

**KNOWLEDGE IS POWER: PHYSICIAN ABANDONMENT AS A
MODEL FOR THE DUTY TO DISCLOSE RESEARCH
FINDINGS**

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ABSTRACT

Millions of Americans have participated in genetic studies over the past few decades. Americans – knowingly and unknowingly – act as donors for these studies by giving samples containing DNA to their physicians or directly to researchers. Occasionally, a study’s findings will have implications for a donor’s short-term or long-term health. The medical profession is currently debating how much is owed, both legally and ethically, to sample donors when a researcher or physician possesses such information. To date, the law has only sporadically provided researchers and physicians with guidance about what duties they owe to sample donors. This Note evaluates the adequacy of the legal relationships that currently exist between parties in a genetic research project. It then proposes that researchers and physicians owe a duty to disclose certain findings to research participants, using the common law tort of physician abandonment as a model for the duty to disclose.

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INTRODUCTION

In 1990, Dr. Judith Green, a primary-care physician, met Diane Jones, a new patient to Dr. Green’s practice. Ms. Jones, a slim, middle-aged woman, had come in for a routine check-up. Dr. Green determined through her preliminary questions that Ms. Jones had a family history of high cholesterol. During the physical examination, Dr. Green was alarmed by Ms. Jones’s high cholesterol levels. Dr. Green had recently read a journal article describing how some versions of the apolipoprotein E (APOE) gene have been linked to faulty cholesterol processing,¹ and she decided that Ms. Jones may be interested in a genetic test that could shed light on why she and her family had high cholesterol. Ms. Jones was eager to learn whether a genetic basis for her high cholesterol existed and immediately agreed to genetic testing. Her blood was drawn that day and sent to a laboratory. Six weeks later, a genetic counselor informed Ms. Jones that she did not have the version of the APOE gene that caused faulty cholesterol processing. Ms. Jones never gave another thought to her blood sample.

What Ms. Jones did not know was that her blood sample would be given to genetic researchers studying the genetic underpinnings of a range of other diseases, as is standard practice in the medical and research communities.² Three years later, in 1993, a laboratory that had been using the genetic samples of hundreds of patients discovered that certain versions of the APOE gene were linked with Alzheimer’s disease.³ After further research, scientists discovered that someone with the same versions of APOE as Ms. Jones had a risk of developing Alzheimer’s disease that was fifteen times higher than the risk within the general population.⁴ This sort of finding,

1. Robert W. Mahley, *Apolipoprotein E: Cholesterol Transport Protein with Expanding Role in Cell Biology*, 240 SCIENCE 622, 622-23 (1988).

2. Companies and doctors’ offices routinely store, and distribute to researchers, biological samples given by patients. Allen Buchanan, *An Ethical Framework for Biological Samples Policy*, in 2 NAT’L BIOETHICS ADVISORY COMM’N, RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE B-1, B-3 (2000) [hereinafter NBAC REPORT].

3. E.H. Corder et al., *Gene Dose of Apolipoprotein E Type 4 Allele and the Risk of Alzheimer’s Disease in Late Onset Families*, 261 SCIENCE 921, 922-23 (1993).

4. Cathleen D. Zick et al., *Genetic Testing for Alzheimer’s Disease and Its Impact on Insurance Purchasing Behavior*, 24 HEALTH AFF. 483, 484 (2005). The APOE gene has three versions: ε2, ε3, and ε4. *Id.* Each person inherits one version of APOE from her mother and one version from her father. *Id.*

which was an original goal of the researchers, will be referred to in this Note as a “direct finding.” In contrast, findings that are only tangentially related to the original purpose for which the genetic sample was examined have been referred to as “incidental findings” in the literature.⁵ The question for scientists and physicians in this situation is whether they have a duty to inform participants about significant medical findings; and, if so, do they have a duty to inform all participants, including those who signed up for the Alzheimer’s disease research *and* participants who, like Ms. Jones, were unaware that they had any role in such research?

The medical profession is currently debating how much is owed, both legally and ethically, to a sample donor when a researcher or physician possesses information that has implications for the donor’s short-term or long-term health.⁶ The vast majority of patients would want to know the results of such a test;⁷ however, to date, the law has only rarely provided the research and medical professions with guidance about what duties they owe to sample donors. Although Ms. Jones’s example is fictional, it exemplifies in many ways the experience of millions of Americans who participate—knowingly or unknowingly—in genetic studies and are unaware that their genetic material rarely stops in the laboratory where it was initially sent.⁸

With few exceptions, such as causes of action sounding in contract, American research scientists owe very few legal duties to their

5. Susan M. Wolf et al., *The Law of Incidental Findings in Human Subjects Research: Establishing Researchers’ Duties*, 36 J.L. MED. & ETHICS 361, 361–62 (2008) (providing examples of incidental findings, including genetic studies finding that paternity is misattributed 10% of the time and neuroimaging studies revealing incidental findings in 47% of “normal” research participants).

6. Erika Check Hayden, *DNA Donor Rights Affirmed*, 483 NATURE 387, 387 (2012).

7. David Wendler & Rebecca Pentz, *How Does the Collection of Genetic Test Results Affect Research Participants?*, 143A AM. J. MED. GENETICS 1733, 1735 (2007) (finding that 78% of participants in an Alzheimer’s disease research study and 90% of cancer patients would want to know the results of a genetic test that was predictive of Alzheimer’s disease if a researcher had already performed the test).

8. I chose to describe a fictional example because I wanted to illustrate that some genes have disparate health implications; however, reported, real-world examples of the ethical conundrums physicians and researchers can encounter when faced with genetic-testing results are also fascinating. See, e.g., Amy Harmon, *Indian Tribe Wins Fight to Limit Research of Its DNA*, N.Y. TIMES, Apr. 21, 2010, at A1 (describing Native American tribe’s fight to discontinue research on DNA samples collected from tribe members), available at <http://www.nytimes.com/2010/04/22/us/22dna.html>; Gina Kolata, *Genes Now Tell Doctors Secrets They Can’t Utter*, N.Y. TIMES, Aug. 25, 2012, at A1 (describing a cancer patient whose doctor had found genetic evidence of AIDS in the patient’s genetic tests), available at http://www.nytimes.com/2012/08/26/health/research/with-rise-of-gene-sequencing-ethical-puzzles.html?_r=1&ref=science.

research participants.⁹ This Note evaluates the adequacy of the current legal relationships that exist between parties in a research project, and it proposes that researchers and physicians owe a legal duty to disclose research findings to research participants and donors. Part I provides a background on the major issues that arise in the areas of genetic testing and genetic research, including where genetic samples come from, what they are used for, and whether the sample donors know, or even want to know, what became of their samples. Part I then provides an overview of the doctrine of physician abandonment, a cause of action under which a patient may recover from a physician who has left her without medical attention at a time when she needs it. Part II uses physician abandonment as a model for how the legal relationship between researchers, physicians, and research participants can be strengthened. Specifically, this Note argues that researchers and physicians owe a duty to research participants to make reasonable efforts to inform them about whatever direct or incidental findings the research produces. This duty arises from the researcher-donor relationship that is established when a researcher accepts the donor's genetic sample. Imposing a "duty to disclose" on researchers protects the interests of research participants by safeguarding their health and giving them medical knowledge they may desire, and to which they believe they are entitled, while imposing only a small administrative burden on researchers and physicians.

I. GENETIC TESTING AND THE RESEARCHER-DONOR RELATIONSHIP

A. Background

During the last twenty years, genetic tests have shown improved accuracy and an increase in the breadth of information they can reveal.¹⁰ Researchers have determined the genetic underpinnings of more than 1600 diseases, and the rate of discovery is increasing.¹¹ Further, genetic tests for more than 700 diseases exist,¹² offering pa-

9. Even the Institutional Review Board process, in many respects, fails to provide meaningful legal protections for research participants. *See infra* text accompanying note 48.

10. *See A Brief History of DNA Testing*, NEW ENG. INNOCENCE PROJECT, <http://www.newenglandinnocence.org/knowledge-center/resources/dna/> (last visited Aug. 31, 2012).

11. Iftikhar J. Kullo & Keyue Ding, *Mechanisms of Disease: The Genetic Basis of Coronary Heart Disease*, 4 NATURE CLINICAL PRAC. CARDIOVASCULAR MED. 558, 558 (2007).

12. GENETICS & PUB. POLICY CTR., REPRODUCTIVE GENETIC TESTING: ISSUES AND OPTIONS

tients information that has implications for short-term or long-term health. Some genetic tests, such as the tests for sickle cell anemia, cystic fibrosis, and Tay-Sachs disease, are used as diagnostic tests because the disease is caused by a single gene.¹³ Other genetic tests provide predictive information based on a looser connection between the gene and the disease. The most famous (and infamous) examples of predictive tests are the tests for the BRCA1 and BRCA2 genes; a mutation in either of these genes increases a woman's chance of developing breast cancer to 60%, compared with 12% in the general population, and increases her chance of developing ovarian cancer at least ten-fold over the general population.¹⁴ Other examples of predictive tests include tests that predict the risk of developing type 2 diabetes, obesity, and schizophrenia.¹⁵ Our understanding of the relationships between genes and diseases has been made possible, in large part, by the genetic contributions of donors and research participants.

Genetic researchers take biological specimens, including genetic, blood, and tissue samples, from patients in ways that run the gamut from aboveboard to strikingly covert. When asked to envision how biological samples are donated, many people would likely think of a willing individual who has decided to donate part of his body—for example, a diseased prostate—after engaging in the informed consent process¹⁶ Although such informed and consensual donations certainly occur, samples are also collected in more secretive ways. For example, samples may be collected during an autopsy,¹⁷ after a routine diagnostic test, such as a blood draw, or after a therapeutic

FOR POLICYMAKERS 31 (2004).

13. MYRTLE R. FLIGHT & MICHAEL R. MEACHAM, *LAW, LIABILITY, AND ETHICS FOR MEDICAL OFFICE PROFESSIONALS* 237 (5th ed. 2010).

14. *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, NAT'L CANCER INST. (May 29, 2009), <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA>. These tests have become infamous because the company that pioneered the tests, Myriad Genetics, has forcefully enforced the tests' patents and reduced patient choice by monopolizing the market. See Marisa Noelle Pins, *Impeding Access to Quality Patient Care and Patient Rights: How Myriad Genetics' Gene Patents Are Unknowingly Killing Cancer Patients and How to Calm the Ripple Effect*, 17 J. INTEL. PROP. L. 377, 379 (2010); Douglas L. Rogers, *Coding for Life – Should Any Entity Have the Exclusive Right to Use and Sell Isolated DNA?*, 12 PITT. J. TECH. L. & POL'Y 1, 3–8 (2011).

15. *Health Reports: Complete List*, 23ANDME, <https://www.23andme.com/health/all/> (last visited Oct. 24, 2012).

16. See, e.g., *Wash. Univ. v. Catalona*, 437 F. Supp. 2d 985, 988–92 (E.D. Mo. 2006), *aff'd*, 490 F.3d 667 (8th Cir. 2007).

17. NBAC REPORT, *supra* note 2, at E-4; Lori Andrews, *The Battle Over the Body*, 42 TRIAL 22, 22 (2006) (describing the indictment of men who had allegedly purchased corpses from funeral homes, pillaged the corpses for organs and bones that could be sold, and sewed the skin of the corpses around PVC pipes before returning them to unwitting family members).

intervention, such as the surgical removal of a tumor.¹⁸ Further, samples may be stored after a diagnostic test or therapeutic treatment without the knowledge or consent of the patient.¹⁹ The common rationale for these practices is that such samples are medical waste that may be disposed of in any way the medical center sees fit (within the parameters of environmental laws).²⁰ Thus, common practice in the medical and scientific communities has undermined the doctrine of informed consent by covertly appropriating the genetic information of individuals without their knowledge or consent.²¹

The current state of the law is problematic because studies show that Americans want access to the results of genetic studies in which they participate²²—even test results that are of unknown clinical significance.²³ Researchers and legal observers have used notions of respect, beneficence, and reciprocity to anchor an ethical duty to disclose a study's results to participants.²⁴ A consensus exists in the scientific and medical communities that researchers have an obligation to disclose the results of a study to its participants;²⁵ however, few researchers actually do.²⁶ For example, one large study analyzed the association between the CDKN2A gene and the chance of developing melanoma, a type of skin cancer.²⁷ Of the nine sites that participated in this research protocol, only one site delivered genetic results to the research participants who had tested positive for a version of the gene that substantially increases one's chance of

18. NBAC REPORT, *supra* note 2, at B-13.

19. *Id.* at A-12.

20. See, e.g., Lisa C. Edwards, *Tissue Tug-of-War: A Comparison of International and U.S. Perspectives on the Regulation of Human Tissue Banks*, 41 VAND. J. TRANSNAT'L L. 639, 659 (2008) (describing how the Eighth Circuit relied on state hazardous waste regulations to deny that plaintiffs had a property interest in their removed tissues).

21. See generally NBAC REPORT, *supra* note 2.

22. David I. Shalowitz & Franklin G. Miller, *Communicating the Results of Clinical Research to Participants: Attitudes, Practices, and Future Directions*, 5 PLOS MED. 714, 714-15 (2008).

23. Dave Wandler & Ezekiel Emanuel, *The Debate Over Research on Stored Biological Samples*, 162 ARCHIVES INTERNAL MED. 1457, 1457 (2002) (finding that 88.8% of patients want to be informed of genetic results that have unknown clinical significance).

24. Emmanuelle Levesque et al., *Return of Research Results: General Principles and International Perspectives*, 39 J.L. MED. & ETHICS 583, 584 (2011).

25. See *id.* at 586.

26. See J. Scott Roberts, *Returning Individual Research Results: Development of a Cancer Genetics Education and Risk Communication Protocol*, 5 J. EMPIRICAL RES. ON HUM. RES. ETHICS 17 (2010).

27. *Id.* at 19-27.

developing melanoma.²⁸ This research group published a first-of-its-kind paper regarding its experience reporting these results to participants.²⁹ Numerous professional societies have promulgated guidelines that encourage disclosure to donors.³⁰ In spite of this popular sentiment, current law does not require researchers to disclose research results or incidental findings to participants and donors.³¹

While the utility of genetic tests has increased, courts have uniformly refused to recognize the property interests of donors who have submitted their genetic material or tissues for testing. In *Moore v. Regents of the University of California*, the California Supreme Court held that a patient could not maintain a cause of action for conversion against his physician who had used deceptive tactics to extract the patient's biological samples.³² Specifically, the patient, John Moore, gave multiple samples of sperm, bone marrow aspirate, skin, and blood to his physician based on the physician's representation that such donations were to help maintain the patient's health as he battled hairy-cell leukemia.³³ Unbeknownst to Moore, his physician patented a cell line derived from Moore's cells.³⁴ At the time of trial, the patent was projected to yield over \$3 billion in profits.³⁵

Similar events unfolded in Florida, where a group of individuals and families afflicted with Canavan disease donated samples of blood and urine to researchers in an effort to identify the genetic underpinnings of the disease.³⁶ In *Greenberg v. Miami Children's Hospital Research Institute*, the plaintiff donors alleged that they had made their tissue donations with the understanding that any genetic testing that was made possible as a result of their donations would be "provided on an affordable and accessible basis."³⁷ The donors

28. *Id.* at 25 (stating that the research group only contacted the subset of participants that had a higher risk of melanoma).

29. *Id.* at 18.

30. See, e.g., *NHLBI Working Group on Reporting Genetic Results in Research Studies*, NAT'L HEART LUNG & BLOOD INST. (July 12, 2004), <http://www.nhlbi.nih.gov/meetings/workshops/gene-results.htm#guidelines>.

31. Wolf et al., *supra* note 5, at 362.

32. *Moore v. Regents of the Univ. of Cal.*, 51 Cal. 3d 120, 124-25 (Cal. 1990) (en banc).

33. *Id.* at 126.

34. *Id.* at 126-27.

35. *Id.* at 127.

36. *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1067 (S.D. Fla. 2003). For an in-depth overview of the history that led up to this litigation, see Gregory P. Lekovic, *Genetic Diagnosis and Intellectual Property Rights: A Proposal to Amend "The Physician Immunity Statute,"* 4 YALE J. HEALTH POL'Y L. & ETHICS 275, 285-94 (2004).

37. *Greenberg*, 264 F. Supp. 2d at 1067.

initiated the suit after the researcher who had collected these samples filed a patent and was named “inventor” of the gene that controls Canavan disease; this patent allowed him to restrict any future prenatal testing or therapy treatments in which the donors wished to engage.³⁸ The *Greenberg* court dismissed the plaintiffs’ cause of action for conversion, finding that they had no property rights in the donated samples.³⁹

Some commentators have proposed that researchers be legally required to disclose direct and incidental findings to research participants.⁴⁰ Susan Wolf asserts that researchers have legal duties that arise under federal research regulations and state common law.⁴¹ However, neither the Common Rule—the federal law that governs informed consent with human research subjects⁴²—nor the Food and Drug Administration’s regulations explicitly requires the disclosure of research results.⁴³ And only two courts, the highest court in Maryland and a federal district court in Illinois, have imposed a common law duty on researchers to disclose findings to their participants.⁴⁴ In *Grimes v. Kennedy Krieger Institute*, the Maryland Court of Appeals found that researchers had an obligation to share the results of their lead paint abatement research with participants.⁴⁵ While this case seems progressive on its face, the *Grimes* court emphasized that it based its holding on the contract that arises when a research participant engages in the informed-consent process.⁴⁶ In *Grimes*, the court faced a particularly egregious set of facts, finding that the researchers had violated the contractual relationship in multiple ways: the researchers told parents that the parents would be informed of all tests and findings in a timely manner, but they were not;⁴⁷ the Institutional Review Board, which was charged with protecting human subjects, aided the researchers in circumventing federal regulations that protect research subjects;⁴⁸ the researchers intentionally put children in homes where they knew that lead-based paint would be

38. *Id.*

39. *Id.* at 1074, 1076.

40. Levesque et al., *supra* note 24, at 589; Wolf et al., *supra* note 5, at 362.

41. Wolf et al., *supra* note 5, at 366–73.

42. See 45 C.F.R. §§ 46.101–.124 (2012).

43. Wolf et al., *supra* note 5, at 366.

44. *Id.* at 370.

45. *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 858 (Md. 2001).

46. *Id.*

47. *Id.* at 825.

48. *Id.* at 814.

present without informing the children's parents;⁴⁹ and the researchers intentionally withheld information from parents, specifically that their children's blood had increased levels of lead, which could have resulted in lead poisoning.⁵⁰

B. Physician Abandonment

A symbiotic relationship exists between researchers and the lay population. Researchers who undertake to expand the body of medical knowledge cannot achieve their goals without research participants who donate genetic material; and Americans want and expect researchers to make discoveries that will promote medical innovations. However, the current legal framework allows researchers to operate in a modern Wild West where they can buy, trade, or sell samples with no accountability to the donors who contributed the samples. To remedy this imbalance, researchers ought to owe a duty to sample donors to keep the donors informed of discoveries that have implications for the donors' health. A duty to disclose would likely need to be imposed by state legislatures or Congress, given the reluctance of courts to find a legally binding relationship between sample donors and researchers that is based in common law.⁵¹ This duty can be modeled after the common law duty a physician has to avoid abandoning her patients. Physician abandonment occurs when a physician (1) terminates the physician-patient relationship, (2) without reasonable notice or excuse, (3) at a time when the patient needs ongoing medical care, (4) which causes the patient to suffer an injury (5) that was the proximate cause of the physician's abandonment.⁵² More than thirty-five states and the District of Columbia have recognized, through statutory or common law, a physician's duty to refrain from abandoning her patients.⁵³

For a plaintiff patient to state a cause of action for physician abandonment, she must first show that a physician-patient relationship was established.⁵⁴ The physician-patient relationship is gov-

49. *Id.* at 824.

50. *Id.*

51. *Contra id.* at 858; *Blaz v. Michael Reese Hosp. Found.*, 74 F. Supp. 2d 803, 804 (N.D. Ill. 1999) (finding that a physician researcher had a duty to warn patients when he discovered that radiation treatments given to patients by a hospital were highly correlated with certain types of tumors).

52. C.T. Drechsler, Annotation, *Liability of Physician Who Abandons Case*, 57 A.L.R.2d 432 (1958).

53. *Id.*

54. *Id.*

erned by a fiduciary obligation—the physician should “focus[] exclusively on the patient’s health.”⁵⁵ In other words, the physician “commits to becoming and remaining scientifically and clinically competent, acts primarily to protect and promote the interests of the patient and keeps self-interest systematically secondary.”⁵⁶ Traditionally, a physician-patient relationship is formed upon mutual consent of the parties, although the specific requirements of this rule vary slightly from state to state.⁵⁷ In Georgia, for example, a physician-patient relationship is established when a “patient knowingly seeks the assistance of the physician and the physician knowingly accepts him as a patient.”⁵⁸ Michigan requires slightly more because it requires the physician to take affirmative action: “A physician-patient relationship exists where a doctor renders professional services to a person who has contracted for such services.”⁵⁹ Many state courts, including Illinois, Kansas, Oregon, and Texas, have found that a physician-patient relationship may be established even in situations when the physician has not personally met or examined the patient.⁶⁰

Once a plaintiff proves that a physician-patient relationship was established, she must show that the physician unilaterally severed their relationship.⁶¹ A physician severs the physician-patient relationship with an express or implied renunciation of the relationship, which can occur when a physician explicitly tells the patient that their relationship has ended.⁶² In *Norton v. Hamilton*, the Georgia Court of Appeals held that a cause of action for abandonment may proceed when a physician defendant “flatly refused to come to the plaintiff’s bedside” while she was in active labor.⁶³ Similarly, in *Gil-*

55. BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* 199 (6th ed. 2008).

56. *Id.* at 200 (quoting LAURENCE B. MCCULLOUGH, *A PRIMER ON BIOETHICS* 3 (2d ed. 2006)).

57. James L. Rigelhaupt, Jr., Annotation, *What Constitutes Physician-Patient Relationship for Malpractice Purposes*, 17 A.L.R.4TH 132 (1982).

58. *Crisp Reg’l Hosp., Inc. v. Oliver*, 621 S.E.2d 554, 560 (Ga. Ct. App. 2005) (quoting *Peace v. Weisman*, 368 S.E.2d 319, 320 (Ga. Ct. App. 1988) (internal quotation marks omitted)).

59. *Oja v. Kin*, 581 N.W.2d 739, 741 (Mich. Ct. App. 1998) (quoting *Hill ex rel. Burston v. Kokosky*, 463 N.W.2d 265, 266 (Mich. Ct. App. 1990) (internal quotation marks omitted)).

60. See, e.g., *Gillespie v. Univ. of Chi. Hosps.*, 900 N.E.2d 737, 740 (Ill. App. Ct. 2008) (“[A] physician-patient relationship may exist even in the absence of any meetings between the physician and the patient, where the physician performs services for the patient.”); *Irvin v. Smith*, 31 P.3d 934, 941 (Kan. 2001); *Mead v. Legacy Health Sys.*, 283 P.3d 904, 910 (Or. 2009) (en banc); *Lection v. Dyll*, 65 S.W.3d 696, 704 (Tex. App. 2001).

61. Drechsler, *supra* note 52.

62. *Id.*

63. *Norton v. Hamilton*, 89 S.E.2d 809, 810, 812 (Ga. Ct. App. 1955).

lette v. Tucker, the Ohio Supreme Court held that a physician had severed the physician-patient relationship when he became upset with a patient who had criticized his surgical skills, and stated to the patient: "Well, if that is the way you feel about it, . . . you can get right out of my office; I wouldn't do any more for you if I could."⁶⁴ A relationship may also be severed implicitly by a physician,⁶⁵ for example, by promising to visit a patient and failing to do so.⁶⁶

A plaintiff must also show that her physician abandoned her at a time when she needed ongoing medical care.⁶⁷ The quintessential examples of a patient needing ongoing care are during surgery, after she has undergone surgery, and while she is in labor.⁶⁸ In *Burnett v. Layman*, the Tennessee Supreme Court reversed a directed verdict for the defendant physician.⁶⁹ The physician in *Burnett* performed a procedure on his patient's bladder and, when he heard a "pop," the physician told the patient that he needed a surgeon and quickly left without any further communication.⁷⁰

A physician may also be liable for abandonment in cases where she prematurely discharges a patient.⁷¹ For example, in *Williams v. Bennett*, a physician discharged a patient who had developed a post-operative infection.⁷² The infection caused her severe pain, and her stomach had swollen to the point that she seemed to be in an "advanced stage of pregnancy."⁷³ In that case, the Supreme Court of Texas overturned a trial court's entry of judgment notwithstanding the verdict in favor of the physician defendant because it found that more than a scintilla of evidence existed to support the jury's verdict in favor of the plaintiff patient.⁷⁴

A physician may avoid liability for abandonment if she shows

64. *Gillette v. Tucker*, 65 N.E. 865, 868 (Ohio 1902) (internal quotation marks omitted), *overruled on other grounds by* *Oliver v. Kaiser Cmty. Health Found.*, 449 N.E.2d 438 (Ohio 1983). In *Gillette*, the physician that became defensive about his surgical abilities had actually left a cheesecloth sponge in the patient's body during surgery. *Id.*

65. Drechsler, *supra* note 52.

66. *See, e.g., Fortner v. Koch*, 261 N.W. 762, 764 (Mich. 1935); *Sinclair v. Brunson*, 180 N.W. 358, 360 (Mich. 1920).

67. Drechsler, *supra* note 52.

68. *Norton*, 89 S.E.2d at 810; *see also* *Lathrope v. Flood*, 63 P. 1007, 1007 (Cal. 1901), *rev'd on other grounds by* 67 P. 683, 684 (Cal. 1902) ("[T]he doctor said [to a woman in labor]: 'You quit your screaming. If you don't quit, I'll quit.'").

69. *Burnett v. Layman*, 181 S.W. 157, 158 (Tenn. 1915).

70. *Id.*

71. Drechsler, *supra* note 52.

72. *Williams v. Bennett*, 610 S.W.2d 144, 145-46 (Tex. 1980).

73. *Id.*

74. *Id.* at 145.

that she gave her patient reasonable notice that their relationship was being severed, or if she can show that the patient's injury was not the proximate cause of the abandonment.⁷⁵ First, notice insulates a physician from liability because it gives the patient enough time to find a new physician.⁷⁶ In California, a physician must give a patient "ample opportunity" to find a new physician.⁷⁷ In *Scripps Clinic v. Superior Court*, the California Court of Appeals held that a triable issue of fact existed as to whether two weeks constituted sufficient notice.⁷⁸ Second, the plaintiff must show that the physician's abandonment was the proximate cause of her injury.⁷⁹ Proximate cause in medical malpractice is usually proven through expert testimony,⁸⁰ and it is a highly fact-based inquiry. For example, the Supreme Court of Virginia found that proximate cause existed in *Vann v. Harden*, where a patient had fractured his leg and the physician who cast the leg refused to examine the cast after the patient complained that his toes had gone numb.⁸¹ Conversely, in *Jakelsky v. Friebling*, the United States District Court for the District of New Jersey granted a defendant physician's motion for summary judgment, where the plaintiff patient alleged that the physician's discharge of the plaintiff, who had Wilson's disease, had caused the plaintiff's injuries at work.⁸² The *Jakelsky* court held that such an allegation was too speculative to establish proximate cause.⁸³

75. Drechsler, *supra* note 52.

76. *See id.*

77. *Scripps Clinic v. Superior Court*, 108 Cal. App. 4th 917, 931 (Cal. Ct. App. 2003) (quoting *Payton v. Weaver*, 131 Cal. App. 3d 38, 45 (Cal. Ct. App. 1982) (internal quotation marks omitted)).

78. *Id.*

79. Drechsler, *supra* note 52.

80. *Johnson v. Vaughn*, 370 S.W.2d 591, 596 (Ky. 1963).

81. *Vann v. Harden*, 47 S.E.2d 314, 316-20 (Va. 1948).

82. *Jakelsky v. Friebling*, 33 F. Supp. 2d 359, 362 (D.N.J. 1999).

83. *Id.*

II. PHYSICIAN ABANDONMENT AS A MODEL FOR THE DUTY TO DISCLOSE

A. *The Researcher-Donor Relationship*

The researcher-donor relationship is not new; however, a duty to disclose research findings would allow the rules governing the researcher-donor relationship to extend to more relationships than are currently recognized and enforceable by the law. As described in Part I, the Maryland Court of Appeals has found that signing an informed consent form can create a legal relationship between a researcher and a research participant.⁸⁴ A contractually established relationship would certainly bind many researchers to their research participants. Informed consent is required by the Common Rule in the therapeutic research context,⁸⁵ and it can be mandated by state statute before a researcher or physician conducts genetic testing.⁸⁶

For a duty to disclose to have any teeth, however, the law must find a way to establish a researcher-donor relationship between researchers and donors who have not signed contracts. This group would encompass the many donors who are unaware that their tissues are being used for research purposes.⁸⁷ The most significant case on point is *Blaz v. Michael Reese Hospital Foundation*, in which the United States District Court for the Northern District of Illinois found that an enforceable contractual relationship existed between a physician researcher, who headed up a research program investigating potential harm to former patients, and the former patients.⁸⁸ The plaintiff in *Blaz* had been exposed to x-rays (a form of radiation) as a part of treatment for infected tonsils and adenoids.⁸⁹ The plaintiff was one of approximately 5000 patients who had received radiation at the defendant hospital over the course of thirty years.⁹⁰ The hospital set up a Thyroid Follow-Up Project to track whether these patients developed tumors.⁹¹ Even though the research project had otherwise contacted the plaintiff, the defendant physician-

84. *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 858 (Md. 2001).

85. 45 C.F.R. §§ 46.101-.124 (2012).

86. FLA. STAT. § 760.40 (2012).

87. *See supra* Part I.

88. *Blaz v. Michael Reese Hosp. Found.*, 74 F. Supp. 2d 803, 804 (N.D. Ill. 1999).

89. *Id.*

90. *Id.*

91. *Id.*

researcher, who headed that project, did not disclose to the plaintiff the high likelihood that he would develop tumors from the treatment.⁹² To determine whether a researcher-patient relationship existed, the *Blaz* court asked: (1) was the harm reasonably foreseeable, (2) what was the likelihood of injury, (3) what was the “magnitude of the burden of guarding against [that harm],” and (4) what were “the consequences of placing that burden upon the defendant.”⁹³ Finding that the risk of harm was reasonably foreseeable to any person (physician and layperson alike) and that the defendant physician-researcher would have shouldered a small burden by communicating the findings to the plaintiff, the *Blaz* court concluded that a special relationship existed between the parties.⁹⁴

This Note will adopt the four-factor test relied on in *Blaz* because it is an excellent way to determine whether a researcher-donor relationship exists, and it is a viable alternative to contract theories. The *Blaz* test, instead of relying on formulaic criteria, balances the needs of each party with the burdens that the party would face if a relationship did or did not exist. This balancing test encapsulates the fairness that donors believe they deserve while simultaneously establishing standards that will give researchers notice of their disclosure obligations. For example, it is easy to determine whether it is reasonably foreseeable that an individual would like to know that she has a significantly increased chance of developing cancer. Virtually anyone would want to have this information so she could map out a plan for prevention, detection, and treatment. Further, the *Blaz* test accounts for the burdens shouldered by the researcher and donor. A burden that is too large may excuse a researcher who breaches her duty to disclose, as discussed in Part II.B below.

B. How a Researcher Abandons a Donor

This section explores the researcher’s duty to disclose within the framework of the physician abandonment cause of action. Where the existing doctrine of physician abandonment and the theoretical duty to disclose diverge, the differences will be noted. As described above, physician abandonment occurs when a physician (1) terminates the physician-patient relationship, (2) without reasonable no-

92. *Id.*

93. *Id.* at 805 (quoting *Kokoyachuk v. Aeroquip Corp.*, 526 N.E.2d 607, 610 (Ill. App. Ct. 1988) and citing *United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947) (L. Hand, J.)).

94. *Id.* at 805-07.

tice or excuse, (3) at a time when the patient needs ongoing medical care, (4) which causes the patient to suffer an injury (5) that was the proximate cause of the physician's abandonment.⁹⁵ This section examines how each of these prongs would function in the research setting.⁹⁶ It concludes that a researcher would have breached her duty to disclose if she failed to contact a donor and tell her of a direct or incidental finding that was reasonably foreseeable to have serious implications for the donor's short-term or long-term health.

The first two prongs that must be satisfied for a plaintiff to state a cause of action for physician abandonment are that (1) the physician terminates the physician-patient relationship (2) without reasonable notice or excuse.⁹⁷ A researcher who had in her possession direct or incidental findings and failed to communicate these findings to the donor (or to the donor's physician) will have unilaterally terminated the researcher-donor relationship. Researchers can keep track of participants by creating a password-protected website where research participants provide their contact information and preferences about whether they would like to be contacted. However, a researcher would not be negligent *per se* if she failed to communicate with the donor; the duty would require making reasonable efforts to contact donors. Thus, a researcher may have a legally adequate excuse if she could not track down a donor after making reasonable efforts. Further, a researcher may also satisfy her duty to disclose if she tells donors that she has no findings that affect them.

The last three factors considered by a court are (3) whether the patient needed ongoing medical treatment and (4) whether the physician's abandonment was the proximate cause of an (5) injury the patient sustained.⁹⁸ In the context of genetic research, a genetic predisposition will exist until a patient dies—either from the disease or disorder to which he had a predisposition or from some other cause. In non-genetic research, a researcher could, for example, find that a patient has a tumor by looking at a CT scan, ultrasound, or MRI. Such a finding would also likely have implications for short-term or long-term health and would not likely go away on its own. Thus, in circumstances where a researcher finds a condition that likely has implications for the donor's health, the duty to disclose should be

95. Drechsler, *supra* note 52.

96. Giving a donor "notice" is less relevant in the research setting than giving a patient notice in the medical setting. Researchers should give donors notice if, for example, they have lost research funding prematurely and have not drawn any scientifically valid conclusions.

97. Drechsler, *supra* note 52.

98. *Id.*

triggered. In that vein, the causation element in a donor's suit against a researcher will likely be more attenuated than in a physician abandonment action. For example, it is clear that causation for an emotional distress suit exists in situations where a physician leaves his patient while she is in labor,⁹⁹ or where a doctor sets a cast too tightly and refuses to reexamine his work.¹⁰⁰ In the researcher-donor relationship context, however, it is unlikely that the researcher caused the donor's medical problem; instead, she was more likely a bystander. Thus, in cases where a researcher has information that has health implications for her donors, the duty to disclose should be assessed according to whether disclosure could have prevented or mitigated a future harm. In other words, a court should ask whether a researcher should have reasonably foreseen that a donor's malady would have a significant impact on the donor's short-term or long-term health. If so, then proximate cause is established because a donor would not likely know that she should seek further diagnostic tests, preventative examinations, or therapeutic treatments.

This Note advocates that researchers should disclose findings that are reasonably foreseeable to cause donors a significant health-impairment. It may be useful, however, to compare three different approaches that would require disclosure of different information¹⁰¹: (1) what the prudent patient would want to know; (2) conditions that, with reasonable certainty, will significantly impact the donor's health; and (3) a list of statutorily-prescribed ailments.

The prudent-patient standard is taken from the area of informed consent.¹⁰² Almost half of states mandate that during the informed consent process physicians disclose all potential side effects of a treatment, available alternative treatments, and potential risks of foregoing a course of treatment that a prudent patient would want to be told.¹⁰³ The standard helps the patient make an informed decision. In the research setting, if this standard were used to shape disclosure by researchers, it would require researchers to assess what a

99. *Lathrope v. Flood*, 63 P. 1007, 1007 (Cal. 1901), *rev'd on other grounds by* 67 P. 683 (Cal. 1902) ("[T]he doctor said [to a woman in labor]: 'You quit your screaming. If you don't quit, I'll quit.'").

100. *Vann v. Harden*, 47 S.E.2d 314, 316 (Va. 1948).

101. In situations where researchers are using de-identified samples, a researcher would satisfy her duty to disclose by informing the physician's office that sent the sample to the researcher. Then, it would be incumbent upon the physician to contact the sample's donor and relay the researcher's findings.

102. See, e.g., *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972).

103. FURROW ET AL., *supra* note 55, at 240.

reasonable person would want to know. An alternate standard, which is advocated in this Note, would require disclosure of findings that are reasonably foreseeable to cause a significant health-impairment. These two standards seem similar, so the following example about misattributed paternity aims to help differentiate them. Genetic researchers have reported discovering misattributed paternity in 10% of cases.¹⁰⁴ Would a prudent patient want to know this information about herself? Likely yes, because her genetic lineage may be material to her future medical care. But is misattributed paternity reasonably likely to cause a significant health-impairment? The answer would likely be in the negative, unless the donor inherited a genetic disease or predisposition.

Last, a list of statutorily-prescribed ailments would certainly be the most clear-cut way of setting out what researchers should disclose and would help researchers reduce potential litigation; such ailments could include tumors or a gene variant that raises one's cancer predisposition to be two-fold higher than the general population. However, most legislatures would likely have trouble keeping such a list up-to-date. Each of these standards is different, and it should be up to a legislature to weigh the benefits and burdens of each.

C. Preserving the Status Quo

The most prevalent argument for not imposing duties upon researchers comes from patent law: changing the status quo will stifle innovation. Advocates of patents argue that patents promote innovation by putting the inventor's information in the public domain while simultaneously rewarding the inventor with a limited monopoly that allows her to realize profits.¹⁰⁵ To disallow certain patents, the argument goes, would decrease innovation because the incentive for costly investments evaporates.¹⁰⁶ In the field of medical research, requiring researchers or physicians to track down donors would arguably stifle innovation because such a requirement would

104. Nina M. Schroder, *The Dilemma of Unintentional Discovery of Misattributed Paternity in Living Kidney Donors and Recipients*, 14 CURRENT OPINION ORGAN TRANSPLANTATION 196, 196 (2009).

105. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998) ("[T]he patent system . . . encourages both the creation and the public disclosure of new and useful advances in technology [T]he interest in motivating innovation and enlightenment by rewarding invention with patent protection . . . has been a feature of the federal patent laws since their inception.").

106. Stephen H. Schilling, *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents*, 61 DUKE L.J. 731, 733 (2011).

force researchers and physicians to use limited research funds on a burdensome administrative task. This argument has some merit—it would certainly cost money to contact and communicate with donors. However, a duty to disclose is not so burdensome that it would stifle innovation. Researchers would only need to contact donors whose short-term or long-term health may be jeopardized as a result of nondisclosure. This would likely be a small subset of any research project, even those that investigate deadly genes. For example, the Roberts group investigated CDKN2A, a gene that is very influential in the development of melanoma,¹⁰⁷ a highly lethal type of skin cancer that causes one death every hour in the United States.¹⁰⁸ Yet, even though each participant in the Roberts study had been diagnosed with melanoma, only 1.1% of the study's 663 participants actually had a CDKN2A mutation.¹⁰⁹ Because devastating genetic mutations are so rare, the relative burden of contacting donors will likely be modest for many researchers compared to the potential health and financial impact for the donors who do not receive early warnings.

Further, some may find it unappealing to subject researchers to a new avenue of tort liability for failure to communicate with sample donors, a practice which is likely out of the average researcher's area of expertise. Specifically, communicating direct or incidental findings to donors would likely be considered a form of "ancillary care" because it is not within the normal spectrum of care participants receive from a researcher. Ancillary care is defined as care that "goes beyond the requirements of scientific validity, safety, keeping promises, or rectifying injuries."¹¹⁰ Imposing an ancillary care requirement upon researchers could be plainly unfair if the researcher is open to tort liability in spite of her best efforts. For example, a researcher may make a mistake at any point throughout the research—retrieving a batch of de-identified samples, performing genetic tests on those samples, interpreting the results of the genetic tests, determining whether to inform certain donors of their genotypes¹¹¹—which leads to incorrect information, or none at all, being

107. Roberts, *supra* note 26, at 19.

108. AM. CANCER SOC'Y, CANCER FACTS & FIGURES 2010 (2010), available at <http://www.cancer.org/acs/groups/content/@nho/documents/document/acspc-024113.pdf>.

109. Roberts, *supra* note 26, at 22.

110. Henry S. Richardson & Leah Belsky, *The Ancillary-Care Responsibilities of Medical Researchers: An Ethical Framework for Thinking About the Clinical Care that Researchers Owe Their Subjects*, 34 HASTINGS CENTER REP. 25, 26 (2004).

111. A genotype is "all or part of the genetic constitution of an individual or group."

relayed to the donor. These concerns, although relevant, could almost certainly be addressed through the legislative process. Researchers and physicians will make some mistakes, but avoiding tort liability does not require perfection. In the medical malpractice realm, tort liability attaches when a physician has performed below the professional standard of care: "A physician . . . is required to provide his patients with that same degree of care, skill and diligence which would be provided by a minimally competent, reasonably prudent physician in the same general field of practice, under the same or similar circumstances" ¹¹² In short, physicians are not held to the highest standard of medical practice—they are held to a standard of minimal competence. Similarly, duty-to-disclose laws would not require a researcher to be perfect, but would instead require a good-faith effort to keep donors informed.

CONCLUSION

Researchers and physicians owe a duty to disclose research findings to the donors who make research in this country possible. Research is a substantial factor in spurring innovation and increasing our body of scientific and medical knowledge. However, as a society, we should not allow it to continue unbridled and unaccountable. Research is currently conducted at the expense of donors and participants—who may only learn of adverse health conditions once their lives have been impacted for the worse—and for the benefit of researchers, patent-holders, and future patients. To remedy that problem, this Note has proposed that researchers and physicians face tort liability for failing to disclose medical conditions or genetic predispositions that will have a significant impact on the donor's short-term or long-term health. The duty to disclose arises from the researcher-donor relationship and can be modeled after the common law tort of physician abandonment. It also fits with our ethical intuitions; the American public overwhelmingly thinks that when a person donates a piece of herself to researchers, and those researchers have drawn a medical conclusion about her, she should be entitled to that knowledge. This entitlement to reciprocity is echoed in the medical ethics literature. Researchers and physicians have been struggling with what is, and should be, owed to research partici-

Genotype Definition, MERRIAM-WEBSTER ONLINE, <http://www.merriam-webster.com/dictionary/genotype> (last visited Oct. 25, 2012).

112. FURROW ET AL., *supra* note 55, at 337 (quoting Mississippi jury instructions).

pants and donors. It is not enough to let researchers choose whether to disclose direct and incidental findings because recent history shows that, with few exceptions, researchers will take the easier route—publish their data and move on. It is also apparent that donors, who make research possible, are left footing the bill. A legislatively-imposed duty to disclose will reverse the modern trend in which some donors—those with medical problems such as in-born genetic predispositions or undiagnosed tumors—are left without the tools or knowledge to proactively prevent or treat their conditions.