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Testing for Genetic Traits: The Need for a New Legal Doctrine of Informed Consent

Elizabeth B. Cooper

*Fordham University School of Law, ecooper@law.fordham.edu*

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TESTING FOR GENETIC TRAITS: THE NEED FOR A NEW LEGAL DOCTRINE OF INFORMED CONSENT

ELIZABETH B. COOPER*

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* Associate Professor of Law, Fordham University School of Law. B.A., University of Pennsylvania; J.D., New York University School of Law. I wish to thank James Cohen, Katherine Franke, Bruce Green, Tracy Higgins, James Kainen, Minna Kotkin, Nancy Wackstein, and “the writing group” for their thoughtful guidance; Alissa Brownrigg, Kim Nohilly, and Evangeline Shih for their tremendous research assistance; and Fordham University School of Law for its generous support.

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INTRODUCTION

Innovative medical technology has made it possible to test whether you are at increased risk for certain types of cancer. The mere processing of a vial of blood can reveal whether you have a genetic predisposition to develop breast, ovarian, or prostate cancer, or other life-threatening conditions. The Human Genome Project, an international endeavor seeking to map our genetic structures, has facilitated this increasing ability to test for genetic flaws. It is expected that as the human genetic map is filled in, and as flaws in our fundamental building blocks are identified, there will be a concomitant

1. Michael J. Malinowski & Robin J.R. Blatt, Commercialization of Genetic Testing Services: The FDA, Market Forces, and Biological Tarot Cards, 71 TUL. L. REV. 1211, 1224-25 (1997); see also infra Part I. Some of these conditions are “those for which a genetic mutation may be neither causally necessary nor sufficient for the occurrence of the disease.” Rather, they are illnesses “where the presence of particular environmental conditions or family histories is an essential part of the causal nexus that links a specific genetic mutation and a disease.” Robert Wachbroit, The Question Not Asked: The Challenge of Pleiotropic Genetic Tests, 8 KENNEDY INST. ETHICS J. 131, 132 (1998). At the same time, scientists also are finding that a single-gene mutation may be “involved in multiple, apparently unrelated diseases,” such as coronary heart disease and Alzheimer’s disease. Id.

2. See Genome Project Chief Calls for Privacy, Non-Discrimination Laws, Health Care Daily Rep. (BNA), at D-10 (July 23, 1997) [hereinafter Genome Project Chief] (describing the project’s effort “to produce detailed maps of the 23 pairs of human chromosomes and sequence the 3 billion nucleotide bases that comprise the human genome” by the year 2005). Francis Collins, Director of the Human Genome Project, announced at the 126th American Public Health Association Annual Meeting in November 1998 that the project is ahead of schedule and expects to be finished by 2003. Francis Collins, Remarks at the 126th American Public Health Association Annual Meeting (Nov. 17, 1998). Some commentators suggest that because “[g]enetics research is almost always research about groups of people, smaller than nation-states and larger than individuals[,] . . . the group, whenever possible, should have some say in the research.” Henry T. Greely, The Control of Genetic Research: Involving the “Groups Between,” 38 HOUS. L. REV. 1997, 1430 (1997). But see Eric T. Juengst, Groups as Gatekeepers to Genomic Research: Conceptually Confusing, Morally Hazardous, and Practically Useless, 8 KENNEDY INST. ETHICS J. 183, 183 (1998) (asserting that it is neither possible nor desirable to obtain groups’ permission, so that “it may fall to individuals to protect the interests of the groups they care about, and to scientists to warn their subjects of the need to do so”).
drive to test for these genetic differences outside of the research setting. Indeed, genetic tests already are being commercially marketed, particularly for genetic flaws linked to breast, ovarian, and prostate cancers. This marketing is occurring despite a dearth of guidance regarding the meaning of these tests, the situations in which they should be offered, the nature or availability of potential treatment, and the type of consent that should be obtained prior to their administration.

As such tests begin to migrate from the research laboratory to your doctor's office, we must confront these and other compelling legal and ethical dilemmas. Among the first issues to require our

3. See Scott Burris & Lawrence O. Gostin, Genetic Screening from a Public Health Perspective: Some Lessons from the HIV Experience, in Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era 137, 137 (Mark A. Rothstein ed., 1997) [hereinafter Genetic Secrets] (stating that the “medical and biotechnology industries have been quick to find diagnostic and therapeutic uses for [genetic screening] in the care of individual patients”); Georgia L. Wiesner, Clinical Implications of BRCA1 Genetic Testing for Ashkenazi-Jewish Women, 7 Health Matrix 3, 3 (1997) (noting that “widespread [genetic] testing and screening is now possible for all women regardless of their previous risk profile for developing breast cancer”); Benjamin S. Wilford & Kathleen Nolan, National Policy Development for the Clinical Application of Genetic Diagnostic Technologies: Lessons from Cystic Fibrosis, 270 JAMA 2948, 2948 (1993) (asserting that commercial interests, clinicians' desires to allay legal liability, and demands of patients to obtain genetic information are likely to drive the use of all technically feasible tests).

4. See Wiesner, supra note 3, at 5 (noting that the Genetics and In-Vitro Fertilization Institute of Fairfax, Virginia, “is currently marketing a breast cancer test to general physicians and oncologists for patients outside of scientific research protocols”); see also Malinowski & Blatt, supra note 1, at 1212-15 (noting that genetic research companies are actively marketing genetic tests for breast and ovarian cancer, along with other diseases).

5. See Eugene B. Brody, Biomedical Technology and Human Rights 136 (1993) (discussing a European report that identified potential sources of misuse of genetic testing procedures, including inadequate methodology, insufficient numbers of properly trained test providers, lack of understanding of genetics and genetic testing, and difficult use, interpretation, and follow-up of tests for common diseases); Wendy C. McKinnon et al., Pre-disposition Genetic Testing for Late-Onset Disorders in Adults: A Position Paper of the National Society of Genetic Counselors, 278 JAMA 1217, 1219 (1997) (noting that “there is a dearth of data regarding appropriate medical management for gene mutation carriers and the psychological aspects of testing”); Mendel E. Singer & Randall D. Cebul, BRCA1: To Test or Not to Test, That Is the Question, 7 Health Matrix 163, 175 (1997) (discussing issues surrounding the BRCA1 genetic test, including the lack of data establishing the accuracy of the test, the probability of a positive test, and the emotional effect of the test results).

6. See Malinowski & Blatt, supra note 1, at 1214-17 (noting that a few companies are already marketing genetic tests).

7. See id. at 1219 (explaining that the dangers inherent in genetic testing include overuse of testing, misinterpretation by patients and doctors, and misuse by employers and insurance companies); see also Andrea Farkas Patenaude, The Genetic Testing of Children for Cancer Susceptibility: Ethical, Legal, and Social Issues, 14 Behav. Sci. & L. 393, 406 (1996) ("Few things are clear yet about the impact of genetic testing, except for the significance and variety of the issues it raises."). Note that some genetic testing already occurs in routine ways, e.g., testing of newborns for phenylketonuria, galactosemia, and congenital hy-
attention are whether such testing can be conducted without our consent; and, if not, what concerns must be addressed to ensure that our consent is informed?

Current informed consent doctrine generally does not apply to the drawing of blood and its analysis; instead, it is raised most frequently in the context of seriously invasive procedures that pose medical risks, such as surgery, laparoscopy, and angioplasty.\(^8\) The significant exception to this is the blood test used to diagnose HIV infection. In most states, statutes require HIV pre-test counseling and consent by the patient;\(^9\) often, this consent must be in writing.\(^10\) In this context, disclosure focuses on the social risks related to HIV/AIDS, rather than any minuscule medical risk that may accompany the drawing of blood.

The environment surrounding genetic testing for predisposition to cancerous conditions today is remarkably similar to that enveloping HIV-antibody testing in its early years: both cancer and HIV are stigmatizing and place one at risk for significant discrimination;\(^11\) both conditions have the potential to be life-threatening; positive test results for both conditions are likely to have significant psychological ramifications; in both situations, the test was developed prior to the discovery of any effective treatment;\(^12\) and these powerful tests are be-

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pothyroidism. See John M. Naber & David R. Johnson, Mandatory HIV Testing Issues in State Newborn Screening Programs, 7 J.L. & HEALTH 55, 57 (1992-93). Such testing is accepted largely because there is little to no stigma associated with these conditions and because there are readily available treatments or cures. See Lori B. Andrews, Prenatal Screening and the Culture of Motherhood, 47 HASTINGS L.J. 967, 972 (1996) (noting that some states mandate testing for the purpose of "detect[ing] certain diseases early enough for the infant to be treated in a timely fashion"). Genetic testing is also frequently associated with amniocentesis and related issues of reproductive choice. See Barbara Bowles Biesecker, Privacy in Genetic Counseling, in GENETIC SECRETS, supra note 3, at 108, 110 (discussing counseling procedures for a pregnant woman wishing to receive amniocentesis).

Although the observations made and conclusions reached in this Article may inform discussions regarding routine genetic testing for non-life-threatening conditions currently in place, as well as genetic counseling during pregnancy, this Article is primarily concerned with the growing availability of tests that can detect genetic flaws that reveal a predisposition to cancer or other life-threatening conditions and for which there may be limited, or no, treatment. See infra Part I.

8. See infra notes 44-50 and accompanying text.

9. See infra notes 52, 242-247 and accompanying text. Some commentators prefer the term "health care consumer" to "patient." See, e.g., Malinowski & Blatt, supra note 1, at 1286. Although use of this phrase creates a stronger image of the person seeking medical care, this Article uses the more traditional term.

10. See infra notes 242-247 and accompanying text.


12. For example, there is still no cure or vaccine for HIV, but the test for HIV was approved by the FDA in 1985. See infra note 232 and accompanying text.
ing marketed for general use prior to the appropriate education of health care providers or their patients.\textsuperscript{13}

This Article seeks to establish the contours of informed consent in this new arena of genetic testing for life-threatening conditions by setting forth the basic elements of what must be discussed with a patient to ensure that her consent to testing is, indeed, informed. Specifically, this Article proposes a set of basic statutory requirements for pre-test genetic counseling and suggests that these requirements can be adapted, in significant part, from the essential principles of HIV-related counseling.\textsuperscript{14} These basic elements are shaped, in part, by lessons learned from a critical assessment of current informed consent legal doctrine and by precautions to guard against the significant pressures posed by managed care reimbursement programs. This proposed regimen of genetic counseling represents a conscious approach to ensuring that each time a person consents to or refuses such testing, the decision is one that is voluntary and informed.

Part I of the Article begins with a discussion of how blood tests generally are conducted and describes the presently available technology to detect flaws in genetic characteristics and reports on predictions of advancements in this area. It continues with an exploration of the ways in which genetic testing for life-threatening conditions is different from other kinds of blood testing. Part II contains both a review of the existing legal doctrine of informed consent, based in constitutional theory, statutes, and common law, and a critique of this doctrine based on pragmatic applications of these laws and on critical legal theories. Part III examines the development of statutory pre-test counseling in the context of the HIV/AIDS epidemic and assesses its strengths, weaknesses, and relevance to genetic pre-test counseling. Part IV presents a model for genetic pre-test counseling that is drawn from the HIV/AIDS statutory format, the critique of current informed consent doctrine, and a review of existing genetic testing statutes. The Article concludes with a recommendation to adopt the model statute introduced in Part IV to remedy the identified weaknesses in

\textsuperscript{13} See supra note 5, infra note 27 and accompanying text.

\textsuperscript{14} This Article does not suggest that legislation is always the best way to confront public policy concerns raised by innovative scientific technology. See generally ROGER B. DWORKIN, LIMITS: THE ROLE OF THE LAW IN BIOETHICAL DECISION MAKING (1996) (arguing for the limits of law generally, and legislation specifically, in the realm of bioethics). For reasons that Dworkin acknowledges, however, such as the slow pace of change in the development of common law, id. at 9-10, and the ability of legislation to be "forward looking," id. at 12, this Article argues that the minimal legal response capable of dealing with the social issues presented by this technology is the enactment of carefully crafted legislation. Nonetheless, dangers that may ensue from this approach also are discussed. See infra Part IV.B.5.

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existing informed consent doctrine, particularly its failure to incorporate disclosure and discussion of social risks attendant to genetic testing.

I. THE INFLUENCE OF CHANGING MEDICAL TECHNOLOGY: THE IMPACT OF THE ABILITY TO TEST FOR GENETIC PREDISPOSITION TO LIFE-THREATENING ILLNESS

A. An Overview: Past, Present, and Future Concerns Associated with Diagnostic Blood Tests

Many of us resist going to see a physician. Many of us also have a hard time adhering to a doctor’s medical advice once we have left his office. It is easy to “forget” to lose the extra ten pounds, to start exercising, to stop smoking, maybe even to complete the course of medicine we were given.15

Yet, when we are present at the doctor’s office, the clinic, or the hospital, we tend to be quite conciliatory.16 Often towards the end of an examination, the doctor will suggest drawing some blood “just to make sure everything is ok” or “because it’s been awhile since we’ve checked things out.” Perhaps he has a hunch that something is not quite right, or perhaps he just wants to fulfill his obligation to conduct a thorough examination.

Although no one enjoys having her blood drawn, it is a relatively noninvasive and quickly accomplished procedure. In reality, it is rare that we object.17 We express our consent by rolling up a sleeve and presenting an arm. The assistant draws our blood and sends it to the lab; usually, we get a phone call from the doctor’s office about a week later saying everything checked out just fine; or, perhaps the news is not so good.18

15. See JAY KATZ, THE SILENT WORLD OF DOCTOR AND PATIENT xiv (1984) (noting that “studies on patient compliance have consistently supported the depressing conclusion that a great many patients do not comply with their doctors’ prescriptions”).

16. Cf. id. (stating that “[a]t least since Hippocratic days, patients have been asked to trust their physicians without question”).

17. See id. at 82-83 (describing physicians’ offices as “surrender-prone medical settings”).

18. It is, of course, much more difficult to communicate about test results, and other medical matters, with those persons who cannot afford homes or telephones. See Helen Rodriguez-Trias & Carola Marte, Challenges and Possibilities: Women, HIV, and the Health Care System in the 1990s, in WOMEN RESISTING AIDS: FEMINIST STRATEGIES OF EMPOWERMENT 301, 304 (Beth E. Schneider & Nancy E. Stoller eds., 1995) (contending that “[p]oor people, persons from ethnic or racial minorities, persons with disabilities, those living in rural or isolated areas, persons who are homeless are among the many who are excluded from the benefits of our highly stratified [health care] system”).
It is questionable, however, whether this consent is truly informed.19 In contrast to bygone times, when physicians relied primarily on physical examinations to diagnose our ailments,20 scientists have significantly expanded the tools available to understand the functioning, and malfunctioning, of the human body: from x-rays, to CT scans, to blood tests that can determine not only our blood count and our cholesterol, but also whether we are at increased risk for other conditions for which there is still no cure.21 These new diagnostic techniques often pose little medical risk to the patient; they do, however, present a host of social risks related to access to health care,22 stigma,23 psychological well-being,24 and potential

19. See Katz, supra note 15, at xiv (noting that informed consent imposes “the dual obligations to inform patients and to obtain their consent”).

20. See Albert R. Jonsen, The Impact of Mapping the Human Genome on the Patient-Physician Relationship, in The Human Genome Project and the Future of Health Care 1, 4-7 (Thomas H. Murray et al. eds., 1996) (illustrating the manner in which physicians’ identification of medical conditions has evolved since the nineteenth century, from diagnosing almost exclusively from the patient’s described symptoms, to relying largely on results of blood tests and new diagnostic techniques); cf. Morgan v. MacPhail, 704 A.2d 617, 622 (Pa. 1997) (Nigro, J., dissenting) (arguing that the current battery theory of informed consent requires consent for “technological advances that are invasive but no longer require a surgical cut”).

21. See Malinowski & Blatt, supra note 1, at 1225 (noting that “the discovery of genetic alterations linked to many health conditions comes well before those discoveries can be turned into therapies”); see generally Deborah Schrag et al., Decision Analysis—Effects of Prophylactic Mastectomy and Oophorectomy on Life Expectancy Among Women with BRCA1 or BRCA2 Mutations, 336 New Eng. J. Med. 1465, 1465 (1997) (noting that women in the general population have about a 12% risk of developing breast cancer and a 1.5% risk of developing ovarian cancer during their lifetimes); Jeffrey P. Struewing et al., The Risk of Cancer Associated with Specific Mutations of BRCA1 and BRCA2 Among Ashkenazi Jews, 336 New Eng. J. Med. 1401, 1401 (1997) (noting that the presence of the BRCA1 or BRCA2 mutations in women with family histories of cancer indicate a 76% to 87% risk of breast cancer, and a 32% to 87% risk of ovarian cancer during their lifetimes); infra Part I.B.

22. See infra notes 32-34 and accompanying text.

23. See Timothy F. Murphy, The Genome Project and the Meaning of Justice, in JUSTICE AND THE HUMAN GENOME PROJECT 1, 7 (Timothy F. Murphy & Marc A. Lappé eds., 1994) (asking whether “the genome project [will] mark difference as an undesirable trait and justify its eradication?”); Report of the Pennsylvania Bar Association Interdisciplinary Committee on Medical and Health Related Issues, The New Biotechnology—Does Patient Protection Require A Legislative Response To Genetic Testing?, 65 Pa. BAR ASS’N Q. 86, 87 (1994) [hereinafter Report] (describing the risk of stigmatization as particularly pertinent “because of the public’s perception that DNA and genes constitute the essence of a person[,] ... whereas non-genetic medical information is perceived as describing what has happened to a person” and noting that someone with a trait for Huntington’s disease may be perceived as ‘defective,’ whereas someone who suffered health consequences from an accident would not be); see also infra notes 96-97 and accompanying text.

24. Lori B. Andrews, Public Choices and Private Choices—Legal Regulation of Genetic Testing, in JUSTICE AND THE HUMAN GENOME PROJECT, supra note 23, at 46, 55 (“[G]enetic screening can lead to psychological trauma. Some people have committed suicide when they learned they were affected by Huntington’s disease.”). Even negative test results may cause psycho-
discrimination, particularly with regard to employment and insurance.\textsuperscript{25}

With the advent of this new medical technology, the physician's duty to "do no harm"\textsuperscript{26} is an increasingly ambiguous one. For example, suppose your doctor thinks that it is in the best interests of each of her female patients with a family history of breast, ovarian, or prostate cancer to know whether she is carrying a gene that increases the likelihood that she will develop breast cancer. Your doctor may think that this is a legitimate and important part of preventive medicine.\textsuperscript{27} You, on the other hand, are not so sure you want to know about any additional risk factor. These days everything you do and everything you eat seems to put you at increased risk for something bad. Maybe you are also concerned about having the test done: What would it really mean? How would the knowledge affect you? What treatment is available? Who guarantees that your insurance company or your employer will not be told your results—or that you won't lose your

logical harm in the form of "survivor's guilt" wherein people wonder why they do not have the gene in question, but other family members do. \textit{See} Andrews, \textit{supra} note 7, at 977.

25. \textit{See infra} notes 28-29, 33 and accompanying text.

26. \textit{See HIPPOCRATES, The Oath, in 1 THE GENUINE WORKS OF HIPPOCRATES} 779, 780 (Classics of Medicine Library ed. 1985) (Francis Adams trans., 1849) ("I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous."); Robert M. Veatch, \textit{A Theory of Medical Ethics, in LAW, SCIENCE \& MEDICINE} 290, 291 (Judith Areen et al. eds., 2d ed. 1996) (identifying the core of the Hippocratic tradition and of professional physician ethics as the requirement to protect a patient from harm).

27. \textit{See} Lori B. Andrews, \textit{Past as Prologue: Sobering Thoughts on Genetic Enthusiasm, 27 SETON HALL L. REV.} 893, 901 (1997) ("[B]elief in genetics is so strong that some physicians coerce people to learn their genetic status and take action upon it. In some instances, physicians surreptitiously test pregnant women's blood for carrier status for genetic disease. In other instances, physicians mislead pregnant women into undergoing genetic testing..." (citations omitted)); Andrews, \textit{supra} note 7, at 991 (reporting that some physicians wish to "test fetuses for the breast cancer gene"); Malinowski \& Blatt, \textit{supra} note 1, at 1219 (explaining that physicians increasingly are making genetic testing technology available to their patients, even as they are insufficiently trained in its function, interpretation, and implementation); cf. Ingfei Chen, \textit{Who Should Be Tested?, 11 HIPPOCRATES} \& 10 (1997) (visited Sept. 18, 1998) <http://www.medscape.com/time/hippocrates/1997/v11.n12/h111202.chen.html> (noting that "[w]omen who seek to have their genes scanned often have the rosy view that they can easily change the future health of their daughters and granddaughters"). This approach, however, is contrary to the positions adopted by leading genetic and oncologic organizations, such as the American Society of Clinical Oncology, American Society of Human Genetics, and the National Advisory Council for Human Genome Research to the National Institutes of Health. \textit{See} Karen H. Rothenberg, \textit{Breast Cancer, the Genetic "Quick-Fix," and the Jewish Community, 7 HEALTH MATRIX} 97, 123 n.146 (1997) (indicating that many medical groups have concerns that doctors are currently unable to communicate properly the benefits and drawbacks of genetic testing and may misuse or misread results); Wiesner, \textit{supra} note 3, at 28 (noting that restraint should be used in providing genetic testing until standards are in place to provide informed consent and counseling).
coverage or your job? What would you tell your family—especially siblings or children who may share the same genetic flaw?

There are, indeed, widely varying reasons for wanting or refusing to have such powerful diagnostic tests performed. However, following the adage, "if you build it, they will come," insurance companies, health care institutions, and individuals at-risk already are developing a market for genetic testing; there is little doubt that insurance companies and employers will want to know our test results. In turn, this knowledge is likely to facilitate discrimination against those with test results indicating the presence of a genetic flaw. Such possible mus-

28. Loss of coverage may be especially worrisome if you are contemplating a change in jobs and expecting to be in need of a new health insurance policy. While in many circumstances the Health Insurance Portability and Accountability Act of 1996 prevents insurers from denying coverage solely on the basis of genetic information when a person moves from one job to another, it does not ban them from charging a higher—and perhaps prohibitively expensive—premium. See 29 U.S.C. § 1181(b)(1)(B) (Supp. 1996) (clarifying that "[g]enetic information" without an actual diagnosis of the condition shall not be treated as a pre-existing condition under 29 U.S.C. § 1181(a)(1) (Supp. 1996)).

29. See Rothenberg, supra note 27, at 109-13 (discussing the inadequacies of state legislation to protect individuals from discrimination based on genetic makeup and noting that federal genetic-specific health insurance proposals have not passed). Although federal and state laws prohibit employment discrimination on the basis of disability, it is unclear how these laws will be applied if an individual suffers discrimination based on genetic test results. See Barbara Bowles Biesecker, Future Directions in Genetic Counseling: Practical and Ethical Considerations, 8 KENNEDY INST. ETHICS J. 145, 150 (1998) (noting that "[f]ear of genetic discrimination directly affects the decisions genetic counseling clients make about predictive gene testing"). But see Wachbroit, supra note 1, at 141 (objecting to the notion that a person should avoid genetic testing because there is a "risk of discrimination and stigmatization" and stating that "[i]f a patient becomes uninsurable when a genetic condition is discovered, the proper target for criticism is the insurance industry, not the discovery, and making similar arguments regarding employment discrimination).

30. See supra text accompanying notes 22-25.

31. See Malinowski & Blatt, supra note 1, at 1212-17 (noting that companies are already marketing genetic testing services, some of which can test for several gene alterations in the same test, and can sell for as much as $2400); Wiesner, supra note 3, at 3 (noting the growing commercial availability for genetic testing, outside of scientific research protocols, through general physicians and oncologists); Wilford & Nolan, supra note 3, at 2948 ("It may also seem inevitable that virtually every test that is technically feasible will be routinely used. Commercial interests may promote testing; clinicians may use tests to allay fears of legal liability; and patients themselves may demand testing to obtain genetic information.").

32. See Genome Project Chief, supra note 2, at D-10 (reporting on congressional testimony by the Health Insurance Association of America's Chief Operating Officer that access to genetic test information is necessary to identify those likely to develop serious illness or disease).

33. See Chen, supra note 27, ¶ 32 (discussing a recent survey of 332 people with a variety of genetic disorders and noting that more than 20% believed they or a relative had been denied health or life insurance because of the flawed DNA and that 15% believed they had lost or been denied a job because of their status); Rothenberg, supra note 27, at 108 (noting that the availability of genetic information to third parties causes "fear that . . .
ings are hardly the result of idle speculation. Some of these events already have started to occur.34

Moreover, these concerns arise against a troubling historical backdrop. The eugenics movement, so often linked with Nazi Germany,35 also has roots in the United States.36 Indeed, “[r]estrictive immigration laws, forced sterilization, and prohibitions on interracial marriage were in part a legacy of mixing genetics, race, and class”37 in the United States and elsewhere.38 While this domestic eugenics movement most often is associated with socially regressive policies of the early twentieth century, African Americans, Latinas, and low-income people were subjected to mandatory race-based experimentation39 and sterilization40 through the 1960s and 1970s.41 As such,

individuals and their families may face discrimination”); Wiesner, supra note 3, at 28-29 (explaining that "studies are essential to explore the issues surrounding a patient’s desire to know their genetic diagnosis when coupled with potential employment and insurance discrimination”); see also Direct Mail Campaign from Lois Waldman, Director, Commission for Women’s Equality, American Jewish Congress (soliciting funds because genetic testing “may be used by insurance companies or . . . employer[s] to discriminate . . .” and noting that “[b]y submitting to genetic testing, [one] could join ‘an insurance underclass’ subject to job discrimination[,] . . . excessive health and life insurance premiums . . . or denial of insurance coverage altogether” and enclosing newspaper clipping by Susan Ferraro, Balking at Breast Cancer Test, DAILY NEWS (Jan. 1998) (on file with author); infra Part I.B.

34. See Chen, supra note 27, ¶ 32 (detailing a study revealing discrimination experienced by persons with genetic disorders); UCSF Cancer Center to Offer Genetic Testing For Breast Cancer Genes (visited Jan. 30, 1998) <http://www.pslgroup.com/dg/124b2.htm> [hereinafter UCSF Cancer Center] ("A recent study published in the journal Science showed that 47 percent of people questioned on health insurance applications about genetic diseases were subsequently rejected for coverage.").


36. See id. at 31 (recounting the forced sterilization programs sponsored by the United States government designed to “prevent[] the spread of ‘bad’ genes to future generations”); see also Andrews, supra note 27, at 918 (“It is useful to realize that the turn-of-the-century purveyors of genetic ideas did not consider themselves evil. They saw themselves on a laudable quest for human betterment.”); Daniel J. Kevles, Eugenics and the Human Genome Project: Is the Past Prologue?, in JUSTICE AND THE HUMAN GENOME PROJECT, supra note 23, at 14, 18 (“[Eugenic sterilization] laws were declared constitutional in the 1927 U.S. Supreme Court decision of Buck v. Bell, [279 U.S. 200 (1927),] in which Justice Oliver Wendell Holmes delivered the opinion that three generations of imbeciles were enough.”); cf. James E. Bowman, Genetics and African Americans, 27 SETON HALL L. REV. 919, 936 (1997) (observing that “do-gooders and well-meaning people may be more difficult to challenge than organizations and individuals with blatant eugenic objectives”).

37. Caplan, supra note 35, at 31; see also Andrews, supra note 27, at 907 (noting that “African-American citizens were thought to be so inferior that interracial marriage was prohibited to prevent the birth of defective offspring”).

38. Caplan, supra note 35, at 30-31; see also Kevles, supra note 36, at 18 (stating that more than 20 states had enacted eugenic sterilization laws by the late 1920s).

commentators describe a "collective Black consciousness which still influence[s] African Americans' reaction to the health care system."\textsuperscript{42}

What does this mean for the future of patient autonomy and patient participation in health care decision making? Who should decide whether a certain test is performed? What information do you need before agreeing to be tested for a significant genetic trait?\textsuperscript{43}

It is most useful to begin thinking about these questions by examining current legal doctrine concerning medical decision making, un-

them with antibiotics); \textit{id.} at 199 (discussing widespread "collect[ion of] blood samples from seven thousand Black youths" under the guise of testing for anemia, but instead "looking for signs that the children were genetically predisposed to criminal activity"); \textit{id.} at 200 (chronicling abuses in the prison system, which houses a disproportionate number of African Americans, and the military, in which Blacks are overrepresented, and noting that "soldiers cannot refuse to participate in the government's medical experiments").

40. \textit{Id.} at 203 (discussing the behavior of some doctors in the 1970s who would only deliver babies or perform abortions on pregnant African American women if the women consented to sterilization and noting that "[o]ther women were threatened with the withdrawal of their welfare benefits if they did not agree to sterilization"). Randall links mandatory and routine sickle cell screening in the 1970s, which led to "widespread discrimination against African Americans" in employment and insurance, to the history of misguided medical policies directed at Blacks. \textit{Id.} at 201; \textit{see also} Andrews, \textit{supra} note 24, at 52 (identifying two waves of genetic screening in the United States so far: mandatory sterilization laws linked to eugenic policies and testing for sickle cell anemia); Lisa C. Ikemoto, \textit{The Racialization of Genomic Knowledge}, 27 SETON HALL L. REV. 937, 943-44 (1997) (arguing that "the genetic presumption has already given rise to definitions of disease and defect that police normalcy along racially subordinating lines" and discussing the legal treatment of the sickle cell trait in these terms).

41. It would be inappropriate to conceive of a monolithic African American community, Latino community, or any other population group—just as it would be inappropriate to envision a monolithic white community. The challenge is "to begin to know the numerous communities" within our overall diversity. \textit{Cf.} Randall, \textit{supra} note 39, at 235.

42. Randall, \textit{supra} note 39, at 200.

43. Perhaps this new wave of development in "medical science" will prompt further development of informed consent doctrine. \textit{See Katz, supra} note 15, at xvi (noting that "[w]ithout the emergence of medical science, the legal doctrine of informed consent probably could not have been promulgated"). A report by a Pennsylvania Bar Association Committee anticipates some of these new issues:

The stability of DNA also raises special privacy concerns in that DNA may be tested for years after a sample has been taken. The biological information available in a person's DNA expands dramatically and continuously as new technologies for testing are developed. Future examination of the DNA sample therefore . . . might be used in ways that are adverse to the subject in ways unforeseeable at the time permission to test was granted and therefore not implicit in the consent initially given.

Report, \textit{supra} note 23, at 87; \textit{see also infra Part IV. But see} Biesecker, \textit{supra} note 29, at 152 (predicting that "an increase in the treatability of disease" likely will lead to genetic tests becoming "more routine," "less . . . associated with significant psychosocial issues," and further will encourage providers "to be directive in recommending that testing be performed").
nderstood most commonly as the doctrine of informed consent. As noted earlier, a review of recent case law and pertinent statutes reveals that this doctrine continues to exist almost exclusively in the realm of significantly invasive procedures. Few informed consent cases raise concerns about unwanted blood tests or other minimally invasive diagnostic techniques.

The one area, however, where there has been concern, manifest through litigation and legislation, about diagnostic blood testing without informed consent, is in the realm of HIV disease. The precedent of HIV/AIDS provides quite the object lesson in the importance of considering carefully the power of a medically significant diagnostic test, particularly one involving ostensibly minimal bodily invasion. In the mid-1980s, once a test for the presence of

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45. See supra text accompanying note 8.

46. See infra Part II.B.

47. See, e.g., Leckelt v. Board of Comm’rs of Hosp. Dist. No. 1, 909 F.2d 820, 833 (5th Cir. 1990) (holding that a nurse who refused to submit HIV test results was not “otherwise qualified” and that therefore her dismissal was not discriminatory and did not violate the Rehabilitation Act of 1973, a state civil rights statute, constitutional equal protection, or privacy rights); Hill v. Evans, No. Civ. A. 91-A-626-N, 1993 WL 595676, at *5 (M.D. Ala. Oct. 7, 1993) (holding that an Alabama statute which “allows a doctor to have a patient tested for HIV infection simply because the doctor considers the patient to be at high risk for the infection” is unconstitutional); Doe v. Ohio State Univ. Hosps. & Clinics, 663 N.E.2d 1369, 1376 (Ohio Ct. App. 1995) (affirming judgment for hospital where plaintiff was tested for HIV without giving consent because physician did not knowingly submit blood sample for HIV test).

48. As new treatments have been developed to counter both HIV infection and its manifestations (e.g., multiple bouts of bacterial pneumonia, gynecologic infections resistant to treatment, wasting), health experts have adopted the phrase “HIV disease” or “HIV/AIDS” to refer to the range of symptoms that a person living with HIV may experience. See Lawrence O. Gostin & Zita Lazzarini, Human Rights and Public Health in the AIDS Pandemic vii (1997) (utilizing the phrase HIV/AIDS); Helena Brett-Smith & Gerald H. Friedland, Transmission and Treatment, in AIDS Law Today: A New Guide for the Public 18, 30 (Scott Burris et al. eds., 1999) [hereinafter AIDS Law Today] (same).

49. This Article uses the term “diagnostic blood test” to refer to the technology that is capable of testing for genetic sequences revealing predispositions to cancer and other life-threatening conditions.

HIV infection became widely available,\(^5\) numerous states passed laws requiring that patients provide their informed consent prior to the administration of the test.\(^6\)

Although a limited number of jurisdictions have started to grapple with the issue of consent to genetic testing,\(^7\) there is little indication of a legislative consensus regarding the approach that will be adopted by our state legislatures and courts.\(^8\) It is essential that the doctrine of informed consent remains current with our changing medical technology.

The need for establishing such parameters is especially important as physicians\(^9\) begin to adjust to the new technology. When any new

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52. See, e.g., CAL. HEALTH & SAFETY CODE § 125107(d) (West Supp. 1998) (providing that a "pregnant woman [must] voluntarily consent[ ] to [HIV] testing"); CAL. INS. CODE § 799.03(a) (West Supp. 1998) (mandating that "[a]n insurer that requests an applicant to take an HIV-related test shall obtain the applicant's written informed consent"); Fla. Stat. Ann. § 381.004(3)(a) (West 1998) (stating that "no person . . . shall perform a test designed to identify [HIV] without first obtaining the informed consent of the person upon whom the test is being performed"); 410 ILL. COMP. STAT. ANN. 305/4-4 (West 1997) (stating that "no person may order an HIV test without first receiving the written informed consent of the subject of the test"); N.Y. INS. LAW § 2611(a) (McKinney Supp. 1998) (stating that "[n]o insurer or its designee shall request or require an individual proposed for insurance coverage to be the subject of an HIV related test without receiving the written informed consent of such individual"); Tex. Health & Safety Code Ann. § 81.105(a) (West 1992) (mandating that "a person may not perform a test designed to identify HIV . . . without first obtaining the informed consent of the person to be tested"). Some, but not all, statutes require the informed consent to be in writing. See, e.g., 410 ILL. COMP. STAT. ANN. 305/4-4 (stating that "[n]o person may order an HIV test without first receiving the written informed consent of the subject of the test or the subject's legally authorized representative"); N.Y. INS. LAW § 2611(b)(6) (requiring that "[w]ritten informed consent to an HIV related test shall consist of a written authorization that . . . includes . . . the signature of the applicant"); Tex. Health & Safety Code Ann. § 81.105(b) (explaining that "[c]onsent need not be written if there is documentation in the medical record that the test has been explained and the consent has been obtained").

53. See infra notes 289, 322 and accompanying text.

54. See generally infra Part IV.B.

55. This Article intentionally focuses on the physician-patient relationship and the responsibility of doctors to provide proper counseling to their patients regarding genetic testing. Although nurses or trained genetic counselors often perform health care related counseling, ultimately it is the responsibility of the physician in charge of a particular office, clinic, or hospital to ensure that the patient receives proper counseling. See Biesecker, supra note 29, at 145-46 (discussing the training, stature, and role of genetic counselors). While genetic counselors traditionally have worked in the prenatal and neonatal settings, increasingly they are filling a need in the numerous research environments that are exploring the nature and incidence of genetic flaws linked to cancer and other life-threatening conditions. Telephone Interview with Regina Zimmerman, Registry Director, Metropolitan New York Registry of Breast and Ovarian Cancer Families (Mar. 18, 1998). In fact, schools increasingly are offering degrees in genetic counseling in an attempt to remedy
medical procedure is developed, there is an inherent lag between the availability of the test and the education of physicians regarding its use, recommended application, and understanding of test results. Experience has shown that this lag may be significant and that patients suffer from this delay when they are not provided with a thorough explanation of what the test might reveal, what the results mean, and what their treatment options are, if any. These problems already have arisen in the context of genetic testing.

Physicians also are grappling with the impact of new methods of reimbursement for the provision of medical care and services. The growing presence of managed care in health care reimbursement systems is exerting remarkable financial pressures on the manner in which physicians organize their offices and provide health care services. While some of these pressures result in a "trimming" of the proverbial "fat" off of the provision of medical care, they also have had

the current shortage. Id.; cf. JEROO S. KOTVAL, NEW YORK STATE LEGISLATIVE COMMISSION ON SCIENCE AND TECHNOLOGY, DNA BASED TESTS: POLICY IMPLICATIONS FOR NEW YORK STATE 16 (1994) (citing a 1990 New York survey estimating that the current workload "warranted 50% more genetic counselors than were available"). However, "widespread genetic testing is unlikely to be provided by genetic counselors alone." Biesecker, supra note 29, at 151. Regardless, the recommendations proposed herein also would apply to all medical personnel who engage, or ought to engage, in patient counseling. See infra Part IV.

56. See Dorothy C. Wertz, Society and the Not-So-New Genetics: What Are We Afraid of? Some Future Predictions from a Social Scientist, 13 J. CONTEMP. HEALTH L. & POL'Y 299, 306 (1997) (explaining that due to a lack of sufficient genetic counselors and geneticists, patients may depend on the advice of primary care physicians, who have gaps in their knowledge about genetic disorders); Susan Gilbert, Doctors Often Misread Results of Genetic Tests, Study Finds, N.Y. TIMES, Mar. 26, 1997, at C8 (reporting the results of a study finding that nearly one-third of the physicians who referred patients for genetic testing for colon cancer misinterpreted the results).

57. See Malinowski & Blatt, supra note 1, at 1245-46 (discussing the fact that, because health care providers currently lack adequate genetic education and depend on developers and manufacturers for information about genetic tests, neither providers nor consumers reasonably can evaluate the technology).

58. See Chen, supra note 27, ¶ 15 (reporting on a recent study of physicians who administered the commercially available test for a gene linked to colon cancer, and noting that, "in more than 80 percent of the cases, doctors either failed to provide or arrange for thorough counseling for the patient or forgot to get written informed consent," and that "in nearly a third of the cases, the physicians mistakenly read inconclusive findings as negative results").

59. See Ezekial J. Emanuel & Nancy Neveloff Dubler, Preserving the Physician-Patient Relationship in the Era of Managed Care, 273 JAMA 323, 325 (1995) (stating that, because "[i]nsurance companies and managed care plans may discourage utilization of or exclude coverage for certain physicians, procedures, and treatments, or may prohibit patients from going to specialty hospitals for treatment," such practices "may serve to overrule informed patient and physician choices"); Mark A. Hall, A Theory of Economic Informed Consent, 31 GA. L. REV. 511, 514 (1997) (explaining that affordable insurance "does not allow [patients] to demand all the care that is of any conceivable benefit regardless of cost," so that a "compromise" must be reached between health care cost and "patient welfare").
adverse effects. Complaints abound, for example, that women are
not provided with sufficient recuperation time in the hospital follow-
ing either childbirth or mastectomy.

A more hidden effect, and one with perhaps even greater long-
term impact on both individuals and institutions, is the implicit or
explicit pressure on health care providers to minimize the time they
spend on such nondiagnostic activities as counseling or patient sup-
port. For example, an insurance program may provide reimburse-
ment for the taking and processing of a diagnostic blood test, but not
provide reimbursement (or, only minimal reimbursement) for coun-
seling the patient regarding the risks and benefits of performing that
test. Similarly, an insurance program that requires a physician to see
a certain number of patients to achieve a particular level of compen-
sation, or to participate in the program, is implicitly pressuring that pro-

60. See Elaine Lu, Comment, The Potential Effect of Managed Competition in Health Care on Provider Liability and Patient Autonomy, 30 HARV. J. ON LEGIS. 519, 532 (1993) (contending that "[a]lthough the general perception is that much of the medical care that is currently rendered is unnecessary, and even harmful, it is simply too optimistic and naive to believe that managed care will be able to trim all the fat out of the current system without sacrificing some quality" (footnote omitted)).

61. See generally 26 U.S.C.A. § 9811(a) (1)(A) (West Supp. 1998) (providing that health care plans cannot restrict benefits for inpatient hospital care to a time period of less than 48 hours following a normal vaginal delivery and of less than 96 hours following a delivery by cesarean section); CAL. HEALTH & SAFETY CODE § 1367.62(a)(1) (West Supp. 1998) (same); Scott MacStravic, Managing Utilization: The Old Way and the New Way, HEALTH CARE STRATEGIC MGMT., Oct. 1996, at 1, 22 (stating that "the resulting scandals around ‘drive-through deliveries’ . . . resulted in many states passing legislation requiring minimum stays"). See also Nancy Henderson, How One Physician Can Make a Difference: Kristen Zarfos’ Campaign Against Drive-Through Mastectomy, MEDICAL ECON., July 28, 1997, at 64, 64 ("In 1991, only 1.6 percent of mastectomies performed in the U.S. were done on an outpatient basis, but by 1995 this figure had increased almost five-fold, to 7.6 percent.").

62. See Emanuel & Dubler, supra note 59, at 328 (voicing concerns that “[p]roductivity requirements may translate into pressure on physicians to see more patients in shorter time periods, reducing the time to discuss patient values, alternative treatments, or the impact of a therapy on the patient’s overall life"); cf. Francis S. Collins, Preparing Health Professionals for the Genetic Revolution, 278 JAMA 1285, 1286 (1997) (explaining that "time constraints in managed care [dictate that patient] partnerships with members of a health care team such as physician assistants, nurses, psychologists, and social workers will be essential").

63. See Collins, supra note 62, at 1286 (proposing that managed care should provide for adequate patient counseling regarding testing issues through "health care team[s]” due to time constraints imposed on physicians by reimbursement plans); see also Biesecker, supra note 29, at 146 (describing genetic counseling as "both an education and a short-term psychotherapeutic process that assists clients in accepting and adjusting to a genetic condition or risk they or family members face"). But see Wachbroit, supra note 1, at 139, 142 (stating that “[t]he need for genetic counseling is not based on the special severity of the harms associated with genetic information; it is based on a reaction to the history of eugenics,” and further asserting that we sometimes have "the obligation . . . to know our genetic condition," even if there are limited medical benefits).
vider to limit contact with each patient. The financial incentives and pressures to expedite patient care are significant and increasing, and have the power to affect profoundly the nature and structure of the doctor-patient relationship.

Unless mandated by statute, existing legal doctrine does not generally apply to diagnostic testing, and, unless regulated by statute, most insurance programs exercise significant autonomy over their reimbursement policies. Together, these facts work to undermine the traditionally accepted goal of facilitating patient self-determination in the health care setting.

While the establishment of a structure to guide doctor-patient communication regarding genetic testing and treatment, such as the

64. See Emanuel & Dubler, supra note 59, at 325-28 (noting that many insurance plans or managed care providers require physicians to shorten patient visits and limit time for patient-physician discussions on alternative treatments or the impact of treatment on the patient’s life).

65. Id. at 326 (observing that, due to “bureaucratic demands for preprocedure permission, postprocedure justification, multiple reimbursement forms, and other administrative requirements [that] take up significant physician time,” doctors “may be forced to see more patients and shorten each visit”).

66. One commentator notes that:

[The] lack of access [to health care] coupled with other issues affecting African Americans—racism, homelessness, violence, drugs, etc.—means that they will come into managed care products with poorer health status and needing more, not less, health care services. In a system focused on decreasing utilization, it seems difficult to imagine that African Americans will receive “more” health care services, while others receive “less.” If managed care products do not provide culturally relevant care, then African Americans may have technical access to health care, but not quality health care.

Randall, supra note 39, at 218-19 (footnote omitted).

67. See infra Part II.B.1 (discussing the recognition of bodily integrity and the right to decisional privacy by the Supreme Court, but noting that the Court has not addressed informed consent issues in the context of minimally invasive, diagnostically significant procedures, such as genetic testing); infra Part II.B.2 (exploring application of informed consent statutes and case law to diagnostic blood tests); cf. Andrews, supra note 7, at 1001 (reporting that the federal government treats genetic tests differently from other blood tests in that they are not exempt from full Institutional Review Board review on the basis that they “present greater than minimal risks due to psychological risks and social risks including ‘stigmatization, discrimination, labelling, and potential loss of or difficulty in obtaining employment or insurance’” (citation omitted)).

68. See Tom L. Beauchamp & James F. Childress, Principles of Biomedical Ethics 126 (4th ed. 1994) (noting that “the right to self-determination . . . supports various autonomy rights, including those of confidentiality and privacy”); cf. Brody, supra note 5, at 62 (arguing that the sensitive and drastic decisions created by new biomedical technology should be left primarily to “[t]he interaction of the individual patient and family[ ] with the responsible, socially sanctioned caretaker, [and] the physician who has worked intimately with the case”); Katz, supra note 15, at 112 (“If physicians were to pay greater attention to conversation—to patients’ capacities to reflect about choices—it could change their traditional attitudes towards patients’ capacities to make their own decisions and, in turn, could radically transform the current state of physician-patient decision making.”).
one described in this Article, does not necessarily guarantee that these discussions either will occur or that they will be meaningful, this Article argues that the creation of this structure would be an important step towards ensuring that patients will participate more fully in their care and treatment, that they will be in a position to provide consent that is truly informed, and that legal doctrine will not be outpaced by medical advancements and eliminated by financial pressures.

B. What Is “Exceptional” About Genetic Testing?

As researchers with the Human Genome Project (HGP) identify how mutations in genetic sequences may be linked with particular diseases, genetic tests will be developed that increasingly will be accessible to the general public. Existing tests can detect not only the presence of genetic or hereditary conditions (e.g., Huntington’s disease), but also genetic predispositions to illness (e.g., cancers of the breast, ovary and colon). Scientists are hopeful that they will be able to develop therapies or treatments to prevent or cure genetic disease

69. See Adrienne Asch & Gail Geller, Feminism, Bioethics, and Genetics, in Feminism & Bioethics: Beyond Reproduction 318, 323 (Susan M. Wolf ed., 1996) [hereinafter Feminism & Bioethics] (citing a 1988 report of the National Research Council Committee on Mapping and Sequencing the Human Genome which asserts that “encoded [in the DNA sequence] are the mutations and variations that cause or increase susceptibility to many diseases responsible for much human suffering”).

70. See Malinowski & Blatt, supra note 1, at 1224 (“Biotech companies are using such discoveries [of the link between a gene or biological marker and a physical or mental condition] to develop and commercialize predictive screening tests for an abundance of health conditions in addition to breast and ovarian cancer.”). Commenced in 1990, the Human Genome Project was designed to identify and determine the “linkages between genes and health conditions,” id. at 1218, and currently is succeeding in doing so on a weekly, if not daily, basis, id. at 1224.

71. While some genetic mutations determine that a person will develop a particular disease—such as Huntington’s Disease, cystic fibrosis, and hemophilia—other mutations detect only a susceptibility to diseases—such as breast cancer, colon cancer, and bipolar-affective disorder. In the latter case, a person may not develop the disease without the presence of additional influences (e.g., exposure to harmful chemicals, dietary habits, smoking, and other environmental factors). See Carson Strong, Ethics in Reproductive and Perinatal Medicine 136 (1997) (“The term susceptibility is used because these diseases are considered to be multifactorial; the fact that an individual has an associated gene (or genes) does not necessarily mean that the disease will occur . . .”); see also Ruth Hubbard & R.C. Lewontin, Pitfalls of Genetic Testing, 334 New Eng. J. Med. 1192, 1193 (1996) (noting that the “breast-cancer genes BRCA1 and BRCA2 . . . [have] been linked to increased susceptibility to breast or ovarian cancer”); Yoshio Miki et al., A Strong Candidate for the Breast and Ovarian Cancer Susceptibility Gene BRCA1, 226 Science 66, 66 (1994) (stating that “[m]utation of one gene, BRCA1, is thought to account for approximately 45% of families with significantly high breast cancer incidence and at least 80% of families with increased incidence of both early-onset breast cancer and ovarian cancer”).

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through ongoing research. Unfortunately, these advances are far from being fully realized.

Although scientific breakthroughs make testing a viable option for some individuals at risk for genetically linked disease, the indeterminate nature of test results combined with various concerns—about lack of disease-appropriate treatment, or access thereto; potential psychological harm to the person being tested; ramifications for other family members; possible breaches of privacy; and the risk of discrimination based on positive results—must be considered.

72. Gene Therapy: When, and for What?, LANCET, Mar. 25, 1995, at 739, 740 (noting that progress in gene therapy is being made toward interference with tumor development, treatment of AIDS, and management of chronic diseases of the nervous system). But see Andrews, supra note 27, at 901 (reporting that, as of 1995, there was "little or no evidence of therapeutic benefit [of gene therapy] in patients, or even animal models" and that a "federally-appointed committee investigating gene therapy condemned most of the efforts as 'pure hype'" (first alteration in original) (citation omitted) (quoting Laurie Garrett, The Dots Are Almost Connected. . . . Then What?, L.A. TIMES, Mag., Mar. 3, 1996, at 22).

73. See Murphy, supra note 23, at 6 ("It is likely that there will be considerable lag time between the identification of genetic dysfunctions and interventions that can successfully alter them. It is also unclear at the present time whether widespread use of genetic characterizations (and possible treatments) will significantly improve the health of a nation's population.").

74. See Biesecker, supra note 29, at 150 ("Predisposition test results can provide more accurate genetic risk assessment but are generally imprecise in estimating penetrance (the likelihood that the disease will develop)."; Malinowski & Blatt, supra note 1, at 1243 (explaining that the "predictive capability of many genetic tests remains scientifically undefined").

75. See Malinowski & Blatt, supra note 1, at 1244 (noting that, even if genetic conditions can be diagnosed accurately, "often there is no available treatment, or treatment exists but is price-prohibitive" (footnote omitted)).

76. See id. at 1249 (stating that patients who have undergone genetic testing for Huntington's disease "have experienced detrimental psychological reactions to the results even when they are negative," and that those who have tested positive have a 35% higher suicide rate than the general population).

77. See Patenaude, supra note 7, at 404 ("Genetic information is unlike other medical information in that the utility of the information is not limited to the individual who presents as the identified patient. Rather, the information has direct relevance for both prior and future generations, as well as potential implications for siblings of the patient.").

78. See Andrews, supra note 7, at 988-89 (reporting on survey results revealing that 24% of U.S. geneticists "would share the patient's genetic information with employers without the patient's consent"; and that 58% "said that they would disclose the risk of Huntington's disease to a relative without the patient's permission," even though the disease is untreatable and "less than 15% of individuals at risk" for it decide to be tested to see if they have it (emphasis added) (citations omitted)).

79. See Malinowski & Blatt, supra note 1, at 1249 (noting that "genetic information already is disrupting the lives of individuals and their families by subjecting them to discrimination from employers and insurers"); see also Andrews, supra note 7, at 985-87 (noting that "[a]mong people in families with a known genetic condition, 31% have been denied health insurance coverage of some service or treatment because of their genetic status, whether or not they were sick" and that "[i]n the early 1970s, employers discriminated against African American employees and job applicants who were carriers of sickle
by clinicians who plan to offer genetic testing. Indeed, the ability to conduct such a test, particularly when viewed in conjunction with the repercussions of being tested, highlight the importance of the pre-test counseling process and a genuine expression of informed consent.

An understanding of the BRCA1 and BRCA2 genes illustrates the importance of assuring that an individual's decision to test for genetic mutations that indicate an increased risk for life-threatening illness is fully informed. Discovered in 1994 and 1995 respectively, the BRCA mutations signal an increased risk for both breast and ovarian cancer in their female carriers. Out of women in the general population, one in eight or nine who live to the age of eighty-five will develop breast cancer. Women who carry the BRCA1 or BRCA2 gene, how-

cell anemia, even though carrier status had no relation to the individual's health or ability to perform the job.

80. See Chen, supra note 27, ¶ 6 (cautioning that "the uncertainties of treatment and the lack of legal protections in place against insurance and employment discrimination" warrant a slow pace in genetic testing); Malinowski & Blatt, supra note 1, at 1243-54 (discussing the many factors and concerns which ought to be taken into account when considering genetic testing); Murphy, supra note 23, at 8 (questioning whether the genome project, and its attendant testing capabilities, will enlarge the "differences . . . between people that are used as pretexts for their subjugation and vilification"); Rothenberg, supra note 27, at 106-10 (expressing concern about the discrimination to which the use of genetic testing results might give rise).

81. See Judy E. Garber & Deborah Schrag, Testing for Inherited Cancer Susceptibility, 275 JAMA 1928, 1928 (1996) (explaining that "comprehensive education and counseling to promote informed decision making must be provided before blood is ever drawn, with a separate visit for results disclosure"); see also Rothenberg, supra note 27, at 106 (noting that "[t]he emphasis [in genetic testing counseling] is on disclosure of the psychological and societal risks for the individual and family receiving the information," not on the procedure itself); cf. Andrews, supra note 27, at 904 ("Currently, . . . informed consent is often compromised in the clinical setting, with people being tested without their knowledge or consent or receiving inadequate information about the nature or purpose of genetic testing or the use to which the results can be put."). Andrews further notes that ",[t]he practice of unconsented-to testing is likely to grow" with the development of "multiplex tests" through which "fifty or one hundred different genes can be assessed at the same time." Id. at 905.

82. The availability of tests to detect BRCA genes have received significant attention from the mainstream, as well as scientific, media. They are characteristic of tests for other genetic flaws which reveal a greater likelihood of an individual's developing a specific life-threatening condition for which there is little to no effective treatment or cure, and which do not identify whether that person will, indeed, acquire the disease. Most people have an average of 8-12 or more flawed genes, most of which are largely innocuous or which may indicate a predisposition for certain treatable conditions. See Andrews, supra note 7, at 986. This Article is primarily concerned with consent-to-testing issues that arise with the ability to conduct genetic tests for life-threatening conditions.

83. See Wylie Burke et al., Recommendations for Follow-up Care of Individuals with an Inherited Predisposition to Cancer, 277 JAMA 997, 998 (1997) (noting that "[m]utations in 2 recently identified genes, BRCA1 and BRCA2, confer an inherited predisposition to breast and ovarian cancer[,]" and that "the lifetime risk of cancer in mutation carriers is high").

84. See Chen, supra note 27, ¶ 18.
ever, have a 56% to 87% lifetime risk of developing breast cancer.85
While only 5% to 10% of all breast cancer cases run in families, BRCA
mutations account for about 80% of all inherited breast tumors.86

Women who carry BRCA1 have a 40% to 60% lifetime risk of ova-
rian cancer; women who carry BRCA2 have a 10% to 20% lifetime
risk;87 and women without the mutations have about a 1.5% risk.88
BRCA1 also has been linked to a small risk of colon cancer in both
genders and prostate cancer in men; BRCA2 has been linked to a 6% chance of breast cancer in men.89

Because the predictive value of a BRCA test for a given woman is
not known, medical experts continue to recommend that such testing
be restricted to women at high risk and in the context of research
protocols.90 These recommendations, however, are not being heeded
by all concerned. Tests for the BRCA genes already are commercially
available and multiple companies are likely to seek to market these
and other genetic tests.91

85. See id. ¶ 7. Chen notes, however, that breast cancer gene tests deal only in
probabilities, and that such tests "can tell whether a woman is susceptible to developing the
disease, [but] not whether she will get it." Id.; see also Struwing et al., supra note 21, at
1401 (affirming that women with the BRCA1 or BRCA2 mutation have an increased risk of
breast or ovarian cancer).
86. Chen, supra note 27, ¶ 18.
87. See id. Chen also emphasizes that available risk statistics come from "surveys of very
high-risk women in families with a pattern of breast cancer." Id. ¶ 23.
88. Schrag et al., supra note 21, at 1465.
89. Chen, supra note 27, ¶ 23; see Burke et al., supra note 83, at 998 (noting that one
"pedigree [of BRCA2] was reported which had multiple cases of male breast cancer and no
female breast cancer"); cf. Patenaude, supra note 7, at 403 (noting that women with female
ancestors who had breast or ovarian cancer "are less shocked to think they may carry a
BRCA1 mutation than women who inherited an altered BRCA1 gene from their fathers,
even though the risks faced by both groups are the same").
90. See Wiesner, supra note 3, at 4 ("Several national groups have strongly recom-
mended a cautious approach to incorporating genetic testing into medical practice, and
have published guidelines for BRCA1 testing which propose that it be limited to high-risk
women under scientific protocols." (footnote omitted)); see also Bernardine Healy, BRCA
Genes—Bookmaking, Fortunetelling, and Medical Care, 336 New Eng. J. Med. 1448, 1449
(1997) (stating that "[i]t is too early to use BRCA gene testing in every-day clinical prac-
tice"). Dr. Healy is the former director of the National Institutes of Health.

Those considered to be at elevated risk include women with three close relatives who
have had breast or ovarian cancer; those who themselves, or whose relatives, have been
diagnosed with cancer before the age of 45; those with tumors found in both breasts, and
women of Ashkenazi descent with less striking family history of either cancer. See Wiesner,
supra note 3, at 4 (noting that Ashkenazi-Jewish women exhibit a "high frequency" of a
particular type of gene mutation related to breast cancer).
91. Malinowski & Blatt, supra note 1, at 1212-16 (noting that OncorMed, Genetics &
IVF Institute, and Myriad are marketing BRCA gene tests and that other laboratories are
introducing their own genetic tests); see also Andrews, supra note 27, at 917 (reporting on
the efforts of biotechnology companies and physicians to "heavily market genetic services
Once testing positive for either BRCA1 or BRCA2, women face uncertainty regarding possible preventive measures. While prophylactic steps include modifications in lifestyle to avoid environmental cancer-inducing factors, such as dietary changes, and continual surveillance for signs of cancer, some BRCA carriers opt to have their breasts or ovaries removed before any sign of disease develops. Although this approach significantly increases the odds of averting breast or ovarian cancer, it does not guarantee prevention. Understandably, for many women, these radical procedures may not be acceptable.

and products" and noting that the "supposedly neutral scientists developing them often share a cut of the profits"). Because of this, Andrews warns, "This commercialized setting makes it more likely that tests will be implemented prematurely, that they will be performed without appropriate concern for informed consent, and that the poor and disadvantaged will be least likely to share in any benefits." Id.

92. See Chen, supra note 27, ¶ 10 (agreeing that "the BRCA tests [are] a therapeutic illusion that suggest[ ] there's a way of warding off breast cancer when in fact no foolproof remedy exists"); Jerome Groopman, Decoding Destiny, New Yorker, Feb. 9, 1998, at 42, 44 (describing a physician counseling a BRCA1 carrier about preventing breast or ovarian cancer as being "faced [with presenting] two unsatisfactory choices: one conservative, waiting under surveillance, and one radical, undergoing surgery, with no real middle ground"); see also Marlene Gimons, Should She Take Tamoxifen?, L.A. TIMES, Feb. 6, 1999, at A1, available in LEXIS, News Library, Lattimes File (noting that although tamoxifen has been shown to decrease the incidence of breast cancer by 50%, associated risks include birth defects, uterine cancer, and blood clots); Fox Market Wire, Fighting Cancer—How Treatment Targets Genes (visited May 18, 1998) <http://www.foxmarketwire.com/wires/0518/f_ap_0518_13.sml> (reporting on positive results achieved, in part, with the drug Herceptin to treat women whose breast cancer is linked to multiple copies of the HER2 gene).

93. See Schrag et al., supra note 21, at 1469 (noting that currently women and their physicians often consider mastectomy and oophorectomy as the most effective of the options available to prevent cancer); see also Wiesner, supra note 3, at 10 (discussing a woman’s decision to have a prophylactic removal of her ovaries in light of the cluster of cancer in her family); Groopman, supra note 92, at 44 (noting that the only options are medical surveillance or a complete mastectomy and oophorectomy).

94. See Chen, supra note 27, ¶ 11 (discussing a Mayo Clinic study in which 950 healthy but high-risk women had double mastectomies, diminishing their risk of breast cancer by an estimated 91%, and noting that risks continue to exist “[b]ecause surgeons can’t cut out all of the suspect tissue;” and further noting that 2% to 11% of women undergoing oophorectomies to reduce their risk “still go on to develop the disease”); see also Lynn C. Hartmann et al., Efficacy of Bilateral Prophylactic Mastectomy in Women with a Family History of Breast Cancer, 340 New Eng. J. Med. 77, 82-83 (1999) (reporting a reduction in the incidence of breast cancer of at least 90% for women undergoing prophylactic mastectomy); Singer & Cebul, supra note 5, at 179 (explaining that prophylactic mastectomy is the only established potentially preventative option available, but that breast cancer can still develop in remaining cells after the procedure).

95. See Andrews, supra note 24, at 55 (“A person may choose to refuse a medical intervention to avoid potential psychological harm, not just potential physical harm.”); Andrea Eisen et al., Prophylactic Mastectomy—The Price of Fear, 340 New Eng. J. Med. 137, 138 (1999) (noting that notwithstanding the success of prophylactic mastectomy in preventing breast...
Receipt of a positive test result also may cause a woman to internalize society's messages regarding the stigma of cancer, and of illness more generally.96 The social construction of illness can cause extraordinary pain in and of itself.97 People with cancer and people with genetic traits for serious illness report that they face significant societal stigma, ranging from neighbors and coworkers acting differently towards them to the denial of employment or insurance.98

Among the more difficult issues posed by such testing is the extent of information that a patient chooses to share with her family.99 Indeed, positive and negative tests may be fraught with meaning, particularly in families in which there is a history of breast cancer.100 A

cancer, many women who likely would not get breast cancer or who would survive with less-invasive measures opt to undergo the "disfiguring and potentially psychologically damaging operation" out of fear; Groopman, supra note 92, at 45 (noting that these prophylactic procedures may represent not only the loss of breasts and ovaries, but also of self-image and libido).

96. Health care providers report that upon giving a patient a diagnosis for a chronic or life-threatening condition, they often see the patient adopt a more negative self-image by identifying herself as a person with a "dis-ease." See SHERMAN ELIAS & GEORGE J. ANNAS, REPRODUCTIVE GENETICS AND THE LAW 47 (1987) (asserting that "[g]enetic disorders are often viewed with disdain in a sociocultural sense because parents transmit them to their children," and that "[t]he individual affected by a genetic disorder may also stigmatize himself or herself as inadequate or unworthy because the effect of the condition is extrapolated to the whole person"); see also supra notes 23-24 and accompanying text; cf. Jonsen, supra note 20, at 9-10 ("[I]t remains true that the convergence of many factors needed to trigger the disease may not come about and may be avoided by behaviors, but still, the chanciness and luck of the draw that accompany present-day risk assessment will be replaced by the clear mark of the susceptibility in one's very identity.").

97. See SUSAN SONTAG, ILLNESS AS METAPHOR 7-9 (1978) (discussing the demoralization that occurs when diagnosed with cancer because of the stigma and discrimination associated with the disease); Charles E. Rosenberg, Disease and Social Order in America: Perceptions and Expectations, 64 Milbank Q., Supp. 1, 34, 34-35 (1986) ("[D]isease does not exist as a social phenomenon until it is somehow perceived as existing. . . . Meaning is not necessary but negotiated, the argument follows; disease is constructed not discovered.").

98. See supra notes 28-29, 33-34, infra notes 322-323 and accompanying text.

99. See Biesecker, supra note 29, at 152-53 ("As genes are identified that lead to treatable conditions such as diabetes and hypertension, counselors, nurses, and physicians will find it increasingly difficult to honor the rare client's request not to notify family members. Genetic counselors may come to consider families, rather than individuals, as their clients."); Patenaude, supra note 7, at 403-04 (discussing familial issues that are likely to arise in the context of genetic counseling and testing); Rothenberg, supra note 27, at 119 (examining the ways in which the context of genetics affects the individual's decision whether to share test results with family members); supra notes 77-78 and accompanying text.

100. See Andrews, supra note 7, at 978 (observing that obtaining genetic information may lead one to avoid family events in order not to face a family member with whom they do not wish to share results, or that a bond created between siblings who perceive themselves to be at risk for a genetic flaw may change significantly if they learn that only one of them has the gene); Rothenberg, supra note 27, at 119 (asking "[i]f the patient, in fact, the individual, or the family unit?" and discussing the intergenerational implications for testing).
woman who learns that she is carrying a gene for breast cancer may think differently about a number of compelling questions. What should she tell her siblings, who also may have the flawed gene? What information should she provide to her partner? What impact will it have on her decision about bearing children? A daughter who has the gene has an increased risk for breast cancer; a son with the gene is at increased risk for prostate cancer. If she already has children, what information should she provide to them? These are excruciating questions, with no easy answers.

Indeed, because flaws in the BRCA genes indicate that an individual has an increased risk of becoming ill sometime during her life, insurance companies and employers alike would value the ability to obtain this information. Once privy to it, they are likely to use it in

101. See Chen, supra note 27, ¶ 2 (citing a case in which a woman who tested positive for the breast cancer gene opted for a double mastectomy despite being in good health); Patenaude, supra note 7, at 405 (arguing that genetic counseling must take into account "the psychological and family processes that govern our family relationships and reproduction" (quoting M. Richards, Family Kinship, and Genetics, in THE TROUBLED HELIX: SOCIAL AND PSYCHOLOGICAL IMPLICATIONS OF THE NEW HUMAN GENETICS 249, 270 (T. Martineau & M. Richards eds., 1996))).

102. See Patenaude, supra note 7, at 403 (noting that "people find it hard to believe that, 'chance has no memory,'" and commenting that whether one sibling does (or does not) test positive for a genetic attribute has no impact on whether the other sibling might in fact also have the gene in question).

103. See Andrews, supra note 7, at 979-80 (discussing studies that indicate that genetic knowledge affects decisions to marry, as well as the frequency and satisfaction of sexual relationships); see also Andrews, supra note 27, at 911 (reporting about a rabbi who has advocated that "women with the defective BRCA1 have a duty to inform their prospective mates of that fact" (citation omitted)).


105. See Andrews, supra note 7, at 982-83 (noting that the genetic knowledge a women learns about herself or her child can affect the parent-child relationship).

106. See Patenaude, supra note 7, at 405 (asking "what [do] children have a right to know about their genetic heritage when they come of age and assume management of their own medical care[?]”).

107. See Wiesner, supra note 3, at 5-8 (relating the story of a woman who had a high incidence of cancer in her family, decided to undergo genetic testing, tested positive for the BRCA gene, and then faced the dilemma of how to deal with her 14-year-old daughter’s risk); see also Patenaude, supra note 7, at 405 (discussing ethical conflicts faced by physicians who have a duty of confidentiality to their patients and who may feel a duty to warn other members of the patient’s family).

108. See BRODY, supra note 5, at 137 (warning that “[n]ew genetic screening technologies can give insurance companies even more data for stratifying the risk in the pool of potentially insurable people” so as to exclude them); Rothenberg, supra note 27, at 114 (noting that employment opportunities and health insurance coverage are intertwined because “[t]he employer has a business interest in having a healthy work force to limit health insurance claims”).
a discriminatory manner. Firm protections against such use have not yet been put in place. A decision to test, yielding a genetic marker for cancer, could leave a woman in the sadly ironic position of needing health insurance more than ever before, and not being able to obtain it.

These dilemmas are extraordinary. Indeed, if nothing else, they point out the need for a new legal doctrine of informed consent to provide a framework for patients to consider carefully, with their physicians, a decision to undergo genetic testing.

II. INFORMED CONSENT: LEGAL AND ETHICAL UNDERPINNINGS

A. A Starting Point

The formal doctrine of informed consent is influenced by numerous disciplines, particularly law, ethics, and public policy. This Part begins with an overview of constitutional, statutory, and common law sources of the legal doctrine of informed consent. It continues with a critical analysis of this doctrine, informed particularly by gender, race, and economic viewpoints. This analysis challenges some of the basic assumptions of traditional informed consent theory and provides insight into areas in which reform might be needed, especially with regard to genetic testing.

109. See Brody, supra note 5, at 137 (noting that insurers are likely to misuse genetic information by overestimating individual risk); see also Eric Mills Holmes, Solving the Insurance/Genetic Fair/Unfair Discrimination Dilemma in Light of the Human Genome Project, 85 Ky. L.J. 503, 558-67 (1997) (discussing ways in which genetic testing information is subject to abuse by insurers who are likely to decrease the accessibility and affordability of health-related insurance coverage).

110. See Rothenberg, supra note 27, at 115 (noting that “there is no federal law that specifically addresses genetic privacy and confidentiality,” but only “a patchwork of legislative sources” that insufficiently deals with these concerns); Mark A. Rothstein, Genetic Secrets: A Policy Framework, in GENETIC SECRETS, supra note 3, at 451, 476 (noting that “state employment discrimination laws are woefully inadequate” to address the potential for “genetic discrimination in employment”).

111. See Kathleen Kennedy Townsend, The Double-Edged Helix: Advances in Genetic Testing Reveal Yet Another Reason We Need National Health Insurance, WASH. MONTHLY, Nov. 1997, at 36, 36 (“[E]xtraordinary medical benefits [from genetic research] are clouded by the fact that gene research now offers insurance companies new ways to trim their expenses by denying coverage to those most in need of insurance.”).

112. See Linda F. Smith, Medical Paradigms for Counseling: Giving Clients Bad News, 4 CLINICAL L. REV. 391, 395 (1998) (explaining that a patient’s right to medical information “come[s] from three interrelated sources: the expectations of society in general, the recognition of truth-telling as part of the code of ethics of the medical profession, and case precedence in law” (internal quotation marks omitted) (quoting ROBERT BUCKMAN, HOW TO BREAK BAD NEWS: A GUIDE FOR HEALTH CARE PROFESSIONALS 11 (1992))); see also KATZ, supra note 15, at xiv (“The problems of informed consent . . . require an exploration of the historical evolution of medicine and the medical profession, law, the psychology of physicians and patients, and the state of the art and science of medicine.”).
B. Doctrinal Development of Informed Consent Theory

1. Constitutional Theory: Bodily Integrity and Medical Decision Making.—The Supreme Court has recognized the existence of a right to informed consent,113 but it has yet to define its parameters clearly. The roots of informed consent doctrine lie in privacy theory,114 in three pertinent areas: the right to informational privacy,115 the right to bodily integrity,116 and the right to informed decision making.117 This Article is concerned with the guidance that the Court might provide regarding the latter two rights.

The origins of a right to bodily integrity can be traced to the early part of this century. An individual's liberty to refuse medical treatment, although not framed in these terms, first was recognized by the Court in Jacobson v. Massachusetts,118 when the Court recognized that there exists a "sphere within which the individual may assert the supremacy of his own will and rightfully dispute the authority of any human government ... to interfere with the exercise of that will."119

Initially, the Court focused on the potential conflict between a state's interest in exercising its police power and the interest of the

113. See Cruzan v. Director, Mo. Dep't of Health, 497 U.S. 261, 269 (1990) (recognizing that "informed consent is generally required for medical treatment").
114. The Court has recognized the right of privacy within a number of contexts. See Roe v. Wade, 410 U.S. 113, 158 (1973) ("This right of privacy . . . is broad enough to encompass a woman's decision whether or not to terminate her pregnancy."); Griswold v. Connecticut, 381 U.S. 479, 482-84 (1965) (recognizing the right of a married couple to use contraception without interference from the state); Skinner v. Oklahoma ex rel. Williamson, 316 U.S. 535, 541 (1942) (recognizing the right to procreate); Pierce v. Society of Sisters, 268 U.S. 510, 534-35 (1925) (recognizing the right to "direct the . . . education of children"); Meyer v. Nebraska, 262 U.S. 390, 399 (1923) (recognizing the right "to marry, establish a home and bring up children"). These privacy rights have been drawn from the First, Fourth, Fifth, Ninth, and Fourteenth Amendments. See Roe, 410 U.S. at 152-53 (citing privacy cases involving these Amendments).
115. See Whalen v. Roe, 429 U.S. 589, 599-600 (1977) (stating that privacy interests include avoiding disclosure of personal matters).
117. See Cruzan, 497 U.S. at 269 (recognizing that "informed consent is generally required for medical treatment"); cf. Planned Parenthood of S.E. Pa. v. Casey, 505 U.S. 833, 872 (1992) (deciding that a state may enact rules to ensure that a woman's choice to terminate her pregnancy is thoughtful and informed).
118. 197 U.S. 11, 25-29, 39 (1905) (upholding a state law requiring individuals to submit to a smallpox vaccination on the ground that this intrusion was a reasonable exercise of the police power to protect the public health).
119. Id. at 29.
individual in determining what happens to her body.\footnote{120} It was in this context, almost fifty years after \textit{Jacobson}, that the Court explicitly recognized a right to bodily integrity founded in the Due Process Clause.\footnote{121}

It was not, however, until 1990 that the Court first addressed the tension that might arise between the state’s interest in preserving life and an individual’s interest in preserving bodily integrity in the context of medical care.\footnote{122} At that time, and in subsequent cases, the Court recognized a “‘liberty interest in refusing medical treatment,’”\footnote{123} but has resisted the conclusion that “any and all important, intimate, and personal decisions are so protected.”\footnote{124}

Most recently, in \textit{Washington v. Glucksberg},\footnote{125} the Court drew this line by rejecting the claim that a constitutional right to physician-assisted suicide exists.\footnote{126} Still, the Court reaffirmed that the Due Process Clause “provides heightened protection against government

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120. See, \textit{e.g.}, \textit{Skinner v. Oklahoma ex rel. Williamson}, 316 U.S. 535, 544 (1942) (Stone, C.J., concurring) (agreeing that a state law requiring the sterilization of habitual criminals, except white collar criminals, should be invalidated, but on the ground that “such an invasion of personal liberty” violates due process, in contrast to the majority’s reliance on equal protection grounds).

121. \textit{Rochin}, 342 U.S. at 172-73 (declaring that forcible administration of an emetic used to extract morphine capsules from a suspect’s stomach violated the Due Process Clause). In this opinion, Justice Frankfurter reasoned that “[d]ue process of law is a summarized constitutional guarantee of respect for those personal immunities which, as Mr. Justice Cardozo twice wrote for the Court, are ‘so rooted in the traditions and conscience of our people as to be ranked as fundamental,’ or are ‘implicit in the concept of ordered liberty.’” \textit{Id.} at 169 (quoting \textit{Snyder v. Massachusetts}, 291 U.S. 97, 105 (1934); \textit{Palko v. Connecticut}, 302 U.S. 319, 325 (1937)); cf. \textit{Washington v. Harper}, 494 U.S. 210, 221-22 (1990) (recognizing that an inmate “possesses a significant liberty interest in avoiding the unwanted administration of antipsychotic drugs under the Due Process Clause of the Fourteenth Amendment”). The \textit{Harper} Court nevertheless upheld a prison policy permitting administration of the drugs without the inmate’s consent in light of the state’s obligation to “combat[] the danger posed by a person to both himself and others” in the prison environment. \textit{Id.} at 225.

122. \textit{See Cruzan}, 497 U.S. at 278-80 (recognizing a general liberty interest in refusing medical treatment, but balancing this interest against a state’s interest in preserving human life). In her concurrence, Justice O’Connor emphasized that “the liberty interest in refusing medical treatment flows from decisions involving the State’s invasions into the body.” \textit{Id.} at 287 (O’Connor, J., concurring).


126. \textit{Id.} at 2275; \textit{see also Vacco v. Quill}, 117 S. Ct. 2293, 2302 (1997) (holding that New York’s ban on assisted suicide does not violate the Fourteenth Amendment).}
interference with certain fundamental rights and liberty interests," including the right to "bodily integrity."\(^{127}\)

Although the nexus between one’s right to bodily integrity and one’s right to make important personal decisions, particularly with regard to medical treatment, is quite close, the line of cases related to the latter is comparatively recent. The decisional right grew out of the right to privacy acknowledged in *Griswold v. Connecticut*\(^{128}\) and its progeny.\(^{129}\) Admittedly, this right has had a somewhat tortured history in the relatively short time since its recognition.

The Court’s rulings in the area of decisional privacy are overwhelmingly concerned with the kind of information a woman should receive—or should not receive—prior to consenting to, or refusing, an abortion. The politically fraught nature of this subject matter makes it difficult to draw lessons from these rulings and apply them to cases that involve medical decision making outside of the reproductive rights arena.

For example, the Court initially acknowledged that informed consent was critical to making important medical decisions, including the decision whether to have an abortion.\(^{130}\) Although the Court nominally has continued to support this approach, it has done so

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127. *Glucksberg*, 117 S. Ct. at 2267 (citing Rochin v. California, 342 U.S. 165 (1952)). In his concurrence, Justice Souter reiterated that "every human being of adult years and sound mind has a right to determine what shall be done with his own body in relation to his medical needs." *Id.* at 2288 (Souter, J., concurring) (quoting Schloendoff v. Society of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914)). He further elucidated the importance of this liberty interest in the context of medical care by observing that "the good physician is not just a mechanic of the human body whose services have no bearing on a person’s moral choices, but one who does more than treat symptoms, one who ministers to the patient." *Id.* at 2288 (citing Roe v. Wade, 410 U.S. 113, 153 (1973); Griswold v. Connecticut, 381 U.S. 479, 482 (1965)).

128. 381 U.S. 479 (1965).

129. See Whalen v. Roe, 429 U.S. 589, 599-600 (1977) (explicitly recognizing "the interest in independence in making certain kinds of important decisions"). Whalen was concerned primarily with the confidentiality of personal (medical) information and recognized "the individual interest in avoiding disclosure of personal matters." *Id.* at 599; see also *Glucksberg*, 117 S. Ct. at 2267 (recognizing the right to bodily integrity as a liberty specially protected by the Due Process Clause); City of Akron v. Akron Ctr. for Reprod. Health, Inc., 462 U.S. 416, 419 (1983) (acknowledging that the right of privacy encompasses the decision whether to terminate pregnancy), *overruled on other grounds* by Planned Parenthood of S.E. Pa. v. Casey, 505 U.S. 833, 882 (1992) (plurality opinion); *Roe*, 410 U.S. at 153 (same).

130. Planned Parenthood of Cent. Mo. v. Danforth, 428 U.S. 52, 66-67 (1976). The Court upheld a state regulation requiring a woman’s written consent before performing an abortion on the ground that:

The decision to abort, indeed, is an important, and often a stressful one, and it is desirable and imperative that it be made with full knowledge of its nature and consequences. The woman is the one primarily concerned, and her awareness of
while upholding regulations that require physicians to provide pregnant women with information designed to dissuade them from choosing abortion, and regulations that restrict the information that publicly funded providers could give to their patients regarding the availability of abortion services.

In these abortion cases, the Court perceived the "doctor-patient relation[ship]" as separate from "the right to make family decisions and the right to physical autonomy." By contrast, Justice Blackmun perceived an essential link between the provision of information by a physician and a patient's ability to make important medical decisions. In his dissent in Rust, he specifically noted the importance of protect-

the decision and its significance may be assured, constitutionally, by the State to the extent of requiring her prior written consent.  

Id. at 67. Note, however, that reproductive rights advocates objected to this requirement for written consent as a deterrent to a woman's exercise of her right to make independent medical decisions. Seven years later, the Court reiterated that it envisioned that a physician would provide a woman with information about the abortion procedure and its consequences, so that she could make an informed decision regarding whether to have an abortion. See City of Akron, 462 U.S. at 442-44 (recognizing the validity of an informed consent requirement, but invalidating the one at issue because it was intended to persuade women to forego abortion), overruled by Casey, 505 U.S. at 882 (plurality opinion) (upholding informed consent requirements designed to influence a woman to continue a pregnancy).

131. Casey, 505 U.S. at 881-87 (plurality opinion). This information included extensive and detailed information regarding the abortion procedure, the relative health risks of abortion and of childbirth, and the probable gestational age of the fetus. Id. at 881. Reasoning that such detailed information would ensure that a woman's decision to terminate her pregnancy be mature and informed, a plurality found that even when the information expresses a state's preference for childbirth over abortion, the regulations imposed no undue burden on a woman's liberty interest in making a decision regarding abortion. Id. at 883; see infra note 141. The plurality reached this result despite the Court's reiteration "that the Constitution places limits on a State's right to interfere with a person's most basic decisions about family and parenthood." Casey, 505 U.S. at 849 (citations omitted).

132. Rust v. Sullivan, 500 U.S. 173, 193-94 (1991). The Court defined the provision of abortion-related information as an abortion service, and held that, under the Due Process Clause, the government has no constitutional duty to subsidize this service, and may encourage childbirth instead. Id. at 201. The Court reassured itself that the restrictions imposed by the regulations were not absolute because "a doctor's ability to provide, and a woman's right to receive, information concerning abortion and abortion-related services outside the context of the Title X [government-funded] project remains unfettered." Id. at 203. But see id. at 217 (Blackmun, J., dissenting) (asserting that the regulations "obliterated the freedom to choose as surely as if it had banned abortions outright," especially with regard to poor women with limited access to medical care).

133. Casey, 505 U.S. at 884 (plurality opinion). In this case, the Court addressed the regulations' potential interference with the physician-patient relationship by noting that they allow a physician to decide against providing the required information "if he or she can demonstrate by a preponderance of the evidence, that he or she reasonably believed that furnishing the information would have resulted in a severely adverse effect on the physical or mental health of the patient." Id. at 883-84 (quoting 18 PA. CONS. STAT. § 3205 (1990)).
ing physician-patient dialogue and trust by observing that "[o]ne seeks a physician's aid not only for medication or diagnosis, but also for guidance, professional judgment, and vital emotional support,"\(^{134}\) indeed, "each of us attaches profound importance and authority to the words of advice spoken by the physician."\(^{135}\) With this understanding, although protection of the doctor-patient relationship may not inherently rise to the level of a fundamental right, it may serve as a vehicle for ensuring, or enhancing, a patient's right to privacy and autonomy.

As indicated by the discussion above, the Court primarily has addressed medical decision making in the reproduction context; yet in *Cruzan v. Director, Missouri Department of Health*,\(^{136}\) and elsewhere, the Court has recognized that a competent person may possess a constitutionally protected liberty interest in the right to refuse medical treatment.\(^{137}\)

However, because the Court has not fully addressed the extent of information, or the degree of bodily integrity, that must be afforded to a patient in the less politicized, nonabortion context, it remains to us to intuit whatever guidance the Court ultimately may provide. At a minimum, there is a liberty interest\(^{138}\) in informed medical decision

\(^{134}\) *Rust*, 500 U.S. at 218 (Blackmun, J., dissenting).

\(^{135}\) Id.


\(^{137}\) Id. at 278; *see also* Washington v. Glucksberg, 117 S. Ct. 2258, 2269 (1997) ("[W]e assumed that the Constitution granted competent persons a 'constitutionally protected right to refuse lifesaving hydration and nutrition.'" (quoting *Cruzan*, 497 U.S. at 279)). Despite this assumption, the *Cruzan* Court denied the petitioner-family members' request to terminate the patient's artificial hydration and nutrition for lack of clear and convincing evidence that she would have desired this action. *Cruzan*, 497 U.S. at 280. In her concurrence, Justice O'Connor wrote:

> As the Court notes, the liberty interest in refusing medical treatment flows from decisions involving the State's invasions into the body. Because our notions of liberty are inextricably entwined with our idea of physical freedom and self-determination, the Court has often deemed state incursions into the body repugnant to the interests protected by the Due Process Clause.

*Id.* at 287 (O'Connor, J., concurring) (citation omitted) (citing *Rochin v. California*, 342 U.S. 165, 172 (1952)).

\(^{138}\) Originally, the Court recognized the right to bodily integrity, and then the right to decisional privacy, as falling within the small range of "personal rights that can be deemed 'fundamental' or 'implicit in the concept of ordered liberty' [that] are included in [a] guarantee of personal privacy." *See Roe v. Wade*, 410 U.S. 113, 152 (1973) (recognizing that the right of privacy encompasses a woman's right to have an abortion) (citing *Palko v. Connecticut*, 302 U.S. 319, 325 (1937)); *see also* *Eisenstadt v. Baird*, 405 U.S. 438, 453-55 (1972) (striking down, on principles of privacy and equal protection, a Massachusetts criminal statute barring the distribution of contraceptives to married people except by physicians and pharmacists); United States v. Vuitch, 402 U.S. 62, 78 (1971) (noting that "the right of privacy" applies to intimate family decision making); *Griswold v. Connecticut*, 381 U.S. 479, 485 (1965) (holding that a law prohibiting the use of contraceptives violated the right to privacy).
making and the right to bodily integrity, it is not clear whether, in other settings, these rights will be recognized as fundamental. There is no doubt, however, that the Court has recognized that the right to bodily integrity and the right to decisional privacy are of sufficient importance to deserve constitutional protection.

It is not likely that the Court will have the opportunity to address these issues in the context of minimally invasive, yet diagnostically significant tests any time soon. The precipitating events that brought Casey, Rust, and other cases to the Court were the decisions by legislatures to mandate the type of information a patient was to receive, or not receive. Although legislative bodies have mandated pre-test or pre-procedure counseling in some limited (non-abortion) settings, such as HIV or hysterectomy, such counseling has been seen as an

More recently, however, at least in the context of abortion, the Court has characterized these previously identified fundamental rights as "liberty interests." See, e.g., Casey, 505 U.S. at 869 (plurality opinion) (noting that "it is a constitutional liberty of the woman to have some freedom to terminate her pregnancy"); Webster v. Reproductive Health Servs., 492 U.S. 490, 520 (1989) (plurality opinion) (characterizing abortion as a "liberty interest protected by the Due Process Clause").

139. See supra notes 114-117, 150-151.
140. See supra note 127; cf. Lilich v. Hartigan, 735 F. Supp. 1361, 1376 (N.D. Ill.) (holding that restrictions on a couple's decision to use genetic tests on a fetus are unconstitutional unless they further a compelling state interest in the least restrictive manner possible), aff'd, 914 F.2d 260 (7th Cir. 1990).
141. While any restriction of a fundamental right is subject to strict scrutiny review, a restriction on a liberty interest is permissible if it does not unduly burden the exercise of the interest. See Casey, 505 U.S. at 874 (plurality opinion) ("Only where state regulation imposes an undue burden on a woman's ability to make this decision [about abortion] does the power of the State reach into the heart of the liberty protected by the Due Process Clause."); Webster, 492 U.S. at 520 (plurality opinion) (arguing that a restriction on abortion that is "reasonably designed" to ensure that it is not performed when the fetus is viable is valid because the end is "legitimate"). If the right to informed medical decision making and the right to bodily integrity are "fundamental," then they provide greater protection to the individual because the state could not intrude on them "without substantial justification." Griswold, 381 U.S. at 502-03 (citation omitted). Should these rights be found to be "liberty interests," in order for a restriction to be upheld, a state need only show that a restraint upon an interest does not pose an "undue burden" to those seeking to realize it.
142. See, e.g., Casey, 505 U.S. at 881 (plurality opinion) (challenging a Pennsylvania statute requiring abortion providers to provide a woman with printed materials describing the fetus, available medical assistance for childbirth, access to child support from the father, and a list of adoption agencies); Rust v. Sullivan, 500 U.S. 173, 192 (1991) (challenging regulations prohibiting providers receiving Title X funds from all discussion of abortion with patients, but compelling provision of information promoting continuation of pregnancy to term).
143. See N.Y. PUB. HEALTH LAW §§ 2496-2498 (McKinney 1993) (directing the creation of a comprehensive written summary explaining, among other things, the "common diagnoses for which hysterectomy is a common treatment," the "alternative treatments to hysterectomy for such diagnoses," and the "common physiological changes, side effects, risks and benefits" resulting from each treatment, and mandating that the written summary
important shield to protect against efforts to mandate HIV testing\textsuperscript{144} and as a necessary response to a history in which coerced sterilizations were performed.\textsuperscript{145} Indeed, existing legislative protocols in these areas serve to assist patients in making informed, voluntary decisions regarding testing and treatment.\textsuperscript{146}

As one might expect, most of these counseling requirements have been established with the support and guidance of public health organizations and those most likely to receive this counseling. Therefore, even though subjects such as AIDS and sterilization can evoke significant emotion and political activity,\textsuperscript{147} the community-based support for these forms of mandated medical counseling indicates that these provisions are not likely to be the subject of constitutional legal challenge.\textsuperscript{148}

shall be provided "by a physician to each person under such physician's care, when a hysterectomy is under consideration for that person"). Section 2781 provides:

Informed consent to an HIV related test shall consist of . . . (a) an explanation of the test, including its purpose, the meaning of its results, and the benefits of early diagnosis and medical intervention . . . ; and (b) an explanation of the procedures to be followed, including that the test is voluntary, that consent may be withdrawn at any time, and a statement advising the subject that anonymous testing is available; and (c) an explanation of the confidentiality protections afforded confidential HIV related information . . . including the circumstances under which and classes of persons to whom disclosure of such information may be required, authorized or permitted . . .

\textit{Id.} § 2781.

144. \textit{Cf.} Lawrence O. Gostin \& David W. Webber, \textit{HIV Infection and AIDS in the Public Health and Health Care Systems: The Role of Law and Litigation}, 279 \textit{JAMA} 1108, 1109 (1998) (noting that "counseling and consent are thought to be important to enhance patient autonomy").

145. \textit{See} Lori L. Heise, \textit{Reproductive Freedom and Violence Against Women: Where Are the Intersections?}, in \textit{APPLICATIONS OF FEMINIST LEGAL THEORY TO WOMEN'S LIVES: SEX, VIOLENCE, WORK, AND REPRODUCTION} 1032, 1035 (D. Kelly Weisberg \textit{ed.}, 1996) [hereinafter \textit{FEMINIST LEGAL THEORY}] ("In the United States, . . . instances of involuntary sterilization of poor, minority, and mentally retarded young women during the early 1970s led to the enactment of more stringent sterilization regulations in 1978."); Laurie Nsiah-Jefferson, \textit{Reproductive Laws, Women of Color, and Low-Income Women}, in \textit{FEMINIST LEGAL THEORY}, supra, at 1007, 1014 ("Complete information is crucial to voluntary choice, yet many women elect sterilization under the mistaken belief that the procedure is reversible. Medical personnel often encourage that belief by referring to the procedure as 'tying the tubes'; many women assume that what can be tied, can be untied later.").

146. \textit{See} CAL. HEALTH \& SAFETY CODE § 1690(a) (West 1990) ("Prior to the performance of a hysterectomy, physicians and surgeons shall obtain verbal and written informed consent."); N.Y. PUB. HEALTH LAW § 2498 (McKinney 1998) (requiring a written summary of hysterectomy information to be provided to patients); \textit{see also infra} note 242 and accompanying text.

147. \textit{See} Rachel Lurie, \textit{Translating Issues into Actions: Introduction, in WOMEN, AIDS \& ACTIVISM} 211, 211-12 (Cynthia Chris \& Monica Pearl \textit{eds.}, 1990) (discussing activist strategies against AIDS in the context of "social injustices").

148. As medical organizations often resist the imposition of legislative mandates regarding counseling, it remains to be seen whether these organizations would file suit to chal-
2. The Development of a Common Law and Statutory Legal Theory of Informed Consent.—Traditional informed consent doctrine derives from tort law, specifically, the common law prohibition on battery. Early court decisions that allowed recovery for a claimant asserting that a doctor performed procedures to which the patient had not consented were treated as disputes involving "unauthorized touching." The focus in these cases, however, was on the complete absence of consent, rather than on whether sufficient information had been conveyed to the patient to enable voluntary decision making.

Gradually, as medical procedures grew more complicated and as courts struggled to develop a mechanism to compensate patients whose consent had been lacking, but not wholly absent, a legal theory of "informed consent" grew to be expressed as a separate tort, grounded in negligence and influenced by contract theory. Today, many states recognize two separate, though related, causes of action: the intentional tort of battery, defined as a touching for which there has been no consent; and a cause of action in negligence, defined as a touching for which the patient did not give informed consent.

LENGE THEIR APPLICABILITY. ONE MIGHT EXPECT, HOWEVER, THAT THE SIGNIFICANT LIKELIHOOD OF NEGATIVE MEDIA REPORTS MIGHT DISCOURAGE SUCH LitIGATION.

149. See Pratt v. Davis, 79 N.E. 562, 564 (Ill. 1906) (affirming a judgment for trespass against a physician who performed a hysterectomy without consent); Mohr v. Williams, 104 N.W. 12, 16 (Minn. 1905) (holding a physician liable for assault for operating on a patient's left ear without permission); Schloendorff v. Society of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914) (noting that "a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages"), overruled in part by Bing v. Thunig, 143 N.E.2d 3 (N.Y. 1957); Rolater v. Strain, 137 P. 96, 98 (Okla. 1913) (holding that an operation beyond the scope of consent constituted an assault); Faden & Beauchamp, supra note 44, at 120 (describing these four battery decisions as "almost universally credited with formulating the basic features of informed consent in American law").

150. Mohr, 104 N.W. at 16 (using the phrase "unauthorized touching" to describe the tort of battery); see also Faden & Beauchamp, supra note 44, at 26-27.

151. See Mohr, 104 N.W. at 15 ("If the operation was performed without plaintiff's consent, and the circumstances were not such as to justify its performance without, it was ... unlawful."); see also Faden & Beauchamp, supra note 44, at 26-27.

152. See Katz, supra note 15, at 73 (noting that courts have been reluctant to explore the extent to which partial disclosure or partial consent may vitiate a patient's claim for lack of consent).

153. See Faden & Beauchamp, supra note 44, at 125-40 (discussing the evolution of the duty to obtain consent, rooted in a battery theory, to the duty to disclose risks, which incorporated elements of negligence and which arose from the quasi-contractual physician-patient relationship); Peter H. Schuck, Rethinking Informed Consent, 103 Yale L.J. 899, 902 (1994) ("[I]nformed consent does not simply pursue the contract law goals of individual autonomy, efficiency, and anti-statism; it also advances two related ideas, fault and duty, that pervade and moralize tort law.").

154. See, e.g., Doe v. Noe, 690 N.E.2d 1012, 1021 (Ill. App. Ct. 1997) (distinguishing "between a total lack of consent for the contested act (battery) and the lack of informed consent")
Although requirements vary somewhat from state to state, an informed consent claim generally consists of the following elements: (1) a physician’s duty to disclose material risks; (2) the failure to disclose or inadequate disclosure of those risks; (3) as a direct and proximate result of the failure to disclose, the patient consented to treatment to which she otherwise would not have consented; and (4) the patient was injured by the proposed treatment.

155. See, e.g., N.Y. PUB. HEALTH LAW § 2805-d(1) (McKinney 1993) (defining lack of informed consent as the failure “to disclose to the patient such alternatives [to the treatment] and the reasonably foreseeable risks and benefits involved as a reasonable . . . practitioner under similar circumstances would have disclosed, in a manner permitting the patient to make a knowledgeable evaluation”); Daum v. Spinecare Med. Group, Inc., 61 Cal. Rptr. 2d 260, 268 (Ct. App. 1997) (setting forth a two part test for determining whether consent was informed: whether the physician disclosed (1) the risk of death, serious harm, or complications, and (2) additional information that a skilled practitioner would provide under similar circumstances); Ditto v. McCurdy, 947 P.2d 952, 958-59 (Haw. 1997) (refusing to require a physician to disclose his qualifications or lack thereof to the patient, and leaving it to the state’s board of medical examiners to establish standards of informed consent pursuant to statutory authority); Guidry v. Neu, 708 So. 2d 740, 743-44 (La. Ct. App. 1997) (defining the elements of lack of informed consent as a causal connection between the physician’s failure to disclose the existence of a material risk that he had a duty to disclose, and the actual risk sustained by the patient); Noe, 690 N.E.2d at 1021 (noting that a cause of action premised on informed consent requires that, as a result of the physician’s breach of a duty to disclose material risks, the patient consented to treatment that she otherwise would not have consented to and that resulted in harm).

156. The shift from battery to negligence results in an emphasis upon the elements of causation and actual (not merely dignitary) harm. See N.Y. PUB. HEALTH LAW § 2805-d(3) (requiring the plaintiff to show that a reasonably prudent patient in her position would not have undergone the treatment if she had been fully informed); Posta v. Chung-Loy, 703 A.2d 368, 378-79 (N.J. Super. Ct. App. Div. 1997) (stating that the plaintiff failed to prove the element of causation because a reasonably prudent patient in his position would have undergone the surgeries at issue even after being informed of the risk), cert. denied, 713 A.2d 500 (N.J. 1998); Noe, 690 N.E.2d at 1021 (setting forth proximate cause and injury as elements of an action based on lack of informed consent); Faden & Beauchamp, supra note 44, at 29 (noting the shift from an action in battery to one in negligence where the plaintiff then had to show harm actually done); Katz, supra note 15, at 69 (“[N]egligence law generally does not redress dignitary injuries in the absence of physical injury. It leaves little
Traditionally, a reasonable physician standard has guided the determination of what information is material and therefore should have been disclosed to a patient.\textsuperscript{157} Pursuant to this approach, which still exists in many jurisdictions, if a patient asserts that she was not provided with sufficient or accurate information concerning the risks and benefits of a procedure, the patient will succeed in her cause of action only if the undisclosed risk caused her harm, and disclosure of the risk is required by "the recognized standard of acceptable professional practice in the profession and in the specialty."\textsuperscript{158} This approach is firmly rooted in the belief that physicians have specific, expert knowledge regarding not only the provision of medical treatment, but also the extent of information that ought to be shared with their patients.\textsuperscript{159}

Not surprisingly, although this standard persists in a number of jurisdictions,\textsuperscript{160} there has been a perceptible movement towards the

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\textsuperscript{157} See Natanson v. Kline, 350 P.2d 1093, 1106 (Kan. 1960) (limiting the duty to disclose to risks "which a reasonable medical practitioner would make under the same or similar circumstances"); Marchione v. State, 598 N.Y.S.2d 592, 593 (App. Div. 1993) (noting that the duty of care is satisfied when "a physician discloses all the facts that a reasonable physician under similar circumstances would have disclosed"); see also Katz, \textit{supra} note 15, at 69 ("The choice of negligence theory allowed judges to defer gracefully to medical judgment, permitting physicians to continue to exercise the wisdom of their profession and making them liable only for failure to disclose what a typical, and hence, reasonable doctor would have revealed under the circumstances").

\textsuperscript{158} Sanders v. Whitfield, No. 01-A-01-9707CV-00357, 1997 WL 778988, at *2 (Tenn. Ct. App. Dec. 19, 1997) (citing Tenn. Code Ann. § 29-26-118) (1980)); see Weber v. McCoy, 950 P.2d 548, 551 (Wyo. 1997) (noting that a plaintiff must establish "'(1) the accepted standard of medical care or practice, (2) that the doctor's conduct departed from the standard, and (3) that his conduct was the legal cause of the injuries suffered'" (quoting Harris v. Grizzle, 625 P.2d 747, 751 (Wyo. 1981))); \textit{see also Faden & Beauchamp, \textit{supra} note 44, at 31 ("All the courts adopting the professional practice rule require expert testimony from members of relevant professional groups to determine whether a physician has violated a duty to disclose the risk in question."); Schuck, \textit{supra} note 153, at 916 ("In slightly over half the states, the legal standard for disclosure to patients is that which a 'reasonable medical practitioner' would provide.").

\textsuperscript{159} See Faden & Beauchamp, \textit{supra} note 44, at 30 (noting that, pursuant to the professional practice standard, "[d]isclosure, like treatment, is . . . a job belonging to physicians by virtue of their professional expertise, role, and commitment"). The "reasonable physician" standard also is the measure applied in medical malpractice actions generally. \textit{See id. at 29-31} (noting that lack of informed consent is treated as a type of medical malpractice, and that the requirement of expert testimony from medical professionals can be hindered by "professional solidarity").

\textsuperscript{160} \textit{See, e.g.}, N.Y. PUB. HEALTH LAW § 2805-d (1) (using a "reasonable practitioner" standard). New York, however, mitigates the severity of this standard by requiring that the required information be disclosed "in a manner permitting the patient to make a knowledgeable evaluation." \textit{Id.; see also} Sanders, 1997 WL 778988, at *2 (invoking "the recognized standard of accepted professional practice in the profession and in the specialty" (citing...
adoption of a "reasonable patient" standard.\textsuperscript{161} Under this approach, if a "reasonable patient, in what the physician knows or should know to be the patient's position, would be 'likely to attach significance to the risk or cluster of risks' in deciding whether to forego the proposed therapy or to submit to it,"\textsuperscript{162} those risks should be disclosed.\textsuperscript{163} However, because this is a claim sounding in negligence, the patient must suffer harm from the undisclosed risk to prevail.\textsuperscript{164}

Even under the reasonable patient standard, there is a large, amorphous middle—between the perspective of the individual claimant and the objectively assessed reasonable person in the claimant's position—that is the subject of judicial and jury-based decision making.\textsuperscript{165} Neither courts nor legislatures have provided sufficient gui-

\textsuperscript{161} T enn. Code Ann. § 29-26-118); Weber, 950 P.2d at 552 (setting forth the traditional, reasonable practitioner view).


\textsuperscript{163} See, e.g., Or. Rev. Stat. § 677.097 (Supp. 1998) (requiring a physician to respond to a patient's questions in detail, including alternatives, "unless to do so would be materially detrimental to the patient"); 40 PA. Cons. Stat. Ann. § 1301.811-A(b) (West Supp. 1998) ("Consent is informed if the patient has been given a description of a procedure . . . and the risks and alternatives that a reasonably prudent patient would require to make an informed decision as to that procedure.") (emphasis added); Canterbury, 464 F.2d at 785 (rejecting the professional practice standard and requiring the duty to disclose to be measured by a reasonable lay person standard); Carr v. Strode, 904 P.2d 489, 499 (Haw. 1995) (adopting "the patient-oriented standard applicable to a physician's duty to disclose risk information prior to treatment"); Caputa v. Antiles, 686 A.2d 356, 361 (N.J. Super. Ct. App. Div. 1996) (noting that, under the prudent patient standard, "a physician must disclose all information material to a reasonably prudent patient's treatment decision").

\textsuperscript{164} See Guidry v. Neu, 708 So. 2d 740, 743 (La. Ct. App. 1997) (discussing lack of informed consent where a physician allegedly failed to disclose the risk of endophthalmitis prior to eye surgery, and patient subsequently suffered a loss of vision); Posta v. Chung-Loy, 703 A.2d 368, 372 (N.J. Super. Ct. App. Div. 1997) (discussing plaintiff's claim that he would not have undergone abdominal surgery had he been informed of the possibility of a hernia, which he in fact suffered), cert. denied, 713 A.2d 500 (N.J. 1998); see also Faya v. Alvarez, 329 Md. 435, 447-48, 620 A.2d 327, 333 (1993) (holding that patients bringing negligence claims against a surgeon who failed to reveal that he had AIDS at the time of the operations may recover damages for emotional distress to the extent that this injury can be objectively demonstrated for the period between learning of the doctor's illness and receiving HIV-negative results).

\textsuperscript{165} In disability law, courts attempt to assess the elements of "significant risk" as determined by Congress and the Supreme Court. Compare Rehabilitation Act of 1973, 29 U.S.C. § 794(a)(1994) (prohibiting discrimination against any "otherwise qualified individual" in programs or activities receiving federal financial assistance) with School Bd. v. Arline, 480 U.S. 273, 287 n.16 (1987) (noting that, under the Rehabilitation Act, a person who poses a significant risk not capable of being ameliorated through reasonable accommodation is not otherwise qualified); see also Americans with Disabilities Act, 42 U.S.C. § 12111(3) (1994) (defining a direct threat as one posing a "significant risk" to the health and safety of
dance to interpret adequately this large middle area. The next Part provides a critical analysis of the theory and practice of informed consent. As such, it helps serve as a foundation for the proposals set forth in Part IV, developing a new model for informed consent in the context of genetic testing.

C. Does Informed Consent Doctrine Work?

1. An Analysis of Informed Consent Doctrine in Practice.—Current informed consent doctrine has been criticized as inadequate to protect the needs, and the rights, of most patients. In the words of Jay Katz, "The legal vision of informed consent, based on self-determination, is still largely a mirage." In practice, courts tend to focus more on the formalities of whether consent was obtained than on whether a patient’s consent truly was based on an appropriate disclosure and discussion of material risks and benefits. Although most patients challenge a health care provider's failure to disclose risks and benefits attendant to a medical procedure by bringing a claim in negligence for "lack of informed consent," it sometimes seems that we have not ventured very

others); 29 C.F.R. Pt. 1630.2(r) App. (enumerating four factors necessary to assess a direct threat: the duration of the risk, the nature and severity of the potential harm, the likelihood the potential harm will occur, and the imminence of the potential harm). In the context of informed consent, however, neither the courts nor legislatures have developed such a standard of "significant risk," or a means of assessing it.

166. Louisiana has rejected both the reasonable physician and the reasonable patient approaches, and instead provides a list of risks of which patients must be informed. See La. Rev. Stat. Ann. § 40:1299.40 (West 1992) (rejecting both the reasonable physician and reasonable patient standards and instead requiring that patients be informed of "the nature and purpose of the procedure ... together with the known risks, if any, of death, brain damage, quadriplegia, paraplegia, the loss or loss of function of any organ or limb, [and] of disfiguring scars," and that their questions be answered "in a satisfactory manner," and that their consent be in writing).

167. Katz, supra note 15, at 84; see also supra notes 36-42 and accompanying text (recounting the medical profession's failure to seek (informed) consent from African Americans and low-income women in some contexts, including mandated sterilization, blood tests (including sickle cell), and the Tuskegee Experiment).

168. For example, in most jurisdictions, the existence of a written consent form triggers a presumption that the patient's consent was "informed." See, e.g., Hondroulis v. Schuhmacher, 553 So. 2d 398, 405 (La. 1988) (holding that a signed consent form, prepared according to statute, established a rebuttable presumption of informed consent). But see Hartman v. D'Ambrosia, 665 So. 2d 1206, 1209-11 (La. Ct. App. 1995) (finding a lack of informed consent because, although the patient had signed a written consent for bunion surgery, a reasonable person in her position might have refused surgery if given more information).

169. See supra notes 152-154 and accompanying text.
far from the days when patients brought most claims as intentional
torts, sounding in battery, for "lack of consent."170

Some commentators assert that the inherent lack of positional
equality171 between physician and patient undermines any attempt by
the physician to obtain the patient's true consent.172 These writers
note that physicians traditionally have exercised a great deal of au-
thority based on their extensive education and training.173 In addi-
tion, the demographic distinctions between physicians, who tend to
be white, although less often male than in the past, and patients, who
represent all races and both genders,174 have influenced the tradi-
tional modalities of physician-patient interaction.175

These observations regarding the power relations between pro-
vider and patient only bolster the need for a thorough critique of in-
formed consent theory. Indeed, to end the review of informed
consent doctrine at this point would merely be an accommodation of

170. See supra notes 149-154 and accompanying text; see also Katz, supra note 15, at 68
(discussing factors influencing the transition from battery to negligence, and noting both
the misunderstanding that battery required an element of malicious intent or intent to
influence actual damage, and the reluctance of courts to find liability when touching that falls
within the standards of care occurs without full disclosure of material risks). The doctrine
of informed consent is, in fact, relatively new, dating only from the late 1950s. Id. at 59.

171. Brony, supra note 5, at 59 (arguing that biotechnological advances are reinforcing
the power and "sacrosanct status" of physicians in society); Mary B. Mahowald, On Treat-
ment of Myopia: Feminist Standpoint Theory and Bioethics, in FEMINISM & BIOETHICS, supra note
69, at 95, 103 (discussing the "dominant and dominating role of the paternalistic physician
. . . within the health care hierarchy"); see also supra notes 35-42 and accompanying text
(discussing historical expressions of disempowerment of racial minorities and women in
medical settings).

172. See Gail Geller et al., Genetic Testing for Susceptibility to Adult-Onset Cancer: The Process
and Content of Informed Consent, 277 JAMA 1467, 1468 (1997) (discussing as one obstacle to
informed consent “the imbalance of power inherent in the relationship between partici-
pants [in medical research] and medical professionals”).

173. See Katz, supra note 15, at 1 (“Disclosure in medicine has served the function of
getting patients to ‘consent’ to what physicians wanted them to agree to in the first
place.”); Mahowald, supra note 171, at 102 (“[Patients] are often considered only as the
assumed object of beneficence, or in the context of [doctors] permitting them to exercise
autonomy.”). This disparity may be manifest in doctors implicitly or explicitly asking to be
called, and our addressing them as, “Dr.,” while they, in turn, more often address us by our
first name.

174. Mahowald, supra note 171, at 103 (noting that “the majority of patients are women
and the majority of physicians are still men” (citing CHARLOTTE F. MULLER, HEALTH CARE
AND GENDER 7-10 (1992))).

175. See infra notes 186-187, 192-194, 211-228 and accompanying text (discussing cul-
tural and socioeconomic factors that can complicate the process of obtaining informed
consent); see also Andrews, supra note 7, at 990 (discussing studies that reveal that the gen-
der of the physician or genetic counselor “can . . . influence the amount of pressure” put
on patients to consent to testing, with female counselors being “more sensitive to personal
autonomy issues and more concerned with the overall effect that testing may have on the
family unit as a whole” (citations omitted)).
existing disparities. A critical assessment may be able to identify mechanisms to help reduce, if not eliminate, these power differentials;\textsuperscript{176} at a minimum, new mechanisms may help us to establish guidelines to ensure that when consent is given, it is, indeed, informed.

An individual’s medical decision making is dependent upon whether she trusts her health care provider.\textsuperscript{177} Indeed, trust is perhaps the most amorphous\textsuperscript{178} and most important element in the conscious and unconscious medical decision-making process.\textsuperscript{179} The medical-legal principle of “informed consent” has the potential to foster the highly personal expression of “trust” between physician and patient, but only insofar as it serves to minimize the common power imbalance between the two. A number of factors may inhibit the development of trust, and hence the process of getting, or giving, informed consent in a medical setting.

At its most basic, establishing a relationship of trust between doctor and patient requires the provider to reveal both the risks and benefits of a particular test or procedure, and to respond to the patient’s concerns—from those that are eminently practical to those that are solely emotional. The patient must be provided sufficient time and opportunity to express concerns and to ask questions.\textsuperscript{180} An array of personal, economic, and social factors may influence the nature of information one needs in order to consent to a given medical procedure. In addition, the physician must be willing to credit the patient

\textsuperscript{176} Mahowald, supra note 171, at 104 (advocating that the physician-patient relationship be one of “mutuality,” in which “physicians and patients alike have rights and responsibilities vis-à-vis each other”).

\textsuperscript{177} Cf. Katz, supra note 15, at xiv (arguing that the requirement of informed consent indicates that “trust in the professional is no longer viewed as sufficient protection of the integrity of the physician-patient relationship”).

\textsuperscript{178} See id. at xv (“Although . . . mutual trust is difficult to embrace and to sustain, it is important to strive for it.”).

\textsuperscript{179} Cf. id. at 229 (“Both [patient and physician] must be trusted, but . . . they can only be trusted if they first learn to trust each other.”).

\textsuperscript{180} See generally id. at 82-83 (arguing that, in addition to disclosure of risks by physicians, informed consent requires a dialogue with physicians in which patients “are viewed as participants in medical decisions affecting their lives”); Smith, supra note 112, at 412-13 (describing a six-step protocol to deliver bad news in the medical setting: (1) “get[ ] the physical context right,” meaning a private setting in which the patient is encouraged to relate how she is feeling; (2) “obtain from the patient an impression of what . . . she already knows”; (3) learn from the patient how much she wants to understand about her medical condition; (4) if the patient wishes to be fully informed, begin the “information sharing” stage by including information about the diagnosis, treatment plan, and prognosis; (5) “give a narrative of events . . . to help the patient understand what has been happening”; and (6) “clarify and reinforce information by repeating important points and asking the patient to review what he has understood”) (citing Buckman, supra note 112)).
"with knowledge about his own condition that textbooks, articles, or even experience with other patients cannot provide."\textsuperscript{181}

As discussed earlier, managed care organizations create disincentives for this type of communication to occur, as evidenced by their decisions regarding reimbursement and patient load.\textsuperscript{182} These entities generally value informed consent much differently than would a patient faced with making a decision whether to undergo a significant medical procedure or a powerful diagnostic test.\textsuperscript{183} This is especially troubling because studies about patients' adherence to medical advice show that "nonadherence [is] more common when patients [do] not receive feedback from the physician or explanations of the cause of the illness."\textsuperscript{184}

While spending time with patients may facilitate the exchange of information, time alone is not necessarily the solution if the medical counseling is "filled with medical jargon unintelligible to the patients."\textsuperscript{185} Even good faith attempts to communicate can be significantly complicated when language and cultural differences separate a patient and a physician. It frequently is difficult enough to discuss sensitive medical issues when the parties speak a common language. Introducing a translator, assuming one is available, will not necessarily facilitate more than rudimentary communication.\textsuperscript{186} Differences in cultural expectations of what type of interaction is expected in a medical setting also can lead to profound miscommunication.\textsuperscript{187}

At times, there may even be a difference between what a provider interprets as consent and what the patient experiences as expressions

\textsuperscript{181} Mahowald, supra note 171, at 108. Mahowald describes a physician who successfully negotiates this relationship as one who can self-consciously put aside "her own nearsightedness" and arrogance in favor of "the privileged status of patients' experience and knowledge of their own illness." \textit{Id.}

\textsuperscript{182} See supra notes 59-66 and accompanying text.

\textsuperscript{183} See Lu, supra note 60, at 542 (noting "the physician's incentive not to disclose costly diagnostic or therapeutic options" in the managed care context).

\textsuperscript{184} Smith, supra note 112, at 393 (noting that "patient satisfaction was directly related to the amount of information they received, and most patients wanted more information"); see also Katz, supra note 15, at 78 ("Safeguarding self-determination requires assessing whether patients' informational needs have been satisfied by asking them whether they understand what has been explained to them.").

\textsuperscript{185} Smith, supra note 112, at 393.

\textsuperscript{186} See Elysa Gordon, \textit{Multiculturalism in Medical Decisionmaking: The Notion of Informed Waiver}, 23 \textit{Fordham Urb. L.J.} 1321, 1325 (1996) (noting that "educational and language barriers may inhibit active participation in medical decisionmaking").

\textsuperscript{187} See id. at 1343 (noting that "Western culture's bias towards individualism implies a preference for active participation in medical decisionmaking[,] whereas members of non-Western cultures "may feel more comfortable deferring to a physician's authority").
of doubt, concern, or passive acceptance.\(^{188}\) Naturally, this miscommunication is more likely to occur when only the verbal assent of the patient is required prior to the performance of a test or procedure. Still, it is not unheard of in the context of a requirement of written consent. For example, it is not unusual for health care providers, or their assistants, to seek a patient’s written consent immediately prior to the performance of a procedure, when a patient is not in the physical or emotional condition to consider rationally whether consenting to the proposed procedure is advisable.\(^{189}\) Although the patient is likely to sign the form, one must question the nature and quality of her consent.\(^{190}\)

The goal of ensuring that a patient’s consent is voluntary and informed is complicated by the reality that the nature and type of information that one person needs in order to give consent may vary significantly from what another might need; indeed, even “a given patient’s desires may change over the course of treatment.”\(^{191}\)

A patient who distrusts the health care system—because of personal, familial, or historical reasons—may need a greater degree of information before she can give “informed consent.”\(^{192}\) A patient who is made to feel alienated from the health care system, perhaps because of gender, race, or class, also may have a need for more thorough, or different, education and counseling prior to giving, or with-

188. See Wilkerson v. Mid-America Cardiology, 908 S.W.2d 691, 693-95, 700 (Mo. Ct. App. 1995) (noting the factual ambiguity as to whether a patient expressly or impliedly consented to angioplasty).

189. See id. at 694 (noting that the patient had been informed that his questions regarding angioplasty would be answered at the catheterization lab, the site of the procedure).

190. See Burris & Gostin, supra note 3, at 140 (“Merely signing a form does not assure genuine informed consent.”).

191. Smith, supra note 112, at 394.

192. See Nancy Ehrenreich, The Colonization of the Womb, 43 DUKE L.J. 492, 515 (1998) (“African-American women, along with Latina (especially Puerto Rican) and Native American women, were subjected to forced sterilization in appalling numbers up through the 1970s, a practice that continues in ‘milder’ forms today.” (citations omitted)); Randall, supra note 39, at 191 (observing that “[m]any people are surprised at the level of distrust of the health care system held by African Americans[,]” but describing such fear and distrust as a “natural and logical response to the history of experimentation and abuse”); Lynda Richardson, Experiment Leaves Legacy of Distrust of New AIDS Drugs, N.Y. TIMES, Apr. 21, 1997, at A1 (noting African American distrust of the health care system in light of the Tuskegee Experiment, wherein Black men with syphilis were not given available antibiotic treatment, but instead were “observed” to learn more about the natural history of the disease); Helen Rodriguez-Trias, Presidential Address to the 121st Meeting, AMERICAN PUBLIC HEALTH ASSOCIATION (Oct. 25, 1993) (noting that the relatively recent experience of many Latina women with coerced and forced sterilization engenders distrust of health care institutions); see also supra notes 37-42, 145, and infra notes 193-194, 199-207.
holding, "informed consent" to a procedure. Yet, at the same time, those most likely to distrust or feel alienated from the health care system often are those with the least access and least choice in health care providers or health care institutions.

For example, Medicaid managed care programs may impose substantial limits on patient choice, and public clinics rarely can assure a given patient that she will—or will not—be seen by a particular doctor. Under these circumstances, there is little room for a patient to question her physician about her treatment or to raise concerns about the care she is receiving, especially if she is concerned that her physician will provide her with a lesser level of care if she does raise questions. This stands in stark contrast to the individual with private health insurance who can far more readily change health care providers if she is not given sufficient explanation of a proposed course of treatment, or if she feels put off by her doctor's manner, or if she is concerned that he is not adequately trained in a certain specialty or technique.

2. A Critical Theory Analysis: Current Informed Consent Doctrine and Its Application to Genetic Testing.—The foregoing discussion explores a range of problems that patients may experience with current in-

193. See Ikemoto, supra note 40, at 937 (observing that genetic data is never neutral, but instead is "knowledge that has social content"); Dorothy E. Roberts, The Nature of Blacks' Skepticism About Genetic Testing, 27 SETON HALL L. REV. 971, 974 (1997) (noting that as a result of a long history of "medical abuses, many Blacks harbor a well-founded distrust of technological interference with their bodies and genetic material at the hands of white physicians"); cf. Susan M. Wolf, Introduction: Gender and Feminism in Bioethics, in FEMINISM & BIOETHICS, supra note 69, at 3, 17-18 (discussing the "significance of being identified with a certain group" in the context of health care); see also supra notes 186-187, infra notes 213-228, and accompanying text.

194. See Randall, supra note 39, at 206 ("To African Americans, the continued disparity between the health status of African Americans and European Americans is significant evidence that the health care system is not to be trusted."); Roberts, supra note 193, at 975 (noting that "an African American perspective of bioethical matters 'will be inclined to distrust the 'ethics of trust' that some physicians espouse' because of medicine's insensitivity to African American needs" (citation omitted)); cf. Ehrenreich, supra note 192, at 520 (stating that physicians are more likely to suspect minority and poor mothers of abusing drugs and being more litigious than white mothers).

195. See Rodriguez-Trias & Marte, supra note 18, at 304 (noting that low-income women in large cities suffer from unequal access to medical services due to their reliance on public hospitals and Medicaid clinics); cf. Regular Doctor, Not Coverage, is More Significant, Am. Pol. Network—HEALTH LINE, Mar. 14, 1998, at 13, 13 (reporting on a study that concludes that "having a regular physician is a stronger predictor than having insurance coverage of whether a person has adequate access to health care").

196. See generally Emanuel & Dubler, supra note 59, at 325 ("Without health insurance or significant financial resources, the uninsured do not have any meaningful choice of health care setting or of a primary care physician.").
formed consent practices. There are, however, additional concerns that are best understood through a critical lens, particularly as informed by the viewpoints of feminist critical theory and critical race theory, which acknowledge the role of poverty, race, and class in the development and application of law.

Historical experience with eugenics and ongoing occurrences of racial disparities in the delivery of health care mean that it is

197. Commentators also have criticized informed consent doctrine from the perspectives of economic efficiency, tort theory, and constitutional theory. See, e.g., Faden & Beauchamp, supra note 44, at 25-48 (examining the tort and constitutional components of the informed consent doctrine); Hall, supra note 59, at 511-12 (asserting that the theory of "economic informed consent" requires managed care organizations to inform customers of cost containment rules and incentives imposed upon physicians); Schuck, supra note 155, at 907-13 (describing the central principles of informed consent in tort law generally); Valerie J. Pacer, Note, Salvaging the Undue Burden Standard—Is it a Lost Cause? The Undue Burden Standard and Fundamental Rights Analysis, 73 Wash. U. L.Q. 295, 320-22 (1995) (proposing a modified undue burden standard to assess the constitutionality of an informed consent requirement).

198. Each of these critical perspectives supports the importance of incorporating the voice of the person affected by the legal or public policy issue at hand in its development. See Wolf, supra note 193, at 25 ("There has been great concern with patients' and research subjects' rights, but those people tend to be the objects of concern rather than full members of the ethical conversation."). Viewed through this lens, individual narrative is not only shaped by experience living under the law, but also should shape laws. See Dorothy E. Roberts, The Priority Paradigm: Private Choices and the Limits of Equality, 57 U. Pitt. L. Rev. 363, 399-404 (1996) (advancing the concept that equality and liberty must be understood in light of preexistent discriminatory structures harmful to blacks); Patricia J. Williams, Alchemical Notes: Reconstructing Ideals from Deconstructed Rights, 22 Harv. C.R.-C.L. L. Rev. 401, 410 (1987) (asserting that racial minorities should use the rhetoric of rights to destabilize establishment values, and making use of personal narrative to illustrate perspectival differences in rights valuation). Although Jay Katz does not identify his work as incorporating critical legal theory, perhaps because it was written 15 years ago, his bold critiques of existing informed consent theory and practice resonate with these concepts. See generally Katz, supra note 15, at 78 (arguing that instead of focusing on objective and subjective tests to determine whether informed consent was given, the courts "should . . . consider[ ] . . . the patients' plight and require[ ] physicians to learn new skills: how to inquire openly about their patients' individual information needs and patients' concerns, doubts, and misconceptions about treatment—its risks, benefits, and alternatives").

199. One commentator has noted:

Racism, prejudice, and genetics have made for a socially combustible and often deadly mix. The mixture has proven so toxic that a strong case can be made that applying knowledge from the realm of human genetics to public policy has led to far more misery, confusion, and suffering in the twentieth century than it has to human betterment.

Caplan, supra note 35, at 32-33; see also Andrews, supra note 27, at 908 (noting that "genetic arguments were part of the Social Darwinism that insisted that those on the bottom of the social ladder belonged there"); Randall, supra note 39, at 196-97 (describing the testing of smallpox and typhoid vaccines, as well as the development of anesthetics, on African Americans without informed consent); supra notes 35-42 and accompanying text.

200. See Bowman, supra note 36, at 921 (noting that policy makers frequently comment on the scarcity of health care resources, but that, in fact, they are scarce only for the poor)
especially important to develop an appropriate informed consent process in the context of genetic testing.\textsuperscript{201} As explained by Lisa Ikemoto, there is particular fear in minority communities of a "racialization of genomic knowledge,"\textsuperscript{202} or the use of genetic knowledge in a way "that reinforces and recreates racial subordination."\textsuperscript{203} This could happen, as it has in the past, with the conflation of "whiteness with a medicalized understanding of good citizenry."\textsuperscript{204} Should this occur with continued disparate access to medical care, the danger of misuse of genetic information without benefit to the patient would

Randall, \textit{supra} note 39, at 210-13, 218-19 (noting the recent closure of hospitals in primarily African American neighborhoods; the serious underrepresentation of blacks in the health care professions; and the inadequacy of managed care, as currently operated, to meet the needs of African Americans).

\textsuperscript{201} See Murphy, \textit{supra} note 23, at 7 (wondering whether, in the absence of appropriate action, "the genome project [will] generate new classes of human inferiority" and whether it will "mark difference as an undesirable trait and justify its eradication").

\textsuperscript{202} Ikemoto, \textit{supra} note 40, at 937.

\textsuperscript{203} Id. at 937-38. Similarly, Professor Andrews notes that African Americans, immigrants, and women are "the groups most likely to have their individual decisions overridden sometimes on the grounds that it is for their own good, other times for the supposed good of society." Andrews, \textit{supra} note 27, at 908. For example, "pregnant African-American women are tested for the sickle cell mutation (which is of high prevalence among African-Americans) without their advance knowledge or consent," while "pregnant white women [are tested] for the cystic fibrosis mutation (which is of high prevalence among Whites) [only following] elaborate consent procedures." \textit{Id.} at 909. Similarly, with cystic fibrosis, a disease in which both parents must transmit the trait for the condition to be inherited—it is often the woman who is tested first. Only if she tests positive is the man tested, sending the message that "once again, it is women who are expected to be guarantors of their children's health." \textit{Id.} at 910. When asked why they did not ask African American women for their consent to test for the sickle cell test, physicians at "an elite medical school" indicated: "the women 'wouldn't understand,'" it was done for their benefit; and "other types of testing are performed without consent during pregnancy." Andrews, \textit{supra} note 7, at 1003.

\textsuperscript{204} See Ikemoto, \textit{supra} note 40, at 941 (noting that "disease and health, like genomic knowledge, are constructs that are socially and historically located, informed by the matrices of domination"). Ikemoto looks at recent efforts to determine whether a link exists between genetics and violence and notes that such studies tend to move the focus away from societal factors that may foster violent behavior. \textit{Id.} at 944-45. When we "isolate[ ] the source of disorder within the individual[, we are] relie[ved] from having to acknowledge the matrix of domination or to examine our social structures, our institutional arrangements, and ourselves." \textit{Id.} at 946. When knowledge about genetics is taken to represent our understanding of humanity, "genetic disease [is viewed] as a bad component that can be isolated and removed." \textit{Id.} at 942. Seen in the light of historical and ongoing medical mistreatment based on race, class, or gender, an intent to "cure" flawed genes may be (perceived as) dangerously close to our prior experience with eugenics. \textit{Id.} at 940; see also Andrews, \textit{supra} note 27, at 913 ("It is likely that any medical intervention to curtail the manifestation of alleged criminal genes would be applied in a discriminatory fashion."); Randall, \textit{supra} note 39, at 204 (observing that "science" has been the source of theories perpetuating the notion "that Blacks were biologically inferior to whites").
increase;\textsuperscript{205} concomitantly, existing distrust of and alienation from health care institutions would be reinforced.\textsuperscript{206} To counter this risk, it becomes especially important to incorporate this “mistrust of the medical profession and social justice concerns . . . into ethical deliberations about genetic testing and research.”\textsuperscript{207} Not unexpectedly, commentators emphasize the importance of ensuring that patients be given the opportunity to provide—or withhold—genuine informed consent in the context of genetic testing.\textsuperscript{208}

The foregoing considerations have an impact on the common law doctrine of informed consent; in this context, it is evident that the “reasonable physician” standard, which determines the nature and scope of information that must be disclosed to a patient solely from the perspective of the physician, and which generally has fallen out of favor, is particularly inadequate to meet the needs of those who may be disenfranchised from the health care system.\textsuperscript{209} In comparison, a shift to a “reasonable patient” standard is one that is more likely to benefit and protect health care consumers—even across race, gender, and class lines. For example, judges and juries are likely to be more sympathetic to claims onto which they can, consciously or uncon-

\textsuperscript{205} See Murphy, supra note 23, at 10 (questioning whether “genetic disease [will] become another affliction of the poor” if certain steps are not taken); Randall, supra note 39, at 204 (stating that fear and distrust lead African Americans to believe that traditional principles of bioethics (autonomy, beneficence, nonmaleficence, and justice) will not protect against mistreatment and abuse of genetic information); Roberts, supra note 193, at 971 (“Racial minorities are particularly vulnerable to the misuse of genetic information.”); Dorothy E. Roberts, Reconstructing the Patient: Starting with Women of Color, in FEMINISM & BIOETHICS, supra note 69, at 116, 117 (noting that “[b]ecause racism makes the oppressive use of medicine so obvious to many of them, women of color may be more suspicious of doctors’ claims of beneficence”); cf. Andrews, supra note 24, at 51 (noting that the expense of genetic tests may prevent lower-income people from having access to a health care device that may grow to be an important part of health care services).

\textsuperscript{206} See Andrews, supra note 27, at 898 (“Today’s geneticists reject the earlier genetic assessments as due to poor science, and insist that their own analysis is credible. But the incentives today (obtaining scientific prizes and funding, legitimating the social status quo) are much the same as before, and the results look strikingly similar.”); Randall, supra note 39, at 217 (noting that the fears of African Americans “are, at best, put on the back burner and are, at worst, discounted as unreasonable”).

\textsuperscript{207} Roberts, supra note 193, at 979 (noting, in addition, that “we should be less concerned about overcoming Blacks’ cultural resistance to genetic testing and more concerned about eliminating the racist practices that underlie Blacks’ skepticism about genetic testing”).

\textsuperscript{208} See Bowman, supra note 36, at 935 (noting further that patient education must be conducted with ethically relevant materials); Randall, supra note 39, at 234 (calling on bioethicists to “construct[ ] a practical, ethical approach to the anxiety and fear which would lead to community empowerment”).

\textsuperscript{209} See supra notes 157-161 and accompanying text.
sciouously, graft their own perceptions of what they would like to know prior to consenting to a given medical procedure.210

Still, the "reasonable patient" standard does not always adequately consider the life circumstances of an individual patient.211 Most courts characterize the "reasonable patient" standard as an objective measure of the "materiality of the risk,"212 and define "reasonableness" as "what a [reasonable] prudent person in the patient's position would have decided if suitably informed."213 Some courts further modify this definition by adding the phrase, "in what the physician knows or should know to be [in] the patient's position."214 To the extent this modifying phrase is applied, the "reasonable patient" standard remains remarkably close to the "reasonable physician" stan-

210. This shift also is likely to facilitate a patient's bringing an informed consent claim by reducing (although not eliminating) the cost of retaining experts. In states that maintain the "reasonable physician" standard, plaintiffs must incur the expense of retaining a medical expert to establish what "a reasonable practitioner of like training would have disclosed in the same or similar circumstances" and that "the departure . . . from a recognized standard of practice was a proximate cause of her injury." Weber v. McCoy, 950 P.2d 548, 552 (Wyo. 1997) (quoting Havens v. Hoffman, 902 P.2d 219, 222 (Wyo. 1995) (quoting Roybal v. Bell, 778 P.2d 108, 112-13 (Wyo. 1989))).

Under the "reasonable patient" standard, expert testimony on the existence of a duty to disclose is theoretically unnecessary because "the jury itself can determine the reasonableness of the disclosure." Faden & Beauchamp, supra note 44, at 32. Note, however, that even under this standard, most plaintiffs must retain medical experts to help establish causation. See, e.g., Canterbury v. Spence, 464 F.2d 772, 792 (D.C. Cir. 1972) (observing that medical experts "are normally needed on issues as to the cause of any injury or disability suffered by the patient"). But see infra note 218 and accompanying text (noting criticisms of the reasonable patient standard).

211. See Randall, supra note 39, at 230-31 (criticizing current bioethical principles as Eurocentric in their valuing of the individual and autonomy and their failure to incorporate Afrocentric beliefs concerning the importance of parents and community); Wolf, supra note 193, at 15 (noting that "universal moral rules or principles posited for the abstract, generic person erase that person's gender (not to mention race, class, and other characteristics)"). Jay Katz observes that it should not be the patient's burden to show she has suffered a physical harm or injury; rather, the lack of full disclosure should be recognized as an injury in itself. See Katz, supra note 15, at 79 ("[P]atients are wounded when physicians begin treatment without fulfilling their disclosure obligation."). Although this approach is appealing, it also has flaws, particularly with regard to its inherent indeterminacy and its open invitation to less-than-substantial claims.

212. See Faden & Beauchamp, supra note 44, at 32 (characterizing "materiality" as the significance of the information to the decision-making process of the patient).

213. Katz, supra note 15, at 75 (alteration in original) (quoting Canterbury, 464 F.2d at 791); see Faden & Beauchamp, supra note 44, at 32 (stating that "[t]he reasonable person standard requires a physician to divulge any fact that is material to a reasonable person's decision").

standard: the perspective of the physician is the lens through which liability must be assessed. 215

If a court were concerned only with the viewpoint of the "prudent patient," (i.e., not modified by what the physician knew or should have known about the position of the patient), 216 there would be more room to acknowledge aspects of the subjective position of a patient who is asked to consent to a particular medical procedure. 217 However, even in this circumstance, the life experiences of the trier-of-fact (judge or jury) may cause her to define the "prudent patient" rather differently than a particular claimant would define the term. 218

This phenomenon may be particularly manifest should the gender, race, or socioeconomic background of the judge and jury differ

215. Cf. Randall, supra note 39, at 231 ("Eurocentric bioethical principles such as autonomy, beneficence, and informed consent do not have the same force when viewed through the African American bioethical perspective of distrust. These principles leave considerable room for individual judgment by health care practitioners. . . . In a racist society (such as ours), the judgment is often exercised in a racist manner[, such as unconsent-to medical experimentation].").

216. See, e.g., Canterbury, 464 F.2d at 787 (noting that the standard for disclosure "remains objective with due regard for the patient's informational needs and with suitable leeway for the physician's situation"); Daum v. Spinecare Med. Group, Inc., 61 Cal. Rptr. 2d 260, 269 n.4 (Ct. App. 1997) (defining material information as that "which the physician knows or should know would be regarded as significant by a reasonable person in the patient's position") (citing California jury instruction BAJI No. 6.30); Percle v. St. Paul Fire & Marine Ins. Co., 349 So. 2d 1289, 1300 (La. Ct. App. 1977) (adopting an objective test for the establishment of causation, namely, "what a prudent person in plaintiff's position would have decided if adequately informed"); Largey, 540 A.2d at 508 ("A risk would be deemed 'material' when a reasonable patient, in what the physician knows or should know to be the patient's position, would be 'likely to attach significance to the risk or cluster of risks' in deciding whether to forego the proposed therapy or to submit to it." (quoting Canterbury, 464 F.2d at 787)).

217. See FADEN & BEAUCHAMP, supra note 44, at 33 (noting that the degree to which the reasonable person standard incorporates factors relevant to the individual patient exists on a continuum that depends on how literally the standard is applied "[b]ecause application of the abstract reasonable person standard . . . requires the incorporation of specific facts of the case, [and] the pressing question is always what the reasonable person would need to know 'under the same or similar circumstances'").

218. See MARTHA MINOW, NOT ONLY FOR MYSELF: IDENTITY, POLITICS, AND THE LAW 100 (1997) (critiquing the reasonable person standard "for installing the views and beliefs of only some people—typically, middle-class, white, Protestant, able-bodied men—rather than helping to create new common-law categories for setting standards of care or reasonableness"). See generally Anita Bernstein, Treating Sexual Harassment with Respect, 111 HARV. L. REV. 445, 450, 453 (1997) (arguing that in the context of sexual harassment, the defendant should be held "to the standard of a respectful person" rather than the defective standard of reasonableness); Dan M. Kahan & Martha C. Nussbaum, Two Conceptions of Emotion in Criminal Law, 96 COLUM. L. REV. 269, 321-23 (1996) (examining the role of "reasonableness" and "emotion" in criminal law); Victoria Nourse, Passion's Progress: Modern Law Reform and the Provocation Defense, 106 YALE L.J. 1331, 1395 (1997) (proposing a provocation defense based on emotion in light of a feminist critique of objective standards).
from that of the plaintiff. Some commentators suggest that we should shift our understanding of the "prudent patient" standard so as to incorporate the perspective of the person bringing a claim.

While adapting this standard to incorporate the experiences of "groups to which actors may belong," it is equally important not to fall into a "trap of essentialism" that can be as damaging as ignoring the context of a person's life. As such, when taking the viewpoint of the patient into account, one must avoid stereotyping each patient's experience. As Susan Wolf has written, "[O]ne can remain alert to difference and seek to be schooled by the varieties of experience, and still investigate the significance of being identified with a certain group.

Martha Minow pointedly asks whether it is possible to devise an alternative to the "faulty neutrality of the 'reasonable person' standard," without falling prey to the temptation to replace the "reasonable person" standard by a "reasonable woman" or by a "reasonable

219. See supra notes 192-194, 199-207.

220. See Faden & Beauchamp, supra note 44, at 33 ("If patients have a right to make idiosyncratic choices, they may need information that would not be considered material by reference to the standard of a reasonable person . . . ."); id. at 306 (describing the subjective standard as "the most adequate" because it is based on "the specific informational needs of the individual patient or subject"); Katz, supra note 15, at 78 (arguing against "obliterating the 'subjective' person in an 'objective' mass of persons"); see also Roberts, supra note 205, at 119 ("[P]hysicians can successfully care for patients only by considering much more about them than the pathophysiology of their illness, including their own values and relationships.").

221. Wolf, supra note 193, at 17 (arguing that bioethics ought to look beyond dyadic relationships like that "between a doctor and patient, between a researcher and subject, or between a nurse and physician"); see also Roberts, supra note 205, at 116-17 (appealing to medical ethicists to explore the perspective of women of color because the combination of race and gender oppression "profoundly affect[s] their relationship to medical practice"); Roberts, supra note 193, at 979 (arguing that blacks' resistance to genetic testing is "based largely on mistrust of the medical profession and social justice concerns, [and that this reality] should be incorporated into ethical deliberations about genetic testing and research"); Susan Wolf, Foreword: Bioethics—From Mirror to Window, 15 St. Louis U. Pub. L. Rev. 183, 185 (1996) (noting that "[t]he documented persistence of racial and gender disparities in health care made it even clearer that not all patients faced the same problems").

222. Wolf, supra note 193, at 17; see also Mahowald, supra note 171, at 102 (noting that "taking account of cultural, racial, and class differences can also involve generalizations that ignore significant differences among women belonging to the same culture, race, and class").

223. Wolf, supra note 193, at 17; see id. at 27 (arguing for the need to "travel back and forth between specific cases and higher-order normative generalizations" to see problems with the existing system of physician-patient relationships); see also Mahowald, supra note 171, at 106 ("Of necessity, just caring requires recognition of the link between health and the personal and societal conditions that influence health."
Caribbean American gay male" standard.\textsuperscript{224} She suggests that "[o]ne route would retain 'reasonable person' but link it to 'the circumstances,' where circumstances include encountering the meanings of group identity in a given community during a specific time period."\textsuperscript{225} One advantage to this approach is that it would "permit testimony and even expert evidence about such meanings while resisting the easy but faulty route of assigning individuals to group categories that then acquire the force of a legal norm."\textsuperscript{226}

This approach would accomplish three important goals: The physician would have an obligation to be attuned to her patient's standpoint;\textsuperscript{227} the physician is less likely to be blindsided by a patient with individualistic needs that she has not expressed to the physician;\textsuperscript{228} and the patient would have a certain degree of flexibility regarding the type of claims and evidence she could bring and use to show what someone generally in her position reasonably would need to know for consent to be informed.

Admittedly, these goals are difficult to achieve without specific guidance. As such, it may well be worthwhile to examine and learn from statutory provisions that attempt to supply support for this type of structure. Perhaps the best example of this approach is the informed consent statutory scheme that was developed in response to the HIV/AIDS epidemic.

III. AN HIV-SPECIFIC MODEL OF INFORMED CONSENT

The advent of HIV/AIDS has led to a reexamination of some basic assumptions concerning the appropriate way to deliver health care and services.\textsuperscript{229} The disease that came to be known as Acquired Im-

\textsuperscript{224} Minow, supra note 218, at 100. Minow further notes that "the practical problems posed by proliferating subgroup standards are immense, and so are the symbolic and psychological risks of confining individuals to governmentally prescribed group categories." Id.

\textsuperscript{225} Id. Minow suggests other routes as well, such as articulating more fully the standards of care that the law demands, or shifting burdens of care to those best able to anticipate them. Id. at 100-01.

\textsuperscript{226} Id. at 100.

\textsuperscript{227} See Mahowald, supra note 171, at 105 (arguing that "[d]iscovery and treatment of [a patient's] needs are impossible without attunement to the patient's standpoint as privileged epistemologically and ethically").

\textsuperscript{228} This, of course, would be one of the chief problems with a wholly subjective standard. For an excellent exploration of the difficulties inherent within objective and subjective standards, see Richard Delgado, Shadowboxing: An Essay on Power, 77 Cornell L. Rev. 813, 815-16 (1992) (including a discussion of informed consent to medical treatment).

\textsuperscript{229} For example, in 1989, in response to further understanding of the hepatitis-B virus and HIV, the Centers for Disease Control and Prevention (CDC) established guidelines urging the implementation of "universal precautions" (e.g., use of latex gloves, safe dispo-
immune Deficiency Syndrome (AIDS) first was recognized in 1981. It was not until 1983 that the human immunodeficiency virus (HIV) was determined to be the causative agent of AIDS. In 1985, a mechanism to test for antibodies to HIV was approved by the Federal Drug Administration (FDA), specifically to allow for the screening of the nation’s blood supply. In 1987, the CDC issued guidelines regarding HIV counseling and testing.

These advances both caused extraordinary relief and signaled an alarm. A widely accepted means of testing for HIV-antibodies, as a significant breakthrough in the diagnosis of HIV, raised hopes that treatment would soon follow. However, because the initial demographic groups to be diagnosed with AIDS—gay men and injection

sal of needles and other “sharps”) in dealing with blood and bodily fluids. See CDC, U.S. DEP’T OF HEALTH & HUMAN SERVS., Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers, 38 MORTALITY & MORTALITY WKLY. REP. (June 23, 1989). However, it was not until the early 1990s, when the alleged transmission of HIV from a dentist to six of his patients was made public, that both health care providers and health care consumers began to insist on the use of such precautions. CDC, U.S. DEP’T OF HEALTH & HUMAN SERVS., Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures, 40 MORTALITY & MORTALITY WKLY. REP. (July 12, 1991).

230. See CDC, U.S. DEP’T OF HEALTH & HUMAN SERVS., Pneumocystis Pneumonia—Los Angeles, 30 MORTALITY & MORTALITY WKLY. REP. 250, 251 (June 5, 1981) [hereinafter CDC, Pneumocystis Pneumonia] (suggesting “the possibility of a cellular immune dysfunction . . . that predisposes individuals to opportunistic infections” in light of five case reports where homosexual men all had cytomegalovirus (CMV), candidal mucosal infection, and pneumocystis carinii pneumonia (PCP)).

231. See generally F. Barré-Sinoussi et al., Isolation of a T-Lymphotrophic Retrovirus from a Patient at Risk for Acquired Immune Deficiency Syndrome (AIDS), 220 SCIENCE 868, 870 (1983) (reporting the discovery of a retrovirus that belonged to the human T-cell leukemia virus (HTLV) family, transmitted horizontally in humans and perhaps involved in several pathological syndromes, including AIDS).

232. See SENAK, supra note 50, at 181 (noting that “[t]he test was originally designed to screen blood donations to stem the flow of transmission by that route”; see also Brett-Smith & Friedland, supra note 48, at 28-29 (noting a marked reduction in the risk of “transfusion-associated transmission” since March 1985 “when nationwide antibody screening of the blood supply was introduced”).


234. See SENAK, supra note 50, at 167 (noting that testing for HIV permits knowledge of one’s status and the possibility of acquiring medical care, but also may serve as a means for discrimination and mistreatment); RANDY SHILTS, AND THE BAND PLAYED ON: POLITICS, PEOPLE, AND THE AIDS EPIDEMIC 471 (1987) (noting the concern in the gay community at the prospect of a registry of everyone whose blood donations proved to be infected that “such a list would amount to little more than a registry of homosexual men” that “could be put to nefarious use in the twenty-five states where gay sexual acts remained illegal”).

235. See SENAK, supra note 50, at 181 (stating that “the HIV antibody test quickly became the instrument by which many hoped to stop the spread of AIDS”); SHILTS, supra note 294, at 450 (recounting the declaration of Health and Human Services Secretary Margaret
drug users—had been subject to substantial stigma and discrimination, numerous communities raised concerns that the test would be used to segregate and quarantine, not to conduct outreach and deliver treatment.

Indeed, traditional informed consent doctrine would neither meet the needs nor protect the rights of people who might seek, or be targeted for, HIV-antibody testing. The doctrine of informed consent was designed to meet a different need than that posed by the availability of HIV testing. The crudeness of original informed consent doctrine, based on an intentional tort theory of battery, in some ways correlated to the less sophisticated medical care that was available in the earlier part of this century. Although the doctrine has shifted from requiring that a patient “consent” to touching, to requiring that a doctor obtain “informed consent” prior to performing a medical procedure, the focus largely remains on the medical nature of the procedure and the risks and benefits that might be associated with its performance. The availability of a procedure that could test for the presence of HIV antibodies brought with it a series of social risks that were not, and in fact, could not be addressed under then-existing informed consent doctrine.

Heckler that “[t]oday’s discovery [of HTLV-III antibody testing] represents the triumph of science over a dreaded disease”).

236. See CDC, U.S. DEP’T OF HEALTH & HUMAN SERVS., Prevention of Acquired Immune Deficiency Syndrome (AIDS): Report of Inter-Agency Recommendations, 32 MORBIDITY & MORTALITY Wkly. Rep. 101, 101 (Mar. 4, 1983) (noting that “[m]ost cases have been reported among homosexual men with multiple sexual partners, abusers of intravenous (IV) drugs, and Haitians”); CDC, U.S. DEP’T OF HEALTH & HUMAN SERVS., Update on Acquired Immune Deficiency Syndrome (AIDS)—United States 1982, 31 MORBIDITY & MORTALITY Wkly. Rep. 507, 507 (1982) (stating that, among the early cases of AIDS, approximately 75% occurred among homosexual or bisexual males, and that among the 20% of known heterosexual cases (males and females), the prevalence of intravenous drug abuse was about 60%).

237. See SENAK, supra note 50, at 180-81 (noting that, with AIDS affecting disadvantaged groups, some may desire to enact policies that will be construed as punishing those with the disease); supra note 234 and accompanying text.

238. See SENAK, supra note 50, at 178-79 (discussing the effect of mandatory names reporting). See generally id. at 163-87 (discussing the importance of patient confidentiality and testing in the context of HIV).

239. See supra notes 149-154 and accompanying text (discussing the transition from battery to negligence as the basis for informed consent when medical procedures grew more complicated).

240. See FADEN & BEAUCHAMP, supra note 44, at 131 (noting that, under theories of both battery and negligence, a “procedure’s nature, consequences, and risks, as well as its alternatives, all had to be transmitted”).

241. See SENAK, supra note 50, at 181-82 (indicating that the test was sometimes used “to discriminate, and to punish and exclude people with HIV from employment, schooling, and even medical treatment”); supra notes 22-25 and accompanying text.
A number of state legislatures heeded the call for protection against forced testing and implemented careful counseling requirements. New York led the way by requiring consent to be indicated in writing, and by defining informed consent to include “at least the following” elements:

(a) an explanation of the test, including its purpose, the meaning of its results, and the benefits of early diagnosis and medical intervention; and

(b) an explanation of the procedures to be followed, including that the test is voluntary, that consent may be withdrawn at any time, and a statement advising the subject that anonymous testing is available; and

(c) an explanation of the confidentiality protections afforded confidential HIV related information under this article, including the circumstances under which and classes of persons to whom disclosure of such information may be required, authorized or permitted under this article or in accordance with other provisions of law or regulation.

A person conducting an HIV-related test also is required to provide “an explanation of the nature of AIDS and HIV related illness, information about discrimination problems that disclosure of the test result could cause and legal protections against such discrimination, and information about behavior known to pose risks for transmission and contraction of HIV infection.”

Finally, the person who communicates the test results to the person tested must provide her with:

counseling or referrals for counseling: (a) for coping with the emotional consequences of learning the result; (b) regarding the discrimination problems that disclosure of the result could cause; (c) for behavior change to prevent trans-

242. See Cal. Health & Safety Code § 125107(b), (f) (West Supp. 1998) (requiring health care providers to “offer human immunodeficiency virus (HIV) information and counseling to every pregnant patient," and clarifying that “[n]othing in this section shall be construed to require testing”); N.J. Stat. Ann. § 26:5C-16(a) (West 1996) (stating that “[a] physician or other health care practitioner who is the primary caregiver for a pregnant woman or a woman who seeks treatment within four weeks of giving birth, shall ... provide the woman with information about HIV and AIDS," and that “[a] woman shall not be denied appropriate prenatal or other medical care because she decides not to be tested for HIV”); Tex. Health & Safety Code Ann. §§ 81.105-106, 81.109 (West 1992) (requiring informed consent before administering an HIV test, and that “[a] positive test result may not be revealed to the person tested without giving that person the immediate opportunity for individual, face-to-face post-test counseling”).


244. Id. § 2781(3).
mission of HIV infection; (d) to inform [the patient] of available medical treatments; and (e) regarding the . . . need to notify his or her contacts.245

These provisions were designed to make the patient aware of the full range of social risks and medical benefits to be found in consenting to the test.246 Indeed, throughout the mid-to-late 1980s, many AIDS experts believed that the counseling process was at least as important—if not more important—than the actual HIV-antibody test.247

What led to this extraordinary valuation of counseling? A number of factors. First, when the antibody test initially was developed there were no treatments for the underlying HIV infection and few for the symptoms of advanced stages of infection.248 Therefore, although knowing that one was HIV-infected did not necessarily do much for one’s health or general well-being, there was optimism that knowledge might influence an individual to practice safe sex.249

Second, as noted above, because doctors initially identified AIDS in gay men and in intravenous drug users, it was a highly stigmatizing condition.250 The assumption was clear: if a person had AIDS he

245. Id. § 2781 (5).

246. See generally David W. Lyter et al., The HIV Antibody Test: Why Gay and Bisexual Men Want or Do Not Want to Know Their Results, 102 PUB. HEALTH REPS. 468, 469 (1987) (stating that the use of the test as a screening tool may result in "tremendous social stigma and discrimination associated with infection with this virus").

247. See GOSTIN & LAZZARINI, supra note 48, at 80 (noting that, while testing alone may not effect behavioral change, pre- and post-test counseling may help create "a supportive climate in which individuals are more likely to alter their conduct prudently, regardless of test results").

248. See JONATHAN KWITNY, ACCEPTABLE RISKS 142-43 (1992) (noting that AZT, the first drug available to fight against HIV itself, rather than manifestations of HIV-related illness, was not developed until 1986).

249. Lewis H. Kuller & Lawrence A. Kingsley, The Epidemic of AIDS: A Failure of Public Health Policy, 64 MILBANK Q. (Supp. I) 56, 64-65 (1986) (discussing the importance of HIV testing, particularly among people who had engaged in risky conduct, with the hope that behavior modification would follow, and stating that "[r]ecent changes in sexual behavior, most notably a decrease in both the number of partners and high-risk sexual practices . . . suggest that behavioral change is an achievable goal" (citations omitted)).

250. AIDS initially was diagnosed among young gay men at least in part because they otherwise were healthy. It was odd—and noteworthy—to discover such rare medical conditions as PCP and Kaposi’s Sarcoma in this population. These events were so unusual that treating physicians related their occurrence to the CDC. See CDC, Pneumocystis Pneumonia, supra note 230, at 251 (noting the unusual occurrence of pneumocystis pneumonia in five previously healthy homosexual men). This 1981 document was the first report of what initially, and informally, became known as “GRID” (Gay-Related Immune Deficiency), and what the CDC later named “AIDS” (Acquired Immune Deficiency Syndrome). See SENAK, supra note 50, at 84. Still, as early as 1981, not insignificant numbers of drug-using and former drug-using women were falling ill and not recovering from conditions that nor-
either was gay or used drugs—or both.251 At the same time, the legal protections available to people living with HIV/AIDS were minimal. The Americans with Disabilities Act would not be passed until 1990 and would not begin to go into effect until 1992.252 The Federal Rehabilitation Act of 1973 had been enacted, but was limited in applicability to federal institutions or those entities that received federal funding,253 thereby eliminating most employment settings. Moreover, it was not until 1987 that the Supreme Court even hinted that the Act might apply to people living with HIV/AIDS.254 While a number of states and localities had passed statutes that protected people with disabilities from discrimination,255 it was quite some time before it became widely accepted that people living with HIV/AIDS were people living with a disability deserving of such protection.256

Still, despite the growing recognition of the legal rights of people living with HIV/AIDS, the late 1980s were replete with initiatives to quarantine people living with HIV disease;257 to preclude HIV-in-

251. Cf. Senak, supra note 50, at 84 (noting that “[t]he reaction of families was often more severe to the news that a son or brother was dying because he had had sex with another man than it was to the fact that he was dying”).


253. See 29 U.S.C. §§ 701-797, 794(a) (1994) (limiting the antidiscrimination prohibition of the Act to “any program or activity receiving Federal financial assistance” or programs conducted by an executive agency).

254. See School Bd. v. Arline, 480 U.S. 273, 282 n.7 (1987) (deciding that a non-contagious carrier of TB is not barred from bringing a claim under the Rehabilitation Act and declining to analogize to the context of AIDS because that was not the question presented to the Court); see also Bragdon v. Abbott, 118 S. Ct. 2196, 2207 (1998) (holding that an individual with asymptomatic HIV infection may be considered a person with a disability, and as such, may bring a claim under the ADA); cf. Daniel R. Mandelker, Housing Issues, in AIDS LAW TODAY, supra note 48, 320 (noting that in 1988, Congress amended the Fair Housing Act to prohibit discrimination based on “handicap” in the sale or rental of housing (citing 42 U.S.C. §§ 3604-3606 (1988))).


256. See id. at 3 (asserting that “legal protections from HIV-related discrimination have been fragmented and inconsistent,” and noting that there are gaps and definitional problems in state and federal law). The Supreme Court recently resolved a conflict among the circuits as to whether asymptomatic HIV infection can be a disability under the ADA. See Bragdon, 118 S. Ct. at 2207 (holding that asymptomatic “HIV infection is a physical impairment which substantially limits a major life activity, as the ADA defines it”).

257. See Senak, supra note 50, at 178-79. This was, in fact, the policy that was developed by the government of Cuba. See Brody, supra note 5, at 49.
fected children from attending school\textsuperscript{258} and HIV-infected adults from teaching school,\textsuperscript{259} and to require testing of immigrants,\textsuperscript{260} inmates,\textsuperscript{261} and others.\textsuperscript{262} There was a sense of hysteria that frequently surrounded an individual’s disclosure that he or she was HIV-infected.\textsuperscript{263} Indeed, many people lost their jobs, their homes, their insurance, and that which could not be legislated against: their family and friends.\textsuperscript{264} As a result, counseling came to be valued as a means by which to assist those tested with coping with such discrimination.

Third, health care providers and public health organizations almost uniformly issued guidelines calling on the public to react to the

\textsuperscript{258} See generally Elizabeth B. Cooper, \textit{AIDS Law: The Impact of AIDS on American Schools and Prisons}, 1987 ANN. SURV. AM. L. 117. In many of the early cases, children became HIV-infected as a result of the blood product they had received to treat their hemophilia prior to the development of a test to detect HIV antibodies. Indeed, testing the blood supply was the initial impetus for the development of such a test. Some people took extraordinary measures to ensure that families with HIV-infected children would be barred from school: one family’s home was torched in an incident that was linked to the HIV status of the couple’s three sons. \textit{Id.} at 129; see also \textit{Senak}, supra note 50, at 201 (noting the case of Ryan White).

\textsuperscript{259} See, \textit{e.g.}, Chalk v. District Court, 840 F.2d 701, 712 (9th Cir. 1988) (issuing an injunction to restore a teacher to his classroom duties after he had been assigned to administrative duties on the basis of his AIDS diagnosis).

\textsuperscript{260} See 42 C.F.R. §§ 34.2(4), 34.3(a)(1), (b)(i-iv) (1997) (requiring HIV testing for aliens applying for immigrant visas, student visas, refugee status, and adjustment of status under immigration law).

\textsuperscript{261} See Alexa Freeman, \textit{HIV in Prison, in AIDS Law Today, supra} note 48, at 263, 269 (stating that, as of 1991, “eighteen prison systems, including the Federal Bureau of Prisons, mandate HIV antibody testing of all prisoners in order to identify those who are positive”).

\textsuperscript{262} See Scott Burris, \textit{Testing, Disclosure, and the Right to Privacy, in AIDS Law Today, supra} note 48, at 115, 127 (noting that “[s]ome states authorize involuntary testing of, and disclosure of information about, people in prisons, mental hospitals, juvenile facilities, and residential centers for the developmentally disabled”); Donna I. Dennis, \textit{HIV Screening \& Discrimination: The Federal Example, in AIDS Law Today, supra} note 48, at 187, 187 (noting that the United States government requires HIV testing in the four areas “over which it exercises complete control—the military, the Foreign Service, the Job Corps, and immigration policy”); Larry Gostin, \textit{Traditional Public Health Strategies, in AIDS Law Today, supra} note 48, at 59, 60 (indicating that compulsory screening has been employed “by the Department of Defense, the State Department, the Job Corps, and the Immigration and Naturalization Service”).

\textsuperscript{263} See Arthur S. Leonard, \textit{Discrimination, in AIDS Law Today, supra} note 48, at 297, 297 (stating that “a secondary epidemic of fear has accompanied the epidemic of illness and death, generating a wave of discrimination against those identified with the disease”).

\textsuperscript{264} See \textit{Senak, supra} note 50, at 84 (noting that, although discrimination is often thought to occur only in formal relationships, such as between employer and employee, it also occurs “in informal relationships with friends and family”); Leonard, \textit{supra} note 263, at 297 (noting that a 1990 survey of civil rights agencies revealed approximately thirteen thousand complaints of HIV-related discrimination ranging from “discrimination in access to health care, insurance, housing, or public benefits to workplace discrimination against employees or customers”).
facts about HIV, rather than the fear it tended to generate.\textsuperscript{265} Recognizing the degree of generalized AIDS hysteria, these medical experts, working in tandem with leadership from the gay and lesbian community,\textsuperscript{266} acknowledged the need for certain protections, consistent with public health principles, to ensure that individuals came forward to be tested and to receive HIV-related care, as it became available, rather than to drive the epidemic underground.\textsuperscript{267}

In addition to mandating HIV-related counseling to ensure that an individual was prepared to receive his test results,\textsuperscript{268} the essential elements of this new approach included extensive confidentiality protections to help preclude incidents of discrimination,\textsuperscript{269} and the enactment of provisions that would provide a cause of action if an HIV-infected individual suffered from discrimination.\textsuperscript{270} Indeed, these elements provide the underpinning to comprehensive legislation passed in many states in the late 1980s to help stem the spread of the epidemic and its ancillary effects.\textsuperscript{271}

\textsuperscript{265} Centers for Disease Control and Prevention, American Public Health Ass’n, American Medical Ass’n, Ass’n of the Bar of the City of New York, position statements (on file with author). Such facts included that HIV was difficult to transmit, except through significant exposure to the blood or bodily fluids of an HIV-infected person. Despite a mailing containing these facts to every household in the United States by the Surgeon General in 1987, considerable misinformation continued to influence public perception and behavior. See generally C. Everett Koop, U.S. Department of Health & Human Services, Surgeon General’s Report on Acquired Immune Deficiency Syndrome (1987) (reporting factual information about AIDS in order to educate and alleviate fear).

\textsuperscript{266} See Ronald Bayer, Public Health Policy and the AIDS Epidemic: An End to HIV Exceptionalism?, 924 NEW ENG. J. MED. 1500, 1501 (1991) (noting that “[i]n the first decade of the AIDS epidemic, an alliance of gay leaders, civil libertarians, physicians, and public health officials began to shape a policy for dealing with AIDS”). This Article posits that, at least in part, the changing demographics of HIV/AIDS (i.e., the increasing percentage of low-income, people of color diagnosed with AIDS) has precipitated the growing acceptance of more restrictive public policy and legislative approaches to people living with HIV/AIDS. See generally id. at 1503 (noting that “policy directed toward the poor is often characterized by authoritarian tendencies”).

\textsuperscript{267} See Senak, supra note 50, at 166 (discussing “HIV exceptionalism,” a doctrine that “divorced HIV from the traditional model for handling sexually transmitted diseases” in order to encourage people to come forward for testing).

\textsuperscript{268} See supra text accompanying notes 243-245 (discussing New York’s informed consent law). See generally Senak, supra note 50, at 168 (noting that “[a] person should know as much as possible about an HIV test before taking it” because “[i]t is a test of your insurability, of your friends, of your family, of your relationship with a spouse or significant other, of your employer, of your legal rights, and of your physician’s loyalty to you”).

\textsuperscript{269} See Senak, supra note 50, at 166 (“State legislatures around the nation, particularly in the epicenters of the AIDS epidemic, enacted laws providing for the confidentiality of people who stepped forward to take an HIV-antibody test.”).

\textsuperscript{270} Id. (noting that “[i]t became illegal in many jurisdictions to reveal to third parties that a person had tested antibody-positive”).

\textsuperscript{271} See generally ACLU, AIDS Project, supra note 255, at 88-133 (containing an appendix of state disability discrimination laws); Leonard, supra note 263, at 297-98 (noting that,
This approach to conducting a diagnostic test was significantly different from most other pre-test procedures because it provided an externally imposed structure to ensure that an individual considering HIV testing was aware of the social risks, as well as the medical benefits, of testing.272

By the early 1990s, however, sufficient attention had been drawn to this phenomenon that a new phrase was coined: “HIV exceptionalism.”273 Most frequently, this term is used in a derogatory manner, implying that consent procedures are inappropriate and exist largely because of a “powerful AIDS lobby,” primarily supported by gay men. Therefore, some argue, we should curtail such protections and treat HIV/AIDS the way we treat other conditions.274 At times, however, health care professionals caring for people living with HIV/AIDS also use the phrase to draw attention to the significant ways in which society constructively has come to terms with the epidemic, recognizing that this disease does, in fact, require a new approach to testing and prevention efforts.275

The debate concerning HIV exceptionalism, however, begs the question of whether existing standards of informed consent—in the realm of HIV and otherwise—are appropriate. Instead of questioning whether HIV-related policies should reflect approaches developed regarding other medical conditions, it is important to consider whether the lessons learned from HIV/AIDS should more directly influence the development of policy concerning health conditions generally, and genetic testing specifically.

The statutory proposal described in the next section provides a unique response to the view that HIV-related pre-test counseling constitutes a form of inappropriate HIV exceptionalism.276 This proposal
during the early days of HIV, there was no existing body of law to deal with discrimination due to a contagious condition, and that, as the epidemic progressed through the 1980s, “lawyers, judges and legislators responded to the need for answers by adopting disability discrimination law . . . to [address] this new problem”).

272. See supra text accompanying notes 243-246.

273. See Bayer, supra note 266, at 1500 (coining the term “HIV exceptionalism” to indicate that AIDS had not fallen under “the [traditional] policies developed to control sexually transmitted diseases or other communicable conditions,” such as use of public health registries and quarantine).

274. See Bayer, supra note 266, at 1503 (noting that “the effort to sustain a set of polities treating HIV infection as fundamentally different from all other public health threats will be increasingly difficult”).

275. See Senak, supra note 50, at 87 (noting that “[t]he public health strategy to fight the epidemic was based on creating an atmosphere that would encourage people to come forward voluntarily to be tested”).

276. See generally Bayer, supra note 266, at 1503 (“[T]he effort to sustain a set of policies treating HIV infection as fundamentally different from all other public threats will be in-
asserts that the difference between HIV disease and other conditions is best minimized, not by reducing HIV-related counseling, but by increasing the requirements for counseling in other medical contexts. 277 Such increased requirements will enhance the likelihood that the consent granted is, indeed, informed consent.

IV. Towards a New Model of Informed Consent: Meeting the Challenge of Genetic Testing

A. Introduction

It is not possible for this Article to resolve the full host of conflicts and problems that have been highlighted regarding the informed consent doctrine and its application. Instead, this Part seeks to identify a core set of principles that can be used to guide the development of this doctrine through the potential land mines of new medical technology, changing reimbursement systems, and individual needs that may occur in the context of genetic testing. 278

As noted previously, unless legislated by Congress, or perhaps a state assembly, traditional principles of informed consent generally do not apply to the drawing of blood to perform diagnostic tests. Thus, statutorily required pre-test counseling and obtaining of written consent as preconditions to HIV-antibody testing are significant. 279 Legislative approval of these requirements reflects a consensus among public health professionals that this approach was essential both for the emotional and physical well-being of the person considering testing, and for the general public health. 280

The context of genetic testing today is quite similar to the context in which researchers first identified HIV and developed a test that could detect its antibodies. Medical treatment is, at best, limited; societal stigma and discrimination exist, with limited means of recourse, especially with regard to insurance and employment; the scientific community is urging caution, but the market and the political environment are making the tests more widely available; and the medical

creasingly difficult. Inevitably, HIV exceptionalism will be viewed as a relic of the epidemic's first years.").

277. Cf. Gabriel Rotello, AIDS Is Still an Exceptional Disease, N.Y. TIMES, Aug. 22, 1997, at A23 (arguing that HIV is still a unique exceptional disease and that confidentiality should be maintained).

278. See Andrews, supra note 27, at 897 ("To a great extent, it will be the law that will be the caretaker of our values as we decide upon the proper uses of genetic technologies.").

279. See supra notes 47-54,143-144, and 242-247.

280. See Bayer, supra note 266, at 1501 (noting the existence of a "broad consensus that . . . people should be tested only with their informed voluntary and specific consent").
profession does not quite know what to do with the information the testing can provide or how to advise patients.281

Not surprisingly, the core set of elements identified as essential to appropriate pre-test genetic counseling and consent procedures look remarkably similar to those valued so highly in the context of HIV testing and counseling.282 This approach attempts not only to warrant that patients who seek such testing are provided with a standard review of risks and benefits that might inure as a result of being tested, but also to ensure that patients have the opportunity to have a full discussion (with health care providers, counselors, and family members) regarding the implications—positive and negative—that might follow a decision to be tested.283

As the HIV epidemic showed, it is not wise to allow hospital committees and doctors' offices to blunder into a "standard of care" regarding genetic pre-test counseling.284 Instead, states should enact appropriate statutory protections to ensure that each person who considers genetic testing is the ultimate decision maker regarding the administration of such tests.285 Ideally, such a law would be enacted federally, in order to provide the greatest and most consistent protection.286 However, because the regulation of general health and well-

281. See supra notes 69-81, 91-111 and accompanying text.
282. See generally Ellen Wright Clayton, Informed Consent and Genetic Research, in Genetic Secrets, supra note 3, at 126, 126-35 (reviewing the numerous considerations to be shared with participants in genetic research protocols). See also infra notes 283, 285, 290 and accompanying text.
283. See Andrews, supra note 27, at 918 ("[T]he law should guarantee that individuals can refuse genetic testing and other genetic interventions, that they receive accurate information upon which to base their decisions about using genetic technologies, that they control access to their genetic test results, and that they are protected from discrimination based on their genotype."); Geller et al., supra note 172, at 1970-72 (discussing the importance of informing potential testees about the ramifications of genetic testing, and providing guideposts to counseling); Patenaude, supra note 7, at 404 (observing that "genetic counseling must involve a two-way dialogue").
284. See supra Part III (noting the importance of pre-test HIV counseling as proscribed by statutory provisions); supra notes 60-68 and accompanying text (discussing how financial pressures can affect the doctor-patient relationship in the absence of a legal standard to guide diagnostic testing).
285. See supra notes 243-245 and accompanying text (discussing New York's informed-consent legislation); see also Andrews, supra note 7, at 994 (noting that "[v]arious blue ribbon panels of government, ethics organizations, and entities like the Institute of Medicine have already concluded that, due to the various psychological and social risks of genetic testing, genetics services should be voluntary"). Andrews further observes that national advisory groups have stressed the importance of incorporating education and counseling into any genetic testing program. Id. at 977.
286. Legislation also should guard against discrimination in insurance, employment, and the like. See Malinowski & Blatt, supra note 1, at 1502 (arguing that national legislation is needed to overcome regulatory disparities in state insurance law and the preemptive
being is an area in which the federal government traditionally defers to the states, it is necessary to look to each state's legislature to enact protective legislation.\textsuperscript{287} One of the richest sources from which these statutes can be developed is the statutory model of HIV-related counseling and testing that constitutes the standard of care in the United States.

B. A Model Statute for Informed Consent to Genetic Testing for Life-Threatening Conditions

A model statute, while ambitious, is important to contemplate. Its roots appropriately are found in HIV testing and consent statutes and in a New York statute that sets forth pre-test counseling and consent requirements for genetic testing, the first state to do so.\textsuperscript{288} Notably, the design of New York's genetic testing statutory scheme\textsuperscript{289} draws directly from the state's HIV testing statute.\textsuperscript{290}

\begin{footnotesize}
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\item \textsuperscript{287} Cf. Report, supra note 23, at 87 ("[I]t would be impractical and unwise to try to resolve all of these [complex, ethical, societal, and legal] problems in a single omnibus bill. . . . [I]nitial legislation in the field should have as its aim assuring strict confidentiality of the collection, retention, use and dissemination of genetic information."). This is the highest priority, in part, because "[f]uture examination of a DNA sample . . . might exceed the intended use granted by the original consent." \textit{Id}. As such, it "might be used in ways that are adverse to the subject in ways unforeseeable at the time permission to test was granted and therefore not implicit in the consent initially given." \textit{Id}.
\item \textsuperscript{288} See N.Y. CIV. RIGHTS LAW § 79-l (McKinney Supp. 1998).
\item \textsuperscript{289} See id. Only three other states have enacted statutes that reflect an interest in ensuring that consent to genetic testing is informed or that test results are protected, although none of these statutes is as comprehensive as the New York law. See Ga. CODE ANN. §§ 33-54-(3), (4) (1996) (requiring prior written consent to genetic testing and prohibiting insurers from using such information for any nontherapeutic purpose); 410 ILL. COMP. STAT. ANN. 513/20(a) (West 1997) (stating that an insurer may "not seek information derived from genetic testing for use in connection with a policy of accident and health insurance"); N.J. STAT. ANN. § 10:5-48 (West Supp. 1998) (calling upon the Commissioner of Health and Senior Services to promulgate regulations "governing procedures for obtaining informed written consent" for genetic testing and further providing that these provisions "shall not apply to newborn screening requirements established by State or federal law").
\item \textsuperscript{290} Compare N.Y. CIV. RIGHTS LAW § 79-l(2)(a) (providing that "[n]o person shall perform a genetic test on a biological sample taken from an individual without [ ] prior written informed consent") with N.Y. PUB. HEALTH LAW § 2781(1) (McKinney 1993) (stating that "no person shall order the performance of an HIV related test without first receiving the written, informed consent of the subject of the test"). \textit{See also KOTVAL, supra note 55, at 29 ("Although the public health concern related to HIV testing does not directly apply to genetic testing, the social consequences of the misuse of genetic information are similar to those related to knowledge about HIV information.").
\end{itemize}
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1. The Model Statute: Essential Elements of Pre-Test Genetic Counseling.—Consistent with the statutory model for HIV pre-test counseling and consent, the genetic testing model statute should start with the requirement that no genetic testing shall occur without the signed and dated informed consent of the person to be tested.\textsuperscript{291} The consent form itself should be designed to ensure that the patient is given sufficient information so that her consent—or refusal to consent—is informed. Its contents should include the following: a description of the test and a statement of its purpose;\textsuperscript{292} a description of the disease(s) or condition(s) for which a test will be conducted;\textsuperscript{293} an explanation of the risks of stigma and discrimination;\textsuperscript{294} and assurances that the patient's medical confidentiality will be protected, with any pertinent exceptions specifically stated.\textsuperscript{295} Indeed, these requirements would be appropriate for virtually any diagnostic test that requires minimal invasion but whose results, if positive, carry significant social risks.\textsuperscript{296}

The model statute also must specifically address concerns unique to genetic testing. The New York genetic testing statute provides an important starting point. For example, the statute appropriately mandates that individuals considering testing should be informed of "the level of certainty[, if known,] that a positive test result for that disease or condition serves as a predictor of such disease,"\textsuperscript{297} they should be provided with a statement that only those tests authorized will be per-

\textsuperscript{291} See N.Y. Civ. Rights Law § 79-l(2)(a); see also Report, supra note 23, at 87 ("[L]egislation should require that genetic tests must be preceded by a signed document assuring the informed consent of the person to be tested. Such consent must be preceded by pre-test counseling consisting of an explanation of the test, including its purpose, potential use, limitations, interpretation and the consequences of test results.").

\textsuperscript{292} See N.Y. Civ. Rights Law § 79-l(2)(b)(1), (2).

\textsuperscript{293} Id. § 79-l(2)(b)(4).

\textsuperscript{294} Cf. N.Y. Pub. Health Law § 2781(3) (including disclosure of risks of stigma and discrimination attendant to a positive HIV test).

\textsuperscript{295} See Report, supra note 23, at 87 (affirming that any authorization for genetic testing "must specifically provide that further disclosure is prohibited"); Paul M. Schwartz, Privacy and the Economics of Personal Health Care Information, 76 Tex. L. Rev. 1, 42 (1997) (noting that "[c]onsiderable evidence exists of a strong consumer desire for health care privacy"); see also infra notes 311-323 and accompanying text.

\textsuperscript{296} See supra notes 22-25, 49-50, 95-111, 234-238, 250-264, infra notes 308-310 and accompanying text.

\textsuperscript{297} N.Y. Civ. Rights Law § 79-l(2)(b)(5).
formed; and they must be given information regarding other options to assess their risk of disease.

Provisions not currently codified in New York, but which must be incorporated into the model statute, include the requirement that the counselor provide a review of the available treatment options, if any; the potential for inaccurate test results; the costs of testing and counseling, if any; and the risk of transmission to offspring. The patient also should be reassured that she can withdraw her consent—to having the blood drawn, having the test processed, or having the results told to her—at any time.

This model statute is designed to ensure that a patient has the opportunity to explore the range of risks and benefits that may attend to a decision to consent or refuse to test for particular traits that reveal an increased risk for life-threatening illness. The areas of heightened sensitivity primarily fall into three categories: treatment options; dis-

298. Id. § 79-l(2)(b)(7). The statute further states that a “general waiver” that does not comply with the foregoing “shall not constitute informed consent,” unless executed for research purposes. Id. § 79-l(2)(c). This provision is especially important in light of the advent of tests that can detect more than one trait. See Wachbroit, supra note 1, at 132-33. The consent form also should contain a statement that, either prior to the test or following receipt of a positive result, “the individual . . . may wish to consider further independent testing, consult their physician or pursue genetic counseling.” N.Y. Civ. Rights Law § 79-l(2)(b)(3).

299. See McKinnon et al., supra note 5, at 1218 (encouraging counselors to discuss the “feasibility of alternative measures” to genetic testing with their patients).

300. See supra notes 92-95 and accompanying text.

301. See McKinnon et al., supra note 5, at 1218 (directing counselors to discuss the “accuracy of the [genetic] test”).

302. See generally George C. Cunningham, A Public Health Perspective on the Control of Predictive Screening for Breast Cancer, 7 HEALTH MATRIX 31, 41 (1997) (arguing that “[t]estees must be informed of . . . the current limitations on our knowledge of the consequences of potential interventions [with respect to breast cancer]”); Lerman et al., supra note 104, at 1886 (noting that risks of genetic testing include “uncertainties inherent in cancer risk figures, the absence of proven strategies for preventing cancer in carriers . . . and the potential for negative psychological consequences of learning one’s genetic status” (footnote omitted)); McKinnon et al., supra note 5, at 1218 (urging counselors to discuss “the life-altering impact testing may have on the individual”). In addition to face-to-face pre-test counseling, providing the patient with written or videotaped information to reinforce her understanding of the test, as well as the information it may reveal, may encourage the patient to consider her options further in a more comfortable setting, such as her home. See id. (noting that written summaries “allow[ ] the person to refer to the information at a later date, and to share it with family members and support people”); infra notes 344-345 and accompanying text (discussing the methods and costs of educating the public about pre- and post-test genetic counseling).

303. See Geller et al., supra note 172, at 1469 (arguing that “those considering genetic testing must be given every chance to rethink and confirm their final decision”). This reinforces the principle that medical care generally, and the testing process specifically, is available for the patient’s benefit, not the physician’s. See Katz, supra note 15, at 83-84 (arguing that informed consent serves the benefit of patient self-determination).
Physicians must provide an explanation of the correlation, if known, between carrying a particular genetic trait and developing a serious illness because an assessment of this risk may have a significant impact on an individual's decision to pursue testing—particularly if treatment options are limited.\textsuperscript{304} It should also be the responsibility of the physician and genetic counselor to know and to describe to the patient the range of treatment that may be available. For example, the fact that there is no treatment for Huntington's disease contributes significantly to the low rate of testing among those at risk.\textsuperscript{305} Similarly, the lack of palatable treatment options may reasonably deter a woman from testing for the BRCA genes;\textsuperscript{306} alternatively, for a woman willing to undergo prophylactic mastectomy or oophorectomy, being tested either can obviate this action or reaffirm her decision.\textsuperscript{307}

The nature of genetically linked illness ensures that among the most troubling concerns of a person considering genetic testing are likely to be: "What will this information reveal about me and my family"? and "What information should I disclose to my family"? Although having a genetic trait for cancer is not contagious,\textsuperscript{308} learning that one has such a trait raises painful questions about disclosure to one's siblings, partner, children, and parents. Moreover, because genetic flaws are transmissible, a woman who wishes to bear children, but has not yet done so, faces complex dilemmas concerning the risk of transmission to her future children.\textsuperscript{309} If she already has children,

\textsuperscript{304} See Biesecker, supra note 7, at 152 (predicting that "[o]nce there is sufficient evidence that a disease can be effectively treated or prevented . . . [g]enetic tests will become more routine").

\textsuperscript{305} See supra notes 71, 76 and 78 and accompanying text.

\textsuperscript{306} See supra notes 92-95 and accompanying text.

\textsuperscript{307} See supra notes 93-95 and accompanying text.

\textsuperscript{308} See Lori B. Andrews, Torts and the Double Helix: Malpractice Liability for Failure to Warn of Genetic Risks, 29 Hous. L. Rev. 149, 177-78 (1992) (comparing uncommunicable genetic disorders with AIDS or other communicable diseases, for which some argue disclosure to current and former partners is necessary). As noted earlier, knowing that one has a trait for a particular type of cancer, or other life-threatening condition, raises other questions concerning disclosure, especially to family members. See id. at 178 ("Since genetic disorders are not communicable, one can argue that no legitimate reason exists for disclosing them to a spouse. However, the spouse may have great interest in the genetic information in order to protect any potential children from risk."); Rothenberg, supra note 27, at 118 (noting that in the orthodox Jewish Community, there is fear that genetic testing may threaten the privacy of families, or hamper the prospects of marriage).

\textsuperscript{309} See Rothenberg, supra note 27, at 122-23 (discussing a mother's decision whether to terminate a pregnancy after learning of genetic mutation in a parent). Of course, these concerns also must be addressed by men considering genetic testing. See Joseph M. Healey, Jr., The Legal Obligations of Genetic Counselors, in GENETICS AND THE LAW II 69, 72 (Aubrey
she must confront difficult questions regarding disclosure to them, because they also may carry her genetic predisposition to the illness.310

Legislatively prescribed confidentiality provisions—and any gaps therein—can have a significant impact on a person’s decision to consent to genetic testing.311 As such, it is prudent to set forth, with as much specificity as possible, the confidentiality protections that ought to be incorporated into the proposed model statute. Once again, it makes sense to start with existing law.

The confidentiality provisions of the New York genetic testing statute are similar to the requirements found in the state’s HIV testing law. Both statutes attempt to protect against breaches of confidentiality in two ways: by mandating that the counselor identify the name of the person, categories of persons, or organizations to whom the test results may be disclosed,312 and by providing that disclosure of results to anyone not named on the original informed consent form cannot occur without the further informed consent of the tested individual.313 Notwithstanding some important exceptions,314 all records related to the genetic test are deemed confidential.315

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310. These are excruciating questions. See Rothenberg, supra note 27, at 122 (emphasizing that reproductive decision making will grow only more complicated as it becomes possible to select embryos with normal BRCA1 genes for implantation, and as genetic testing increasingly becomes available to pregnant women). While the patient must decide how to respond to these questions, she must be given the opportunity to discuss them during both pre-test and post-test counseling. See Andrews, supra note 7, at 967-68, 1005 (discussing the range of genetic testing related dilemmas faced by women during pregnancy).

311. See McKinnon et al., supra note 5, at 1218 ("At-risk persons must understand the advantages and disadvantages of sequestering genetic information and that, even with protections in place, confidentiality cannot be guaranteed."); Rothenberg, supra note 27, at 112 (discussing how insurers are not prohibited from "requiring or requesting genetic testing . . . [and] results," and that this information may be used to "deny coverage or affect the terms and conditions of insurance"); Schwartz, supra note 295, at 22 (stating that, with respect to genetic testing, people will avoid seeking care rather than risk loss of employment and social discrimination); supra text accompanying note 243.


313. See N.Y. CIV. RIGHTS LAW § 79-l(3)(a); N.Y. PUB. HEALTH LAW § 2782(5)(a). The genetic testing statute also provides that the biological (blood) sample shall be destroyed within 60 days, unless otherwise specified in the written consent form. N.Y. CIV. RIGHTS LAW § 79-l(2)(b)(7), (2)(f). There are some rare exceptions to these provisions in both the genetic testing and HIV statutes. See id. § 79-l(4); N.Y. PUB. HEALTH LAW § 2782(1)(c)-(p).

314. See N.Y. CIV. Rights Law § 79l(3)(a), 4(a-d), (6), (7), (8); infra note 318.

315. N.Y. CIV. RIGHTS LAW § 79-l(3).
The New York genetic testing statute also incorporates a unique provision prohibiting the incorporation of the results of an individual’s genetic test “into the records of a non-consenting individual who may be genetically related to the tested individual,” and further provides that no “inferences [shall] be drawn, used, or communicated regarding the possible genetic status of the non-consenting individual.” These statutory elements are crucial because genetic test results for a particular individual may reveal genetic information about family members who do not wish to be tested or who may draw inaccurate conclusions.

Notably, however, none of these confidentiality provisions applies to authorized insurers, and the statute does not mandate that patients be informed of this exception. The risk of discrimination by insurance companies is not insignificant and is a matter that the patient should consider. When a patient seeks insurance reimbursement, the insurance company will know that the patient wanted to be tested (an indication that she may perceive herself to be at risk for a particular genetic condition), and may learn the results of the test. The company may then use, or attempt to use, that knowledge as a means of restricting insurance coverage. If the employer is self-insured,

316. Id. § 79-l(3)(b).
317. Id.
318. See Kotval, supra note 55, at 16.
319. See N.Y. Civ. Rights Law § 79-l(6). In addition, the statute is not designed to apply to any test “in routine use that has been or may be hereafter found to be associated with a genetic variation,” id. § 79-l(1)(a), to genetic testing of newborn infants, id. § 79-l(7), or to specified, anonymous research, id. § 79-l(9).
320. See Biesecker, supra note 7, at 150 (noting that “[i]f a federal law is passed that protects clients from insurance and employment discrimination based on a genetic condition or risk, one of the concerns about confidentiality will be addressed”).
321. See Geller et al., supra note 172, at 1471 (noting that “insurance providers may gain access to [patients’] genetic test results through their physician’s records, hospital records, or disclosure by the participant in an insurance application process”).
322. See UCSF Cancer Center, supra note 34 (reporting on a study in the journal Science which showed that “47 percent of people questioned on health insurance applications about genetic disorders were subsequently rejected for coverage”); see also supra notes 28, 33-34, 79-80, 108-111 and 321.

States are just beginning to enact legislation regarding genetic testing and insurance; of the handful that have done so, most permit test results to be used, so long as “informed consent” is given, regarding the issuance of life and health insurance. See, e.g., Ariz. Rev. Stat. Ann. § 20-448.02(A) (West Supp. 1997) (stating that genetic testing shall not be performed without “specific written informed consent” and that results are “privileged and confidential”); Cal. Ins. Code § 10148 (West Supp. 1998) (asserting that “[n]o insurer shall require a test for the presence of a genetic characteristic for the purpose of determining insurability other than in accordance with the informed consent and privacy provisions of this article”); Haw. Rev. Stat. Ann. § 431:10A-118(a), (c) (Michie 1998) (stating that, while no insurer may use genetic information to deny or limit any coverage, this limitation
there also is a risk that the testee’s employer will learn her test results. As such, a model statute ought to ensure that insurers are not permitted to obtain genetic test results without explicit consent by an individual. Absent this provision, patients must be informed of this gap in confidentiality protection.

To guard further against discrimination by insurers or employers, and in this way to encourage genetic testing, it may be especially appropriate to make available anonymous genetic testing. Anonymous testing has been used widely in the context of HIV.

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does not apply to “life insurance, disability income insurance, and long-term care insurance”); Ind. Code Ann. § 16-39-5-2 (Michie 1993) (requiring written consent for an insurance company to obtain test results); Minn. Stat. Ann. § 72A.139 (West Supp. 1998) (stating that life insurance companies can conduct genetic tests, but only with the individual’s written informed consent); N.Y. Ins. Law § 2612(a), (e) (McKinney 1998) (mandating that insurers receive written informed consent prior to requiring individuals to be tested, but also permitting “adverse underwriting decision[s]” on the basis of the test).

Apparently only Georgia and New Jersey prohibit insurers from using genetic tests to determine insurability. See Ga. Code Ann. § 33-54-1(4) (1996) (noting that the intent of this section is to prohibit insurers “from using information derived from genetic testing to deny access to accident and sickness insurance”); N.J. Stat. Ann. § 17B:30-12(f) (West Supp. 1998) (prohibiting “any unfair discrimination against an individual in the application of the results of a genetic test or genetic information in the issuance, withholding, extension, or renewal of a policy of life insurance”).

Cf. Haw. Rev. Stat. Ann. § 431:10A-118(a)(1) (prohibiting insurers—except those providing life, disability, or long-term care insurance—from using an individual’s or family member’s genetic information to deny or limit any coverage); Ind. Code Ann. § 16-39-5-2(e) (Michie 1993) (stating that except for life insurance companies, insurers cannot use test results to exclude a person from coverage if they were received “inadvertently”).

323. See Rothenberg, supra note 27, at 114 (noting that employers offering self-funded plans can alter benefits for specific conditions or procedures in light of genetic information). Despite attempts to limit the flow of information between the employer and its insurance arm, the transfer of information between these entities is not unusual. See id.; Mark A. Rothstein, The Law of Medical and Genetic Privacy in the Workplace, in Genetic SECRETS, supra note 3, at 281, 290-91 (“[A]llowing access to the [genetic] information facilitates surreptitious discrimination by the unknown number of employers determined to exclude form the workplace all individuals with certain genetic traits, predispositions, or conditions.”). Furthermore, in the case of self-insured plans, many state and local (genetic) antidiscrimination provisions are pre-empted by ERISA. See Rothenberg, supra note 27, at 109-10.

While both the Rehabilitation Act of 1973, 29 U.S.C. §§ 701-797 (1994), and the Americans with Disabilities Act, 42 U.S.C. §§ 12101-12213 (1994), prohibit certain types of disability-based discrimination, it remains to be seen whether these laws will apply to genetic flaws. See supra note 256 (discussing the Supreme Court’s recent resolution of whether the ADA applies to asymptomatic HIV). Of course, even if these laws do apply, a patient’s vindication of her rights through litigation can be a long, painful, and ultimately uncertain process.

324. See Senak, supra note 50, at 169-70 (discussing anonymous testing in the context of HIV). A number of states and localities have established anonymous test sites. See N.Y. Pub. Health Law § 2781(4) (McKinney 1993) (requiring health care providers, who are unauthorized and unable to provide anonymous HIV tests, to refer patients seeking anony-
proach, a person seeking to be tested is given a number, or other means by which her test sample will be tracked, without revealing her identity. Standard pre-test counseling is required; post-test counseling occurs when the testee returns for her results.325

Because the test is anonymous, and it is impossible for the test site to conduct follow-up without the testee returning to the facility, this approach also provides a person with an easily exercised "opt-out," should she decide she is not yet ready to learn her test results.326 Anonymous testing has been an important vehicle for encouraging HIV testing, especially in the context of ongoing stigma and discrimination.327 Unfortunately, expense is among the greatest barriers to making such programs available in the context of genetic testing.328

As already noted, a dialogue between the physician or counselor and the patient is the essential prerequisite to voluntary and informed medical decision making.329 The model statute is designed to provide the structure in which this dialogue can occur. As reluctant as health care providers, or counselors, may be to discuss issues such as insurance, confidentiality, and discrimination with people who are considering testing, it is vitally important that they do so.330 In the context

mous testing "to a test site which does provide anonymous testing"); HIV Testing: Voluntary Testing Programs Expanded Around the Nation, HEALTH LETTER ON THE CDC, July 7, 1997, available in 1997 WL 7716417 [hereinafter Voluntary Testing] (offering information about anonymous testing sites nationwide via a toll-free hotline).

325. See SENAK, supra note 50, at 169.

326. Cf. KATZ, supra note 15, at 104-05 (providing an overview of the contemporary debate over patient self-determination); Groopman, supra note 92, at 42 (stating that patients at the author's particular medical institution may elect not to know genetic test results immediately, but may wait or even change their minds and never know the results).

327. See SENAK, supra note 50, at 169-70 (noting that anonymous testing protects one from adverse consequences from "an employer, a physician, a parent, a teacher, or, most important of all, an insurance company").

328. See Rothstein, supra note 110, at 458-59 (noting that an insurer will not pay for an anonymous genetic test, so that it would be restricted to those who can afford it, and that genetic tests are complex in comparison to the "relatively easy" task of establishing HIV seropositivity). The comparatively lower cost of HIV tests, in tandem with the desire of public health officials to stem the spread of the epidemic through testing, were strong reasons for public entities to pay to establish anonymous testing sites. See Voluntary Testing, supra note 324 (discussing state and corporate sponsorship of National HIV Testing Day).

329. See supra notes 177-181, 184-196 and accompanying text; see also KATZ, supra note 15, at 78 (noting that "[s]afeguarding self-determination requires assessing whether patients’ informational needs have been satisfied by asking them whether they understand what has been explained to them").

330. See Burke et al., supra note 83, at 998 (arguing that counseling should take into account "[q]uality of life, insurance concerns, and other personal considerations"); Geller et al., supra note 172, at 1471 ("Participants should be informed that genetic testing for cancer susceptibility may limit their ability to obtain health, life, or disability insurance,
of such powerful diagnostic blood tests, a failure to ensure that a patient’s “consent” truly is informed is tantamount to testing without consent.\textsuperscript{331} Making the disclosures described herein, and having the attendant discussions, reflect an acknowledgment that a person is more than the disease she may have.\textsuperscript{332} For some people, the countervailing realities of their lives may lead them to conclude that it is inappropriate to be tested.\textsuperscript{333} As difficult as it sometimes may be for “outsiders” to understand this decision, so long as it is an informed decision, it must be accepted.\textsuperscript{334} Proceeding in the manner set forth in the model statute can help foster self-determination for the person considering genetic testing.\textsuperscript{335} Indeed, this process would reinforce

may lead to limitations in coverage, or may result in higher premiums for insurance products.”); Wertz, supra note 56, at 327 (pointing out that, despite legal and ethical emphasis on privacy, disclosure of genetic information to health insurers and employers is rarely discussed in today’s counseling).

\textsuperscript{331} Cf. Katz, supra note 15, at 84; Burris & Gostin, supra note 3, at 140 (noting that completely voluntary testing requires adequate information, not merely a signature on a consent form).

\textsuperscript{332} See Katz, supra note 15, at xix (indicating that, because doctors sometimes engross themselves with the “disease in the body in the bed,” the physician-patient relationship becomes depersonalized).

\textsuperscript{333} See, e.g., Roberts, supra note 195, at 976 (noting that values other than patient autonomy, such as “family integrity and physician responsibility, are as important as individual rights and have been downplayed as a result of Western cultural biases on the part of the medical and bioethics communities”); Groopman, supra note 92, at 42 (describing a patient’s father who opposed genetic testing because, having fled from Poland prior to the Nazi invasion, he feared the potential abuse of genetic information). See also supra notes 29-24, 28-29, 33-34, 75-80, 96-111, 308-311 and 320-333 (discussing the lack of available treatment, potential psychological ramifications, and risk of discrimination as reasons, among others, that some people reject the option of genetic testing).

\textsuperscript{334} See McKinnon et al., supra note 5, at 1218 (“The person’s right not to know [whether they carry genetic alterations] must be respected.”); Wertz, supra note 56, at 324 (arguing for nondirective genetic counseling, which “means helping clients determine what decisions are best for them, in view of their own values and goals,” even if the medical professional disagrees with the decision). Compare Bieseker, supra note 29, at 146-49 (describing the traditional function of genetic counseling as “facilitating and supporting clients’ decision making, rather than persuading or coercing them to choose a particular outcome,” as appropriate because “the counselor, in most circumstances, does not know what outcome would be best for the client”) with Sonia M. Suter, Value Neutrality and Nondirectiveness: Comments on Future Directions in Genetic Counseling, 8 KENNEDY INST. ETHICS J. 161-63 (1998) (noting that, based on their expertise and experience, “genetic counselors can sometimes correctly determine the best decision for a particular client”).

\textsuperscript{335} Some may suggest that, as in the context of abortion, any mandated counseling is paternalistic and inappropriate. See Anita L. Allen, Genetic Privacy: Emerging Concepts and Values, in GENETIC SECRETS, supra note 3, at 31, 47 (discussing the argument that choices about counseling should be voluntary and “free of unwanted governmental or other third-party interference”). To the extent that the state offers genetic counseling to patients, without forcing them to listen to or to read certain information, this criticism can be withstood. Moreover, because genetic testing of the sort described in this Article is so new, much of this education is likely to occur in the context of patient pre-test counseling. This counsel-
the concept of the patient as an equal partner in the physician-patient relationship.\textsuperscript{336}

2. \textit{The Model Statute: Elements of Post-Test Counseling}.—Assuming a person chooses to be tested for a particular condition, it is critically important that the model statute require that she be provided with appropriate post-test counseling.\textsuperscript{337} This is the first step to ensuring that she is provided with appropriate health care and support services. As with HIV testing, a person receiving test results (regardless of whether they are positive or negative) must be provided with appropriate emotional support or, at a minimum, referrals to counseling resources.\textsuperscript{338}

During post-test genetic counseling, it is essential to confirm that the patient truly understands the nature of the diagnostic blood test, what it reveals (or does not reveal), and the potential for disease progression should the tested-for trait be present.\textsuperscript{339} If the test reveals a genetic flaw, the patient also must be provided with post-test counseling to inform her of any available medical treatment, as well as to discuss the ramifications of disclosing (or not disclosing) test results to

\begin{itemize}
\item[A] professional's insistence that he and his patient-clients converse and think together should be honored, even if the dialogue has to be forced. That much invasion of privacy must be permitted in order to safeguard patient-clients' autonomy through insight, and not to abandon it to corruption by unnecessary fears, blind misconceptions, and false certainties.
\end{itemize}

Jay Katz, Disclosure and Consent: In Search of Their Roots, in GENETICS AND THE LAW II, supra note 309, at 121, 125; see also supra notes 130-143 and accompanying text (discussing recent Supreme Court jurisprudence concerning medical counseling).

336. See Healey, supra note 309, at 72 (discussing the principle of the patient rights movement that "the patient is a person who does not surrender his/her rights by entering the health care process").

337. See McKinnon et al., supra note 5, at 1219 (stating that test results should be "disclosed in a face-to-face encounter" by a medical professional with an established relationship with the testee); Report, supra note 23, at 87 (stating that post-test counseling must accompany the disclosure of test results to the subject of the test).

338. See N.Y. PUB. HEALTH LAW § 2781 (McKinney 1993) (requiring doctors to provide counseling or referrals for counseling "]a]t the time of communicating the test result[s] in order to help patients "cop[e] with the emotional consequences of learning the results"); McKinnon et al., supra note 5, at 1219 (arguing that genetic counselors should refer patients to medical specialists and support organizations as part of the follow-up procedure). It may be particularly problematic for persons without health insurance or other appropriate coverage to obtain appropriate follow-up counseling. See supra notes 62-66, 195-196 and accompanying text.

339. See Patenaude, supra note 7, at 404 (observing that although disclosure of genetic information does not necessarily convey information about "immediate physical risks," it could be useful if it spurs the testee to engage in behavior that would reduce the chances of developing the condition for which she is at increased genetic risk).
family members. She must be given the opportunity to discuss her medical and disclosure options and to reach decisions, tentative as they may be, with which she is comfortable. Ideally, the patient should not leave the facility without an appointment to come back for follow-up care, whether it is for one week or one year hence, as appropriate. In addition, she should be provided with as much guidance as possible regarding what she should expect physiologically and emotionally, and how she can best take care of herself.

3. Non-Statutory Concerns: Creating Institutional Supports to Ensure Informed Consent—Although time is at a premium in any health care setting, it is particularly valuable in the context of pre- and post-test counseling for genetic traits and conditions. While economies of scale can be achieved through use of videotapes and written materials to provide some basic information, decisions regarding testing remain remarkably complex. Therefore, to the extent physicians are going to offer genetic testing, they have the obligation to create sufficient time in their schedules to provide appropriate pre- and post-test counseling.

340. See Biesecker, supra note 29, at 152-53 ("As genes are identified that lead to treatable conditions such as diabetes and hypertension, counselors, nurses, and physicians will find it increasingly difficult to honor the rare client's request not to notify family members. Genetic counselors may come to consider families, rather than individuals, as their clients."); cf. Geller et al., supra note 172, at 1468 (stating that "primary risks and benefits of testing at this time are psychological and social rather than physical (because the efficacy of preventive and therapeutic strategies has not been proven").

341. See generally Katz, supra note 15, at 121-28 (discussing the process of self-reflection as an element of patient autonomy); Groopman, supra note 92, at 44 (relating the experience of a BRCA carrier deciding between surveillance and removal of her breasts and ovaries).

342. See McKinnon et al., supra note 5, at 1219 (stating that counselors should "[e]ncourage follow-up, in person sessions" and "[p]rovide access by telephone for questions and concerns that may arise").

343. See Geller et al., supra note 172, at 1472 (discussing types of treatments to reduce morbidity and mortality after a positive genetic test).

344. See Groopman, supra note 92, at 42-45 (illustrating through a patient's experience the importance of providing information as well as time to consider carefully the numerous implications of genetic testing).


346. See Patenaude, supra note 7, at 408 (noting that although videos, brochures, CD-ROMs and the like will be useful, "personal discussion with an informed professional of the anticipated meaning and utility of the genetic information should be included in any decision-making process").
Even when our health care providers say that certain decisions are up to us, we often know what they want us to do. Sometimes our physician explicitly tells us his recommendation; sometimes we can sense his preferences from word choice or body language. It is of utmost importance, however, that we believe that we will receive the best available care and services, regardless of our decision to follow our physician’s (implicit or explicit) advice.

It is this expression of trust that is at the heart of the successful physician-patient relationship: Our physician must trust that we will make decisions that are in our own best interest, and we must trust that our physician will continue to provide us with the (one hopes high) standard of care that we have been receiving.

One way to facilitate the development of this relationship is to incorporate assurances into both pre- and post-test counseling that the physician will still provide the patient with care, regardless of her decisions. Indeed, by integrating this message into patient counseling, the physician and patient are more likely to solidify a trusting relationship.

Whether an individual will consent to diagnostic genetic testing also is influenced by her opportunity realistically to obtain health care services that will address the discoveries found in such testing. Indeed, as has been true in the HIV epidemic, merely testing positive, without having available necessary care and services, is of limited use. In fact, it would be quite cruel to encourage an individual to be tested, only to learn that she has no means of obtaining treatment.

347. See Candace West & Richard M. Frankel, Miscommunication in Medicine, in "MISCOMMUNICATION" AND PROBLEMATIC TALK 166, 178 (Nikolas Coupland et al. eds., 1991) (noting that "physicians use different linguistic registers . . . to enhance, limit, and exclude patients' participation over the course of medical encounters").

348. See Katz, supra note 15, at 102-03 (discussing “mutual trust” between physician and patient); see also supra notes 177-181 and accompanying text (emphasizing the function of trust in the medical decision-making process). As noted earlier, this may be particularly difficult to achieve for a patient who is dependent on certain managed care programs, Medicaid, or other public funds for health care services. See supra notes 62-66, 193-196 and accompanying text.

349. See Katz, supra note 15, at xvi (offering "historical evidence that patients' participation in decision making is an idea alien to the ethos of medicine").

350. See Emanuel & Dubler, supra note 59, at 325 (discussing the benefit of a continued relationship between patient and physician). A statutory prohibition against discrimination on the basis of "genetic predisposition or carrier status" also would serve to bolster this trust. See, e.g., N.Y. EXEC. LAW § 296 (McKinney Supp. 1998).

351. See supra notes 62-66, 75, 193-196 and accompanying text.

352. Cf. Gostin & Lazzarini, supra note 48, at 72 (noting that “[e]ducational efforts tend to fail unless individuals have the means with which to follow public health advice”). The only potential benefit to testing for HIV, without access to care, is the finding of some studies that people are more likely to engage in risk-reduction behavior if they know them-
Although it is not possible for physicians, or their staffs, to conduct a detailed, individualized assessment of available care for each patient, it is important, before testing, that they obtain at least a basic understanding of the patient’s available coverage (if any), and that they ensure the patient also understands the scope of her coverage. It may, in fact, be most important for the provider to encourage the patient to contact her insurance company to learn what services may be provided.\textsuperscript{353}

Existing barriers to physician-patient communication must be removed to ensure that a patient’s consent is truly informed. First, medical language must be simplified to ensure that the pre-test and post-test counseling is understood.\textsuperscript{354} Making this change is likely to facilitate discussion between the patient and physician (or counselor) by removing an important element of intimidation. Second, for those individuals who do not speak English, translators must be available to assist in pre- and post-test counseling.\textsuperscript{355} Absent quality services in this area, it is likely that large segments of immigrant populations will not be able to give informed consent to a testing procedure.\textsuperscript{356}

As important, the physician must be able to acknowledge and confront institutional barriers that may interfere with an individual’s willingness to engage in comfortable discussion regarding something as significant as genetic testing.\textsuperscript{357} For example, the physician must be able to take into consideration that an African American woman who is dependent on government benefits is going to experience the medical system differently from the way the physician experiences it

\textsuperscript{353} See McKinnon et al., supra note 5, at 1218 (arguing that counselors should discuss insurance related issues with testees). Even this act, however, may be fateful for the patient, especially if there is no prohibition on insurance companies denying coverage to individuals based on genetic testing. See also Patenaude, supra note 7, at 408 ("Removing fears of uninsurability . . . would significantly alter the balance between risk and benefit."); supra notes 28-29, 33-34, 79-80, 108-111 and 320-322.

\textsuperscript{354} See McKinnon et al., supra note 5, at 1218 (noting that genetic counseling should be provided in a client-centered approach, providing information in “clear language” that simplifies “complicated concepts”); supra notes 167-196 (discussing generally suggestions for rendering consent truly informed).

\textsuperscript{355} See Gordon, supra note 186, at 1355 n.193 (stating that health care providers should use non-family translators).

\textsuperscript{356} See id. at 1321-24, 1341 (discussing the effects of cultural differences on informed consent).

\textsuperscript{357} See supra notes 37-42, 145, 192-194, 199-207, infra notes 358-359 and accompanying text (discussing the effects of alienation from the health care system due to gender, race, or class).
(as a doctor or as a patient). 358 Regardless of whether she has had negative experiences with health care institutions previously, it is possible that she will be aware of institutionalized discrimination against racial minorities that has occurred in medical settings. 359 The concerns she may have regarding institutional abuse or nonfeasance are quite tangible to her. They must be recognized and confronted, or else her consent, if given, will be obtained through intimidation, not information. 360

4. Enforcement.—Once a statute setting forth a protocol for informed consent to genetic testing is established, its successful implementation will depend on two things: education and enforcement. Each state health department and relevant professional organization will have the responsibility of educating health care providers regarding their duties under the informed consent statutory scheme. Indeed, even absent passage of legislation, the growing availability of genetic testing requires that these activities occur.

Just as education of professionals constitutes a positive inducement to engage in appropriate pre-test counseling, enforcement mechanisms provide a complementary obligation to comply with the law. This statute should be enforceable through a private right of action by an individual who believes she was not provided with statutorily mandated pre- or post-test counseling. 361 Similarly, the state

358. See Ehrenreich, supra note 192, at 492-95 (comparing the differences in health care treatment between a 32-year-old middle class academic and a 32-year-old unemployed mother of three); Dorothy E. Roberts, Crime, Race, and Reproduction, 67 Tul. L. Rev. 1945, 1961-64 (1993) (illustrating how the perspective of African American women toward health care may be shaped by this country’s history of depriving them of reproductive choice as means of punishment, as well as out of eugenic motives).


360. See generally Ehrenreich, supra note 192, at 495-96 (focusing attention on “instances of forced medical treatment during pregnancy”); Roberts, supra note 359, at 305 (discussing the background and ramifications of “policies aimed at restricting the fertility of poor women of color”).

361. See, e.g., N.Y. Civ. Rights Law § 79-l(2)(a), 3(a) (McKinney Supp. 1998) (providing penalties for any person who “perform[s] a genetic test on a biological sample taken from an individual without . . . prior written informed consent” or who discloses “records, findings and results of any genetic test . . . without the written informed consent of the person”); N.Y. PUB. HEALTH LAW § 2783(4) (McKinney 1993) (allowing recovery for ordering
attorney general should be permitted to bring an enforcement action if necessary.

Under New York's genetic testing statute, one who violates the statute may be subject to a "civil fine of not more than one thousand dollars," however, one who willfully violates the statute "shall be guilty of a misdemeanor punishable by a fine of not more than five thousand dollars or by imprisonment for not more than ninety days or by both such fine and imprisonment." Not surprisingly, these punishments mirror the provisions contained in the state's HIV testing statute.

Discussions with New York State and City officials and a review of pertinent case law reveal no reports of HIV-related testing without the consent of the patient. Although there have been reports related to breaches of confidentiality, the State Human Rights Commission has initiated actions only if the person living with HIV/AIDS has suffered from discrimination as a result of the disclosure. It is not clear how the state would respond to an individual who wished to pursue a claim merely for the breach.

This information is both encouraging and disturbing. The apparent lack of unconsented to testing is positive; however, it is not possible to measure the extent of testing that may occur without a patient's fully informed consent. Similarly, it is good to know that the state assists claimants when they have suffered harm as a result of a breach in HIV-related confidentiality. However, one must question the extent to which the decision not to pursue "mere" breaches in confidentiality serves to discourage the reporting of such claims and sends an unfortunate message regarding the serious nature of such breaches.

an HIV test "based on a failure to provide information, explanations, or counseling prior to the execution of a written informed consent, or based on a lack of informed consent").

363. Id. § 79-l(5)(b).
364. See N.Y. PUB. HEALTH LAW § 2783(4) (imposing fines for violation of the statute).
365. Telephone Interviews with Representatives, AIDS Institute, New York State Department of Health (Mar. 25, 1998); New York City Commission on Human Rights.
366. Search of WESTLAW, New York State and Federal Cases Database (Nov. 16, 1998) (HIV /s Test /s Consent) (retrieving thirteen cases, none of which described HIV-related testing without the consent of the patient).
367. This does not include state-mandated HIV-testing of all newborns, and select other exceptions, to the statutory requirement of informed consent. See N.Y. PUB. HEALTH LAW § 2500-f (McKinney Supp. 1998) (allowing for the testing of newborns for HIV); § 2785-a (McKinney Supp. 1998) (mandating HIV-related testing pursuant to a court order). By definition, it does not include unconsented to testing of which the patient is never aware.
Because the New York genetic testing statute was enacted only recently, it is too soon to reach any conclusions regarding the effectiveness of its enforcement mechanisms. One must hope that, with the increasing visibility of the work of the Human Genome Project, health care providers and patients will recognize the value of informed consent to genetic testing, legislatures will discern the importance of enacting legislation such as that described in this Article, and mechanisms to prevent and punish breaches in consent or confidentiality will be available and effective. The New York enforcement provisions, allowing for both a private right of action and a misdemeanor prosecution, are a good place to start. Time will reveal whether they are sufficient to protect patients' rights to informed decision-making in this age of rapidly advancing technology.

5. Arguments Against a Model Statute.—There are those who would argue that legislating in the realm of public health, particularly in an area as new as genetic testing, is inappropriate. Some believe, as a matter of principle, that controversies such as those explored in this Article, are best resolved in the private sector by private actors. In such cases, should an "unresolvable" conflict arise, the parties can turn to a court of law, asking it to apply traditional legal concepts to resolve the dispute. Using this approach, an appropriate body of law and practice is expected to develop over time.

Others believe that it is inappropriate to legislate in the realm of genetic testing, counseling, and confidentiality because of concerns that it would create, or reinforce, a form of "genetic exceptionalism." This theory, echoing the criticism of HIV exceptionalism, asserts that the only reason genetic testing is "exceptional" is because we

370. See McKinnon et al., supra note 5, at 1217 (discussing the work of the National Society of Genetic Counselors in response to "[r]apid advances, such as those related to the Human Genome Project").
371. See supra text accompanying notes 362-363.
372. See generally Dworkin, supra note 14 (arguing that it may be misguided to enact such legislation).
373. See Biesecker, supra note 29, at 152 ("Consent to undergo genetic testing eventually will be obtained by primary care providers in a manner similar to consent for other medical tests.").
374. Robert L. Wachbroit notes that, excepting reproduction because of the historical use of eugenics in this area, "[t]he expansion of genetic counseling to other areas of medicine . . . encourages a 'genetic exceptionalism,' as if the mere fact that genetic methodologies were used requires providing the patient with special support and care. This genetic exceptionalism is dubious at best." Wachbroit, supra note 1, at 139-40.
treat it that way. Proponents of this approach assert that if, instead, we were to treat genetics as a routine health matter, we would be taking important steps to reducing stigma and discrimination.

It is true that components of the model legislation proposed herein may, one day, appear unnecessary or inappropriate. Indeed, should the factors that currently support the creation of legislation—lack of treatment, stigma, risk of discrimination in employment and insurance—change, then it may be appropriate to amend the statute. For the foreseeable future, however, the potential for "social harm" remains significant. Therefore, while legislation may pose some of the dangers described herein, it would be irresponsible to refuse the invitation to legislate—carefully—elements of informed consent and confidentiality in the burgeoning realm of genetic testing.

375. See Thomas H. Murray, Genetic Exceptionalism and "Future Diaries:" Is Genetic Information Different from Other Medical Information?, in GENETIC SECRETS, supra note 3, at 60, 71 ("The more we repeat that genetic information is fundamentally unlike other kinds of medical information, the more support we implicitly provide for genetic determinism, for the notion that genetics exerts special power over our lives."); Wachbroit, supra note 1, at 140 ("[T]o insist that counseling should be routinely provided whenever the medical test is genetic leads to a mystique surrounding the idea of genes that encourages misunderstandings about what genes are and distorts their significance.").

376. See Burris & Gostin, supra note 3, at 149-50 ("By 'protecting' those with genetic 'differences' from stigma and discrimination, we are actually reinforcing the belief in their inferiority or otherness."). Others may object to the cost of establishing rigorous consent mechanisms; there are, however, ways to moderate these expenses. See supra notes 344-345 and accompanying text (discussing costs and achieving economies of scale through use of videotapes, CD-ROMS, and brochures).

377. See supra notes 14, 273-277 and accompanying text. For example, as a society, we deal differently with HIV/AIDS than we did ten or fifteen years ago. This has led some to call for changes to our approach to dealing with the epidemic. See Chandler Burr, The AIDS Exception: Privacy vs. Public Health, ATLANTIC MONTHLY (June 1997). Others note that because HIV/AIDS remains a condition that leads to significant stigma and discrimination and for which there is insufficient (accessibility to) treatment, it is too soon to make such changes. See Scott Burris, Law and the Social Risk of Health Care: Lessons from HIV Testing, 61 ALB. L.R. 831 (1998); Lynda Richardson, Wave of Laws Aimed at People With HIV, N.Y. TIMES, Sept. 25, 1998, at A1. One should expect that this tension will be echoed in the realm of genetic testing as society struggles to develop appropriate law and policy to protect individuals in the course of preserving public health.

378. See Patenaude, supra note 7, at 406 ("The social and ethical constructions which are devised to guide clinicians and consumers of genetic testing in its use must be flexible in incorporating changes in scientific information and accumulating data on social and psychological impact of genetic testing.").

379. See Arthur C. Upton, Forward to GENETIC SECRETS, supra note 3, at xi, xiii (arguing that the current investment in genetic technology demands that we develop policies to ensure its wise use, and that we not simply ignore the "social, ethical, and legal ramifications" of these questions). As discussed throughout this Part of the Article, this legislation also is designed to influence the way the medical community generally approaches counseling, testing, and privacy. See supra notes 276-277 and accompanying text (suggesting
CONCLUSION

Significant problems exist with the legal doctrine of informed consent as it now stands: Neither the "reasonable physician" nor the "reasonable patient" standard adequately protects the rights or recognizes the needs of most patients; even the more appropriate "reasonable patient" standard frequently is filtered through the physician's perceptions of what risks a reasonable person in the patient's position would want to know; informed consent is required chiefly in the context of significantly invasive procedures, because this doctrine was developed to warn of medical risks, not social risks; and mere nondisclosure of a nonoccurring risk without ensuing harm is not actionable.380 These deficiencies are exacerbated by the growth in available genetic testing technology, the financial pressures inherent in managed care reimbursement and public health programs, and historic inequalities in access to appropriate health care services.381

The model statute proposed in this Article has the potential to remedy, or at least ameliorate, these problems. The statute itself creates a base of information that must be provided to the patient. While this is, perhaps, somewhat paternalistic, the goal of the statute is quite to the contrary: to support the patient's exercise of autonomy. History, particularly in the HIV/AIDS epidemic, has shown that when advances in medical testing technology are teamed with the potential for discrimination and lack of available treatment, statutory provisions focusing on informed consent constitute an essential wall of protection for the patient regarding informed medical decision making.382

Moreover, while the statute cannot dictate the bounds of human behavior, it seeks to support an environment in which physicians and counselors are encouraged to discuss the range of concerns that may trouble a patient. By so doing, the statute seeks to implement a "reasonable person as defined by the circumstances" standard, in which the patient has an obligation to express her concerns, but can do so only if the health care provider both gives her the opportunity and informs her of the range of potential consequences (positive and negative) that may occur as a result of consenting, or choosing not to consent, to genetic testing. As such, the primary burden lies with the health care provider and a secondary burden with the patient.

that the problems of exceptionalism are best overcome by increasing the requirements for informed consent in all areas of medicine).

380. See supra Part II.B.2 (providing background on the development of informed consent legal doctrine).

381. See supra notes 4, 59-66, 69-72, 198-200, 204, 209-211 and accompanying text.

382. See supra notes 228-277 and 335.
This statute implicitly incorporates the critique of informed consent doctrine levied by critical theorists, in that the physician is required to engage the patient regarding the patient's concerns. Her anxieties may arise out of her experiences as an affluent individual with health insurance and the full range of treatment available to her, or they may arise out of her experiences as a low-income person dependent on government benefits with a more limited range of options. Nevertheless, the physician, or counselor, has the responsibility to elicit his patient's concerns and to respond to them.\footnote{383}{See supra Part II.B.1 (discussing current informed consent doctrine and its inadequacy in protecting the needs and rights of most patients).}

Although the statutory provisions proposed herein are not required by the federal Constitution, they are fully consistent with existing holdings regarding medical decision making and bodily autonomy. Regardless of whether the Supreme Court ultimately were to determine that such rights are "fundamental" or more accurately characterized as "liberty interests," the terms of the proposed model statute are compatible with both standards.\footnote{384}{See supra Part II.A-B (tracing the constitutional, statutory, and case law history of informed consent).}

Legal doctrine is obligated to keep pace with medical technology as it continues to develop in ways that were hardly conceivable just a few years ago. Financial pressures notwithstanding, it is the moral obligation of our physicians to speak with us and to get to know us and our needs, particularly with something as complex as genetic testing. The statute proposed in this Article is hardly radical; indeed, its core is taken from another complex medical condition—HIV/AIDS. We have before us a wonderful opportunity to learn from our past, to develop a cogent genetic testing statutory framework, and to ensure that legal doctrine continues to respond to both physicians and patients in these swiftly changing times.