

2007

Medicine and Public Health: Crossing Legal Boundaries

Wendy K. Mariner

Boston University School of Law

Follow this and additional works at: https://scholarship.law.bu.edu/faculty_scholarship

 Part of the [Health Law and Policy Commons](#), and the [Privacy Law Commons](#)

Recommended Citation

Wendy K. Mariner, *Medicine and Public Health: Crossing Legal Boundaries*, 10 *Journal of Health Care Law and Policy* 121 (2007).
Available at: https://scholarship.law.bu.edu/faculty_scholarship/359

This Article is brought to you for free and open access by Scholarly Commons at Boston University School of Law. It has been accepted for inclusion in Faculty Scholarship by an authorized administrator of Scholarly Commons at Boston University School of Law. For more information, please contact lawlessa@bu.edu.



BOSTON UNIVERSITY SCHOOL OF LAW

WORKING PAPER SERIES, PUBLIC LAW & LEGAL THEORY
WORKING PAPER NO. 07-13



MEDICINE AND PUBLIC HEALTH: CROSSING LEGAL BOUNDARIES

WENDY K. MARINER

Copyright 2007 WK Mariner

published in the JOURNAL OF HEALTH CARE LAW & POLICY, Vol. 10, p. 121 (2007)

This paper can be downloaded without charge at:

The Boston University School of Law Working Paper Series Index:
<http://www.bu.edu/law/faculty/scholarship/workingpapers/2007.html>

The Social Science Research Network Electronic Paper Collection:

MEDICINE AND PUBLIC HEALTH: CROSSING LEGAL BOUNDARIES

WENDY K. MARINER*

INTRODUCTION

On December 14, 2005, the New York City Department of Health and Mental Hygiene adopted a new diabetes surveillance program. The new health code regulations require medical laboratories to submit to the Health Department the results of every patient's blood sugar tests, together with the patient's name, date of birth, address, physician, and other information.¹ The report does not require the patient's consent. The Health Department will review the reports to see which patients are not controlling their blood sugar levels and will contact the physician, or sometimes the patient, to encourage the patient to change his or her behavior by losing weight, eating better, taking medication, and seeing a physician more often. Is this an innovative way to improve the health of several hundred thousand New Yorkers, a presumptuous invasion of privacy, or usurpation of the physician's role?

Dr. Thomas R. Frieden, Commissioner of the New York City Department of Health and Mental Hygiene, is enthusiastic about the new program, hoping it will reduce the number of people in New York City with uncontrolled diabetes, particularly Type 2 diabetes.² Critics, on the other hand, worry that the program

Copyright © 2007 by Wendy K. Mariner.

* Professor of Health Law, Bioethics and Human Rights, Boston University School of Public Health; Professor of Law, Boston University School of Law (Boston, MA); Professor of Socio-Medical Sciences and Community Medicine, Boston University School of Medicine (Boston, MA). This article is adapted from the author's lecture at the Association of American Law Schools' Annual Meeting in Washington, D.C., *Empirical Scholarship: What Should We Study and How Should We Study It?*, which was co-sponsored by the AALS Sections on Law, Medicine and Health Care; Socio-Economics; and Torts and Compensation Systems, entitled *Public Health in Law* (January 2006).

1. NEW YORK CITY, N.Y., 24 HEALTH CODE §§ 13.03-.04 (2006). See *infra* note 6 for the text of these regulations, which took effect on January 15, 2006.

2. David B. Caruso, *NYC Proposes Tracking Diabetics, Raising Privacy Fears: Critics Say Consent Must Be Asked Before Collecting Data to Help Patients*, THE STAR-LEDGER (NEWARK, NJ), July 26, 2005, at 28. Type 2 diabetes arises, typically in adulthood, from a body's inability to use insulin properly and is believed to result from excess body weight and physical inactivity. World Health Org., Fact Sheet No. 312, Diabetes (2006), <http://www.who.int/mediacentre/factsheets/fs312/en/index.html> [hereinafter Fact Sheet No. 312]. It accounts for about ninety percent of diabetes cases worldwide. *Id.* Type 1 diabetes is a genetic condition in which the pancreas fails to produce insulin; it is usually diagnosed in childhood and typically well-controlled. Am. Diabetes Ass'n, Type 1 Diabetes, <http://www.diabetes.org/type-1-diabetes.jsp> (last visited Nov. 10, 2006); Lucile Packard Children's

invades personal privacy.³ Physicians worry that the City will tell them how to treat their patients. Critics may also be concerned that what begins as a benevolent effort to encourage better medical care may mutate into requiring compliance with a medical regimen as a condition for Medicaid eligibility, private health insurance, public or private employment, or even a general duty to stay healthy.⁴ A disproportionate number of diabetics in New York City are Medicaid beneficiaries or disadvantaged minorities and the City would benefit financially from any reduction in the cost of their care.⁵ If the City or state can monitor a chronic condition like diabetes, why not heart disease, cancers, asthma, hypertension, low back pain, and other chronic conditions?

This article examines these different perspectives on disease reporting and the legal arguments for them. Part I describes the New York City diabetes blood sugar test results reporting program and reasons for its adoption. Part II critiques the justifications put forth for the program, finding that they fail to satisfy basic legal principles governing patient autonomy and privacy. Part III places the program in the broader context of the evolution of public health to encompass not merely communicable diseases and environmental hazards, but, increasingly, personal behaviors and the medical treatment of chronic conditions. Part III considers whether public health is being privatized or good health is being made a public duty. In either case, the boundary between the fields of medicine and public health is blurring, with important and perhaps ominous implications for the legal rights and duties of individuals, especially patients and physicians. This article concludes

Hosp., Diabetes & Other Endocrine and Metabolic Disorders, <http://www.lpch.org/DiseaseHealthInfo/HealthLibrary/diabetes/type1.html> (last visited Nov. 10, 2006). A third form of diabetes, gestational diabetes, in which placental hormones block insulin's effect in pregnancy, affects about four percent of pregnant women, but normally disappears after delivery. Am. Diabetes Ass'n, Gestational Diabetes, <http://www.diabetes.org/gestational-diabetes.jsp> (last visited Nov. 10, 2006). For a layperson's description of each type of diabetes, see Am. Diabetes Ass'n, All About Diabetes, <http://www.diabetes.org/about-diabetes.jsp> (last visited Nov. 10, 2006); Fact Sheet No. 312, *supra*.

3. *E.g.*, Rob Stein, *New York City Starts to Monitor Diabetics*, WASH. POST, Jan. 11, 2006, at A3 (quoting opponents who describe the plan as "a recipe for invasion of privacy" and who fear the "information could be taken out of the data bank and disseminated to people or places [the diabetic doesn't] necessarily want it to be disseminated"); David B. Caruso, *New York Pushes Plan to Track Diabetes*, HOUSTON CHRON., July 26, 2005, at A7 (quoting a representative of health care groups concerned with privacy who argued that "[Diabetes] isn't smallpox. The State, or the city in this case, does not have a compelling interest in the health of an individual that overrides that individual's right to privacy.").

4. *See infra* Part III.

5. RICHARD ALBA & DAVID STROGATZ, *THE QUIET CRISIS: MINORITY-MAJORITY DISPARITIES FOR DIABETES IN UPSTATE NEW YORK CITIES* (2006), available at http://www.albany.edu/news/pdf_files/UAlbany_CEMHD_Minority-Majority_Diabetes_UpstateNY_Cities.pdf. Across the United States, an estimated 10% of non-Hispanic blacks have diagnosed diabetes, compared with 5.6% of non-Hispanic whites, 6.5% of Mexican-Americans, and 15.8% of all Americans age 65 and older. Catherine C. Cowie et al., *Prevalence of Diabetes and Impaired Fasting Glucose in Adults in the U.S. Population: National Health and Nutrition Examination Survey 1999-2002*, 29 *DIABETES CARE* 1263, 1265 tbl.1 (2006).

that the general goal of improving public health is too vague and malleable a concept to justify depriving individuals of their personal privacy. A far more precise and principled concept of public health threat is necessary to justify involuntary reporting of personally identifiable medical information and compliance with medical recommendations.

Chronic disease registries raise epistemological questions about distinguishing professional roles and determining whether public health is becoming medicalized or overtaking the role of physicians. This is an intriguing debate, but I am interested instead in the effect of this trend on the law governing patients and, more broadly, fundamental principles of autonomy and privacy. It hardly matters whether people call themselves medical or public health practitioners. What law they follow does matter. Where public health programs seek to override legal principles protecting patient autonomy and privacy, it matters very much what the law is.

I. THE NEW YORK CITY HEMOGLOBIN A1C REGISTRY

The New York City Board of Health amended its Health Code in December 2005 to require the reporting of blood sugar (Hemoglobin A1C) test results, together with the patient's name, address, and date of birth.⁶ The Health

6. NEW YORK CITY, N.Y., 24 HEALTH CODE §§ 13.03-.04 (2006). The ordinance, adopted by the New York City Board of Health on December 14, 2005, amends the New York City Health Code to provide the following:

§ 13.04. Reporting of Hemoglobin A1C.

(a) All clinical laboratories, as defined under §13.01 of this Article, that report laboratory test results electronically to the Department and which use a file up-load method, shall electronically report to the Department all laboratory results for Hemoglobin A1C tests, as defined in subsection (b) of this section, within 24 hours.

(b) The "Hemoglobin A1C" laboratory test represents an index of blood glucose control measuring average blood sugar over the past 90 days, and shall mean the following for the purposes of this section: HgbA1c; HgbA1c by HPLC; HbA1c; Glycohemoglobin A1C; Gycolhaemoglobin; Glycohemoglobin; Glycated Hgb; Glyco-Hb; GHb; Ghb. As defined in this section, "Hemoglobin A1C" shall not mean the following: Hgb; Hemoglobin; Hb; Hb without reference to glycated or glycosylated or A1C; or Glycohemoglobin total.

(c) Reports required by subsection (a) shall contain the information required in Section 13.03 (a)(1) through (6) of this Article.

(d) Hemoglobin A1C test results and other identifying information reported to the department pursuant to this section shall be confidential and shall not be disclosed to any person other than the individual who is the subject of the report or to such person's treating medical providers. If the subject of the report is a minor, information can be disclosed to the subject's parent or legal guardian.

The ordinance requires clinical laboratories to report the following identification information:

§ 13.03. Report of positive findings.

(a) The director of a clinical laboratory shall report to the Department within 24 hours all laboratory findings which indicate the presumptive presence of any disease required to be reported by §11.03 of this Code. Reports shall state the particulars required by §11.05 and shall include:

(1) The full name of the person from whom the specimen was taken, the date of birth and address of such person.

Department's reason for adopting the new program was set forth in its preface to the new ordinance:

Diabetes, a life-long disease, has recently become epidemic in New York City (NYC) and is a major public health problem. The prevalence of diabetes in NYC has doubled in the past ten years. The NYC 2003 Community Health Survey (CHS) estimates that 9% (530,000) of adult New Yorkers and 20% of adults over 65 have diagnosed diabetes. People may have diabetes an average of 4-7 years before being diagnosed, and it is estimated that another 265,000 may have diabetes and not yet know it. Diabetes is now the fourth leading cause of death in New York City, moving up from 6th in 2002. This epidemic condition requires similar or greater urgency in public health response to that traditionally accorded to infectious disease monitoring and control.⁷

The program was certainly inspired by a desire to improve health and to postpone early deaths. Diabetes is a serious problem for a growing number of people.⁸ The Centers for Disease Control and Prevention (CDC) estimates that almost fifteen million Americans—five percent of the population—had diabetes in 2004,⁹ approximately twice the number of cases on record twenty years ago.¹⁰

(2) The medical record number if known, identification number or code assigned to the person, if any, and other personal identifiers as may be required by the Department.

(3) The name and address of the physician or other authorized person or clinical laboratory who submitted the specimen.

(4) The name and address of the clinical laboratory which performed the test.

(5) The date the test or tests results were first available.

(6) The name(s) of test or tests performed.

7. DEP'T OF HEALTH & MENTAL HYGIENE, BD. OF HEALTH, NEW YORK CITY, NOTICE OF ADOPTION TO AMEND ARTICLE 13 OF THE NEW YORK CITY HEALTH CODE 1 (2005), *available at* <http://www.nyc.gov/html/doh/downloads/pdf/public/notice-adoption-a1c.pdf> [hereinafter NOTICE OF ADOPTION].

8. Ctrs. for Disease Control & Prevention, Diabetes Public Health Resource, Data & Trends [hereinafter Diabetes Data & Trends], <http://www.cdc.gov/diabetes/statistics/prev/national/figpersons.htm> (last visited Nov. 10, 2006). Diabetes is diagnosed when fasting blood levels of glucose (sugar) are at least 126 mg/dl. Am. Diabetes Ass'n, All About Diabetes, <http://www.diabetes.org/about-diabetes.jsp> (last visited Nov. 10, 2006).

9. U.S. Census Bureau, Table 1: Annual Estimates for the United States and States, and for Puerto Rico: April 1, 2000 to July 1, 2004 (2004), *available at* <http://www.census.gov/popest/states/tables/NST-EST2004-01.pdf>. The total U.S. population has grown 24% from 238,948,000 in 1985 to 296,410,404 in 2005. U.S. Census Bureau, Monthly Estimates of the United States Population: April 1, 1980 to July 1, 1999, with Short-Term Projections to November 1, 2000 (2001), *available at* <http://www.census.gov/popest/archives/1990s/nat-total.txt>; U.S. Census Bureau, Table 1: Annual Estimates of the Population by Sex and Five-Year Age Groups for the United States: April 1, 2000 to July 1, 2005, (2006), *available at* <http://www.census.gov/popest/national/asrh/NC-EST2005/NC-EST2005-01.xls>. The Census Bureau estimates that 36,790,114 Americans are sixty-five years of age or over. *Id.*

10. Diabetes Data & Trends, *supra* note 8 (reporting that 14.7 million Americans had diagnosed diabetes in 2004). In 1982, an estimated six million people—2.4% of the population—had diabetes. U.S. DEP'T OF HEALTH & HUMAN SERVS., DIABETES IN THE 1980'S: CHALLENGES FOR THE FUTURE, REPORT OF THE NATIONAL DIABETES ADVISORY BOARD 1 (1982). Not all the individuals included in the estimate have been diagnosed with diabetes for a variety of reasons, such as lack of access to medical

Furthermore, while diabetes was the sixth most common cause of death in the United States in 2003, it was the fourth most common cause of death in New York City.¹¹

Beyond the commendable goal of improving health, taking action against diabetes may be financially necessary. The rise in diabetes appears to parallel rising pharmaceutical prices and possible reductions in state Medicaid budgets. The New York City Health Department says that in “New York State, 31% of diabetic patients in commercial managed care and 42% in Medicaid Managed Care have an A1C > 9.0%,” which is higher than the recommended level of less than 7 percent.¹² The Health Department further argues that “tight blood sugar control” can reduce “by over 25%” the small blood vessel complications that lead to eye disease, kidney complications and peripheral nerve disorders.¹³ Thus, the Health Department concludes, “[k]eeping the average blood sugar (A1C) under 7.0% can prevent many diabetes-related complications and deaths.”¹⁴

care. Estimates may vary with how diabetes is measured. More recently, researchers at the National Institute of Diabetes and Digestive and Kidney Diseases estimated that 6.5% of Americans have been diagnosed with diabetes and another 2.8% are undiagnosed. Cowie et al., *supra* note 5, at 1265 tbls.1 & 2. Another 26% had higher than normal blood sugar levels, but not high enough to qualify as diabetes. *Id.* at 1266.

11. Arialdi M. Miniño et al., *Deaths: Preliminary Data for 2004*, 54 NAT'L VITAL STAT. REP. 1, 4 tbl.B (2006), http://www.cdc.gov/nchs/data/nvsr/nvsr54/nvsr54_19.pdf; Press Release, New York City Dep't of Health & Mental Hygiene, Diabetes Is Now the Fourth Leading Cause of Death in New York City (Dec. 22, 2004). Deaths from all causes in 2004 totaled 2,398,365, with heart disease accounting for 654,092; cancers for 550,270; stroke for 150,147; respiratory disease for 123,884; unintentional injuries for 108,694; and diabetes for 72,815 deaths. Miniño et al., *supra*, at 4 tbl.B. Age-adjusted death rates for heart disease have been declining since 1980, for cancer since 1993, and for stroke since 1958. Donna L. Hoyert et al., *Deaths: Final Data for 2003*, 54 NAT'L VITAL STAT. REP. 1, 8 (2006), http://www.cdc.gov/nchs/data/nvsr/nvsr54/nvsr54_13.pdf. Complicating the picture is the fact that diabetes was (and still is) not always listed as a contributing or underlying cause of death, perhaps because the frequent causes of death among people with diabetes are heart disease, stroke, atherosclerosis, and renal disease. See Ctrs. for Disease Control & Prevention, *Premature Mortality from Diabetes Mellitus—Use of Sentinel Health Event Surveillance to Assess Causes*, 35 MORBIDITY & MORTALITY WKLY. REP. 711, 711 (1986) [hereinafter *Premature Mortality from Diabetes*]; Ctrs. for Disease Control & Prevention, *Premature Mortality in the United States: Public Health Issues in the Use of Years of Potential Life Lost*, 35 MORBIDITY & MORTALITY WKLY. REP. 1S, 5S (Supp. 1986) (critiquing statistical methods to reflect underlying diseases in tabulations of causes of death or years of life lost).

12. NOTICE OF ADOPTION, *supra* note 7, at 2. Normal blood sugar levels in the general population are typically less than 6% or less than 135 mg/dl. Robert Steinbrook, *Facing the Diabetes Epidemic—Mandatory Reporting of Glycosylated Hemoglobin Values in New York City*, 354 NEW ENG. J. MED. 545, 546-47 (2006); see also The Mayo Clinic, Blood Sugar Tests: Understanding Your Results, <http://www.mayoclinic.com/health/blood-sugar/SA00102> (last visited Nov. 13, 2006) (noting that 100 mg/dl is the population's normal blood sugar level). The A1C test measures the average level of glycemia over the preceding two to three months. Steinbrook, *supra*, at 546. The American Diabetes Association recommends such tests twice a year for patients in good condition and four times a year for patients who have unstable blood sugar levels. *Id.*

13. NOTICE OF ADOPTION, *supra* note 7, at 2.

14. *Id.*

This goal may prove difficult to achieve. As the Department acknowledges, the CDC has found that “only 37% of US adults with diabetes have an A1C < 7% and 20% have an A1C > 9%.”¹⁵ Moreover, blood sugar levels are not the only measure of diabetes control. Patients are also encouraged to keep their blood pressure and blood lipid levels under control.¹⁶ The question is whether lowering one or even all of these measures—blood sugar, blood pressure, and blood lipids—is sufficient to reduce the risk of heart disease, stroke, renal disease, or retinopathy to normal levels.¹⁷ After all, a high level of any one of these is just the first of several steps on the way to disease symptoms. Even if this is the right goal, many patients find it difficult to achieve the target levels.¹⁸

Although New Yorkers may be doing especially poorly, most Americans do not or cannot achieve the recommended levels of control. New York City’s experiment has obvious implications for the rest of the country. On the one hand, if New York City is successful in getting people to control their blood sugar, other

15. *Id.* (citing Nat’l Ctr. for Health Statistics, U.S. Dep’t of Health & Hum. Servs., National Health and Nutrition Examination Survey: 1999-2000, http://www.cdc.gov/nchs/about/major/nhanes/nhanes99_00.htm (last visited Nov. 13, 2006)).

16. Recommendations for treating diabetes Type 2 include exercising and following a diet, with or without medications, to reduce “bad” cholesterol and hypertension; having regular eye examinations to detect retinopathies; and paying attention to foot and other infections. Am. Diabetes Ass’n, *Standards of Medical Care in Diabetes*, 28 DIABETES CARE S4, S12-S13, S19-S20 (Supp. 2005); Am. Heart Ass’n, *What’s the Difference Between LDL and HDL Cholesterol?*, <http://www.americanheart.org/presenter.jhtml?identifier=180> (last visited Oct. 16, 2006) (explaining that LDL cholesterol is “bad” and HDL cholesterol is “good”); see also European Diabetes Policy Group 1998, *A Desktop Guide to Type 1 (Insulin-Dependent) Diabetes Mellitus*, 16 DIABETIC MED. 253 (1999) (outlining similar recommendations for the treatment and management of Type 1 diabetes). The American Diabetes Association issues Clinical Practice Recommendations for physicians to use in caring for people with diabetes. Am. Diabetes Ass’n, *Standards of Medical Care in Diabetes—2006*, 29 DIABETES CARE S4 (Supp. 2006). Blood or serum lipid control refers to blood tests for cholesterol, with the target being serum LDL-cholesterol below 100 mg/dL and triglycerides below 150 mg/dL. *Id.* at S10. Blood pressure control is defined as less than 130/80 mm Hg. *Id.*; see also F.D. Richard Hobbs, *Reducing Cardiovascular Risk in Diabetes: Beyond Glycemic and Blood Pressure Control*, 110 INT’L J. CARDIOLOGY 137, 137 (2006) (“Low-density lipoprotein cholesterol is the first priority for treatment [to prevent cardiovascular disease], with a statin in adequate dosage as the first choice for pharmacological therapy.”).

17. Patrick J. O’Connor, *Setting Evidence-Based Priorities for Diabetes Care Improvement*, 15 INT’L J. FOR QUALITY HEALTH CARE 283, 283 (2003) (noting that “clinical trials have not yet proven that HbA1c lowering significantly reduces the risk of heart attacks or strokes,” while “control of hypertension, control of lipid disorders, and aspirin use substantially reduce cardiovascular morbidity or mortality in those with diabetes”).

18. There is extensive literature on educating patients about managing their diabetes in order to prevent serious disease, much of which attests to a need to maintain long-term contact with patients to encourage and support difficult behavior changes. See, e.g., K. M. Knight et al., *The Diabetes Educator: Trying Hard, But Must Concentrate More on Behaviour*, 23 DIABETIC MED. 485, 495-96 (2006) (reviewing educational studies and noting that there is little empirical support for the widespread assumption that transferring knowledge will improve health outcomes, that knowledge may be “necessary” but not “sufficient” for behavior change, that “single interventions, cognitive or behavioral, produce disappointing results,” and that “interventions to change [complex human] behavior need to reflect that complexity”).

jurisdictions may follow suit. On the other hand, if controlling blood sugar alone is not sufficient to significantly reduce the risk of serious disease, it is not clear how much will have been gained.

The possible benefits of the program may be contrasted with its possible costs. The cost of diabetes care has long been a concern.¹⁹ Routine expenses include physician visits, drugs, insulin, blood testing equipment, and other supplies that are relatively inexpensive, but may nevertheless pose problems for low-income patients. These costs may increase if patients see physicians more frequently or require additional medication and monitoring. Major expenses are concentrated in hospitalizations for heart disease, stroke, kidney failure, and foot problems, which tend to appear after many years with diabetes.²⁰ Intangible costs of diabetes include loss of productivity from an acute episode of illness or chronic disability, as well as pain and inconvenience.²¹ Nevertheless, a successful program could enable more patients to live longer with fewer disabilities, reducing productivity losses.²²

The New York City program is modeled after an experiment being conducted in Vermont.²³ Researchers created a study—a randomized controlled trial funded

19. World Health Org., *Diabetes: The Cost of Diabetes* (2003), http://www.who.int/hpr/NPH/docs/gs_diabetes.pdf (estimating that, in 2000, 177 million people worldwide had diabetes); Can. Diabetes Ass'n, *The Prevalence and Costs of Diabetes* (2006), <http://www.diabetes.ca/files/prevalence-and-costs.pdf> (confirming the WHO estimate, and adding that “[b]y 2025, this figure will top 300 million”); U.S. Dep’t of Health & Human Servs., *Study Shows Sharp Rise in the Cost of Diabetes Nationwide* (2003), <http://www.dhhs.gov/news/press/2003pres/20030227a.html> (reporting that the direct medical costs of diabetes care in the United States rose from \$44 billion in 1997 to approximately \$92 billion in 2002); Ctrs. for Disease Control & Prevention, *Studies on the Cost of Diabetes* (1998), <http://www.cdc.gov/diabetes/pubs/costs/appendices.htm> (summarizing various studies on the cost of diabetes, including the 1997 Am. Diabetes Ass’n study, which estimated the direct cost of diabetes as \$44 billion).

20. U.S. DEP’T OF HEALTH & HUMAN SERVS., *PREVENTING CHRONIC DISEASES: INVESTING WISELY IN HEALTH 1* (2003), available at <http://healthierus.gov/steps/summit/prevportfolio/Diabetes-HHS.pdf>.

21. Loss of productivity was estimated at \$54 billion in the U.S. in 1997, suggesting that the cost of care could offset productivity losses to an appreciable degree. *Id.*

22. The program may have financial value for the health department, regardless of any savings in patient care costs. It may provide the department with a rationale for preserving or increasing its budget and staff at a time when state and local funding is tight. Federal financial support for both research and prevention have begun to decline. Ctrs. for Disease Control & Prevention, *Budget for the Centers for Disease Control and Prevention* (2006), www.cdc.gov/fmo/PDFs/FY06FundFunctAreaTable.pdf; Nat’l Insts. of Health, U.S. Dep’t of Health & Human Servs., *Estimates of Funding for Various Diseases, Conditions, Research Areas*, <http://www.nih.gov/news/fundingresearchareas.pdf> (last visited Mar. 4, 2007); cf. Ian Urbina, *Cost and Effect: Rising Diabetes Threat Meets a Falling Budget*, N.Y. TIMES, May 16, 2006, at A1 (describing how treatment and research programs are being cut for lack of funding).

23. NOTICE OF ADOPTION, *supra* note 7, at 2. The NYC Health Department states that the Vermont Diabetes Information System offers an example of a similarly promising approach, without noting that the Vermont program is a research study conducted with the consent of patients who do not object to their enrollment as research subjects. *Id.*; see Charles D. MacLean et al., *The Vermont Diabetes Information System (VDIS): Study Design and Subject Recruitment for a Cluster Randomized Trial of a*

by a grant from the National Institutes of Health—to test an information system, the Vermont Diabetes Information System (VDIS), for physicians and their patients.²⁴ Physicians and patients were invited to become research subjects and only those patients who did not object were enrolled.²⁵ The study collects the results of multiple tests, such as blood sugar, lipids, cholesterol, and results of eye exams, and sends physicians' recommendations for particular treatment options for each patient.²⁶ It might be thought of as a computer-based diabetes medical treatment protocol, coupled with an algorithm that applies the protocol to individual test results.

The VDIS costs about \$1 per patient per month.²⁷ If New York City's system cost the same, it could require at least \$12-24 million a year to operate. The program anticipates receiving between one and two million test results annually.²⁸ The City would therefore have to save at least that amount, perhaps in Medicaid expenditures, to make the program cost-neutral.

The New York City Health Department's diabetes program is both narrower and broader than the VDIS. It is narrower because it is limited to obtaining only A1C test results—not all information needed for diabetes treatment decisions—which it will enter into a new diabetes registry, the New York City Hemoglobin A1C Registry. It plans to “report a roster of patients to clinicians, stratified by patient A1C levels, highlighting patients under poor control (e.g., A1C > 9.0%) who may need intensified follow-up and therapy.”²⁹ It is broader than the VDIS study because it is not limited to providing treatment protocol information to physicians and patients. The Health Department plans to use the data “for public health surveillance and monitoring of trends of blood sugar control in people with diabetes.”³⁰ Specifically, it will “[p]lan programs in the Diabetes Prevention and Control Program” and “[m]easure outcomes of diabetes care.”³¹

Decision Support System in a Regional Sample of Primary Care Practices, 1 CLINICAL TRIALS 532, 536, 538 (2004).

24. Charles D. MacLean et al., *Diabetes Decision Support: Initial Experience with the Vermont Diabetes Information System*, 96 AM. J. PUB. HEALTH 593, 595 (2006). Final results of that ongoing study are not yet available. *Id.* at 594. The study is supported by the National Institute of Diabetes and Digestive and Kidney Diseases, *id.* at 595, which is one of the National Institutes of Health. Nat'l Insts. of Health, U.S. Dep't of Health & Human Servs., Institutes, Centers & Offices, <http://www.nih.gov/icd> (last visited Mar. 4, 2007).

25. MacLean et al., *supra* note 23, at 535-36, 538.

26. *Id.* at 533-34, 537.

27. MacLean et al., *supra* note 24, at 594.

28. NOTICE OF ADOPTION, *supra* note 7, at 1-2.

29. *Id.* at 2.

30. *Id.* The proposed ordinance received little public attention. *Id.* at 1 (stating that the Department received 31 written comments and 10 individuals testified at its Aug. 16, 2005 public hearing). Even so, some people objected to having their personally identifiable test results sent to the Health Department. Stein, *supra* note 3, at A3. The Health Department responded by allowing individuals to opt out of being contacted directly by the Health Department, but still requires that the person's A1C test results be reported to the Department. Dep't of Health & Mental Hygiene, New York City A1C Registry: “Do Not Contact” Request (2006), available at <http://home2.nyc.gov/html/doh/downloads/pdf/diabetes/diabetes->

The next part of this article considers whether these goals justify the compulsory reporting of identifiable patient information, and whether they could be achieved equally well without requiring identifiable data.

II. THE LEGAL BASIS FOR THE NEW YORK CITY DIABETES REPORTING PROGRAM

There are at least three arguments that New York City does not have the legal authority to adopt or implement its diabetes reporting program. The first is that the Health Department's regulatory authority over clinical laboratories does not include the power to require the reporting of personally identifiable medical information. The second is that neither the State nor the City of New York has the power to require the reporting of such information in the absence of a credible threat posed by the patients whose information is reported to the health or safety of other people. The third is that when the department collects and uses this identifiable information, it is engaged in research with human subjects that requires the patient's consent. However, as will be discussed in this part, it is possible for the Health Department to acquire information relevant to its role without insisting upon compulsory reporting of identifiable information.

A. *New York City's Regulatory Authority*

The New York City Health Department cited its authority to regulate clinical laboratories and to supervise the reporting and control of chronic diseases as the legal foundation for its diabetes program.³² The New York City Charter authorizes the city health department to "analyze, evaluate, supervise and regulate clinical laboratories, blood banks, and related facilities providing medical and health services and services ancillary thereto."³³ The New York City Board of Health has

a1coptout-form.pdf. Ironically, a person who does not want to be contacted must submit to the Health Department a "contact information" form with the person's name, date of birth, address, and phone number. *Id.*

31. NOTICE OF ADOPTION, *supra* note 7, at 2.

32. *Id.* at 1. New York City is governed by a Charter, which creates a Department of Health with the powers of a local health department and a Commissioner of Health and Mental Hygiene as its head. The Charter grants the department "jurisdiction to regulate all matters affecting health in the city of New York and to perform all those functions and operations performed by the city that relate to the health of the people of the city, including but not limited to the mental health, mental retardation, alcoholism and substance abuse-related needs of the people of the city." N.Y. CITY, N.Y., N.Y. CITY CHARTER ch. 22 §§ 551, 556 (2005).

33. N.Y. CITY CHARTER ch. 22, § 556(c)(4). This subsection is part of a list of twelve powers for the "supervision of public health" that includes supervising the registration of births and deaths; the reporting of communicable and chronic diseases and conditions hazardous to life and health; the abatement of nuisances; providing services and facilities for the mentally disabled; inspecting hospitals, clinics, nursing homes, clinical laboratories, and blood banks; inspecting and investigating service providers for the mentally disabled; regulating public health aspects of the water supply, sewage disposal, and water pollution; regulating production and distribution of milk and milk products; regulating the food and drug supply of the city; regulating the disposal of human remains; regulating the public health aspects of ionizing radiation, the handling of radioactive waste and radioactive materials; and making rules covering the services of mental health providers. *Id.* § 556(c)(1)-(12). The New York

the authority to amend, add, or repeal provisions of the city health code, and to “confer additional powers on the department not inconsistent with the constitution, laws of this state or this charter.”³⁴ However, the Board of Health may not change the health code beyond the “matters and subjects to which the power and authority of the department extends.”³⁵

It is unlikely that the power to “regulate clinical laboratories” includes or even implies the power to prescribe mandatory reporting of specific identifiable information about patients.³⁶ Certainly the State, and here the City, can regulate facilities like clinical laboratories with respect to their adherence to sanitation and similar standards. Laboratory regulation historically has been limited to requiring licensure conditioned on meeting standards for the quality of the building, equipment, ownership, and its personnel, and sometimes by setting quality standards for tests performed by a laboratory.³⁷ The power to regulate hospitals has never been considered to include the power to require hospitals to routinely report identifiable information about their patients directly to the health department that licenses the facility.³⁸ Such reporting has historically been authorized pursuant to an independent statute or regulation.

A more promising source of authority might be the power in Section 556(c)(2) of the Charter to “supervise the reporting and control of communicable and chronic diseases and conditions hazardous to life and health.”³⁹ This provision is open to interpretation. On the one hand, it might be read broadly to imply the power to require the reporting of any specific disease or condition. On the other hand, the power to supervise reporting does not necessarily include the power to require reporting; it might be limited simply to ensuring the proper collection and storage of reports that are authorized or required by other legislation. This provision may be an example of the typically general language used in health legislation; the range of health concerns and possible responses are so varied that detailed rules would be impractical in the text of a general delegation of authority. Such language is broad enough, for example, to cover requiring restaurants to observe standards of hygiene and sanitation and requiring industry to dispose of

City Administrative Code does not contain any provisions governing laboratories or hospitals. It does contain one section requiring the commissioner to prevent a communicable disease from spreading from one part of the City to another and to forbid communication with the house or family of a person infected with a communicable disease. N.Y. CITY, N.Y., ADMIN. CODE ch. 1, § 17-104 (2005).

34. N.Y. CITY CHARTER ch. 22, § 558(b).

35. *Id.* § 558(c).

36. *Id.* § 556(c)(4); *see supra* note 33 and accompanying text.

37. *See, e.g.*, 42 U.S.C. § 1395nn (2000 & Supp. 2006). The Anti-Referral Statute (Stark) applies to all designated health services including clinical laboratories. *Id.* The statute prohibits all referrals for the provision of designated health services and all claims for federal reimbursement for such services furnished pursuant to a referral if the physician has a financial relationship with the entity. *Id.*

38. Health departments often require hospitals to report instances of unexpected patient injury or death and to allow the department to investigate particular circumstances as part of its power to monitor the quality of care. *E.g.*, N.Y. PUB. HEALTH LAW § 2805-1 (McKinney 2002).

39. N.Y. CITY CHARTER ch. 22, § 556(c)(2).

hazardous waste safely. However, the substance of the rules would be subject to scrutiny for compliance with constitutional and state requirements. Interpreting Section 556(c)(2) to provide a blanket authorization for imposing any and all standards of conduct on clinical laboratories, much less individual residents, would raise significant constitutional questions, as discussed in the next subpart.⁴⁰

For these reasons, the idea that the power to supervise the reporting and control of communicable and chronic diseases includes the power to obtain identifiable personal information without the knowledge or consent of the individual seems the least plausible interpretation and the one most vulnerable to challenge. This conclusion is supported by the fact that failure to report would be a criminal offense.⁴¹ The power to create crimes is not to be lightly inferred from general language historically intended to regulate the quality of care and the environment.

B. Collecting Personally Identifiable Information for Public Health Purposes

1. Possible Goals

The New York City Health Commissioner reportedly advocated the A1C Registry on the ground that the Health Department, “should know how many New Yorkers have diabetes that is badly out of control, where they are, and who cares for them.”⁴² Certainly the Health Department has an interest in how many New Yorkers have diabetes. Whether it has an interest in identifying each person is a different question. The Health Department might claim a role in monitoring the quality of care that physicians provide to their patients. Of course, the argument for ensuring quality applies equally to all kinds of medical care, not just to blood sugar levels of diabetic patients. This suggests that the Health Department is claiming the power to receive reports about all diseases and conditions that physicians treat. If the power is to be limited to A1C test results, there should be a reason that justifies limiting the exercise of this power to that specific test or at least to diabetes.

Three reasons for limiting reporting to A1C tests might be considered. The first is that diabetes is expensive to treat and the city needs to reduce its expenditures for that treatment.⁴³ Of course, the cost argument cannot be limited to diabetes. It would apply to any expensive condition, such as heart disease, stroke, cancer, liver disease, kidney failure, and serious injuries. Because this reasoning could apply to so many other kinds of conditions, it does not offer a persuasive principle for limiting reporting to A1C test results. A second possible reason is that

40. See *infra* notes 43-83 and accompanying text.

41. N.Y. CITY CHARTER ch. 22, § 558(e) (“Any violation of the health code shall be treated and punished as a misdemeanor.”).

42. Steinbrook, *supra* note 12, at 546.

43. Neil Osterweil, *New York City Plans Diabetes Patient Tracking*, MEDPAGE TODAY, July 26, 2005, <http://www.medpagetoday.com/tbprint.cfm?tbid=1422>.

diabetes affects a growing number of people whose lives could be significantly improved with appropriate care.⁴⁴ This is certainly a good reason for expanding access to good quality care. But it does not explain the need for the Health Department to create a registry of identifiable A1C test results.

The third and most likely explanation for the Registry lies in the expansion of the concepts of both “epidemics” and “disease surveillance” among public health practitioners, which encourages the notion that health departments are entitled to personally identifiable health information about everyone in the state. To laypersons, the word epidemic may bring to mind memories of SARS or the HIV epidemic, or even history lessons about smallpox or plague.⁴⁵ To many epidemiologists and public health practitioners today, however, an epidemic is any increase in the number of people with a particular disease or condition that is higher than would be expected based on past experience.⁴⁶ Thus, we read news reports of an epidemic of obesity or breast cancer.⁴⁷ Calling such conditions “epidemics” may create a perception that people with chronic diseases should be treated as though they have a contagious disease, using laws formerly reserved for preventing epidemics of smallpox and similar contagious diseases.⁴⁸ Historically, state and local health departments required physicians to report cases of certain communicable diseases so that the department could investigate the source of an

44. See *supra* notes 7-11 and accompanying text.

45. For good histories of epidemics see generally JOHN M. BARRY, *THE GREAT INFLUENZA: THE EPIC STORY OF THE DEADLIEST PLAGUE IN HISTORY* (2004); MARILYN CHASE, *THE BARBARY PLAGUE: THE BLACK DEATH IN VICTORIAN SAN FRANCISCO* (2003); HOWARD MARKEL, *QUARANTINE! EAST EUROPEAN JEWISH IMMIGRANTS AND THE NEW YORK CITY EPIDEMICS OF 1892* (1997).

46. Michael B. Gregg, *A Walk-Through Exercise: A Food-Borne Epidemic in Oswego County, New York*, in *FIELD EPIDEMIOLOGY* app. 413, 415 (Michael B. Gregg ed., 2d ed. 2002). An outbreak of disease is a sudden increase in the number of cases of a disease beyond what is normally expected, ordinarily in a particular locality. Richard C. Dicker, *A Brief Review of the Basic Principles of Epidemiology*, in *FIELD EPIDEMIOLOGY* *supra*, at 22. An epidemic is a broader outbreak in a larger geographic area. *Id.* However, some epidemiologists treat any outbreak as equivalent to an epidemic. Gregg, *supra*, at 415. A pandemic is an epidemic that spreads to several countries. Dicker, *supra*, at 22.

47. See, e.g., WORLD HEALTH ORG., *TECHNICAL REPORT SERIES NO. 894, OBESITY: PREVENTING AND MANAGING THE GLOBAL EPIDEMIC 2* (2000) (describing obesity as “one of the most significant contributors to ill health” and “a key risk factor in the natural history of other chronic and noncommunicable diseases”); Katherine M. Flegal et al., *Excess Deaths Associated With Underweight, Overweight, and Obesity*, 293 *JAMA* 1861, 1863-65 (2005) (estimating that approximately 112,000 deaths in 2000 were attributable to obesity and critiquing earlier methodologies in Ali H. Mokdad et al., *Actual Causes of Death in the United States, 2000*, 291 *JAMA* 1238, 1240 (2004) (estimating about 400,000 deaths were attributed to poor diet and physical inactivity)); Ali H. Mokdad et al., *Correction: Actual Causes of Death in the United States, 2000*, 293 *JAMA* 293, 293 (2005) (correcting errors in the Mokdad et al. article cited in 291 *JAMA*, *supra*).

48. W. Wayt Gibbs, *Obesity: An Overblown Epidemic?*, 292 *SCI. AM.*, 70, 72 (2005) (acknowledging skeptics of the assertion by Dr. Julie L. Gerberding, Director of the Centers for Disease Control and Prevention, that “if you looked at any epidemic—whether it’s influenza or plague from the Middle Ages—they are not as serious as the epidemic of obesity in terms of the health impact on our country and our society”). Some commentators have called obesity the new frontier of public health law. E.g., Michelle M. Mello et al., *Obesity — The New Frontier of Public Health Law*, 354 *NEW ENG. J. MED.* 2601, 2601 (2006).

outbreak that could quickly spread infection to the public.⁴⁹ A successful example was the identification of the risks for AIDS in the early 1980s.⁵⁰ More recent examples include identifying the source of Toxic Shock Syndrome⁵¹ and investigating fungal infections in the eyes of individuals who used a particular Bausch & Lomb contact lens solution.⁵²

Chronic diseases like diabetes are not infectious, of course, and cannot be transmitted from person to person. They pose no imminent threat to the public.⁵³ There is no need for the Health Department to investigate the source of a virus or bacterium or to find people who might have been infected unknowingly.

With the decline in the prevalence of infectious diseases in the United States, health departments have turned their attention to chronic diseases. The New York City Health Commissioner made a strong appeal that public health efforts should focus more on controlling chronic diseases.⁵⁴ This makes sense to the extent that health departments can contribute to reducing the burden of disease. For example, health departments can and do draw upon research to provide general information to the public about how to reduce the risks of particular diseases⁵⁵ and to the medical profession about how to recognize or treat them.⁵⁶ They can and do create or fund

49. Ruth L. Berkelman et al., *Public Health Surveillance*, in 2 OXFORD TEXTBOOK OF PUB. HEALTH 759, 759-760 (Roger Detels et al. eds., 4th ed. 2002). Not all infections are contagious. An infectious disease is any disease that can be transmitted *to* a human being by means of a virus, bacterium, or parasite, which infects the person. DORLAND'S ILLUSTRATED MED. DICTIONARY 536 (30th ed. 2003). A contagious disease is an infectious disease that can be transmitted *from* one person to another person or via contact with an infected object like a blanket or towel. *Id.* at 531. Anthrax is infectious, but not contagious, for example. Many statutes use the term "communicable" as a synonym for contagious to emphasize the communicability of the disease and, by implication, to exclude application to other infectious diseases. *Id.* at 530. *See, e.g.*, MICH. COMP. LAWS § 331.304 (1999); N.Y. PUB. HEALTH LAW § 2(1) (McKinney 2002).

50. Berkelman et al., *supra* note 49, at 760 ("Even before . . . HIV was identified, surveillance data contributed to identifying modes of transmission, population groups at risk for infection, and . . . population groups not at risk for infection.").

51. Richard Severo, *Mystery of Toxic Shock Cases Is Unfolding at Disease Center*, N.Y. TIMES, Oct. 9, 1980, at 1.

52. Barnaby J. Feder, *More Infections Tied to Bausch Contact Cleaner*, N.Y. TIMES, May 10, 2006, at C2. The investigations helped to determine which cases were linked to the product and which may have been caused by poor hygiene. *Id.* Such investigations can determine whether it is appropriate to recall a product or issue recommendations for patients.

53. *See* Lori B. Andrews, *A Conceptual Framework for Genetic Policy: Comparing the Medical, Public Health, and Fundamental Rights Models*, 79 WASH. U. L.Q. 221, 271 (2001) ("[T]he mere fact that a disease affects numerous people, and is thus a major societal concern, does not mean that it is a public health threat.").

54. Thomas R. Frieden, Editorial, *Asleep at the Switch: Local Public Health and Chronic Disease*, 94 AM. J. PUB. HEALTH 2059, 2059 (2004) ("[N]oncommunicable diseases, which accounted for less than 20% of U.S. deaths in 1900, now account for about 80% of deaths. Our local public health infrastructure has not kept pace with this transition.") (citations omitted).

55. *See, e.g.*, N.Y. State Dep't of Health, Communicable Disease: Tuberculosis (2004), http://www.health.state.ny.us/diseases/communicable/tuberculosis/docs/fact_sheet.pdf.

56. *See, e.g.*, Antonia C. Novello, Commissioner, N.Y. State Dep't of Health, Letter to Long Term Care Facility Administrators (Feb. 16, 2006),

clinics that offer medical care to people without adequate or any health insurance coverage.⁵⁷ They can and do offer free or affordable voluntary programs where people can obtain screening for various diseases or conditions, including high cholesterol. These are all valuable functions for a health department. Yet, none of them requires the collection of identifiable patient information.

The United States Supreme Court has recognized that patients have an interest in maintaining the privacy of their medical information, which is protected by the due process clauses of the Fifth and Fourteenth Amendments.⁵⁸ Compelled disclosures of identifiable information require justification.⁵⁹ The imminent threat of an epidemic justified nineteenth and early twentieth century laws requiring reporting of communicable diseases.⁶⁰ In each case, reporting was justified because

http://www.health.state.ny.us/professionals/nursing_home_administrator/docs/dal_06-03_guidelines_for_tuberculosis_control.pdf.

57. Ctrs. for Disease Control & Prevention, *Continuing Diabetes Care – Rhode Island, 1991*, 43 MORBIDITY & MORTALITY WKLY. REP. 798, 798-99 (1994) (describing the success of the Rhode Island Diabetes Control Program, established in 1979, which distributes brochures for patients in clinics and hospitals; makes recommendations to physicians for annual eye examinations and eye care for diabetes patients; provides patient care in neighborhood health centers; and contributed to the finding that the majority of people with diabetes in Rhode Island get eye care in accordance with recommendations, in comparison with fewer than half of adults with diagnosed diabetes receiving appropriate eye care nationally).

58. *See* Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 900-01 (1992) (upholding abortion reporting law without woman's name or address as meeting the *Danforth* standard); *Thornburgh v. Am. Coll. of Obstetricians & Gynecologists*, 476 U.S. 747, 765-67 (1986) (striking down abortion reporting law that could identify women and chill exercise of a constitutional right to terminate pregnancy); *Nixon v. Adm'r of Gen. Servs.*, 433 U.S. 425, 457 (1977) ("One element of privacy has been characterized as 'the individual interest in avoiding disclosure of personal matters . . .'" (quoting *Whalen v. Roe*, 429 U.S. 589, 599, 606 (1977) (upholding the reporting of names and addresses of persons who have obtained prescriptions for controlled substances)); *Planned Parenthood of Cent. Mo. v. Danforth*, 428 U.S. 52, 80-81 (1976) (upholding abortion recordkeeping and reporting requirements "that are reasonably directed to the preservation of maternal health and that properly respect a patient's confidentiality and privacy" where the state demonstrated that regulations met important health needs).

59. Federal courts of appeal have drawn some of the contours of the constitutional right to information privacy. *See, e.g., Sterling v. Minersville*, 232 F.3d 190, 196 (3d Cir. 2000) (recognizing that sexual orientation is "entitled to privacy protection"); *Denius v. Dunlap*, 209 F.3d 944, 956 (7th Cir. 2000) ("[T]he right [of confidentiality] clearly covers medical records and communications."); *Bartnicki v. Vopper*, 200 F.3d 109, 122 (3d Cir. 1999) ("[T]he right not to have intimate facts concerning one's life disclosed without one's consent" is "a venerable [right] whose constitutional significance we have recognized in the past." (citing *Paul P. v. Verniero*, 170 F.3d 396, 401-02 (3d Cir. 1999))); *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."); *Alexander v. Pepper*, 993 F.2d 1348, 1351 (8th Cir. 1993) (suggesting that "highly personal medical or financial information" is confidential); *Walls v. City of Petersburg*, 895 F.2d 188, 194 (4th Cir. 1990) ("Financial information . . . is protected by a right to privacy."); *United States v. Westinghouse Elec. Corp.*, 638 F.2d 570, 577 (3d Cir. 1980) ("[T]he full measure of the constitutional protection of the right to privacy has not yet been delineated."). *But see* *Cutshall v. Sundquist*, 193 F.3d 466, 481 (6th Cir. 1999) (refusing to extend *Whalen*, 429 U.S. 589, in the absence of specific language in the Constitution supporting "a general right to nondisclosure of private information"); *Doe v. Wigginton*, 21 F.3d 733, 740 (6th Cir. 1994).

60. *See generally* C.E.A. WINSLOW, *THE LIFE OF HERMANN M. BIGGS: PHYSICIAN AND STATESMAN OF THE PUBLIC HEALTH* (1929). The first mandatory reporting law was enacted by Michigan in 1893, although tavern owners in Rhode Island had been required to report customers with

of the specific characteristics of the infectious agent—how easily it was transmitted, the severity of the resulting disease, and the absence of an effective vaccine to prevent infection or medicine to cure disease.⁶¹ Thus, tuberculosis, which is an airborne bacillus transmitted by coughing or sneezing and can cause serious, permanent illness, remains a reportable contagious disease.⁶² In contrast, the common cold, which is similarly transmitted but rarely causes significant illness, is not reportable.

In addition, laws authorized reporting the identity of the infected person when that information was needed in order to permit an investigation of the source of the infection, with the expectation that it could be removed or eliminated.⁶³ Health officials often needed to find out where the patient might have been exposed to infection. For example, a report of salmonella often prompts an interview with the patient and an investigation into the possibility of contaminated food at a particular restaurant, so that the food can be disposed of or food handlers can be trained in hygiene.⁶⁴ In rare cases, it may be necessary to seek a court order to isolate the patient who is unable or unwilling to avoid exposing other people to infection.⁶⁵ Knowledge of personal identity is obviously necessary in such circumstances.

The New York City AIC Registry will not be used to contact anyone with a contagious disease or investigate an outbreak of infection or control an epidemic in the historical sense of the word. It does not fit the model of communicable disease

cholera, smallpox, and yellow fever to local officials since 1741. *Id.* at 138. New York first adopted a reporting law for tuberculosis in 1897. *Id.* at 143-44.

61. JAMES A. TOBEY, PUBLIC HEALTH LAW 133 (3d ed. 1947) (noting that the requirement that diseases dangerous to health be reported has been upheld by courts on a number of occasions) (citing *Davis v. Rodman*, 227 S.W. 612 (Ark. 1921); *Smythe v. State*, 86 So. 870 (Miss. 1921); *City of Chicago v. Craig*, 172 Ill. App. 126 (1912); *Johnson v. District of Columbia*, 27 App. D.C. 259 (1906); *People v. Shurly*, 91 N.W. 139 (Mich. 1902); *Kansas City v. Baird*, 92 Mo. App. 204 (1902); *People v. Brady*, 51 N.W. 537 (Mich. 1892); *State v. Wordin*, 56 Conn. 216 (1887); *Robinson v. Hamilton*, 14 N.W. 202 (Iowa 1882)).

62. Ctrs. for Disease Control & Prevention, *Tuberculosis Control Laws — United States, 1993: Recommendations of the Advisory Council for the Elimination of Tuberculosis*, 42 MORBIDITY & MORTALITY WKLY. REP. 1, 3 (1993); Health-Cares.Net, What is Tuberculosis? (2005), <http://respiratory-lung.health-cares.net/tuberculosis.php>.

63. See generally Lawrence O. Gostin & James G. Hodge, Jr., *The “Names Debate”: The Case for National HIV Reporting in the United States*, 61 ALB. L. REV. 679, 695-98 (1998) (describing the development of state AIDS reporting programs).

64. E.g., Roderick C. Jones et al., *Salmonella Enterica Serotype Uganda Infection in New York City and Chicago*, 10 EMERGING INFECTIOUS DISEASES 1665, 1665-66 (2004). Other types of state reporting statutes have a similar goal of immediate investigation. For example, reports of injuries from firearms and knives are used for the purpose of criminal investigations. E.g., *In re Grand Jury Investigation in New York County*, 779 N.E.2d 173, 177-78 (N.Y. 2002) (quashing subpoena for medical records from twenty-three hospitals by Manhattan District Attorney seeking to identify assailant in a murder investigation because it required the kind of medical determination of causation that patients are entitled to expect will remain private). Reports of child and elder abuse are used to investigate whether the person needs protection. See generally New York City Admin. for Children’s Servs., Prevent Child Abuse and Neglect, http://www.nyc.gov/html/acs/html/child_safety/prevent_abuse.shtml (last visited Nov. 12, 2006).

65. See, e.g., *City of Newark v. J.S.*, 652 A.2d 265 (N.J. Super. Ct. Law Div. 1993).

reporting systems. Diabetes is a public health problem—in the broad sense that it affects a large or growing number of people—but it does not pose any immediate threat to the public. The Health Department’s intervention is not needed to tell physicians, who order blood sugar tests for their patients and receive the results, what physicians should already know. In the absence of any requirement that either physicians or patients comply with Health Department medical regimen recommendations, there is little reason to believe that the Registry will affect physician treatment decisions or patient behavior.⁶⁶ There appears to be no rational relationship between the compulsory reporting of A1C test results and the goal of reducing the risks of diabetes. Thus, if the regulation’s goal is to reduce diabetes, the regulation is vulnerable to challenge as an impermissible violation of patients’ constitutional right to information privacy.

2. *Additional Uses of Data*

The Board of Health’s notice of adoption of the reporting rule concludes that “[t]he reporting of all A1C test results is important for program planning, education, outreach, disease management and surveillance purposes.”⁶⁷ The preceding subpart argued that compulsory reporting of individually identifiable information cannot be justified for purposes of disease management alone. The other purposes quoted above offer even less support for the Registry, although the reasoning behind that conclusion is somewhat more complicated.

Program planning, education, outreach, and surveillance are all reasonable functions of a health department. They all are also feasible without the collection of personally identifiable medical information.⁶⁸ An example of program planning might be deciding whether to fund a mobile van to offer voluntary cholesterol screening in specific geographic areas. It would be helpful to know whether people in that area would be interested in obtaining such screening. That information could be obtained by surveying the population. It is not likely to be obtained from a registry of blood sugar test results. Education programs might include distributing brochures explaining diabetes, encouraging people to find out whether they have diabetes, describing ways for diabetic patients to reduce their risk of disease, and similar information.⁶⁹ Such information could be provided by nurses or health educators in willing clinics or even non-health care settings. Again, individually identifiable A1C Registry data are not necessary to create such programs. Outreach

66. Therefore, unlike compulsory reporting of contagious diseases, the A1C registry appears to be an unlikely and unnecessary means to prevent harm to the public. Kaveh G. Shojania et al., *Effects of Quality Improvement Strategies for Type 2 Diabetes on Glycemic Control: A Meta-Regression Analysis*, 296 JAMA 427, 434 (2006) (finding that, by themselves, electronic patient registries were not associated with reducing blood sugar levels in diabetic patients).

67. NOTICE OF ADOPTION, *supra* note 7, at 3.

68. The exception would be communicable disease surveillance to investigate a disease outbreak, which, as discussed *supra*, is inapplicable to the A1C Registry.

69. *E.g.*, Ctrs. for Disease Control & Prevention, *supra* note 57, at 798-99.

activities often target educational programs or services for populations at risk. It is helpful to know what populations are at risk, but it is hardly necessary to know which individuals have high blood sugar. Indeed, people who have had an A1C test are receiving medical care and should already know they are at risk. A more effective form of outreach might be a program designed to educate physicians about current best practices in caring for diabetic patients, such as synthesizing the literature on effective ways to encourage patients to take better care of themselves, or providing a list of support programs to which physicians could refer their patients.⁷⁰

Surveillance is an alternative, plausible reason for having an A1C Registry. In the nineteenth and early twentieth centuries, disease surveillance consisted almost entirely of case reporting for purposes of outbreak investigation.⁷¹ If limited to that concept, it is subject to the objections set forth above and offers no independent reason for compulsory reporting of identifiable blood sugar test results. In 1986, a CDC note on an article about diabetes mortality stated:

The model surveillance system employed for infectious diseases, which includes reporting and compiling cases at a central source and rapidly disseminating results, is not currently a feasible approach for chronic disease surveillance. Infectious disease control—the investigation of causes and development of control strategies—is relatively straightforward. Chronic disease surveillance and control are comparatively more difficult because 1) chronic diseases are more complicated to diagnose, 2) there are often multiple and poorly defined etiologic factors for disease, and 3) there are long latency periods between these factors and the onset of disease. In addition, the factors responsible may be behaviors or practices (or neglect thereof) of affected persons or health care providers.⁷²

During the past two decades, however, the public health community has expanded its view of disease surveillance to encompass the collection of information about all kinds of diseases and conditions, including chronic diseases, injuries, and even behaviors like tobacco and drug use.⁷³ Instead of case reporting or disease surveillance, most public health practitioners currently use the term

70. Medical specialty organizations do provide these kinds of information for physicians. *E.g.*, Am. Diabetes Ass'n, Professional Meetings/Education, <http://www.diabetes.org/for-health-professionals-and-scientists/profed.jsp> (last visited Nov. 12, 2006).

71. *See supra* notes 60-62 and accompanying text.

72. *Premature Mortality from Diabetes*, *supra* note 11, at 713.

73. Stephen B. Thacker, *Historical Development*, in *PRINCIPLES AND PRACTICE OF PUBLIC HEALTH SURVEILLANCE* 6 (Steven M. Teutsch & R. Elliott Churchill eds., 2d ed. 2000) (“Public health surveillance information is used to assess public health status, define public health priorities, evaluate programs, and conduct research.”). Many public health practitioners and scholars define surveillance so broadly that it includes collecting information to be used in program planning, education, and outreach, as well as outbreak investigation. *E.g.*, *id.* at 8 tbl.1-1. Because those purposes are mentioned separately in NOTICE OF ADOPTION, *supra* note 7, at 3, it is difficult to know exactly what New York City means by surveillance in this context.

“public health surveillance” or just “surveillance” to capture the broad range of subject matter.⁷⁴ In contrast to its earlier view, quoted above, the CDC now strongly encourages states to collect data about cancer and other chronic diseases and is the largest source of funding for surveillance programs in many states.⁷⁵

The state’s police power undoubtedly includes the power to collect anonymous statistical information about the types of diseases affecting its population. Whether and when that power extends to collecting individually identifiable information are separate questions. Counting the number of cases of a disease can be done without collecting identifiable information, such as names and addresses.⁷⁶ Requiring names, addresses, and other individually identifiable data simply to produce statistical summaries appears to violate the constitutional right to information privacy.⁷⁷ Even the American Diabetes Association, while agreeing

74. Nonetheless, public health scholars and practitioners still rely on Alexander Langmuir’s 1963 definition of disease 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 dissemination to those who ‘need to know. . . .’ [I]n short, surveillance implied ‘information for action.’” (citations omitted). Berkelman et al., *supra* note 49, at 759.

75. See Cancer Registries Amendment Act, Pub. L. No. 102-515 (codified as amended at 42 U.S.C. § 280e(a) (2000 & Supp. III 2005)) (authorizing the CDC to fund the creation of cancer registries in states where no NIH Surveillance, Epidemiology and End Results (SEER) cancer research program exists). The availability of CDC funding encouraged states to create or expand cancer registries and, to meet CDC funding guidelines, some states adopted laws requiring the reporting of cancer cases to the registry. See also Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, 42 U.S.C. § 300ff-13 (2000 & Supp. III 2005) (allocating grant funding for HIV/AIDS treatment programs primarily on the basis of the number of cases in the grantee’s state or city, which encouraged states to adopt compulsory HIV reporting laws); INST. OF MED., MEASURING WHAT MATTERS: ALLOCATION, PLANNING, AND QUALITY ASSESSMENT FOR THE RYAN WHITE CARE ACT 239-46 (2004).

76. Case reporting, with or without names, is one of several possible methods of collecting data on the incidence or prevalence of disease. Other methods include sentinel surveys, sample surveys in which a random or convenience sample of the relevant population is asked to participate in a survey, and seroprevalence surveys, in which anonymous tissue or blood samples are tested for the presence of the indicator of interest, such as HIV infection. Increasingly sophisticated epidemiological and statistical methods offer new techniques for use in surveillance of all types. INST. OF MED., *supra* note 75, at 80-83.

77. *Tuscon Woman’s Clinic v. Eden*, 371 F.3d 1173, 1193 (9th Cir. 2004) (“Even 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.”); *Planned Parenthood v. Casey*, 505 U.S. 833 (1992) (upholding an abortion reporting law that prohibited reporting the patient’s name, but striking down reporting of a patient’s reasons for not notifying her husband); *Planned Parenthood v. Danforth*, 428 U.S. 52, 80 (1976) (noting that abortion “[r]ecordkeeping 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”). Birth, death, and marriage registries can be justified on the ground that the individuals named in the documents need state verification of their existence or status in order to qualify for certain rights or privileges. See Berkelman et al., *supra* note 49, at 759 (“[H]ealth information systems (for example, registration of births and deaths, routine abstraction of hospital records, health surveys in a population) that are general and not linked to specific prevention and control programmes do not, by themselves, constitute surveillance.”).

that New York City's A1C Registry could be valuable for both patients and doctors, has noted that reporting should not be done without the patient's consent.⁷⁸

The CDC takes the position that, when the same person is reported more than once over time or by multiple sources (as is usually the case), statistical summaries of case reports cannot be entirely accurate unless names and other identifying information are included.⁷⁹ The identifying information allows the collecting agency to recognize duplicate reports and count each person only once.⁸⁰ The goal of numerical precision, however valuable to statisticians, is not likely to outweigh a person's right to privacy of medical information. Moreover, there are other statistical methods to de-duplicate case reports without using names. All methods, including reporting with names, are subject to various errors that may make it impossible to achieve 100% accuracy.⁸¹ Nonetheless, even accounting for slight variations, they may be sufficiently accurate to achieve the purpose for which they are collected.

C. *Creating a Registry for Research Studies*

The New York City A1C Registry appears to be intended to intervene in the care of an identifiable patient, not merely to collect statistics.⁸² However, mention of purposes like program planning, education, and surveillance⁸³ suggests that the Health Department plans to use the data in the Registry for much more than checking on medical care. One, if not the only, purpose is likely to be research.⁸⁴ Since the Health Department will not use the A1C Registry to investigate any communicable disease outbreak, does it use the term surveillance to mean research with Registry data? In other words, when the Department says its purpose is to conduct surveillance, does it really mean it will conduct research? If so, it is difficult to defend the mandatory collection of individually identifiable information.

78. David B. Caruso, *New York Enacts Code to Keep Tabs on Diabetics, Blood Tests*, CHARLESTON GAZETTE & DAILY MAIL (W. Va.), Dec. 15, 2005, at 9A.

79. INST. OF MED., *supra* note 75, at 93.

80. *Id.*

81. Ctrs. for Disease Control & Prevention, *CDC Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome*, 48 MORBIDITY & MORTALITY WKLY. REP. 1, 19-20 (1999).

82. NOTICE OF ADOPTION, *supra* note 7, at 2. ("Evaluating [blood sugar] trends can be used to . . . [d]irect more efficient interventions to health care institutions, health care providers and *people with diabetes.*") (emphasis added).

83. *Id.* at 3.

84. This possibility was heightened when the Health Department allowed patients to request that the Department not contact the patient or send the patient's blood sugar test results to the patient's physician. New York City Dep't of Health & Mental Hygiene, Diabetes Prevention and Control, <http://www.nyc.gov/html/doh/html/diabetes/diabetes-nycar.shtml> (last visited Mar. 6, 2007).

The use of personally identifiable data (medical or otherwise) in research qualifies as using human subjects in research and therefore requires a subject's competent, voluntary, and informed prior consent to the use of his or her own personally identifiable information.⁸⁵ The State's power to collect individually identifiable medical information without consent for disease surveillance purposes does not necessarily include the power to collect or use the information for purposes of research.⁸⁶ Certainly, collecting identifiable data without consent solely for research studies would violate both the personal liberty and information privacy protected by the Fourteenth Amendment.⁸⁷

Even accepting the dubious assertion that a health department has the authority to compel the reporting of personally identifiable information for the purpose of intervening in the person's medical care, there remains the question of

85. The "Common Rule," which governs federally funded research with "human subjects," defines a human subject to include "a living individual about whom an investigator . . . conducting research obtains . . . [i]dentifiable private information." *E.g.*, 45 C.F.R. § 46.102(f) (2005). For a review of the case law governing informed consent to research with human subjects, see GEORGE J. ANNAS ET AL., INFORMED CONSENT TO HUMAN EXPERIMENTATION: THE SUBJECT'S DILEMMA 1-59 (1977); RUTH R. FADEN & TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT 53-226 (1986), WENDY K. MARINER, *Human Subjects Research, Law, Common Law of Human Experimentation*, in 2 ENCYCLOPEDIA OF ETHICAL, LEGAL, AND POLICY ISSUES IN BIOTECHNOLOGY 654, 654-71 (Thomas H. Murray & Maxwell J. Mehlman eds., 2000) (reviewing the case law governing informed consent for research with human subjects). The HIPAA Privacy Rule, 45 C.F.R. pts. 160 & 164, permits, but does not require hospitals, physicians, and other covered entities to disclose personally identifiable information without patient consent to public health authorities "for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury . . . and the conduct of public health surveillance, public health investigations, and public health interventions." 45 C.F.R. § 164.512(b)(1)(i). Whether research is included within the meaning of these purposes remains a matter of debate. This provision was not intended to and does not affect the validity of state law governing reporting, research, or privacy. Standards for Individually Identifiable Information, Background, 65 Fed. Reg. 82463, 86264 (2000) (codified as amended at 45 C.F.R. pts. 160 & 164). *See also* NAT'L INSTS. OF HEALTH, RESEARCH REPOSITORIES, DATABASES, AND THE HIPAA PRIVACY RULE 2 (2004), *available at* http://privacyruleandresearch.nih.gov/pdf/research_repositories_final.pdf (explaining that the HIPAA Privacy Rule does not govern health departments' surveillance activities because such programs are not covered entities within the meaning of the rule).

86. Most distinctions between medical research and practice rely on the principles of the National Commission for the Protection of Human Subjects of Biomedical Research. NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL RESEARCH AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979), *reprinted in* NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS app. D at 161 (2001) ("'[P]ractice' 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 By contrast, the term 'research' designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge. . . .").

87. *See supra* notes 58-59 and accompanying text. State common law also recognizes a right of privacy in personal medical information. *See, e.g.*, *Alberts v. Devine*, 479 N.E.2d 113, 118-19 (1985) (describing public policy basis for recognizing a physician's duty not to disclose medical information without patient's consent). *See generally* DANIEL J. SOLOVE ET AL., INFORMATION PRIVACY LAW 345-450 (2d ed. 2006).

whether it may use that same data in a research study. Whether data collected legitimately for one purpose may be used for another purpose depends on an independent justification for the second (or third or fourth) purpose. This is why controversy remains over whether individuals who agree to participate in one research study are entitled to allow researchers to use their identifiable information in future unspecified research studies.⁸⁸ The controversy is not over whether their consent is required—all agree it is. Rather, there is disagreement over whether consent can be given in advance or whether it must be given at the time the future research is proposed, so that the person has knowledge of what she is agreeing to and an opportunity to refuse.⁸⁹

In the public health field, there is some uncertainty over what aspects of surveillance and other public health programs qualify as research for which individual consent is required.⁹⁰ Since epidemiologists use many different methods to study the distribution and causes of disease, it is not surprising that research methods are sometimes conflated with non-research methods. Regardless of the methodology used, the threshold question is whether a study constitutes research with human subjects.⁹¹ Health departments often analyze surveillance data to produce statistical summaries of the incidence and prevalence of specific diseases. Such summaries are not strictly defined as regular surveillance activities because they are not used to prevent or control disease.⁹² However, statistical summaries that do not identify individuals rarely implicate individual privacy interests, provided that the data were legitimately collected in the first place. Many other data analyses, however, look more like traditional medical or social science research. For example, an analysis of how many patients improve their A1C counts after specific recommendations from their physicians mimics a typical research study of the treatment outcomes, which would require the informed consent of the research subjects whose identifiable information is used. More detailed analysis might reveal that people with specific characteristics, such as gender, race, income, or education, are more likely to lower their blood sugar than the general population. Surveillance data can also be used to study disease etiology, risk factors associated

88. See NATIONAL BIOETHICS ADVISORY COMMISSION, I RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE 47-49, 62-66 (1999), available at <http://www.georgetown.edu/research/nrcbl/nbac/hbm.pdf> (discussing both points of view on whether consent can be given in advance or whether it must be given at the time the future research is proposed).

89. *Id.*

90. See Amy L. Fairchild, *Dealing with Humpty Dumpty: Research, Practice, and the Ethics of Public Health Surveillance*, 31 J.L. MED. & ETHICS 615, 618-20 (2003) (describing objections by some CDC officials and the NYC Health Department to the NIH Office for the Protection from Research Risks's conclusion that analyses of surveillance data to produce generalizable knowledge were research studies that had to comply with federal regulations governing human subject protection).

91. 45 C.F.R. § 46.101 (2005). For example, reviewing anonymous statistical data is not research with human subjects, while conducting a case-control study with individually identifiable information qualifies as research. See *id.*

92. See Berkelman et al., *supra* note 49, at 759.

with a disease, treatment efficacy, and similar subjects. Where identifiable information is used, such analyses are indistinguishable from research studies that require subject consent.

Public health agencies and their advocates sometimes take the position that almost none of their uses of surveillance data should be considered research with human subjects.⁹³ Remarkably, this is usually presented as a conclusion without any supporting argument or evidence.⁹⁴ One observer familiar with research was surprised to find that surveillance “was such a sacred cow” among many CDC officials.⁹⁵ A few commentators argue that studies with health data should not be deemed to be research when they are conducted by a government agency, such as a health department.⁹⁶ Yet the notion that the legal requirements for research depend on who conducts it is implausible on its face. The National Institutes of Health are dedicated to conducting research and its investigators routinely seek subject consent for research with human beings, including research using only individually identifiable information.⁹⁷ Health agencies do conduct research and are not immune from the laws governing research when they do.⁹⁸

Many state laws authorize health departments to conduct research.⁹⁹ The mere authorization delegates to the agency the power to conduct research, but, without more, it does not automatically authorize the agency to conduct research with human subjects without consent. Health departments generally recognize this. Moreover, when contracting with outside universities or investigators, health departments generally require those third parties to comply with requirements for obtaining subject consent, as well as maintaining the confidentiality and security of the information.

93. See N.Y. PUB. HEALTH LAW § 2442 (McKinney 2002) (requiring voluntary informed consent for human research). Another section provides that “[h]uman research shall not, however, be construed to mean the conduct of biological studies exclusively utilizing tissue or fluids after their removal or withdrawal from a human subject in the course of standard medical practice, or to include epidemiological investigations.” *Id.* § 2441. The term “epidemiological investigations” is not defined. It is not clear that this definition would withstand legal challenge. Moreover, the provisions of the New York law expressly do not apply to research that is subject to federal regulations for the protection of human subjects. *Id.* § 2445.

94. See James G. Hodge, Jr., *Health Information Privacy and Public Health*, 31 J.L. MED. & ETHICS 663, 663 (2003) (“Identifiable health data are the lifeblood of public health practice.”).

95. Fairchild, *supra* note 90, at 617.

96. Scott Burris et al., *Applying the Common Rule to Public Health Agencies: Questions and Tentative Answers About a Separate Regulatory Regime*, 31 J.L. MED. & ETHICS 638, 641-42 (2003) (arguing that when the legislature enacts a law requiring the disclosure of information for research purposes, the law should be deemed to be the community’s consent to research, dispensing with the need for individual consent).

97. See, e.g., National Cancer Institute Surveillance Epidemiology and End Results (SEER) Program, which conducts cancer surveillance using research methods, <http://seer.cancer.gov>.

98. See Thacker, *supra* note 73, at 6; NAT’L INSTS. OF HEALTH, *supra* note 85, at 6-7.

99. E.g., N.Y. PUB. HEALTH LAW § 2500-a (McKinney 2002). Some states, such as New York, expressly authorize newborn genetic screening programs to conduct research concerning whether new tests are accurate and reliable and whether early intervention prevents disease. *Id.*

Data collected by state and federal agencies offer researchers ready-made and often free databases for various kinds of research.¹⁰⁰ However, the existence of a database or registry does not eliminate an individual's right to decline to participate in research. The Supreme Court has recognized the importance of the purpose for which data is collected and rejected statutory interpretations that would give others "an effort-free tool" to get information for different purposes.¹⁰¹ This suggests that the Court would not agree with any interpretation of a statute authorizing the collection of data for one purpose to be used by that agency or a third party for different purposes without complying with any legal prerequisites that would exist in the absence of the database. It also provides support for the conclusion that researchers should not be able to use, for their own research, personally identifiable information collected by a health department, or a federal agency, without the informed consent of the individuals involved, because the researchers would need informed consent to obtain the information in the absence of the database. The database unfairly gives researchers "an effort-free tool" for their research.¹⁰²

For these reasons, mandatory collection of identifiable A1C test results for a registry cannot be justified if its sole purpose is to provide a database for research. Moreover, even if the initial collection of the data were justifiable for a non-

100. See, e.g., Timothy Caulfield & Nola M. Ries, *Consent, Privacy and Confidentiality in Longitudinal, Population Health Research: The Canadian Legal Context*, 12 HEALTH L.J. 1 (Supp. 2004) (exploring issues of consent, privacy, and confidentiality with respect to collection of biological samples in databases for analysis); Barbara von Tigerstrom et al., *Legal Regulation of Cancer Surveillance: Canadian and International Perspectives*, 8 HEALTH L.J. 1, 4-5 (2000) (arguing in favor of increased cancer registries to facilitate research); Kenneth D. Mandl et al., *Newborn Screening Program Practices in the United States: Notification, Research, and Consent*, 109 PEDIATRICS 269, 269 (2002) (describing newborn genetic screening databases); Jeffrey R. Botkin et al., *Newborn Screening Technology: Proceed With Caution*, 117 PEDIATRICS 1793, 1797 (2006); ROBERT F. WEIR & ROBERT S. OLICK, *THE STORED TISSUE ISSUE: BIOMEDICAL RESEARCH, ETHICS, AND LAW IN THE ERA OF GENETIC MEDICINE* 23-26 (2004) (discussing the availability of data about tissues in storage).

101. In *Pierce County, Wash. v. Guillen*, 537 U.S. 129, 146 (2003), a unanimous Supreme Court, in an opinion by Justice Thomas, interpreted a state statutory evidentiary privilege narrowly so as to avoid allowing pre-trial discovery of data collected or compiled by state highway departments for the specific purpose of applying for federal funds to remove highway hazards: "By amending the statute, Congress wished to make clear that § 152 was not intended to be an effort-free tool in litigation against state and local governments. . . . However, the text of § 409 evinces no intent to make plaintiffs worse off than they would have been had § 152 funding never existed. Put differently, there is no reason to interpret § 409 as prohibiting the disclosure of information compiled or collected for purposes unrelated to § 152, held by government agencies not involved in administering § 152, if, before § 152 was adopted, plaintiffs would have been free to obtain such information from those very agencies." (citations omitted). See, e.g., *Robertson v. Union Pac. R.R. Co.*, 954 F.2d 1433, 1435 (8th Cir. 1992) (recognizing that § 409 was intended to "prohibit federally required record-keeping from being used as a 'tool . . . in private litigation'").

102. Both surveillance databases and research using their data are encouraged by the availability of federal funding and the fact that they offer an inexpensive source of data for researchers in an era of reduced revenues for public health and medical research. See *supra* note 75 and accompanying text. New information technology makes it easier to link different databases to create new data sets. See U.S. GEN. ACCOUNTING OFFICE, *RECORD LINKAGE AND PRIVACY: ISSUES IN CREATING NEW FEDERAL RESEARCH AND STATISTICAL INFORMATION* 14-15 (2001) (discussing the emergence of record linkage).

research reason, the data could not be used without consent for subsequent research studies. The legal basis for the A1C Registry rests on thin, if not ephemeral, grounds. The next part of this article examines why the lack of a firm legal rationale did not spur the Health Department to seek alternative ways to reduce the toll of diabetes.

III. MEDICALIZATION OF PUBLIC HEALTH OR PUBLIC HEALTHIFICATION OF MEDICINE?¹⁰³

In 1958, historian George Rosen could still write, honestly, that “[p]rotection of the community against communicable diseases and sanitation of the environment have been and still are major aspects of the public health program.”¹⁰⁴ By the end of the twentieth century, however, chronic diseases had overtaken communicable diseases as the leading causes of death. Even with the HIV/AIDS epidemic’s enormous toll, the top three causes of death in the United States remain heart disease, cancers, and stroke, which collectively kill more than 1,396,000 Americans annually.¹⁰⁵ Despite the publicity over possible avian influenza or bioterrorist attacks, and although infectious diseases will undoubtedly always be public health threats, rates of premature death in the United States are not likely to decline significantly without a reduction in the age of onset of chronic diseases.¹⁰⁶

Most people in public health today are keenly aware of the importance of chronic diseases.¹⁰⁷ Since public health measures its success in terms of reduced death rates—mortality, usually from specific diseases—and reduced rates of illness or disability—morbidity¹⁰⁸—the public health community and health departments, in particular, may be under pressure to demonstrate their continued value to the state by reducing chronic disease death rates. Yet, chronic diseases can be much more complicated to prevent and treat than infectious diseases. Chronic disease treatments or interventions are primarily medical, as that term has been understood traditionally—medications prescribed by physicians and nutrition and exercise management in the case of diabetes. It may appear that if public health is to succeed in reducing the rate of chronic diseases, it may have to adopt practices from the

103. Ilan H. Meyer & Sharon Schwartz, Editorial, *Social Issues as Public Health: Promise and Peril*, 90 AM. J. PUBLIC HEALTH 1189, 1189 (2000).

104. GEORGE ROSEN, *A HISTORY OF PUBLIC HEALTH* 320 (expanded ed. 1993).

105. See Miniño et al., *supra* note 11, at 4 tbl.B.

106. Death rates overall will not decline, because everyone will die. The concern is with the number and proportion of people who die before achieving a normal life expectancy, however “normal” may be defined in statistical or philosophical terms.

107. Leslie M. Beitsch et al., *Public Health at Center Stage: New Roles, Old Props*, 25 HEALTH AFF. 911, 912 (2006) (noting that “the burden placed on society by largely preventable chronic diseases became more apparent” in the last half of the twentieth century when communicable diseases no longer accounted for most deaths).

108. Wendy K. Mariner, *Law and Public Health: Beyond Emergency Preparedness*, 38 J. HEALTH L. 247, 257 (2005) (arguing that public health measures its success in terms of population outcomes, not processes, so that it “cannot account for individual values in the same manner as medicine”).

medical profession. Whether public health officials *should* act like personal physicians is a vexing question. More important, however, is the question whether, unlike physicians, public health officials are empowered to use the force of law to compel compliance with their recommendations.

The New York City A1C Registry is the most recent example of a public health program expanding into the field of chronic diseases.¹⁰⁹ Paradoxically, to meet the modern challenge of chronic diseases, the Health Department advocates case reporting—a technique developed more than a century ago to halt the spread of contagious diseases. Diabetes, like other chronic diseases, is not contagious.¹¹⁰ The disease cannot be stopped by vaccinating people against diabetes or by isolating them to prevent them from “infecting” other people with diabetes. Could the Registry represent what has been called the “public healthification” of a medical problem?¹¹¹ Or, as another writer suggested in a letter critiquing a public health study that attributed homelessness primarily to personal characteristics, could it be that the “tools define the problem”?¹¹² In this case, if what one does is study case reports, then the problem is not enough case reports. Thus, if cases of

109. It also follows the reasoning laid out by Frieden in his published articles. See Thomas R. Frieden et al., *Applying Public Health Principles to the HIV Epidemic*, 353 *NEW ENG. J. MED.* 2397, 2400 (2005) (arguing for increased public health monitoring of HIV testing and treatment); Frieden, *supra* note 54. This is not the first time that New Yorkers have resisted public health efforts to measure and monitor their health. In 2004, for example, the Health Department tried to persuade a representative sample of 2,000 city residents to participate in a survey of health status to create a health profile for the City. Richard Pérez-Peña, *For Health Survey, Many Offer More Excuses Than Details*, *N.Y. TIMES*, Sept. 3, 2004, at B1. Residents were approached at their apartments and asked to be measured for height, weight, and blood pressure and to give blood to be tested for “sugar, tobacco smoke exposure, pesticides, hepatitis C and herpes simplex virus, and poisons like lead, mercury, cadmium and arsenic.” *Id.* One goal was to try to get a more accurate measure of obesity than may be obtained by telephone interviews, where respondents may not be entirely honest. *Id.* The response rate was, perhaps predictably, poor, especially in affluent neighborhoods. *Id.* In addition to individuals who refused to participate, reasons for the lack of response included working people not at home and doormen refusing entrance. *Id.* Some of those contacted participated out of a sense of altruism or the possibility of obtaining a free clinic visit, while others refused because of uncertainty about the identity of the canvassers, fear of having their personal information made available, or because they considered public health projects to be for the poor. *Id.* In the case of blood sugar levels, the Department may have believed that gaining direct access to medical test results would produce more information than could be obtained by seeking voluntary cooperation from individual New Yorkers. *Id.* However, administrative convenience alone has never been a sufficient reason to override personal privacy.

110. Am. Diabetes Ass’n, *Diabetes Myths*, <http://www.diabetes.org/diabetes-myths.jsp> (last visited Nov. 12, 2006). One can argue that, in affluent countries today, HIV infection is both an infectious disease that can be transmitted to others and a chronic disease that, with appropriate treatment, can be managed for a normal lifetime. WORLD HEALTH ORG., *THE WORLD HEALTH REPORT 2003 – SHAPING THE FUTURE*, CHAPTER 3: HIV/AIDS: CONFRONTING A KILLER 43 (2003), available at http://www.who.int/whr/2003/en/whr03_en.pdf.

111. Meyer & Schwartz, *supra* note 103, at 1189.

112. Benjamin E. Alexander-Eitzman, Editorial, *Examining the Course of Homelessness: Right Direction, Wrong Approach*, 96 *AM. J. PUB. HEALTH* 764, 764 (2006) (referring to the axiom that if all you have is a hammer, then every problem is a nail).

communicable diseases become relatively rare, compared with cases of chronic disease, then to remain viable, a reporting system needs to cover chronic diseases.

Health departments have policy options beyond reporting systems. The first is a tried and true public health tool—education to alert people to a disease, its causes and effects, and ways to prevent it, including encouraging people to get medical care. The second is to offer the services of physicians to provide appropriate medical care to those who cannot otherwise obtain it, which public health has often done by funding physicians and other health care providers and clinics. The third is to make eligibility for state benefits and services conditional upon meeting specific health standards.¹¹³ The fourth is to obtain legislation or regulations that require people to improve their health, perhaps by seeing a physician, taking medication, or changing their unhealthful behaviors.

The New York City diabetes reporting program purports to take the second approach, but may ultimately take the third or fourth.¹¹⁴ After all, the only law needed for the first and second approaches are basic authorizations of power to prepare educational materials and establish clinics and appropriations to fund those activities, which should already exist. New law was needed to require clinical laboratories to report personally identifiable information to the City Health Department without the patient's consent. New laws would also be needed to implement the third and fourth approaches.

New York City Mayor Michael R. Bloomberg endorsed his Health Commissioner's idea that chronic diseases are America's biggest health threat in a speech to a public health law conference sponsored by the CDC, by stating, "[n]ew threats result from, and are aggravated by, our forbearance, and even social and

113. See, e.g., West Virginia Medicaid Member Agreement, http://www.wvdhhr.org/bms/oAdministration/bms_admin_WV_SPA06-02_20060503.pdf (requiring Medicaid beneficiaries to agree to certain conditions, including taking prescribed medications and keeping appointments, to qualify for an "Enhanced Benefits Plan"). A variation on this option would be to pay people to take better care of their health or imposing a tax on those who do not. Some private employers use this approach by discounting employee group health insurance premiums for compliance with wellness programs, which might also be viewed as imposing a surcharge on those who fail to participate or meet target health goals. See Joanne Wojcik, *Health Care Education Lacking at Work: Study*, BUS. INS., May 16, 2006, <http://www.businessinsurance.com/cgi-bin/news.pl?newsID=7737>. Such programs are a small, but growing element of employee group health plans, typically offered to reduce employer costs as well as prevent employee illness. *Id.* Employee responses to such programs vary from appreciation for learning about how to prevent possible illness to fear of the loss of privacy or even termination or retaliation for one's medical condition. Barbara Rose, *Firms Try to Predict Health of Workers; Warding Off Employee Illnesses Cuts Costs*, CHI. TRIB., May 31, 2005, at C1. States are rarely capable of subsidizing their population for wellness and are more likely to use incentives and penalties in programs like Medicaid. E.g., CTR. FOR MEDICAID AND STATE OPERATIONS, CTRS. FOR MEDICARE & MEDICAID SERVS., VALUE-BASED . . . RESULTS-DRIVEN . . . HEALTHCARE: THE MEDICAID/SCHIP QUALITY INITIATIVE, 1 (2005) available at <http://www.cms.hhs.gov/MedicaidSCHIPQualPrac/Downloads/qualitystrategy.pdf>; Speaker Judith E. Fradkin, *The Medicaid Buy-In Program: Lessons Learned From Nine "Early Implementer" States*, Summary Minutes of the Diabetes Mellitus Interagency Coordinating Committee (DMICC) Meeting on Apr. 11, 2003, available at <http://www.niddk.nih.gov/federal/dmicc/Final-April-11-Summary.pdf>.

114. NOTICE OF ADOPTION, *supra* note 7, at 2.

economic encouragement, of such behavior as tobacco addiction, unhealthy nutrition and excessively sedentary lifestyles.”¹¹⁵ Mayor Bloomberg also encouraged the, “forceful application of law . . . as the principal instrument of our public health policy.”¹¹⁶ Law has always been an effective tool to implement public health policy. Laws governing sewerage, food, drugs, and vaccinations have helped prevent the spread of contagious diseases.¹¹⁷ Yet, where the state overrides an individual’s right to information privacy, it requires specific justification beyond general appeals to improve health.¹¹⁸

The New York City Health Department may rely on just such general appeals to public health found in the handful of court decisions upholding reporting laws.¹¹⁹ A full explanation of why these decisions provide a shaky foundation for the diabetes and similar reporting laws is beyond the scope of this article.¹²⁰ For purposes of this discussion, three points are most important. First, the constitutionality of mandatory reporting laws has not been rigorously examined for decades. Only a few cases since the 1970s have considered any reporting law. These have upheld laws requiring the reporting of prescriptions for controlled substances,¹²¹ performance of abortions,¹²² test results for HIV/AIDS, a contagious disease,¹²³ and newborn genetic testing for conditions that require immediate treatment to prevent severe disabilities.¹²⁴ The Third Circuit Court of Appeals’s 1980 statement remains true today: “Generally, the reporting requirements which have been upheld have been those in which the government has advanced a need to acquire the information to develop treatment programs or control threats to public

115. Diane Cardwell, *Laws Can Be Good for You, Mayor Tells Health Officials*, N.Y. TIMES, June 15, 2006, at B3.

116. *Id.*

117. *See supra* notes 54-57 and accompanying text.

118. *See supra* notes 58-59 and accompanying text.

119. *See supra* notes 58 and 61 and accompanying text.

120. I develop that argument in a forthcoming article in B.U. L. REV.

121. *Whalen v. Roe*, 429 U.S. 589, 603-04 (1977).

122. *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 900-01 (1992); *Planned Parenthood of Cent. Mo. v. Danforth*, 428 U.S. 52, 80-81 (1976). *But see Thornburgh v. Am. Coll. of Obstetricians & Gynecologists*, 476 U.S. 747, 765-67 (1986) (striking down a Pennsylvania abortion reporting law). *See supra* note 58.

123. *See Middlebrooks v. State Bd. of Health*, 710 So. 2d 891, 892-93 (Ala. 1998) (upholding an action to compel physician to provide names and addresses of his patients with HIV/AIDS as required by Alabama’s reporting statute); *ACT-UP Triangle v. Comm’n for Health Services of N.C.*, 483 S.E.2d 388, 393 (N.C. 1997) (upholding the health department’s decision to end anonymous HIV testing by local health departments, without addressing the validity of the reporting law); *N.Y. State Soc’y of Surgeons v. Axelrod*, 572 N.E.2d 605, 610 (N.Y. 1991) (upholding state health commissioner’s discretion to refuse to require HIV reporting).

124. *Douglas County v. Anaya*, 694 N.W.2d 601, 608 (Neb. 2005) (denying parents’ claim that statute requiring newborns to be tested for several genetic conditions violated their First Amendment right to freedom of religion and Fourteenth Amendment right to raise their child because, under rational basis review, the state had “an interest in the health and welfare of all children born in Nebraska” and the testing could identify a condition leading to mental retardation or other severe disability that could be prevented with immediate treatment).

health.”¹²⁵ However, the United States Supreme Court has not reviewed a disease reporting law. The reasoning supporting these decisions does not encompass the mandatory reporting of personally identifiable information about patients with chronic disease conditions, because there is neither a threat to others nor any immediate need for treating a child.¹²⁶

A second reason to be wary of these decisions is that the courts use very general language to describe the law’s goal and offer little explanation of their reasoning. The few state court decisions on disease reporting simply note that the reporting information is sought to prevent or control disease, perhaps because the courts view the threat as obvious. The absence of language explaining why one disease or condition differs from any other makes it difficult to determine the limits of any principle being applied.¹²⁷ The most logical limit comes from the facts of the case, specifically the threat to the public posed by the condition to be reported and the utility of identifiable information in investigating that threat. However one interprets these decisions, it is difficult to extend their reasoning to uphold mandatory reporting of chronic disease indicators for identifiable individuals.

All reporting laws—perhaps all laws—have some ultimate goal to protect public health or welfare.¹²⁸ But, as the United States Supreme Court observed, if

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

126. For example, tests for genetic and metabolic conditions for which there is no treatment or which can be treated later in life if symptoms arise are difficult to justify on *parens patriae* grounds, because they offer no immediate benefit to the newborn. See Sheila Wildeman & Jocelyn Downie, *Genetic and Metabolic Screening of Newborns: Must Healthcare Providers Seek Explicit Parental Consent?*, 9 HEALTH L.J. 61, 63 (2001) (arguing that consent is required for genetic testing); Botkin et al., *supra* note 100, at 1795 (noting that because some “conditions . . . are only marginally treatable or untreatable,” newborn screening programs may “produce more harm than benefit” for the children screened).

127. However, the abortion reporting cases do provide some analysis of when the threat to privacy is significant enough to preclude reporting without consent. Where the disclosure of information also impinges on other rights or personal autonomy, courts scrutinize the justification for disclosure more carefully. See cases cited *supra* note 122; see also *Sheets v. Salt Lake County*, 45 F.3d 1383, 1387 (10th Cir. 1995) (concluding that disclosure by the state of sex or health information, which is the type of information in which “an individual has a legitimate expectation or confidentiality,” requires strict scrutiny); *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” (citing *Barry v. City of N.Y.*, 712 F.2d 1554, 1559 (2d Cir. 1983); *Thorne v. City of El Segundo*, 726 F.2d 459, 469 (9th Cir. 1983))). Cf. *Whalen v. Roe*, 429 U.S. 589, 597-98, 606 (1977) (finding that a law requiring the submission of copies of prescriptions for controlled substances to the health department was a “rational legislative decision” based on the reasonable assumption that patient identification could help to deter, detect, or investigate criminal drug diversion, and therefore did not invade “any right or liberty protected by the Fourteenth Amendment” without expressly stating which standard of review it applied).

128. See, e.g., Ctrs. for Disease Control & Prevention, *HIPAA Privacy Rule and Public Health: Guidance from CDC and the U.S. Department of Health and Human Services*, 52 MORBIDITY & MORTALITY WKLY. REP. 1, 10 (Supp. 2003). The CDC used this type of reasoning to characterize surveillance as practice rather than research: “The majority of public health activities (e.g., public health surveillance, and disease prevention and control projects) are based on scientific evidence and data collection or analytic methods similar to those used in research. However, they are not designed to

one looked to the ultimate purpose of a law, anything might be justified.¹²⁹ This is why it is essential to judge the law by its immediate or primary operation and effect. For example, biomedical research ultimately serves the worthy public purpose of preventing or perhaps curing disease, but this does not mean that a research study need not obtain subject consent. Yet, under the reasoning offered to justify the diabetes reporting program, individuals could be compelled to provide personal information for a research study simply because it may ultimately serve the public good.¹³⁰

Finally, the decisions upholding mandatory reporting emphasize the need to maintain the confidentiality of personally identifiable information within the agency that first collects it, including provisions for keeping the data secure and penalties for unauthorized disclosure.¹³¹ However, the requirements for confidentiality and security are in addition to, not instead of, the government's obligation to prove that requiring personally identifiable information is at least a rational means of achieving a legitimate state interest. The Health Department and a few commentators may assume that mandatory reporting is acceptable as long as personally identifiable data is kept secure and confidential within the Health Department. That assumption amounts to a claim that confidentiality is not merely necessary but also sufficient to override an individual's right to information privacy. No court has expressly adopted that standard. Moreover, it offers no limiting principle by which to judge the state's power to compel information disclosure. Rather, it would allow the state to compel anyone to reveal personally identifiable medical information whenever it might be of any potential use in improving medical care, making policy decisions, evaluating budgets, or conducting research—as long as the agency collecting the data kept the data for its

contribute to generalizable knowledge. Their primary purpose is to protect the health of the population through such activities as disease surveillance, prevention, or control." *Id.* Since practice is for the benefit of a particular patient, the CDC went on to assert that "[p]ublic health practice activities (e.g., public health surveillance, disease control, or program evaluation) are undertaken with the intent to benefit a specific community, although occasionally they may provide unintended generalizable benefits to others." *Id.*

129. *Ferguson v. City of Charlestown*, 532 U.S. 67, 84-85 (2001) (explaining that a reporting program in which a hospital provided law enforcement with the results of unconsented to drug tests by pregnant women could not be justified by the program's ultimate goal "[b]ecause law enforcement involvement always serves some broader social purpose or objective," and that such a program must instead be justified by its "specific" or "immediate" purpose).

130. NOTICE OF ADOPTION, *supra* note 7. The NYC Health Department has used the diabetes model to propose additional reporting for HIV cases for the purpose of monitoring their medical care. "An Act to amend the public health law, in relation to the improvement of care and treatment of persons with the human immunodeficiency virus." (copy on file with author); see *Frieden et al.*, *supra* note 109, at 2400-01 (arguing that the Health Department should monitor HIV treatment and case management). The HIV proposal engendered more vocal criticism than the diabetes registry, perhaps because the HIV/AIDS community is better organized than patients with Type 2 diabetes, and remains a proposal as of December 4, 2006.

131. *Whalen v. Roe*, 429 U.S. 589, 605-06 (1977); *Middlebrooks v. State Bd. of Health*, 710 So. 2d 891, 893 (Ala. 1998).

own use. That is no limit at all. It is, in essence, a repudiation of the right to information privacy.

Vague principles create the risk that they will be applied selectively to those who are disadvantaged or least able to protest. As Justice Jackson said, “nothing opens the door to arbitrary action so effectively as to allow . . . officials to pick and choose only a few to whom they will apply legislation and thus to escape the political retribution that might be visited upon them if larger numbers were affected.”¹³² The A1C Registry affects people with diabetes who are disproportionately from low-income and minority populations in New York City.¹³³ Moreover, the individuals who are reported are most likely to have Type 2 diabetes,¹³⁴ which is often perceived as a self-inflicted problem among the elderly who are sedentary and obese.¹³⁵ Although individuals with diabetes certainly

132. *Ry. Express Agency, Inc. v. New York*, 336 U.S. 106, 112-13 (1949) (Jackson, J., concurring).

133. See National Diabetes Information Clearinghouse (NDIC), National Diabetes Statistics, <http://diabetes.niddk.nih.gov/dm/pubs/statistics/index.htm> (last visited Nov. 8, 2006) (noting that in 2005, the total prevalence of diabetes was measured by race/ethnicity and adjusted for age. Hispanic/Latino Americans are “1.7 times as likely to have diabetes as non-Hispanic whites.” In addition, non-Hispanic blacks are “1.8 times as likely to have diabetes as non-Hispanic whites of similar age.”); Michael P. Stern & Braxton D. Mitchell, *Diabetes in Hispanic Americans*, in *DIABETES IN AMERICA* 631, 631, 635 (2d ed. 1995), available at <http://diabetes.niddk.nih.gov/dm/pubs/america/pdf/chapter32.pdf> (noting that four large studies, one of which included information on Puerto Ricans in the New York City area, have “clearly established that the prevalence of non-insulin-dependent diabetes mellitus (NIDDM) is two to three times higher in Mexican Americans than in non-Hispanic whites.”). In addition, NIDDM also affects a disproportionate number of low-income families. In a San Antonio Heart Study, “[s]ubjects were sampled from three types of neighborhoods: low-income barrios, middle-income transitional neighborhoods, and high-income suburbs. In Mexican Americans, NIDDM prevalence was two to four times higher in the barrio than in the suburban neighborhoods.” *Id.* at 633; see also Eugene S. Tull & Jeffrey M. Roseman, *Diabetes in African Americans*, in *DIABETES IN AMERICA* 613, 619-20 (2d ed. 1995), available at <http://diabetes.niddk.nih.gov/dm/pubs/america/pdf/chapter31.pdf> (“In the United States, an inverse relationship has been noted for socioeconomic status (education and income) and the prevalence of diabetes in adults for both black and white Americans. Data from the NHIS show that for both black and white Americans diabetes frequency decreases with increasing level of education and family income.”).

134. Fact Sheet No. 312, *supra* note 2.

135. *E.g.*, Urbina, *supra* note 22, at A1 (“Epidemiologists say the disparity [in funding for cancer as compared to diabetes] is partly explained by lingering but outdated perceptions of diabetes as a slow-moving condition that preys on the old and obese”); Thomas Flower, Editorial, *N.Y. TIMES*, May 21, 2006, at 13 (“It has been clearly established that Type 2 diabetes is a lifestyle disease.”). Public sympathy is more likely to favor children with Type 1 diabetes. *Id.*; Juvenile Diabetes Research Foundation International, *Life with Type 1 Diabetes*, http://www.jdrf.org/index.cfm?page_id=103431 (last visited Nov. 2, 2006) (advocating for research and support for Type 1 diabetes). Type 1 diabetes also received most NIH funded diabetes research funding. *E.g.*, Nat’l Inst. of Diabetes & Digestive & Kidney Diseases, *Help Wanted: Pediatric Endocrinologists; Funding Will Help Train Researchers in Childhood Diabetes* (Jan. 29, 2003), available at <http://www.niddk.nih.gov/welcome/releases/1-29-03.htm>; Diabetes Mellitus Interagency Coordinating Comm. (DMICC) Meeting Reports, *Opportunities for Research to Develop New Therapies for Vascular Complications of Diabetes* (Apr. 11, 2003), available at <http://www.niddk.nih.gov/federal/dmicc/meetings.htm>; Nat’l Inst. of Diabetes & Digestive & Kidney Diseases, *Executive Summary: Report on Progress and Opportunities 5* (2003), available at http://www.niddk.nih.gov/federal/planning/type1_specialfund/execsumm.pdf (last visited Nov. 7, 2006); Griffin Rodgers, Report from the NIDDK Deputy Director, Meeting Minutes for the Department of

deserve help, it is worth asking whether the Registry offers the help they want. Finally, it is troubling that this help is not being offered in the form of more accessible voluntary services, but at the cost of their information privacy.

CONCLUSION

The New York City A1C Registry is an example of public health stretching its mandate into the field of medical care and chronic diseases. The impact of chronic disease on public health has encouraged public health agencies to create new programs to meet twenty-first century needs. There is some irony, therefore, that among the many ways in which health departments might help people with diabetes, an old-fashioned mandatory reporting system was chosen. Created with the best of motives to reduce disability among diabetic patients, the Registry rests on the assumption that individuals have no right to control the use of their personal medical information and risks causing permanent damage to the right to information privacy and perhaps even patient autonomy. The limitless nature of the apparent principle underlying the A1C Registry transforms a well-intentioned program to improve health into a threat to personal liberty.

Health and Human Services, Public Health Services, National Institutes of Health, National Diabetes and Digestive and Kidney Diseases Advisory Council on Feb. 23-24, 2005, *available at* <http://www.niddk.nih.gov/fund/divisions/dea/council/minutes/Feb23-24-05.pdf> (noting that the "NIDDK appropriation is approximately \$1.713 billion (up from about \$1.665 billion in FY04)—excluding a special funding program for type 1 diabetes research, which the NIDDK manages on behalf of the Department."). Federal funding for Type 2 prevention comes mostly from the CDC and totals about one-sixth of NIH diabetes funding. Ian Urbina, *Funds Lag as Diabetes Cases Soar*, DESERET MORNING NEWS, May 16, 2006, at A02. The American Diabetes Association covers all types of diabetes, but is best known for its concern for Type 2 diabetes. *See* Am. Diabetes Ass'n, Diabetes Prevention, <http://www.diabetes.org/diabetes-prevention.jsp> (last visited Nov. 2, 2006).