox Experiences*, 94 AM. J. PUB. HEALTH 1667 (2004).

⁴⁸ Public concern was sparked by the Total Information Awareness (later called Terrorism Information Awareness) program headed by John Poindexter, who was forced to resign as a result of the controversy. See O’HARROW, *supra* note 6, at 191-98, 203-13.

⁴⁹ See Jonathan Krim, *Customer Data Lost, Citigroup Unit Says*, WASH. POST, June 7, 2005, at A1; Robert O’Harrow Jr., *Agencies Not Protecting Privacy Rights, GAO Says*, WASH. POST, Apr. 5, 2006, at A9; David Stout & Tom Zeller Jr., *Vast Data Cache About Veterans Is Stolen*, N.Y. TIMES, May 23, 2006, at A1; see also sources cited *supra* note 10.

⁵⁰ See News Release, Harris Interactive, *The Benefits of Electronic Medical Records Sound Good, but Privacy Could Become a Difficult Issue* (Feb. 8, 2007), available at <http://www.harrisinteractive.com/news/allnewsbydate.asp?NewsID=1174>; Alan F. Westin, Professor Emeritus, Columbia Univ., Presentation at the Hearing on Privacy and Health Information Technology of the Dep’t of Health & Human Servs., Nat’l Comm. on Vital & Health Statistics, Subcomm. on Privacy & Confidentiality (Feb. 23, 2005), available at <http://ncvhs.hhs.gov/050223tr.htm>.

coordinated systems that link all types of health information in an electronic database.⁵¹

Most state surveillance programs today receive funding from federal agencies, primarily the Centers for Disease Control and Prevention (CDC).⁵² Federal agencies have no authority to require states to pass specific laws, but the CDC's recommendations, together with the leverage of funding and the utility of the resulting data analyses, encourage states to adopt compulsory reporting laws.⁵³ States do not necessarily require reporting of all the recommended diseases and conditions.⁵⁴ They do, however, voluntarily submit case reports on most diseases they receive to the CDC.⁵⁵

Data collected by public health surveillance flows through at least three levels, as shown in Figure 1 below. A provider initially collects information from a patient, either orally or from physical examination or diagnostic tests. In the first level of surveillance, the provider reports (discloses) the patient's information to a third party, usually a state or local health department, when required by state reporting laws.⁵⁶ Some health departments outsource the collection of data to a private entity, usually university researchers. At the second level, the state health department reports (discloses) the patient's information to the CDC, without the patient's name.⁵⁷

⁵¹ See, e.g., CDC, BioSense, <http://www.cdc.gov/biosense> (last visited Apr. 1, 2007); CDC, Public Health Information Network (PHIN), <http://www.cdc.gov/PHIN> (last visited Apr. 1, 2007).

⁵² The CDC has general authority to "conduct in the [Public Health] Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies related to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man." Public Health Service Act § 301(a), 42 U.S.C. § 241(a) (2000). The CDC is also authorized to "collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities," see 42 U.S.C. § 241(a)(1), and to cooperate with and advise the states on matters relating to the public health, see 42 U.S.C. § 243.

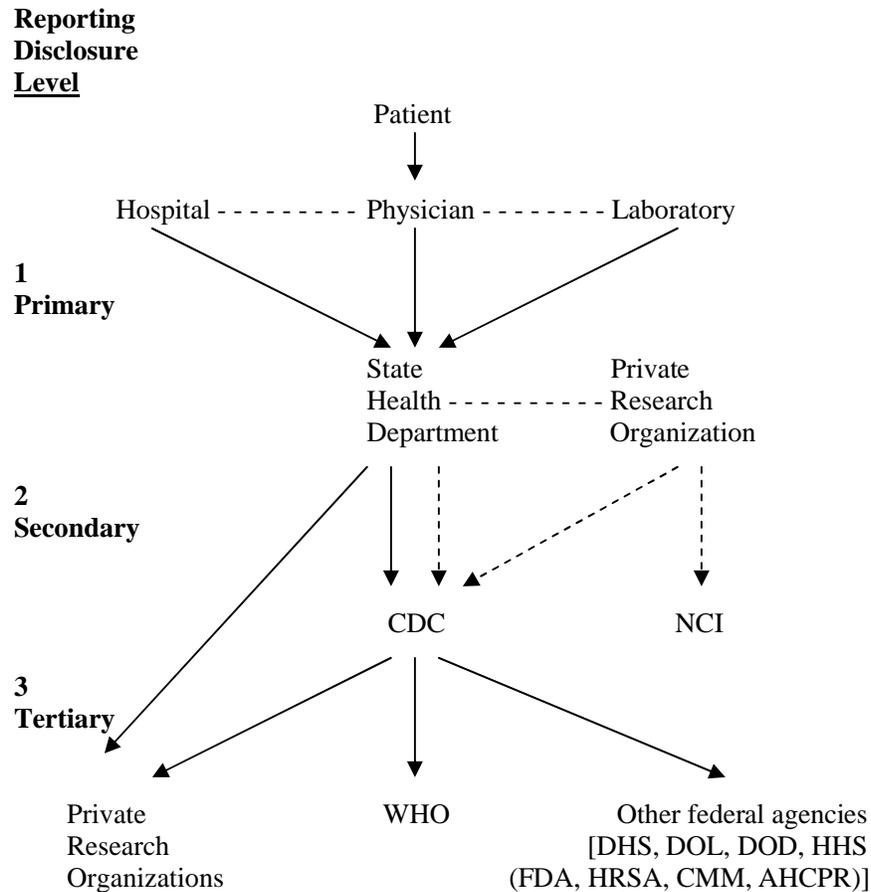
⁵³ See CDC, UPDATED GUIDELINES, *supra* note 22, at 1.

⁵⁴ For example, in 1995 and 1996, the CSTE and CDC recommended adding elevated blood lead levels, silicosis, acute pesticide poisoning, and tobacco use. Roush et al., *supra* note 28, at 165.

⁵⁵ See *supra* note 15.

⁵⁶ Outbreaks are often reported to the local health department, which then reports to the state health department. See, e.g., WIS. STAT. ANN. § 252.05 (West 2007); 105 MASS. CODE REGS. §§ 300.100, 300.110 (2007).

⁵⁷ State law usually authorizes the health department to submit reports to the CDC. It may also authorize the state to allow a different branch of the health department or external researchers to use the data. The release of identifiable data for such secondary research usually requires prior approval by a state agency (and a university's institutional review board) charged with protecting the welfare of human subjects of research.

Figure 1. Surveillance Data Flow Chart

Key: · Dashed lines indicate a contractual/grant relationship.
· Arrows indicate the direction of data reporting.

Note: In Level 1, provider reports of contagious disease cases sometimes go to their local health department (if immediate response is needed), and the local health department then forwards the reports to the state health department. Also, in Level 1, states sometimes contract with university researchers to receive data from providers for specific programs like cancer registries.

At the third level, the CDC sends reports of aggregated national data to the World Health Organization (WHO). The CDC often authorizes other tertiary uses of the data it receives, sharing it with other federal and international agencies for a variety of purposes. Those agencies may combine the data with their own databases and other external databases to conduct various research studies.⁵⁸

II. FUNCTIONS OF SURVEILLANCE

Mandatory reporting laws are adopted for the purposes of protecting public health and preventing (or controlling) disease. In examining whether such goals warrant the different types of surveillance programs described above, we immediately face a problem of definition. What is public health? What counts as preventing or controlling disease? Definitions used in the public health field are now so broad that they encompass anything that might possibly lead to longer life expectancies or a better quality of life.⁵⁹ Consider the following commonly quoted definition from the Institute of Medicine: "Public health is what we, as a society, do collectively to assure the conditions for people to be healthy."⁶⁰ Using such a broad conception, almost anything could be found to promote public health, at least in the long run. If this conception of public health justified the exercise of the state's police power, then the state would

⁵⁸ See generally U.S. GEN. ACCOUNTING OFFICE, *supra* note 40; WORLD HEALTH ORG., ENGAGING FOR HEALTH (2006), available at http://whqlibdoc.who.int/publications/2006/GPW_eng.pdf.

⁵⁹ See, e.g., Abdelmonem A. Afifi & Lester Breslow, *The Maturing Paradigm of Public Health*, 15 ANN. REV. PUB. HEALTH 223, 232 (1994) ("Public health practice embraces all those actions that are directed to the assessment of health and disease problems in the population; the formulation of policies for dealing with such problems; and the assurance of environmental, behavioral, and medical services designed to accelerate favorable health trends and reduce the unfavorable."). See generally COMM. ON ASSURING THE HEALTH OF THE PUB. IN THE 21ST CENTURY, INST. OF MED., *THE FUTURE OF THE PUBLIC'S HEALTH IN THE 21ST CENTURY* (2003).

⁶⁰ COMM. FOR THE STUDY OF THE FUTURE OF PUB. HEALTH, INST. OF MED., *THE FUTURE OF PUBLIC HEALTH* 19 (1988). Nearly a century ago, one scholar proposed a more detailed definition that many would still find accurate today:

Public health is the science and the art of preventing disease, prolonging life, and promoting physical health and efficiency through organized community efforts for the sanitation of the environment, the control of community infections, the education of the individual in principles of personal hygiene, the organization of medical and nursing service for the early diagnosis and preventive treatment of disease, and the development of the social machinery which will ensure to every individual in the community a standard of living adequate for the maintenance of health.

C.-E.A. Winslow, *The Untilled Fields of Public Health*, 51 SCIENCE 23, 30 (1920). For yet another recent definition, see BERNARD J. TURNOCK, *PUBLIC HEALTH: WHAT IT IS AND HOW IT WORKS* 11 (3d ed. 2004) ("[P]ublic health . . . is a broad social enterprise, more akin to a movement, that seeks to extend the benefits of current knowledge in ways that will have the maximum impact on the health status of a population.").

have the authority to enact a wide range of coercive laws, from mandatory reporting of identifiable information to requiring everyone to obey their physicians' recommendations or eat a prescribed diet. Like public welfare, public health is a broad, often vague and malleable concept, susceptible to differing interpretations. This quality undermines its ability to serve as a coherent or even rational basis for compulsory reporting of personal information.⁶¹ A closer look at surveillance programs, however, suggests that, in fact, they serve three more specific and immediate functions: outbreak investigation, identifying newborns for essential medical care, and scientific research. The following sections describe these functions and their uses of personally identifiable information.

A. *Origins and Core Meanings: Outbreak Investigation*

Definitions of disease surveillance typically combine the concept of data collection with that of taking action to prevent the spread of disease.⁶² Reporting systems were, as discussed above, originally designed to detect outbreaks and prevent epidemics.⁶³ Reports to the health department usually included the patient's name and address because of the potential need to contact the patient. Timeliness was also a factor. Investigators needed to know within hours or days that highly contagious diseases such as smallpox had been diagnosed in order to find the source of infection and investigate whether and where it might have spread. Only with quick access to such information could they protect others from imminent infection. Thus, one useful criterion for characterizing data for outbreak investigation and epidemic control is that the data are needed right away to prevent imminent harm.

However, outbreak investigation and epidemic containment comprise only one purpose of surveillance activity today. If mandatory reporting systems were limited to data needed right away to prevent imminent harm, they would not bother to collect reports about the vast majority of illnesses, which are handled adequately by attending physicians. Nevertheless, case reporting systems and mandatory reporting laws typically insist on reports of every case,

⁶¹ See Wendy E. Parmet, *From Slaughter-House to Lochner: The Rise and Fall of the Constitutionalization of Public Health*, 40 AM. J. LEGAL HIST. 476, 477 (1996).

⁶² See Alexander D. Langmuir, *The Surveillance of Communicable Diseases of National Importance*, 268 NEW ENG. J. MED. 182, 182-83 (1963) (defining surveillance as "the continued watchfulness over the distribution and trends of incidence through the systematic collection, consolidation, and evaluation of morbidity and mortality reports and other relevant data" together with timely and regular dissemination to those who "need to know"); see also Berkelman et al., *supra* note 37, at 759; James W. Buehler, *Surveillance*, in MODERN EPIDEMIOLOGY 435, 435 (Kenneth J. Rothman & Sander Greenland eds., 2d ed. 1998); Stephen B. Thacker & Ruth L. Berkelman, *Public Health Surveillance in the United States*, 10 EPIDEMIOLOGY REV. 164, 164 (1988).

⁶³ Outbreak investigations are not limited to contagious diseases. They also include investigations into sources of poisoning, such as pesticides used in the environment, at least where there is no obvious cause.

just to be sure no case is missed.⁶⁴ However, the required reports are rarely submitted or reviewed more often than once a week.⁶⁵ Knowing this, a physician who recognizes a dangerous disease typically telephones the health department to get a timely response.⁶⁶

Traditional case reporting systems are not well suited to rapidly detecting epidemics or bioterrorist attacks using biological or chemical agents.⁶⁷ In recent epidemics, the most accurate, timely, and valuable information came not from official reporting mechanisms, but from alert physicians caring for patients.⁶⁸ New electronic syndromic surveillance systems offer more promise,

⁶⁴ Of course, cases that are not seen by a physician or, if seen, are incorrectly diagnosed, will still be missed. This was the case in the SARS epidemic. The first North American case of SARS was not recognized because the victim, a woman who had returned to Toronto after visiting Hong Kong, died at home without seeking medical care on March 5, 2003. Her son was hospitalized two days later and died on March 13, 2003. Four other family members fell ill and were treated in isolation in four other hospitals, where SARS spread to hospital staff and household contacts. See Monali Varia et al., *Investigation of a Nosocomial Outbreak of Severe Acute Respiratory Syndrome (SARS) in Toronto, Canada*, 169 CAN. MED. ASS'N J. 285, 288 (2003). See generally Tomislav Svoboda et al., *Public Health Measures To Control the Spread of the Severe Acute Respiratory Syndrome During the Outbreak in Toronto*, 350 NEW ENG. J. MED. 2352 (2004).

⁶⁵ Many programs have small numbers of employees, with some working only part-time on surveillance activities. See OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., STATE AND LOCAL BIOTERRORISM PREPAREDNESS, at i-ii (2002), available at <http://oig.hhs.gov/oei/reports/oei-02-01-00550.pdf>; U.S. GEN. ACCOUNTING OFFICE, NO. GAO-03-373, BIOTERRORISM: PREPAREDNESS VARIED ACROSS STATE AND LOCAL JURISDICTIONS 17-22 (2003), available at <http://www.gao.gov/new.items/d03373.pdf>.

⁶⁶ Many health departments require physicians to telephone reports of cases that need immediate investigation, because ordinary weekly or monthly reports would come too late. See J. Lyle Conrad & James L. Pearson, *Improving Epidemiology, Surveillance, and Laboratory Capabilities*, in TERRORISM AND PUBLIC HEALTH 270, 271 (Barry S. Levy & Victor W. Sidel eds., 2003).

⁶⁷ See DENA M. BRAVATA ET AL., BIOTERRORISM PREPAREDNESS AND RESPONSE: USE OF INFORMATION TECHNOLOGIES AND DECISION SUPPORT SYSTEMS 4 (2002), available at <http://www.ahrq.gov/downloads/pub/evidence/pdf/bioit/bioit.pdf>; *Syndromic Surveillance for Bioterrorism Following the Attacks on the World Trade Center – New York City, 2001*, 51 MORBIDITY & MORTALITY WKLY. REP. (SPECIAL ISSUE) 13, 13 (2002), available at <http://www.cdc.gov/mmwr/PDF/wk/mm51sp.pdf>. After September 11 and in preparation for the war in Iraq, the Bush administration encouraged the Department of Defense Advanced Research Projects Agency (DARPA), headed by Vice Admiral John M. Poindexter, to create a computerized network of data that could quickly detect a chemical or biological attack against the United States. Responsibility for a new national bioterrorism warning program was later transferred to civilian control in the CDC. William J. Broad & Judith Miller, *Health Data Monitored for Bioterror Warning*, N.Y. TIMES, Jan. 27, 2003, at A1.

⁶⁸ See Robert A. Weinstein, *Planning for Epidemics – The Lessons of SARS*, 350 NEW ENG. J. MED. 2332, 2334 (2004). In China, physicians reported an outbreak of atypical pneumonia to provincial hospitals in late January 2003, during the Chinese New Year holiday. This was an unhappy coincidence, because many officials were on vacation and

although perhaps less for early warnings of terrorism and epidemics than for ordinary disease surveillance.⁶⁹ Once installed, a computer program automatically scans medical records, logs the number of symptoms of interest without picking up personal information, and electronically transmits the totals to the tracking station, typically in a city or state health department.⁷⁰ The

could not attend to the report, while holiday travel probably exacerbated the spread of disease. Dr. Carlos Urbani, a WHO official, feared that a patient he was treating in Hanoi had avian influenza and contacted the WHO Pacific Regional Office. News of the outbreak was sent through e-mail, internet chat rooms, and local media, rather than the official reporting program. The WHO asked China for information and was told on February 14 that an outbreak consistent with atypical pneumonia was coming under control. LEARNING FROM SARS, *supra* note 44, at 4-6. See generally U.S. GEN. ACCOUNTING OFFICE, NO. GAO-04-564, EMERGING INFECTIOUS DISEASES: ASIAN SARS OUTBREAK CHALLENGED INTERNATIONAL AND NATIONAL RESPONSES (2004).

⁶⁹ A CDC official was reported in January 2003 as saying, “Whether this is going to detect terrorism is unclear. But as a safety net and for tracking an event once it’s going on, it’s very promising.” Broad & Miller, *supra* note 67; see also James W. Buehler et al., *Syndromic Surveillance and Bioterrorism-Related Epidemics*, 9 EMERGING INFECTIOUS DISEASES 1197, 1197 (2003); Charlene Babcock Irvin et al., *Syndromic Analysis of Computerized Emergency Department Patients’ Chief Complaints: An Opportunity for Bioterrorism and Influenza Surveillance*, 41 ANNALS EMERGENCY MED. 447, 447 (2003); Farzad Mostashari et al., *Use of Ambulance Dispatch Data as an Early Warning System for Communitywide Influenza-like Illness, New York City*, 80 (Supp. 1) J. URB. HEALTH i43, i48 (2003); Julie A. Pavlin et al., *Innovative Surveillance Methods for Rapid Detection of Disease Outbreaks and Bioterrorism: Results of an Interagency Workshop on Health Indicator Surveillance*, 93 AM. J. PUB. HEALTH 1230, 1230 (2003).

⁷⁰ See Kenneth D. Mandl et al., *Implementing Syndromic Surveillance: A Practical Guide Informed by the Early Experience*, 11 J. AM. MED. INFORMATICS ASS’N 141, 141 (2004) (“The term *syndromic surveillance* refers to methods relying on detection of clinical case features that are discernable before confirmed diagnoses are made.”). For example, the computer tabulates the number of cases of respiratory distress, fever, headache, and nausea seen, regardless of whether a diagnosis has been made. Arthur Reingold, *If Syndromic Surveillance Is the Answer, What Is the Question?*, 1 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC. & SCI. 77, 77 (2004); see also CDC, 53 MORBIDITY & MORTALITY WKLY. REP., NO. RR-5, FRAMEWORK FOR EVALUATING PUBLIC HEALTH SURVEILLANCE SYSTEMS FOR EARLY DETECTION OF OUTBREAKS: RECOMMENDATIONS FROM THE CDC WORKING GROUP 2 (2004), available at <http://www.cdc.gov/mmwr/PDF/rr/rr5305.pdf>. The CDC BioSense Initiative is a syndromic surveillance system, intended to provide an early warning of diseases that could produce an epidemic. CDC, BioSense, *supra* note 51. CDC funds selected hospitals to participate in the program, including Department of Defense and Veterans Affairs hospitals. *Id.* The National Strategy for Pandemic Influenza calls for the BioSense Initiative to be established in forty-two cities within twelve months – more than CDC had planned – although that goal may be unrealistic. See Bob Brewin, *Critics Question Biosurveillance System Plan*, GOVERNMENT HEALTH IT, May 8, 2006, available at <http://www.govhealthit.com/article94303-05-08-06> (“[H]ealth officials . . . said the timelines for deploying and enhancing [disease surveillance] systems are overly optimistic. The same officials criticized the Bush administration for

tracking agency can review the data relatively promptly, often within twenty-four hours, and contact the hospital to see whether there is a dangerous outbreak.⁷¹

Advantages of syndromic surveillance include speed and privacy. Most systems do not collect patient names or other identifying information.⁷² Almost any passive system could be considered superior to a system that requires affirmative action on the part of human beings. Syndromic surveillance does have limitations, however.⁷³ Systems can be expensive, both to install and to operate.⁷⁴ Because symptoms are common to many diseases, surveillance will produce many false positives and trigger costly investigations into ordinary cases of colds, influenza, and other uncomplicated viral illnesses.⁷⁵ Like sifting through billions of phone conversations, the task is to sift through billions of health records to find a genuine threat to public health. Thus, syndromic surveillance systems may be useful not for detecting bioterrorism, but for detecting slowly developing natural disease outbreaks that go unnoticed by individual physicians.⁷⁶

failing to provide necessary funds to help them meet the challenges of combating a pandemic.”).

⁷¹ For example, if the program shows an abnormally large number of cases of upper respiratory problems, hospital staff might explain that a busload of students with the common cold arrived at the hospital after a motor vehicle accident on a nearby highway. In contrast, if there is no explanation, the health department might send an investigator to interview patients still at the hospital to discover where they may have caught the illness. At that point, the hospital could identify the patients to the health department so that the department employees could interview the patients. Since many biological agents cause upper respiratory problems, it would be important to distinguish between a deliberate terrorist source and a natural source. A collection of definitions of the syndromes that are defined by symptoms is available from the CDC. See SYNDROME DEFINITIONS FOR DISEASES ASSOCIATED WITH CRITICAL BIOTERRORISM-ASSOCIATED AGENTS 4-6 (2003), available at <http://www.bt.cdc.gov/surveillance/syndromedef/pdf/syndromedefinitions.pdf>.

⁷² However, systems could be changed to incorporate patient names. William B. Lober et al., *Syndromic Surveillance Using Automated Collection of Computerized Discharge Diagnoses*, 80 (Supp. 1) J. URB. HEALTH i97, i103 (2003).

⁷³ Reingold, *supra* note 70, at 78-81.

⁷⁴ Brewin, *supra* note 70 (“Some senior health officials questioned the value of disease surveillance systems described in the Bush administration’s plan Dr. Rex Archer, health director of Kansas City, Mo., and president of the National Association of County and City Health Officials, said NBIS would need a level of funding and national commitment comparable to the 1960s’ space race to deliver what the plan calls for within a year.”).

⁷⁵ David L. Buckeridge et al., *Evaluating Detection of an Inhalational Anthrax Outbreak*, 12 EMERGING INFECTIOUS DISEASES 1942, 1946 (2006); Reingold, *supra* note 70, at 79.

⁷⁶ See Richard Pérez-Peña, *System in New York for Early Warning of Disease Patterns*, N.Y. TIMES, Apr. 4, 2003, at A1 (citing the views of Dr. Farzad Mostashari, then assistant commissioner for epidemiology services for the New York City Health Department). *But see* Lawrence O. Gostin, *When Terrorism Threatens Health: How Far Are Limitations on*

Today, surveillance systems primarily use names to improve statistical accuracy in compiling incidence and prevalence data. Because most systems require reports from physicians, hospitals, and laboratories, a person might be reported more than once a year. Surveillance systems use names to de-duplicate reports, ensuring that no case is counted more than once. Most state health departments send the case reports they receive to the CDC.⁷⁷ State health departments replace each patient's name, however, with a Soundex code.⁷⁸ While the CDC does not need (or even want) to know the patients' identities, the information it collects may nonetheless make that possible.⁷⁹

B. *Identifying Newborns for Essential Medical Care*

Newborn genetic screening programs are designed to diagnose newborns with genetic anomalies causing severe developmental disabilities that could be prevented by beginning simple treatments soon after birth. Almost all programs are modeled on phenylketonuria (PKU) screening, which began in the 1960s.⁸⁰ By the mid 1970s, more than forty states required PKU testing for

Personal and Economic Liberties Justified?, 55 FLA. L. REV. 1105, 1129 (2003) (citing a CDC report that advocated for health department surveillance in order to contain bioterrorist attacks).

⁷⁷ See CDC, National Notifiable Disease Surveillance System, 1989, http://wonder.cdc.gov/wonder/sci_data/misc/type_txt/nndss89.asp (last visited Apr. 1, 2007).

⁷⁸ Instructions on how to construct a Soundex code for names are available from the National Archives and Records Administration, an independent federal agency. See Nat'l Archives & Records Admin., Soundex Indexing, <http://www.archives.gov/publications/general-info-leaflets/55.html> (last visited Apr. 1, 2007). The code uses the first letter of a person's surname followed by three numbers assigned to the consonants next appearing in the name: 1 = B, F, P, V; 2 = C, G, J, K, Q, S, X, Z; 3 = D, T; 4 = L; 5 = M, N; 6 = R; 0 = no additional letters in name. It offers examples: the name Washington is coded W252, and Gutierrez is coded G362. *Id.* The result gives a phonetic result without the vowels or H, W, and Y. Some websites automatically convert a surname to a Soundex code. See, e.g., ProGenealogists, Soundex Code Generator, <http://www.progenealogists.com/soundex.htm> (last visited Apr. 1, 2007).

⁷⁹ Individuals might be identified by comparing the phonetic name with other identifying information on the reporting form, such as date of birth, sex, race, and address. Like many organizations concerned with statistical accuracy, the CDC strongly encourages providers to complete all the information requested on reporting forms and evaluates the surveillance programs it funds on the basis of, among other things, the completeness of reports. See CDC, UPDATED GUIDELINES, *supra* note 22, at 16.

⁸⁰ PKU results from a defective enzyme for metabolizing phenylalanine, a common amino acid in protein-rich food, and causes severe neurological damage. A diet low in phenylalanine can prevent or reduce the damage, if begun during infancy. See OFFICE OF TECH. ASSESSMENT, U.S. CONG., HEALTHY CHILDREN: INVESTING IN THE FUTURE 107 (1988) (estimating that the United States saved \$3.2 million dollars for every 100,000 newborns screened for PKU and hypothyroidism, or \$93,000 per diagnosed case, in 1986).

newborns.⁸¹ These laws effectively require physicians to provide, and parents to accept, good medical care for an individual child. Indeed, proponents view mandatory PKU testing laws as enforcing both a legal and an ethical duty of parents to their children.⁸²

Newborn genetic screening laws, however, do not necessarily ensure treatment for the newborn.⁸³ By itself, testing serves only a diagnostic function. The disability can only be prevented with proper treatment. Screening laws that fail to assure treatment cannot serve the function of protecting children. They may only insert the health department into the physician-patient relationship.⁸⁴

Today, almost all of the four million children born each year in the United States have a few drops of blood drawn (usually from the heel) to be tested for PKU and other genetic conditions.⁸⁵ Few parents refuse genetic testing. Most

⁸¹ Nat'l Human Genome Research Inst., The History of Newborn Phenylketonuria Screening in the U.S., <http://biotech.law.lsu.edu/research/fed/tfgt/appendix5.htm> (last visited Apr. 1, 2007).

⁸² See, e.g., Ruth R. Faden et al., *Parental Rights, Child Welfare, and Public Health: The Case of PKU Screening*, 72 AM. J. PUB. HEALTH 1396, 1397 (1982). But see Ellen Wright Clayton, *Screening and Treatment of Newborns*, 29 HOUS. L. REV. 85, 87-88 (1992) (arguing for genetic screening of newborns "only when children can derive substantial benefit from early detection" and when "parents can participate in the screening process"). Parents have a common law, and in some states statutory, duty to provide medically necessary care for their children. See *Prince v. Massachusetts*, 321 U.S. 158, 167 (1944) ("[T]he state has a wide range of power for limiting parental freedom and authority in things affecting the child's welfare; and . . . this includes, to some extent, matters of conscience and religious conviction."); *Saratoga County Dep't of Soc. Servs. v. Hofbauer (In re Hofbauer)*, 393 N.E.2d 1009, 1013 (N.Y. 1979) ("[T]he Legislature has imposed upon the parents of a child the non-delegable affirmative duty to provide their child with adequate medical care."). But see *In re Green*, 292 A.2d 387, 392 (Pa. 1972) ("We are of the opinion that as between a parent and the state, the state does not have an interest of sufficient magnitude outweighing a parent's religious beliefs when the child's life is *not immediately imperiled* by his physical condition."). See generally Walter Wadlington, *Medical Decision Making for and by Children: Tensions Between Parent, State, and Child*, 1994 U. ILL. L. REV. 311 (discussing the development of case law imposing medical treatment for children despite a lack of parental consent).

⁸³ See Kenneth D. Mandl et al., *Newborn Screening Program Practices in the United States: Notification, Research, and Consent*, 109 PEDIATRICS 269, 270 (2002) (finding that only twenty-two states conducted follow-up to confirm that treatment had begun). Screening programs do not typically provide treatment, which often consists of special diets that can be expensive and are not generally covered by health insurance.

⁸⁴ See ASSESSING GENETIC RISKS: IMPLICATIONS FOR HEALTH AND SOCIAL POLICY 261-63 (Lori B. Andrews et al. eds., 1994) [hereinafter ASSESSING GENETIC RISKS].

⁸⁵ U.S. GEN. ACCOUNTING OFFICE, NO. GAO-03-449, NEWBORN SCREENING: CHARACTERISTICS OF STATE PROGRAMS I (2003), available at <http://www.gao.gov/new.items/d03449.pdf>. For current comparative data on state laws requiring screening for

experts agree that newborns should be tested for a condition that is reasonably serious, can be identified with a reliable test, and can be treated with relatively simple and effective measures.⁸⁶ Between six and eight genetic and metabolic conditions meet these criteria.⁸⁷ In the absence of an accurate test or safe, effective treatment, however, testing carries risks that parents have traditionally been permitted to avoid for their children.⁸⁸

New technology can now identify many genetic aberrations for which no treatment exists. Tandem mass spectrometry and DNA analysis make it possible to analyze a single blood sample for dozens of genetic and metabolic conditions at a cost far below testing for several conditions independently.⁸⁹ In 2005, the American College of Medical Genetics recommended that all newborns be screened for twenty-nine diseases.⁹⁰ The report generated criticism because so few of the diseases have effective treatments.⁹¹ Its

specific conditions, see Nat'l Newborn Screening & Genetics Res. Ctr., National Newborn Screening Status Report, <http://genes-r-us.uthscsa.edu> (last visited Apr. 1, 2007).

⁸⁶ See, e.g., Clayton, *supra* note 82, at 87-88; Jean-Louis Dhondt & Jean-Pierre Farriaux, *Impact of French Legislation on Neonatal Screening*, in HUMAN DNA: LAW AND POLICY 285, 286 tbl.I (Bartha Maria Knoppers ed., 1997).

⁸⁷ These conditions include PKU, congenital hypothyroidism, classical galactosemia, hemoglobinopathies (such as sickle cell disease), congenital adrenal hyperplasia, biotinidase deficiency, maple syrup urine disease, and homocystinuria. The last two, however, do not have genuinely effective treatments. ASSESSING GENETIC RISKS, *supra* note 84, at 100 (recommending against screening for conditions for which there is no beneficial treatment).

⁸⁸ See, e.g., George J. Annas, *Mandatory PKU Screening: The Other Side of the Looking Glass*, 72 AM. J. PUB. HEALTH 1401, 1402 (1982) (discussing the potential stigma and fear caused by false positive results during newborn genetic testing); Sheila Wildeman & Jocelyn Downie, *Genetic and Metabolic Screening of Newborns: Must Health Care Providers Seek Explicit Parental Consent?*, 9 HEALTH L.J. 1, 2-3 (2001) (discussing the potential stigma attached to a child who tests positive for a genetic condition that has no treatment).

⁸⁹ See American Academy of Pediatrics Taskforce, *Newborn Screening: A Blueprint for the Future*, 106 PEDIATRICS 389, 389 (2000) [hereinafter *Newborn Screening*]; see also *Neo Gen Screening, Inc. v. New Eng. Newborn Screening Program*, 187 F.3d 24, 26 (1st Cir. 1999) (describing Neo Gen's claim that it had developed a more comprehensive, cheaper testing procedure than that in use by Massachusetts at the time). For recent screening cost estimates when employing tandem mass spectrometry, see PRICEWATERHOUSECOOPERS, NEWBORN SCREENING PROGRAMS: AN OVERVIEW OF COSTS AND FINANCING 14-16 (2001), available at http://www.marchofdimes.com/files/Final_PWC_NBS_Report2.pdf.

⁹⁰ Request for Public Comment on a HRSA Commissioned Report, *Newborn Screening: Toward a Uniform Screening Panel and System*, 70 Fed. Reg. 11,247 (Mar. 8, 2005).

⁹¹ See, e.g., Jeffrey R. Botkin et al., *Newborn Screening Technology: Proceed with Caution*, 117 PEDIATRICS 1793, 1794 (2006). In addition, if new tests are added before they are validated, they can produce false positives that result in damaging a child who receives treatment inappropriately. See Norman Fost, *Genetic Diagnosis and Treatment: Ethical Considerations*, 147 AM. J. DISEASES CHILD. 1190, 1191 (1993) (arguing that, in the early

recommendations, however, have been embraced by organizations like the March of Dimes and parent groups advocating research to develop diagnostic tests or treatments for genetic conditions.⁹²

For conditions for which there is no treatment, the blood samples and linked information are used almost exclusively for research, such as testing experimental diagnostic assays to determine their sensitivity, specificity, and reliability, estimating the incidence and prevalence of genetic conditions, and searching for risk factors.⁹³ The screening program effectively creates a DNA bank. As more states expand their mandatory newborn screening laws to include these additional conditions, they may confront the question of whether their power to protect children includes the power to create a DNA bank for future research.⁹⁴

New York City's diabetes blood sugar reporting system also identifies a chronic medical condition, but for very different reasons.⁹⁵ Unlike early PKU-type newborn screening programs, there is no imperative for immediate treatment to prevent major disability. To be sure, people with diabetes who get their blood sugar levels under control are less likely to develop health problems like heart disease and glaucoma in the future. However, blood sugar levels are not the only risk factor affecting patients with diabetes. Chronic diseases like diabetes are caused by complex factors and may develop into more serious medical problems only over a long period of time. Finally, most diabetes patients are adults, and virtually all those whose blood sugar levels are reported are under the care of physicians. So far, the specific purpose of the program remains murky. It could be to monitor or change physicians' treatment of diabetes, change patient behavior, or collect data for research on diabetes. In the long term, it may be intended to reduce the government's Medicaid costs for patients with diabetes.

C. Research

Data collected from surveillance are used for a variety of research studies. Cancer registries are perhaps the most salient example. In the mid-1930s, the

years of its use, the special diet designed for infants with PKU caused neurological damage in children erroneously diagnosed with the disease).

⁹² See *Newborn Screening*, *supra* note 89, at 389.

⁹³ See Richard S. Olney et al., *Storage and Use of Residual Dried Blood Spots from State Newborn Screening Programs*, 148 J. PEDIATRICS 618, 618 (2006).

⁹⁴ For discussion of whether the consent of blood and tissue donors should be required for future research uses of their samples, see LORI ANDREWS & DOROTHY NELKIN, *BODY BAZAAR: THE MARKET FOR HUMAN TISSUE IN THE BIOTECHNOLOGY AGE* 21-23 (2001); NAT'L BIOETHICS ADVISORY COMM'N, *1 RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE* 62-71 (1999); Ellen Wright Clayton, *Informed Consent and Biobanks*, 33 J.L. MED. & ETHICS 15, 18-20 (2005); Mark A. Rothstein, *Expanding the Ethical Analysis of Biobanks*, 33 J.L. MED. & ETHICS 89, 92-93 (2005).

⁹⁵ See discussion *supra* notes 16-17 and accompanying text.

Connecticut Medical Society began collecting information about patients with various cancers to see if it could identify successful treatments.⁹⁶ The idea was to help physicians improve patient care.⁹⁷ Since then, other organizations have initiated programs with similar goals.⁹⁸ Cancer registries typically collect detailed personally identifiable information, primarily so that they can contact patients periodically to update information.⁹⁹ The data are ordinarily submitted by hospitals, clinics, or physicians, either voluntarily with patient consent or pursuant to a mandatory reporting law. Most registries receive multiple reports about the same person and de-duplicate the reports by comparing names and dates of birth.

The National Cancer Institute (NCI) established its Surveillance, Epidemiology and End Results (SEER) program in 1973 with a similar focus on analyzing methods of cancer treatment and outcomes.¹⁰⁰ Consistent with the NCI's mission, SEER focuses on conducting medical research studies. SEER currently collects data from population-based registries covering over twenty-five percent of the U.S. population.¹⁰¹ The actual operation of the registries is typically delegated to universities, where researchers analyze the data and produce reports. They also follow cases annually to find out how many patients remain alive and to calculate survival rates. SEER publishes anonymous statistics on cancer annually, based on data collected about two years earlier.¹⁰²

⁹⁶ Conn. State Med. Soc'y, History & Milestones, http://www.csms.org/index.php?option=com_content&task=view&id=35&Itemid=43 (last visited Apr. 1, 2007).

⁹⁷ *Id.*

⁹⁸ CDC, NPCR Cancer Surveillance System Rationale and Approach, <http://www.cdc.gov/cancer/npcr/training/css.htm> (last visited Apr. 1, 2007) [hereinafter NPCR-CSS] ("Cancer surveillance is the ongoing, timely, and systematic collection and analysis of information on cancer risk factors (such as lifestyle factors, behavioral influences, genetic predispositions, or environmental exposures), screening and early detection, new cancer cases, cancer deaths, extent of disease at diagnosis, treatment, clinical management, and survival.").

⁹⁹ Private, professional organizations, including the National Cancer Registrars Association and the North American Association of Central Cancer Registries (NAACCR), set voluntary standards for collecting data, such as definitions and data formats, and criteria for completeness, timeliness, and quality of the data. *See generally* N. AM. ASS'N OF CENT. CANCER REGISTRIES, 2 STANDARDS FOR CANCER REGISTRIES: DATA STANDARDS AND DATA DICTIONARY (Lori A. Havener & Dianne Hultstrom eds., 11th ed. 2006), *available at* <http://www.naacr.org/filesystem/pdf/Volume%20II%20Version%2011.1.pdf>. The standards may vary with the specific goals of particular registries. *See generally* Judith Swan et al., *Cancer Surveillance in the U.S.*, 83 *CANCER* 1282 (1998).

¹⁰⁰ *See* Nat'l Cancer Inst., Overview of the SEER Program, <http://seer.cancer.gov/about> (last visited Apr. 1, 2007).

¹⁰¹ *Id.* (listing the states, cities, and rural areas from which data is collected).

¹⁰² *See* Nat'l Cancer Inst., SEER – Frequently Asked Questions, <http://www.seer.cancer.gov/faq> (last visited Apr. 1, 2007).

The National Cancer Act was amended in 1992 to authorize the CDC to fund cancer registries in areas not covered by SEER.¹⁰³ The Act now requires, as a condition of eligibility for funding, that the data held by a CDC-funded cancer registry be made available for a wide range of research, both by the registry itself and by unrelated public or private entities.¹⁰⁴ The difference between the NCI and CDC registries reflects the different methods the agencies use to collect data. The NCI uses a representative sample of cancers to make estimates for the country. The CDC collects data from case reports of every case of disease.

Most registries authorize external researchers to use registry data in a variety of research studies.¹⁰⁵ Personal identifiers make it possible to link cancer registry data to many other data sources, including the Behavioral Risk Factor Surveillance Survey, environmental health department records, Medicare and Medicaid health records, health insurance records, the National Death Index, death certificates and other vital statistics records, geographic information systems, census records, and registries of licensed practitioners (e.g., physicians, nurses, plumbers) and other specific populations (e.g., Vietnam Veterans registry). As information technology advances, the possible linkages are endless.

¹⁰³ See Cancer Registries Amendment Act, Pub. L. No. 102-515, 106 Stat. 3372 (1992) (codified at 42 U.S.C. § 280e (2000)). The Cancer Registries Amendment Act authorized the CDC to “make grants to States” and to “make grants or enter into contracts with academic or nonprofit organizations designated by the State to operate the State’s cancer registry.” *Id.* § 3, 106 Stat. at 3372 (codified at 42 U.S.C. § 280e(a)). The Act further provided that the data to be collected in the CDC-funded registries would include:

- (1) demographic information about each case of cancer;
- (2) information on the industrial or occupational history of the individuals with the cancers, to the extent such information is available from the same record;
- (3) administrative information, including date of diagnosis and source of information;
- (4) pathological data characterizing the cancer, including the cancer site, stage of disease (pursuant to Staging Guide), incidence, and type of treatment; and
- (5) other elements determined appropriate by the Secretary.

Id., 106 Stat. at 3373 (codified at 42 U.S.C. § 280e(a)). CDC grant application requirements specified that “demographic information” should include the patient’s name, address, census tract, race, sex, birth date, and social security number. National Program of Cancer Registries, 59 Fed. Reg. 26,800, 26,801 (May 24, 1994).

¹⁰⁴ See 42 U.S.C. § 280e(c)(2)(D)(vi)-(vii); see also *State Cancer Registries: Status of Authorizing Legislation and Enabling Regulations – United States, October 1993*, 43 MORBIDITY & MORTALITY WKLY. REP. 71, 74 (1994) (“[T]he federal statute requires authorization of cancer registries under state-specific laws and promulgation of regulations that ensure case reporting and use of data for research. . . . Registries provide a means for collecting such information and may assist in conducting population-based epidemiologic and biologic research, allocating of health resources, and evaluating cancer-control and cancer-prevention programs.”).

¹⁰⁵ See, e.g., Kathleen McDavid et al., *Prostate Cancer Incidence and Mortality Rates and Trends in the United States and Canada*, 119 PUB. HEALTH REP. 174, 175 (2004).

Several states have gone beyond authorizing the creation of cancer registries, and have enacted laws or adopted regulations that either permit or require medical providers to report cancer cases to a registry without their patients' consent.¹⁰⁶ In some states, advocacy groups lobbied state legislatures and health departments for a centralized source of information, either in an attempt to explain unusually high rates of cancer in their communities or in response to fears of exposure to hazards from local manufacturing plants.¹⁰⁷ The more important factor appears to be the availability of federal grant funds to create or expand a registry.¹⁰⁸ CDC prefers that registries be located in states that require the reporting of cancer cases by law.

Although the National Cancer Act does not require states to enact any particular laws, undoubtedly because such a federal requirement would violate state sovereignty,¹⁰⁹ grants are unlikely without a mandatory reporting law. The Act requires that statewide cancer registries be legally authorized to obtain all medical records of cancer patients from any individual or organization providing cancer services in order to be eligible for funding.¹¹⁰ It would be difficult to assure access to "all records" without dispensing with consent.¹¹¹

Arguably, any use of personally identifiable surveillance data – apart from outbreak investigation and epidemic containment – could qualify as research with human subjects. Cancer registries squarely present the question of whether the state can demand access to an individual's personally identifiable information for use in research without consent. Since the Nuremberg Code

¹⁰⁶ See, e.g., CAL. HEALTH & SAFETY CODE §§ 103875-103885 (West 2007) (creating a cancer registry and exempting healthcare workers from liability for reporting case information); MASS. GEN. LAWS ch. 111, § 111B (2004) (requiring submission of information on certain brain tumors to state registries); R.I. GEN. LAWS § 5-37.3-4(b)(18) (2007) (allowing disclosure of case information to cancer registries without first obtaining patient consent).

¹⁰⁷ See, e.g., Doug Abrahms, *CDC Tries To Create State-by-State Cancer Database*, GANNETT NEWS SERVICE, Dec. 29, 2002.

¹⁰⁸ While some states had cancer registries for many years, few had enough staff or resources to conduct the research that made their data useful. When NCI funded its SEER sites, a more sophisticated cancer tracking and research program developed in its locations. Elsewhere, data collection depended on the creativity of registry personnel and cooperation from hospitals. Hospitals reportedly pay their cancer registrars more than state cancer registries do. Jeff Parrott, *Indiana Not Part of National Cancer Report*, J. & COURIER (Lafayette, Ind.), Nov. 29, 2002, at 1A.

¹⁰⁹ See *Printz v. United States*, 521 U.S. 898, 912 (1997).

¹¹⁰ 42 U.S.C. § 280e(c)(2)(D)(iii) (2000).

¹¹¹ Dispensing with the consent requirement appears vulnerable to challenge as a warrantless search in violation of the Fourth Amendment's prohibition against unreasonable searches and seizures. See *Tucson Woman's Clinic v. Eden*, 371 F.3d 1173, 1179 (9th Cir. 2004) (finding a Fourth Amendment violation where Arizona regulations required abortion providers to submit to "warrantless, unbounded inspections of their offices and provide DHS inspectors access to unredacted medical records").

was issued in 1947, research with human subjects has been deemed unethical and unlawful unless the subject gives voluntary, informed consent.¹¹² The consent requirement is intended to protect the individual's right of self-determination and the dignity of human beings recognized in all international declarations and covenants on human rights.¹¹³ Without informed consent, humans are being treated only as a means to an end.¹¹⁴ These foundational principles have been embodied in the common law,¹¹⁵ and in regulations

¹¹² The first principle of the Nuremberg Code is that "the voluntary consent of the human subjects is absolutely essential." See 1 NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS app. C, at 151 (2001), available at <http://www.georgetown.edu/research/nrcbl/nbac/human/overvol1.pdf>. For an analysis of the Code's legal status in the United States, see generally George J. Annas, *The Nuremberg Code in U.S. Courts: Ethics Versus Expediency*, in THE NAZI DOCTORS AND THE NUREMBERG CODE 201 (George J. Annas & Michael A. Grodin eds., 1992).

¹¹³ See, e.g., Universal Declaration of Human Rights, G.A. Res. 217(III)A art. 1, U.N. GAOR, 3d Sess., 1st plen. mtg., U.N. Doc A/810 (Dec. 10, 1948).

¹¹⁴ See IMMANUEL KANT, GROUNDWORK FOR THE METAPHYSICS OF MORALS 45 (Allen W. Wood ed. & trans., Yale Univ. Press 2002) (1785) ("[T]he human being, and in general every rational being, exists as end in itself, not merely as means to the discretionary use of this or that will, but in all its actions, those directed toward itself as well as those directed toward other rational beings, it must always at the same time be considered as an end.").

¹¹⁵ See, e.g., *Abdullahi v. Pfizer, Inc.*, No. 01 Civ. 8118, 2002 WL 31082956, at *1, 3-4 (S.D.N.Y. Sept. 17, 2002) (denying defendant's motion to dismiss because the plaintiffs' complaint, which alleged that the defendant had administered experimental antibiotics to plaintiffs without their informed consent, adequately stated a claim under the Alien Tort Claims Act), *vacated in part*, 77 F. App'x 48 (2d Cir. 2003); *Diaz v. Hillsborough County Hosp. Auth.*, No. 8:90-CV-120-T-25B, 2000 U.S. Dist. LEXIS 14061, at *21 (M.D. Fla. Aug. 7, 2000) (approving a settlement in which the defendant compensated a class of pregnant women for conducting research studies on them without their consent); *In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 821 (S.D. Ohio 1995) ("The Nuremberg Code is part of the law of humanity. It may be applied in both civil and criminal cases by the federal courts in the United States."); *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 844 (Md. 2001) (stating that "[a] human subject is entitled to all material information," and rejecting the defendant's claim that it obtained consent because "full material information was not furnished to the subjects"); *T.D. v. N.Y. State Office of Mental Health*, 650 N.Y.S.2d 173, 176 (N.Y. 1996) (striking down regulations which allowed research on mental health patients who were incapable of giving informed consent, because the regulations "violate the State and Federal constitutional rights to due process, as well as the common law right to personal autonomy, of the patients"). *But cf.* *Robertson v. McGee*, No. 01-CV-60-C, 2002 U.S. Dist. LEXIS 4072, at *6-8 (N.D. Okla. Jan. 28, 2002) (dismissing a claim brought by cancer research subjects because the "right to be treated with dignity" established in the Nuremberg Code does not give rise to a private cause of action); *White v. Paulsen*, 997 F. Supp. 1380, 1383 (E.D. Wash. 1998) (finding that "non-consensual medical experimentation violates the laws of nations," but declining to imply the existence of a private right of action for violation of such international law). See generally Wendy K. Mariner, *Human Subjects Research, Law, Common Law of Human Experimentation*, in 2 ENCYCLOPEDIA OF ETHICAL, LEGAL, AND POLICY ISSUES IN BIOTECHNOLOGY 654 (Thomas H.

governing federally funded research known as the “Common Rule,”¹¹⁶ and may have constitutional protection.¹¹⁷ All of these sources support the conclusion that the use of personally identifiable information for research purposes without the subject’s consent violates the subject’s rights.¹¹⁸

Some public health advocates resist the idea that surveillance programs involve “research” with human subjects, and instead argue that most, if not all, surveillance constitutes public health “practice.”¹¹⁹ This argument is based on an analogy to principles of research ethics that distinguish medical research from medical practice, in order to identify which activities are subject to state and federal laws governing research with human subjects.¹²⁰ This analogy,

Murray & Maxwell J. Mehlman eds., 2000) (summarizing common law causes of action in the context of human subjects research).

¹¹⁶ See Federal Policy for the Protection of Human Subjects, 56 Fed. Reg. 28,002 (June 18, 1991). The Common Rule harmonized regulations of more than twenty federal departments and governs human subject research funded by, or submitted to, those departments. See 21 C.F.R. pts. 50, 56 (2006) for the FDA version of the Common Rule, and 45 C.F.R. pt. 46 (2006) for the Department of Health and Human Services version. Most universities, medical centers, and research institutions have executed general assurance agreements with federal agencies, agreeing to apply the Common Rule to all research conducted at the institution, regardless of the source of funding.

¹¹⁷ See *United States v. Stanley*, 483 U.S. 669, 687 (1987) (Brennan, J., concurring in part and dissenting in part) (suggesting that the Constitution protects a right to human dignity, like that described in the Nuremberg Code, which would prohibit research on humans without the subject’s knowledge and consent); *id.* at 710 (O’Connor, J., concurring in part and dissenting in part) (same). Both courts and claimants have begun to cite the Nuremberg Code as support for the conclusion that research without subject consent is unlawful. See cases cited *supra* note 115.

¹¹⁸ See, e.g., 45 C.F.R. § 46.102(f) (2006) (defining a human subject to include “a living individual about whom an investigator . . . conducting research obtains . . . [i]dentifiable private information”).

¹¹⁹ See JAMES G. HODGE, JR. & LAWRENCE O. GOSTIN, COUNCIL OF STATE & TERRITORIAL EPIDEMIOLOGISTS, PUBLIC HEALTH PRACTICE VS. RESEARCH 16 (2004), available at <http://www.cste.org/pdffiles/newpdffiles/CSTEPHResRptHodgeFinal.5.24.04.pdf>; Amy L. Fairchild, *Dealing with Humpty Dumpty: Research, Practice, and the Ethics of Public Health Surveillance*, 31 J.L. MED. & ETHICS 615, 617 (2003). Local public health officials are likely to characterize surveillance as practice rather than research because they are the first to receive case reports and conduct outbreak investigations, in contrast to the CDC, which receives reports from state health departments and conducts more long-range analysis that would normally be seen as research.

¹²⁰ See Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 44 Fed. Reg. 23,192, 23,193 (Apr. 18, 1979) [hereinafter Belmont Report] (“For the most part, the term ‘practice’ refers to interventions that are *designed* solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals. By contrast, the term ‘research’ designates an activity *designed* to test an

however, misses the point. By itself, the fact that an activity might be considered “practice” does not mean that participation can be compelled. For example, a physician’s treatment recommendation to her patient is part of medical practice, but this does not mean that the patient must obey it. Although the federal commission and scholars have distinguished medical practice from research, none has repudiated informed consent to medical care. Similarly, the fact that an activity might be considered research does not always mean that it requires consent.¹²¹

The real issue is whether the state may compel the reporting of personally identifying information without first obtaining the person’s consent for a specific purpose. The answer to that question depends not on whether an activity is characterized as “research” or “practice,” but on the scope and limits of the government’s sovereign power and whether compelled disclosure of identifying patient information infringes upon constitutionally protected rights.

Furthermore, the idea that there is some special set of endeavors called public health practice may be an illusion. All government agencies can equally call what they do “practice.” Indeed, the programs and activities that public health officials call practice are precisely the same in kind, if not in subject matter, as those of almost every other government agency, from the Department of Agriculture to the Securities and Exchange Commission. And almost all these agencies also conduct research. The fact that public health can be a government function does not exclude surveillance from constitutional constraints.¹²² Law enforcement is also a government function, but that does not authorize the police to obtain information about a person in violation of the Fourth Amendment. Similarly, the fact that reporting to a cancer registry is required by state law does not answer the question of whether the law itself is constitutional.

More far-reaching is the argument that public health surveillance is not research because it is *intended* to promote the public good in much the same way that standard medical care is intended to personally benefit a patient. Most medical research also is intended to promote the public good. Similarly, virtually all public health programs are intended to benefit the population as a whole, whether by stopping an epidemic or by collecting data that might be

hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships).” (emphasis added) (footnote omitted)).

¹²¹ Some categories of research might justifiably be conducted without consent, such as research using anonymous data and the collection and analysis of vital statistics from birth, marriage, and death certificates. These categories are also not considered to be surveillance, strictly defined. Berkelman et al., *supra* note 37, at 759.

¹²² See HODGE & GOSTIN, *supra* note 119, at 22 (arguing that the states’ police powers “justify virtually any exercise of state or local government to preserve, protect, or promote the public’s health that does not infringe constitutionally protected . . . rights”). Moreover, public health is not limited to government agencies. Private organizations also provide public health services and conduct public health research.

analyzed to identify a risk that might be studied in the future to determine whether it might cause disease. Thus, using intent as a standard would virtually eliminate the rights of research subjects.¹²³

Instead, a more objective standard is necessary to identify what counts as a research activity requiring consent. In this vein, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research chose to distinguish research from practice based on how the project is “designed.”¹²⁴ If a project is designed to obtain generalized knowledge, rather than help an identifiable patient, it is research. In the public health context, this would mean that research includes projects designed to determine the incidence and prevalence of diseases, to identify common risk factors for diseases by analyzing data, and to evaluate the effectiveness of particular preventive or treatment measures by comparing results, as well as other studies aimed at gleaning similarly generalized knowledge.¹²⁵

Different public health surveillance programs serve very different functions. To complicate matters, the same program can serve a different function at each level of surveillance.¹²⁶ For instance, some contagious disease programs are designed for outbreak investigation at the first level, while at the second level the data almost exclusively serve research and vital statistics functions. Similarly, newborn genetic screening programs serve to protect newborns from severe treatable conditions on the first level of surveillance, while on the second level serve only a research function. A surveillance program may justifiably collect personally identifiable data at the first level for some purposes and uses, but not others, without patient consent. However, that does not necessarily answer the question of whether such data may then be further disclosed to researchers without first obtaining consent for secondary and tertiary uses.

III. CONSTITUTIONAL PROTECTION OF MEDICAL INFORMATION PRIVACY

The central question is whether there is a right of privacy that prevents the government from obtaining medical information about an individual to be used for various public health surveillance purposes without first obtaining the individual’s consent. States adopt reporting laws, of course, because most recognize common law, if not statutory, rights of privacy and confidentiality in

¹²³ See Belmont Report, *supra* note 120, at 23,193 (rejecting intent as too subjective a standard for distinguishing medical practice from medical research).

¹²⁴ *Id.*

¹²⁵ Recognizing the research components of public health surveillance does not preclude also recognizing some exceptions to the requirements for consent for the development and dissemination of information like vital statistics. However, such activities should be recognized as exceptions to general rules for research, and specifically justified by factual and conceptual arguments that do not depend upon spurious distinctions between research and practice.

¹²⁶ See *supra* figure 1.

medical information, which forbid physicians from disclosing patient information and records without consent.¹²⁷ Additionally, federal courts of appeal have recognized Fourteenth Amendment protection for a person's privacy interest in personal medical information and from involuntary disclosure to state and federal agencies.¹²⁸

Unfortunately, this extensive body of case law provides little guidance for determining the justifications for mandatory reporting laws. Such laws have rarely received judicial review. The few U.S. Supreme Court decisions that have addressed the subject have granted state legislatures substantial, but not unlimited, deference. But the Court has yet to consider the constitutionality of modern public health surveillance systems – specifically those that compel disclosure of personally identifiable medical information to allow de-duplication and ensure that such data are accurate enough to be used for research and budget analyses. Indeed, the Court's decisions have rarely analyzed the actual use of the data to be collected, referring to it generally as

¹²⁷ See, e.g., *Hill v. Nat'l Collegiate Athletic Ass'n*, 865 P.2d 633, 658 (Cal. 1994) (recognizing an informational privacy interest “in limiting disclosure of confidential information about bodily condition”); *Alberts v. Devine*, 479 N.E.2d 113, 118-19 (Mass. 1985) (describing a public policy rationale for recognizing a physician's duty to not disclose medical information without the patient's consent). See generally DANIEL J. SOLOVE & MARC ROTENBERG, *INFORMATION PRIVACY LAW* 207-10 (2003). State constitutions also often protect privacy more explicitly than the Federal Constitution. See, e.g., CAL. CONST. art. 1, § 1 (“All people are by nature free and independent and have inalienable rights. Among these are . . . pursuing and obtaining safety, happiness, and privacy.”).

¹²⁸ See, e.g., *Doe v. Delie*, 257 F.3d 309, 317 (3d Cir. 2001) (holding that prisoners have a constitutional right of privacy in their medical information); *Sterling v. Borough of Minersville*, 232 F.3d 190, 197 (3d Cir. 2000) (same); *Denius v. Dunlap*, 209 F.3d 944, 956 (7th Cir. 2000) (stating that the right of confidentiality “clearly covers medical records and communications”); *Bartnicki v. Vopper*, 200 F.3d 109, 122 (3d Cir. 1999) (recognizing the right “not to have intimate facts concerning one's life disclosed without one's consent”), *aff'd*, 532 U.S. 514 (2001); *Doe v. Se. Pa. Transp. Auth.*, 72 F.3d 1133, 1138 (3d Cir. 1995) (acknowledging a limited constitutional right to privacy in one's prescription records); *A.L.A. v. W. Valley*, 26 F.3d 989, 990 (10th Cir. 1994) (“There is no dispute that confidential medical information is entitled to constitutional privacy protection.”); *Doe v. City of New York*, 15 F.3d 264, 267 (2d Cir. 1994) (“Individuals who are infected with the HIV virus clearly possess a constitutional right to privacy regarding their condition.”); *Schail v. Tippecanoe County Sch. Corp.*, 864 F.2d 1309, 1322 n.19 (7th Cir. 1989) (recognizing “a substantial privacy interest in the confidentiality of medical information”); *In re Search Warrant (Sealed)*, 810 F.2d 67, 71 (3d Cir. 1987) (stating that the constitutionally protected right to privacy encompasses medical records); *Trade Waste Mgmt. Ass'n v. Hughey*, 780 F.2d 221, 234 (3d Cir. 1985) (recognizing that personal medical history is protected from random government intrusion). But see *Doe v. Wigginton*, 21 F.3d 733, 740 (6th Cir. 1994) (holding that a prison official's disclosure of a prisoner's HIV status to other corrections officers did not violate the prisoner's constitutional right to privacy); *J.P. v. DeSanti*, 653 F.2d 1080, 1090 (6th Cir. 1981) (“[T]he Constitution does not encompass a general right to nondisclosure of private information.”).

intended to prevent disease or promote public health. In light of recent challenges to the use of personal medical information for other purposes,¹²⁹ however, it is unlikely that such surveillance programs will remain under the radar forever.

In *Whalen v. Roe*,¹³⁰ the Supreme Court upheld a state law requiring any physician who prescribed a Schedule II controlled substance to submit a copy of the prescription to the New York State Department of Health.¹³¹ The petitioners had challenged the law's requirement that patients' names and addresses be collected and retained by the state, arguing that it violated their right to privacy as protected by the Fourteenth Amendment.¹³² The law was intended to prevent the diversion of drugs into "unlawful channels," specifically by preventing individuals from obtaining controlled substances from more than one physician or using stolen or altered prescriptions, preventing pharmacists from refilling dangerous prescriptions, and preventing physicians from over-prescribing.¹³³ If prevention failed, the records would enable investigators to identify – and possibly prosecute – those who were breaking the law. Not surprisingly, the Court found that the goal was reasonable,¹³⁴ and that the prescription system "could reasonably be expected to have a deterrent effect on potential violators as well as to aid in the detection or investigation of specific instances of apparent abuse."¹³⁵ The Court noted

¹²⁹ See, e.g., *Nw. Mem'l Hosp. v. Ashcroft*, 362 F.3d 923, 932-33 (7th Cir. 2004) (affirming the district court's decision to quash a Department of Justice subpoena seeking the medical records of patients who had received late-term abortions); *Aid for Women v. Foulston*, 427 F. Supp. 2d 1093, 1096 (D. Kan. 2006) (permanently enjoining enforcement of the Attorney General's opinion that physicians must report all consensual underage sexual activity because his opinion was inconsistent with the reporting statute's language).

¹³⁰ 429 U.S. 589 (1977).

¹³¹ *Id.* at 603-04; see also N.Y. PUB. HEALTH LAW §§ 3331(6), 3332(2)(a), 3334(4) (McKinney 2002). Prescriptions were filed with the Bureau of Controlled Substances, Licensing and Evaluation. Schedule II drugs include drugs that have some recognized medical uses, but are also subject to some potential for abuse: opium and its derivatives, cocaine, methadone, amphetamines, and methaqualone. *Whalen*, 429 U.S. at 592-93 & n.8.

¹³² *Whalen*, 429 U.S. at 598 & n.23. Petitioners claimed that the law violated both their right to informational privacy – by taking their personal information without their consent – and their right to make personal decisions about their own medical care without government interference. *Id.* at 599-600. They argued that the requirement discouraged physicians from prescribing necessary and appropriate Schedule II drugs, and discouraged patients from accepting treatment with such drugs for fear of being stigmatized. *Id.* at 595 n.16, 600.

¹³³ *Id.* at 591-92.

¹³⁴ *Id.* at 597-98.

¹³⁵ *Id.* at 598 (footnote omitted); see also *ACT-UP Triangle v. Comm'n for Health Servs. of N.C.*, 483 S.E.2d 388, 396 (N.C. 1997) (upholding the state health commission's decision to end anonymous HIV testing by local health departments and institute confidential reporting of names); cf. *N.Y. State Soc'y of Surgeons v. Axelrod*, 572 N.E.2d 605, 606-07 (N.Y. 1991) (upholding the Commissioner of Health's exercise of discretion in refusing to add HIV infection to the list of notifiable diseases "on the ground that . . . it would

that the reporting requirement was not “meaningfully distinguishable from a host of other unpleasant invasions of privacy that are associated with many facets of health care,”¹³⁶ comparing it to “reporting requirements relating to venereal disease, child abuse, injuries caused by deadly weapons, and certifications of fetal death.”¹³⁷

Other Supreme Court decisions on reporting laws have focused specifically on abortion recordkeeping where the woman’s name was not reported. In *Planned Parenthood of Central Missouri v. Danforth*,¹³⁸ the Supreme Court upheld a Missouri law that required reporting data on abortions performed in the state:

Recordkeeping and reporting requirements that are *reasonably directed to the preservation of maternal health* and that *properly respect a patient’s confidentiality and privacy* are permissible. . . . [O]ne may argue forcefully . . . that the State should not be able to impose any recordkeeping requirements that significantly differ from those imposed with respect to other, and comparable, medical or surgical procedures. We conclude, however, that the [Missouri] provisions . . . , while perhaps approaching impermissible limits, are not constitutionally offensive in themselves. Recordkeeping of this kind, if not abused or overdone, can be useful to the State’s interest in protecting the health of its female citizens, and may be a resource that is relevant to decisions involving medical experience and judgment. The added requirements for confidentiality, with the sole exception for public health officers, . . . assist and persuade us in our determination of the constitutional limits.¹³⁹

Later decisions offer little guidance on how to apply *Danforth’s* standards.¹⁴⁰ In *Planned Parenthood of Southeastern Pennsylvania v. Casey*,¹⁴¹ the Supreme Court upheld a Pennsylvania statute that required all

discourage cooperation of affected individuals and would lead to the loss of confidentiality for those infected with the disease”).

¹³⁶ *Whalen*, 429 U.S. at 602.

¹³⁷ *Id.* at 602 n.29. *But cf. id.* at 607 (Brennan, J., concurring) (“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.”).

¹³⁸ 428 U.S. 52 (1976).

¹³⁹ *Id.* at 80-81 (emphasis added) (footnote omitted).

¹⁴⁰ *See, e.g., Thornburgh v. Am. Coll. of Obstetricians & Gynecologists*, 476 U.S. 747 (1968). In *Thornburgh*, the Court struck down a Pennsylvania statute requiring physicians to report information about abortion procedures. The information, which would be made available for public inspection, included each woman’s age, race, marital status, and number of prior pregnancies; the date of her last menstrual period; the basis for any determination that the fetus was not viable; and the method of payment – but not the woman’s name or address. *See id.* at 767-68.

¹⁴¹ 505 U.S. 833 (1992).

abortion to be reported without the patient's name.¹⁴² The Court, however, struck down the law's requirement that the report include a woman's reasons for not notifying her husband of the abortion, suggesting that the state could not require reporting of information about something that it could not constitutionally require of women in the first place.¹⁴³

The *Whalen* Court had distinguished the line of cases protecting what it called "the individual interest in avoiding disclosure of personal matters" from those protecting "independence in making certain kinds of important decisions,"¹⁴⁴ such as raising children,¹⁴⁵ marriage,¹⁴⁶ and procreation.¹⁴⁷ Yet, in the abortion cases, the Court seems to have blended the two almost from the beginning. As one appellate court has suggested, "[t]he more intimate or personal the information, the more justified is the expectation that it will not be subject to public scrutiny."¹⁴⁸ The Supreme Court has recognized that the right to refuse medical treatment may be an aspect of liberty protected by the Fifth and Fourteenth Amendments.¹⁴⁹ And, although it has not expressly addressed non-life-threatening medical decisions, such as diagnostic tests for cancer, diabetes, or HIV, common law protection of patient decision-making autonomy within the privacy of a physician-patient relationship is well

¹⁴² *Id.* at 900. The statute at issue in *Casey* provided: "For the purpose of promotion of maternal health and life by adding to the sum of medical and public health knowledge through the compilation of relevant data, and to promote the Commonwealth's interest in protection of the unborn child, a report of each abortion performed shall be made to the department on forms prescribed by it. The report forms shall not identify the individual patient by name . . ." 18 PA. CONS. STAT. § 3214(a) (1990), *quoted in Casey*, 505 U.S. at 909-10.

¹⁴³ *Casey*, 505 U.S. at 901.

¹⁴⁴ *Whalen*, 429 U.S. at 599-600.

¹⁴⁵ *See Pierce v. Soc'y of Sisters*, 268 U.S. 510, 534-35 (1925).

¹⁴⁶ *See Loving v. Virginia*, 388 U.S. 1, 12 (1967).

¹⁴⁷ *See Roe v. Wade*, 410 U.S. 113, 164 (1973); *Griswold v. Connecticut*, 381 U.S. 479, 485 (1965).

¹⁴⁸ *Walls v. City of Petersburg*, 895 F.2d 188, 192 (4th Cir. 1990); *see also Sheets v. Salt Lake County*, 45 F.3d 1383, 1387 (10th Cir. 1995) ("If an individual has a legitimate expectation of confidentiality, then '[d]isclosure of such information must advance a compelling state interest which, in addition, must be accomplished in the least intrusive manner.'" (alteration in original) (quoting *Mangels v. Pena*, 789 F.2d 836, 839 (10th Cir. 1986))); *Fraternal Order of Police, Lodge No. 5 v. City of Phila.*, 812 F.2d 105, 110 (3d Cir. 1987) ("Most circuits appear to apply an 'intermediate standard of review' for the majority of confidentiality violations, with a compelling interest analysis reserved for 'severe intrusions' on confidentiality." (citations omitted)).

¹⁴⁹ *See Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 278 (1990); *see also Vacco v. Quill*, 521 U.S. 793, 797 (1997) (holding that New York's prohibition on assisting suicide does not violate the Equal Protection Clause, even though patients have a constitutional right to refuse lifesaving medical treatment).

settled.¹⁵⁰ Reporting laws that could deter patients from making diagnostic or treatment decisions may deserve more searching analysis.

A few recent lower court decisions suggest that a more searching analysis might be forthcoming, one that demands a closer fit between the government's interest and the value of the information sought. In 2004, the Ninth Circuit Court of Appeals found that several provisions of Arizona's abortion law violated patients' informational privacy rights by requiring providers to release identifiable patient records unnecessarily.¹⁵¹ The law allowed the state Department of Health Services to "access unredacted patient medical records and retain copies in their offices," and required providers to submit copies of ultrasound prints to a private contractor.¹⁵² Following its earlier decisions, the court found that "[e]ven if a law adequately protects against *public* disclosure of a patient's private information, it may still violate informational privacy rights if an unbounded, large number of government employees have access to the information."¹⁵³ Because the provision had no safeguards to prevent the release of identifiable information to "government employees who [had] no need for the information,"¹⁵⁴ and because "there [was] little, if any, need for much of [the] information, such as the names and addresses of patients,"¹⁵⁵ the court concluded that the regulation violated the informational privacy rights of the patients.¹⁵⁶ The court also reasoned that the goal of monitoring clinic compliance with laws governing clinic licensure and abortion restrictions "could easily be satisfied using a coding system to track records without the release of patient identifying information."¹⁵⁷ "Finally," it concluded, "while the public interest involved – promoting health and safety – is of course a strong one, we fail to see how insisting on unredacted materials promotes this need."¹⁵⁸ This decision suggests that at least some judges may be unwilling to

¹⁵⁰ See *Cruzan*, 497 U.S. at 269-73. See generally GEORGE J. ANNAS, THE RIGHTS OF PATIENTS 246-72 (3d ed. 2004).

¹⁵¹ *Tucson Woman's Clinic v. Eden*, 379 F.3d 531, 553 (9th Cir. 2004).

¹⁵² *Id.* at 551.

¹⁵³ *Id.* at 551-52.

¹⁵⁴ *Id.* at 552.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.* at 553. The court also found that Arizona regulations requiring abortion providers to submit to warrantless, unbounded inspections of their offices violated the Fourth Amendment. *Id.* at 551. The court concluded that abortion clinics were not a closely regulated industry, where expectations of privacy are diminished. *Id.* at 550. Rather, "the expectation of privacy is *heightened*, given the fact that the clinic provides a service grounded in a fundamental constitutional liberty, and that all provision of medical services in private physicians' offices carries with it a high expectation of privacy for both physician and patient." *Id.* Fourth Amendment issues are beyond the scope of this Article.

¹⁵⁷ *Id.* at 553.

¹⁵⁸ *Id.*

uphold the release of identifiable medical information without a more particularized need.¹⁵⁹

IV. WHAT DOES PUBLIC HEALTH JUSTIFY?

The preceding discussion argued that cases like *Whalen* and *Danforth* do not answer the question of whether the state has the power to compel the reporting of identifiable medical information for modern public health surveillance uses. While the Supreme Court has granted considerable deference to legislative determinations of the need for mandatory reporting, it has not considered data uses far removed – both in time and function – from immediate investigations where the information contained names. Particularly unsettled in that context are both the characterization of the right to privacy in one’s personal medical information and the standard of review to be applied in evaluating laws compelling disclosure.

This part outlines possible options for reviewing modern public health surveillance reporting laws. Section A explores why standards for reviewing specific requests for records pursuant to subpoena are inapposite. Section B then critiques the use of the government’s interest in an undefined concept of public health as a goal justifying mandatory reporting, while Section C argues for a more robust concept of medical information privacy. Section D explains why these constitutional principles assume particular importance where federal funding influences the substance of state reporting laws.

A. *Unanswered Questions*

As seen in both *Whalen* and the line of abortion decisions, courts typically balance the government’s interest in information with an individual’s interest in preventing its release. Most decisions outside the context of reporting laws have also considered the following factors, described in *United States v. Westinghouse Electric Corp.*:

the type of record requested, the information it does or might contain, the potential for harm in any subsequent nonconsensual disclosure, the injury from disclosure to the relationship in which the record was generated, the adequacy of safeguards to prevent unauthorized disclosure, the degree of need for access, and whether there is an express statutory mandate, articulated public policy, or other recognizable public interest militating toward access.¹⁶⁰

¹⁵⁹ See also *Planned Parenthood of S. Ariz. v. Lawall*, 307 F.3d 783, 794 (9th Cir. 2002) (Ferguson, J., dissenting) (“[I]t is not only disclosure that is prohibited. It is intrusion itself. . . . Simple curiosity or suspicion, the need to keep statistics, or the mere performance of government work is not enough to justify the intrusion permitted by the Arizona statute. The state must show a particularized, legitimate government need.”).

¹⁶⁰ *United States v. Westinghouse Elec. Corp.*, 638 F.2d 570, 578 (3d Cir. 1980).

However, there is little explicit discussion of whether all the *Westinghouse* factors should be considered or what weight each should bear. In the absence of a more structured weighting system, the test can devolve into a framework for rationalizing decisions based on other grounds.

Westinghouse applied this test not to a reporting law, but to a petition by the National Institute for Occupational Safety and Health (NIOSH) to enforce its subpoena for employee medical records.¹⁶¹ NIOSH sought the records from Westinghouse as part of an investigation into the possible workplace exposure of company employees to hexahydrophthalic anhydride.¹⁶² Both the facts and procedural posture in *Westinghouse* make it an improbable precedent for a general public health exception to privacy.¹⁶³ NIOSH was responding to an employee request for an investigation into the cause of employee health problems. It made a one-time request for records of specific employees, which Westinghouse could and did contest.¹⁶⁴

To evaluate an ongoing requirement for reporting patient information in the absence of any immediate investigatory need, more specific issues should be considered:

- (1) whether the information is personally identifiable (contains personal information sufficient to identify the individual whose information it is);
- (2) whether the information is collected with or without the person's consent;
- (3) what present or future uses will be made of the information;
- (4) whether subsequent uses will be with or without the person's consent;

¹⁶¹ Statutes authorizing agencies to subpoena medical records for certain investigations, such as medical licensure violations, are distinct from general reporting laws. The subpoena power granted to many public agencies poses a lesser risk, primarily because those affected have an opportunity to challenge the subpoena and receive a judicial hearing. *See, e.g.*, *Schachter v. Whalen*, 581 F.2d 35, 36-37 (2d Cir. 1978) (upholding the statutory power of a state medical licensure board to subpoena records of patients treated with laetrile or MA-7 by a particular physician as part of its investigation of the physician's professional conduct).

¹⁶² *Westinghouse*, 638 F.2d at 572.

¹⁶³ The majority of decisions referencing the *Westinghouse* factors involve demands to review information about particular individuals, such as applicants for employment. *See, e.g.*, *Weissberg v. Riverside Twp. Bd. of Educ.*, 180 F. App'x 357, 365 (3d Cir. 2006). *But see* *Sterling v. Borough of Minersville*, 232 F.3d 190, 195 (3d Cir. 2000) ("We cautioned, however, that the right [in *Westinghouse*] is not absolute. Public health or like public concerns may justify access to information an individual may desire to remain confidential.").

¹⁶⁴ *Westinghouse*, 638 F.2d at 573.

- (5) whether the information will be combined or linked with information from other sources to create new information;
- (6) whether the combined or linked information makes it possible to identify individuals;
- (7) whether the information will be disclosed by the recipient to third parties;
- (8) whether the information will be re-disclosed by the third parties to fourth and fifth parties;
- (9) whether the information will be kept secure and inaccessible to anyone without authorization to view it;
- (10) whether the information will be kept or destroyed after use by each user;
- (11) whether the information will be kept confidential by those authorized to view it; and
- (12) whether there is an enforceable (statutory or contractual) duty to keep the information secure and confidential on the part of all parties (recipient, third parties, etc.).

The first question – whether the information is identifiable – is a threshold matter in reviewing any government access to information. As suggested by the sixth factor, however, even information that excludes individual names may be individually identifiable.¹⁶⁵ Given the increasing linkages among government databases, the protection of initial anonymity is diminishing.

B. *Ultimate Goals and Immediate Functions*

Any attempt to specify principles for determining justifiable invasions of privacy runs into the problem of defining public health purposes.¹⁶⁶ Most judicial opinions in cases challenging government demands for personal information perpetuate, rather than clarify, this threshold definitional problem.

¹⁶⁵ Protection against revealing identities may prove increasingly difficult to maintain. See Latanya Sweeney, *Maintaining Patient Confidentiality When Sharing Medical Data Requires a Symbiotic Relationship Between Technology and Policy* 3-15 (MIT Artificial Intelligence Lab., Working Paper No. AIWP-WP344b, 1997), available at <http://privacy.cs.cmu.edu/dataprivacy/projects/law/aiwp.pdf> (comparing various methods intended to de-identify medical record data, and describing ways to identify individuals with limited information, such as birth date and zip code). It is even possible to identify the addresses of patients represented only by black dots on a map. John S. Brownstein et al., Correspondence, *No Place To Hide – Reverse Identification of Patients from Published Maps*, 355 NEW ENG. J. MED. 1741, 1741-42 (2006) (selecting nineteen medical journal articles that contained “maps with the addresses of patients plotted as individuals dots,” and determining the precise address of 432 of the 550 patients plotted on those maps).

¹⁶⁶ See discussion *supra* Part II.

Courts either fail to specify what they mean by public health, or seem to have an understanding that is different from what is intended by public health agencies. While a judge may be thinking of outbreak investigation, public health agencies may have in mind the longer-term goal of using data in a research study to find a cure for cancer.

Compounding the possible misunderstanding, courts in cases like *Whalen* and *Danforth* have limited their analyses to the justification for the initial collection of information – the first level of surveillance. The laws at issue in these first generation cases did not contemplate secondary or tertiary reporting; courts had no need to consider re-disclosures other than accidental or negligent breaches of confidentiality at the first level. Yet it is the subsequent release of information to other public agencies and private entities that dominates the structure of many current surveillance programs. Moreover, a program's function can and often does change from level to level. If the different surveillance levels are not viewed independently, the public health purpose of the first level of reporting may be conflated with the ultimate use of the data. The concept of public health as a legitimate government goal is either emptied of meaningful substance or stuffed with all visions of the general welfare. Neither result serves us well.

Continued reliance on a broad, undefined concept of public health offers no principled way to distinguish between essential responses to immediate threats and unnecessary, compelled participation in research.¹⁶⁷ It perpetuates a highly utilitarian view of personhood, in which autonomy and privacy can be sacrificed whenever they prove inefficient.¹⁶⁸ The public health would undoubtedly improve if all Americans were required to obey their physicians' recommendations, eat a healthier diet, or exercise more. Required submission to clinical research might also serve the public good by facilitating the discovery of new medicines or ways to improve the quality of life. But if mandatory submission to research and medical care seems unsettling, it might

¹⁶⁷ For an argument favoring a broad interpretation of public health, see Gostin, *supra* note 76, at 1168-69 (arguing that immediate risks to society from bioterrorism warrant violating some personal liberties). For arguments favoring continuing protection of personal liberties, see Wendy E. Parmet, *Liberalism, Communitarianism, and Public Health: Comments on Lawrence O. Gostin's Lecture*, 55 FLA. L. REV. 1221, 1223 (2003); Peter P. Swire & Lauren B. Steinfeld, *Security and Privacy After September 11: The Health Care Example*, 86 MINN. L. REV. 1515, 1518-23 (2002).

¹⁶⁸ See, e.g., Richard A. Posner, *The Right of Privacy*, 12 GA. L. REV. 393, 409 (1978) (offering an economic analysis of privacy rights). The many statutes enacted to protect the privacy of information since the early 1970s, however, suggest that society may value information privacy more than rational economic analysis would predict. Moreover, on the bench, Judge Posner has expressed a more sympathetic view of privacy rights. See *Nw. Mem'l Hosp. v. Ashcroft*, 362 F.3d 923, 932-33 (7th Cir. 2004) (protecting the privacy of medical records requested for use in challenging the constitutionality of the Partial-Birth Abortion Ban Act).

suggest that such a notion of public health is too vague to justify broad constraints on personal liberty.

A more rigorous approach to balancing government and individual interests might be accomplished by abandoning vague characterizations of the government's interest, like public health, and substituting the government's actual intended use of information at each level of surveillance. The distortions currently permitted by vague terminology on both sides of the balancing test might be mitigated by more precise definitions of the interests to be weighed and by assigning realistic present values to those interests, in a manner analogous to decision analysis. For example, if the goal is to protect newborns from developmental disabilities by providing immediate treatment, the outcome is both clear and immediate and its value is high. If the goal is to count how many people have a disease, the outcome is clear, but its present value is low. If the goal is to improve longevity by seeing how many people are exposed to a risk and then taking steps to prevent that risk, the outcome is speculative and the present value is very low. Long-term public health goals are highly contingent; they depend upon positive outcomes from a series of future steps. One may need to collect data, analyze and compare results, develop preventive recommendations, obtain funding, implement recommendations, wait for results, and evaluate results to determine whether recommendations worked or why they failed.

Once the goal and outcome are specified, the need for individually identifiable information to achieve that goal is easier to assess. Certain goals, such as outbreak investigation, may demonstrate an actual or at least plausible need for identifiable information at the first surveillance level. The need for names and other identifiable information may diminish significantly at secondary and tertiary levels, depending on the specific goal and outcome intended at that level. For example, names may be needed to investigate the possibility of an outbreak of avian influenza, but unnecessary to prepare reports to federal agencies for the purpose of compiling disease statistics. This secondary goal would have a low present value that would not outweigh an individual's right to refuse the reporting of identifiable information at that level of surveillance. Some secondary and tertiary research functions, however, may reasonably require identifiable information. However, those functions would require additional balancing against the individual's right to decide whether to participate in research at the time of use; secondary and tertiary goals should not be conflated with, or justified by, initial goals.

Using the actual goal and its present value allows a balancing test that compares the current benefits to public health with the current costs to individuals. The Supreme Court appeared to support this approach when it warned that government programs should not rely on long-range health goals to justify the reporting of identifiable medical information without patient

consent.¹⁶⁹ This test, for example, would support the reporting of adverse drug reactions to the FDA because an immediate response, such as removing drugs from the market or halting a clinical research trial, may be needed to prevent or limit actual harm to patients or research subjects.¹⁷⁰ It would also support traditional contagious disease reporting laws targeted at outbreak investigation and epidemic containment – but it would not support laws related to diseases or conditions requiring no immediate response (unless no individually identifiable information were collected). Further, it would not support the collection of any personally identifiable information solely for the purpose of eliminating duplicates to obtain more precise numerical estimates.¹⁷¹

A balancing test requiring specific data uses is also less likely to permit surveillance programs based on mandatory chronic disease case reports to cancer registries. To the extent that the actual use of identifiable information in such reports is to generate scientific hypotheses for research or to conduct research studies, it is indistinguishable from ordinary research requiring the patient's consent.¹⁷² Similarly, mandatory newborn screening programs for genetic conditions that cannot be treated have no immediate present value beyond research and would be difficult to justify.¹⁷³

These suggested outcomes reveal weaknesses in current assumptions about the legitimacy of mandatory public health surveillance reporting laws. A more rigorous approach to reviewing such laws may be more consistent with current public opinion about medical privacy. As the federal government encourages

¹⁶⁹ See *Ferguson v. City of Charleston*, 532 U.S. 67, 82-83 (2001) (“While the ultimate goal of the program may well have been to get the women in question into substance abuse treatment and off of drugs, the immediate objective of the searches was to generate evidence for law enforcement purposes in order to reach that goal.”).

¹⁷⁰ This is also consistent with the holding in *Whalen*, where the defendant used prescription drug records to investigate possible crimes. See *supra* note 135 and accompanying text.

¹⁷¹ The use of case reports to obtain an accurate count of all cases of disease has disadvantages. The most salient is that it cannot count people who are not in medical care, because it relies on health providers and laboratories to submit all reports. See COMM. ON THE RYAN WHITE CARE ACT: DATA FOR RES. ALLOCATION, PLANNING & EVALUATION, INST. OF MED., MEASURING WHAT MATTERS 80 (2004), available at <http://www.nap.edu/catalog/10855.html>.

¹⁷² The CDC states that “[c]ancer surveillance is essential to a unified, scientific and public health approach to cancer prevention and control.” NPCR-CSS, *supra* note 98. Although presented as a premise, the CDC’s statement is a conclusion, and the evidence for it is not provided. Assuming it is correct, however, it does not answer the question of whether surveillance requires the use of case reports or whether it requires patient consent. Cancer registries remain a repository for data that, without more, cannot prevent or control cancer. See generally Bruce K. Armstrong, *Perspective: The Role of the Cancer Registry in Cancer Control*, 3 CANCER CAUSES & CONTROL 569 (1992).

¹⁷³ A more difficult question is whether the fact that technology makes it easier and cheaper to screen for many conditions simultaneously rather than separately warrants including the untreatable conditions in a mandatory program.

combing databases of all kinds to find terrorists, the public may become increasingly concerned about both the immediate need for and ultimate use of surveillance data. Finally, continued trust in the medical profession may be seriously eroded if patients fear that their personal information will be disseminated far beyond their original expectations.¹⁷⁴

C. *Privacy and Human Rights*

In contrast to the broad, future-oriented ideas of public health they embrace, first generation cases like *Whalen* sometimes treat patient privacy as narrow and concrete. Under this approach, highly speculative benefits could be accepted as legitimate reasons to override patient consent. At the same time, costs to the patient must often be both probable and substantial, often in the form of financial loss, in order to weigh in the balance. Even if public health goals are more specifically identified, the definition of privacy in one's medical information may also require more precision in order to achieve meaningful balance.

Like public health, the concept of privacy can be fraught with ambiguity and possibilities for expansion. Privacy is often understood to mean an individual's right to control access to information about herself.¹⁷⁵ Yet the literature contains ample acknowledgement that this is hardly sufficient to explain the many, sometimes contradictory, facets of privacy, much less its exceptions.¹⁷⁶ Certainly the Supreme Court has yet to define the whole of its scope and limits.

¹⁷⁴ See George J. Annas, *Puppy Love: Bioterrorism, Civil Rights, and Public Health*, 55 FLA. L. REV. 1171, 1179-82 (2003) (arguing that public health programs cannot succeed without retaining the public's trust).

¹⁷⁵ See ALAN F. WESTIN, *PRIVACY AND FREEDOM* 7 (1967) ("Privacy is the claim of individuals, groups, or institutions to determine for themselves when, how, and to what extent information about them is communicated to others."); Geoffrey R. Stone, *The Scope of the Fourth Amendment: Privacy and the Police Use of Spies, Secret Agents, and Informers*, 1976 AM. B. FOUND. RES. J. 1193, 1207 (describing the right to privacy as a person's right "to control the flow of information about him").

¹⁷⁶ See, e.g., CHARLES FRIED, *AN ANATOMY OF VALUES: PROBLEMS OF PERSONAL AND SOCIAL CHOICE* 142 (1970) (arguing that privacy is necessary to the values of love, friendship, and trust, which require intimacy and sharing private information); PRIVACY PROT. STUDY COMM'N, *PERSONAL PRIVACY IN AN INFORMATION SOCIETY* 21 (1977) (stating that privacy can be both "a societal value and . . . an individual interest"); JEFFREY ROSEN, *THE UNWANTED GAZE: THE DESTRUCTION OF PRIVACY IN AMERICA* 200-12 (2000) (describing privacy as a means to avoid being judged unfairly on isolated bits of data, a retreat to permit personal identity growth, and protection against offenses to one's dignity); Ken Gormley, *One Hundred Years of Privacy*, 1992 WIS. L. REV. 1335, 1340 (arguing that legal privacy consists of five interrelated species); Robert C. Post, *Three Concepts of Privacy*, 89 GEO. L.J. 2087, 2087 (2001) ("Privacy is a value so complex, so entangled in competing and contradictory dimensions, so engorged with various and distinct meanings, that I sometimes despair whether it can be usefully addressed at all."); William L. Prosser,

Even in the absence of consensus on the overall concept, however, it is still both possible and defensible to treat personal medical information privacy as a specific aspect of privacy for the purpose of examining when that information is justifiably subject to involuntary disclosure – and re-disclosure – to government. The analysis of the concept of privacy for purposes of public health surveillance should be limited to information, from whatever source, about an identifiable individual's health status, medical care, genetic characteristics, personal behavior, or exposure to health risks.

The Supreme Court has referred to information privacy in part as “the individual interest in avoiding disclosure of personal matters.”¹⁷⁷ This “disclosure” can take several forms. The first and most commonly thought of is disclosure to the public, in the form of deliberate or negligent publication of personal facts to society at large. This is the type of injury that impelled Warren and Brandeis to argue for a right to privacy.¹⁷⁸ However, it is probably the least likely harm to individuals whose information is reported to a public health surveillance program.

The second form of disclosure, and the primary focus of this discussion, is the compulsory revelation or transmission to a government agency. As emphasized by several judges in the abortion cases discussed above, this form of disclosure is more accurately characterized as a possible invasion of privacy, because, metaphorically at least, the government forces its way into one's personal space to extract information that a person wishes to keep secret. This form of disclosure/invasion takes place at each level of surveillance. While concern for deliberate or negligent revelations to the public at large may exist with respect to any collection of information, including information voluntarily disclosed, it is likely that the core concern of information privacy is with invasions of privacy in which the government obtains personal information without consent.¹⁷⁹

Privacy, 48 CAL. L. REV. 383, 389 (1960) (“The law of privacy comprises four distinct kinds of invasion of four different interests of the plaintiff, which are tied together by the common name, but otherwise have almost nothing in common except that each represents an interference with the right of the plaintiff, in the phrase coined by Judge Cooley, ‘to be let alone.’” (footnote omitted)); Daniel J. Solove, *Conceptualizing Privacy*, 90 CAL. L. REV. 1087, 1126-29 (2002) (arguing that privacy can best be conceptualized not by isolating its essential characteristics, but rather by examining the various specific contexts in which it plays a role).

¹⁷⁷ *Nixon v. Adm'r of Gen. Servs.*, 433 U.S. 425, 457 (1977) (quoting *Whalen v. Roe*, 429 U.S. 589, 599 (1977)).

¹⁷⁸ See Samuel D. Warren & Louis D. Brandeis, *The Right to Privacy*, 4 HARV. L. REV. 193, 196 (1890); see also *Olmstead v. United States*, 277 U.S. 438, 478 (1928) (Brandeis, J., dissenting).

¹⁷⁹ See *Nw. Mem'l Hosp. v. Ashcroft*, 362 F.3d 923, 929 (7th Cir. 2004) (“Even if there were no possibility that a patient's identity might be learned from a redacted medical record, there would be an invasion of privacy.”).

The concept of privacy attached to one's personal information seems to include, at its essence, a sense of autonomy and self-determination – not just physical control over papers or computer files. Unlike other forms of property, the information has value because of what it reveals about a person.¹⁸⁰ Personal information is thus an aspect of the human being; it involves one's identity and dignity.¹⁸¹ Loss of personal information can seem as much a violation of a person's dignity as a physical invasion of the body. In this respect, privacy protects one's sense of self. When government has the power to take that personal knowledge, it invades that sense of self. This may be why the violation of privacy often provokes feelings of outrage, even when the facts acquired are not embarrassing. An invasion of privacy violates one's dignity, even if it fails to produce economic injury. Yet courts have failed to frame this aspect of privacy as a cognizable cause of action.

Even though not everyone would agree on what types of information would be embarrassing if revealed, the central issue is whether that choice is theirs to make. If we conclude that the information should be revealed because a majority of people don't care, we dispense with the principle that everyone has prima facie control over the choice of revelation. That is not an especially persuasive argument against requiring consent, and it fails to consider whether revelation should be a matter of personal or social choice. Even where there is a persuasive argument for social choice, the question remains whether that choice should be made through legislation or by some other more stringent mechanism, such as obtaining a warrant based on probable cause.

Changes in social and cultural norms are often reflected in debates over privacy. Alan Westin argues that privacy protects conduct that is consistent with social norms.¹⁸² Socially accepted behaviors are typically relegated by consensus to the sphere of private life and personal choice, whereas socially unacceptable conduct is labeled a matter of public concern that should not be left to personal choice.¹⁸³ To be sure, consensus does not mean unanimity, and different sectors of society often revisit and revise the social norms according to their personal and political philosophies. The most wrenching debates

¹⁸⁰ For discussion of the concept of information as property and the use of DNA, see generally ROBERT F. WEIR & ROBERT S. OLICK, *THE STORED TISSUE ISSUE: BIOMEDICAL RESEARCH, ETHICS, AND LAW IN THE ERA OF GENOMIC MEDICINE* (2004); Gary E. Marchant, *Property Rights and Benefit-Sharing for DNA Donors?*, 45 *JURIMETRICS J.* 153 (2005).

¹⁸¹ Galison and Minow make a related argument that privacy "takes its significance from its association with a widely (but not universally) shared notion of self." Peter Galison & Martha Minow, *Our Privacy, Ourselves in the Age of Technological Intrusions*, in *HUMAN RIGHTS IN THE 'WAR ON TERROR'*, *supra* note 8, at 258, 284.

¹⁸² Alan F. Westin, *Social and Political Dimensions of Privacy*, 59 *J. SOC. ISSUES* 431, 433 (2003).

¹⁸³ For example, contraception, once the subject of criminal prohibition, is generally considered a matter for personal choice without public or government interference. *See id.* at 438; *see also* James A. Morone, *Morality, Politics, and Health Policy*, in *POLICY CHALLENGES IN MODERN HEALTH CARE* 13, 14 (David Mechanic et al. eds., 2005).

undoubtedly take place as people begin to shift their perceptions of specific behaviors from unacceptable to acceptable or the reverse.

The expanding concept of public health suggests that we may currently be experiencing a shift in perceptions about the social legitimacy of health status. Contemporary debates over illicit drugs, tobacco, alcohol, and now obesity and “fitness” suggest that these behaviors and conditions are moving from the sphere of personal choice to that of public interest. This trend contrasts with the transition of many earlier behaviors, such as the use of contraception, from public to private status. The emotion revealed in the current debates also suggests that people whose lifestyles or health statuses are targeted recognize that they are prospective subjects of public scrutiny and perhaps eventually regulation. The more that certain behaviors or conditions are viewed as affecting the public – or public health – the more likely it is that the government will claim an interest in access to personal information about those behaviors and conditions. For this reason, the government’s claim to information can appear to be especially threatening to a person’s sense of self.

This all suggests that the Supreme Court’s separation of privacy into distinct areas of self-determination and information, while on the surface a seemingly logical and generally accepted distinction, may miss the central importance of information privacy. Information reveals past decisions, actions, risks, or consequences that define who an individual is. Thus, government control over the decision to reveal such information is more like the abortion decision than is conventionally thought.

One argument against this concept of information privacy is that individuals should not necessarily be entitled to control all information about themselves, even to protect their own dignity. For example, a convicted criminal is not able to prevent the fact of his or her conviction from becoming a matter of public record (not to mention front-page news, depending on the notoriety of the case). The idea that one should be able to define himself can conflict both with the fact that no one can wholly control what others really think and with the value placed on truth. The idea that one should be able to control information about oneself, then, states the claim too broadly. The most salient question becomes: What is *relevant* information to which society may legitimately claim entitlement? Refined for purposes of surveillance, the question becomes: What is relevant identifiable information that the government may legitimately obtain without consent?

Both the government’s claim of entitlement to information and the individual’s claim of entitlement to control (or withhold) information seem more or less compelling depending upon the content of the information. Information about one’s health status, however, seems an easy case for personal control. Even when a patient voluntarily gives the information to a physician, it remains secreted within a confidential relationship that is protected by public policy and law. Information in medical records is not part of a public repository, and it should not be treated as though it were an effort-

free source of data.¹⁸⁴ Consent to medical care cannot realistically be presumed to include consent to any and all uses of identifiable information by the state (or private parties).¹⁸⁵

There are circumstances in which the government may demonstrate a real and immediate need for medical information to accomplish an important health goal. The *Whalen* court suggested that laws requiring the reporting of child abuse, for example, leave patients with a lesser expectation of privacy in their medical records.¹⁸⁶ A closer analysis might reveal, however, that it is not that the patient's expectation of privacy is lessened in such instances, but that the government's demonstration of need for specific information in specific circumstances overwhelms the expectation of privacy. If patient expectations of privacy are deemed to be lessened by the existence of reporting laws, then there is little basis for challenging the laws themselves.¹⁸⁷ By carving out so many broad exceptions to privacy to accommodate public health surveillance, courts may leave medical privacy too tattered to endure.

In this regard, the International Bill of Human Rights¹⁸⁸ offers a relevant principle. Article 4 of the International Covenant on Economic, Social and Cultural Rights recognizes that at times states may need to restrict some human rights in order to protect other human rights.¹⁸⁹ For example, restrictions on

¹⁸⁴ In *Pierce County, Washington v. Guillen*, 537 U.S. 129 (2003), a unanimous Court noted that data compiled by state highway departments for the purpose of applying for federal funds should not be used as an "effort-free tool" in litigation against the state. *See id.* at 146. Although the case concerned the meaning of the state's statutory evidentiary privilege, the Court's opinion stressed that the data collected by the state should not be accessible to third parties unless they were otherwise entitled to obtain the information from the state for independent reasons. *See id.*

¹⁸⁵ Surveys of public opinion on privacy are notoriously unreliable, largely because how the questions are framed can influence responses. Nonetheless, there is considerable evidence of public support for medical record privacy. *See supra* note 50 and accompanying text; *see also* Standards for Privacy of Individually Identifiable Health Information, Background, 65 Fed. Reg. 82,462, 82,463 (2000) (summarizing testimony presented during a hearing on a proposed HIPAA rule in favor of increased protection for medical records).

¹⁸⁶ *Whalen v. Roe*, 429 U.S. 589, 602 (1977).

¹⁸⁷ *See Galison & Minow, supra* note 181, at 261 ("Without deliberate effort, a downward spiral can become a vicious circle, eroding privacy through legal permission, technological access to unprecedented amounts of personal information, and diminishing public expectations of privacy.").

¹⁸⁸ The International Bill of Human Rights, available at http://www.ohchr.org/english/about/publications/docs/part1_1.pdf, is composed of the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights, and the International Covenant on Economic, Social and Cultural Rights.

¹⁸⁹ International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI), art. 4, U.N. GAOR, 21st Sess., Supp. No. 16, U.N. Doc. A/6316 (Dec. 16, 1966), available at http://www.unhchr.ch/html/menu3/b/a_cescr.htm ("[T]he State may subject such rights only to such limitations as are determined by law only in so far as this may be

personal liberty may be necessary to isolate a person with a dangerous contagious disease who threatens to spread it to others.¹⁹⁰ Additionally, access to personal information could be justified by a compelling need to identify terrorists. However, such restrictions remain carefully bounded exceptions to the general obligation to protect liberty and privacy. The U.N. Committee on Economic, Social and Cultural Rights explained the limited reach of this exception as follows:

Issues of public health are sometimes used by States as grounds for limiting the exercise of other fundamental rights. The Committee wishes to emphasize that the Covenant's limitation clause, article 4, is primarily intended to protect the rights of individuals rather than to permit the imposition of limitations by States. Consequently, a State party which, for example, restricts the movement of, or incarcerates, persons with transmissible diseases . . . has the burden of justifying such serious measures in relation to each of the elements identified in article 4. Such restrictions must be in accordance with the law, including international human rights standards, compatible with the nature of the rights protected by the Covenant, in the interest of legitimate aims pursued, and strictly necessary for the promotion of the general welfare in a democratic society.¹⁹¹

This is, in essence, a rule against pretexts. The Committee's explanation offers a reminder that any limitation on liberty and privacy requires demonstration that it actually contributes to preserving human rights, serves a real purpose, and is "strictly necessary for the promotion of the general welfare in a democratic society." This reminder argues in favor of ensuring that intrusions on medical privacy are not casually accepted for speculative long-range goals. In particular, it supports the idea that general assertions of public health goals cannot justify overriding individual rights to refuse medical care or participation in research.

D. *Reporting Conditions for Federally Funded Programs*

Even if states adopted a more rigorous balancing test that weighed the present value of a specific health goal against the value of medical information privacy, it is still possible that public health surveillance programs would nonetheless continue their mission creep. The impetus for many state

compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society.").

¹⁹⁰ For discussion of the human right to health, see generally Sofia Gruskin & Daniel Tarantola, *Health and Human Rights*, in PERSPECTIVES ON HEALTH AND HUMAN RIGHTS 3 (Sofia Gruskin et al. eds., 2005); Eleanor D. Kinney, *The International Human Right to Health: What Does This Mean for Our Nation and World?*, 34 IND. L. REV. 1457 (2001).

¹⁹¹ U.N. Econ. & Soc. Council [ECOSOC], Comm. on Econ., Soc. & Cultural Rights, *Report on the Twenty-Second, Twenty-Third and Twenty-Fourth Sessions*, annex IV, ¶ 28, U.N. Doc. E/2001/22, E/C.12/2000/21 (2001).

reporting laws increasingly comes from federal agencies seeking data from state and local agencies. Many state public health surveillance programs depend on federal funding for their operation, and federal funding increasingly comes with strings attached. Some, like HIV surveillance and CDC cancer registry programs, condition funding on submitting reports to the federal agency and complying with federal agency standards for the kind and amount of information that must be reported.¹⁹² States that wish to create or continue a surveillance program may feel pressure to enact laws that require detailed case reporting of medical conditions, regardless of the merits of either the law or the reporting system. In effect, such laws require providers to report to the state identifiable information about their patients simply because the state has agreed to send that information to a federal agency.

Of course, state laws enacted under such circumstances might be challenged as violating medical privacy for the reasons discussed above. However, a successful challenge could leave the state with little or no funding to conduct needed surveillance in a constitutionally justifiable manner. Only a successful challenge to the federal funding law or an agency's implementing regulations could alter the state's financial situation. Such a challenge would undoubtedly face significant obstacles in light of the generally deferential review that the Supreme Court has given to the exercise of Congress' spending power.¹⁹³ Despite some judicial and scholarly arguments for a more robust application of the requirement that a funding condition must advance the federal government's interest underlying the federal law authorizing the spending,¹⁹⁴ the Court has not yet attempted a reconsideration of its conception of the

¹⁹² The Ryan White CARE Act may place additional financial pressure on states that seek funding for HIV and AIDS treatment programs. Pursuant to the Act, Department of Health and Human Services funding is distributed according to an allocation formula based on the estimated number of cases in an area, "as indicated by the number of cases reported to and confirmed by" the CDC. 42 U.S.C. § 300ff-28(a)(2) (2000); *see also supra* note 38 and accompanying text. The statute does not require any state to report to the CDC. Nor does it specify what form any voluntary reports should take. Nevertheless, the CDC interprets its mandate to "confirm" cases (together, perhaps, with its conditions on separate funding for state surveillance programs) as allowing it to insist that states submit data from case reporting systems that themselves require reporting patient names to the state health department. Since states must enact legislation to compel named reporting, the effect is to pressure states to enact mandatory named reporting laws in order to obtain funding, not for surveillance, but for AIDS treatment programs.

¹⁹³ *See, e.g.,* South Dakota v. Dole, 483 U.S. 203, 212 (1987); Oklahoma v. U.S. Civil Serv. Comm'n, 330 U.S. 127, 143 (1947).

¹⁹⁴ *See Dole*, 483 U.S. at 213 (O'Connor, J., dissenting); Lynn A. Baker, *Conditional Federal Spending After Lopez*, 95 COLUM. L. REV. 1911, 1914 (1995) ("[W]ith *Dole*, the Court offered Congress a seemingly easy end run around any restrictions the Constitution might impose on its ability to regulate the states."). *But see* Erwin Chemerinsky, *Protecting the Spending Power*, 4 CHAP. L. REV. 89, 90-93 (2001) (arguing for a broad interpretation of the spending power).

spending power. In practice, this may mean that conditions on spending are likely to be upheld unless they would require the state to take action that would itself be unconstitutional.¹⁹⁵ However, if the Court were to recognize a more searching analysis of mandatory reporting laws and find those compelling the reporting of personally identifiable information for general research purposes to be beyond the power of the states, then constitutional protection for medical privacy might present an independent constitutional bar.¹⁹⁶

CONCLUSION

The parallel growth of information technology, chronic diseases, and public health programs has transformed the function of disease surveillance. Public health surveillance provides databases for outbreak investigation, medical care, and research of all kinds. In a post-September 11 world, where epidemics are both rare and terrifying, emergency preparedness has encouraged more expansive public health surveillance programs with links to multiple independent sources of information. Public health's contribution to reducing premature death and illness should not be underestimated. Yet, like the public reaction to terrorism surveillance, both the public and the judiciary may worry that some calls to sacrifice personal privacy go too far.

If public health, writ large, is a sufficient public purpose to justify compelled disclosures of identifiable medical information, then it may be sufficient to justify the compelled disclosure of personal information for other equally grand, non-health, purposes. It may also be sufficient to justify limiting the liberty to consent to or refuse medical care and participation in research. If, on the other hand, public health does not justify the use of personally identifiable medical information for purposes beyond immediate outbreak investigation, then many mandatory reporting laws are vulnerable to challenge.

Public health encompasses so many functions and activities that far more specificity is needed to begin to analyze exactly what kind of public health purposes are sufficient to override an individual's right to keep personal information private. *Whalen's* first generation balancing test fails to offer an

¹⁹⁵ Although a state might argue that it was compelled to accept the condition because of its need for funding, this type of financial pressure has not yet been viewed as pressure that "turns into compulsion." *Dole*, 483 U.S. at 211 (quoting *Steward Mach. Co. v. Davis*, 301 U.S. 548, 590 (1937)); see also Michael T. Gibson, *Congressional Authority To Induce Waivers of State Sovereign Immunity: The Conditional Spending Power (and Beyond)*, 29 HASTINGS CONST. L.Q. 439, 440 (2002).

¹⁹⁶ Separate issues are whether a state would be willing to challenge a federal funding law at all and, if not, whether individuals would have standing to do so. In a footnote in *Pierce County, Wash. v. Guillen*, 537 U.S. 129 (2003), the Supreme Court declined to consider "whether private plaintiffs have standing to assert 'states' rights' under the Tenth Amendment where their States' legislative and executive branches expressly approve and accept the benefits and terms of the federal statute in question." *Id.* at 148 n.10.

adequate limiting principle for modern public health surveillance, especially with respect to secondary and tertiary uses of data. When an undefined public good is balanced against one person's immediate, concrete harm, there is little opportunity to seriously evaluate the merits of any possible invasion of privacy. The deck is stacked before the game begins.

A more searching analysis – one that balances the present value of the particular information to achieve specific public health functions against the dignitary cost of invading privacy – may better align basic constitutional principles with the real world of public health today. A limiting principle based on the International Bill of Rights may retain the value of public health surveillance for the common good without sacrificing the value of patient privacy. It may also help to assure the public that their dignity as well as their privacy will not be violated without justification.