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Whose Business Is Your Pancreas? Potential Privacy Problems in New York City's Mandatory Diabetes Registry

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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 nearly all diabetics in the city be stored in a centralized registry.¹ 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.² 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.³

New York City's program has not yet been implemented in its 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

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1. RULES OF THE CITY OF NEW YORK, HEALTH CODE tit. 24, § 13.04 (2003—2006).

2. *See id.* at n.1.

3. *See id.*; Ryung Suh, *An Aging Workforce: Health-Related Productivity and the Economic Value of Health Promotion*, MEDSCAPE PUB. HEALTH & PREVENTION, Aug. 2006, <http://www.medscape.com/viewarticle/543680>.

fully operational. We conclude in Part III with cautionary advice regarding future efforts to create public health registries.

PART I—DIABETES TESTING AND REGISTRIES

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 (“NYCDOHMH”).⁴ The city intends to use these test results to address the growing diabetes epidemic among its residents.⁵ 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.⁶ Physicians may also conduct an instantaneous test during patient appointments. However, these tests measure a diabetic’s blood sugar level only at the moment the test is taken.⁷ Moreover, instantaneous tests may produce false readings if the patient fails to administer the test properly.⁸ Even if the test is conducted at a doctor’s office, the diabetic’s blood sugar level may be abnormally high on any given day, in which case the results would not reflect an accurate depiction of the patient’s average blood sugar level.⁹

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 prior 120 days.¹⁰ Sugar in the diabetic’s blood stream binds to the hemoglobin in the red blood cells through a process called glycosylation.¹¹ Once the sugar binds to the hemoglobin, the sugar stays bound for the entire 120 day life of the red blood cell.¹² The greater the amount of sugar in the diabetic’s blood stream, the more hemoglobin binds with sugar, and

4. *See id.*

5. *See id.*

6. American Diabetes Association, A1C Test, <http://www.diabetes.org/type-1-diabetes/A1C-test.jsp> (last visited Nov. 14, 2007) [hereinafter, American Diabetes Association, A1C Test].

7. *Id.*

8. *Id.*

9. *Id.*

10. *Id.*

11. Diabetic Drug Store, The ABCs of Hemoglobin A1C Testing, <http://www.diabetestoolbox.com/HbA1C.asp> (last visited Sept. 16, 2007).

12. *Id.*

therefore the more hemoglobin becomes glycosylated.¹³ The A1C test measures the percentage of hemoglobin that has been glycosylated.¹⁴ This glycosylation level indicates the amount of glucose present in a diabetic's blood for the prior 120 days.¹⁵

Because the A1C test measures a diabetic's A1C level over a 120 day period, the test result is not affected by momentary spikes in the diabetic's blood sugar level.¹⁶ 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.¹⁷ The American Diabetes Association ("ADA") recommends that diabetics maintain a glycosylation (A1C) level below seven percent,¹⁸ and suggests that all diabetics receive the A1C test between two and four times per year.¹⁹ A diabetic patient may also submit a blood sample to his doctor or any certified lab for an A1C test.²⁰

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 NYCDOHMH.²¹ The Code requires each lab to submit the following information to NYCDOHMH²²:

- The full name, date of birth, and address of the diabetic.

13. *See id.*

14. *See* Nancy J. Nordenson, *Glycosylated Hemoglobin Test*, Blue Cross & Blue Shield of Mass., July 14, 1999, <http://www.ahealthyme.com/topic/a1ctest> (last visited Nov. 14, 2007).

15. *Id.*

16. American Diabetes Association, A1C Test, *supra* note 6.

17. *Id.*

18. American Diabetes Association, Checking Your Blood Glucose, <http://www.diabetes.org/type-2-diabetes/blood-glucose-checks.jsp> (last visited Nov. 14, 2007).

19. *Id.*

20. *See id.*

21. RULES OF THE CITY OF NEW YORK, HEALTH CODE tit. 24, § 13.04(c) (2003—2006).

22. RULES OF THE CITY OF NEW YORK, HEALTH CODE tit. 24, § 13.03(a) (2003—2006). *But cf.* The Joint Commission, Search Results: State of New York, General Laboratory Tests, http://www.qualitycheck.org/consumer/searchResults.aspx?ddstatelist2=NY&ddcitylist=-1&st_cd=&st=NY&st_nm=NEW+YORK&cty_nm=&cty_id=-1&careId=161&careIDtracker161 (last visited Nov. 14, 2007). There are over 100 laboratories in the State of New York that are outside the purview of the NYCDOHMH because they are located outside New York City; if New York City residents have their blood tests performed outside the city, they will not be included in the registry. *Id.*

- 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 NYCDOHMH.
- The name and address of the physician or clinical laboratory who submitted the blood specimen.
- The name and address of the clinical laboratory which performed the test.
- The date the test results were first available.
- The name(s) of any other tests performed in addition to the A1C test.²³

3. Implementation of the Diabetes Registry

New York City stores all the data required by Article 13 in the A1C registry.²⁴ The city hopes to use this data as a tool in learning to control diabetes and other related diseases.²⁵ 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.²⁶ 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).²⁷ 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.”²⁸

While New York City’s objective of controlling the diabetes epidemic is commendable, the scope of the initiative currently is quite limited. The NYCDOHMH has only three staff members and \$950,000 annually dedicated to controlling diabetes.²⁹ Moreover, diabetics who use a home

23. *Id.*

24. *See id.*

25. RULES OF THE CITY OF NEW YORK, HEALTH CODE tit. 24, § 13.04 n.1(2003—2006).

26. *Id.*

27. *Id.*

28. Diana K. Berger et al., *Diabetes Prevention and Management*, 24 CITY HEALTH INFORMATION 1, 2 (Jan. 2005), available at <http://home2.nyc.gov/html/doh/downloads/pdf/chi/chi24-1.pdf> [hereinafter Berger et al., *Diabetes Prevention and Management*]. *See also* RULES OF THE CITY OF NEW YORK, HEALTH CODE tit. 24, § 13.04 (2003—2006).

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

test will not be part of the registry.³⁰ The city is aware of this problem, but estimates that the registry will capture the test results of eighty to ninety-five percent of the city's diabetics.³¹ 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.³² 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 caring for diabetics (approximately \$132 billion annually).³³ The more diabetics learn to care for themselves, the less money the government needs to 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.³⁴ 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."³⁵ The city intends to use registry data to evaluate trends and:

- Plan programs in the Diabetes Prevention and Control Program;
- Measure outcomes of diabetes care, and thereby;
- Direct more efficient interventions to health care institutions, health care providers and people with diabetes.³⁶

The cornerstone of the registry plan is a notification system. Although the city intends eventually to install a city-wide notification program, it will initially implement the program only in the South Bronx.³⁷ Forty-eight thousand adults in the South Bronx have been diagnosed with diabetes, and twelve thousand of those adults are estimated to have an A1C level of

30. RULES OF THE CITY OF NEW YORK, HEALTH CODE tit. 24, § 13.03 (2003—2006).

31. Steinbrook, *supra* note 29, at 547.

32. Berger et al., *Diabetes Prevention and Management*, *supra* note 28, at 2.

33. *Id.* at 1.

34. *See* Steinbrook, *supra* note 29, at 546.

35. *Id.*

36. RULES OF THE CITY OF NEW YORK, HEALTH CODE tit. 24, § 13.04 n.1 (2003—2006).

37. Letter from Thomas R. 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> (last visited Nov. 14, 2007).

greater than nine percent.³⁸ The city plans to provide South Bronx physicians with a quarterly roster of their diabetic patients (stratified according to their patients' A1C level), along with recommendations for controlling patients' diabetes.³⁹ The city may also notify the patient of his deteriorating diabetic condition if his glycosylated hemoglobin value is above a certain level, and provide that individual with helpful information for alleviating high A1C levels.⁴⁰ Diabetics may opt out of receiving such information by submitting a "Do Not Contact" request to the city,⁴¹ but in the case of a diabetic minor, the city nonetheless may send the notice to the minor's parent or guardian.⁴²

The medical community's reaction to the registry has been mixed. Many in the medical community believe that the notification system will provide an important service to diabetic patients.⁴³ 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.⁴⁴ 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.⁴⁵ 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.⁴⁶

Conversely, others in the medical community are concerned that the registry could infringe upon patient privacy. For example, while the ADA

38. Steinbrook, *supra* note 29, at 547.

39. *Id.*

40. *Id.*

41. New York City Department of Health and Mental Hygiene, The New York City A1C Registry, <http://home2.nyc.gov/html/doh/html/diabetes/diabetes-nycar.shtml> (last visited Nov. 14, 2007).

42. Steinbrook, *supra* note 29, at 548.

43. See Letter from David M. Keepnews, Director, Office of Policy Development, New York Academy of Medicine, to Thomas R. Frieden, Commissioner, New York City Department of Health and Mental Hygiene, 1 (Aug. 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 (Aug. 16, 2005) (statements by Maria Pitaro, Associate Medical Director of UNITE Health Center) (transcript available at the New York City Department of Health and Mental Hygiene).

44. See Amy Fairchild, *Diabetes and Disease Surveillance*, 313 SCIENCE 175, 176 (2006).

45. Letter from David M. Keepnews, *supra* note 43, at 1.

46. See DIANA K. BERGER & LYNN D. SILVER, N.Y. CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE, IMPROVING DIABETES CARE FOR ALL NEW YORKERS (2005), <http://home2.nyc.gov/html/doh/downloads/pdf/diabetes/diabetes-presentation-a1c-registry.pdf> (noting that only ten percent of diabetics in New York know their A1C level).

endorses the “idea of helping people with diabetes better manage their disease,” it is also concerned that personal patient information may not remain private.⁴⁷ 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.⁴⁸ 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 information the program will generate, and argued that the registry will aggravate the problem of escalating health care costs.⁴⁹ 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.⁵⁰ This will substantially increase the workload for lab personnel, as they will frequently be required to contact doctors to obtain missing information.⁵¹ 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 (“AMA”) has not released an official statement commenting on the program.

B. History of Public Health Registries

To understand the novel aspects 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 monitoring of and intervention against specific diseases have become central features of public health systems in most developed countries.⁵² Registry systems designed to collect detailed data enabling governments to track and prevent dangerous diseases are one of the most widely-used forms of government monitoring.⁵³

47. Rob Stein, *New York City Starts To Monitor Diabetics*, WASH. POST, Jan. 11, 2006, at A3.

48. Letter from JoAnne Glisson, Senior Vice President, American Clinical Laboratory Association, to Rena Bryant, Secretary to the New York City Board of Health, 3 (Aug. 16, 2005), <http://www.clinical-labs.org/documents/A1cComment.pdf>.

49. *Id.* at 2-4.

50. *See id.* at 1.

51. *Id.* at 2.

52. Beate Ritz et al., *Can Lessons from Public Health Disease Surveillance Systems Be Applied to Environmental Public Health Tracking*, 113 ENVTL. HEALTH PERSP. 243, 243-44 (2005).

53. *See* Benedict C. Nwomeh et al., *History and Development of Trauma Registry: Lessons From Developed to Developing Countries*, WORLD J. EMERGENCY SURGERY, Oct. 2006, at 1. *See, e.g.*, National Committee on Vital Health Statistics, *Frequently Asked*

The vast majority of public health registries in the past century have focused on collection of infectious disease data. In the United States, for example, Congress authorized the Bureau of Census in 1902 to collect vital statistics data relating to diseases such as yellow fever, cholera, and small pox.⁵⁴ 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.⁵⁵ 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.⁵⁶ During the second half of the twentieth century, aggressive programs mandated tracking, screening and immunization for infectious diseases, including tuberculosis, measles, mumps, rubella, diphtheria, and polio.⁵⁷

The middle of the twentieth century also witnessed the creation and expansion of state cancer registries. In 1939, New York was one of the first states to begin collecting information on cancer diagnoses, though the program initially excluded New York City.⁵⁸ 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.⁵⁹ Currently, the New York cancer registry participates in the National Program of Cancer Registries, a federally funded and standardized network of state cancer registries that share data through the Center for Disease Control and Prevention.⁶⁰ As with infectious disease registries, a major

Questions About Medical and Public Health Registries, <http://www.ncvhs.hhs.gov/9701138b.htm> (last visited Nov. 14, 2007).

54. National Library of Medicine, Images from the History of Public Health Service, Introduction: Two Centuries of Health Promotion, Jan. 27, 2005, http://www.nlm.nih.gov/exhibition/phs_history/intro.html (last visited Nov. 14, 2007).

55. *Id.*

56. 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) [hereinafter Fairchild et al., *Public Goods, Private Data*].

57. See, e.g., Scott F. Wetterhall et al., *The Role of Public Health Surveillance: Information for Effective Action in Public Health*, 41 MMWR Suppl. 207, 209 (Dec. 1992). See also Centers for Disease Control & Prevention, *Achievements in Public Health, 1900-1999: Control of Infectious Diseases*, 48 MMWR 621, 624 (July 30, 1999).

58. New York Department of Health, About the New York Cancer Registry, Feb. 2007, <http://www.health.state.ny.us/statistics/cancer/registry/about.htm> (last visited Nov. 14, 2007).

59. *Id.*

60. Centers for Disease Control & Prevention, National Program of Cancer Registries, June 21, 2007, <http://www.cdc.gov/cancer/npcr> (last visited Nov. 14, 2007).

goal of the cancer registry was to identify and control environmental, occupational, and lifestyle factors that may contribute to higher cancer rates in different populations.⁶¹ 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.⁶²

As the government became ever more involved in monitoring and regulating public health, concerns for autonomy and privacy increased.⁶³ 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 an invasion of the traditional right of voluntary consent prior to use of private medical data.⁶⁴ Many feared that individually identifiable registry data would be used to disadvantage parties with infectious diseases, particularly diseases such as AIDS, which frequently provoked condemnation from the general public.⁶⁵ Although health officials generally stressed the confidentiality of disease registries, this confidentiality had limits.⁶⁶ The AMA Code of Medical Ethics has already acknowledged that "peculiar circumstances" could limit protection of confidentiality; in response to an increased emphasis on public knowledge, the AMA expanded its ethical code to recognize a duty to the general community.⁶⁷ 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.⁶⁸

The controversies developing over the past fifty or more years 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.⁶⁹ Even those who take the side of government intervention, however, justify such intrusion by citing the overwhelming

61. New York Department of Health, *supra* note 58.

62. *Id.*

63. Fairchild et al., *Public Goods, Private Data*, *supra* note 56, at 8.

64. *Id.* at 9. See also AMY L. FAIRCHILD, HISTORY AND HEALTH POLICY IN THE UNITED STATES—PUTTING THE PAST BACK IN 125–26 (Stevens et al., eds., Univ. of Cal. Press 2006).

65. Fairchild et al., *Public Goods, Private Data*, *supra* note 56, at 7, 9.

66. *Id.* at 8.

67. *Id.* See also Robert M. Gellman, *Prescribing Privacy: The Uncertain Role of the Physician in the Protection of Patient Privacy*, 62 N.C. L. REV. 255, 268–69 (1982).

68. Fairchild et al., *Public Goods, Private Data*, *supra* note 56, at 8.

69. *Id.* at 9.

need to halt the spread of infectious diseases or root out environmental and occupational health risks that pose serious threat to the surrounding community.⁷⁰ 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 United States to mandate collection of individual testing data in order to study the effectiveness of current treatment.⁷¹

Although diabetes registries have become more prevalent in the past decade, these registries bear important distinctions from the New York City plan. The Vermont Diabetes Information System ("VDIS"), for example, sponsored by the National Institutes of Health,⁷² 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),⁷³ 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.⁷⁴ Unlike the New York registry, however, the VDIS relies entirely on voluntary enrollment from hospitals and primary care practices,⁷⁵ and allows patients to opt out of participation in the registry altogether by calling a toll-free number.⁷⁶ The VDIS has also emphasized protecting patient data from questionable secondary uses.⁷⁷ For example, when registry officials wanted to analyze links between diabetes and socioeconomic characteristics, such as health education, literacy, and alcohol abuse,⁷⁸ the officials allowed researchers to obtain such personal

70. *Id.* at 11.

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

72. 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>.

73. *NYC Starts Diabetes Registry*, *supra* note 71. See also Steinbrook, *supra* note 29, at 547.

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

75. *Id.* at 594.

76. Benjamin Littenberg & Charles MacLean, *Passive Consent for Clinical Research in the Age of HIPAA*, 21 J. GEN. INTERNAL MED. 207, 209 (Mar. 2006) [hereinafter Littenberg & MacLean, *Passive Consent for Clinical Research*].

77. *Id.* at 208.

78. Benjamin Littenberg & Charles MacLean, *Intra-cluster Correlation Coefficients in Adults with Diabetes in Primary Care Practices: the Vermont Diabetes Information System Field Survey*, 6 BMC MED. RESEARCH METHODOLOGY 20 (May 3, 2006), available at <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1513389>.

information only after obtaining additional voluntary written consent from the registry patient whose data were subject to analysis.⁷⁹

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,⁸⁰ relies on voluntary reporting of all diabetes diagnoses by participating physicians.⁸¹ 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.⁸²

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 nearly all recorded incidents of diabetes in the entire county of Skaraborg (population 280,000).⁸³ Although the SDR mandates that all diabetic patients enroll, registry information is used only for purposes of aggregate data collection,⁸⁴ and any personal data or further contact with a patient depends upon affirmative consent from the patient.⁸⁵ 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.⁸⁶

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 been justified by the overriding need to protect the public from the spread of

79. *Id.*

80. Belgian Diabetes Registry, Homepage, <http://www.bdronline.be/index.php?n=55&id=55&taal=E> (last visited Nov. 14, 2007) (translated from the original French).

81. 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, 841 (2002).

82. Belgian Diabetes Registry, Projects, <http://www.bdronline.be/index.php?n=41&id=41&taal=E> (last visited Nov. 14, 2007) (translated from the original French).

83. Gunnar Stenström et al., *HLA-DQ Genotypes in Classic Type 1 Diabetes and in Latent Autoimmune Diabetes of the Adult*, 156 *AM. J. EPIDEMIOLOGY* 787, 788 (2002).

84. See Bo Berger et al., *The Prevalence of Diabetes in a Swedish Population of 280,411 Inhabitants*, 21 *DIABETES CARE* 546, 546 (1998) [hereinafter Berger et al., *The Prevalence of Diabetes*].

85. See *id.* See also Stenström et al., *supra* note 83, at 787.

86. Berger et al., *The Prevalence of Diabetes*, *supra* note 84, at 546. See also Stenström et al., *supra* note 83, at 788.

dangerous disease.⁸⁷ 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.⁸⁸ 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.⁸⁹ 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.

PART II—LEGAL AND ETHICAL PROBLEMS OF DIABETES REGISTRIES

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 was previously 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.⁹⁰ 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.⁹¹ Finally, physicians may also suffer if the registry information is disclosed in response to a public health investigation or lawsuit. These privacy problems are not yet endemic, but the potential for invasions is not unrealistic, 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

87. Fairchild et al., *Public Goods, Private Data*, *supra* note 56, at 8.

88. New York Department of Health, *supra* note 58.

89. Littenberg & MacLean, *Passive Consent for Clinical Research*, *supra* note 76, at 208; Belgian Diabetes Registry, *Projects*, *supra* note 82; Stenström et al., *supra* note 83, at 787.

90. FAM. CT. ACT, N.Y. JUDICIARY LAW § 1046(a)(vii) (McKinney 1999 & Supp. 2007); *People v. Gissendanner*, 399 N.E.2d 924 (N.Y. 1979); Steinbrook, *supra* note 29, at 546.

91. See WILLIAM R. VANCE, *HANDBOOK ON THE LAW OF INSURANCE* 372 (3d. ed., West Publishing Co. 1951).

York Court of Appeals in the case of *Schulman v. New York City Health & Hospital Corporation* and the United States Supreme Court, in *Whalen v. Roe*, upheld the creation of public health registries.⁹² In both cases, the courts used a rational basis standard of review,⁹³ and found that the statutes at issue advanced legitimate state interests.⁹⁴ 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.⁹⁵

Schulman involved a section of the New York City Health Code that required hospitals to file a special report listing each patient's name and address with the NYCDOHMH after any abortion procedure.⁹⁶ 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.⁹⁷ 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.⁹⁸ In this case, the court held that the registry's

92. *Whalen v. Roe*, 429 U.S. 589, 603–04 (1977); *Schulman v. N.Y.C. Health & Hosp. Corp.*, 342 N.E.2d 501, 507 (N.Y. 1975).

93. *Whalen*, 429 U.S. at 597–98; *Schulman*, 342 N.E.2d at 506–07. *But see Doe v. Poritz*, 662 A.2d 367, 406 (N.J. 1995) (applying an intermediate standard of review).

94. *Whalen*, 429 U.S. at 598; *Schulman*, 342 N.E.2d at 504.

95. *See, e.g., Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260, 1269 (9th Cir. 1998) (holding 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)). *But 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 (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.").

96. *Schulman*, 342 N.E.2d at 236.

97. *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").

98. *Whalen*, 429 U.S. at 592–94.

purpose to “aid in the enforcement of laws designed to minimize the misuse of dangerous drugs” amounted to a legitimate state interest that took precedence over individual patients’ privacy concerns.⁹⁹

Furthermore, 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, neither statute interfered with decision-making by patients or doctors, but merely required reporting of actions already taken.¹⁰⁰ Second, both statutes included express confidentiality provisions protecting patient information from public disclosure.¹⁰¹

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 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 survive a constitutional challenge.¹⁰² Like the statutes at issue in both *Whalen* and *Schulman*, § 13.04 of New York City’s Health Code 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.¹⁰³ 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.¹⁰⁴

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

99. *Id.* at 598.

100. *Id.* at 603; *Schulman*, 342 N.E.2d at 240–41.

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

102. *See also* Rollins v. Ulmer, 15 P.3d 749, 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); Ark. Dep’t of Human Serv. v. Heath, 848 S.W.2d 927, 928 (Ark. 1993) (holding that registry for unsubstantiated allegations of child abuse is permissible).

103. *See* RULES OF THE CITY OF NEW YORK, HEALTH CODE tit. 24, § 13.04(d) (2003-2006).

104. RULES OF THE CITY OF NEW YORK, HEALTH CODE tit. 24, § 13.04 n.1 (2003-2006).

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.¹⁰⁵ As one diabetic man stated, “I was regarded as a damaged piece of meat. . . . It was like, ‘You’re one of those, and we can’t have one of those.’”¹⁰⁶ Numerous lawsuits have claimed that employers, school officials, and others denied diabetics fair opportunities in work and school.¹⁰⁷ Some diabetics have faced difficulty when requesting 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.¹⁰⁸

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.¹⁰⁹ Until 2003, insulin-dependent diabetics were not allowed to obtain commercial driver’s licenses because aggregate data suggested that they are more likely to be involved in accidents.¹¹⁰ Similarly, until 2006, the National Fire Protection Association did not recommend hiring insulin-dependent diabetics.¹¹¹

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.¹¹² Given that confidentiality provisions in other New York registries are rarely absolute, one could infer that the drafters purposely

105. American Diabetes Association, Legal Advocacy at ADA, <http://www.diabetes.org/advocacy-and-legalresources/discrimination/advocacy.jsp> (last visited Nov. 14, 2007).

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

107. See American Diabetes Association, Employment Cases Dealing with Discrimination on the Basis of Diabetes, Aug. 11, 2006, <http://www.diabetes.org/uedocuments/CaseList0806.pdf> (last visited Nov. 14, 2007).

108. Kleinfeld, *supra* note 106, at 1.

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

110. American Diabetes Association, Frequently Asked Questions About Commercial Driver’s Licenses, <http://www.diabetes.org/advocacy-and-legalresources/discrimination/CDLFAQ.jsp> (last visited Nov. 14, 2007).

111. Kleinfeld, *supra* note 106, at 1.

112. RULES OF THE CITY OF NEW YORK, HEALTH CODE tit. 24, § 13.04 (2003-2006).

removed any mention of exceptions to the confidentiality requirement in the diabetes registry statute. On its face, therefore, the provision is absolute, brooking no exceptions.

The Health Insurance Portability Act of 1996 (“HIPAA”) regulations are also aimed at limiting the disclosure of a patient’s individually-identifiable medical information (“IIM”).¹¹³ The HIPAA regulations, however, do not prohibit NYCDOHMH from collecting patient information and using it for research. The regulations prevent “covered entities” like health plans, health care clearinghouses, and health care providers from disclosing a patient’s IIM without their consent.¹¹⁴ The covered entities, however, are exempted from seeking patients’ consent when the covered entities are disclosing their IIM to a public health authority for the purpose of conducting public health surveillance, public health investigations, and public health interventions.¹¹⁵ HIPAA regulations define public health authority as “an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency . . . that is responsible for public health matters as part of its official mandate.”¹¹⁶ NYCDOHMH claims to be a hybrid entity that has a health care provider component and a public health authority component.¹¹⁷ Courts are likely to view part of NYCDOHMH as a public health authority because NYCDOHMH is responsible for public health matters in New York City. Therefore, the NYCDOHMH public health authority component correctly claims to be exempted from seeking patients’ consent for collecting their IIM for conducting public health surveillance. Moreover, because NYCDOHMH claims to be a public health authority, HIPAA does not require public health providers to seek the patient’s consent for disclosing the patient’s IIM to NYCDOHMH. Additionally, the HIPAA regulations do not require the NYCDOHMH to seek patients’ consent before using their IIM for research purposes as long as the NYCDOHMH seeks approval from its institutional review board (“IRB”) or a privacy board.¹¹⁸ In giving approval, the board weighs the patient’s privacy interest

113. See 45 C.F.R. § 164.514 (2006).

114. See *id.* § 164.506.

115. See *id.* § 164.512.

116. See *id.* § 164.501.

117. New York City Department of Health and Mental Hygiene, Notice of Privacy 1, Apr. 14, 2003, <http://www.nyc.gov/html/doh/downloads/pdf/public/hipaa.pdf> (last visited Nov. 14, 2007).

118. See 45 C.F.R. § 164.512(i)(1)(i) (2007).

against the importance of the research and the steps taken to minimize the risks to the patient's privacy.¹¹⁹

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, 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.¹²⁰ The New York City Health Code provision stating that such information "shall not be subject to subpoena" has been interpreted by the New York Court of Appeals as providing absolute confidentiality.¹²¹ The diabetes registry, on the other hand, lacks such an explicit provision, and therefore the unconditional nature of its protection against subpoena is questionable.¹²²

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 other judicial contexts.¹²³ 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.¹²⁴ Courts have also bypassed statutory evidentiary rules, permitting admission of evidence which in other contexts would be barred by the Fourth Amendment exclusionary rule.¹²⁵ If courts or legislators determine that the new AIC Registry confidentiality provision should be waived in the same manner as physician-patient and other privileges, family law proceedings could be directly impacted.

Information in the AIC 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,¹²⁶ it is plausible that a family law court would desire information on an individual's AIC level. In at least one case, a court took diabetic

119. See 45 C.F.R. § 164.512(i)(2)(ii)(A)-(C) (2007).

120. RULES OF THE CITY OF NEW YORK, HEALTH CODE tit. 24, § 11.07(a)-(b) (2006).

121. *In re Baker's Mut. Ins. Co. of N.Y.*, 92 N.E.2d 49, 50-51 (N.Y. 1950).

122. See RULES OF THE CITY OF NEW YORK, HEALTH CODE tit. 24, § 13.04 (2003—2006).

123. *In re Doe Children*, 402 N.Y.S.2d 958, 959-60 (Fam. Ct. 1978).

124. FAM. CT. ACT, N.Y. JUDICIARY LAW § 1046(a)(vii) (McKinney 1999 & Supp. 2007).

125. See *In re Cassandra R.*, 504 N.Y.S.2d 602, 603 (Fam. Ct. 1986).

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

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.¹²⁷ 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.¹²⁸

It is also conceivable that a violation of confidentiality might arise in the context of a criminal proceeding, where a defendant could invoke his or her Sixth Amendment right to confront a witness, permitting the defendant to obtain the otherwise confidential information of a third party.¹²⁹ 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

Despite the confidentiality provisions, New York public health authorities may disclose private information to researchers. New York City officials stated at the time the registry was established that the information to be obtained would be invaluable in studying and preventing further incidence of the disease.¹³⁰ 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 information on weight. Health officials would need to review each diabetic's medical file to get the type of information that would be beneficial to understanding the course of the disease. Indeed, New York authorities noted that they were modeling the city's approach on the Vermont program, in which more data than mere A1C levels were assessed.¹³¹ It is thus reasonable to conclude that despite the confidentiality provision, city officials may well intend to permit researchers to analyze

127. *Florence B. v. Carol M.*, 576 N.Y.S.2d 981, 988–89 (Fam. Ct. 1991).

128. *In re Mark R.*, No. B185475, 2005 WL 3418252, at *9 (Cal. Ct. App. Dec. 14, 2005); *In re Brinkman*, No. 259377, 2005 Mich. App. LEXIS 1204, at *2–4 (May 12, 2005); *Anna Mae B. v. Harold H.*, 488 N.Y.S.2d 112, 112, (N.Y. App. Div. 1985); *In re John W.*, 682 A.2d 930, 931–32 (R.I. 1996).

129. *See, e.g., People v. Gissendanner*, 399 N.E.2d 924 (N.Y. 1979).

130. *See id.* at n.1. *See also Steinbrook, supra* note 29, at 546.

131. Littenberg & MacLean, *Passive Consent for Clinical Research, supra* note 76, at 208.

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.

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.¹³² 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.¹³³ If more than one address is on record, or a notification is returned, staff will become involved to a greater extent. Therefore, the notification plan itself strongly suggests that city authorities will not keep the information completely confidential.

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 ago for medical purposes. Personally identifiable samples were supposed to be used only with the consent of the person involved, but the Swedes were dismayed to learn that the registry was used for forensic purposes in the Anna Lindh murder investigation without their consent.¹³⁴ The extent of confidentiality pledged under the city scheme is similarly in question.

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.

Because all of the A1C registry data is transferred and stored electronically, the NYCDOHMH must guard against hackers who may break into the A1C registry, 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

132. Frieden, *supra* note 37.

133. See RULES OF THE CITY OF NEW YORK, HEALTH CODE tit. 24, § 13.04 (2003-2006).

134. See Klaus Hoeyer, *Biobanks and Informed Consent in Umeå University Medical Dissertations New Series No. 929*, at 17 (Nov. 12, 2004) (on file with Umeå University Library), available at <http://www.diva-portal.org/umu/theses/abstract.xsql?dbid=358>. See generally Claudia Mund, *Biobanks—Data Sources without Limits?* (Sept. 15, 2005), http://www.privacyconference2005.org/fileadmin/PDF/mund_e.pdf.

military installation databases.¹³⁵ In other instances, agency employees themselves have illegally sold the information for a small profit.¹³⁶ 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.

Although New York City has promised confidentiality in its notification program, the possibility remains that an AIC test notification could be mishandled. 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 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 AIC results.

Because the city notifies parents of the AIC 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.¹³⁷ 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.¹³⁸ It is not 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

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

136. Associated Press, *Uh, Folks, Your Data was Swiped*, WIRED, May 23, 2005, available at <http://www.wired.com/politics/security/news/2005/05/67616>.

137. N.Y. PUB. HEALTH LAW § 18(2)(c) (McKinney 2007).

138. N.Y. PUB. HEALTH LAW § 2504(1) (McKinney 2007); N.Y. C.P.L.R. § 4504(a) (McKinney 2007).

is removed. Reports collected under New York's regulatory scheme create a treasure trove of information for both public health 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.¹³⁹ 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.¹⁴⁰ 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.¹⁴¹ In another case, *Washington University v. Catalona*, the Eighth Circuit decided that tens of thousands of tissue samples collected for prostate cancer research could be used by the collecting university for unrelated purposes.¹⁴² 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.¹⁴³

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 purposes. Prior to New York 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 of information contained in an A1C registry.¹⁴⁴ 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.¹⁴⁵ The Task Force

139. BERGER & SILVER, *supra* note 46.

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

141. *Id.* (discussing *Havasupai Tribe v. Ariz. St. Univ.*, No. 3:04-CV-1494 (D.Ariz. 2004); *Tilousi v. Ariz. St. Univ.*, No. 3:04-CV-1290 (D.Ariz. 2004); *Tilousi v. Ariz. St. Univ.*, No. 2:04-CV-1290 (D.Ariz. 2004)).

142. *Wash. Univ. v. Catalona*, 490 F.3d 667, 676–77 (8th Cir. 2007).

143. *See* Lori B. Andrews, *supra* note 140, at 10–11.

144. *See* 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> (last visited Nov. 14, 2007).

145. *Id.* at 15–16.

explicitly addressed the potential for use of A1C registry information in research studies when it set the goal of obtaining aggregate statistics to track diabetes risk.¹⁴⁶ Such goals are only attainable if researchers conduct additional studies with the inclusion of personal identifying information such as 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.¹⁴⁷ Among other purposes, the aggregate statistics are used by the CDC to identify risk groups.¹⁴⁸ Aggregate data are grouped for reports based on age, ethnicity, race, poverty level, and region of the country.¹⁴⁹ 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,¹⁵⁰ 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.¹⁵¹

The New York State Cancer Registry, which tracks more than one hundred pieces of information including race, gender, place of birth, and

146. *Id.*

147. Pamela A. Meyer et al., *Surveillance for Elevated Blood Lead Levels Among Children—United States, 1997-2001*, Centers for Disease Control & Prevention, Sept. 12, 2003, <http://www.cdc.gov/MMWR/preview/mmwrhtml/ss5210a1.htm> (last visited Nov. 14, 2007).

148. *Id.*

149. *Id.*

150. RULES OF THE CITY OF NEW YORK, HEALTH CODE tit. 24, § 11.07(d) (2006) (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).

151. ACOSTA ET AL., *supra* note 144, at 15. *See also* Diabetes in California Task Force, California’s Plan for Diabetes, 2003-2007, 7, http://www.caldiabetes.org/content_display.cfm?contentID=91&categoryID=10 (last visited Oct. 23, 2007) (California already uses epidemiological information obtained from diabetics in scientific and medical studies in the California Diabetes Program); Division of Research at Kaiser Permanente, Diabetes Registry, <http://www.dor.kaiser.org/studies/diabetes/Diabetes-06.shtml> (last visited Nov. 14, 2007) (the Kaiser Permanente insurance group maintains a registry of all residents with diabetes in the Northern California region as part of the California Diabetes Registry, and information in the registry has been used to facilitate a series of epidemiologic and health service projects).

ethnicity,¹⁵² 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.¹⁵³ 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 information such as street-by-street and residence-by-residence cancer incidence and detailed family and occupational histories.¹⁵⁴

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 occupation. 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 past¹⁵⁵ 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 are also more likely to have higher A1C levels even if they are not diabetic.¹⁵⁶

Full disclosure of all permissible research purposes should be made prior to collection of the identifying characteristic information needed for studies

152. New York Department of Health, About the New York State Cancer Registry, Feb. 2007, <http://www.health.state.ny.us/statistics/cancer/registry/about.htm> (last visited Nov. 14, 2007).

153. New York Department of Health, New York State Cancer Registry, June 2007, <http://www.health.state.ny.us/statistics/cancer/registry> (last visited Nov. 14, 2007).

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

155. See, e.g., Kleinfield, *supra* note 106 at 1; *Kapche v. City of San Antonio*, 304 F.3d 493, 493 (5th Cir. 2002).

156. 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, 187 (Apr. 14, 2005).

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 produce 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 could 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.¹⁵⁷

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.¹⁵⁸ The A1C 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.¹⁵⁹ 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.¹⁶⁰

157. In addition to insurability implications, other undesired consequences may also flow from the use of individualized notifications. For example, 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, though misleading to others. *How Advertising Affects Prescriptions*, 22 Harvard Mental Health Letter, Issue 2, August 2005, at 7. See also Richard L. 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). Although 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.

158. American Diabetes Association, A1C Test, *supra* note 6 (although the A1C test is generally used to monitor blood sugar levels of diagnosed diabetics, doctors could use the A1C test as an initial diagnosis, in which case a warning letter regarding high A1C levels would serve as the patient's first notification that he has diabetes. Such a notification raises important policy implications wholly separate from the insurability issue).

159. American Diabetes Association, *Standards of Medical Care in Diabetes-2006*, 29

Registry notice of an unfavorable A1C level would most often notify patients that their blood sugar levels have not been properly maintained.¹⁶¹ 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.¹⁶²

Despite the importance of A1C levels in monitoring blood sugar levels, one New York City Health Department study found that only eleven percent of people with diabetes in New York State were aware of their A1C level.¹⁶³ 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 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 an individual policy because of the insured's change in health status.¹⁶⁴ In addition, an insurer would likely have access to A1C test results regardless of whether that information is tracked in the registry.¹⁶⁵ Health insurance companies have broad rights to inspect medical information in order to evaluate medical claims.¹⁶⁶ Therefore, patients' subjective knowledge of their A1C

DIABETES CARE Supp. 1, S4, S4 (Jan. 2006).

160. *Id.* at S9 – S10; American Diabetes Association, A1C Test, *supra* note 6.

161. RULES OF THE CITY OF NEW YORK, HEALTH CODE tit. 24, § 13.04 n.1 (2003—2006) (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 120 days).

162. *Id.*

163. L. E. Thorpe et al., *Diabetes is Epidemic*, 2 NYC VITAL SIGNS Vol. 2, 1–4 (Jan. 2003), available at <http://www.nyc.gov/html/doh/downloads/pdf/survey/survey-2003diabetes.pdf>.

164. N.Y. INS. LAW § 3216(g)(1)(F) (McKinney 2007). *But cf.* 29 U.S.C. § 1144(b)(2)(A)-(B) (2006) (noting 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).

165. American Diabetes Association, Commonly Asked Questions about Health Insurance, <http://www.diabetes.org/advocacy-and-legalresources/healthcare/healthinsurance/faq.jsp#3> (last visited Oct. 27, 2007) [hereinafter American Diabetes Association, Commonly Asked Questions].

166. *Id.*

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

On the other hand, 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 the applicant, and which benefits to offer.¹⁶⁷ In many states, diabetes is a condition for which most medical underwriters will automatically deny coverage.¹⁶⁸ However, it should be noted that employer sponsored group health insurance plans are subject to consumer protection against individual underwriting.¹⁶⁹ 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 in regards to their application.¹⁷⁰ 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.¹⁷¹ Both a diagnosis of diabetes and an unfavorable A1C level would be considered material facts pertinent to insurance underwriters.¹⁷²

167. Karen Pollitz et al., *Falling through the Cracks: Stories of How Health Insurance Can Fail People with Diabetes*, 8, Feb. 8, 2005, <http://web.diabetes.org/Advocacy/healthresearchreport0505.pdf>.

168. American Diabetes Association, *Commonly Asked Questions*, *supra* note 165.

169. American Diabetes Association, *Employer-Sponsored Coverage*, <http://www.diabetes.org/advocacy-and-legalresources/healthcare/healthinsurance/employer-sponsored.jsp> (last visited, Oct. 23, 2007) [hereinafter American Diabetes Association, *Employer-Sponsored Coverage*].

170. See VANCE, *supra* note 91, at 372.

171. 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).

172. See VANCE, *supra* note 91, at 372. Because some companies already use diabetes information in their underwriting, New York City's A1C reporting requirement will not overwhelmingly change these practices. 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. Also, if diabetes is linked to genetic transmission, insurance companies might plausibly use the existence of diabetes in

However, New York law provides that residents cannot be refused an individual or small group health insurance policy because of a health condition.¹⁷³ New York law also requires “community rating” of individual and small group health insurance policies to ensure that residents cannot be charged higher rates because of their health conditions.¹⁷⁴ In addition, patients in employer-provided group plans, which may not be controlled by state law, receive similar protection under federal law.¹⁷⁵ About half of New York City residents have employer-provided health insurance plans; the other half have individual plans, are insured through public programs, or are uninsured.¹⁷⁶ Under ERISA, employer provided plans are also not allowed to turn down individuals or charge them more based on their health status.¹⁷⁷

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.¹⁷⁸

Under New York state 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 the enrollment date.¹⁷⁹ A health insurer may not exclude coverage based on

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. *Id.*

173. N.Y. INS. LAW § 3231(a) (McKinney 2007).

174. *Id.*

175. American Diabetes Association, Employer-Sponsored Coverage, *supra* note 169.

176. Danielle Holahan et al., *Health Insurance Coverage in New York, 2002*, 3, May 3, 2004, http://www.uhfnyc.org/usr_doc/chartbook2004.pdf.

177. American Diabetes Association, Employer-Sponsored Coverage, *supra* note 169.

178. 29 U.S.C. § 1144(b)(2)(A)-(B) (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).

179. N.Y. INS. LAW § 3232(b) (McKinney 2006).

pre-existing symptoms alone.¹⁸⁰ 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 notice 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.¹⁸¹

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.¹⁸² 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.¹⁸³ In recent years employers who provide health insurance coverage for employees have faced increasing insurance rates.¹⁸⁴ Small business employers can be especially affected by high insurance rates, since they usually 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.¹⁸⁵ Some employers throughout the U.S. have responded to increasing insurance costs by firing employees or declining applicants with

180. Michael J. Camilleri & David J. Larkin, Jr., *Regulation of Accident and Health Insurers*, BENDER’S N.Y. INS. LAW § 35.04 (Lawrence A. Kaplan ed., 1999) (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)).

181. N.Y. INS. LAW § 3232(b) (McKinney 2006) (individual and small group plans); American Diabetes Association, *Employer-Sponsored Coverage*, *supra*, note 169; American Diabetes Association, *Direct and Indirect Costs of Diabetes in the United States*, <http://www.diabetes.org/diabetes-statistics/cost-of-diabetes-in-us.jsp> (last visited Oct. 23, 2007) (“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%”).

182. See Kleinfeld, *supra* note 106.

183. See *id.*

184. See Lisa Belkin, *Sick and Vulnerable, Workers Fear for Health and Their Jobs*, N.Y. TIMES, Dec. 17, 2005, at A1.

185. *Id.*

a high risk of medical costs, such as those with diabetes.¹⁸⁶ However, the risk of such employment discrimination by a small business employer is lessened in New York. State law requires insurers to use community rating for small group health insurance plans.¹⁸⁷ Thus, New York protects small businesses from suffering escalating insurance costs based on the medical experience of a few of its employees.

Federal and state laws 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.¹⁸⁸ 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.¹⁸⁹ The question of whether diabetes substantially limits major life activities is a factual determination made on a case by case basis.¹⁹⁰ Both New York State and New York City also have laws prohibiting adverse employment actions based on a disability.¹⁹¹ The New York statutes provide greater protection because they define “disability” broadly instead of limiting protection to those impairments that substantially limit a major life activity.¹⁹² Additionally, prohibitions under New York State and city law apply to employers with four or more employees,¹⁹³ while the Act applies only to employers with fifteen or more employees.¹⁹⁴

Despite these protections, employment discrimination against individuals

186. *See id.* (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).

187. *See* N.Y. INS. LAW §3231(a) (McKinney 2007) (requiring community rating of individual and small group plans); N.Y. COMP. CODES R. & REGS. tit. 11, § 360.2 (2001) (defining small group plans as those covering between two and fifty member employees).

188. 42 U.S.C.A. § 12112(a) (West 2006).

189. 42 U.S.C.A. § 12102(2) (West 2006).

190. U.S. Equal Employment Opportunity Commission, Questions and Answers about Diabetes in the Workplace and the Americans with Disabilities Act, Oct. 29, 2003, <http://www.eeoc.gov/facts/diabetes.html>.

191. *See generally* N.Y. EXEC. LAW §§ 290-21 (McKinney 2005); N.Y., N.Y. ADMIN. CODE tit. 8, § 102 (2007).

192. *See* N.Y. EXEC. LAW §§ 292(21), 296(1)(d) (McKinney 2007) (defining disability to include any medically diagnosable condition); N.Y., N.Y. ADMIN. CODE tit. 8, § 102(16) (2007) (defining disability to include any “impairment of any system of the body”).

193. N.Y. EXEC. LAW § 292(5) (McKinney 2007); N.Y., N.Y. ADMIN. CODE tit. 8, § 102(5) (2007).

194. 42 U.S.C.A. § 12111(5)(A) (2006) (the Americans with Disabilities Act applies to employers with fifteen or more employees).

with diabetes persists.¹⁹⁵ 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.¹⁹⁶

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

As with health insurers in many states, life or disability insurance companies can charge higher premiums or reject applicants based on actuarial information.¹⁹⁷ For a patient diagnosed with diabetes, life or disability insurance can become considerably more expensive and extremely difficult to obtain.¹⁹⁸ A1C levels, which indicate how well a patient is managing his diabetes, are a central factor for the life or disability insurance company.¹⁹⁹ As one insurance agent writes, disability insurance companies are looking for “[c]ontrol, control, control!!!”²⁰⁰ An unfavorable A1C level can be the deciding factor which precludes coverage or raises premiums.²⁰¹

195. See, e.g., *Rubick v. Cattaraugus & Wyo. Counties Project Head Start*, No. 00-CV-0057E(F), 2000 U.S. Dist. LEXIS 15402, at *12 (W.D.N.Y. Oct. 5, 2000); *Arena v. Agip U.S.A. Inc.*, No. 95 Civ. 1529, 2000 U.S. Dist. LEXIS 2578, at *1 (S.D.N.Y. Mar. 8, 2000); *DiPol v. N.Y. City Transit Auth.*, 999 F. Supp. 309, 315 (E.D.N.Y. 1998); *Kelly v. Town of N. Hempstead*, 103 A.D.2d 767 (N.Y. App. Div. 1984).

196. See generally 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*, Feb. 4, 2004, <http://www.eeoc.gov/ada/adahandbook.html#dodonts> (the Americans with Disabilities Act allows employers to inquire about an applicants ability to perform job requirements but employers should not inquire about medical conditions and treatment) (last visited Nov. 14, 2007).

197. American Diabetes Association, *Life Insurance Information for People with Diabetes*, <http://www.diabetes.org/advocacy-and-legalresources/healthcare/lifeinsurance.jsp> (last visited Nov. 14, 2007) [hereinafter American Diabetes Association, *Life Insurance Information*]. See generally N.Y. WORKERS' COMP. LAW §§ 200–206 (McKinney 2006); Edward I. Pitts & Ronald E. Weiss 1–14 N.Y. Workers' Compensation Handbook § 14.08 (LexisNexis 2006). The New York State Disability Benefits Law requires most employers to provide short-term disability insurance coverage to protect employees from loss of wages (regardless of medical conditions such as diabetes) in the event that a disability is not covered through worker's compensation. 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. *Id.*

198. See American Diabetes Association, *Life Insurance Information*, *supra* note 197.

199. *Id.*; Steve Crawford, *Obtaining Insurance for Diabetics*, <http://www.about-disability-insurance.com/diabetes.html> (last visited Nov. 14, 2007).

200. Crawford, *supra* note 199.

201. See American Diabetes Association, *Life Insurance Information*, *supra* note 197;

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.²⁰² 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.²⁰³ However, if the insurance company already requires A1C testing at the time of the application, a diabetic's duty to disclose his A1C level may be of little consequence.

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 under future health insurance plans.²⁰⁴ Despite federal and state law protections, employers may ask diabetics 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.²⁰⁵ 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 apply 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

Crawford, *supra* note 199.

202. VANCE, *supra* note 91, at 372.

203. See generally Crawford, *supra* note 199 (stating that insurance companies will perform the A1C test on diabetics at the time of application).

204. N.Y. INS. LAW § 3232(b) (McKinney 2006).

205. American Diabetes Association, Life Insurance Information, *supra* note 197; American Diabetes Association, Commonly Asked Questions, *supra* note 165.

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 NYCDOHMH 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 NYCDOHMH for inclusion in the A1C Registry.²⁰⁶ The statute goes on to address patient confidentiality regarding personal information, but prescribes no limits on the use of physician information.²⁰⁷

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 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

206. *Id.*

207. RULES OF THE CITY OF NEW YORK, HEALTH CODE tit. 24, § 13.04(d) (2003-2006).

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, the New Jersey Health Care Profile provides similarly misleading information, in the form of malpractice payouts. This information is available to the public in individual physician profiles via the New Jersey Health Care Profile.²⁰⁸ The website even states 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.”²⁰⁹ Similarly, the State of New York has also made physician-specific medical malpractice information available to the public.²¹⁰

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.

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.

208. Office of the Attorney General, Division of Consumer Affairs, New Jersey Health Care Profile, <http://12.150.185.184/dca> (last visited Nov. 14, 2007).

209. *Id.*

210. See N.Y. State Dep’t of Health, Professional Misconduct and Physician Discipline, <http://www.health.state.ny.us/nysdoh/opmc/main.htm> (last visited Oct. 20, 2006). See also Berkeley Rice, *Publishing Physician Profiles: What’s Fair?*, MED. ECON., Dec. 17, 2004, available at <http://www.memag.com/memag/issue/issueDetail.jsp?id=5255> (discussing the public release of individual physicians’ malpractice information).

Additionally, if doctors are categorized based on the A1C performance of their patient population, they 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.²¹¹ Additionally, some individuals have dangerous allergic reactions to insulin, including hives, difficulty in breathing and swelling.²¹² Besides insulin, doctors might prescribe other diabetes medicines, but these too may have dangerous side effects, including bloating, weight gain, leg swelling, liver disease, and anemia.²¹³

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 tests 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.²¹⁴ The side effects of overdosing on insulin alone are extreme. Overdoses of insulin can result in hypoglycemia, seizures, coma, and other negative consequences.²¹⁵ Although more rare than accidental overdoses, intentional overdoses of insulin have also been reported.²¹⁶ Clearly, the effects of overdosing are extremely severe for diabetics. If the diabetes registry leads

211. Drugs.com, Insulin, <http://www.drugs.com/insulin.html> (last visited Nov. 14, 2007).

212. *Id.*

213. National Diabetes Information Clearinghouse, Medicines for People with Diabetes, http://diabetes.niddk.nih.gov/dm/pubs/medicines_ez/specific.htm (last visited Nov. 14, 2007).

214. *Taking Many Medications*, 19 DIABETES SPECTRUM 39–40 (2006). See Nick I. Batalis & Joseph A. Prahlow, *Accidental Insulin Overdose*, 49 J. FORENSIC SCI. 1117, 1119 (Sept. 2004).

215. *Initiate Treatment Early to Avoid Fatality Following Antidiabetic Overdose*, 14 DRUGS & THERAPY PERSP., Issue 5, August 1999, at 15.

216. *Id.* at 13.

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 NYCDOHMH, 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 of New York City's Health Code suggest that the NYCDOHMH could use the A1C registry to generate a list for clinicians highlighting patients under poor control who may need intensified follow-up and therapy.²¹⁷ Further, the initial small-scale version of the registry, being implemented in the 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.²¹⁸

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 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 mistake by a lab in sending an unnecessary notice or in failing to send a notice where required, although seemingly harmless, 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 where early detection and treatment can benefit a child.²¹⁹

217. RULES OF THE CITY OF NEW YORK, HEALTH CODE tit. 24, § 13.04 n.1 (2003–2006).

218. BERGER & SILVER, *supra* note 46.

219. COMM. ON ASSESSING GENETIC RISKS, INST. OF MED., ASSESSING GENETIC RISKS: IMPLICATIONS FOR HEALTH AND SOCIAL POLICY, 68–69 (Lori B. Andrews et al., eds., National Academy Press 1994).

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.²²⁰ In particular, the Maryland Department of Health and Mental Hygiene has a webpage dedicated to the pitfalls of newborn screening for hereditary disorders, where 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.”²²¹

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.²²² Nonetheless, the A1C registry’s lack of confidentiality provisions protecting physicians’ privacy opens the door to counterproductive interference in the physician-patient relationship, and should be addressed accordingly.

PART III—RECOMMENDATIONS FOR THE FUTURE

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

220. Brian K. Stallsmith, *Pitfalls in Newborn Screening*, <http://www.dhmd.state.md.us/labs/html/NSpitfalls.html> (last visited Nov. 14, 2007).

221. *Id.*

222. Littenburg & MacLean, *Passive Consent for Clinical Research*, *supra* note 76, at 207.

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:

- We recommend that the statute expressly state that no information contained in the registry may be subject to a subpoena.
- 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.
- 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.
- Both insurance companies and employers should be forbidden by law to ask that individuals disclose their A1C results on employment or insurance applications.
- The Health Code should specifically protect physician privacy by preventing disclosure of physician names other than for purposes of notification.