

**WHOSE BUSINESS IS YOUR PANCREAS?: POTENTIAL PRIVACY PROBLEMS
IN NEW YORK CITY'S MANDATORY DIABETES REGISTRY**

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In 2006, New York City authorities passed a regulation mandating that individual medical data from all diabetics in the City be stored in a centralized registry. New York's diabetes registry is the first in the nation to require collection of personal testing data for the purpose of monitoring treatments for a noninfectious disease. In establishing the registry, public health officials seek to study, monitor and eventually slow the rising tide of diabetes diagnoses among City residents. Incidences of diabetes-related health problems and even deaths have increased exponentially in recent years, and the toll on worker productivity and tax dollars has been substantial.

New York City's program has not yet been implemented in entirety. Nonetheless, the registry's potential to compromise individual privacy warrants examination now to ensure that other cities do not copy New York's model (both with respect to diabetes and other noninfectious diseases) without carefully considering the privacy concerns at stake in such registries. In Part I of this paper we first describe New York City's diabetes registry, and then distinguish the City's program from prior registries in the United States and Europe. Part II sketches some of the legal and ethical problems that may arise as the registry program becomes fully operational. We conclude in Part III with cautionary advice regarding future efforts to create public health registries.

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I

A. The New York City Diabetes Registry

On January 15, 2006, New York City implemented a regulation requiring all testing labs in the city to report the test results of all A1c diabetes test subjects to the New York City Department of Health and Mental Hygiene (“NYDHMH”). The City intends to use these test results to address the growing diabetes epidemic among its residents. This section explores the test reporting program and its planned uses by the City.

1. The A to C of A1c Testing

Diabetics can check their blood sugar level on a daily basis by using a self-administered instantaneous test.¹ Physicians may also conduct an instantaneous test during patient appointments. These tests, however, measure a diabetic’s blood sugar level only at the moment the test is taken.² Moreover, instantaneous tests may lead to false readings if the patient fails to administer the test properly.³ Even if the test is conducted at a doctor’s office, the diabetic’s blood sugar level may be abnormally high that day, in which case the results would not reflect an accurate depiction of the patient’s average blood sugar level.⁴

The A1c test, unlike instantaneous blood sugar tests, guards against false readings by measuring the average amount of sugar in the diabetic’s blood over the past three months.⁵ Sugar in the diabetic’s blood stream binds to the hemoglobin in the red blood cells through a

¹ *A1c Test*, AM. DIABETES ASS’N (2007), <http://www.diabetes.org/type-1-diabetes/a1c-test.jsp>.

² *Id.*

³ *Id.*

⁴ *Id.*

⁵ *Id.*

process called glycosylation.⁶ Once the sugar binds to the hemoglobin, the sugar stays bound for the entire three-month life of the red blood cell.⁷ The greater the amount of sugar in the diabetic's blood stream, the more hemoglobin binds with sugar, and therefore the more hemoglobin becomes glycosylated.⁸ The A1c test measures the percentage of hemoglobin that has been glycosylated.⁹ This glycosylation level indicates the amount of sugar present in a diabetic's blood for the past three months.¹⁰

Because the A1c test measures a diabetic's A1c level over an entire three month period, the test result is not affected by momentary spikes in the diabetic's blood sugar level.¹¹ Moreover, if the results from a diabetic's self-administered instantaneous tests are inconsistent with the A1c test, the diabetic's doctor may infer that the diabetic is not administering the instantaneous test properly.¹² The American Diabetes Association ("ADA") recommends that diabetics maintain a glycosylation (A1c) level below seven percent,¹³ and suggests that all diabetics receive the A1c test between two and four times per year.¹⁴ A diabetic patient may also submit a blood sample to his doctor or any certified lab for an A1c test.¹⁵

⁶ Veterans Health Administration Diabetes Program, *The ABCs of Hemoglobin A1c Testing*, DIABETIC DRUG STORE, (2007), <http://www.diabetestoolbox.com/HbA1c.asp>.

⁷ *Id.*

⁸ *Id.*

⁹ Nancy J. Nordenson, *Glycosylated Hemoglobin Test*, (The Thompson Corp. 2004), <http://www.ahealthyme.com/topic/a1ctest>.

¹⁰ *Id.*

¹¹ *A1c Test*, AM. DIABETES ASS'N (2007), <http://www.diabetes.org/type-1-diabetes/a1c-test.jsp>.

¹² *Id.*

¹³ *Checking Your Blood Glucose*, AM. DIABETES ASS'N (2007), <http://www.diabetes.org/type-2-diabetes/blood-glucose-checks.jsp>.

¹⁴ *Id.*

¹⁵ *Id.*

2. A1c Results: Out of the Lab and Into the A1c Registry

Article 13 of New York City’s Health Code requires that all certified laboratories report A1c test results to the NYDHMH.¹⁶ The Health Code requires each lab to submit the following information to NYDHMH:

- (1) The full name, date of birth, and address of the diabetic.
- (2) The medical record number if known, identification number or code assigned to the diabetic, if any, and other personal identifiers as may be required by NYDHMH.
- (3) The name and address of the physician or clinical laboratory who submitted the blood specimen.
- (4) The name and address of the clinical laboratory which performed the test.
- (5) The date the test results were first available.
- (6) The name(s) of any other tests performed in addition to the A1c test.¹⁷

3. Why the City Wants A1c Data and What it Plans to Do with the Data

New York City stores all the data required by Article 13 in the A1c registry. The City hopes to use this data as a tool in learning to control diabetes and other related diseases.¹⁸ The number of diabetic residents in New York City has doubled in the past ten years, and diabetes is now the fourth-leading cause of death in the City.¹⁹ Studies indicate that diabetics who control their A1c levels may lessen their risk of small blood vessel complications (e.g., eye disease, kidney disease and peripheral nerve disorders).²⁰ Additionally, a well-managed A1c level may “significantly reduce [a diabetic’s] risk of microvascular complications, visual loss, stroke, heart failure, and diabetes-related death.”²¹

¹⁶ 24 RCNY Health Code Reg. § 13.04 (2006).

¹⁷ *Id.* at 13.04(c); *Id.* at 13.03(a)(1)-(6).

¹⁸ *Id.* at § 13.04 (notes section).

¹⁹ *Id.*

²⁰ *Id.* (“[F]or every drop of 1% in the A1c level, there is a 35% reduction in small blood vessel complications”).

²¹ Diana K. Berger & Lynn Silver, *Diabetes Prevention and Management*, 24 N.Y. CITY DEP’T OF HEALTH & MENTAL HYGIENE 1-6 (Jan. 2005), <http://home2.nyc.gov/html/doh/downloads/pdf/chi/chi24-1.pdf>; *see also* 24

While New York City’s objective of controlling the diabetes epidemic is commendable, the City has limited resources to execute its plan. The City health department has only three staff members and \$950,000 annually dedicated to controlling diabetes.²² The City has an obvious interest in helping its residents learn to manage their own diabetes, and in fact has described individual patient meal planning, physical activity, blood glucose monitoring, and diabetes education as the keys to controlling diabetes.²³ Effective diabetes management will also help the City reach other patients who require health care. The United States currently spends ten percent of its healthcare dollars, or approximately \$132 billion annually, on caring for diabetics.²⁴ The more diabetics learn to care for themselves, the less healthcare money the government need spend caring for them.

New York City’s Health Commissioner, Thomas Frieden, envisions the A1c registry as playing a critical role in controlling diabetes among City residents.²⁵ According to Frieden, the “knowledge [obtained from the A1c registry] should be very powerful for assessing how we are doing on a population basis and in reaching out to doctors and, through doctors wherever possible, to their patients to provide more support.”²⁶ The City intends to use registry data to evaluate trends and

1. Plan programs in the Diabetes Prevention and Control Program,
2. Measure outcomes of diabetes care, and thereby
3. Direct more efficient interventions to health care institutions, health care providers

RCNY Health Code Reg. § 13.04.

²² Robert Steinbrook, M.D., *Facing the Diabetes Epidemic—Mandatory Reporting of Glycosylated Hemoglobin Values in New York City*, 354 NEW ENG. J. MED. 545, 548 (2006).

²³ Berger & Silver, *supra* note 21.

²⁴ *Id.*

²⁵ Steinbrook, *supra* note 22.

²⁶ *Id.*

and people with diabetes.²⁷

The cornerstone of the registry plan is a notification system. Although the City intends eventually to install a city-wide notification program, it is initially implementing the program only in the South Bronx.²⁸ 48,000 adults in the South Bronx have been diagnosed with diabetes, and 12,000 of those adults are estimated to have an A1c level of greater than nine percent.²⁹ The City plans to provide South Bronx physicians with a quarterly roster of their diabetic patients, stratified according to their patients' A1c level, and recommendations for controlling patients' diabetes.³⁰ The City also notifies the diabetic himself of his deteriorating diabetic condition, and provides each individual with helpful information for alleviating high A1c levels.³¹ Diabetics may opt out of receiving such information by submitting a "Do Not Contact" request to the City.³² In the case of a diabetic minor, the City may inform the minor's parent or guardian.³³

Reaction to the registry from the medical community has been mixed. Many in the medical community believe that the notification system will provide an important service to

²⁷ *Id.*

²⁸ Letter from Thomas Frieden, Commissioner of the New York Department of Health and Mental Hygiene, to health care professionals (May/June 2006), <http://home2.nyc.gov/html/doh/downloads/pdf/csi/diabeteskit-letter.pdf>.

²⁹ Robert Steinbrook, M.D., *Facing the Diabetes Epidemic—Mandatory Reporting of Glycosylated Hemoglobin Values in New York City*, 354 *NEW ENG. J. MED.* 545, 548 (2006).

³⁰ *Id.*

³¹ *Id.*

³² N.Y. City Dep't of Health & Mental Hygiene, *The New York City A1c Registry* (2007), <http://home2.nyc.gov/html/doh/html/diabetes/diabetes-nycar.shtml>. It should be noted that, because the City has chosen to initiate the monitoring program in an area with a large number of economically disadvantaged residents who lack consistent access to internet, the City must make a concerted effort to ensure that all potential participants in the program are aware of the opt-out feature *before* they enter the program. Simply posting information on the City's website is not sufficient.

³³ *Id.* The effectiveness of the City's plan is somewhat in question, because a home A1c test is already available for a moderate price, and diabetics who use the home test will not be part of the registry. The City is aware of this problem, but estimates that the registry will capture the test results of 95% of the city's diabetics. However, because the registry creates an incentive to switch to the home test both for patients who are concerned about their privacy and for doctors who are concerned that they will be stigmatized or punished for having too many patients who are not keeping their blood sugar levels under control, the registry may be less comprehensive than the City hopes.

diabetic patients.³⁴ Columbia University professor of sociomedical studies Amy Fairchild, for example, endorsed the program as a kind of “soft paternalism” that merely tries to help people who cannot or will not help themselves.³⁵ Those who support the registry often find the City’s plan to provide doctors with a chart of their diabetic patients’ progress (or regress) as particularly beneficial, because the ability to track changes may be an important tool for doctors in developing treatment strategies for their patients. Supporters also believe that the City’s plan to mail test results directly to patients will help drive home the importance of managing their blood sugar levels.³⁶

Conversely, others in the medical community are concerned that the registry could infringe upon patient privacy. For example, while the ADA endorses the “idea of helping people with diabetes better manage their disease,” it is also concerned that personal patient information may not remain private.³⁷ The American Clinical Laboratory Association (“ACLA”) has also expressed concern about the privacy of patients amidst the City’s intrusion into the patient-doctor relationship.³⁸ Additionally, it questioned the necessity of reporting personal information for non-infectious diseases, doubted the Health Department’s ability to utilize the massive amount of

³⁴ See Letter from David M. Keepnews, Director, Office of Policy Development, New York Academy of Medicine, to The New York City Department of Health and Mental Hygiene (August 15, 2006) (on file with the New York City Department of Health and Mental Hygiene); see also Public Hearing on the Notice of Intention to Amend Article 13 of the New York City Health Code, August 16, 2005 (statements by Maria Pitaro, M.D., Associate Director of UNITE Health Center) (on file with the New York City Department of Health and Mental Hygiene).

³⁵ Amy Fairchild, *Diabetes and Diabetes Surveillance*, 313 SCIENCE 175 (July 14, 2006).

³⁶ Only ten percent of diabetics know their own A1c level. See Diana K. Berger & Lynn D. Silver, *Improving Diabetes Care for All New Yorkers*, NYC HEALTH, <http://www.nyc.gov/html/doh/downloads/pdf/diabetes/diabetes-presentation-a1c-registry.pdf>.

³⁷ Rob Stein, *New York City Starts To Monitor Diabetics*, Washington Post, January 11, 2006, p. A3.

³⁸ Letter from JoAnne Glisson, Senior Vice President, American Clinical Laboratory Association, to the New York City Board of Health (Aug. 16, 2005), <http://www.clinical-labs.org/documents/A1cComment.pdf>.

information the program will generate, and argued that the registry will aggravate the problem of escalating health care costs. For example, the ACLA pointed out that the language of the Health Code, if taken literally, requires labs to report information that they may not have, such as the address of the patient. This will substantially increase the workload for lab personnel, as they will frequently be required to contact doctors to obtain missing information. The additional labor will undoubtedly result in increased costs for the labs—costs that they may pass on, at least partially, to consumers. The American Medical Association has not released an official statement commenting on the program.

B. History of Public Health Registries

To understand the drastic nature of the new registry more fully, we briefly sketch the evolution of public health monitoring. Governments and public health officials have long struggled to protect their citizens from health crises, and over the past century intentional monitoring of and intervention against specific diseases have become central features of public health systems in most developed countries.³⁹ Registry systems⁴⁰ designed to collect detailed data enabling governments to track and prevent dangerous diseases are one of the most widely-used forms of government monitoring.

The vast majority of public health registries in the past century have focused on collection of data with regard to infectious diseases. In the United States, for example, Congress authorized

³⁹ *Established Surveillance Systems: History, Goals and Properties*, 113(3) ENVTL. HEALTH PERSP. 243-49 (2005).

⁴⁰ See Benedict C. Nwomeh, et al., *History and Development of Trauma Registry: Lessons from Developed to Developing Countries*, WORLD J. EMERGENCY SURGERY 1: 32 (2006). A disease registry is a collection of uniform data describing individuals who meet specific inclusion criteria, in which medical, demographic and other data are documented in an ongoing and systematic manner in order to serve predetermined purposes.

the Bureau of Census in 1902 to collect vital statistics data relating to diseases such as yellow fever, cholera, and small pox. A decade later, Congress expanded the powers of the federal Public Health Service by sanctioning investigations into tuberculosis, hookworm, malaria, and leprosy and their relationship to socioeconomic factors such as inadequate water supply and sewage disposal.⁴¹ When instances of infectious diseases such as diphtheria, smallpox or polio occurred, officials placarded the homes of the infected or published daily lists in local newspapers of the names and addresses of individuals afflicted with such diseases.⁴² During the second half of the twentieth century, aggressive programs mandated tracking, screening and mandatory immunization for infectious diseases, including tuberculosis, measles, mumps, rubella, diphtheria, and polio.⁴³

The mid-late twentieth century also witnessed the creation and expansion of state cancer registries. New York was one of the first states to begin collecting information on cancer diagnoses in 1939, though the program initially excluded New York City.⁴⁴ The cancer registry, which began as a simple reporting of tumor diagnoses, has expanded in scope such that more than one hundred discrete pieces of information, including race, gender, place of birth, and ethnicity are now collected for each individual.⁴⁵ As with infectious disease registries, a major

⁴¹ Images from the History of Public Health Service, *Introduction: Two Centuries of Health Promotion*, NAT'L LIBR. MED. (2005), http://www.nlm.nih.gov/exhibition/phs_history/intro.html.

⁴² *Id.*

⁴³ *Id.*

⁴⁴ N.Y. Dep't of Health, *About the New York Cancer Registry*, (2007), <http://www.health.state.ny.us/statistics/cancer/registry/about.htm>.

⁴⁵ *Id.* Currently, the New York cancer registry participates in the National Program of Cancer Registries, a federally funded, standardized, network of state cancer registries which share data through the Center for Disease Control and Prevention. Centers for Disease Control & Prevention, *Nat'l Program of Cancer Registries* (2007), <http://www.cdc.gov/cancer/npcr>.

goal of the cancer registry was to identify and control environmental, occupational, and lifestyle factors which may contribute to higher cancer rates in different populations. The cancer registries, however, did not assess treatment in specific cases, but sought rather to study incidence of the disease on a broader scale and attempt to correlate such statistics with social and environmental trends.

As the government became ever more involved in monitoring and regulating public health, concerns for autonomy and privacy increased.⁴⁶ Two distinct sides formed in the debate over the government's authority to supervise and dictate treatment for public health matters: many Americans increased their demand for governmental monitoring and the protections they believed would follow, while others opposed mandatory collection of medical data as invading the traditional right of voluntary consent prior to use of private medical data.⁴⁷ Many feared that individually identifiable registry data would be used to incriminate parties with infectious diseases, particularly diseases such as AIDS that frequently provoked condemnation from the general public.⁴⁸ Although health officials generally stressed the confidentiality of disease registries, this confidentiality had limits.⁴⁹ The American Medical Association ("AMA") code of ethics already acknowledged that "peculiar circumstances" could limit protection of confidentiality; in response to an increased emphasis on public knowledge, the AMA expanded

⁴⁶ Amy Fairchild et al., *Public Goods, Private Data: HIV and the History, Ethics, and Uses of Identifiable Public Health Information*, 122 PUB. HEALTH REP. 1, 8 (2007).

⁴⁷ *Id.*; see also Fairchild, *The Democratization of Privacy: Public Health Surveillance Changing Conceptions of Privacy in the Twentieth Century* in HEALTH CARE HISTORY AND POLICY IN THE UNITED STATES (Stevens et al., eds., Univ. of California Press) (2006).

⁴⁸ Fairchild, *supra* note 46, at 9.

⁴⁹ *Id.*

its ethical code to recognize a duty to the general community.⁵⁰ As a result, health officials began to release the names and addresses of those with contagious diseases when deemed necessary to fulfill the officials' duty to warn the public.⁵¹

The controversies developing over the past fifty years or more have been animated by a deep divide between those who believe that the government's responsibility to protect public health warrants extensive use of individual data, and those whose notions of privacy and individual rights demand strict limitations on the government's collection and use of individual medical data. Even those who take the side of government intervention, however, justify such intrusion by citing the overwhelming need to halt the spread of infectious diseases or root out environmental and occupational health risks that pose serious threat to the surrounding community. The suggestion that the government has any role in regulating individual cases of noninfectious disease is far more controversial, and New York City's diabetes registry is the first noninfectious disease registry in the U.S. to mandate collection of individual testing data in order to study the effectiveness of current treatment.⁵²

Although diabetes registries have become more prevalent in the past decade, these registries also bear important distinctions from the plan at stake in New York. The Vermont Diabetes Information System ("VDIS"), for example, sponsored by the National Institutes of

⁵⁰ *Id.* at 8; see also Gellman, *Prescribing Privacy: the Uncertain Role of the Physician in the Protection of Patient Privacy*, 62 N.C. L. REV. 255-94 (1982).

⁵¹ Fairchild, *supra* note 46, at 8.

⁵² NYC Starts Diabetes Registry: Mandatory Monitoring Diabetes Treatment in New York City, *THE LANCET*, Jan. 21, 2006, http://www.natap.org/2006/HIV/012506_03.htm.

Health,⁵³ is the most renowned active diabetes registry and care system in the United States. Much like the New York registry (which in fact claims the VDIS as its inspiration),⁵⁴ the VDIS is primarily intended to improve adult diabetes treatment by monitoring patients closely, testing frequently, and discovering new information for advancing diabetes management by providing researchers with access to collected data.⁵⁵ Unlike the New York registry, however, the VDIS relies entirely on voluntary enrollment from hospitals and primary care practices,⁵⁶ and allows patients to opt out of participation in the registry altogether by calling a toll-free number.⁵⁷ The VDIS has also emphasized protecting patient data from questionable secondary uses; when registry officials wanted to analyze links between diabetes and socioeconomic characteristics, health education, literacy, alcohol abuse, and many other factors,⁵⁸ the officials allowed researchers to obtain such personal information only after obtaining additional voluntary written consent from the registry patient whose data were subject to analysis.⁵⁹

European diabetes registries also bear notable differences from the New York plan. The Belgian Diabetes Registry (“BDR”), for example, which registers and tracks nearly every new diabetes case in patients under forty years old in the entire country of Belgium,⁶⁰ relies on

⁵³ Press Release, University of Vermont, UVM Study Aims to Improve Diabetes Outcomes Statewide (Apr. 6, 2004), <http://list.uvm.edu/cgi-bin/wa?A2=ind0404&L=uvnews&T=0&P=299>.

⁵⁴ THE LANCET, *supra* note 52; *see also* Robert Steinbrook, M.D., *Facing the Diabetes Epidemic—Mandatory Reporting of Glycosylated Hemoglobin Values in New York City*, 354 NEW ENG. J. MED. 545 (2006).

⁵⁵ Charles D. MacLean et al., *Diabetes Decision Support: Initial Experience with the Vermont Diabetes Information System*, 96 AM. J. PUB. HEALTH 593-95 (2006).

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ Benjamin Littenberg & Charles MacLean, *Intra-cluster Correlation Coefficients in Adults with Diabetes in Primary Care Practices: the Vermont Diabetes Information System Field Survey*, *BioMed Central Research Methodology*, <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1513389>, (May 3, 2006).

⁵⁹ *Id.*

⁶⁰ Belgian Diabetes Registry, Homepage, <http://www.bdronline.be/index.php?n=65&id=65&taal=F> (translated from

voluntary reporting of all diabetes diagnoses by participating physicians.⁶¹ Although the registry is primarily designed as a means for researchers to identify genetic, environmental and sociological risk factors for development of diabetes, follow-up patient participation in the registry program (and further study by physicians and researchers) may take place only after affirmative consent from the patient.⁶²

Similarly to the BDR, the Skaraborg Diabetes Registry (“SDR”), created in 1991 in Skaraborg County, Sweden, established Sweden’s first comprehensive diabetes registry system by tracking all recorded incidents of diabetes in the entire county of Skaraborg (population 280,000).⁶³ Although the SDR mandates that all diabetic patients enroll, registry information is used only for purposes of aggregate data collection,⁶⁴ and any personal data or further contact with a patient depends upon affirmative consent from the patient.⁶⁵ The SDR is primarily intended to estimate the prevalence of diabetes in the general population and study the effects of insulin treatment on adult diabetics.⁶⁶

As the examples above demonstrate, the New York City plan operates very differently from historic public health registries. While governments have often mandated registry and treatment in the case of infectious diseases, such infringement on personal choice and privacy has

the original French).

⁶¹ Ilse Weets et al., *The Incidence of Type 1 Diabetes in the Age Group 0-39 Years has not Increased in Antwerp (Belgium) Between 1989 and 2000*, 25 *DIABETES CARE* 840 (2002).

⁶² Belgian Diabetes Registry, Projects, <http://www.bdronline.be/index.php?n=36&id=36&taal=F> (translated from the original French).

⁶³ *Id.*

⁶⁴ Diana K. Berger & Lynn D. Silver, *Improving Diabetes Care for All New Yorkers*, NYC HEALTH, <http://www.nyc.gov/html/doh/downloads/pdf/diabetes/diabetes-presentation-a1c-registry.pdf>.

⁶⁵ Stenström et al., *HLA-DQ Genotypes in Classic Type 1 Diabetes and in Latent Autoimmune Diabetes of the Adult*, 156 *AM. J. EPIDEMIOLOGY* 787-796 (2002).

⁶⁶ Berger & Silver, *supra* note 64.

been justified by the overriding need to protect the public from the spread of dangerous disease. Cancer registries, on the other hand, have been motivated largely by the desire to identify and mitigate environmental and occupational risks, and as such focus on external factors rather than targeting the individual patient. The few registries that are already in place for diabetes, rather than mandating enrollment, rely on patient and doctor consent, or at the least avoid collecting identifiable individual data except by patient consent. A program such as New York's diabetes registry, which mandates individual enrollment in a noninfectious disease registry and records and uses individual data for tracking and treatment purposes, raises potential legal and ethical concerns that merit thorough discussion.

II

This section explores the legal and ethical issues raised by New York City's mandatory diabetes registry. A diabetic's A1c level is generally confidential information, known only to the physician and patient. Including such information in the registry, however, may lead to wider disclosure of what used to be private information. Despite the regulatory pledge of confidentiality, information in the database may be disclosed to third parties through litigation, public health research, misdirected notifications to physicians and patients, or sloppy handling by public health officials. Moreover, some patients may object to secondary use of their information in research projects of which they disapprove. Individuals subject to the registry may also face the prospect of limited insurance options if required to disclose their A1c status to insurance companies. Finally, physicians may also suffer if the registry information is disclosed in response to a public health investigation or lawsuit. Our point is not that the privacy problems

are endemic, but that the potential for invasions is not fanciful, and the loopholes for such invasions should be closed.

A. Legality of Registries

Some state registries of health information have been challenged by patients as an unjustifiable invasion of privacy. However, both the New York Court of Appeals, in the case of Schulman v. NYC Health & Hosp. Corp. and the U.S. Supreme Court, in Whalen v. Roe, upheld creation of public health registries.⁶⁷ In both cases, the courts used a rational basis standard of review,⁶⁸ and found that the statutes at issue advanced legitimate state interests.⁶⁹ The legality of such registries has not been challenged since these two cases were decided in the 1970s. In subsequent cases involving other uses of medical information, courts have consistently held that such use implicates a right to privacy under the Constitution.⁷⁰

Schulman involved a section of the New York City Health Code that required hospitals to

⁶⁷ Whalen v. Roe, 429 U.S. 589 (1977); Schulman v. NYC Health & Hosp. Corp., 342 N.E.2d 501 (N.Y. 1975).

⁶⁸ Whalen, 429 U.S. at 597-98; Schulman, 342 N.E.2d at 243-44.

⁶⁹ Whalen, 429 U.S. at 598; Schulman, 342 N.E.2d at 240.

⁷⁰ *See, e.g.*, Norman-Bloodsaw v. Lawrence Berkeley Lab., 135 F.3d 1260 (9th Cir. 1998) (nonconsensual medical testing of employees by state-run institution implicated right to privacy under U.S. Constitution); Middlebrooks v. State Bd. of Health, 710 So. 2d 891, 892 (Ala. 1998) (state law requiring doctors to report cases of certain health conditions, including AIDS, to the state board of health did not violate the constitutionally-protected right to privacy; applying factors from United States v. Westinghouse Elec. Corp., 638 F.2d 570, 578 (3d Cir.1980)). Unlike Whalen and Schulman, however, most courts addressing the right to confidentiality have applied an intermediate standard of review. Doe v. Poritz, 142 N.J. 1, 78 (N.J. 1995). Still, not all circuit courts have adopted the view that the Constitution includes a privacy interest in keeping private information confidential in addition to a privacy interest in autonomous decisionmaking. *See* Jessica Ansley Bodger, *Taking the Sting out of Reporting Requirements: Reproductive Health Clinics and the Constitutional Right to Informational Privacy*, 56 DUKE L.J. 583, 600 n.120 (2006) (“The Sixth, Eighth, and District of Columbia Circuits do not recognize a constitutional right to informational privacy”); Joel Glover & Erin Toll, *The Right to Privacy of Medical Records: Balancing Competing Expectations*, 79 DENV. U. L.REV. 540, 542-43 (2002); *see also* J.P. v. DeSanti, 653 F.2d 1080, 1089 (6th Cir. 1981) (“[W]e are unable to see how such a constitutional right of privacy can be restricted to anything less than the general ‘right to be let alone’”); Am. Fed’n Gov’t Employees v. Dep’t of Hous. & Urban Dev., 118 F.3d 786, 791 (D.C. Cir. 1997) (“The Supreme Court has addressed the issue [of a right to privacy] in recurring dicta without, we believe, resolving it”).

file a special report listing each patient's name and address with the NYDHMH after any abortion procedure.⁷¹ The New York Court of Appeals reasoned that the state's interest in assuring "safe and adequate facilities and procedures in abortions subject to governmental regulation" made the law legitimate.⁷² In Whalen, individuals challenged a New York statute that required the names, addresses, and prescription details for all persons receiving Schedule II medication prescriptions to be reported to the Department of Health, which stored the information in a computerized database.⁷³ In this case, the Court held that the registry's purpose to "aid in the enforcement of laws designed to minimize the misuse of dangerous drugs" amounted to a legitimate state interest which took precedence over individual patients' privacy concerns.⁷⁴

The courts in these cases further found no violation of a constitutional right to privacy or autonomy in either statute, basing such finding in part on two factors: first, that neither statute interfered with decision-making by patients or doctors, but merely required reporting of actions already taken,⁷⁵ and second, that both statutes included express confidentiality provisions protecting patient information from public disclosure.⁷⁶

The A1c registry's purpose is arguably distinguishable, because it is not being used to monitor for criminal behavior, as with the prescription registry in Whalen, nor is it being used to

⁷¹ *Schulman*, 342 N.E.2d at 236.

⁷² *Id.* at 243; *see also* *Planned Parenthood of Cent. Mo. v. Danforth*, 428 U.S. 52, 80 (1976) (holding that state abortion reporting requirements "that are reasonably directed to the preservation of maternal health and that properly respect a patient's confidentiality and privacy are permissible").

⁷³ *Whalen*, 429 U.S. at 592-95.

⁷⁴ *Id.* at 598.

⁷⁵ *Id.* at 603; *Schulman*, 342 N.E.2d at 240-41.

⁷⁶ *Whalen*, 429 U.S. at 602; *Schulman*, 342 N.E. 2d at 244.

track the safety of a medical procedure, as in Schulman. Rather, the A1c registry will be used to supervise the non-criminal behavior of private citizens, namely, how well diabetics are managing their own blood sugar levels.

Despite these differences, in light of Whalen and Schulman it is likely that New York City's A1c registry would nonetheless survive a constitutional challenge.⁷⁷ Like the statutes at issue in both Whalen and Schulman, § 13.04 does not directly interfere with patient or physician decision-making. Additionally, § 13.04(d) contains a brief confidentiality provision that limits disclosure to the patient, the medical provider and, in the case of minors, the patient's parents or guardians. Thus § 13.04 satisfies the factors that the courts in Whalen and Schulman considered in determining the constitutionality of those registries. Further, a detailed statement of the basis and purpose of the registry, which would almost certainly support the rational basis of the statute, was published in the City Record.⁷⁸

B. Potential for Disclosure Despite Statutory Confidentiality

Diabetics have reason to fear disclosure of personal information contained in the A1c registry. Diabetes is an expensive and potentially debilitating disease to which myriad public myths and misconceptions still attach. As a result, diabetics often face discrimination at work, in school, and even in prison.⁷⁹ As one diabetic man stated, "I was regarded as a damaged piece of

⁷⁷ For other cases, see *Rollins v. Ulmer*, 15 P.2d 749 (Alaska 2001) (upholding constitutionality of medical marijuana registry on grounds that the scheme assured confidentiality, at least on its face, and assuming that the measure rationally allowed for compliance with rules regulating marijuana use); *Arkansas Dep't of Human Services v. Heath*, 848 S.W.2d 927 (Ark. 1993) (holding that registry for unsubstantiated allegations of child abuse is permissible).

⁷⁸ See 24 RCNY Health Code Reg. § 13.04, notes section.

⁷⁹ *Legal Advocacy at ADA*, AM. DIABETES ASS'N (2007), <http://www.diabetes.org/advocacy-and-legalresources/discrimination/advocacy.jsp>.

meat. It was like, ‘You’re one of those, and we can’t have one of those.’”⁸⁰ Numerous lawsuits have claimed that employers, school officials, and others denied diabetics fair opportunities in work and school.⁸¹ Some diabetics have faced difficulty when they asked for simple accommodations to allow them to deal with their disease on the job. For example, according to a New York Times article, a diabetic bank employee in Oregon who needed to eat at her desk in order to keep her blood sugar in check was refused permission to do so, and an insulin-dependent worker in a Wisconsin candy company was fired after asking where to dispose of her hypodermic needles.⁸²

Discrimination against diabetics is often the result of a fear that faintness caused by a sudden drop in blood sugar—experienced by a few diabetics—poses a safety risk to others. The San Antonio Police Department, for example, imposed a blanket rule disqualifying any applicants who were insulin-dependent until one such applicant sued to enforce his right to be individually assessed as a safety risk under federal law.⁸³ Until 1995, insulin-dependent diabetics were not allowed to obtain commercial driver’s licenses because aggregate data suggest that they are more likely to be involved in accidents.⁸⁴ Similarly, until 2006 the National Fire Protection Association did not recommend hiring insulin-dependent diabetics.⁸⁵

⁸⁰ N. R. Kleinfield, *Diabetics in the Workplace Confront a Tangle of Laws*, N.Y. TIMES, Dec. 26, 2006, at 1.

⁸¹ The American Diabetics Association maintains a brief list of cases involving employment discrimination based on diabetes at <http://www.diabetes.org/uedocuments/CaseList0806.pdf>.

⁸² Kleinfield, *supra* note 79, at 1.

⁸³ *Kapche v. City of San Antonio*, 304 F.3d 493 (5th Cir. 2002).

⁸⁴ *See Frequently Asked Questions About Commercial Driver’s Licenses*, AM. DIABETES ASS’N (Nov. 2006), <http://www.diabetes.org/advocacy-and-legalresources/discrimination/CDLFAQ.jsp>.

⁸⁵ Kleinfield, *supra* note 79, at 1.

Confidentiality requirements in the New York City diabetes statute circumscribe the City's disclosure of registry data. The A1c registry confidentiality provision states that test results and identifying information will only be available to the test subject and that person's medical provider. Given that confidentiality provisions in other New York registries are rarely absolute, one could infer that the drafters purposely removed any mention of exceptions to the confidentiality requirement in the statute creating the diabetes registry. On its face, therefore, the provision is absolute, brooking no exceptions.

1. Potential for Use in Legal Proceedings

Doubt remains, however, as to the unqualified nature of the New York City diabetes registry's confidentiality. First, it should be noted that, in the case of health records regarding highly sensitive information such as AIDS or sexually transmissible diseases, the City has taken care explicitly to forbid subpoena of such confidential information for use in court proceedings.⁸⁶ The New York City Health Code provision stating that such information "shall not be subject to subpoena" has been interpreted by the NY Court of Appeals as providing absolute confidentiality.⁸⁷ The diabetes registry, on the other hand, lacks such an explicit provision, and therefore the unconditional nature of its protection against subpoena is in question.

Family law proceedings are one context in which the confidentiality of information in the diabetes registry might be breached. Due to their closed nature and the paramount state interest in children's safety and well-being, such proceedings allow for use of evidence inadmissible in

⁸⁶ 24 RCNY Health Code Reg. § 11.07(a) (2006).

⁸⁷ *In re Baker's Mutual Ins. Co. of N.Y.*, 92 N.E.2d 49 (1950).

other judicial contexts.⁸⁸ Physician-patient privileges, psychologist-client privileges, and related confidentiality provisions do not apply to child protective proceedings initiated under the New York Family Court Act.⁸⁹ Courts have also bypassed statutory evidentiary rules, permitting admission of evidence which, in other contexts, would be barred by the Fourth Amendment exclusionary rule.⁹⁰ The new A1c Registry could impact family law proceedings directly if courts or legislators determine that its confidentiality provision should be waived in the same manner as physician-patient and other privileges.

Information in the A1c registry may be directly relevant in a family law proceeding. Because family law courts have used diabetes as a factor against the “fitness” of a parent in neglect, termination, and custody hearings,⁹¹ it is plausible that a family law court would desire information on an individual’s A1c level. In at least one case, a court took diabetic status into account when deciding between two equally fit caregivers, making an aunt’s continuing custody of her nephew contingent on properly managing her diabetes.⁹² Case law from various jurisdictions including New York reveals that parental rights have also been terminated when parents are unable to adhere to the treatment regimen prescribed for a diabetic child.⁹³

It is also conceivable that a violation of confidentiality might arise in the context of a criminal proceeding, where the defendant’s Sixth Amendment right to confront a witness could

⁸⁸ *In re Doe Children*, 402 N.Y.S.2d 958 (1978).

⁸⁹ NY FAM. CT. ACT § 1046(a)(vii) (2007).

⁹⁰ *In the Matter of Cassandra R.*, 504 N.Y.S.2d 602, 603 (1986).

⁹¹ *See, e.g., In re W.N.*, 801 N.Y.S.2d 243 (Fam. Ct. Onondaga Cty. 2005).

⁹² *Florence B. v. Carol M.*, 576 N.Y.S.2d 981 (Fam. Ct. Queens Cty. 1991).

⁹³ *Anna Mae B. v. Harold H.*, 110 A.D.2d 978 (N.Y. App. Div. 1985) (mother denied custody); *In re John W.*, 682 A.2d 930 (R.I. 1996) (mother’s parental rights terminated); *In re Brinkman*, 2005 Mich. Ct. App. LEXIS 1204 (unpublished) (termination of parental rights); *In re Mark R.*, 2005 WL 3418252 (Cal. Ct. App., 2005) (unpublished).

permit a defendant to obtain the otherwise confidential information of a third party.⁹⁴ For instance, a defendant might wish to impeach the testimony of a witness on the ground that he or she was in diabetic shock at the time of the incident. Although the risk that information from the diabetes registry could be subject to subpoena seems slight, the lack of statutory language explicitly prohibiting subpoena of registry information may result in disclosure of information contained in the registry.

2. Disclosure of Private Information to Public Health Researchers

An additional concern is that, despite the confidentiality provisions, New York public health authorities may disclose private information to researchers. At the same time that New York City officials established the registry, they announced a pilot program for notifications of elevated A1c levels to patients and their physicians.⁹⁵ The process of notification itself could well violate the confidentiality provisions, because unless the process is fully automated, someone other than the physician and patient will have to work with the registry to ensure that proper notifications are sent. Each successive notification would violate the literal terms of the regulation.⁹⁶ If more than one address is on record, or a notification is returned, staff must become even more involved. The notification plan itself therefore strongly suggests that City authorities will not keep the information completely confidential.

New York City officials also stated at the time the registry was established that the information to be obtained would be invaluable in studying and preventing further incidence of

⁹⁴ See, e.g., *People v. Gissendanner*, 48 N.Y.2d 543 (1979).

⁹⁵ Letter from Thomas Frieden, Commissioner of the New York Department of Health & Mental Hygiene, to health care professionals (May/June 2006), <http://home2.nyc.gov/html/doh/downloads/pdf/csi/diabeteskit-letter.pdf>.

⁹⁶ 24 RCNY Health Code Reg. § 13.04 (2006).

the disease.⁹⁷ In order to formulate policies to limit the increase in diabetes, public health officials must be able to assess A1c trends in conjunction with other data. For example, child obesity has been strongly linked to diabetes, and yet the registry data do not contain such information. Health officials would need to review each diabetic's medical file to get the type of information that would be beneficial in understanding the course of the disease. Indeed, New York's authorities noted that they were modeling the City's approach on the Vermont program, in which more data than mere A1c levels were assessed.⁹⁸ It is thus reasonable to conclude that, despite the confidentiality provision, City officials may well intend to permit researchers to analyze personal information in order to develop a more comprehensive understanding of and response to diabetes. The more people that have access to personal information, the greater the chance for a breach of privacy.

Private information in other medical registries has indeed been divulged for a variety of reasons. For instance, a nationwide registry of DNA samples in Sweden was established approximately thirty years for medical purposes. Personally identifiable samples were supposed to be used only with the consent of the person involved, but Swedes were dismayed to find that the registry was used for forensic purposes in the Anna Lindh murder investigation without their consent.⁹⁹ The extent of confidentiality pledged under the City scheme is similarly in question.

⁹⁷ *Id.* at § 13.04 (notes section); *see also* Robert Steinbrook, M.D., *Facing the Diabetes Epidemic—Mandatory Reporting of Glycosylated Hemoglobin Values in New York City*, 354 *NEW ENG. J. MED.* 545 (2006).

⁹⁸ NYC Starts Diabetes Registry: Mandatory Monitoring Diabetes Treatment in New York City, *THE LANCET*, Jan. 21, 2006, http://www.natap.org/2006/HIV/012506_03.htm.

⁹⁹ Claudia Mund, *Biobank—Data Sources without Limits?*, presentation to the 27th International Conference on Privacy and Personal Data Protection (2005), in Jusletter, Oct. 5, 2005, http://www.privacyconference2005.org/fileadmin/PDF/mund_e.pdf); Klaus Hoeyer, *Biobanks and Informed Consent* (Nov. 12, 2004) (doctoral dissertation, Umea Univ.), <http://www.diva-portal.org/umu/theses/abstract.xsql?dbid=358>

3. Inadvertent Disclosure of Private Information

Aside from those instances in which the City knowingly may allow registry data to be disclosed, registry data may inadvertently be divulged to unauthorized individuals, and potentially used for discriminatory or otherwise wrongful purposes, in several ways.

Because all of the A1c registry data is transferred and stored electronically, the NYDHMH must guard against hackers who may break into the A1c registry data, whether for bragging rights or a desire to pass on the data to the highest bidder. Keeping electronic data secure is a challenge even for government agencies guarding top secret information. Hackers have found their way into well guarded NASA, Pentagon, and military installation databases.¹⁰⁰ In other instances, agency employees themselves have illegally sold the information for a small profit.¹⁰¹ Hackers similarly could likely find a market for the information they obtain. Pharmaceutical companies, in particular, would find the information beneficial in their research and marketing efforts.

While New York City has promised confidentiality in its notification program, the possibility remains that an A1c test notification could be mishandled or delivered to the wrong address. At a minimum, staff must process the information to facilitate notification. Thus, even if the registry database is itself secure, identifiable information in the hands of staff (or researchers) will likely not be secure, and no published protocols govern the security of

at 17.

¹⁰⁰ John Leyden, Brit Charged with Hacking Pentagon, NASA, THE REGISTER, Nov. 13, 2002, http://www.theregister.co.uk/2002/11/13/brit_charged_with_hacking_pentagon/.

¹⁰¹ Associated Press, Uh, Folks, Your Data was Swiped, May 23, 2005, <http://www.wired.com/news/privacy/0,1848,67616,00.html>.

information in staff members' or researchers' hands. Inadvertent mistakes—whether because of an unsecured database, misplaced laptop, or simply charts left lying around—can occur.

Moreover, the City's notifications may themselves be delivered to the wrong address, raising the possibility that neighbors, strangers, or even non-custodial parents could learn of an individual's A1c results.

Because the City notifies parents of the A1c results for minor children, there is also a possibility that the City will improperly send a notification to the parents of minors who are entitled to keep their medical information confidential from their parents. Under New York law, parents may access a minor's medical records from a health care provider only where the parent consented to the care or where emergency care was given without consent.¹⁰² By contrast, individuals under eighteen who are themselves married or parents have the right to consent to their own medical treatment, and records of their treatment are confidential.¹⁰³ It is not instantly apparent that the City's procedures adequately protect the privacy rights of such minors. In summary, private information under New York's scheme may be disclosed to staff, to researchers, or to unintended third parties. The consequences of such disclosure may be severe to diabetics.

4. Uses of Registry Information in Research Studies

Diabetics may also be concerned with the potential secondary uses of epidemiological information in the registry, even if identifying information is removed. Reports collected under New York's regulatory scheme create a treasure trove of information for both public health

¹⁰² N.Y. Pub. Health Law § 18(2)(c) (McKinney 2006).

¹⁰³ NY CLS Pub. Health § 2504(1); N.Y. CPLR § 4504(a) (McKinney); 8 N.Y.C.R.R. § 29.1(8).

officials and researchers alike. Researchers will be able to match A1c levels by neighborhood and evaluate trends as the A1c levels dip or rise. Indeed, the prospect for such epidemiological research in part prompted creation of the diabetes registry. Diabetics, however, may object to use of their information for such purposes.

The problem of secondary uses has long plagued the medical profession. For example, members of the Havasupai Tribe permitted Arizona State University's researchers to study potential causes of the tribe's high diabetes rate, but the researchers used the group's medical records and blood samples also to study schizophrenia, migration, and inbreeding in the tribe.¹⁰⁴ The tribe filed suit against the university asking for both damages and an injunction to prevent further unauthorized use of the medical records and samples.¹⁰⁵ In another case, Wash. Univ. v. Catalona,¹⁰⁶ the Eighth Circuit decided that tens of thousands of tissue samples collected for prostate cancer research could be used by the collecting university for purposes to which the patients did not consent.¹⁰⁷ Privacy advocates hope that these cases, and others like them, will illustrate the danger that research subjects face in having their private health information used in ways other than specifically authorized.

Although the confidentiality provision governing the A1c registry does not explicitly allow for disclosure of test results and information for use in scientific and medical studies, there are reasons to believe that registry information will be used for such studies. Prior to New York

¹⁰⁴ Lori B. Andrews, *Havasupai Tribe Sues Genetic Researchers*, 4 LAW & BIOETHICS REPORT 10 (2004).

¹⁰⁵ *Id.*, see also Court Link Docket Information, "Lexis Nexis" Havasupai Tribe et al. v. Ariz. St. Univ., et al., civil docket no. 3:04-CV-1494, (D.Ariz. 2004); Tilousi, et al. v. Ariz. St. Univ., et al., civil docket no. 3:04-CV-1290 (D.Ariz. 2004); Tilousi, et al. v. Ariz. St. Univ., et al., civil docket no. 2:04-CV-1290 (D.Ariz. 2004).

¹⁰⁶ Wash. Univ. v. Catalona, --- F.3d ---, 2007 WL 1758268 (8th Cir. 2007).

¹⁰⁷ Lori Andrews, *Who owns your body? A Patient's Perspective on Wash. Univ. v. Catalona*, J.L. MED. & ETHICS, at 398 (Summer 2006).

City’s establishment of the A1c registry, the Diabetes Task Force of New York State issued a “Strategic Plan for the Prevention of Diabetes” which addressed the potential use for information contained in an A1c registry.¹⁰⁸ The Task Force suggested that creating a diabetes registry would help researchers assess the quality of care being provided to people with diabetes and track the risk of diabetes associated with obesity.¹⁰⁹ The Task Force explicitly addressed the potential for use of A1c registry information in research studies when it declared of goal of obtaining aggregate statistics to track diabetes risk.¹¹⁰ Such goals are only attainable if researchers conduct additional studies with the inclusion of personal identifying information such as age or weight. Even if all identifying characteristics can be removed, the question remains whether diabetics should have a right to object to particular research conducted based on information they involuntarily provide to the registry.

Similar New York City registries have used database information for further research purposes. The data obtained by the Child Blood Lead Level Registry in New York, for example, is given to the Center for Disease Control (“CDC”), which then uses the information in monitoring the child blood lead level for the entire U.S. population.¹¹¹ Among other purposes, the aggregate statistics are used by the CDC to identify risk groups.¹¹² Aggregate data are

¹⁰⁸ Michael A. Acosta et al., *New York State Strategic Plan for the Prevention and Control of Diabetes*, <http://www.health.state.ny.us/diseases/conditions/diabetes/docs/stateplandiabetes.pdf>.

¹⁰⁹ *Id.* at 15.

¹¹⁰ *Id.*

¹¹¹ Pamela A. Meyer, et al., *Surveillance for Elevated Blood Lead Levels Among Children—United States, 1997-2001*, CTR. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/MMWR/preview/mmwrhtml/ss5210a1.htm> (Sep. 12, 2003).

¹¹² *Id.*

grouped for reports based on age, ethnicity and race, poverty level, and region of the country.¹¹³

Although the statutory language controlling the Child Blood Lead Level Registry allows for more general discretionary disclosure to a person or agency if the disclosure will contribute to the protection of public health,¹¹⁴ it is foreseeable that the A1c database will be treated in a similar fashion because aggregate registry data could provide important insights into optimal control of diabetes and its risks.¹¹⁵

The New York State Cancer Registry, which tracks more than one hundred pieces of information including race, gender, place of birth, and ethnicity are now collected for each individual,¹¹⁶ also makes some registry information available to the public on the Department of Health website, where visitors can track the prevalence of different cancer types by county, borough and neighborhood.¹¹⁷ The availability of some information from the registry has led to public demand for even more—researchers and breast cancer activists have demanded release of

¹¹³ *Id.*

¹¹⁴ 24 RCNY Health Code Reg. § 11.07(d). The provision governing both the Child Blood Lead Level Registry and the Immunization Registry allows for more general discretionary disclosure of information for specific purposes. Information obtained in both the Child Blood Lead Level Registry and the Immunization Registry may be disclosed to a person or agency if the disclosure will contribute to the protection of the public health.

¹¹⁵ Michael A. Acosta et al., *New York State Strategic Plan for the Prevention and Control of Diabetes*, <http://www.health.state.ny.us/diseases/conditions/diabetes/docs/stateplandiabetes.pdf>, at 23. California already uses epidemiological information obtained from diabetics in scientific and medical studies. The California Diabetes Program, funded by the CDC, collects epidemiological data (including results of A1c tests) by facilitating reporting from community health organizations and other groups. California's Plan for Diabetes, 2003-2007; Diabetes in California Task Force, 2003, <http://www.caldiabetes.org>. For example, the Kaiser Permanente insurance group maintains a registry of all residents with diabetes in the Northern California region. Division of Research at Kaiser Permanente, *Diabetes Registry* (2002), <http://www.dor.kaiser.org/studies/diabetes/Diabetes-06.shtml#TopOfPage>. Kaiser Permanente's registry, just one of many in the ambitious California Diabetes Program, has been used to facilitate a series of epidemiologic and health service projects. The research group has published data on the costs associated with diabetes, effectiveness of drug treatment, impact of hormone replacement, genetic epidemiology, and ethnic disparities in complications of diabetes. *Id.*

¹¹⁶ N.Y. Dep't of Health, *About the New York State Cancer Registry* (2007), <http://www.health.state.ny.us/statistics/cancer/registry/about.htm>.

¹¹⁷ N.Y. Dep't of Health, *New York State Cancer Registry* (2007), <http://www.health.state.ny.us/statistics/cancer/registry>.

information such as street-by-street and residence-by-residence cancer incidence and detailed family and occupational histories.¹¹⁸

Diabetics may not realize that by checking their A1c levels, they are also exposing private information to researchers. One can imagine characteristics in addition to obesity that would be of interest to researchers to correlate with diabetes, such as race, age or vocation. As researchers compare unique characteristics with diabetes, negative consequences for diabetics may arise, including discrimination based on aggregate data and the loss of privacy through revelation of identity or mistake.

Diabetics have experienced discrimination in the past¹¹⁹ and are vulnerable to additional discrimination resulting from conclusions produced by epidemiological studies. In order to complete these studies, scientists will need more information about diabetic patients. The A1c registry likely will expand to encompass multiple other characteristics for such public health studies in order to serve these research needs. The potential conclusions of such studies could lead the public to believe that certain characteristics are always indicative of high A1c levels and diabetes in general, which could then lead to discrimination. Thus, even if the identifying information in the A1c registry data remains confidential, aggregate data may well have a tendency to create harmful presumptions about the capabilities of diabetics. The tendency is even more problematic for racial minorities in New York City, who are not only more than twice as likely as whites to be diabetic, but also are more likely to have higher A1c levels even if they are

¹¹⁸ Joan Swirsky, *State Cancer Map: One Step In the Search for the Cause*, N.Y. TIMES, Long Island Weekly Section (Mar. 5, 2000).

¹¹⁹ See, e.g., N. R. Kleinfield, *Diabetics in the Workplace Confront a Tangle of Laws*, N.Y. TIMES, Dec. 26, 2006, at 1; *Kapche v. City of San Antonio*, 304 F.3d 493 (5th Cir. 2002).

not diabetic.¹²⁰

Full disclosure of all permissible research purposes should be made prior to collection of the identifying characteristic information needed for studies such as those proposed by New York State's Diabetes Task Force. While aggregate data created by the A1c registry could lead to important medical findings, public health officials must also weigh potential benefits against the possibility that aggregate data can have unintended consequences—such as stigmatization and economic discrimination—for the very people the medical community is trying to help.

C. Impact on Insurance Coverage and Eligibility

Even apart from confidentiality concerns regarding the information in New York's registry, A1c registry notifications may adversely affect a patient's ability to obtain or retain health, disability or life insurance. The A1c registry notifications can potentially inform patients of unknown and unsolicited information about their own health. Receipt of such health-related information could in turn affect the patient's ability to obtain insurance.

1. Effect of Notice on Patient's Knowledge

When a registry notice informs a patient of his unfavorable A1c level, it is possible, but unlikely, that the notice will serve as the patient's first notice that he has diabetes.¹²¹ The A1c

¹²⁰ Shona J. Kelly et al., *Is Hemoglobin A1c Level Associated with Measures of Socio-economic Status in Non-diabetics After controlling for Known Explanatory Factors?*, 21 STRESS & HEALTH 185 (Apr 14, 2005).

¹²¹ The A1c test is generally used to monitor the blood-sugar level of diagnosed diabetics. *A1c Test*, AM. DIABETES ASS'N, (2007), <http://www.diabetes.org/type-1-diabetes/a1c-test.jsp>. However, it is conceivable that a doctor might use the test for initial diagnosis of a patient. By looking at the patient's past control of his blood sugar using the A1c test, the doctor could avoid the possibility of a false positive test based on a transient spike in the patient's blood sugar. If this were the case, the possibility arises that a patient's first diagnosis of diabetes could arrive via the warning letter that his blood sugar is out of control, rather than in the doctor's office. Individuals in this situation would not have an opportunity to ask urgent questions regarding their newly discovered disease, and could come under undue stress from such an informal diagnosis of a potentially life-threatening disease.

test results typically will not be a patient's first notice of diabetes because the A1c test is not the recommended test for making an initial diabetes diagnosis.¹²² Instead, A1c tests are recommended for use periodically after the initial diagnosis to assist with developing and monitoring a diabetes management plan, which may include diet, exercise, and medication.¹²³

Registry notice of an unfavorable A1c level would most often notify patients that their blood sugar levels have not been properly maintained.¹²⁴ For the well-informed diabetes patient, warning of an unfavorable A1c level will also serve as notice of a higher risk of diabetes complications. Studies have shown a correlation between high A1c levels and an increased risk of small blood vessel complications, such as eye disease, kidney disease, and peripheral nerve disorders.¹²⁵

Despite the importance of A1c levels in monitoring blood sugar levels, one New York City Health Department study found that only ten percent of people with diabetes in New York State were aware of their A1c level.¹²⁶ While registry notice of an unfavorable A1c level would be unlikely to inform a patient of the fact of diabetes, it could provide patients with information

In addition, the notification system creates a massive marketing opportunity for pharmaceutical companies—raising the prospect of unwanted junk mail for diabetics in New York City. With every notice mailed to individuals, the city could—without violating its confidentiality code—enclose marketing literature targeted to diabetics. The city could help fund the cost of the registry with fees from drug companies, and the information could be helpful to some. However, it is important to emphasize that pharmaceutical advertisements can influence patients to request and receive inappropriate prescriptions. See “How Advertising Affects Prescriptions,” Harvard Mental Health Letter, August 2005, Vol. 22 Issue 2 at 7; see also Kravitz et al., *Influence of Patients' Requests for Director-to-Consumer Advertised Antidepressants: A Randomized Controlled Trial*, 293 J. AM. MED. ASS'N 1995-2002 (2005). While the City has not announced any plan to take advantage of this marketing opportunity, nothing in the code prevents it from doing so in the future.

¹²² Am. Diabetes Ass'n, *Standards of Medical Care in Diabetes-2006*, 29 DIABETES CARE S5 (Supplement 1 2006).

¹²³ *Id.* at S8-9; *A1c Test*, *supra* note 120.

¹²⁴ A patient who conducts regular home tests for current blood sugar level will already have some idea of his A1c level, since the A1c test measures a patient's average blood sugar level for the preceding three months.

¹²⁵ 24 RCNY Health Code Reg. § 13.04 (2005) (notes section).

¹²⁶ Public Hearing on Intention to Amend Article 13 of the New York City Health Code, Aug. 16, 2005.

about their medical condition and future medical risks that they may not otherwise have received.

2. Effect on Patient's Current Health Insurance Relationship

An A1c registry notification will not affect a patient's current relationship with health insurance carriers. New York law provides guaranteed renewability—a health insurer may not cancel a policy because of the insured's change in health status.¹²⁷ In addition, an insurer would likely have access to A1c test results regardless of whether that information is tracked in the registry. Health insurance companies have broad rights to inspect medical information in order to evaluate medical claims. Therefore, patients' subjective knowledge of their A1c level or diabetic condition, gained from a registry notice, would not likely impact their relationship with their current health insurer.

3. Effect on Ability to Obtain Health Insurance

A patient's enhanced subjective knowledge of his medical condition can be relevant to his ability to obtain health insurance. This section considers two relevant health insurance issues: medical underwriting and pre-existing condition exclusions.

a. Medical Underwriting

Most states allow health insurance companies to engage in medical underwriting. That is, health insurers can consider an applicant's health condition, and the risk of insuring him or her, when deciding whether to insure the applicant, how much to charge, and what benefits to

¹²⁷ N.Y. Ins. Law § 3216(g) (McKinney 2006). Note, however, that 'self-insurers,' or employers that pay employee health care costs out of a fund that they set aside for that purpose, are not subject to state law under ERISA. 29 U.S.C. § 1144(b)(2)(A)-(B) (2006).

offer.¹²⁸ In many states diabetes is a condition for which most medical underwriters will automatically deny coverage.¹²⁹ In these states, health insurers will likely inquire about existing health conditions, and applicants have a duty to disclose known circumstances that would influence the insurer's decision on how to act on an application.¹³⁰ As a result, an applicant's failure to disclose known material facts while applying for such insurance may be sufficient grounds for the health insurer later to cancel the policy.¹³¹ An unfavorable A1c level would be considered a material fact, as would the fact of a diabetes diagnosis.¹³²

However, New York law provides that residents cannot be refused an individual or small group health insurance policy because of a health condition.¹³³ New York also requires 'community rating' of individual and small group health insurance policies to ensure that

¹²⁸ Georgetown University Health Policy Institute, *Falling through the Cracks: Stories of How Health Insurance Can Fail People with Diabetes* (Feb. 8, 2005), <http://web.diabetes.org/Advocacy/healthresearchreport0505.pdf>.

¹²⁹ *Commonly Asked Questions about Health Insurance*, AM. DIABETES ASS'N (2007), <http://www.diabetes.org/advocacy-and-legalresources/healthcare/healthinsurance/faq.jsp#3>.

¹³⁰ William R. Vance, *Handbook on the Law of Insurance* 372 (3d. ed. 1951).

¹³¹ Eric Mills Holmes, *Solving the Insurance/Genetic Fair/Unfair Discrimination Dilemma in Light of the Human Genome Project*, 85 KY. L. J. 503, 546 (1997).

¹³² In states where insurance companies are allowed to underwrite their policies, companies already use diabetes as a way to classify the insured. Diabetes is statistically correlated with significantly increased medical costs, including the costs of monitoring and treating diabetes, and treating diabetes complications. So "discrimination" against individuals with diabetes in the health insurance industry is not new. In that sense, New York City's A1c reporting requirement will not overwhelmingly change the underwriting policies of the insurance industry. However, the A1c registry may affect the ability of persons with diabetes to obtain health insurance in less direct ways. New York's emphasis on the A1c test in particular could cause insurance companies to place greater emphasis on that data, especially if it becomes more readily available to them. Such an emphasis on the A1c test could unfairly harm individuals susceptible to false positives, or deceptively high scores on the A1c test. In addition, the studies that potentially flow from the collection of A1c data could reveal new correlations between diabetes and other characteristics, potentially informing future health insurance determinations. Although unlikely, family members of diabetics also could be unfavorably impacted by research stemming from the A1c registry. As pointed out *supra* at note 61, much recent focus in diabetes research has centered around studying whether diabetes is genetically transmissible. If diabetes is indeed linked to genetic transmission, insurance companies might plausibly use the existence of diabetes in one individual to insist on higher premiums for other family members. This fear, however, seems distant at best, both because the possibility of genetic links in diabetes is still largely unknown, and because unfavorable A1c tests alone—the only testing information the NYC registry explicitly measures—have an even more dubious connection to poor diabetes management among family members.

¹³³ N.Y. Ins. Law § 3231(a) (McKinney 2006).

residents cannot be charged higher rates because of their health conditions.¹³⁴ In addition, patients in employer-provided group plans, which may not be controlled by state law, receive similar protection under federal law. About half of New York City residents have employer-provided health insurance plans rather than individual policies.¹³⁵ Under ERISA, employer provided plans are also not allowed to turn down individuals or charge them more based on their health status.¹³⁶

Because New York residents cannot be denied individual or group insurance based on their health status, A1c notifications will not alter patients' insurability by enhancing their knowledge of their condition or even by informing them initially of their diabetes. Disclosure of A1c tests therefore would not jeopardize health insurance coverage.

b. Pre-Existing Condition Exclusions

A second health insurance issue implicated by A1c notifications is coverage for pre-existing conditions. Health insurance companies may seek to limit their risk of liability by excluding coverage for pre-existing health conditions. Such provisions are subject to state law requirements.¹³⁷

Under New York law, health insurers may only exclude coverage for certain pre-existing conditions: those for which medical advice, diagnosis, care or treatment was in fact recommended or received by the covered person during the six months immediately preceding

¹³⁴ *Id.*

¹³⁵ United Hospital Fund, Health Insurance Coverage in New York, 2002 (May 3 2004), http://www.uhfnyc.org/usr_doc/chartbook2004.pdf.

¹³⁶ *Employer-Sponsored Coverage*, AM. DIABETES ASS'N (2007), <http://www.diabetes.org/advocacy-and-legalresources/healthcare/healthinsurance/employer-sponsored.jsp>.

¹³⁷ Note, however, that 'self-insurers,' or employers that pay employee health care costs out of a fund that they set aside for that purpose, are not subject to state law under ERISA. 29 U.S.C. § 1144(b)(2)(A)-(B) (2006).

the enrollment date.¹³⁸ A health insurer may not exclude coverage based on pre-existing symptoms alone.¹³⁹ The A1c notification is designed to encourage recipients to seek and comply with medical advice, diagnosis, care or treatment. Thus, receipt of an A1c notification may make diabetes a ‘pre-existing condition’ if it is the first such recommendation that an individual has received.

As discussed above, it is unlikely that an A1c notification would serve as a patient’s first treatment recommendation, since the A1c test is commonly administered only after diabetes is diagnosed. However, in those cases in which the registry first alerts an individual to the need for diabetes treatment, that individual could face significant costs under certain new insurance policies. A new health insurer could refuse to cover the costs of diabetes treatment for up to one year.¹⁴⁰

4. Health Insurance and Employment Discrimination

Individuals with diabetes who obtain health insurance through their employers are also at risk of losing insurance coverage because of discrimination by their current or potential employers. Employment discrimination against individuals with disabilities can be motivated by concern for employee absence, poor performance, or by a desire to lower the costs of providing insurance. In recent years employers who provide health insurance coverage for employees have

¹³⁸ N.Y. Ins. Law § 3232(b) (McKinney 2006).

¹³⁹ Michael J. Camilleri & David J. Larkin, Jr., *Regulation of Accident and Health Insurers*, 3-35 BENDER’S N.Y. INS. LAW § 35.04 (LEXIS 2006) (citing *Bunk v. Blue Cross & Blue Shield*, 648 N.Y.S.2d 291 (N.Y. Sup. Ct. 1996), *aff’d as modified*, 668 N.Y.S.2d 121 (N.Y. App. Div. 1996)).

¹⁴⁰ N.Y. Ins. Law § 3232(b) (McKinney 2006) (individual and small group plans); *Employer-Sponsored Coverage*, *supra* note 135 (employer-sponsored plans). “The per capita annual costs of health care for people with diabetes rose from \$10,071 in 1997 to \$13,243 in 2002, an increase of more than 30%.” *Direct and Indirect Costs of Diabetes in the United States*, AM. DIABETES ASS’N (2007), <http://www.diabetes.org/diabetes-statistics/cost-of-diabetes-in-us.jsp>.

faced increasing insurance rates. Small business employers are especially affected by high insurance rates, since they do not benefit from the same discounted group rates as larger employers, and because one sick employee can substantially affect insurance rates for a small group of insured employees. Some employers have responded to increasing insurance costs by firing employees or declining applicants with a high risk of medical costs, such as those with diabetes.¹⁴¹

Federal and state laws do protect disabled individuals from employment discrimination. The Americans with Disabilities Act (“Act”) prohibits employers from discriminating against qualified individuals with disabilities by firing or refusing to hire them because of their disability.¹⁴² However, the Act protects only certain impaired individuals: those with physical or mental impairments that “substantially limit[] one or more ... major life activities,” those with a history of such an impairment, and those who have been regarded as having such an impairment.¹⁴³ The question of whether diabetes substantially limits major life activities is a factual determination made on a case by case basis.¹⁴⁴ Both New York State and New York City also have laws prohibiting adverse employment actions based on a disability.¹⁴⁵ The New York statutes provide greater protection because they define “disability” broadly instead of limiting

¹⁴¹ See Lisa Belkin, *Sick and Vulnerable, Workers Fear for Health and Their Jobs*, N.Y. TIMES, Dec. 17, 2005, at A1 (relating experiences of employees who were fired after becoming seriously ill); see also Milt Freudenheim & Robert Pear, *Health Hazard: Computers Spilling Your History*, N.Y. TIMES, Dec. 3, 2006, § 3, at 1 (describing risk of employment discrimination resulting from electronic storage of medical data).

¹⁴² 42 U.S.C. § 12112(a) (2007).

¹⁴³ 42 U.S.C. § 12102(2) (2007).

¹⁴⁴ U.S. Equal Employment Opportunity Commission, *Questions and Answers about Diabetes in the Workplace and the Americans with Disabilities Act (2003)*, <http://www.eeoc.gov/facts/diabetes.html>.

¹⁴⁵ Human Rights Law, N.Y. Exec. Law §§ 290-321 (Consol. 2007); N.Y. City Admin. Code § 8-102.

protection to those impairments that substantially limit a major life activity.¹⁴⁶ Additionally, prohibitions under New York State and City law apply to employers with four or more employees,¹⁴⁷ while the Act applies only to employers with fifteen or more employees.¹⁴⁸

Despite these protections, employment discrimination against individuals with diabetes persists.¹⁴⁹ Although the A1c registry notifications are not intended as notifications to employers, they could indirectly facilitate employment discrimination. Employers who are aware of the A1c registry might ask employees about whether they have received notifications or whether they are aware of their A1c level. Employers may inappropriately rely on A1c level data to determine whether to hire or retain an individual instead of concentrating on whether they can satisfy the job requirements.¹⁵⁰

5. Effect on Ability to Obtain Life Insurance or Disability Insurance

Much like health insurance in many states, life or disability insurance policies can charge higher premiums or reject applicants based on actuarial information.¹⁵¹ For a patient diagnosed

¹⁴⁶ N.Y. Exec. Law §§ 292(21), 296(1)(d) (defining disability to include any medically diagnosable condition); N.Y.C. Admin. Code § 8-102(16) (defining disability to include any “impairment of any system of the body”).

¹⁴⁷ N.Y. Exec. Law § 292(5); N.Y. City Admin. Code § 8-102(5).

¹⁴⁸ The Americans with Disabilities Act applies to employers with fifteen or more employees. 42 U.S.C. § 12111(5)(A) (2007).

¹⁴⁹ See, e.g., DiPol v. N.Y. City Transit Auth., 999 F. Supp. 309 (E.D.N.Y. 1998); Arena v. Agip U.S.A., No. 95-1529, 2000 U.S. Dist. LEXIS 2578 (S.D.N.Y. Mar. 7, 2000); Rubick v. Cattaraugus & Wyo. Counties Project Head Start, No. 00-0057E(F), 2000 U.S. Dist. LEXIS 15402 (W.D.N.Y. Oct. 4, 2000); Kelly v. N. Hempstead, 103 A.D.2d 767 (N.Y. App. Div. 1984).

¹⁵⁰ U.S. Equal Opportunity Employment Commission, The Americans with Disabilities Act:

A Primer for Small Business, Hiring Do’s and Don’ts—Pre-Job Offer (2004),

<http://www.eeoc.gov/ada/adahandbook.html#dodonts> (the Act allows employers to inquire about an applicant’s ability to perform job requirements but employers should not inquire about medical conditions and treatment).

¹⁵¹ The New York State Disability Benefits Law requires most employers to provide short-term disability insurance coverage to protect employees from loss of wages in the event that a disability is not covered through worker’s compensation. See Disability Benefits Law, N.Y. Workers’ Comp. Law § 200 et seq. (Consol. 2007); Edward I. Pitts et. al, *Private Long Term Disability Benefits*, 1-14 N.Y. Workers’ Compensation Handbook § 14.08

with diabetes, life or disability insurance can become considerably more expensive and extremely difficult to obtain.¹⁵² A1c levels, which indicate how well a patient is managing his, are a central factor for the life or disability insurance company.¹⁵³ As one insurance agent writes, disability insurance companies are looking for “Control, control, control!!!”¹⁵⁴ An unfavorable A1c level can be the deciding factor which precludes coverage or raises premiums.¹⁵⁵

Because high A1c levels (as opposed to just a diabetic condition) can be material to an insurer’s decision whether to enter into a contract with an applicant, an applicant’s fraudulent non-disclosure of such information can serve as a basis for the insurer to void the contract. For patients who are not otherwise aware of their diabetes diagnosis or their poor management of diabetes, a registry notification will create a new affirmative duty in the patient to disclose those newly learned material facts when applying for a new life or disability insurance policy. Such disclosure would adversely affect the patient’s ability to obtain insurance.¹⁵⁶

In sum, the A1c registry notification system can trigger negative insurance consequences for a diabetic. Receipt of a registry notification could constitute a recommendation for “medical advice, diagnosis, care or treatment,” and possibly invoke a pre-existing condition exclusion

(LexisNexis 2006). Thus, most New York state employers must provide short term disability insurance coverage to all of their employees—regardless of medical conditions such as diabetes. However, long-term disability insurance is not required under the statute, and insurance companies may charge higher premiums or deny coverage under such policies for high risk applicants, such as individuals with diabetes.

¹⁵² *Life Insurance Information for People with Diabetes*, AM. DIABETES ASS’N (2007), <http://www.diabetes.org/advocacy-and-legalresources/healthcare/lifeinsurance.jsp>.

¹⁵³ *Id*; Steve Crawford, *Obtaining Insurance for Diabetics About Disability Insurance*, (2001), <http://www.about-disability-insurance.com/diabetes.html>.

¹⁵⁴ Crawford, *supra* note 152.

¹⁵⁵ *Life Insurance Information*, *supra* note 151; Crawford; *supra* note 152.

¹⁵⁶ However, if the insurance company already requires A1c testing at the time of application, a diabetic’s duty to disclose his A1c level may be of little consequence. One commentator writes that such testing is required for diabetic applicants. Crawford, *supra* note 152.

under future health insurance plans. Despite federal and state law protections, employers may ask a diabetic about their A1c levels or A1c notifications and fire or refuse to hire them because of the heightened cost of insuring them. Further, a diabetic who receives notice of an unfavorable A1c level may then be required to disclose that information to disability or life insurers, who will likely charge more or refuse coverage. These results reflect the reality of an actuarially-based insurance system, where those with a high risk of medical costs, disability, or premature death must bear a greater burden in health, disability, or life insurance premiums. However, the potential loss of insurance or increase in insurance costs resulting from an A1c notification is disconcerting considering the mandatory nature of the A1c registry, which issues notifications without consent (unless a diabetic affirmatively opts out).

D. Detrimental Effects on the Physician-Patient Relationship Arising From the A1c Registry

Regardless of what disclosure protections may exist for diabetics, none run to physicians. In particular, nothing in New York's diabetes registry statute prevents the information in the registry from being used to generate aggregate data about individual physicians' patient populations. Depending on how that information is used, the registry could create incentives for doctors to over- or under-prescribe the A1c test, or to over-medicate patients with high A1c levels. These misuses of the A1c test would result in an erosion of patient confidence, and in turn, of the physician-patient relationship. Further, the existence of the A1c program itself might suggest to patients that doctors are incapable of properly treating diabetes, in which case patients could come to trust the notices from the NYDHMH regarding their A1c results in lieu of the advice of their own physicians. For a project whose ultimate goal is to help patients by assisting

their doctors, weakening the physician-patient relationship would be highly undesirable.

1. Possible Harmful Incentives Created by the A1c Registry

Section 13.04(c) of New York City's Health Code requires clinical laboratories to include the name and address of the doctor, along with specific patient information, with each test result reported to the NYDHMH for inclusion in the A1c Registry.¹⁵⁷ The statute goes on to address patient confidentiality regarding personal information, but prescribes no limits on the use of physician information.

Potentially, the registry could be used to create a list of doctors who have a high percentage of patients with elevated A1c levels. If so, the implications for doctors could be significant: doctors could be stigmatized or subjected to official discipline; some doctors may be seen as practicing poor medicine when they are actually just willing to take on more high risk patients; the registry could be used against doctors in malpractice suits; and the registry could lead to higher malpractice insurance premiums for doctors, depending on how poorly their patients are managing diabetes. The mere fact that all these concerns exist indicates that the registry may create powerful incentives for doctors to minimize their number of high-A1c patients.

One might argue that use of A1c levels to measure physician effectiveness is of minimal concern because patient A1c levels are so tenuously related to the skill level of individual doctors. At best, a doctor can prescribe medicine and give advice on lifestyle changes, but the ultimate decision to heed the advice of the doctors rests with the individual patients. Doctors in

¹⁵⁷ 24 RCNY Health Code Reg. § 13.04(c) (2005).

low income areas, or those who cater to populations with higher incidence of diabetes, will necessarily have greater numbers of patients with increased A1c levels, despite their best efforts to help these patients. Thus, because these numbers might tend to be misleading, one would assume that they would not be used to rank doctors.

This assumption, however, might not be valid. For example, similarly misleading information, in the form of malpractice payouts, is available to the public in individual physician profiles via the New Jersey Health Care Profile.¹⁵⁸ The website itself even admits that this information may be misleading, and notes that “malpractice payments may be made for any number of reasons that may not necessarily reflect negatively on the professional competence or conduct of a practitioner.”¹⁵⁹ Similarly, New York State has also made physician-specific medical malpractice information available to the public.¹⁶⁰

If information regarding medical malpractice payments by individual doctors has been deemed important to individual consumers as a comparative tool, despite the tenuous relationship between such payments and the actual skill level of the physician, then it is certainly conceivable that patient-population A1c scores might also be deemed informative. While there are no known plans as of yet to use the A1c data in this way, the possibility could create incentives for doctors to over-prescribe the test, under-prescribe the test, or over-medicate patients with high A1c levels in order to manipulate their number of patients with high A1c results.

¹⁵⁸ Office of the Attorney General, Division of Consumer Affairs, New Jersey Health Care Profile (2007), <http://12.150.185.184/dca>.

¹⁵⁹ *Id.*

¹⁶⁰ See *Professional Misconduct and Physician Discipline*, N.Y. STATE DEP'T OF HEALTH (2006), <http://www.health.state.ny.us/nysdoh/opmc/main.htm>; see also Rice, *Publishing Physician Profiles: What's Fair?*, MED. ECON. (Dec. 17, 2004), for a discussion of the public release of individual physicians' malpractice information.

If doctors are categorized based on the A1c performance of their patient population, then some physicians might also be tempted to prescribe the test to diabetic individuals whose blood sugar is well under control, in order to dilute the numbers of tests coming back with high A1c levels. An even more far-fetched, but still plausible, possibility is that doctors could prescribe the test to individuals who are not diabetic at all, in order to increase the number of their patients whose blood sugar is in control.

Alternatively, if doctors fear adverse action by state authorities because they have too many patients with high A1c results, they may begin to under-prescribe the test for those patients whose blood sugar is consistently out of control. If patients with high A1c values are not tested, then their results are not included in the registry, and thus the doctor's patient population appears healthier.

Additionally, if doctors were categorized based on the A1c performance of their patient population, doctors might also have an incentive to over-prescribe insulin (either in higher dosages or at more frequent intervals), in order to reduce the number of patients whose blood sugar is out of control. However, low blood sugar, and its dangerous side effects, may result when too much insulin is absorbed, and detrimental side effects may also occur at the site of injection. Additionally, some individuals have dangerous allergic reactions to insulin, and in severe cases may even lose consciousness.¹⁶¹ Besides insulin, doctors might prescribe other diabetes medicines, but these too may have dangerous side effects, including bloating, weight

¹⁶¹ *Insulin*, Drug Information Online (2007), <http://www.drugs.com/insulin.html>.

gain, leg swelling, liver disease, anemia, and difficulty breathing.¹⁶²

In any of the above situations, doctors would no longer be acting in the best interest of their patients, whether by prescribing unnecessary tests, failing to prescribe the test in situations where the results would be extremely valuable to the patient, or over-prescribing medications. If patients became aware of these actions, the physician-patient relationship would almost certainly suffer.

The physician-patient relationship could also suffer because of actions taken by the patient. If the diabetes registry causes patients to be concerned that their personal information will be turned over to the database, patient self-medication could pose another area of concern. In recent years patients have become increasingly involved in administering their own medications, and this will only increase if patients fear taking tests where the results must be recorded in a city-wide registry. It is particularly easy for diabetic patients to overdose, because diabetes often correlates with other medical problems, and patients may take medications for many different diseases.¹⁶³ The side effects of overdosing on insulin alone are extreme. Overdoses of insulin can result in hypoglycemia, seizures, coma, and other negative consequences.¹⁶⁴ Although less rare than accidental overdoses, intentional overdoses of insulin have also been reported.¹⁶⁵ Clearly, the effects of overdosing are extremely severe for diabetics. If the diabetes registry leads

¹⁶² National Diabetes Information Clearinghouse, *Medicines for People with Diabetes* (2002), http://diabetes.niddk.nih.gov/dm/pubs/medicines_ez/index.htm#5.

¹⁶³ *Taking Many Medications*, 19 *DIABETES SPECTRUM* 39-40 (2006); Batalis N. Prahlow, *Accidental insulin overdose*, 49 *J. FORENSIC SCI.* 5 (Sept. 2004).

¹⁶⁴ *Initiate Treatment Early to Avoid Fatality Following Antidiabetic Overdose*, 14 *DRUG THERAPY PERSP.* 13-16 (1999).

¹⁶⁵ *Id.*

patients to treat themselves and avoid consulting with their physicians, patients could suffer real harm.

Even those patients who are not concerned about the privacy implications of the registry may nonetheless have misgivings about their physicians because of the registry scheme. Patients could interpret the registry's implementation as the government's statement that physicians are not doing enough to combat the growing diabetes threat. Patient notifications from the NYDHMH, originally intended to aid physicians in working with their patients, might actually lead patients to distrust physician consultation. Again, the physician-patient relationship would suffer, this time from patients' unwillingness to cooperate with physicians.

2. Undue Reliance on the A1c Registry

Apart from harmful incentives caused by the registry, some physicians may simply focus inordinately on the registry notifications as opposed to actual test results. The notes immediately following § 13.04 suggest that the NYDHMH could use the A1c registry to generate a list for clinicians highlighting patients under poor control who may need intensified follow-up and therapy.¹⁶⁶ Further, the initial small-scale version of the registry, being implemented in South Bronx, will send letters to individual patients when their A1c levels are higher than eight percent and will provide daily alerts to physicians about which patients have elevated A1c levels.¹⁶⁷

Physicians may eventually come to rely on these notices, rather than the results of the A1c tests themselves, as diagnostic tools. The presence of a notice would indicate that a patient had

¹⁶⁶ 24 RCNY Health Code Reg. § 13.04 (notes section) (2005).

¹⁶⁷ Diana K. Berger & Lynn D. Silver, *Improving Diabetes Care for All New Yorkers*, NYC HEALTH, <http://www.nyc.gov/html/doh/downloads/pdf/diabetes/diabetes-presentation-a1c-registry.pdf>.

uncontrolled blood sugar, and the absence of a notice would indicate that a patient's blood sugar was under control, regardless of what the actual test results were. A common, seemingly harmless, mistake by a lab, either in sending an unnecessary notice or in failing to send a notice where required, might have devastating consequences if compounded by a physician's failure to verify the actual test results.

Detrimental reliance on the presence or absence of notices as a diagnostic tool has already presented itself in the area of newborn screening. All states have programs in place to test newborn infants for certain diseases in which early detection and treatment can benefit a child.¹⁶⁸ Problems have arisen, however, where physicians have come to assume that the tests have been conducted and the absence of any result means that the child is healthy. In particular, the Maryland Department of Health and Mental Hygiene has a webpage dedicated to the pitfalls of newborn screening for hereditary disorders, on which the primary mistake made by doctors is “[a]ssuming that the result of the newborn screening test is negative (or normal) because you have not heard otherwise.”¹⁶⁹

Despite these concerns, it should be noted that there is little evidence thus far that the Vermont Diabetes Information System (“VDIS”), upon which the New York City registry is based, has led to any of the behaviors described above. To date, only three patients in the VDIS have filed complaints, and all were resolved satisfactorily.¹⁷⁰ Nonetheless, the A1c registry's

¹⁶⁸ Lori B. Andrews et al., *Assessing Genetic Risks: Implications for Health and Social Policy*, Committee on Assessing Genetic Risks, Institute of Medicine, (The National Academies Press 1994).

¹⁶⁹ Brian K. Stallsmith, *Pitfalls in Newborn Screening* (2004), <http://www.dhmd.state.md.us/labs/html/NSpitfalls.html>.

¹⁷⁰ Benjamin Littenburg & Charles MacLean, *Passive Consent for Clinical Research in the Age of HIPAA*, 21 J.

lack of confidentiality provisions protecting physicians' privacy opens the door to counterproductive interference in the physician-patient relationship, and should be addressed accordingly.

III

In light of the increasingly epidemic nature of diabetes, and the detrimental health effects of the disease on its sufferers, the New York City A1c registry may be an initial step on the path toward better understanding and management of the disease. The information gathered by the registry may help determine which groups are most at risk, so that resources can be directed to those groups. Information in the registry also may further current research regarding the overall effects of the disease. However, gathering this wealth of information may also detrimentally affect diabetics and physicians, and therefore clear protections must be in place to ensure that diabetics and physicians are not harmed by creation of the registry.

Specifically, an amended statute should expressly guarantee confidentiality and security of patient data against use in court proceedings. The statute should also more explicitly protect against inappropriate use of patient information. Moreover, no use of private information, whether for notification or research, should be permitted without the affirmative consent of the patient. Secondary uses of the information, even for the purposes of epidemiological studies, could also harm diabetics by encouraging discrimination against certain groups who are found to be more prone to diabetes. Therefore patients should have the opportunity to withhold their

information from any use that was not disclosed at the time the information was initially provided. Finally, because of the concern that the registry will cause the physician-patient relationship to suffer, physicians' names should only be disclosed for purposes of notification. Other registries based on the New York City scheme will undoubtedly trigger distinct problems, but in light of the New York registry, we suggest the following changes to the current statutory framework.

1. We recommend that the statute expressly state that no information contained in the registry may be subject to a subpoena.
2. Any patient notification system should be based on affirmative consent, rather than on an opt-out system, in order to protect against unwanted notification and minimize the risk of delivery error.
3. Any use of private identifiable information for research purposes should be permitted only after affirmative consent of the patient. Patients should be afforded the opportunity to opt out of each subsequent use not substantially related to the purpose for which the initial consent was granted, even if private information is excised.
4. Both insurance companies and employers should be forbidden by law to ask that individuals disclose their A1c results on employment or insurance applications.
5. The Health Code should specifically protect physician privacy by preventing disclosure of physician names other than for purposes of notification.