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TEST AT YOUR OWN RISK: YOUR GENETIC REPORT CARD AND THE DIRECT-TO-CONSUMER DUTY TO SECURE INFORMED CONSENT

Deepthy Kishore

ABSTRACT

On June 26, 2000, President Bill Clinton and Prime Minister Tony Blair announced that new gene sequencing techniques had accelerated the progress of the Human Genome Project; for the first time ever, scientists had completed a "rough draft" of the human genome. The announcement inspired a worldwide debate about cloning and genetic engineering, prompting both public curiosity and fierce debate about the nebulous science of predicting one's lifespan and assessing the likelihood for developing disease. A host of companies, some of which market their services over the Internet, have since made genetic testing available directly to consumers.

The emergence of direct-to-consumer (DTC) genetic testing raises important questions about how best to protect consumers from misinterpreting the meaning of their genetic makeup and has sparked discussion about how much and what kind of information a company should disclose to adequately warn consumers of the risks of undergoing genetic testing. Moreover, recent news events suggest that the Food and Drug Administration (FDA) will soon attempt to regulate DTC genetic testing: In May 2010, CVS drugstores and sixty thousand Walgreens drugstores suspended their plans to sell genetic test kits after the FDA announced that it would investigate DTC genetic testing companies.

Selling access to individual genetic information has transposed the physician–patient relationship into a company–consumer context, calling for a novel examination of how consumer and patient protections overlap and where federal regulation ends and tort law begins. This Comment applies principles of products liability and informed consent to the context of genetic testing to argue that tort liability, rather than greater regulation of genetic tests, is the best way to protect consumers of DTC genetic testing. This Comment demonstrates that without professional assistance, consumers risk misinterpreting the meaning of their genetic test results and may even be driven to take drastic actions based on that information. Thus, it asserts that

where genetic testing services are marketed directly to consumers, the required level of disclosure should be the same as that under the doctrine of informed consent: Courts should impose a duty on companies engaged in DTC genetic testing to provide complete warnings, akin to the warnings physicians must provide patients in accordance with informed consent. The ultimate goal of the duty of disclosure proposed by this Comment is to protect and promote the autonomy of the consumer-patient.

INTRODUCTION

In medical genetics, we have seen first hand in the faces of expectant mothers undergoing prenatal testing or in the families of patients with rare disorders, the power of information to disrupt emotions and lives.[1]

—James P. Evans & Robert C. Green

I know no safe depository of the ultimate powers of the society but the people themselves; and if we think them not enlightened enough to exercise their control with a wholesome discretion, the remedy is not to take it from them but to inform their discretion by education.[2]

—Thomas Jefferson

On September 30, 2008, the American actress Christina Applegate appeared on *The Oprah Winfrey Show* to explain to millions of viewers her dramatic decision to have both her breasts removed as a result of information she received from a genetic test.[3] Applegate made her decision after an MRI and biopsy detected early-stage cancer in her left breast, and subsequent genetic testing revealed that she had inherited BRCA, the "breast cancer gene."[4] Fearful that her other breast was also at risk because of her genetic predisposition, Applegate decided to undergo a double mastectomy.[5] "I'm clear. Absolutely 100 percent clear and clean,"[6] she assured viewers on *Good Morning America*, and "I'm definitely not going to die from breast cancer."[7] Her preemptive strike against recurring breast cancer was not without emotional costs: "I cry at least once a day about it because it's hard to overlook it when you're standing there in the mirror."[8]

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[1] James P. Evans & Robert C. Green, Commentary, *Direct to Consumer Genetic Testing: Avoiding a Culture War*, 11 GENETICS MEDICINE 568, 568 (2009).

[2] ROY J. HONEYWELL, THE EDUCATIONAL WORK OF THOMAS JEFFERSON 150 (1931) (quoting a September 28, 1820, letter from Thomas Jefferson to William Charles Jarvis).

[3] *The Oprah Winfrey Show: Breast Cancer Battles* (CBS television broadcast Sept. 30, 2008), *available at* http://www.oprah.com/ health/Breast-Cancer-Battles.

[4] *Id.*

[5] *Id.*

[6] Brian O'Keefe & Lee Ferran, *Applegate Underwent Breast Removal to Stop Cancer*, ABCNEWS.COM (Aug. 19, 2008), http://abcnews.go.com/GMA/Story?id=5606034&page=1 (quoting Applegate's remarks made on *Good Morning America*).

[7] *Id.*

[8] *The Oprah Winfrey Show*, *supra* note 3.

Imagine that a twenty-seven-year-old graduate student, Sarah,[9] watches the show. Having seen her mother survive breast cancer, she is especially vulnerable to suggestions that she might develop it herself.[10] Applegate's plight inspires her to undergo genetic testing, and a quick Google search reveals that she can order a whole-genome scan for $499; a doctor's authorization is not required.[11] Sarah mails the company her saliva sample, and just days later it sends her a report informing her that she has inherited a gene variant that gives her a 60%–90% chance of developing breast cancer.[12] Her obsession with her high risk grows, and she searches constantly for a lump in her breast. She avoids her family members to prevent them from worrying about her and is haunted by memories of chemotherapy appointments that aged her mother.[13] She is overwhelmed with a sense of doom and confused about her numerical odds—what does it mean to have a 10%–40% chance of never developing breast cancer? Should she undergo a mammogram every year? Every few months? Should she see an oncologist to discuss her fears? A plastic surgeon to remove her breasts?

This hypothetical demonstrates why consumers should be apprised of the implications and possible impact of genetic test results before purchasing such services.[14] If Sarah had been aware of the emotional risks in advance of receiving information about her genetic makeup, would she have wanted to learn of her genetic risks? At the time she ordered the genetic scan, Sarah did not realize that receiving information about her genetic susceptibilities could give rise to difficult decisions about how to manage her risk for breast

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[9] This hypothetical is based on the similar circumstances of Northwestern medical resident Deborah Lindner, who ultimately underwent a prophylactic double mastectomy. *See* Amy Harmon, *Cancer Free at 33, but Weighing a Mastectomy*, N.Y. TIMES, Sept. 16, 2007, *available at* http://www.nytimes.com/2007/09/16/health/16gene.html.

[10] *See* BURRILL & CO./CHANGEWAVE RESEARCH, PERSONALIZED MEDICINE AND WELLNESS SURVEY: EXECUTIVE SUMMARY 4 (2008), *available at* www.burrillandco.com/content/CWSurvey_61708.pdf ("[C]oncerns about family history and concerns about a specific disease also will drive use of genetic tests.").

[11] 23andMe, a privately-held personal genetics services company based in Mountain View, California, offers a genetic testing service that provides information about a customer's health and ancestry for $499, and the service can be ordered from the company's website and paid for by credit card. *See Choose the DNA Test That's Right for You*, 23ANDME, https://www.23andme.com (last visited June 18, 2010); *23andMe, Inc. Completes Series A Financing*, 23ANDME (May 22, 2007), https://www.23andme.com/about/press/20070522/.

[12] *See* Harmon, *supra* note 9 (describing how Deborah Lindner's genetic test results revealed that she had inherited the breast cancer gene).

[13] *See id.*

[14] *See* Nora Wong et al., *Genetic Counseling and Interpretation of Genetic Tests in Familial Adenomatous Polyposis and Hereditary Nonpolyposis Colorectal Cancer*, 44 DISEASES COLON & RECTUM 271, 276 (2001) ("Individuals need to know the implications and possible impact of genetic test results before testing.").

cancer,[15] or that it might cause her significant anxiety regarding the genetic makeup of her family members and future children.[16] She did not anticipate the distress that might accompany "inconclusive" results.[17] Nor did she expect to discover that Applegate's assurances were not exactly correct—a double mastectomy significantly decreases the chances of later developing breast cancer but does not guarantee prevention.[18] Had she sought genetic counseling before ordering the test, Sarah might have benefited from such disclosures.[19] However, the direct-to-consumer genetic testing company has no legal responsibility to provide her with any such information.[20]

Fortunately, Sarah can pursue prophylactic surgery or other treatments[21] to reduce her risk for developing breast cancer. But other consumers may learn

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[15] *See, e.g.*, Monica Morrow, Editorial, *Insurance Policies for Prophylactic Surgery: To Cover or Not to Cover?*, 7 ANNALS SURGICAL ONCOLOGY 321 (2000) (discussing which groups of women insurers should provide coverage for: women who receive inconclusive results, all women who decide to undergo prophylactic mastectomies, or only those women who have both a family history and a positive genetic test result for the breast cancer gene).

[16] *See* Janice L. Berliner & Angela Musial Fay, *Risk Assessment and Genetic Counseling for Hereditary Breast and Ovarian Cancer: Recommendations of the National Society of Genetic Counselors*, 16 J. GENETIC COUNSELING 241, 245 (2007) (explaining that genetic "[r]isk assessment for cancer can raise a number of psychosocial issues," including "potentially difficult decisions for managing [patients'] cancer risks . . . and worry about potential risks for their children and other family members"); *see also* Abigail L. Rose et al., *Attitudes and Misconceptions About Predictive Genetic Testing for Cancer Risk*, 8 COMMUNITY GENETICS 145, 148 (2005). In one study, researchers found that "pointless anxiety" from potential test results was the most frequently cited reason to forego genetic testing, with some research participants citing their relationships with family members as a reason they did not want to know of their genetic risks. *Id.*

[17] *See* Caren J. Frost et al., *Decision Making with Uncertain Information: Learning from Women in a High Risk Breast Cancer Clinic*, 13 J. GENETIC COUNSELING 221, 233 (2004) (describing the frustration experienced by patients who receive "[r]esults of uncertain significance" when they "expect [either] a positive or a negative result").

[18] *See, e.g.*, Niki J. Agnantis et al., Editorial, *Preventing Breast, Ovarian Cancer in BRCA Carriers: Rational[e] of Prophylactic Surgery and Promises of Surveillance*, 11 ANNALS SURGICAL ONCOLOGY 1030, 1032–33 (2004) (advocating prophylactic surgery for certain high-risk patients, but admitting that "prophylactic surgery does not [completely] cure the cause, namely the mutated genes").

[19] *See, e.g.*, Yuichi Shoda et al., *Psychological Interventions and Genetic Testing: Facilitating Informed Decisions About BRCA1/2 Cancer Susceptibility*, 5 J. CLINICAL PSYCHOL. MED. SETTINGS 3, 13 (1998) ("It has been widely recognized that individuals who are at high risk for hereditary breast and ovarian cancer need counseling to prepare them to make well-informed decisions about genetic testing and its potential consequences and to provide support for the complex emotional reactions that may be triggered in this uncertain and potentially anxiety-provoking context . . . ." (citations omitted)).

[20] *See infra* Part I.A–B (explaining how direct-to-consumer genetic testing companies evade federal regulation); *see also infra* text accompanying note 344 (explaining why direct-to-consumer genetic testing companies are not subject to products liability rules).

[21] Women who test for a high genetic risk for developing breast cancer have been advised to consider prophylactic mastectomies, undergo administration of Tamoxifen (a chemo-preventative agent), and undergo annual mammography and breast examinations at an earlier age than women who are not at risk. Theodore W.

that no clinical interventions are available to address their particular genetic risks, and they may experience severe emotional distress as a result.[22] For example, would a consumer agree to purchase a genetic testing service if she were to know in advance that she may learn of a high risk for developing Alzheimer's disease, for which there is currently no cure or preventative treatment?[23]

Prenatal genetic tests are of particular concern because consumers might use the information from the tests to decide whether to terminate a pregnancy.[24] In many states consumers can order such tests without a physician's authorization and at an affordable price.[25] One company, Counsyl, sells a testing service that can determine whether couples are at risk of conceiving children with cystic fibrosis, alpha thalassemia, Tay-Sachs, and sickle cell disease, among other disorders.[26] Here, the danger of misunderstanding test results is not to be ignored—prospective parents may make profound life decisions based on this genetic information, including choosing to adopt a child instead of conceiving one or choosing to undergo in vitro fertilization to screen embryos for dangerous genes.[27]

The completion of the Human Genome Project in the last decade[28] has led to a flurry of studies by biotechnology companies eager to market their genetic

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Marcy et al., *Genetic Testing for Lung Cancer Risk: If Physicians Can Do It, Should They?*, 17 J. GEN. INTERNAL MED. 946, 946 (2002).

[22] Bridget M. Kuehn, *Risks and Benefits of Direct-to-Consumer Genetic Testing Remain Unclear*, 300 J. AM. MED. ASS'N 1503, 1504 (2008).

[23] *See id.* at 1505.

[24] Lucy Modra, *Prenatal Genetic Testing Kits Sold at Your Local Pharmacy: Promoting Autonomy or Promoting Confusion?*, 20 BIOETHICS 254, 256 (2006) (describing prenatal genetic testing as especially "controversial, partly because it facilitates selective abortion-termination of pregnancy on the grounds that the foetus has unfavourable genetic characteristics").

[25] For example, the Center for Medical Genetics offers screening for Down syndrome and Trisomy 18, among other genetic disorders, at an affordable price. *See Patient Information: Ultra-Screen™—A baby provides joy and excitement. We provide reassurance*, CTR. FOR MED. GENETICS, http://www.geneticstesting.com/patient_info/ultrascreen_patient.htm (last visited June 18, 2010). Consumers need to fill out an online form to order a test that the company claims can screen for Down Syndrome with 90% accuracy.

[26] Andrew Pollack, *Firm Brings Gene Tests to Masses*, N.Y. TIMES, Jan. 29, 2010, at B1.

[27] Steven Pinker, *My Genome, My Self*, N.Y. TIMES, Jan. 11, 2009, at MM24. After learning of the high chance that his offspring would inherit his gene for familial dysautonomia, an incurable disorder of the autonomic nervous system that leads to a high chance of premature death, Pinker felt thankful that he had never had children, but realized that his nieces and nephews would one day have to get tested for the gene. *Id.*

[28] For a description of the history, goals, and methods of the Human Genome Project and summary of the research that has followed the announcement of the project's completion, see *All About the Human Genome Project (HGP)*, NAT'L HUMAN GENOME RESEARCH INST., http://www.genome.gov/10001772 (last visited June 18, 2010).

tests.[29] And thanks to various scientific advances, a variety of direct-to-consumer (DTC) genetic testing companies can now perform individual genotyping for a modest cost.[30] Meanwhile, in the realm of products liability, the direct marketing of pharmaceutical drugs and medical devices to consumers has given rise to a "nascent and undeveloped field of liability."[31]

DTC genetic testing services represent the intersection of these phenomena, enabling companies to market groundbreaking technology based on brand-new science without the intervention or approval of health care professionals. Selling access to individual genetic information has transposed the physician–patient relationship into a company–consumer context,[32] calling for a novel examination of how consumer and patient protections overlap and where federal regulation ends and tort law begins. Putting individualized genetic information in the hands of consumers certainly can empower them to make vitally important medical decisions and other choices about their health. However, because this information can also cause consumer anxiety, lead to unnecessary medical procedures, and deplete valuable medical resources,[33] consumers should be made aware of the risks and benefits of undergoing genetic testing before ordering such services.

Several commentators already have argued that the risk to patients from inaccurate test results necessitates heightened federal regulation of DTC genetic testing to ensure the clinical accuracy of tests and sound reporting of results.[34] But surprisingly few commentators have proposed patient-centered disclosure requirements in the context of genetic testing or analyzed whether DTC companies owe any duties in tort to their consumers. And to date, no commentator has applied principles of informed consent to argue that courts should require the companies to provide adequate warnings to ensure informed decision making by consumers.

Recognizing that federal regulations alone would be insufficient to fully protect consumers, this Comment argues that courts should apply principles of

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[29] Bryn Williams-Jones & Vural Ozdemir, *Challenges for Corporate Ethics in Marketing Genetic Tests*, 77 J. BUS. ETHICS 33, 34 (2008).

[30] Jonathan M. Gitlin, *Direct to Consumer Genetic Testing Raises Concerns*, ARS TECHNICA (Apr. 4, 2008, 11:50 AM), http://arstechnica.com/science/news/2008/04/direct-to-consumer-genetic-testing-raises-concerns.ars.

[31] Erik Volker Ernst Eisele, *A Dose of Reality: Revisiting Pharmaceutical Manufacturer Liability for an HIV Vaccine*, 30 HOUS. J. INT'L L. 703, 733 (2008).

[32] Modra, *supra* note 24, at 263.

[33] Evans & Green, *supra* note 1, at 568.

[34] *See, e.g.*, sources cited *infra* notes 42, 94 & 99.

informed consent to impose a common law duty of care on DTC genetic testing companies that would ensure adequate disclosures about the risks of genetic testing.

Part I argues that, despite the fact that the companies often market genetic testing services as "informational" or "recreational," many genetic tests are profoundly medical in nature, necessitating adequate patient protections. It describes the regulatory vacuum surrounding DTC genetic testing and explains how tort liability can protect consumers where federal regulations or state consumer protection statutes are insufficient. Part II explains how the interest in protecting patient autonomy forms the foundation of the doctrine of informed consent, while Part III illustrates how the DTC model of genetic testing can diminish consumer autonomy when companies fail to provide sufficient warnings. Specifically, it demonstrates that genetic information placed in the hands of consumers without the assistance of a medical professional can cause anxiety and lead to unnecessary medical procedures, causing both direct and indirect harm to the consumer.[35]

Part IV presents the heart of this Comment's argument. It asserts that under the principles of informed consent discussed in Part II, DTC genetic testing companies bear a legal duty to provide adequate disclosures to consumers. First, it draws an analogy—after exploring the social and scientific context in which states adopted informed consent statutes for HIV testing, it argues that similar policy motivations apply to genetic testing. It then examines case law and concludes that where genetic testing services are marketed and sold directly to consumers—diminishing the role of the medical professional and endangering the consumer's medical autonomy—the level of disclosure required should be akin to that under the doctrine of informed consent.

I. MEDICAL TESTS IN A REGULATORY VACUUM: THE COMMERCIALIZATION OF GENETICS

The advent of DTC genetic testing has raised complex questions about what constitutes a medical test, what entity should regulate genetic testing services, and how consumers might interpret information about their genetic makeup.[36] Although DTC genetic testing bypasses the traditional health care

[35] Evans & Green, *supra* note 1, at 568.
[36] *Id.*

hierarchy,[37] many of the companies involved are in fact providing "medical services" and therefore should not be able to evade tort liability under informed consent, which traditionally has governed the practice of medicine.

This Part establishes that DTC genetic testing companies provide consumers with information that is clearly "medical" in nature and explains the merits of adopting tort standards of liability as a mechanism of consumer protection. Section A briefly notes the advantages of the DTC model in promoting the goals of consumerism in health care, while section B demonstrates that federal regulations—though necessary to ensure the scientific accuracy of genetic tests and to protect consumers from fraudulent advertising—ultimately are insufficient to protect consumer health or promote consumer autonomy in medical care decisions. Section C explains the merits of tort liability by discussing how a common law cause of action is more likely to be invulnerable to federal preemption than would a state law providing for minimum warnings.

A. The "Medical Services" Quandary of Direct-to-Consumer Genetic Testing

Genetic tests initially were available to patients only through their physicians.[38] Today, companies market genetic testing services directly to the consumer through the Internet, print advertisements, and retail pharmacies.[39] The term "direct-to-consumer" refers to the method of marketing and administering the genetic testing service[40]—the genetic test itself is the same whether administered at home or in the physician's office.[41] Under the DTC model, the consumer can order genetic test results directly from the testing company, without having a physician administer the test or interpret the results.[42] Some DTC services diagnose an individual's risk of developing or carrier status for particular diseases, such as Huntington's or Alzheimer's.[43] Others, like the company 23andMe, offer more general information about the consumer's genetic makeup and allow the consumer to compare her test results

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[37] Yuping Liu & Yvette E. Pearson, *Direct-to-Consumer Marketing of Predictive Medical Genetic Tests: Assessment of Current Practices and Policy Recommendations*, 27 J. PUB. POL'Y & MARKETING 131, 133 (2008).

[38] *Id.* at 131.

[39] *Id.*

[40] *See* Kristine Goodwin, *Information Overload?*, STATE LEGISLATURES, Sept. 2008, at 30.

[41] *Id.*

[42] Jennifer A. Gniady, Note, *Regulating Direct-to-Consumer Genetic Testing: Protecting the Consumer Without Quashing a Medical Revolution*, 76 FORDHAM L. REV. 2429, 2430 (2008).

[43] *Id.* at 2430–31.

on an ongoing basis with a rapidly developing body of newly discovered genetic linkages.[44]

This section introduces the principal pillar of consumer-driven health care: the goal of individual autonomy. It then describes how genetic tests are "medical" and canvasses legal definitions of the "practice of medicine" to explain why courts should hold DTC genetic testing companies to the standard of disclosure that is imposed upon medical professionals.

1. The Competing Goals of Consumerism and the Need to Protect Patients from Harm

Direct access to genetic tests offers many advantages to consumers, including lower cost, greater privacy, and an opportunity to discover adverse genetic risks before the onset of disease.[45] Learning of such risks may encourage consumers to reduce harmful behaviors, increase surveillance for early signs of the disease, or pursue preventative therapy.[46] Medical researchers believe that genetics will soon revolutionize the practice of medicine,[47] and, presumably, the availability of DTC genetic testing services will allow consumers to remain at the forefront of relevant medical breakthroughs.

By allowing consumers direct access to genetic testing and empowering them with genetic self-knowledge, the DTC model is consistent with the movement in American health care towards consumerism.[48] This trend has shifted the central role physicians have traditionally played in making medical decisions towards a balance that favors the patient's particular risk and value preferences.[49] Under the consumer-based model, the patient is empowered to

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[44] *See id.* at 2430.

[45] Liu & Pearson, *supra* note 37, at 131; *see also* Jacek Gronwald et al., *Direct-to-Patient BRCA1 Testing: The* Twoj Styl *Experience*, 100 BREAST CANCER RES. TREATMENT 239, 239 (2006) (describing how a single magazine advertisement, which offered free genetic testing to the first five thousand qualified applicants to respond, alerted 198 women to their genetic predisposition for breast cancer).

[46] Marcy et al., *supra* note 21, at 946.

[47] Evans & Green, *supra* note 1, at 568.

[48] *See* Marshall B. Kapp, *Patient Autonomy in the Age of Consumer Driven Health Care: Informed Consent and Informed Choice*, 2 J. HEALTH & BIOMEDICAL L. 1, 2–3 (2006) (observing how the advent of consumer-driven health care in the United States has engendered debate about the proper breadth of patient autonomy in the areas of bioethics, health law, and health policy); Steven H. Woolf et al., *Promoting Informed Choice: Transforming Health Care to Dispense Knowledge for Decision Making*, 143 ANNALS INTERNAL MED. 293, 294 (2005) (describing how the American "culture of consumerism" has led to greater patient autonomy).

[49] *See* Kapp, *supra* note 48, at 2; Woolf et al., *supra* note 48, at 294.

purchase a particular test regardless of the fact that her physician may regard the test as clinically futile or wasteful.[50]

Notwithstanding the significant benefits of promoting direct access to information about one's genetic makeup, consumers must be made aware of the dangers they may face when they receive genetic testing services without the guidance of a medical professional. For instance, consumers may receive inadequate or misleading information about the reliability of genetic tests.[51] Perhaps most troubling is the fact that a misinformed consumer may be injured and left without any recourse.[52] But does the fact that a consumer may face such dangers warrant heightened legal protection? After all, people are free to spend their money on frivolous recreational services, like having their fortunes told at a carnival[53]—so why should laws protect consumers who voluntarily choose to have their genomes scanned? The answer is that paying a fortune teller may be seen as a waste of money, but it can be justified as harmless entertainment.[54] Direct-to-consumer genetic testing companies, on the other hand, charge hundreds or thousands of dollars to provide genetic information that carries profound health implications[55] and that can cause anxiety, lead to unnecessary medical procedures, and deplete valuable health resources.[56]

2. Genetic Testing Services and the "Practice of Medicine"

A threshold question is whether DTC genetic testing services fall within the scope of medical practice and, if so, to what extent a health care provider must be involved.[57] Non-physician entities—such as DTC genetic testing services—may violate state laws when they engage in activities that qualify as the "practice of medicine."[58] States generally define the practice of medicine based not on the *credentials* of the entity performing a health-related service, but rather by the *nature* of the activity.[59] Thus, questions about whether

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[50] Williams-Jones & Ozdemir, *supra* note 29, at 36.

[51] *Id.* at 34–35; Gniady, *supra* note 42, at 2459–60.

[52] Gniady, *supra* note 42, at 2459–60.

[53] Williams-Jones & Ozdemir, *supra* note 29, at 36.

[54] *Id.*

[55] *Id.*

[56] Evans & Green, *supra* note 1, at 568.

[57] *See* Cynthia Marietta & Amy L. McGuire, *Direct-to-Consumer Genetic Testing: Is It the Practice of Medicine?*, 37 J.L. MED. & ETHICS 369, 369 (2009) ("[P]ersonal genome testing blurs the boundaries of when the performance of a genetic test constitutes the practice of medicine.").

[58] Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 U. KAN. L. REV. 149, 161–62 (2004).

[59] *See id.*

someone has engaged in the unauthorized practice of medicine commonly involve non-physicians whose conduct crosses the line into the practice of medicine.[60]

Although the definitions contained in state statutes vary widely, most include "diagnosis" as a component of medical practice.[61] Genetic testing companies argue that their services are not "medical" because they only inform consumers of a genetic predisposition for disease, rather than providing a diagnosis for an existing disease.[62] However, some states already have rejected this argument, equating the dissemination of genetic test results to the provision of "medical advice." For example, the California Department of Health has required DTC genetic testing companies to obtain licenses as clinical laboratories and warned them that genetic tests can only be ordered by a doctor, not by consumers.[63] Courts, too, have defined the bounds of "the practice of medicine" very broadly. For instance, one court ruled that physicians who work for health insurers must comply with professional licensing requirements even if they do not care for patients.[64] Another court held that a physician who testified as an expert witness in a medical malpractice action had engaged in the practice of medicine.[65]

In the context of DTC genetic testing, the answer is complex because of the many different types of genetic information companies may offer, including information related to susceptibility to disease, nutritional and metabolic assessments, individual traits (such as athletic performance or ear wax type), and ancestry.[66] While a genetic test analyzing ancestry or athleticism seems patently non-medical, a test for the gene that determines whether one has

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[60] *See id.* at 164 & n.62. For example, states have prosecuted non-physicians for practicing herbalism and midwifery. *See* State v. Miller, 542 N.W.2d 241, 246–47 (Iowa 1995) (rejecting arguments that the administration of vitamins and nutrients did not constitute the practice of medicine); State Bd. of Nursing v. Ruebke, 913 P.2d 142, 147, 155–62 (Kan. 1996) (considering whether the lower court properly denied an injunction sought by the State Board of Healing Arts and State Board of Nursing against a lay midwife who allegedly engaged in "the practice of medicine and nursing," but ultimately concluding that "midwifery itself is not the practice of the healing arts," and the midwife's activities were not illegal because she had worked under the supervision of a licensed physician).

[61] Noah, *supra* note 58, at 162.

[62] *See* Andrew Pollack, *Gene Testing Questioned by Regulators*, N.Y. TIMES, June 26, 2008, at C1.

[63] *Id.* New York and California have sent cease-and-desist letters to several genetic testing companies, ordering them to stop soliciting business from their residents. *Id.*

[64] Noah, *supra* note 58, at 162 & n.57 (citing Murphy v. Bd. of Med. Exam'rs, 949 P.2d 530, 536 (Ariz. Ct. App. 1997)).

[65] *Id.* at 162–63 & n.58 (citing Joseph v. D.C. Bd. of Med., 587 A.2d 1085, 1088–91 (D.C. 1991)).

[66] Marietta & McGuire, *supra* note 57, at 369.

Huntington's disease is clearly medical[67] in that it offers an individual a diagnosis for an incurable, fatal, neurological genetic disease.[68] The more difficult question is whether providing information about an individual's risks for one day developing conditions like migraine headaches or obesity constitutes "the practice of medicine." And there is another consideration: Unlike Huntington's disease, where everyone who carries the defective gene and lives long enough will develop the condition, most genes have only a *probabilistic* influence on disease.[69]

Some companies expressly disclaim that they are providing medical information. For example, 23andMe—which provides customers with information about their carrier status for such genetic disorders as Tay-Sachs and cystic fibrosis, along with information about disease risks and ability to respond to certain drugs[70]—asserts that its services are for "research and educational use only," that it does not provide medical advice, and that its services "cannot be relied upon . . . for diagnostic purposes."[71] Moreover, it warns its consumers that "[r]eliance on any information provided by 23andMe . . . is solely at your own risk."[72] Companies like 23andMe have evaded regulation[73] by touting themselves as providers of "recreational" or "informational"—not medical—services.[74] But this assertion is inconsistent with the companies' advertisements, which promise to provide medically useful information.[75] For example, the 23andMe website displays a father playing with his baby, alongside a prominent heading: "Let your DNA help you plan for the important things in life. Take charge of your health and wellness today."[76]

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67 *Id.* at 370.

68 *Learning About Huntington's Disease*, NAT'L HUMAN GENOME RESEARCH INST., http://www.genome.gov/10001215 (last visited June 18, 2010) ("A person who inherits the [Huntington's] gene, and survives long enough, will sooner or later develop the disease.").

69 Pinker, *supra* note 27.

70 *Health Reports: Complete List*, 23ANDME, https://www.23andme.com/health/all (last visited June 18, 2010).

71 *Terms of Service*, 23ANDME, https://www.23andme.com/about/tos (last visited June 18, 2010).

72 *Id.*

73 *See infra* text accompanying notes 102–13.

74 Navigenics and 23andMe, for example, argue that they are offering personal genetic information services, not medical testing. Pollack, *supra* note 62.

75 *See* Sarah E. Gollust et al., *Limitations of Direct-to-Consumer Advertising for Clinical Genetic Testing*, 288 J. AM. MED. ASS'N 1762, 1762–63 (2002) (listing examples of advertisements for genetic testing services that tout the medical benefits of the tests, but that are often confusing and hyperbolic); Kuehn, *supra* note 22, at 1504 ("The companies argue they are not offering medical care . . . though they advertise the potential health benefits of such testing.").

76 *Health*, 23ANDME, https://www.23andme.com/health/ (last visited June 18, 2010).

To say that genetic testing services are merely recreational is to trivialize the profound effects that genetic risk information can have on consumers, who often look to DTC genetic tests for medical information.[77] In fact, one study showed that aside from low cost, consumers' primary motivation for ordering a DTC genetic test was concern about developing heart disease and cancer.[78] These consumers were motivated by a family history of a genetic disease or the desire to diagnose an existing health problem.[79] Similarly, a consumer might take into account the results of her genetic test when making serious medical decisions, like whether to have children, undergo a prophylactic surgery, or continue routine surveillance for certain cancers.[80] Although individuals often rely on genetic test results in profound ways, even the most well-respected DTC companies claim that the genetic information they provide "is for information and education only and is not meant to help diagnose, cure, treat, mitigate, or prevent a disease or other impairment or condition, or to ascertain health."[81] Such a contention is clearly at odds with the fact that these companies test for the presence of genes that implicate a strong risk for disease.[82] These companies not only sell information that has medical significance, but they also advertise their services as medically useful.[83] It is therefore reasonable to expect that some consumers may rely upon this information in ways that turn out to be detrimental to their health.[84] As a result, courts should regard DTC genetic testing companies that provide information about consumers' risks for developing *medical conditions* as providers of medical services.

Since many aspects of DTC genetic testing fall within the "practice of medicine," the question follows whether the services must be regulated in the same way as traditional medical practice. Ordinarily, states control medical

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77 *See* BURRILL & CO./CHANGEWAVE RESEARCH, *supra* note 10, at 4 (noting results from a survey in which respondents were asked how willing they would be to take a genetic test to determine their risk for developing various medical conditions).

78 *Id.*

79 *Id.*

80 Williams-Jones & Ozdemir, *supra* note 29, at 36.

81 Evans & Green, *supra* note 1, at 569 (quoting a spokesperson for 23andMe) (internal quotation marks omitted).

82 *See id.* (describing the contention of a DTC company that its data was not medical as logically inconsistent based on the fact that the company tests for BRCA1/2 Ashkenazi founder mutations and provides "information that is decisive in leading individuals to seek risk-reducing surgery, enhanced surveillance, or pharmacologic intervention").

83 *See supra* notes 70–82 and accompanying text.

84 *See infra* Part III (illustrating how consumers may misunderstand the genetic information or be misled by advertisements for the testing services).

licensure, requiring physicians to hold a license in every state in which they practice.[85] However, the growing use of the Internet for medical transactions has led most states to amend their licensure statutes, with some requiring physicians who remotely prescribe medication for state residents to hold a special certificate for the practice of "telemedicine."[86] For the same reasons that "[t]elemedicine is oblivious to state boundaries,"[87] DTC genetic testing services are likely to defy traditional licensure.

But the answer is not to keep genetic testing under the auspices of the medical profession or to subject it to heavy-handed state licensure; rather, the DTC genetic testing model "pose[s] little threat to the informed consumer[,] and unwarranted intervention might slow the growth in this exciting new area of science."[88] Moreover, individuals who want to know about their genetic makeup should have the ability to freely access such information—paternalistic laws limiting that access would stifle the growth of the personal genomics industry and thwart consumers' ability to exercise autonomy in deciding whether to undergo genetic testing.[89] The next section will demonstrate that "indirect regulation" through tort liability can effect important consumer protections regardless of whether federal regulations or state licensing regimes are in place.

B. Federal Regulations Are Necessary but Insufficient to Protect Consumers

Direct-to-consumer genetic testing raises two legal issues concerning consumer safety.[90] The first is whether regulatory oversight of genetic testing

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[85] BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS 130 (6th ed. 2008).

[86] *Id.*

[87] *Id.*

[88] Alexander van Voorhees, Note, *Truth in Testing Laws: A Shot in the Arm for Designer Gene Tests*, 16 HEALTH MATRIX 797, 816 (2006).

[89] *See, e.g.*, Daniel H. Farkas & Carol A. Holland, Editorial, *Direct-to-Consumer Genetic Testing: Two Sides of the Coin*, 11 J. MOLECULAR DIAGNOSTICS 263, 264–65 (2009) ("As molecular diagnosticians and physicians, we may (or may not) agree with the dissemination of genomic information directly to consumers without physicians as middlemen, but we will betray our convictions if we hinder the consumer's right to acquire it." (footnote omitted)); Pinker, *supra* note 27 (arguing, based on the norm of free information available on the Internet, that "[f]or better or for worse, people will want to know about their genomes. The human mind is prone to essentialism—the intuition that living things house some hidden substance that gives them their form and determines their powers.").

[90] *See Comments to the Food and Drug Administration (FDA) on Direct to Consumer Marketing of Genetic Tests*, GENETIC ALLIANCE (Nov. 2, 2005), http://www.geneticalliance.org/statements.fda.tests ("[T]wo related, but distinctly different, areas of concern are: The current state of regulatory oversight of genetic tests. . . . [and] [t]he potential for irresponsible or misleading promotion of genetic tests."). In the statement letter presented to the FDA on behalf of the Genetic Alliance, President and CEO Sharon F. Terry states that

is adequate to ensure the tests' safety and scientific accuracy.[91] The second is whether consumers face real danger from misleading marketing of testing services.[92] The latter concern, in turn, raises two important questions: whether consumers can be expected to make informed decisions about undergoing testing and, once tested, whether they can be expected to accurately interpret the results.

Several commentators have urged legislators to shore up federal laws regulating DTC genetic testing services, arguing that federal agencies like the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) are in the best position to assess the accuracy[93] of genetic tests and to evaluate the marketing of DTC genetic testing services.[94] Indeed, these federal agencies have the statutory authority and expertise to determine whether genetic tests are scientifically accurate and free of product defects and to require that genetic testing services be marketed without fraud or misrepresentation.[95] Because "genetic tests can lead to profound life-altering decisions"[96] like the decision to undergo surgery or to become pregnant,[97] ensuring the accuracy and non-fraudulent marketing of the tests should indeed be a chief concern for regulators.[98] But the commentators who urge greater federal regulation are primarily concerned with assuring clinical accuracy in the companies' interpretation of test results and scientific accuracy in the processing of test results,[99] so their proposals are only sufficient in the most general sense.

"the *accessibility* of genetic tests" is "just as important to our organization and its members as safety and accuracy." *Id.*

91 *Id.*

92 *See id.*

93 Inaccurate genetic information can be caused by poor quality control of the tests themselves or inadequate scientific evidence supporting the tests, among other factors. Gabrielle Kohlmeier, *The Risky Business of Lifestyle Genetic Testing: Protecting Against Harmful Disclosure of Genetic Information*, UCLA J.L. & TECH., Fall 2007, at 1, 17.

94 *See, e.g.*, Neil A. Holtzman, *FDA and the Regulation of Genetic Tests*, 41 JURIMETRICS 53 (2000); Michael J. Malinowski, *Separating Predictive Genetic Testing from Snake Oil: Regulation, Liabilities, and Lost Opportunities*, 41 JURIMETRICS 23 (2000).

95 Kohlmeier, *supra* note 93, at 15.

96 *Id.* at 17 n.47 (quoting JAVITT & HUDSON, *infra* note 99, at 6).

97 *Id.*

98 *See* Pollack, *supra* note 62 ("Pressure is . . . mounting for the federal government to take more action. A report . . . by a federal advisory committee said there were significant gaps in the oversight of genetic tests that could lead to patient harm.").

99 *See, e.g.*, GAIL H. JAVITT & KATHY HUDSON, GENETICS & PUB. POLICY CTR., PUBLIC HEALTH AT RISK: FAILURES IN OVERSIGHT OF GENETIC TESTING LABORATORIES 19 (2006), *available at* http://www.dnapolicy.org/images/reportpdfs/PublicHealthAtRiskFinalWithCover.pdf (arguing the need to enact a regime

Regulation at the federal level is by itself insufficient to ensure adequate protections for consumers, as direct-to-consumer genetic testing services have managed to remain in a regulatory loophole—safeguarding certain important consumer protections lies outside the statutory authority and expertise of the relevant federal agencies. For example, the FDA regulates testing machinery and reagents as "medical devices" under the Federal Food, Drug, and Cosmetic Act (FDCA), while both the FDA and the Centers for Medicare and Medicaid Services (CMS) regulate commercial laboratory services under the Clinical Laboratory Improvement Act (CLIA).[100] Ordinarily, the FDA has oversight of laboratory tests to ensure scientific accuracy of the results.[101] But DTC testing companies escape FDA regulation by using their own reagents to process test results in their own laboratories, rather than sell the test kits to others.[102]

Moreover, the FDA is not authorized to regulate the *nature or quality* of a medical procedure,[103] even when it can regulate the materials used in the performance of that procedure.[104] Therefore, promulgating or enforcing regulations that require warnings about potential consumer harms such as emotional distress, negative health impacts, unnecessary financial burdens, and

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that properly certifies laboratory procedures for genetic testing); Gniady, *supra* note 42, at 2474 ("[T]he regulatory scheme should be limited to FDA and [Clinical Laboratory Improvement Act] approval requirements for test materials and laboratories carrying out the test processing . . . .").

[100] LORI B. ANDREWS ET AL., GENETICS: ETHICS, LAW AND POLICY 226–27, 230 (2002). The CMS oversees the certification of the laboratories that process the test results while the FDA regulates the scientific accuracy and clinical reliability of the genetic tests themselves. *Id.*

[101] Kohlmeier, *supra* note 93, at 33.

[102] *See* ANDREWS ET AL., *supra* note 100, at 227.

[103] The boundary between medical products and medical procedures is sometimes unclear, but the FDA can never regulate the "practice of medicine." Richard A. Merrill, *Genetic Testing: A Role for FDA?*, 41 JURIMETRICS 63, 64 (2000). Due to the increasing overlap between the use of medical technology and the diagnosis of medical conditions, the FDA's purview has been expanding over what may be considered the "practice of medicine," an area traditionally regulated by the states. Many commentators have decried this expansion. *See, e.g.*, Alexander Volokh, *Software Pirates*, REASON, Nov. 1997, at 38, 39. Volokh observes:

> Once upon a time, there were drug and device companies, which were subject to FDA regulation, and doctors, who were shielded by the FDA's inability to regulate medical practice. Back then, it was easy to tell which was which. But times change. . . . As technology brings drug and device companies into the realm of medical practice, it brings medical practice closer to the jurisdiction of the FDA. Without any changes in the law, the FDA's purview is growing.

Id. at 39.

[104] *See* Merrill, *supra* note 103, at 64–65.

changes in family dynamics[105] would lie far outside the FDA's statutory authority and expertise.[106]

The FTC is another potential channel for federal regulation of DTC genetic test marketing.[107] By requiring disclaimers for product assertions that have not been cleared by the FDA,[108] the FTC's regulatory role provides one mechanism for ensuring that consumers receive accurate information as to claims made by product manufacturers that have evaded FDA review.[109] Indeed, perhaps in response to complaints filed against DTC genetic testing companies, the FTC has issued a consumer alert, warning that "some . . . tests lack scientific validity, and others provide medical results that are meaningful only in the context of a full medical evaluation."[110] But the FTC's regulatory authority extends only to prohibiting clearly false or misleading advertising, limiting its usefulness for accomplishing meaningful protection of consumers.[111] Deceptive marketing of genetic testing services constitutes a legal ground for consumer complaint,[112] but it is difficult to establish deception in the legal sense because the ads often use "vague and ambiguous language" and contain "carefully written 'disclaimers.'"[113] Moreover, the FTC lacks the scientific expertise to decide whether claims made by DTC genetic testing companies are valid. For genetic tests that are supported by some scientific

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105 *See* Cheryl Berg & Kelly Fryer-Edwards, *The Ethical Challenges of Direct-to-Consumer Genetic Testing*, 77 J. BUS. ETHICS 17, 20–21 (2008) (discussing the potential risks and harms arising from genetic testing).

106 *See* Merrill, *supra* note 103, at 64.

107 For example, the FTC has regulated advertisements for dietary supplements. Gniady, *supra* note 42, at 2453.

108 *See* 15 U.S.C. § 45(a)(1) (2006).

109 Gniady, *supra* note 42, at 2453.

110 FED. TRADE COMM'N, AT-HOME GENETIC TESTS: A HEALTHY DOSE OF SKEPTICISM MAY BE THE BEST PRESCRIPTION 1 (2006), *available at* www.ftc.gov/bcp/edu/pubs/consumer/health/hea02.pdf.

111 *See* Gail H. Javitt et al., *Direct-to-Consumer Genetic Tests, Government Oversight, and the First Amendment: What the Government Can (and Can't) Do to Protect the Public's Health*, 57 OKLA. L. REV. 251, 282–87 (2004) (describing First Amendment commercial free speech limitations on FTC regulations of deceptive advertising and discussing the FTC's lack of authority to weigh consumer benefits from receiving certain information).

112 Ludvig Beckman, *Are Genetic Self-Tests Dangerous? Assessing the Commercialization of Genetic Testing in Terms of Personal Autonomy*, 25 THEORETICAL MED. & BIOETHICS 387, 391 (2004) (explaining that providing genetic self-tests "is a commercial activity and as such makes use of an existing legal framework that enable[s] contracts with customers" but noting that the law cannot enforce deceptive contracts).

113 *Id.*

evidence, the FTC may find it difficult to determine whether a particular company's claim is exaggerated or provides incomplete information.[114]

As this Comment will demonstrate, DTC genetic testing raises significant consumer safety issues that transcend concerns about the scientific accuracy of genetic information or the dangers of false advertising.[115] Although legislative action and administrative control by federal agencies are necessary to prevent certain types of consumer injuries,[116] Part II will demonstrate that even *accurate* information is deleterious to consumer autonomy if it leads to false expectations or misunderstanding.[117] *Indirect* regulation of the DTC genetic testing industry through tort law,[118] on the other hand, could help promote consumer autonomy by ensuring that consumers receive sufficient information from genetic testing services.[119] Thus, to protect consumers from the dangers of inadequate or misleading information, courts should hold DTC genetic companies accountable in tort, specifically through causes of action for the failure to secure informed consent.[120]

C. The Solution: "Regulation" Through Tort Liability

Tort remedies operate indirectly[121]—the threat of liability, rather than the effect of direct supervision, induces a company selling products or services to provide adequate warnings to the consumer or patient.[122] Tort liability creates

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[114] Kathy Hudson et al., *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, 81 AM. J. HUMAN GENETICS 635, 636 (2007) ("FTC regulators may be insufficiently knowledgeable to detect the misleading nature of such claims.").

[115] *See also* Merrill, *supra* note 103, at 65 ("[T]he FDCA's product-focused requirements provide an odd-fitting framework for regulating what is basically an information service."); Am. Coll. of Med. Genetics Bd. of Dirs., *ACMG Statement on Direct-to-Consumer Genetic Testing*, 6 GENETICS MED. 60, 60 (2004) (noting the "complexities of genetic testing and counseling" and stating that the "[p]otential harms [of DTC genetic testing] include inappropriate test utilization, misinterpretation of test results, lack of necessary follow-up, and other adverse consequences.").

[116] *See* Richard A. Epstein, *Legal Liability for Medical Innovation*, 8 CARDOZO L. REV. 1139, 1139 (1987).

[117] *See* Kohlmeier, *supra* note 93, at 18 ("Misinterpretation includes both misperceptions and misunderstandings of what the data means, even if the data are accurate.").

[118] Epstein, *supra* note 116, at 1139.

[119] *See infra* Parts II & IV (discussing informed consent and how the doctrine applies to DTC genetic testing companies).

[120] *Id.*

[121] Epstein, *supra* note 116, at 1139.

[122] *See id.* at 1145 (explaining that the threat of liability can incentivize manufacturers to warn of the side effects from a medical treatment or product); *see also* William W. Buzbee, *Federal Floors, Ceilings, and the Benefits of Federalism's Institutional Diversity*, *in* PREEMPTION CHOICE: THE THEORY, LAW, AND REALITY OF FEDERALISM'S CORE QUESTION 98, 106 (William W. Buzbee ed., 2009) ("Producers selling an outdated

economic incentives for both physicians and drug manufacturers to provide detailed risk information to health care consumers[123]: Strict products liability drives manufacturers to disclose potential drug risks to consumers, and the threat of liability resulting from the failure to secure informed consent encourages physicians to properly communicate safety information to their patients.[124]

State tort suits offer individualized, fact-specific adjudication, which is more appropriate than prospective rule-making when Congress is not well-suited to address particular issues either because of its lack of expertise in an area or because of the complexity of decision making that would be involved. The U.S. Supreme Court has explained that when a decision would "encompass[] a vast range of economic and social enterprises and endeavors," the matters in question "must be addressed in the usual course of law, through case-by-case resolution and adjudication."[125] It also has emphasized the importance of case-by-case adjudication where the issues at stake are likely to be highly fact-specific and technical: Although agencies make rules prospectively and are therefore less prone to making ad hoc determinations than are courts,[126] enacting rigid requirements would render administrative processes "inflexible and incapable of dealing with many of the specialized problems" that are likely to arise.[127]

DTC genetic testing services rely on a complex body of scientific information that evolves constantly as scientific journals publish newly discovered genetic linkages. Though recent years have brought substantial advances in the genomic sciences, the field is rife with scientific uncertainty as researchers seek to understand various genetic linkages and attempt to translate scientific advances into information useful for the clinical management of consumers. As one panel of scientists commented, "we are far from the end of this particular voyage, and recent discoveries are nothing more than initial forays into the *terra incognita* of our genomes. We remain unable to explain

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product and regulators who may be captured, lazy, or overworked can be jolted into action by the tort system.").

123 Richard C. Ausness, *Learned Intermediaries and Sophisticated Users: Encouraging the Use of Intermediaries to Transmit Product Safety Information*, 46 SYRACUSE L. REV. 1185, 1232 (1996).

124 *Id.* at 1232–33.

125 Babbitt v. Sweet Home Chapter of Communities for a Greater Oregon, 515 U.S. 687, 690 (1995) (considering whether an agency head could promulgate regulations penalizing an action not expressly prohibited by the Endangered Species Act of 1973).

126 SEC v. Chenery Corp., 332 U.S. 194, 202 (1947).

127 *Id.*

more than a small proportion of observed familial clustering for most multifactorial traits . . . ."[128] An agency like the FDA or FTC would lack both the expertise and rule-making speed required to stay abreast of such a rapidly developing and highly technical scientific field. Thus, the burden should be on the DTC companies, not agencies or Congress, to fashion warnings that are apace with genomic science.

But even if Congress were to pass federal laws requiring DTC genetic testing companies to provide some consumer warnings, a common law-based cause of action is more likely to withstand a challenge based on implied federal preemption than a state statute prescribing what constitutes sufficient warnings.[129] Heightened regulations are foreseeable: recent media attention, legal commentary, and lobbying by professional organizations and state health departments[130] may encourage the federal government to strengthen laws regulating DTC genetic testing companies.[131] Indeed, in May 2010, many CVS drugstores and sixty thousand Walgreens drugstores suspended their plans to sell genetic test kits after the FDA announced an investigation of DTC genetic testing companies.[132] Earlier the same month, the FDA sent a letter to the company Pathway Genomics requesting information about the testing kits.[133] Conversely, the federal government might instead choose to relax regulations, making advertising of the genetic testing services easier for companies by lifting disclosure requirements for broadcast advertisements, as the FDA did for prescription drugs.[134] In either scenario—federal regulation or deregulation—a state regulation or statute attempting to regulate DTC genetic

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[128] Mark I. McCarthy et. al, *Genome-Wide Association Studies for Complex Traits: Consensus, Uncertainty and Challenges*, 9 NATURE REVS. GENETICS 356, 367 (2008).

[129] The Supremacy Clause effectively forbids states from passing laws that conflict directly with federal laws. U.S. CONST. art. VI, cl. 2 ("This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.").

[130] *See* Kuehn, *supra* note 22, at 1505 (explaining that the American Medical Association and the American College of Medical Genetics have "weighed in" and that the American Society of Human Genetics has drafted a policy statement emphasizing the importance of verifying the accuracy of test results).

[131] For instance, former Senators Edward Kennedy and Barack Obama introduced bills mandating closer control of genetic testing. *Scientists Formulate Testing Guidelines; FDA Seeks Control*, 27 BIOTECHNOLOGY L. REP. 315, 316 (2008).

[132] Bruce Japsen, *CVS Drops Plans To Sell Genetic Testing Kits*, CHICAGOTRIBUNE.COM, May 18, 2010, *available at* http://articles.chicagotribune.com/2010-05-18/business/ct-biz-0519-cvs-genetics-kit-20100518_1_kits-cvs-fda.

[133] *Id.*

[134] *See* William E. Holtz, *Consumer-Directed Prescription Drug Advertising: Effects on Public Health*, 13 J.L. & HEALTH 199, 200–01 (1999) (explaining how draft guidance issued by the FDA made broadcast advertising of prescription drugs easier for manufacturers).

testing may be in greater danger of federal preemption than a common law-based action that seeks to guard against consumer injury.

In *Riegel v. Medtronic, Inc.*,[135] the U.S. Supreme Court ruled that state products liability suits were preempted by a 1976 federal law,[136] leaving patients injured by FDA-approved medical devices with no legal recourse.[137] The ruling turned largely on principles of statutory interpretation, which led to a finding of express preemption,[138] so until recently it remained unclear whether the Court would rule similarly where the statute in question *does not* expressly preempt state law.[139] In December 2008, in *Altria v. Good*, the Court rejected the defendants' implied preemption argument.[140] There, the issue was whether federal law regulating the labeling of cigarettes impliedly preempts state-law-based fraudulent marketing claims.[141] The Court concluded that Congress intended for the labeling statute to preempt only those state laws that were premised on the notion that federal warning requirements were inadequate.[142] In other words, Congress intended for federal warning requirements to prevent states from imposing their own rules relating to cigarette package labels, but Congress did not intend to preempt state laws that created a *general common law duty* for companies not to deceive consumers.[143] Thus, courts could continue to hold manufacturers liable in tort for deceptive statements and fraudulent marketing. Arguably, the Court's reasoning in *Altria* indicates that a tort action based on informed consent—a common law cause of action that creates a general duty to provide patients with adequate information—would not be preempted by federal laws requiring warnings about the scientific accuracy of genetic testing services.[144]

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135 552 U.S. 312 (2008).

136 *Id.* at 329–30.

137 *See id.* at 337 (Ginsburg, J., dissenting) (arguing that Congress could not have meant to remove all judicial recourse for injured plaintiffs).

138 "[A]s *Riegel* plainly shows, the Court is no longer willing to unreasonably interpret expressly pre-emptive federal laws in the name of 'congressional purpose,' . . . . The text of the statute must control." Altria Group, Inc. v. Good, 129 S. Ct. 538, 558 (2008) (Thomas, J., dissenting).

139 *See* Wyeth v. Levine, 129 S. Ct. 1187, 1193 (2009). The *Wyeth* ruling turned on "whether the FDA's drug labeling judgments 'preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use.'" *Id.* (quoting petition for cert. at 1).

140 129 S. Ct. at 551.

141 *Id.* at 552 (Thomas, J., dissenting).

142 *Id.* at 544 (majority opinion).

143 *See id.* at 547, 549.

144 *See id.*

The Court revisited the question of implied preemption in March 2009, this time in the pharmaceutical context.[145] In *Wyeth v. Levine*, it ruled that federal approval of drug warning labels regarding side effects should not bar a failure-to-warn tort action under state law.[146] State tort suits, it said, could "peacefully coexist with the FDA's labeling regime"[147] and "provide incentives for drug manufacturers to disclose safety risks promptly."[148] Because Congress had not expressly authorized a federal agency to make determinations that would preempt private lawsuits based on the failure to warn, the Court declined to defer to the FDA's position that state tort suits interfere with its statutory mandate.[149]

Wyeth and *Altria* together demonstrate that as the national mood turns strongly toward greater regulation, the Supreme Court may show a greater appreciation for plaintiffs' rights to hold companies accountable for negligence.[150] For the foregoing reasons, this Comment argues not for shoring up existing federal regulations or enacting new state laws, but for implementing a state tort regime to effect important consumer protections that would not otherwise exist.

II. INFORMED CONSENT AND AUTONOMY

Part I demonstrated that DTC genetic testing services are "medical" in the legal sense and explained why federal regulations are insufficient to ensure adequate disclosures to consumers. This Part proposes the common law doctrine of informed consent as the best way to protect consumers from the harms of inadequate disclosures. It argues that because informed consent is a *right* crucial for protecting medical consumers and a *duty* required of all medical providers, it should not be denied to consumers of DTC genetic testing companies.

Section A highlights the core legal components of informed consent and addresses how consumers can overcome the "causation hurdle." Section B explains the origins of the doctrine and shows that the "most fundamental

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145 *See* Wyeth v. Levine, 129 S. Ct. 1187 (2009).

146 *Id.* at 1204.

147 *Id.* at 1231.

148 *Id.* at 1202.

149 *Id.* at 1204.

150 *See* Editorial, *Big Loss for Tobacco*, N.Y. TIMES, Dec. 16, 2008, at A36 (discussing *Altria*'s implications for tobacco companies).

normative argument"[151] in favor of the informed consent requirement is the principle of autonomy,[152] which Part I established as the principle central to the culture of consumerism in health care. Section C considers the relationship between autonomy and disclosure requirements to assert that courts should adopt a patient-centered standard for determining adequate disclosure.

A. The Legal Doctrine of Informed Consent

Because "[i]nformed consent is a subcategory of professional negligence doctrine,"[153] a professional's failure to secure informed consent gives rise to a cause of action in tort.[154] Specifically, a patient may sue a health care professional for failing to disclose information material to obtaining consent to the medical procedure.[155] Patients view the informed consent requirement as a right, and for health care providers, informed consent imposes a corresponding duty of disclosure.[156]

Informed consent is most commonly litigated when a patient has undergone a seriously invasive procedure,[157] but courts also have applied the doctrine to situations where a patient has undergone a sensitive blood test or even a routine procedure.[158] Surgery, laparoscopy, and angioplasty are all considered seriously invasive and pose medical risks that the physician must disclose to

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151 Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 924 (1994).

152 *Id.*

153 Marjorie Maguire Shultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 YALE L.J. 219, 232 (1985).

154 *See* RUTH R. FADEN & TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT 26 (1986) ("In recent informed consent cases, negligence is the theory of liability almost always applied."). Courts have moved away from battery as the preferred theory because it is useful only in limited circumstances, such as "where the nature of the procedure has not been disclosed at all or an action intentionally exceeds the scope of the consent." *Id.* at 29. Moreover, the physical contact requirement of battery is "too literal a demarcation for what is a much broader, non-tangible interest in patient choice." Shultz, *supra* note 153, at 229. Under the negligence theory, however, the defendant can be held liable for carelessness and unintentional acts or omissions. FADEN & BEAUCHAMP, *supra* at 27.

155 BARRY R. FURROW ET AL., *supra* note 85, at 395; *see also* Shultz, *supra* note 153, at 226 ("Most litigation about patient autonomy now occurs over doctors' non-disclosure of information, analyzed as an issue of professional negligence.").

156 JESSICA W. BERG ET AL., INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE 14–15 (2d ed. 2001).

157 Wendy E. Parmet, *Informed Consent and Public Health: Are They Compatible When It Comes to Vaccines?*, 8 J. HEALTH CARE L. & POL'Y 71, 83 n.89 (2005).

158 *See, e.g.*, Doe v. Div. of Youth and Family Servs., 148 F. Supp. 2d 462, 501–02 (D.N.J. 2001) (finding that a mother had stated a claim under New Jersey law by asserting she had withdrawn her consent for HIV testing); Truman v. Thomas, 611 P.2d 902, 907 (Cal. 1980) (explaining that a physician must inform the patient about the risks of refusing to undergo a pap smear).

the patient.[159] But a simple blood test for HIV antibodies, for example, is subject to heightened disclosure requirements under the doctrine of informed consent.[160] For HIV testing, most states require extensive pre- and post-test counseling for the patient,[161] and many also require written consent[162] despite the fact that the test itself carries far fewer medical risks than most surgical procedures.[163] Similarly, the fact that the results of a genetic test can present sensitive information places consumers in need of pre- and post-test counseling even though the test is not a seriously invasive procedure and carries few medical risks. As this Comment will argue, courts should impose heightened disclosure requirements under the doctrine of informed consent.[164]

As with most negligence actions, to establish negligence based on lack of informed consent[165] the plaintiff must satisfy four elements: duty of care, breach of duty, causation, and injury.[166] Because consent to a medical test or procedure requires the patient's informed exercise of choice, the professional's standard of care is one based on *disclosure*[167]: the physician must have

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159 Elizabeth B. Cooper, *Testing for Genetic Traits: The Need for a New Legal Doctrine of Informed Consent*, 58 MD. L. REV. 346, 349 (1999).

160 *See infra* Part IV.A (discussing the emphasis on mandatory counseling for patients undergoing HIV testing); *see also infra* notes 161–62.

161 Cooper, *supra* note 159, at 349. For example, a Virginia statute requires that "[p]rior to performing any test to determine infection with [HIV], a medical care provider shall inform the patient that the test is planned, provide information about the test, and advise the patient that he has the right to decline the test." VA. CODE ANN. § 32.1-37.2(A) (2010). The statute also requires post-test counseling. *Id.* § 32.1-37.2(B) ("Every person who has a confirmed positive test result for [HIV] shall be afforded the opportunity for individual face-to-face disclosure of the test results and appropriate counseling.").

162 For example, Michigan's Public Health Code provides: "[A] physician, or an individual to whom the physician has delegated authority . . . shall not order an HIV test for the purpose of diagnosing HIV infection without first receiving the written, informed consent of the test subject . . . . [W]ritten, informed consent consists of a signed writing executed by the test subject or the legally authorized representative of the test subject . . . ." MICH. COMP. LAWS § 333.5133 (2009).

163 *See infra* Part IV.A (discussing sensitive concerns about patient well-being surrounding HIV testing and their relevance for genetic testing).

164 *See infra* Part IV.A (discussing the parallelism in the advent of HIV testing and genetic testing); *see also infra* Part IV.B (discussing the sensitive nature of genetic information, such as the potential psychological consequences of learning of one's adverse genetic risks).

165 Negligence is the theory of liability that courts almost always apply in modern informed consent actions. *See supra* discussion at note 154 (contrasting negligence and battery as theories of liability for informed consent and describing how the contemporary trend has moved away from battery theory). Even the "most obvious battery cases," like those in which a surgeon amputates the wrong leg, can be brought under a negligence theory. FURROW ET AL., *supra* note 155, at 311.

166 BERG ET AL., *supra* note 156, at 140–41. If the risk that the physician failed to disclose materializes and the patient suffers harm, the physician can be liable for resulting harm. Damages in informed consent cases can include mental suffering, added medical expenses, and other out-of-pocket expenses. BARRY R. FURROW ET AL., HEALTH LAW 335 (2d ed. 2000).

167 BERG ET AL., *supra* note 156, at 140.

provided enough information to allow the patient to assess all the treatment options and their attendant risks.[168] Thus, even if the patient cannot prove that the health care provider erred in treating or diagnosing her, the provider may be liable under negligence for any injurious consequences of risks that he failed to disclose.[169]

Some commentators have worried that consumers of genetic tests will have difficulty proving causation in a negligence action.[170] After all, genetic tests themselves are not inherently risky; rather, it is the information obtained from the tests and the decisions made in reliance upon them that might cause harm to the patient.[171] Furthermore, because harms from some genetic tests may be remote, and the tests generate only probabilistic information about *future* health outcomes,[172] there is room for superseding and intervening causes.[173] And where a physician has participated in the patient's treatment, the physician's participation may break the chain of causation.[174]

However, the fact that genetic tests are marketed directly to consumers likely will lead courts to relax traditional causation requirements. For example, in suits against prescription drug manufacturers, courts have "effectively reliev[ed] plaintiffs of their duty to prove cause-in-fact"[175] by applying the substantial factor test and market share liability theory.[176] In addition, a recent development in tort litigation—the adoption of negligent

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168 FADEN & BEAUCHAMP, *supra* note 154, at 133.

169 FURROW ET AL., *supra* note 166, at 342–43.

170 *See, e.g.*, Pilar N. Ossorio, *Product Liability for Predictive Genetic Tests*, 41 JURIMETRICS 239, 243 (2001). *See generally* Thomas O. McGarity, *The Regulation–Common Law Feedback Loop in Nonpreemptive Regimes*, *in* PREEMPTION CHOICE, *supra* note 122, at 235, 236 ("The plaintiff in common law litigation . . . has the burden of proving that the defendant's product or activity violated the relevant legal standard, and that it was both a cause-in-fact and a proximate cause of a legally cognizable harm.").

171 Ossorio, *supra* note 170, at 243.

172 *Id.*

173 *Id.*

174 *See, e.g.*, Perez v. Wyeth Labs., Inc., 734 A.2d 1245, 1260 (N.J. 1999) (stating that "[t]he more difficult question is whether the role of the physician breaks the chain of causation" when the physician writes a prescription for a patient who has learned about the prescribed drug through the manufacturer's DTC advertising efforts).

175 Richard C. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?*, 37 WAKE FOREST L. REV. 97, 138 (2002). Some jurisdictions have also recognized a related cause of action, the tort of negligent misrepresentation. *See, e.g.*, Bloskas v. Murray, 646 P.2d 907, 909, 915 (Colo. 1982) (recognizing the tort of negligent misrepresentation in a suit for malpractice and failure to secure informed consent where the physician failed to disclose that amputation might be a possibility following an ankle replacement, and the patient reasonably relied on that misrepresentation).

176 Ausness, *supra* note 175, at 138.

marketing as a new theory of liability—indicates courts' preference for ensuring patient protections in the face of DTC marketing.[177]

In *Perez v. Wyeth Laboratories, Inc.*, the plaintiffs sued a drug manufacturer for failing to warn women of side effects associated with the contraceptive Norplant.[178] The New Jersey Supreme Court applied the substantial factor test to establish causation.[179] After explaining that finding proximate cause is as much a policy determination as it is a factual one,[180] the court stated: "On balance, we believe that *the patient's interest in reliable information* predominates over a policy interest that would insulate manufacturers [from liability]."[181]

Consider, for example, the hypothetical discussed in the Introduction, where Sarah learns of her genetic predisposition for breast cancer. Her reaction was a reasonably foreseeable risk of the company's failure to disclose adequate information because:

> [i]t has been widely recognized that individuals who are at high risk for hereditary breast . . . cancer need counseling to prepare them to make well-informed decisions about genetic testing and its potential consequences and to provide support for the complex emotional reactions that may be triggered in this uncertain and potentially anxiety-provoking context.[182]

Thus, she may be able to recover damages for emotional suffering (like the debilitating anxiety affecting her daily life) that resulted from learning of her 60%–90% chance of developing breast cancer.[183]

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[177] *Id.* Negligent marketing is a relatively new theory of tort recovery based on the principle that manufacturers should be required to market their products in a way that minimizes risks of harm to the consumer. *Id.* As of 2002, almost all cases involved handguns, but plaintiffs have also used this theory in a few prominent prescription drug cases. *Id.* at 123, 138. Ausness predicts that negligent marketing claims therefore could give rise to additional tort liability for manufacturers of prescription drugs. *Id.* at 136.

[178] *Perez*, 734 A.2d at 1247.

[179] *Id.* at 1261 ("A proximate cause need not be the sole cause of harm. It suffices if it is a substantial contributing factor to the harm suffered.").

[180] *Id.* ("We have described proximate cause as an expression as much of policy as it is an expression of the effect of sequential events.").

[181] *Id.* at 1262 (emphasis added).

[182] Shoda et al., *supra* note 19, at 13.

[183] Ossorio, *supra* note 170, at 244 (explaining how causation might be established in the case of Nancy Seeger, a woman who chose to have her ovaries removed after receiving inaccurate, misreported genetic test results).

Now imagine that Sarah is successful in finding a surgeon to perform a prophylactic double mastectomy.[184] After discovering from the surgeon that Christina Applegate's assurance was not exactly correct—the mastectomy would reduce, but not completely eliminate, her chances of getting breast cancer—Sarah realizes that, had she never been tested, she could have avoided significant anxiety and fear. Assume further that the surgeon neglected to inform her that the mastectomy was not guaranteed to eliminate her risk of breast cancer and she went through with the procedure as a result; she might still have a cause of action against the DTC genetic testing company. Even though the surgeon might be considered an intervening cause of Sarah's mastectomy, a court could nevertheless find that the genetic testing service was a *substantial factor*, and therefore a cause in fact, of Sarah's plight.[185] Arguably, the information from the DTC genetic test proximately caused her emotional suffering and consequent double mastectomy (notwithstanding the surgeon's failure to inform), because it was reasonably foreseeable that a woman would choose prophylactic surgery based on her genetic test results.[186]

B. Autonomy as the Foundation of Informed Consent

One way to define "informed consent" is to conceptualize it as the autonomous action taken by a patient to authorize her medical professional to initiate health care actions.[187] The doctrine owes its origin to strong judicial deference to individual autonomy.[188] Informed consent encourages collaboration between the patient and the physician, reallocating decisional power between the two by "reducing the [physician]'s paternalistic grip on treatment decisions."[189] If patients are to make informed, autonomous choices, they must know of the risks—the "side effects, collateral hazards, dangers, and perils"[190]—of the suggested treatment.[191] Thus, the doctrine of informed

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184 *See supra* note 9; *see also* Introduction (discussing Applegate's statements made on national television).

185 *See supra* text accompanying notes 175–81 (discussing how courts have applied the substantial factor test to relax traditional causation requirements, with public policy driving their decisions); *see also* Ossorio, *supra* note 170, at 244.

186 *See* Ossorio, *supra* note 170, at 244; *see also infra* note 252 (citing a study showing that anxiety about cancer is a major factor leading women to undergo prophylactic mastectomies).

187 BERG ET AL., *supra* note 156, at 116.

188 FURROW ET AL., *supra* note 166, at 310.

189 *Id.* at 343.

190 BERG ET AL., *supra* note 156, at 46.

191 Beckman, *supra* note 112, at 395. Beckman argues that DTC genetic testing does not undermine personal autonomy so long as the information about the genetic tests is accurate and the genetic information "is not misunderstood." *Id.*

consent has helped bolster patients' abilities to make decisions about their own health, recalibrating the power held by physicians in medical relationships.[192]

Justice Cardozo famously articulated the patient's right to autonomous decision making in the oft-cited case of *Schloendorff v. Society of New York Hospital*[193]: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body."[194] This stands as a classic and influential statement of the patient's right of autonomy.[195] His opinion is particularly noteworthy because it incorporated and advanced the meaning of "autonomy" from earlier decisions. As subsequent cases adopted the principles set forth in *Schloendorff*,[196] autonomy became the most cited rationale for the legal doctrine of informed consent.[197] Thus, the requirement to secure informed consent has become essential for upholding respect for patient autonomy—a norm valuable in its own right[198]—by promoting individual choice in the "widest possible range of situations."[199] In fact, the practical consequences of applying the doctrine of informed consent, such as the potential for increasing costs of litigation, seem less important to courts than the value of promoting patient autonomy.[200]

C. "Adequate Disclosure" and Informed Consent Are "Two Sides of the Same Coin"

"Informed consent" does not merely refer to the patient's agreement to undergo treatment.[201] The requirement is two-pronged: The patient's consent must have been truly voluntary (not given under duress, for example),[202] and

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192 FURROW ET AL., *supra* note 166, at 343.

193 105 N.E. 92 (N.Y. 1914).

194 *Id.* at 93.

195 FADEN & BEAUCHAMP, *supra* note 154, at 123–24.

196 "In these early cases, physician behavior was often egregious . . . . As the informed consent doctrine developed and the problems grew more subtle, the law could have turned away from the language of self-determination, but instead came increasingly to rely on this rationale as its fundamental premise." *Id.*

197 *Id.* at 124.

198 FURROW ET AL., *supra* note 166, at 343. "Respect for autonomy is the most frequently mentioned moral principle in the literature on informed consent, where it is conceived as a principle rooted in the liberal Western tradition of the importance of individual freedom and choice . . . ." FADEN & BEAUCHAMP, *supra* note 154, at 7.

199 FURROW ET AL., *supra* note 166, at 343.

200 Courts rarely speak of the practical consequences of enforcing the doctrine, such as the costs of litigation, but instead emphasize the value of autonomy and of the patient's improved decision-making ability. Schuck, *supra* note 151, at 939.

201 BERG ET AL., *supra* note 156, at 65.

202 *Id.* at 67.

the patient must have been fully informed about the risks, benefits, and other aspects of treatment.[203] The amount of material information the patient receives directly affects to the patient's ability to act autonomously.[204]

A patient's decisions need not be rational to be autonomous; a patient exercises autonomy as long as she is adequately informed when she makes the decision.[205] A medical professional satisfies his full legal duty under informed consent once he makes all relevant disclosures, even if the outcome is adverse for the patient.[206] Thus, a patient assumes the risks of her decision once she has received all the relevant information.[207] Whether the provider is a physician or a genetic testing company, this rule reflects the policy that the "inevitable errors of calculation made by individual patients should not be the source of extensive liabilities for either physicians or manufacturers who have properly supplied the relevant information."[208]

In the landmark case *Canterbury v. Spence*,[209] the court observed that the emphasis in informed consent jurisprudence is on the duty to make adequate disclosures rather than on actually ensuring a patient's understanding of the risks:

> In duty-to-disclose cases, the focus of attention is more properly upon the nature and content of the physician's divulgence than the patient's understanding or consent. Adequate disclosure and informed consent are . . . two sides of the same coin—the former a *sine qua non* of the latter.[210]

The duty imposed on the physician to make adequate disclosures to the patient is the "truly distinguishing and innovative aspect of contemporary informed consent doctrine."[211] By requiring physicians to disclose all material risks of a

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[203] *Id.* at 46. "True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each." Canterbury v. Spence, 464 F.2d 772, 780 (D.C. Cir. 1972).

[204] FADEN & BEAUCHAMP, *supra* note 154, at 239.

[205] BERG ET AL., *supra* note 156, at 24.

[206] Epstein, *supra* note 116, at 1149.

[207] *Id.* at 1146.

[208] *Id.*

[209] 464 F.2d at 772.

[210] *Id.* at 780.

[211] BERG ET AL., *supra* note 156, at 65.

procedure, it emphasizes the importance of informing the patient fully and thereby promotes patient autonomy.[212]

D. The Patient-Based Standard as a Consumer-Based Standard

Courts have applied two standards in determining what constitutes adequate disclosure in informed consent cases: the physician-based standard and the reasonable patient standard.[213] Under the physician-based standard, the chief interest is protecting the patient's physical well-being,[214] but the physician is presumed to know what is best for the patient.[215] Therefore, the physician need only disclose risks that would be explained by a reasonable physician in the same or similar community.[216] Under this rationale, a physician may even invoke the "therapeutic privilege," which gives her the right to withhold material information when, in the opinion of the physician, the disclosure might harm the patient.[217] Commentators have argued that the therapeutic privilege exception to the physician's duty of disclosure is a "recipe for paternalism" because it undercuts the patient's right to decide.[218]

On the other hand, the reasonable patient standard, adopted in a substantial minority of jurisdictions,[219] aspires to protect patient *choice* over patient physical well-being.[220] By requiring DTC genetic testing companies to disclose risks that a reasonable person would find material,[221] the patient-centered standard would entitle a customer to receive sufficient information to make informed health care decisions.[222] As the South Dakota Supreme Court

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[212] *Id.* at 46 ("It is self-evident that if persons are to make informed, autonomous choices, they must be told not only that the procedures are intended to diagnose or treat the condition from which they suffer but also that the procedures may fail to do so, or that patients may be worse off after the procedures. . . . [W]ithout this information, most patients are unable to make the kind of informed decisions that are central to the ethical notion of informed choice.").

[213] FURROW ET AL., *supra* note 166, at 313. Furrow lists a third possibility, the subjective patient standard, but notes that no court has yet adopted it. *Id.* at 315.

[214] *See* Shultz, *supra* note 153, at 249 ("[M]ost states, responding to physical well-being as the protected interest, have chosen professionalized standards of care . . . .").

[215] BERG ET AL., *supra* note 156, at 46.

[216] FURROW ET AL., *supra* note 166, at 314.

[217] FADEN & BEAUCHAMP, *supra* note 154, at 36–37.

[218] *Id.*

[219] FURROW ET AL., *supra* note 85, at 240 (citing a recent study that found that twenty-five states have adopted a physician-based standard, two have adopted a hybrid standard, and the rest have adopted a patient-based standard); Shultz, *supra* note 153, at 249.

[220] Shultz, *supra* note 153, at 249.

[221] *See* FURROW ET AL., *supra* note 166, at 314 (explaining physicians' disclosure requirements under the reasonable patient standard).

[222] *Id.*

has observed, the patient's "right to know—to be informed—is a fundamental right personal to the patient and should not be subject to restriction by medical practices that may be at odds with the patient's informational needs."[223]

This Comment endorses the reasonable patient standard because a standard that protects patient choice is consistent with the consumer movement in health care, recognizes the role of the informed patient in health care decisions, and makes more sense in light of the potential financial conflict of interest between a genetic testing company and its customers.[224] The physician-based standard is inconsistent with consumer-driven health care and is unworkable in the context of DTC genetic testing because it not only deemphasizes the right of the consumer to receive adequate disclosures, but it also presumes the existence of a factor obviously absent in DTC genetic testing—physician involvement.

As a for-profit entity with no personal connection to the consumer beyond a commercial transaction,[225] a DTC genetic testing company should not be permitted to assert the therapeutic privilege. Such a privilege, which would shield a company from liability for failing to disclose particular risks, is inapplicable to a testing company that, unlike a physician, has no fiduciary relationship with the consumer.[226] Moreover, the obvious conflict of interest between the company—which stands to profit from selling its testing services—and the consumer—whose autonomy should be of paramount importance, particularly where sensitive medical information is concerned—counsels against allowing DTC genetic testing companies to benefit from the lower, physician-centered standard. Indeed, courts have recognized that because physicians enjoy a position of dominance over their patients, "[p]atients are thus vulnerable, and this vulnerability imposes on physicians

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223 Wheeldon v. Madison, 374 N.W.2d 367, 374 (S.D. 1985).

224 *See* Perez v. Wyeth Labs., Inc., 734 A.2d 1245, 1257 (N.J. 1999) (finding that where the contraceptive Norplant was marketed directly to consumers, disclosure of risks was required under the "objectively-prudent-patient rule" long recognized in New Jersey as advancing the "informed role of the patient in health-care decisions").

225 *But see* Evans & Green, *supra* note 1, at 568 (arguing that DTC companies that use high-quality testing methods based on peer-reviewed scientific evidence have goals that are closely aligned with consumers' interests in acquiring self-knowledge about health, and therefore "we should resist the urge to impugn [DTC company executives'] motives[] simply because they lead for-profit companies").

226 The corporation–consumer relationship is unlike the physician–patient relationship because a physician has special fiduciary obligations to her patient that have been compared to friendship and described as a "sacred trust." FURROW ET AL., *supra* note 85, at 199–200 (quoting HANS JONAS, *Philosophical Reflections on Experimenting with Human Subjects*, *in* PHILOSOPHICAL ESSAYS: FROM CURRENT CREED TO TECHNOLOGICAL MAN (1980)).

a[n] . . . obligation" to disclose conflicts of interests.[227] Similarly, a DTC genetic testing company enjoys a position of superiority over its consumers: It has easy access to the latest research on genetic linkages; it is less concerned about the consumer's health than is the consumer; and the likelihood that the consumer is ill-equipped to process complex genetic information is great. This unequal relationship weighs in favor of requiring the company to bear the burden of disclosing relevant risks.[228]

However, endorsing one standard over the other may overstate the practical value of drawing such a distinction—although courts and commentators debate which disclosure standard should govern, "all agree that informed consent requires the health care provider, or the manufacturer of a health care product, to convey information to a patient that a layperson might not otherwise be expected to know."[229] Direct-to-consumer genetic testing companies should provide warnings that are sufficient to help consumers develop realistic expectations for the tests, understand the uncertain nature of genetic risks, and make educated decisions based upon the test results. As explained in Part I,[230] a total ban or heavy regulation of direct-to-consumer genetic testing would thwart patient autonomy and interfere with the market-based culture of consumerism, both of which are integral to our system of health care.[231] In contrast, the tort doctrine of informed consent can promote consumer autonomy by allowing consumers direct access to genetic tests, while at the same time inducing companies to provide adequate disclosures to the consumer.[232] Thus, the ultimate goal of the duty of disclosure proposed by this Comment is to protect and promote the autonomy of the consumer-patient.

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[227] FURROW ET AL., *supra* note 85, at 268.

[228] *Id.* at 241 n.4 ("The effect of a patient-oriented disclosure standard is to ease the plaintiff's burden of proof . . . .").

[229] Parmet, *supra* note 157, at 83–84.

[230] *Supra* notes 45–56 & 88–90 and accompanying text.

[231] *See* GENETIC ALLIANCE, *supra* note 90 ("We must find a balance between regulation that accomplishes the desired goals—quality genetic tests that improve public health—and excessive regulation that places too onerous a burden on laboratories and limits the availability of tests."); *see also* Beckman, *supra* note 112, at 395 (explaining that the availability of genetic self-testing increases individual autonomy and allows people to enhance their own understanding about their future health and concluding that information from genetic testing does not pose a threat to autonomy as long as the information about the services is correct and consumers understand the genetic test results). Moreover, a complete ban would likely drive the genetic testing companies to countries or states that have not enacted prohibitions, from which they might continue selling their testing services over the Internet. Gniady, *supra* note 42, at 2470.

[232] *See* van Voorhees, *supra* note 88, at 827 (explaining that implementing a disclosure requirement instead of heightening federal regulatory penalties appeals to advocates of consumer protection because it empowers the consumer).

The next Part will explain the specific problems to be addressed by the doctrine of informed consent.

III. WHEN THE CONSUMER'S AUTONOMY IS DIMINISHED

Genetic testing services offer predictive health information that can significantly impact both individual consumers and their families. As with other medical test results, such information can be confusing and intimidating when it is not appropriately conveyed.[233] Indeed, critics of DTC genetic testing have expressed concern that consumers are vulnerable to being misled by advertisements and that they lack the knowledge needed both to make informed decisions about whether to undergo a genetic test and to properly interpret the results.[234] This Comment does not espouse the view that the DTC model of selling genetic testing services is categorically dangerous or inadvisable. Rather, it argues that adequate disclosures are necessary to prevent consumers from developing misguided expectations about the tests, being misled by aggressive marketing, and making uninformed decisions based upon test results.

At first blush, the DTC model might seem to promote autonomy without endangering it—after all, it offers the individual a convenient opportunity to decide privately whether to order a genetic test.[235] However, in practice, purchasing a genetic test will enhance a consumer's autonomy only to the extent that the information offered about the test is accurate[236] and the test is honestly labeled.[237] To promote autonomy, DTC genetic testing companies must convey detailed information to consumers about the risks of the tests and communicate that information in ways that do not overstate the usefulness of the results.[238] This Part illustrates how inadequate disclosures diminish

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233 GENETIC ALLIANCE, *supra* note 90.

234 *Direct-to-Consumer Genetic Testing: Empowering or Endangering the Public?*, GENETICS & PUB. POL'Y CTR. (May 30, 2008), http://www.dnapolicy.org/policy.issue.php?action=detail&issuebrief_id=32.

235 Beckman, *supra* note 112, at 388; *see also* Modra, *supra* note 24, at 260 (observing that permitting DTC prenatal genetic testing could promote consumer autonomy by "allowing women to test purely for the sake of knowing").

236 Beckman, *supra* note 112, at 392.

237 *See* Evans & Green, *supra* note 1, at 569 ("Transparent labeling leaves the door open for those who wish to pursue [personal genetic] information for personal reasons, but makes it clear that [the medical] utility [of certain tests] is not endorsed by current medical thinking.").

238 Schuck, *supra* note 151, at 948; *see also* GENETIC ALLIANCE, *supra* note 90 (stating that the DTC marketing of genetic tests "presents two discrete areas of concern: the claims made in an advertisement, and the validity and utility of the test itself").

consumer autonomy and explains how the doctrine of informed consent can resolve this issue.

A. Diminished Autonomy Through Misunderstanding

Consumer autonomy is undermined when the consumer does not understand what to expect from a genetic test.[239] Many consumers have significant misconceptions about the functions genetic tests can actually serve.[240] For example, consumers may confuse genetic tests for cancer risk with cancer screening tests, like colonoscopies and mammograms;[241] or they might believe that genetic testing is a diagnostic tool to discover pre-existing cancer.[242] As a result, DTC genetic testing companies should provide information to help consumers understand that the information they receive is *probabilistic*, rather than diagnostic.

In addition, genetic testing companies should inform customers that the results may show a high genetic risk for developing a disease for which there is no preventative option or clinical recourse.[243] The psychological burden of learning that one is at high risk for developing such a disease may outweigh any possible benefit of the test.[244] When a consumer is not fully cognizant of the type of information a genetic test might reveal, the consumer risks "self-overdisclosure"—the receipt of unwanted or potentially harmful excess information.[245]

Moreover, a consumer should understand that "[t]esting positive for a predisposition to a hereditary disease can potentially lead to depression, grief, suicidal thoughts, guilt, and concern for children."[246] The psychological consequences of knowing that premature death is likely may deprive a person

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239 *See* Beckman, *supra* note 112, at 394 (conceding that "people sometimes misinterpret test results in ways that distort their beliefs about what alternatives of action are feasible" and that "the argument could be made that personal autonomy is abated when the implications of the genetic information provided are not properly understood").

240 Rose et al., *supra* note 16, at 148.

241 *Id.*

242 *Id.*

243 Kuehn, *supra* note 22, at 1504.

244 Wong et al., *supra* note 14, at 276. However, when coupled with genetic counseling, genetic testing "will aid in the management of patients who are susceptible to colorectal cancer." *Id.* at 271.

245 Kohlmeier, *supra* note 93, at 19.

246 Berg & Fryer-Edwards, *supra* note 105, at 20; *see also* Gina Kolata, *Advent of Testing for Breast Cancer Genes Leads to Fears of Disclosure and Discrimination*, N.Y. TIMES, Feb. 4, 1997, at C1 (detailing how women with a predisposition to breast cancer are reluctant to inform employers and insurance companies fearing potential discrimination).

of "life-hopes," and learning about future incurable conditions can have devastating psychological effects.[247] Even negative test results can create emotional burdens such as "survivor's guilt," which some patients experience after testing negative for a particular gene mutation that has caused debilitating disease in other family members.[248]

Medical treatment plans are often complex and present the opportunity for the patient to exercise autonomy by choosing those treatment options that best match a patient's value preferences.[249] However, consumers may misunderstand the scientific meaning of positive or negative test results[250] and make ill-informed decisions as a result. For example, consumers who test positive for breast cancer gene mutations might inaccurately perceive their risk as very high, become severely anxious,[251] and desire to undergo severe prophylactic treatment, such as a double mastectomy, even when such drastic action may not be medically advisable.[252] Although some studies have found that worry about cancer enhances adherence to preventative screening protocols, other studies have shown that anxiety about the possibility of discovering breast cancer actually prevents women with less formal education from getting routine mammograms.[253]

Similarly, consumers should be informed that a negative test result does not promise immunity from the disease.[254] Patients who test negative for a breast cancer gene mutation might become complacent and fail to undergo regular monitoring, believing they will never develop breast cancer.[255] However, their risk is still as great as the risk faced by the average individual.[256] "Of all breast cancer cases, 5%–10% are known to be associated with dominantly inherited

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247 Beckman, *supra* note 231, at 393.

248 Berg & Fryer-Edwards, *supra* note 105, at 20.

249 *See* Shultz, *supra* note 153, at 222.

250 *See* Goodwin, *supra* note 40, at 30. "[The absence] of adequate counseling by a licensed health professional further heightens the danger of individuals being misled, or misinterpreting what test results mean." Kohlmeier, *supra* note 93, at 19.

251 *See supra* Introduction (describing the emotional plight of Christina Applegate and the hypothetical character Sarah).

252 Berg & Fryer-Edwards, *supra* note 105, at 20. "Cancer worry or anxiety was also found to influence the choice for prophylactic surgery . . . ." J.R.J. De Leeuw et al., *Predictors of Choosing Life-Long Screening or Prophylactic Surgery in Women at High and Moderate Risk for Breast and Ovarian Cancer*, 7 FAMILIAL CANCER 347, 357 (2008).

253 De Leeuw et al., *supra* note 252, at 353.

254 Goodwin, *supra* note 40, at 30.

255 Berg & Fryer-Edwards, *supra* note 105, at 20.

256 *Id.*

genetic mutations,"[257] meaning that many women who are told they lack the mutation will eventually develop breast cancer. Assessing one's risk for diabetes may present a similarly confusing scenario. For example, a genetic test might reveal that a certain individual has a 25% chance of developing Type 2 diabetes, which is only slightly higher than the average person's 21.9% chance of developing the same condition.[258] But would that test result mean that the individual must manage his weight and other risk factors much more vigilantly than should an average-risk person? Probably not. Conversely, it is possible that test results indicating a slightly lower-than-average risk would cause someone to be far less careful about his weight or to forego other healthful behaviors.

Direct-to-consumer genetic testing companies also must alert the consumer to the fact that she may receive *ambiguous* test results, and that receiving ambiguous test results may be as distressing—or more distressing—than receiving positive test results.[259]

B. Diminished Consumer Autonomy Through Aggressive Advertising

Advertisements for DTC genetic testing services have appeared in local newspapers, on the Internet, and in national magazines.[260] Advertisements that downplay the risks and exaggerate the benefits of genetic testing could unfairly induce vulnerable consumers to purchase the tests, thereby diminishing their autonomy.[261] In addition, the confusingly complex and probabilistic nature of the test results provides a way for advertisers to manipulate consumers' lack of understanding.[262]

Take, for example, the issue of prenatal genetic testing. Consumers in many states can order such services without a physician's authorization and at an affordable price.[263] Such tests are of particular concern because consumers are especially vulnerable when it comes to learning about their newborns, and they might use the genetic information to decide whether to terminate a

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[257] Christine Maheu & Sally Thorne, *Receiving Inconclusive Genetic Test Results: An Interpretive Description of the BRCA1/2 Experience*, 31 RES. NURSING & HEALTH 553, 553 (2008).

[258] *See* Pinker, *supra* note 27 ("For a blessedly average person like me, it is completely unclear what to do with [odds that are slight departures from the norm]. A one-in-four chance of developing diabetes should make any prudent person watch his weight and other risk factors. But then so should a one-in-five chance.").

[259] Wong et al., *supra* note 14, at 276.

[260] Gollust et al., *supra* note 75, at 1762.

[261] van Voorhees, *supra* note 88, at 827.

[262] Gollust et al., *supra* note 75, at 1763.

[263] *See supra* note 25 and accompanying text.

pregnancy.[264] The widely accepted view is that prenatal genetic testing is ethically advisable only where the consumer makes fully autonomous choices at two junctures[265]: First, when deciding whether to undergo the test, and second, when deciding, based on the test results, whether to carry the pregnancy to term.[266] Aggressive advertising can diminish a consumer's autonomy at the first juncture by unduly influencing her to undergo prenatal genetic testing in the first place.[267] For example, the website for a prenatal genetic testing service might suggest conclusive results[268] and thereby promise psychological and emotional reassurance. In one full-page advertisement in a popular pregnancy magazine, a newborn baby gazes at the reader with innocent, blue eyes.[269] The banner reads: "A simple new test could save your baby's life."[270] The text of the advertisement describes a test that can detect more disorders than state-sponsored screening programs, thereby implicitly promising maternal peace of mind.[271]

A prenatal genetic test may indeed alert an expectant mother to a baby's genetic abnormalities; but advertisements for such tests fail to include risk information in fair balance with the claims of conclusiveness.[272] Here, the advertisement fails to mention that most infants will not have the extremely rare conditions for which the consumer is being urged to pursue screening.[273] Moreover, it does not alert the consumer to the psychosocial consequences that can result from knowing the genetic information revealed by the prenatal

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264 Modra, *supra* note 24, at 256 (describing prenatal genetic testing as especially "controversial, partly because it facilitates selective abortion-termination of pregnancy on the grounds that the foetus has unfavourable genetic characteristics").

265 *Id.* at 257.

266 *Id.*

267 *See id.* (referring to the view of opponents of DTC genetic testing, who worry that potentially deceptive marketing campaigns can preclude truly voluntary choice).

268 *See, e.g.*, *Ultra-Screen*™, CTR. FOR MED. GENETICS, http://www.geneticstesting.com/ultrascreen/ultrascreen.htm (last visited June 19, 2010) (stating that the company's Ultra-Screen™ genetic test "is a revolutionary new service that provides conclusive results and reassurance earlier in pregnancy than any other test available").

269 Gollust et al., *supra* note 75, at 1762 (citing Advertisement, FIT PREGNANCY, Aug.–Sept. 2002, at 39).

270 *Id.*

271 *Id.*

272 By way of analogy, consider prescription drugs: FDA regulations for drug advertising require a "brief summary" that alerts consumers about side effects and drug effectiveness. *See* 21 C.F.R. § 202.1(e)(1) (1999) (stating that all relevant advertisements shall require "a true statement of information in brief summary relating to side effects, contraindications . . . and effectiveness"). The FDA regulations also require that an advertisement present a fair balance between adverse reactions and information relating to effectiveness, which often leads to questions as to which side effects are serious enough to be included in the brief summary. *See id.* § 202.1(e)(5)(ii).

273 Gollust et al., *supra* note 75, at 1765.

test.[274] Because the advertisement arguably does not balance risk information fairly with its claims of conclusiveness,[275] it has failed to disclose risks material to the consumer's decision to pursue testing. The problem is further aggravated by the fact that the advertisement encourages the consumer to contact the testing service directly, without first obtaining the advice or counsel of a physician.[276]

Similarly, prenatal genetic testing companies like Counsyl may overstate the usefulness of their services on their websites.[277] Despite the fact that there are thousands of genetic diseases, not just the one hundred or so that Counsyl screens for, the company markets its service as a "Universal Genetic Test."[278] As one geneticist observed, "Everyone hopes there is a test that will provide a perfect baby, but the reality is that [a] single magic bullet doesn't exist."[279] Before undergoing genetic testing, consumers should be made aware that favorable genetic test results do not guarantee the perfect health of a newborn. Consumers also should be told—both before purchasing a genetic test and when they receive the test results—that many of the mutations detectable in parents will not manifest as serious illness in the child. Companies like Counsyl should take steps to ensure that consumers are not needlessly alarmed by such test results.[280]

Moreover, because many diseases have unknown causes, advertising may mislead consumers into thinking that genetic traits alone can determine their

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274 *Id.*

275 *See id.* Problematically, the FDA regulations for prescription drug advertising, *see supra* note 272, fail to take into account the graphics of an advertisement, which can unfairly tip the balance toward misleading consumers. Holtz, *supra* note 134, at 208. Misleading advertisements not only diminish the physician's role as a gatekeeper to dangerous medications that certain patients should not use, but also thwart the ability of consumers to understand information about risks. *Id.* As this section demonstrates, advertisements for DTC genetic tests can raise similar problems.

276 Gollust et al., *supra* note 75, at 1765 (noting that these advertisements "encourage consumers to contact testing services directly, depreciating the role of the health care practitioner or genetic counselor to share in counseling and decision making regarding genetic testing").

277 In May 2010, Counsyl began requiring customers to obtain a physician's order for prenatal genetic testing. Kirell Lakhman, *Counsyl Hangs Up Its DTC Hat*, GENOME WEB (May 25, 2010), http://www.genomeweb.com/blog/counsyl-hangs-its-dtc-hat. Though Counsyl no longer qualifies as a DTC genetic testing service in the strictest sense, if it were to continue marketing its services and reporting results directly to consumers, it still would be subject to liability under the proposal of this Comment.

278 *See* COUNSYL, https://www.counsyl.com/learn/universal-genetic-test (last visited June 13, 2010).

279 Pollack, *supra* note 26.

280 *But see id.* ("Once informed [of their own genetic traits], Counsyl says, couples can take steps like using in vitro fertilization with genetic testing of the embryos, to avoid bearing children who would have the diseases, many of which are incurable and fatal in childhood.").

risk of developing a disease.[281] In truth, factors like family history, lifestyle, and environment often play a significant role in assessing risk.[282] One study showed that 95% of websites for DTC genetic testing services lacked information about the significance of lifestyle, family history, or routine screening.[283] By failing to provide consumers with such information, or by providing inadequate or misleading information, these services exaggerate the benefits of genetic testing and induce consumers to pay for services that may be unnecessary or undesirable,[284] thereby diminishing their autonomy.[285]

Despite its dangers, the advertising associated with DTC genetic testing offers significant benefits. For example, it can reach high-risk audiences that might otherwise fail to be screened for the breast cancer gene. Placing a single announcement in a popular women's magazine helped researchers in one study identify many carriers of breast cancer gene mutations who might not have been identified through conventional health screening.[286] But "[o]nly by measures that reduce false expectations of genetic services and increase correct understandings of genetic information will personal autonomy be secured in the age of geneticization. . . . [Thus, a] concern with the ideal of personal autonomy does not justify prohibiting commercial genetic self-testing . . . ."[287] Although the full effects of DTC marketing of genetic testing remain to be seen, this section has shown that the potential for misleading consumers is great and thus necessitates imposing a heightened duty on DTC genetic testing companies to ensure they provide adequate disclosures about the risks of genetic testing.

C. The Solution: The Doctrine of Informed Consent

The advances of the past few decades have brought a degree of medical uncertainty that has at once underscored the need for professional advice and strengthened the argument for greater patient autonomy in medical decision making[288]: Rapid advances in medical technology and research have provoked

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281 Goodwin, *supra* note 40, at 30.

282 *Id.*

283 Liu & Pearson, *supra* note 37, at 139.

284 *Id.*

285 When they provide biased information or otherwise exaggerate the usefulness of genetic testing, websites and similar advertisements "undermine [a consumer's] self-control and thus [are] contrary to personal autonomy." Beckman, *supra* note 231, at 391.

286 Gronwald et al., *supra* note 45, at 242.

287 Beckman, *supra* note 231, at 396.

288 Shultz, *supra* note 153, at 221–22.

scientific debate within the medical community,[289] and conflicting studies about the environmental and genetic causes of disease appear not only in medical journals, but also in newspapers and on health-related websites.[290] In the face of scientific indeterminacy, patient autonomy has become more central to patient management[291] because conflicting medical advice can be settled by allowing the patient to apply her own risk and value preferences when making medical decisions.[292] As the court explained in *Canterbury v. Spence* in 1972, "it is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests seem to lie."[293] Thus, to promote autonomy, DTC genetic testing companies must provide consumers with a genuine opportunity to consider the risks and benefits of the services these companies are selling.[294]

In practice, the doctrine of informed consent is far from perfect—patients often do not understand the disclosures made by their health care provider,[295] and there is no legal requirement that the patient must actually comprehend the information.[296] And in the context of DTC genetic testing advertisements on the Internet, consumers might simply "point and click" through informed consent agreements without actually reading them.[297] However, jurisdictions that have adopted the patient-centered standard of informed consent espouse the view that patients are capable of understanding complex and voluminous medical information when it is communicated to them properly.[298]

Decision aids, in particular, can facilitate informed consumer decision making. Decision aids can help consumers weigh their choices and articulate their values and personal preferences, thereby facilitating informed choices

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289 *Id.*

290 *Id.*

291 *Id.*

292 *Id.*

293 464 F.2d 772, 781 (D.C. Cir. 1972).

294 *See* BERG ET AL., *supra* note 156, at 64 (arguing that medical professionals must disclose sufficient information to provide patients with a genuine opportunity to participate fully in the selection among appropriate clinical options).

295 *Id.* at 65.

296 *See Canterbury*, 464 F.2d at 780 n.15 (explaining that a physician has a duty to inform his patient about all the risks that may affect her decision, but that the physician "discharges the duty when he makes a reasonable effort to convey sufficient information although the patient, without fault of the physician, may not fully grasp it"); FURROW ET AL., *supra* note 85, at 244 ("Courts do not usually consider whether the patient comprehended the risk discussion. If the patient is competent, the focus is typically on the content of the physician's disclosure . . . .").

297 Kohlmeier, *supra* note 92, at 42.

298 Kapp, *supra* note 48, at 10.

about whether to undergo certain tests or receive particular types of genetic information.[299] For example, story boards, illustrated pamphlets, and DVDs could help consumers develop realistic expectations for genetic testing and improve consumer comprehension[300] of test results, further enhancing their autonomy.

In particular, a web-based, interactive computer program could serve as a powerful decision aid in the DTC genetic testing context. In one 2004 study, researchers found that an interactive computer program was effective in educating women about breast cancer risk and genetic testing in general.[301] The study was designed to address the specific subject matter identified by counselors and other genetics professionals as the most crucial for the informed decision making of those undergoing genetic testing for breast cancer.[302] The researchers concluded that the computer program successfully enhanced participant comprehension by presenting difficult concepts in multiple formats and through simple examples, and by allowing participants to obtain information at their own pace, thus preventing "information overload."[303]

IV. THE DIRECT-TO-CONSUMER DUTY TO SECURE INFORMED CONSENT

Part II introduced the doctrine of informed consent and explained its fundamental premise—consumer autonomy. Part III discussed how this autonomy can be diminished in the context of DTC genetic testing, as when a consumer misunderstands test results or aggressive marketing creates false expectations in the consumer. This Part proposes a novel application of the doctrine of informed consent, asserting that DTC genetic testing companies owe their customers a tort-based duty of care. Because removing the medical professional from the genetic testing process eliminates the consumer's usual

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299 *See* FURROW ET AL., *supra* note 85, at 245–46 (stating that "[n]umerous studies indicate that when decision aids . . . are available to patients and they have the opportunity to participate in medical decision-making with their physician, the patient–physician dialogue improves, and patient well-being improves as well," and noting that the state of Washington creates a statutory presumption of informed consent when a practitioner has used decision aids).

300 *See* Kapp, *supra* note 48, at 10.

301 Michael J. Green et al., *Effect of a Computer-Based Decision Aid on Knowledge, Perceptions, and Intentions About Genetic Testing for Breast Cancer Susceptibility: A Randomized Controlled Trial*, 292 JAMA 442, 449 (2004).

302 *Id.*

303 *Id.*

source of information about potential risks and benefits,[304] the company should be obligated to make adequate disclosures directly to the consumer both when the consumer (1) is deciding whether to undergo genetic testing or receive particular types of genetic information, and (2) receives the actual test results.

By analogizing the context of genetic testing to the environment surrounding HIV testing when it was first developed, section A examines the policies that motivated states to enact special informed consent statutes for HIV testing to suggest that similar informed consent protections are necessary for genetic testing. Case law has shaped what informed consent means for the relationship between physicians and patients and, in the realm of products liability, for the relationship between manufacturers and consumers; the balance of Part III will demonstrate that case law carries analogous implications for the relationship between the DTC genetic testing company and its consumer. In particular, section B explains why courts have imposed a heightened duty of disclosure on providers of elective medical procedures. Section C applies analogous principles from products liability to demonstrate that where the physician's role is attenuated or absent, manufacturers are in the superior position to warn of risks and their duty to warn therefore extends directly to the consumer.

A. Direct-to-Consumer Genetic Testing and Informed Consent for HIV Testing

The advent of HIV/AIDS forced states to reconsider the effectiveness of traditional informed consent in protecting a vulnerable population comprised mainly of gay men and intravenous drug users.[305] When in 1985 the FDA approved a test that could screen for HIV antibodies,[306] states began to enact special informed consent laws that required health care providers to make patients aware of the full range of social risks and medical benefits that could result from being tested.[307] HIV testing raised new social and political

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304 Berg & Fryer-Edwards, *supra* note 105, at 20.

305 Cooper, *supra* note 159, at 393–95.

306 *Id.* at 394.

307 *Id.* at 396–402. New York led the way for such statutes, providing that informed consent for HIV testing must include, *inter alia*: "an explanation of the test, including its purpose, the meaning of its results, and the benefits of early diagnosis and medical intervention." N.Y. PUB. HEALTH LAW § 2781(2)(a) (McKinney 2010). Disclosures particular to HIV testing emphasize the social risks of learning the test results. Cooper, *supra* note 159, at 349; *see also supra* note 161 (listing examples of statutory provisions that require that the patient be made aware of how HIV is transmitted and how to access appropriate medical and social support after learning of positive test results).

concerns about patient confidentiality and potential discrimination.[308] Thus, the resulting state legislation reflected a strong policy interest in ensuring adequate disclosures to protect the emotional and physical well-being of patients contemplating HIV testing.[309]

Several factors particular to HIV testing prompted states to pass these laws.[310] First, when the test was initially developed, treatment of the underlying HIV infection was impossible.[311] Knowing of HIV infection did not necessarily benefit a patient's health or implicate any personalized medical intervention (although public health officials hoped that knowledge of one's HIV status would cause one to practice safe sex).[312] Second, receiving a positive test result was stigmatizing and could lead a person to lose his job or health insurance.[313] Third, health care professionals believed that the advent of HIV infections would require an entirely new approach to testing and prevention efforts.[314] Such particularized attention from health advocates caused scholars to coin the phrase "HIV exceptionalism."[315]

Today, the science, social policy concerns, and medical uncertainty surrounding DTC genetic testing evoke the context in which HIV testing was first developed and promoted.[316] First, knowing of one's genetic predisposition for disease may be medically useless and psychologically detrimental.[317] Consider this example: A chain smoker who learns that he has a high chance of one day developing lung cancer might be expected to quit smoking.[318] However, smokers in a study who were told that their risk of developing lung cancer was "'higher than other smokers who do not have the

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308 Cooper, *supra* note 159, at 402; *id.* at 395 nn.237, 238 & 241.

309 *Id.* at 400.

310 *Id.* at 397 (describing the factors that led to the "extraordinary valuation" of pre- and post-counseling for HIV tests).

311 *Id.*

312 *Id.*

313 *Id.* at 399. Because physicians initially identified AIDS in gay men and in intravenous drug users, being HIV-positive was a highly stigmatizing condition, *see id.* at 397, that resulted in the danger of losing one's job or health insurance. *Id.* at 399.

314 *See id.* at 399–401 (describing the new approach).

315 *Id.* at 401.

316 *See id.* at 403 (observing that "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").

317 Shoda et al., *supra* note 19, at 4–5 (citing the "absence of clear, objective, medical benefits of knowing one's genetic risk" for breast cancer as a reason to ensure the patient's understanding of all possible risks).

318 Marcy et al., *supra* note 21, at 947.

same genetic makeup'"[319] were no more successful at quitting than those who did not know of their genetic risk.[320] This may be explained by the fact that knowing of a strong risk for lung cancer can inspire a sense of powerlessness in a smoker, reducing motivation to quit.[321] Thus, if certain types of genetic information might not encourage healthful decision making or have no demonstrable positive effect on health outcomes, allowing a consumer to pay for genetic testing and then suffer the psychological consequences is difficult to justify from an ethical or legal perspective.[322]

Second, knowing of a certain genetic predisposition for disease could result in social stigma. Some commentators "see the [potential] damages of genetic discrimination as so dire that the full moral outrage of racial discrimination ought to be invoked"[323] and therefore urge Congress to pass new protective legislation.[324] Although some scholars consider such concerns unjustified,[325] there certainly was, in the past, a danger that employers and insurers would use genetic information to discriminate against individuals with predispositions for developing certain diseases.[326] However, much legal analysis has focused on preventing insurers and employers from using adverse genetic information to the disadvantage of the consumer,[327] and the recent passage of the Genetic Information Nondiscrimination Act (GINA) allays many of these concerns.[328]

In addition, consumers of genetic tests face the possibility of social stigma. For example, the availability of prenatal genetic testing has given rise to a strong belief in some segments of society that impaired children should not

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319 *Id.* (quoting Caryn Lerman et al., *Incorporating Biomarkers of Exposure and Genetic Susceptibility into Smoking Cessation Treatment: Effects on Smoking-Related Cognitions, Emotions, and Behavior Change*, 16 HEALTH PSYCHOL. 87, 87–99 (1997)).

320 Marcy et al., *supra* note 21, at 947.

321 *See id.*

322 *Id.* at 950.

323 *See* David F. Partlett, *Misuse of Genetic Information: The Common Law and Professionals' Liability*, 42 WASHBURN L.J. 489, 507 (2002) (discussing some scholars' response to the advent of genetic testing).

324 *Id.*

325 *See id.* at 490, 503 (observing that "discrimination on the basis of genetic makeup has not loomed large in practice anywhere in the world," and urging that "[f]ear of the misuse of genetic information ought not blind policymakers to the benefits that are bestowed by the genetic revolution").

326 *Id.* at 503. "Thirty-four states and the District of Columbia [already] prohibit employers from discriminating based on genetic information and 44 states and the District prohibit health insurers from basing eligibility on genetic information." Goodwin, *supra* note 40, at 31.

327 *Id.* at 507.

328 For information about how GINA addresses genetic discrimination in the context of health insurance and employment, see the National Human Genome Research Institute's fact sheet, which can be found at http://www.genome.gov/24519851 (last visited June 13, 2010).

have been born.[329] Instead of viewing the birth of an impaired child as an unfortunate circumstance, society may see the mothers of such children as blameworthy for failing to prevent it.[330] Consider for example the case of the former Republican governor Sarah Palin, who was hailed by pro-life advocates and chastised by others for her decision to give birth to a baby prenatally diagnosed with Down Syndrome. Writing about the lifelong burden on a disabled child and her parents, one commentator said: "Like many, I am troubled by . . . Sarah Palin's decision to knowingly give birth to a child disabled with Down syndrome."[331] Conversely, would a mother desire knowledge of a genetic condition that may lead her to choose abortion, another decision that may bring social censure? Consider the words of one commentator, who wryly referred to such decisions as "today's 'respectable' eugenics—for a disability-free society."[332]

And, finally, as with HIV testing, the strong potential for discrimination, misunderstanding, and abuse of information has led scholars to debate the merits of adopting "genetic exceptionalism."[333] Such attention to genetic testing through more specialized legal protections would credit the argument that genetic information, because of its ability to impact a patient's sense of identity and implicate privacy problems, "is not like any other sensitive information in a patient's medical record."[334] Thus, this Comment takes the position that genetic information is unique from other medical information and is potentially dangerous because of the high risk that the patient has misperceived information about her genetic susceptibilities.

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329 Liu & Pearson, *supra* note 37, at 142.

330 *Id.*

331 Nicholas Provenzo, *Sarah Palin's Down Syndrome Child and the Right to Abortion*, CAPITALISMCENTER.ORG (Sept. 16, 2008), http://www.capitalismcenter.org/Philosophy/Commentary/08/09-16-08.htm.

332 George Will, *Eugenics by Abortion: Is Perfection an Entitlement?*, WASH. POST, April 14, 2005, at A27.

333 *See, e.g.*, George J. Annas, *Privacy Rules for DNA Databanks: Protecting Coded 'Future Diaries,'* 270 JAMA 2346 (1993); Lawrence O. Gostin & James G. Hodge, Jr., *Genetic Privacy and the Law: An End to Genetics Exceptionalism*, 40 JURIMETRICS 21 (1999); *see also* Deborah Hellman, *What Makes Genetic Discrimination Exceptional?*, 29 AM. J.L. & MED. 77, 80–81 (2003) (explaining one scholar's definition of "genetic exceptionalism" and noting that, although genetic tests are obviously different from blood pressure readings, they may defy clear definition); Mark A. Rothstein, *Why Treating Genetic Information Separately Is a Bad Idea*, 4 TEX. REV. L. & POL. 33 (1999).

334 Teneille R. Brown, *Double Helix, Double Standards: Private Matters and Public People*, 11 J. HEALTH CARE L. & POL'Y 295, 312–13 (2008).

Courts should take a cue from legislatures that have implemented special informed consent statutes in the context of HIV testing to ensure adequate disclosures for patients undergoing genetic testing.

B. The Greater Duty of Disclosure for Elective Procedures

The Supreme Court of New Jersey has explained that when "elective treatments cause significant side effects without any curative effect, increased consumer protection becomes imperative, because these [treatments] are, by definition, not medically necessary."[335] Indeed, where a medical procedure is elective, courts have evinced a greater concern for protecting patient autonomy.[336] The term "heightened electiveness" describes a situation where the patient received elective treatment and the court subsequently found that the medical professional had a duty to provide greater information about potential side effects than is ordinarily required.[337] In cases involving cosmetic surgery, for example, courts hearing negligence cases have been more willing to find that the physician *induced* the treatment, and even have gone so far as to hold the physician accountable for promised results.[338]

Where there is no clear medical benefit of knowing one's genetic susceptibility for disease, the decision to purchase a genome scan from a DTC genetic testing service is an elective one.[339] And because receiving genetic test results can carry profound psychological consequences and thereby lead to a diminished quality of life, a consumer's decision to undergo genetic testing should be fully informed. Positive test results may lead to difficult decisions about prophylactic surgery[340] or cause distress or family crises.[341] Even negative test results can produce undesirable consequences such as survivor guilt or continued uncertainty, diminishing the consumer's quality of life.[342]

Given the developing state of the science of genetics, and the fact that many genomic associations are not yet fully understood by scientists, the benefit of acquiring information about one's genetic risks is questionable.

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335 Perez v. Wyeth Labs., Inc., 734 A.2d 1245, 1257 (N.J. 1999).

336 Shultz, *supra* note 153, at 264.

337 *Id.* at 264–65.

338 *Id.* (citing Hawkins v. McGee, 146 A. 641 (N.H. 1929)).

339 *Cf.* Shoda et al., *supra* note 19, at 5 (arguing that "when there is no 'right' medical recommendation, the decision needs to be based" on an understanding of all potential risks).

340 *Id.*

341 *Id.*

342 Shoda et al., *supra* note 19, at 5.

Thus, companies that sell genetic testing services should acknowledge the potential for adverse impact and exercise great caution when informing a consumer about his genetic makeup.[343] Because DTC genetic testing services *never* are medically necessary and *always* are elective, courts should impose a significant duty of disclosure on the companies involved to protect consumers.

C. The Analogous Duty to Warn in Products Liability and What It Means for Direct-to-Consumer Genetic Testing

Direct-to-consumer genetic testing companies are not governed by the rules of products liability because they provide genetic testing *services*, rather than genetic testing *products* (for example, test kits or chemical reagents).[344] However, the rules of products liability offer useful lessons for courts in the genetic testing context—the principles that form the basis of the informed consent doctrine also underpin failure-to-warn claims in products liability.[345] This section examines failure-to-warn claims, particularly those made in cases involving prescription drugs, to argue that DTC genetic testing companies have a legal duty to provide consumers with adequate disclosures about risks.

1. When the Physician's Role Is Attenuated, Courts Have Placed the Duty to Warn on the Drug Manufacturer

In products liability, manufacturers ordinarily have a duty to warn consumers of "the foreseeable risks of harm posed by the product."[346] An "adequate warning" is one that presents information about all significant risks and discloses the actual likelihood of those risks.[347] Like a physician who obtains a patient's informed consent, a drug manufacturer meets its obligation to warn when it has made all relevant disclosures, even if the consumer ultimately suffers an adverse outcome from taking the drug.[348] In effect, an adequate warning conclusively establishes that the consumer has assumed the risk of taking the drug.[349]

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343 Evans & Green, *supra* note 1, at 568.

344 Ossorio, *supra* note 170, at 239.

345 Schuck, *supra* note 151, at 913.

346 RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(c) (1998).

347 Corey Schaecher, *"Ask Your Doctor if This Product Is Right for You":* Perez v. Wyeth Laboratories, Inc.*, Direct-to-Consumer Advertising and the Future of the Learned Intermediary Doctrine in the Face of the Flood of Vioxx® Claims*, 26 ST. LOUIS U. PUB. L. REV. 421, 425–26 (2007).

348 Epstein, *supra* note 116, at 1149.

349 Schuck, *supra* note 151, at 924.

For over-the-counter drugs, manufacturers must provide package inserts and labels that warn consumers about foreseeable risks of harm[350] of which the manufacturer knew or should have known.[351] But courts treat prescription drugs differently from over-the-counter drugs[352]—because of the complexity of associated risks, manufacturers cannot be expected to convey warnings about prescription drugs in a way the average patient can comprehend.[353] Further constraining the ability of drug manufacturers to warn patients directly is the fact that the prescribing physician must base her choice to treat a patient with a particular prescription drug on that patient's particular medical history.[354]

Because information about prescription drugs is highly technical and prescription drugs can pose significant risks to patients, courts have created an exception to the manufacturer's duty to provide adequate disclosures: Rather than warning all potential consumers of the prescription drug,[355] a manufacturer may discharge its duty to warn by providing an adequate warning to prescribing physicians.[356] Hence, the physician is the "learned intermediary" between the patient and the manufacturer and in effect serves as a liability shield for the manufacturer.[357]

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350 *See* Susan A. Casey, Comment, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 WM. MITCHELL L. REV. 931, 935 (1993).

351 *Id.*

352 *See id.*

353 Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 158–59 (1997); *see also id.* at 159 n.69 (quoting Hill v. Searle Labs., Inc., 884 F.2d 1064, 1070 (8th Cir. 1989) ("[T]he information regarding risks is often too technical for a patient to make a reasonable choice")).

354 *See* Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir. 1974) ("Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers.").

355 *See* West v. Searle & Co., 806 S.W.2d 608, 613 (Ark. 1991) ("[I]t is virtually impossible in many cases for a manufacturer to directly warn each patient.").

356 Thomas v. Hoffman La-Roche, Inc., 949 F.2d 806, 811 (5th Cir. 1992); *see also* Casey, *supra* note 350, at 935.

357 The majority of jurisdictions have adopted the concept of the "learned intermediary," Partlett, *supra* note 323, at 493, relieving the manufacturer of a duty to warn the patient of a drug's dangers when the manufacturer has conveyed the necessary warnings to the prescribing physician. Michael C. Allen, Comment, *Medicine Goes Madison Avenue: Evaluation of the Effect of Direct-to-Consumer Advertising on the Learned Intermediary Doctrine*, 20 CAMPBELL L. REV. 113, 116 (1997). The learned intermediary doctrine acknowledges the physician's training and experience, recognizes the physician's ability to evaluate the patient's needs and wishes, and assumes that the physician is in a better position than the manufacturer to convey the appropriate and applicable warnings to the ultimate user. *Id.* at 120. The doctrine also recognizes that warnings to consumers might interfere with the traditional physician–patient relationship, and that manufacturers face tremendous difficulty in conveying appropriate warnings to the consumer, given the

The ultimate policy goal of the learned intermediary doctrine is to avoid injury to the patient.[358] The doctrine seeks to assign the duty of care[359] in a way that ensures the best health outcomes for individual patients.[360] In *Sterling Drug, Inc. v. Cornish*, the court reasoned that if the physician is properly warned of possible side effects, "there is an excellent chance that injury to the patient can be avoided."[361] The court therefore held that manufacturers have a duty to warn prescribing physicians of side effects, no matter how uncommon their occurrence.[362] The physician's relationship with the patient places her "in the best position to warn individual patients of potential adverse effects."[363] Thus, if the drug manufacturer has failed to provide adequate warnings *to the prescribing physician*, the patient has a direct cause of action against the manufacturer for injuries that resulted from the manufacturer's failure to warn of risks.[364]

Following the same logic, courts have rejected the learned intermediary defense where they have found that the patient–physician relationship was attenuated through heavy marketing towards consumers, as has been the case for oral contraceptives, nicotine patches, breast implants, and intrauterine devices.[365] Courts have also rejected the learned intermediary defense where the physician had no role in the administration of prescription drugs to the patient. The Fifth and Ninth Circuits, for example, have noted that mass immunizations pose a special problem for the learned intermediary doctrine

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individualized needs of the patient. *Id.* Under the learned intermediary doctrine, "a product manufacturer is excused from warning each patient who receives the product when the manufacturer properly warns the prescribing physician of the product's dangers." Porterfield v. Ethicon, Inc., 183 F.3d 464, 467–68 (5th Cir. 1999).

358 Casey, *supra* note 350, at 948.

359 *See* Jennifer Girod, *The Learned Intermediary Doctrine: An Efficient Protection for Patients, Past and Present*, 40 IND. L. REV. 397, 400 (2007) (explaining that "[t]he majority of jurisdictions apply the learned intermediary doctrine as a duty-oriented rule," and viewing the doctrine as such at the summary judgment stage will decrease litigation costs by discouraging plaintiffs from suing on frivolous claims and by helping manufacturers to meet their burden of proof).

360 *Id.* at 399.

361 370 F.2d 82, 85 (8th Cir. 1966).

362 *Id.*

363 Perez v. Wyeth Labs. Inc, 734 A.2d 1245, 1255 (N.J. 1999).

364 Ausness, *supra* note 123, at 1196.

365 Edwards v. Basel Pharm., 933 P.2d 298, 301 (Okla. 1997) (recognizing that many states accept two exceptions to the learned intermediary doctrine: (1) mass immunizations and (2) FDA "mandates that a warning be given directly to the consumer"). The Oklahoma Supreme Court held that an exception to the learned intermediary doctrine existed in a case involving prescription nicotine patches. *Id.*; *see also* Hill v. Searle Labs., 884 F.2d 1064 (8th Cir. 1989) (intrauterine device); Odgers v. Ortho Pharm. Corp., 609 F. Supp. 867 (E.D. Mich. 1985) (oral contraception).

and informed consent jurisprudence.[366] Because mass immunizations in the military, at schools, and at public health departments are administered without physician involvement, the patient no longer benefits from the physician's diagnostic skills and judgment.[367] Therefore, courts have held that the learned intermediary doctrine cannot shield manufacturers from liability for failure to warn the consumer directly of the risks of a vaccine; the consumer has a direct cause of action against the manufacturer.[368]

Most salient for the argument made in this Comment is the New Jersey Supreme Court's extension of the "attenuated-role-of-the-physician reasoning" in *Perez v. Wyeth Laboratories, Inc.*[369] There, the court found that because the contraceptive Norplant was marketed directly to consumers, the manufacturer had a duty to warn *the consumer* of Norplant's risks at a level of detail that recognized the "informed role of the patient in health care decisions,"[370] despite the fact that *a physician* had prescribed Norplant to the patient. The court explained that in the past, "[p]harmaceutical manufacturers never advertised their products to patients, but rather directed all sales efforts at physicians."[371] Under that marketing model, a manufacturer could discharge its duty to warn of the drug's risks by warning only the physician, rather than the ultimate consumer of the drug.[372] Now, in the age of direct-to-consumer marketing, the burden of disclosing risks should fall to the manufacturer, not the physician:[373]

> [W]hen mass marketing of prescription drugs seeks to influence a patient's choice of a drug, a pharmaceutical manufacturer that makes direct claims to consumers for the efficacy of its product should not be unqualifiedly relieved of a duty to provide proper warnings of the dangers or side effects of the product.[374]

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366 *See, e.g.*, Givens v. Lederle, 556 F.2d 1341 (5th Cir. 1977); Reyes v. Wyeth Labs., 498 F.2d 1264 (5th Cir. 1974); Davis v. Wyeth Labs., 399 F.2d 121 (9th Cir. 1968).

367 Kevin J. Dunne & Ciara R. Ryan, *How Management of Medical Costs Is Revolutionizing the Drug Industry*, 62 DEF. COUNS. J. 177, 177 (1995).

368 *Supra* note 366.

369 734 A.2d 1245 (N.J. 1999).

370 *Id.* at 1254–55.

371 *Id.* at 1247.

372 *See supra* notes 362–63 and accompanying text (summarizing the *Sterling* decision and explaining the rationales supporting the learned intermediary doctrine).

373 *Cf.* Girod, *supra* note 359, at 399 (explaining that the "learned intermediary doctrine exists to serve the tort goal of accident cost avoidance").

374 *Perez*, 734 A.2d at 1255.

The Supreme Court of Appeals of West Virginia similarly rejected the learned intermediary defense in *State ex rel. Johnson & Johnson Corp. v. Karl*,[375] observing that consumer-targeted marketing of health care products interferes with the physician–patient relationship.[376] In *Karl*, the patient died after she began taking a drug prescribed by her primary care physician.[377] When her estate sued, the drug manufacturer argued that it had fulfilled its duty to warn about the drug's risks by providing adequate warnings to her primary care physician.[378] The court explained that recent changes in the health care industry made it necessary to consider direct-to-consumer advertising's adverse effects on the physician–patient relationship.[379] The court held that the justifications for the learned intermediary doctrine are no longer viable where drug manufacturers have reduced the role of physicians by advertising directly to consumers,[380] because "[t]he decision to take a drug is [no longer] exclusively a matter for [the physician's] medical judgment."[381] Because consumers are actively involved in the selection of prescription drugs, pharmaceutical companies can no longer hide behind the shield of the learned intermediary doctrine; they must warn consumers directly of a drug's risks.[382]

By adopting the reasoning of *Perez* and *Karl*, courts should find that the duty to provide a consumer with adequate warnings about undergoing a genetic test falls to the DTC genetic testing company. Where genetic testing services are marketed and sold directly to consumers, diminishing the medical professional's gatekeeping role, the required level of disclosure should be the same as that under the doctrine of informed consent.[383]

Courts should borrow an additional lesson from products liability: Section 6(d) of the *Restatement (Third) of Torts: Products Liability* addresses liability for defective or inadequate warnings about drugs, providing that a

> prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to . . . the patient when the manufacturer . . . ha[d] reason to know

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375 647 S.E.2d 899 (W. Va. 2007).
376 *Id.* at 914.
377 *Id.* at 901.
378 *Id.*
379 *Id.* at 907.
380 *Id.* at 907–14.
381 *Id.* at 910 (internal quotations omitted).
382 *Id.* at 907–14.
383 *See* Partlett, *supra* note 323, at 489–90.

> that health-care providers w[ould] not be in a position to reduce the risks of harm . . . .[384]

Arguably, a genetic testing service, albeit not a "product," is not reasonably safe when the dissemination of inadequate or misleading information could have been avoided by providing more detailed warnings. Because DTC genetic testing companies sell test results directly to consumers, they have reason to know that no health care provider would be in a position to provide important disclosures to their consumers to reduce the risks of harm to them. Although the actual administration of a genetic test is not likely to cause serious side effects in the same way that prescription drugs can, the potential negative *psychological* effects of genetic testing can be severe and serious.[385] Under the *Restatement*'s reasoning, a DTC genetic testing company that does not require the involvement of a medical professional should be required to provide adequate disclosures directly to the consumer.

2. DTC Genetic Testing Companies Are in the Superior Position to Inform Consumers of the Risks of Genetic Testing Services

When physicians are in the superior position to convey meaningful information to their patients, courts have held them responsible for warning the patient of drug side effects.[386] However, when the physician's role is attenuated, courts have held the drug manufacturer directly liable to the consumer for the failure to disclose material risks resulting in the consumer's injury.[387] Therefore, the question of who carries the duty of disclosure "turns on who is in a better position to disclose risks."[388]

Most practicing physicians have inadequate training in medical genetics and may have difficulty determining whether a genetic test is appropriate for a

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384 RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) (1998).

385 Liu & Pearson, *supra* note 37, at 139; *see also supra* Part III (discussing how misunderstanding of, and misguided expectations for, genetic testing can be dangerous to a consumer's mental health).

386 Spychala v. G.D. Searle & Co., 705 F. Supp. 1024, 1031–32 (D.N.J. 1988) ("Because prescription drugs are often complex in formula and effect, the physician is in the best position to take into account the propensities of the drug and the susceptibilities of the patient, and to give a highly individualized warning to the ultimate user based on the physician's specialized knowledge."); *see also supra* Part IV.C.1 (discussing courts' reasons for rejecting the learned intermediary doctrine where the physician's role is attenuated or absent).

387 *See* Schuck, *supra* note 151, at 914.

388 Laws v. Johnson, 799 S.W.2d 249, 254 (Tenn. Ct. App. 1990).

particular patient.[389] Although genetic tests have been developed to predict over one thousand diseases, genetic testing is not yet a standard part of primary health care because of the complexity of interpreting test results for diseases that involve the interaction of genetic and environmental factors.[390] A survey of medical school deans indicated that only 77% of medical schools teach medical genetics, and of those, few provide more than minimal instruction in genetics during the clinical years of training.[391] The failure to integrate genetics into the medical curriculum has resulted in a scarcity of physicians who are knowledgeable about it.[392]

Consider this hypothetical[393]: A consumer learns from a genetic test that she has inherited a gene associated with an increased risk of blood clotting, a symptom of the disease thrombophilia.[394] The company warns her that increased clotting can cause thrombosis, embolus to the lungs, and stroke.[395] Frantic, she searches the Internet for more information and discovers that the treatment for thrombophilia is an anticoagulent medication.[396] She then visits her physician to demand treatment.[397] A knowledgeable physician could tell her that the clotting genes for thrombophilia have varied significance and that the patient's family history is a major determinant for whether she will develop the disease.[398] However, a physician who is less familiar with the genes associated with clotting factors might prescribe the medication, or at least recommend that she take an antiplatelet agent.[399] Anticoagulents and antiplatelet agents slow clotting; when given to the wrong patient, they can

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389 Gollust et al., *supra* note 75, at 1765 (citing several studies revealing that physicians lack the skills "to analyze modes of inheritance, calculate genetic risks, or communicate genetic information in a nondirective way," and concluding that physicians will not be prepared for the "flood of new consumers interested in genetic testing").

390 Berg & Fryer-Edwards, *supra* note 105, at 17.

391 John T. Aquino, *DTC Genetic Tests May Give False Security, Doctors Cannot Interpret Data, Speakers Say*, LIFE SCI. L. & INDUSTRY REP., Sept. 11, 2009, at 909.

392 *Id.*

393 NEIL F. SHARPE & RONALD F. CARTER, GENETIC TESTING: CARE, CONSENT, AND LIABILITY 290–91 (2006).

394 Where state law permits direct-to-consumer genetic testing, companies like HealthCheckUSA(http://www.healthcheckusa.com) and MyGenome (http://www.mygenome.com) offer genetic tests for thrombosis, but do not require a physician's order or encourage a medical professional's involvement.

395 SHARPE & CARTER, *supra* note 393, at 290.

396 *Id.* at 291.

397 *Id.*

398 *Id.* at 290.

399 *Id.* at 291.

cause severe bleeding.[400] As this hypothetical illustrates, receiving and relying upon genetic information could result in serious harm to a consumer whose physician is not trained in genetics.

Moreover, genetic testing services can interfere with the relationship between patients and physicians much as DTC advertising of prescription drugs has interfered with that relationship.[401] Most consumers still turn to their physicians to help them understand medical information,[402] and physicians may be faced with the prospect of counseling patients who present them with the results from their DTC genetic tests.[403] When a patient seeks her physician's advice on genetic risks for such conditions as Alzheimer's disease, for which there are no clear preventative options available, the physician may find herself in an awkward position.[404]

Several professional organizations have suggested that consumers should be referred to genetic counselors or other genetic specialists. However, in 2004, there were only four hundred genetic counselors who specialized in cancer genetics, and those counselors were concentrated in major urban areas.[405] Consequently, the demand for counselors is likely to exceed the supply of qualified specialists, and consumers' access to genetic counseling services is limited, particularly in rural regions.

Thus, because the question of who bears the duty of disclosure "turns on who is in a better position to disclose risks,"[406] DTC genetic testing companies bear the responsibility of communicating risk information directly to patients—the companies effectively subsume the role of medical professionals, who likely lack the training or expertise necessary to properly advise patients about the risks of undergoing genetic testing or prevent misunderstanding of test results.[407]

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400 *Id.*

401 *See supra* text accompanying note 380.

402 BURRILL & COMPANY/CHANGEWAVE RESEARCH SURVEY, *supra* note 10, at 3.

403 Kuehn, *supra* note 22, at 1505.

404 *Id.*; *see also supra* text accompanying notes 386–90 (arguing that DTC genetic testing companies are in the best position to warn consumers of the risks of genetic testing).

405 Green, *supra* note 301, at 442–43.

406 Laws v. Johnson, 799 S.W.2d 249, 254 (Tenn. Ct. App. 1990).

407 *See supra* note 226 and accompanying text (describing how the patient–physician relationship and the corporation–consumer relationship are different).

CONCLUSION

This Comment has demonstrated that when no physician or genetic counselor serves a role to help ensure that consumers undergo the appropriate tests and understand the results,[408] the duty to provide adequate disclosures falls to the DTC genetic testing company.

Without professional assistance, consumers risk misinterpreting the meaning of their genetic futures and may even take drastic actions based upon their misperceptions. Therefore, where genetic testing services are marketed directly to consumers, diminishing the medical professional's gatekeeping role, the required level of disclosure should be the same as that under the common law doctrine of informed consent. This means that courts should impose a duty on DTC genetic testing companies to provide warnings to consumers akin to the duty physicians have to secure the informed consent of their patients.

Courts have held manufacturers directly liable to consumers for failing to disclose material risks in the realm of products liability, and this Comment has shown that courts should apply analogous reasoning in the context of DTC genetic testing. Faced with the prospect of significant tort liability, DTC genetic testing companies would likely exercise greater caution in reporting easily understandable test results and may go so far as to provide genetic counseling for their consumers.

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408 Goodwin, *supra* note 40, at 30.

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