

**A CONSTITUTIONAL RIGHT TO KNOW:  
ARE RESEARCH PARTICIPANTS ENTITLED TO RESULTS OF GENETIC  
TESTS?**

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I. INTRODUCTION

This Comment will explore the issue of incidental and future genetic research findings and the participant's right to receive such information in the context of constitutional law. It will attempt to answer the question: does a participant in a voluntary genetic study have a right of access to the results? Thus far, there has been no case law that establishes an answer to the question. Under First Amendment law, a tenuous "right to hear" doctrine has been described, but it refers primarily to citizens' right to absorb a diversity of opinions and gather relevant facts in a political and social context.<sup>1</sup> Similarly, the Fourth and Ninth Amendments are somewhat analogous to the question at hand, but prove ultimately unavailing.<sup>2</sup> A right to the results of genetic tests may, however, be derived from the Fourteenth Amendment. The Fourteenth Amendment provides that no person may be deprived of property without due process of law.<sup>3</sup> Is your genetic information your property? This is a question that has not yet been addressed by the courts and that this Comment will attempt to answer.

This Comment will examine claims that participants might have under several constitutional amendments and will analyze the validity of such claims. It will compare and contrast the issue at hand with the courts' treatment of seemingly analogous issues and examine possible frameworks that courts are likely to use in evaluating such a case were it to reach their dockets.

Ultimately, it will argue that there is a strong moral reason for courts to establish a new constitutional right, borne out of the Fourteenth

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1 *See* Thomas v. Collins, 323 U.S. 516, 534 (1945) (referring to a First Amendment right to hear information).

2 *See infra* Parts VII and VIII.

3 U.S. CONST. amend. XIV, § 1.

Amendment, that would guarantee research participants a right of access to the results upon request.

## II. CONTEXT: SCIENCE AND THE LAW

There has always been an important link between science and the law. Our legal system regulates the way scientific practice proceeds in this country in a variety of ways—through governmental agencies that directly regulate research practices (like the National Institutes of Health (“NIH”), the Food and Drug Administration (“FDA”), and analogous state agencies),<sup>4</sup> through case law, which shapes the future of research and determines which practices are legal and which may subject the researcher to liability,<sup>5</sup> and even through scholarship, which can comment on the law and its relation to science and predict foreseeable issues.<sup>6</sup> These two fields have always been somewhat at odds because the law, in many cases, seeks to prevent undesirable behavior before it happens. And science, by contrast, seeks to forge ahead and pave new ground as rapidly as possible. It is often the case that science plows ahead while the law seeks to regulate what has already been done. A commonly cited example comes from the ever-controversial field of stem cell research. When biologists discovered new ways of creating stem cells with incredible medical potential using human embryos, they forged ahead and broke new ground on the project,<sup>7</sup> while the law and policymakers worked to catch up and determine whether such practices were in fact desirable from a legal and ethical standpoint.

## III. SCIENTIFIC BACKGROUND: GENETIC RESEARCH

One of the most important and rapidly emerging areas of tension between science and the law is the field of genetic research. In some important ways, the law has barely scratched the surface of understanding and regulating genetics. DNA is the blueprint of biology. Each one of us has a code inside our cells that determines how we look, how our body functions, and which diseases we may develop. The code consists of hundreds of millions of base pairs, which are molecules that are “read” in order by our cells and translated into the proteins that make up our being.

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<sup>4</sup> See generally *Regulations*, U.S. DEP’T HEALTH & HUM. SERVICES, <http://www.hhs.gov/regulations/index.html> (last visited Jan. 21, 2013) (providing information on federal agencies and regulations related to scientific research practices).

<sup>5</sup> See *infra* note 43 and accompanying text.

<sup>6</sup> See *infra* notes 90, 92–98.

<sup>7</sup> See generally *Stem Cell Information: The National Institutes of Health resource for stem cell research*, NAT’L INSTS. HEALTH, <http://stemcells.nih.gov/info/basics/basics3.asp> (last visited Jan. 11, 2013).

Our genetic codes are each unique, yet humans have the vast majority of their base pairs in common. Small changes or mutations in base pairs can lead to differential production of proteins, which in turn can lead to both phenotypic changes, like blonde hair and blue eyes,<sup>8</sup> and functional changes, like differently shaped proteins which cause disease.<sup>9</sup> The entire human genome was only sequenced about ten years ago, so the extent of our knowledge about human genetics is limited and still in its infancy.<sup>10</sup> Scientists' knowledge about the genetic code is expanding rapidly, however. The field can only progress by widespread participation in research. Institutions compile mountains of data on people's genetic codes and medical conditions, and statisticians correlate it until they find links.<sup>11</sup>

The most common way to do this type of research today is by a method called single nucleotide polymorphism ("SNP") analysis.<sup>12</sup> Rather than analyzing every single one of the over 200 million base pairs of a person's DNA, SNP analysis condenses the information. An SNP is a single mutation or change in a base pair that makes a person unique from most other humans. Statisticians analyze common SNPs, match that data with medical conditions, and may, in such a way, determine that a particular SNP is associated with an increased risk for a particular disease.<sup>13</sup>

It was by this method that scientists discovered the BRCA1 and BRCA2 mutations, both SNPs that increase the risk of breast and ovarian cancer in women.<sup>14</sup> A BRCA SNP can increase a woman's lifetime risk of breast cancer

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8 See Wojciech Branicki et al., *Model-based prediction of human hair color using DNA variants*, 129 HUMAN GENETICS 443 (2011), available at [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3057002/pdf/439\\_2010\\_Article\\_939.pdf](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3057002/pdf/439_2010_Article_939.pdf).

9 *See How Can Gene Mutations Affect Health and Development?*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/handbook/mutationsanddisorders/mutationscausedisease> (last visited Feb. 18, 2013) (explaining how changing a gene's instruction for making a protein can cause a medication condition). Please note that this Comment refers to genetic testing throughout; however, it should be read to encompass genetic *and* genomic research, including whole genome sequencing research, which raise many of the same issues.

10 *About the Human Genome Project*, HUM. GENOME PROJECT INFO., [http://www.ornl.gov/sci/techresources/Human\\_Genome/project/about.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/project/about.shtml) (last visited Feb. 2, 2013).

11 See, e.g., Cashell E. Jaquish, Commentary, *The Framingham Heart Study, on its way to becoming the gold standard for Cardiovascular Genetic Epidemiology?*, 8 BMC MED. GENETICS 63 (2007), available at <http://www.biomedcentral.com/1471-2350/8/63> (discussing how quality protocols for genetic research assist researchers in analyzing large volumes of data).

12 *What are genome-wide association studies?*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/handbook/genomicresearch/gwastudies> (last visited Jan. 17, 2013).

13 *What are single nucleotide polymorphisms (SNPs)?*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/handbook/genomicresearch/snp> (last visited Jan. 17, 2013).

14 *Breast cancer*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/condition/breast-cancer> (last visited Jan. 17, 2013).

from approximately 12% to 60%, a five-fold increase.<sup>15</sup> Such a striking statistic effectively illustrates the power of certain SNPs to affect disease risk. It also helps to illustrate what a person might do with information about the results of genetic tests. A woman who learns that she carries a BRCA mutation would be advised to significantly increase the frequency of her breast cancer screening, leading to early detection of the cancer, and increased survival rates up to 93%.<sup>16</sup> Detection of the cancer in its later stages only results in about a 15% survival rate.<sup>17</sup> Early detection makes all the difference, and if more women were aware of their increased risk status, they would be much more proactive about screening and prophylactic measures.

SNPs like BRCA1 and BRCA2 serve to substantially alter the risk of certain diseases. But there are also a small handful of diseases for which there is an even clearer and more certain genetic link. A simple SNP analysis can determine whether a person will develop such a disease. Examples of such diseases are Huntington's,<sup>18</sup> cystic fibrosis,<sup>19</sup> and sickle cell anemia.<sup>20</sup> For these conditions, a person with a particular mutation is guaranteed to contract the disease.

#### IV. WHO PARTICIPATES IN GENETIC RESEARCH?

There are various kinds of people in the United States who might have a SNP analysis done on their DNA. The most common demographic of people are newborn babies. All fifty states have some type of newborn screening system in place,<sup>21</sup> and screening of many diseases is mandatory in most states.<sup>22</sup>

Screening newborns for genetic disorders is an effective way to determine whether a child already has a disorder or will develop one, and it makes treatment much easier. In most states, after the mandatory screening

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15 *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, NAT'L CANCER INST., <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA> (last visited Jan. 17, 2013).

16 *Breast cancer survival rates by stage*, AM. CANCER SOC'Y, <http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-survival-by-stage> (Jan. 17, 2013).

17 *Id.*

18 *Huntington disease*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/condition/huntington-disease> (last visited Jan. 17, 2013).

19 *Cystic fibrosis*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/condition/cystic-fibrosis> (last visited Jan. 17, 2013).

20 *Sickle cell disease*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/condition/sickle-cell-disease> (last visited Jan. 17, 2013).

21 *Newborn screening*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/nbs> (last visited Jan. 7, 2013).

22 In fact, all states have a minimum of twenty-one disorders that are mandatorily screened in newborns. *See id.*

is done and the results are returned to the parents, the genetic information about the child remains in the hands of the hospital, which may conduct future research using the DNA. It is worth noting that case law suggests that this type of future research use for DNA obtained for newborn screening purposes is perfectly acceptable; however, informed consent of the parents must be obtained for such future research purposes. The degree of information the parents receive about the type of future research to be conducted, though, is often minimal.<sup>23</sup>

It is important at this point to make a key distinction between genetic testing for clinical purposes versus research purposes. Clinical genetic testing happens when a doctor will actually use the results of a genetic test to determine the diagnosis or treatment for a patient. Newborn screening programs are an example of clinical genetic testing—the hospital collects the genetic information and uses it to determine whether a newborn has or is at risk for a particular disease. The parents are informed of the results of those tests, and the doctors use the information to help treat the children. In the case of clinical genetic testing, there is no issue of whether the patient has a right of access to the results: she always does. After newborn screening is over, however, hospitals retain the babies' genetic information and use it for future research. Once the information is taken out of the clinical arena, the patients no longer have access to the results. This is the question at the heart of this Comment. Genetic testing for research purposes can be either subsequent to clinical testing, as in the case of newborn screening, or completely separate from clinical testing, as some other examples will illustrate. The distinction between clinical and research settings is not only important for the purpose of this Comment, but it is also a key distinction that has distinct consequences for how data collected in either context is treated under the law. For example, while the Health Insurance Portability and Accountability Act ("HIPAA") regulates information in a clinical context, a federal agency regulation called the Common Rule regulates information in a research context.<sup>24</sup> The regulatory framework under which these data are governed dictates how they are treated, as well.

Another group of people who may have their DNA analyzed is people seeking genetic counseling and testing. This is an example of a purely

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<sup>23</sup> See *Bearder v. State*, 788 N.W.2d 144, 149 (Minn. Ct. App. 2010) *rev'd*, 806 N.W.2d 766 (Minn. 2011) ("[T]he health department pamphlet informs new parents that [a]ny bit of leftover blood (without baby's personal information) may be used for public health studies and research to improve screening and protect babies.") (internal quotation marks omitted).

<sup>24</sup> PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, PRIVACY AND PROGRESS IN WHOLE GENOME SEQUENCING 63 (2012), available at [http://bioethics.gov/cms/sites/default/files/PrivacyProgress508\\_1.pdf](http://bioethics.gov/cms/sites/default/files/PrivacyProgress508_1.pdf).

clinical genetic test. If a genetic disease is suspected based on family history or another factor, a pregnant woman or any adult may have a specific genetic test conducted. This type of test usually goes hand-in-hand with a counseling session conducted by a certified genetic counselor, who talks to the patient and helps her understand the potential consequences of getting the test done and walks her through the implications of the results.<sup>25</sup>

A third group of people who may have their genetic information analyzed is people who sign up for a direct-to-consumer genetic testing service, another form of clinical testing (although, admittedly, much different from the “clinical” context we normally associate with a doctor’s office, and, it should be noted, not governed by HIPAA). These services, like the most popular “23 and Me,” are usually websites that require a subscription fee. People send in saliva samples, and a lab analyzes their DNA for any known disease correlations and usually also conducts ancestry analysis and other kinds of analyses. The person views all of their information on the website, which is constantly updated when new science indicates a new DNA association.<sup>26</sup>

And finally, the last group of people likely to have their DNA analyzed is voluntary adult research participants. Adult genetic research can be gathered in two ways. First, genetic research can be conducted within the confines of a completely voluntary research study, such as the Framingham Heart Study.<sup>27</sup> These people are generally healthy and simply donate their time and information to the advancement of medical research. Second, genetic research can be conducted on people who have come into a hospital for a medical procedure such as a surgery, and who sign a consent form allowing the hospital to use their tissue or blood sample to conduct future research.

Both of these scenarios—genetic research as a part of a voluntary study and genetic research subsequent to a clinical encounter—will constitute the main focus of the questions posed in this Comment. In each scenario, the research participant has relinquished control of his DNA to the hospital or research institution, who will use it for large statistical genetic correlation research. However, in each scenario, the institution also possesses knowledge about the research participants that the individuals do not know, and may never otherwise learn. In the case of a mutation like BRCA, a person may always go out on their own and seek genetic testing and

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<sup>25</sup> *Genetic counseling*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/glossary=geneticcounseling> (last visited Jan. 7, 2013).

<sup>26</sup> KEVIN DAVIES, *THE \$1,000 GENOME: THE REVOLUTION IN DNA SEQUENCING AND THE NEW ERA OF PERSONALIZED MEDICINE* 32–33 (2010).

<sup>27</sup> *See generally* Nicolle Strand, *Genetic Notification at the Framingham Heart Study* (Apr. 2010) (unpublished undergraduate thesis, Wellesley College) (on file with author).

counseling, or use a service like “23 and Me” to determine whether they have the SNP; they do not technically *need* to derive the information from the research institution. However, such services cost money, and most people never believe that they have reason to use them. In addition, institutions will discover correlations in the course of research that are not widely tested for clinical purposes. In other words, the option may not exist for the participant to go out on his own and seek the information in a clinical setting. In such a case, the only chance of an individual learning whether he possesses such a mutation, and what it might mean, lies in the hands of the research institution. Whether such an individual deserves access to the results is the question at the heart of this issue.

## V. GENETICS AND OTHER LEGAL ISSUES

Genetic research is a potential minefield of legal issues. Federal and state legislatures have already anticipated some of the major legal hang-ups that genetic research will face. That is why, in 2008, Congress passed the Genetic Information Non-Discrimination Act (“GINA”), which ensures people’s privacy in the arena of genetic testing, and prohibits employers and health insurers from discriminating on the basis of genetic information.<sup>28</sup> In addition to GINA, many state legislatures have passed even more stringent privacy laws concerning genetic information.<sup>29</sup>

Privacy is of particular concern in the realm of genetic research, as common sense would suggest. As outlined above, genetic information can be obtained for either clinical or research purposes. But oftentimes, in a hospital setting, even information obtained for clinical purposes (that is, diagnosis and treatment, with the intent to reveal all pertinent information to the patient), may be used later for research purposes if the patient consents.<sup>30</sup> Common research practice is to de-identify the samples, and therefore conduct the research completely anonymously, once the information is outside of the clinical setting.<sup>31</sup> However, in the case of genetic research, de-identification can only go so far. Of course, if you are a scientist analyzing a person’s DNA, it is of the utmost importance to know where that DNA came from. The person’s sex, age, race, ethnicity, and all the details of their health status are key to analyzing the genetic information

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<sup>28</sup> Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 112 Stat. 881 (codified in scattered sections of 26, 29, and 42 U.S.C.).

<sup>29</sup> See PRIVACY AND PROGRESS IN WHOLE GENOME SEQUENCING, *supra* note 24, app. IV (summarizing the applicable laws of the fifty states).

<sup>30</sup> *How does genetic testing in a research setting differ from clinical genetic testing?*, GENETICS HOME REFERENCE (Jan. 7, 2013), <http://ghr.nlm.nih.gov/handbook/testing/researchtesting>.

<sup>31</sup> See, e.g., Daniel Levy et al., *Consent for Genetic Research in the Framingham Heart Study*, 152 AM. J. MED. GENETICS, Pt. A 1250, 1255 (2010).

and making correlations. So, while a person's name and social security number do not go along with his genetic information in a research setting, essentially everything else about him does.<sup>32</sup> This fact raises concerns about the privacy of genetic information, some of which have been anticipated by the law, others of which have not, but neither of which are the subject of this Comment.<sup>33</sup>

Other laws of a more generic quality may apply to genetic research as well. For example, informed consent is one of the tenets of ethical and legal research in this country, especially in an area as complicated and poorly understood as genetics.<sup>34</sup> In addition, basic laws about the confidentiality of medical information are also important to genetic research.<sup>35</sup> Again, these are important concerns that also lie at the intersection of genetics and the law, but they will not be the focus of this Comment.

## VI. ACCESS TO GENETIC RESEARCH RESULTS

But there is one important issue that the legal landscape has not yet addressed with regards to genetic testing—what happens to people's research results? In the case of newborn screening, for example, the results of that initial test are reported to the parents and to the newborn's physician in order to proceed appropriately with diagnosis and treatment. But once parents consent to the newborn's DNA being used for future research purposes, the information leaves the clinical arena. Any further information that is discovered about the baby will not be reported to the parents or to the physician. The baby and her family may never know that she has a genetic mutation predisposing her to a certain disease, even though someone, somewhere, possesses such information.<sup>36</sup> Common practice in almost every hospital and research institution around the country is *not* to report genetic research results to participants.<sup>37</sup>

This practice differs markedly from the disclosure of research results that are not genetic in nature. When competent adults volunteer for a research study, they understand that the tests being conducted are being used for research purposes, not clinical ones. They are informed that they need to

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<sup>32</sup> *Id.*

<sup>33</sup> See PRIVACY AND PROGRESS IN WHOLE GENOME SEQUENCING, *supra* note 24, at 64 (explaining why the de-identification of genetic information is not foolproof).

<sup>34</sup> Levy, *supra* note 31, at 1250.

<sup>35</sup> See *infra* note 93.

<sup>36</sup> See Kenneth D. Mandl, *Newborn Screening Program Practices in the United States: Notification, Research, and Consent*, 109 PEDIATRICS 269 (2002) (finding that only some states report results to parents).

<sup>37</sup> See Karen J. Maschke, *Biobanks: DNA and Research*, in FROM BIRTH TO DEATH AND BENCH TO CLINIC: THE HASTINGS CENTER BIOETHICS BRIEFING BOOK FOR JOURNALISTS, POLICYMAKERS, AND CAMPAIGNS 11, 13 (Mary Crowley ed., 2008).



continue seeing a regular doctor, and that the diagnostic procedures taking place in the research laboratory are not meant to replace their annual check-ups. However, it is unquestionably the common practice of ethical research institutions to report clinically significant research results to participants when they are discovered.<sup>38</sup> It is undeniably unethical, for example, for researchers to withhold information about a participants' high blood pressure or high cholesterol—or, in the case of a magnetic resonance imaging (“MRI”) study, undeniably unethical for a researcher not to disclose an abnormal radiological finding. Why, then, is the common practice in the case of genetic information so markedly different? If a researcher knows that a participant has the BRCA1 gene, predisposing her to breast cancer, there is no institution in this country that would report this result to the participant.

One could examine thoroughly the ethical dimensions of this fascinating fact. This Comment, though, will focus on the legal dimensions, particularly those deriving from constitutional law. Specifically: if a participant seeks access to her genetic research results, does she have a constitutional right to receive them?

Under what authority is constitutional law implicated? A significant percent of scientific research in this country occurs by government grant.<sup>39</sup> One of the largest DNA databanks in the world is maintained by the NIH.<sup>40</sup> In other words, when a person in this country participates in a genetic research study, the government subsequently possesses her genetic research results, and almost always withholds participant notification of them. Therefore, in most cases, it is the *state itself* against which a research participant would bring a lawsuit for right of access to research results. No court, federal or state, has yet addressed the issue of a right of access to research results that are solely genetic in nature.<sup>41</sup> This Comment will examine the various arguments that a plaintiff might use in order to assert this right of access. It will assess the relative strengths or weaknesses of these constitutional claims, examine the likely framework courts would use to analyze such a case were it to reach a court's docket, and ultimately decide whether there *should* be a recognized constitutional right of access.

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<sup>38</sup> See Strand, *supra* note 27, at 38.

<sup>39</sup> Hamilton Moses III, et al., *Financial Anatomy of Biomedical Research*, 294 J. AM. MED. ASS'N 1333 (2005).

<sup>40</sup> Jocelyn Kaiser, *NIH Unperturbed by New Way of Peering Into Personal Genomic Data*, SCIENCEINSIDER (Apr. 10, 2012, 5:09 PM) <http://news.sciencemag.org/scienceinsider/2012/04/nih-unperturbed-by-new-way.html>; *dbGaP*, NAT'L CENTER BIOTECHNOGY INFO., <http://www.ncbi.nlm.nih.gov/gap> (last visited Jan. 17, 2013).

<sup>41</sup> Matthew P. Gordon, *A Legal Duty to Disclose Individual Research Findings to Research Subjects?*, 64 FOOD & DRUG L.J. 225, 233 (2009). At the time of publication, the Author was unable to find any cases that directly addressed the issue.

## VII. FIRST AMENDMENT ANALYSIS

The First Amendment of the U.S. Constitution primarily protects the freedom of speech.<sup>42</sup> It may seem counterintuitive that access to genetically based research results would have anything to do with the freedom of speech. But, while the majority of the courts' jurisprudence has focused on the speaker's right to speak, there is a distinct minority of jurisprudence that describes certain instances in which there is, instead, a listener's right to hear.<sup>43</sup> Can the loosely defined "right to hear" doctrine be applied to this particular situation regarding disclosure of research results?

There are several cases in which plaintiffs have sought access to medical records under the First Amendment "right to hear" doctrine.<sup>44</sup> The primary case in which a federal court considered this analysis in the medical context is *Gotkin v. Miller*.<sup>45</sup> In *Gotkin*, the plaintiff wished to seize her mental health records from various state hospitals at which she had been a patient.<sup>46</sup> The plaintiff and her husband were writing a book documenting the plaintiff's experience with the mental health care system, and wanted access to the records in order to verify certain details for the book.<sup>47</sup> The court entertained the plaintiff's claims on several constitutional bases—one of which was the First Amendment right to receive or hear information and ideas. The court explained that the right to receive information is a "necessary corollary" to the basic right of free speech.<sup>48</sup> For example, in *Thomas v. Collins*, the Supreme Court explicitly stated that, in the case of labor organizers, requiring registration before recruitment was unconstitutional *both* because of the organizers' right to free speech *and* because of the workers' right to receive the information.<sup>49</sup> But the court in *Gotkin* explained that most of the "vitality and justification" for the court's "right to hear" jurisprudence comes from circumstances in which the information or ideas implicated are of public importance.<sup>50</sup> In fact, the court cited a law review article which explains, more clearly than the *Thomas* Court had, that the "right to hear" is only recognized when the following conditions are met: (1) the issue to be discussed surrounds a public figure

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42 U.S. CONST. amend. I.

43 *See, e.g.*, *Thomas v. Collins*, 323 U.S. 516, 534 (1945).

44 *See, e.g.*, *Gotkin v. Miller*, 379 F. Supp. 859, 862–63 (E.D.N.Y. 1974) (describing situations where the "right to hear" has been recognized); *Ramirez v. Delcore*, No. C-07-48, 2007 WL 2142293, at \*7 (S.D. Tex. July 25, 2007) (denying a due process claim regarding access to medical records).

45 *Gotkin*, 379 F. Supp. at 859.

46 *Id.* at 861.

47 *Id.*

48 *Id.* at 862–63.

49 *See Thomas v. Collins*, 323 U.S. 516, 534 (1945).

50 *Gotkin*, 379 F. Supp. at 863.

or has a larger social importance, (2) the speaker wants to be heard, and (3) the listeners are not *forced* to listen—they may ignore or walk away from the speaker.<sup>51</sup> Interestingly, the court in *Gotkin* ended the analysis there, without explicitly discussing each of the three requirements for the triggering of the “right to hear” doctrine and why they are not met in this case. Within the context of *Gotkin*, the larger issue is whether or not a former mental patient should have access to medical records made about him. It seems clear that at least the third condition listed above is met in that context. The listener may choose to request medical records about himself, or not. This ability to control whether he has access to the records is tantamount to the ability to ignore the information. And, while in *Gotkin* itself, the state hospitals did not wish to share the records with the plaintiff, it is conceivable that a hospital would desire to share the records, but that a state or local policy would prohibit it from doing so. This would amount to a fulfillment of the second condition. And finally, it is not entirely clear that there is no justification for fulfillment of the first condition. While a person may seek access to his records simply for personal use and review, in this case, the plaintiff sought access in order to publish a book that explained the experience of a mental patient and the inner workings of the mental health system. It is at least arguable that a record used for such a purpose *does* in fact have a larger public social value. It is interesting that the court simply rejects the argument under the “right to hear” doctrine without more systematically analyzing it.

The issue of disclosure of genetic research results is very similar to the disclosure of mental hospital medical records. Genetic research results and mental health records are both confidential in nature and concern a primarily private matter. Both are relatively sensitive in nature, in a way that perhaps a normal hospital admittance medical record might not be. In addition, both are conceivably of much greater value to the person seeking the information than a normal hospital admittance record would be. A person who visits the doctor’s office for a certain kind of pain, for example, is usually perfectly coherent when the doctor examines him, asks him questions about the nature and duration of the pain, and explains to him the potential diagnoses and treatment options. The medical records that detail the doctor’s thought process as his examination is occurring are likely to match up quite well with the patient’s own recollection of what occurred. As a result, access to those records has relatively low value. But a patient who is admitted to a mental hospital may be in such a state as to be practically unaware of the doctors’ examinations and procedures. Similarly,

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<sup>51</sup> *Id.* (citing John M. Steel, Comment, *Freedom to Hear: A Political Justification of the First Amendment*, 46 WASH. L. REV. 311, 340–41 (1971)).

the results of a genetic test are completely unknown to the patient or research participant, absent disclosure. For people seeking access to information, genetic research results and mental health patient records are both of high potential value for the seeker.

Ultimately, while the issues of access to mental health records and access to genetic research results are quite similar in nature, it is likely that those who seek disclosure of their genetic research results would lose a claim under the First Amendment. In a predictive sense, as the district court made clear in *Gotkin*, courts are not likely to take these types of claims seriously.<sup>52</sup> The “right to hear” doctrine is extremely limited and not likely to be expanded to something such as this, where the matter at hand seems so inherently private. And, in an ethical sense, it is not clear that the values underpinning the First Amendment are truly implicated in cases such as these. Primarily, the First Amendment protects a person’s right to speak—to disseminate information and ideas at will.<sup>53</sup> Although there is no hard data to quantify such a claim, experience and the general attitudes of scientists and doctors make it doubtful that many geneticists wish that they could disclose any research results to participants at all. In fact, a working group of the National Heart Lung and Blood Institute, a subset of the NIH, proposed a very specific set of characteristics of a genetic mutation that would maximize the benefit and minimize the harm of notifying the participant.<sup>54</sup> Very few SNPs currently meet this criteria. If the researchers themselves do not believe that dissemination of such information is of public value, then one might argue that the First Amendment is not implicated at all. A corollary issue is the right *not* to know. It may not be of great significance to the focus of this Comment, but it should be noted that case law in the health sciences arena has recognized that a person may competently waive his right to know, and should be given such an option.<sup>55</sup> The right not to know, although not explicitly derived from the First Amendment, appears to be stronger than any notion of the right to hear or receive information.

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<sup>52</sup> *Gotkin*, 379 F. Supp at 868–69.

<sup>53</sup> U.S. CONST. amend. I.

<sup>54</sup> See generally Ebony B. Bookman et al., *Reporting Genetic Results in Research Studies: Summary and Recommendations of an NHLBI Working Group*, 140 AM. J. MED. GENETICS 1033, part A (2006) (explaining that there are certain criteria that make a particular genetic mutation notifiable and that such stringent criteria are rarely met).

<sup>55</sup> See *Laskowitz v. CIBA Vision Corp.*, 632 N.Y.S.2d 845, 847 (N.Y. App. Div. 1995). A constitutional right to receive the results of genetic tests would not preclude participants who did not wish to learn their results from exercising their right not to know.

## VIII. FOURTH AMENDMENT ANALYSIS

The Fourth Amendment stands for the proposition that a person may not be subject to an unreasonable search or seizure of his property or person.<sup>56</sup> Although a federal court of appeals case does indicate that obtaining blood for the purposes of DNA testing may constitute a search, which implicates the Fourth Amendment,<sup>57</sup> cases involving patients' right of access to medical records dismiss claims arising from search and seizure grounds.<sup>58</sup> The court in *Gotkin*, for example, summarily dismisses the plaintiff's Fourth Amendment claim on two grounds.<sup>59</sup> First, a hospital's retention of medical records is not a seizure because searches and seizures have been defined primarily in the criminal context, and because the hospital itself created the records, so it has not technically "seized" anything from the patient. And second, even if it were defined as a seizure, it is not unreasonable.<sup>60</sup> The court was correct—even if it could be argued that refusal to release the records was itself a seizure, it is surely a reasonable one. But the court ends the analysis here, without explaining why exactly this kind of seizure could never be considered unreasonable. In the Fourth Amendment criminal context, searches and seizures become reasonable if the government has a warrant and probable cause.<sup>61</sup> In this kind of civil context, it could be argued that the counterpart to probable cause is consent. A patient entering a hospital implicitly consents to a record being drafted that documents his visit. Similarly, a research participant *explicitly* consents to his DNA being tested when he signs a consent form. This consent clearly renders the retention of the information about the patient or participant not unreasonable. Ultimately, given the fact that the information that is the result of a genetic test is generated by the laboratory, not directly "seized" from the participant, and the fact that protections like informed consent are in place which give researchers the ethical and legal right to use the information, a right of access claim is not likely to succeed on Fourth Amendment grounds.

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<sup>56</sup> U.S. CONST. amend. IV.

<sup>57</sup> *See* *Nicholas v. Goord*, 430 F.3d 652, 658 (2d Cir. 2005) (holding that the Fourth Amendment applies to DNA testing and rejecting the district court's suggestion that there is no reasonable expectation of privacy in a person's DNA).

<sup>58</sup> *See, e.g.,* *Ramirez v. Delcore*, 267 F. App'x 335, 335 (5th Cir. 2008) (holding that the defendant-prisoner has no "state-created interest in obtaining his medical records"); *Gotkin v. Miller*, 379 F. Supp. 859 (E.D.N.Y. 1974).

<sup>59</sup> *Gotkin*, 379 F. Supp. at 863.

<sup>60</sup> *Id.*

<sup>61</sup> Erin Murphy, *Relative Doubt: Familial Searches of DNA Databases*, 109 MICH. L. REV. 291, 314 (2010).

## IX. NINTH AMENDMENT ANALYSIS

The Ninth Amendment, which simply states that: “The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people,”<sup>62</sup> has been interpreted differently in different contexts. In the famous case *Griswold v. Connecticut*, Justice Goldberg’s concurring opinion refers to a right, derived from the Ninth Amendment, to a zone of privacy within one’s house and home.<sup>63</sup> This Ninth Amendment right to privacy has developed further since that time. Plaintiffs in right of access to medical records cases sometimes bring claims under the Ninth Amendment, but never to any avail. In *Gotkin*, the court summarily dismissed the Ninth Amendment right to privacy claim as “patently without merit” and, in fact, pointed out that the very right sought to be protected by the Ninth Amendment was in danger of being violated by the release of medical records to the plaintiffs.<sup>64</sup> Similarly, in the case of research studies, a participant’s claim of access to genetic research results would be wholly unaided by a Ninth Amendment right to privacy argument, simply because, while privacy issues may be implicated in genetic research as a whole, it is not a concept of *privacy* from which a participant could derive a right to access his own information.

However, the right to privacy is still extremely important in analyzing issues of genetic information. One of the remarkable and unique things about genetic information is that its scope reaches beyond the individual patient in a way that other medical data does not. The high blood pressure of one man *may* suggest an increased risk of high blood pressure for his brother, or his son.<sup>65</sup> But this slightly increased risk or implication is practically nil and rarely discussed. It would *never*, for example, be argued that a person should not be told that he has high blood pressure because doing so also implicates the privacy of his brother.<sup>66</sup> In the case of genetic information, however, the presence of a certain genetic mutation can, in some instances, amount to a guarantee that a man’s sibling or son has the same mutation. At the very least, the presence of a genetic mutation *significantly* increases the risk of the same mutation existing in family

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<sup>62</sup> U.S. CONST. amend. IX.

<sup>63</sup> *Griswold v. Connecticut*, 381 U.S. 479, 495 (1965) (Goldberg, J., concurring) (describing the “marital relation and marital home” as a “particularly important and sensitive area of privacy”).

<sup>64</sup> *Gotkin*, 379 F. Supp. at 863.

<sup>65</sup> See Camila M. de Oliveira et al., *Heritability of cardiovascular risk factors in a Brazilian population: Baependi Heart Study*, 9 BMC MED. GENETICS art. 32 (2008) (asserting that the data collected from their sample of the Brazilian population provides evidence that a large proportion of cardiovascular risk factors are explained by genetic factors).

<sup>66</sup> See e.g., Strand, *supra* note 27, at 38.

members' DNA.<sup>67</sup> And so, naturally, the disclosure of a genetic research result to a participant *does* implicate the privacy of his family members. Here is where the Ninth Amendment is relevant to the issue at hand.

There is another issue that mirrors the concern for privacy of family members in genetic research—familial database searches for criminal offenses. When a person is convicted of a crime, in many states his blood sample may be banked for better identification in the case of any future crimes. If forensic evidence is subsequently discovered at a crime scene, the police department may obtain DNA from the evidence and scan it against the databank to identify the offender. More controversially, however, several states allow a familial databank search as well. In other words, not only may the DNA from the crime scene be used to identify the offender in the database, it may also be compared with the DNA of convicts to determine whether the offender is *related* to a previously convicted felon.<sup>68</sup> A *Michigan Law Review* article argues that this familial searching violates the privacy of the family members who did not consent to this search.<sup>69</sup> Similar to the case at issue in this Comment, the unique and powerful, heritable aspects of genetic information put the privacy of family members at the forefront of ethical and legal concern.

Although this Comment will not discuss it at length, the crux of the issue becomes not whether the Ninth Amendment right to privacy may afford research participants an avenue to pursue right of access claims, but whether it *precludes* potential plaintiffs' right of access claims because of concerns about violating family members' privacy.<sup>70</sup>

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67 *If a genetic disorder runs in my family, what are the chances that my children will have the condition?*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/handbook/inheritance/riskassessment> (last visited Jan. 17, 2013).

68 Murphy, *supra* note 61, at 292.

69 *See id.* at 338.

70 The analysis is one for a different article. But a quick look indicates that, were the Ninth Amendment to preclude a right of access to genetic research results, implications in other arenas would be widespread and negative. It is an unremarkable and predictable feature of family members that they often have certain commonalities. In the health arena, it would be absurd to suggest that a doctor should consider a family member's privacy in diagnosing a patient with a disease that has a heritable element. In the financial arena, it would be equally absurd to suggest that a bank should withhold information about a couple's credit score for determining mortgage status, because doing so would reveal to one spouse the financial habits of the other. In reality, although family members' privacy rights are implicated when considering disclosure of genetic research results, those concerns are probably not strong enough to completely preclude a claim of right of access.

## X. FOURTEENTH AMENDMENT CLAIM

For the First, Fourth, and Ninth Amendment claims, access to medical records cases have been used as a barometer in this analysis for determining the validity of each type of claim with regard to genetic research results. The courts in the medical records cases have taken the Fourteenth Amendment claims most seriously of all the asserted constitutional causes of action.<sup>71</sup> In addition, the true value underpinning the Fourteenth Amendment is implicated in asserting a right of access to genetic research results, in a way that the values of the three amendments considered above are not. The Due Process Clause of the Fourteenth Amendment is stated in the following terms: “. . . nor shall any State deprive any person of life, liberty, or property, without due process of law . . . .”<sup>72</sup> The piece that is important to the instant case is the deprivation of property. In failing to disclose genetic research results to participants, is the state depriving citizens of their property without due process of law? The answer depends on two distinct factors. First, can genetic test results be considered property, and if so, are they truly the property of the person from whom the specimen was derived? And second, in refusing to disclose those results, is the state depriving the citizen of property without due process of law?<sup>73</sup>

### A. *Property Interest*

Whether or not a person has a property interest in something is a legal matter determined not by the Constitution, but by relevant state and local law.<sup>74</sup> Cases like *Moore v. Regents* have conclusively determined that no property interest exists in profits made from excised bodily tissues.<sup>75</sup> In that case, the plaintiff was treated at a University of California hospital for a rare disease, and his cells were excised and patented by researchers. The researchers made a profit from the patent, and the plaintiff Moore sought to claim those profits as his property. The California court rejected his claim.<sup>76</sup> The situation at issue in this Comment is quite distinct from the issue in *Moore*. In the case of genetic research results, participants are not requesting compensation for profits made from any scientific or medical advancement that derive from research on their DNA. Rather, they are simply requesting the test results themselves. While it cannot logically be argued that the

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<sup>71</sup> See, e.g., *Gotkin v. Miller*, 379 F. Supp. 859, 864–68 (E.D.N.Y. 1974).

<sup>72</sup> U.S. CONST. amend. XIV, § 1.

<sup>73</sup> See *Allen v. Egan*, 303 F. Supp. 2d 71, 76 (D. Conn. 2004) (analyzing deprivation of property as a due process violation).

<sup>74</sup> *Id.* at 77.

<sup>75</sup> See *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990).

<sup>76</sup> *Id.* at 492.



blood or saliva sample or the purified DNA itself is not the property of the person from whom it is derived, the test results are a product of the bare material *plus* some degree of effort and laboratory technique and technology on the part of another person or people. And the “property” in question is not a tangible object, but rather information in the form of either spoken or written words. Federal courts have held that Fourteenth Amendment property interests can be asserted over intangible property,<sup>77</sup> so the fact that the property in question is intangible is not dispositive here. Absent any state or local law to explicitly define it as such, it is unclear whether genetic test results are the property of the person to whom they pertain.

However, in several cases, there *is* relevant state or local law to provide the answers. At least three U.S. states have explicit statutes that state that genetic information is the property of the person from whom it is derived. Georgia’s law states that “[g]enetic information is the unique property of the individual tested.”<sup>78</sup> Colorado’s laws state that “[g]enetic information is the unique property of the individual to whom the information pertains.”<sup>79</sup> Louisiana’s laws say that “[a]n insured or enrollee’s genetic information is the property of the insured or enrollee.”<sup>80</sup> And a bill recently introduced in Massachusetts states that genetic information is “the exclusive property of the individual from whom the information is obtained.”<sup>81</sup> It would be difficult to argue, were a right of access to genetic research results claim brought in either Georgia, Colorado, or Louisiana, that the Fourteenth Amendment right to due process upon deprivation of property was not implicated. Property rights derive from state law, and these laws set out clearly and explicitly both that genetic information is property, and that it belongs to the tested individual.

There is one case that an opponent of right to access might use to refute the clear property interest asserted by the laws of these three states: *Washington University v. Catalona*.<sup>82</sup> In *Washington*, the court of appeals confronted the issue of whether donors of biospecimens “retain an ownership interest allowing the individuals to direct or authorize the transfer of such materials to a third party.”<sup>83</sup> The court’s answer was no.<sup>84</sup>

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77 See, e.g., *Davila Lopes v. Soler-Zapata*, 916 F. Supp. 118, 119–20 (D.P.R. 1996).

78 GA. CODE ANN. § 33-54-1 (2005).

79 COLO. REV. STAT. ANN. § 10-3-1104.7 (West 1994).

80 LA. REV. STAT. ANN. § 22:1023 (1997).

81 Press Release, Forum on Genetic Equity, Landmark Genetic Privacy Bill Introduced on Beacon Hill (2011), available at <http://www.councilforresponsiblegenetics.org/pageDocuments/516QWJYJTE.pdf>.

82 *Wash. Univ. v. Catalona*, 490 F.3d 667 (8th Cir. 2007).

83 *Id.* at 673.

84 *Id.* at 676–77.

This case constitutes compelling evidence that courts are reluctant to assign a property interest in biological tissues or in the products derived from them. Of course, the situation in the instant case is quite different, as the property right being asserted is over information rather than the biological tissue itself. Nonetheless, *Washington* and cases like it represent the greatest threat to assigning property rights in genetic information for the purposes of Fourteenth Amendment analysis.

In New Jersey, the legislature attempted to pass a law similar to the statutes of Georgia, Louisiana, and Colorado, but the Governor vetoed it.<sup>85</sup> The Governor wrote a lengthy conditional veto message, which explained the consequences of creating a property right in genetic information.<sup>86</sup> The Governor wrote that the establishment of a new property right in genetic information would amount to a major shift from current practice, and that it would have chilling effects on research practices.<sup>87</sup> She enumerated two primary concerns. First, she expressed worry over the potential litigation that would ensue when participants sought royalties or compensation for any profits derived from research on their DNA.<sup>88</sup> And second, she worried that “creating a property right would impose a de facto requirement that researchers notify anyone whose genetic information was used or is intended to be used in the course of research.”<sup>89</sup> Current practice dictates that when a person donates her DNA to research, the researchers store it in a biobank, like the NIH database, dbGap. Subsequently, any researcher who requests access may use the information in the biobank for his or her own study.<sup>90</sup> The Governor of New Jersey, in vetoing a bill to make genetic information the property of the donor, feared that every time a researcher wanted to use the data in the biobank, the participant would have to be notified. This is a strange and unfounded concern. There exists a well-developed system of informed consent in all research, particularly genetic. When a participant donates DNA to a biobank, the informed consent appropriately notifies the participant of the context and types of research that her DNA may assist. Because of the role of waiver and consent in the process, even if the information were considered property of the person who donated the specimen, such a designation would not preclude its unrestricted use for any of the projects that the participant was informed might be taking place. In

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85 Letter from Gov. Christine Todd Whitman to N.J. Senate (Sept. 19, 1996) (on file with N.J. Office of Legis. Servs.).

86 *Id.*

87 *Id.* at 2.

88 *Id.* at 2–3.

89 *Id.* at 3.

90 Maschke, *supra* note 37, at 11–12; dbGaP: *GENOTYPES and PHENOTYPES*, NAT’L CENTER BIOTECHNOLOGY INFO., <http://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/about.html> (last visited Feb. 3, 2013).

fact, a designation of genetic information as property affords its owner much greater control over its use in various contexts.<sup>91</sup>

So is there any merit to the New Jersey Governor's argument? Since only a handful of states have considered making a law that would designate genetic information as property, it can be safely assumed that doing so is not a popular concept. Perhaps legislatures in other states have concerns similar to the concerns expressed in New Jersey. However, the consequence with the greatest potential impact would be the implications for Fourteenth Amendment due process rights. If the information is the property of the participant, then the participant should be able to ask for it back.<sup>92</sup> Currently, federal regulation requires participants be given the opportunity to withdraw consent and remove their DNA and information from a biobank at any time.<sup>93</sup> But while withdrawing the information deprives the institution of the property, it does not, strictly speaking, *return* the property to its owner.

Scholars have weighed in as well on whether genetic information should be considered property. For example, Catherine Valerio Barrad describes the various common law elements of a property interest and explains that genetic information in fact shares each of these elements.<sup>94</sup> Catherine Valerio Barrad is one author, among others, who describes the features of property ownership, including exclusive possession, control over use, alienability and devisability.<sup>95</sup> She goes on to explain how, at one point or another, the person to whom the genetic information pertains does enjoy all of these rights in it, thus fitting into the common law picture of property ownership. In addition, she uses the *Restatement of Property* and its description of various types of property ownership to assert that genetic information fits the definition of property as it was formally understood.<sup>96</sup> Jeffery Lawrence Weeden, in another article on the subject, appeals to a moral sensibility, rather than a legal one, in asserting that genetic information should be considered property.<sup>97</sup> He describes the potential

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91 See N.H. REV. STAT. ANN. § 332-I:1 (2011) (providing that, in New Hampshire, individuals have a property interest in the information in their medical records and are thus entitled to that information upon request).

92 See Catherine M. Valerio Barrad, *Genetic Information and Property Theory*, 87 NW. U. L. REV. 1037, 1058–59, 1086 (1993) (arguing for the recognition of protectable property interests in genetic information).

93 *Informed Consent Elements Tailored to Genomics Research*, NAT'L HUM. GENOME RES. INST., <http://www.genome.gov/27026589> (last updated May 19, 2012).

94 Barrad, *supra* note 92, at 1040.

95 *Id.* at 1049.

96 *Id.* at 1053.

97 See Jeffery Lawrence Weeden, *Genetic Liberty, Genetic Property: Protecting Genetic Information*, 4 AVE MARIA L. REV. 611, 616 (2006) (arguing that recognition of genetic information as protectable property “would exclude others from taking, using, receiving, selling, or

pitfalls and abuses of the recent explosion in scientific knowledge about genetic information, and explains that an individual's liberty with regards to his DNA is best protected *not* under a privacy regime, but under a property regime.<sup>98</sup> The author argues that privacy law is an ever-changing and unstable force, and that property law by contrast is rigid and well-established. Therefore, he claims, categorizing genetic information as property affords citizens greater protection under the law.<sup>99</sup>

By contrast, Professor Sonia Suter argues that the privacy regime is perfectly adequate to protect genetic research participants, and that moving to a property regime strips the medical research process of its tenets of trust and affords it instead a sense of commodification and disaggregation.<sup>100</sup>

For the purposes of this Comment, the analysis will proceed assuming that the right of access claim to genetic research is being asserted in either Louisiana, Colorado, or Georgia. Genetic information being considered property is not enough for a plaintiff to prevail. A court would further continue to the due process analysis.

### *B. Deprivation Without Due Process*

If there is an established property right in genetic information, what process is due to a research participant who requests that information? Due process analysis has been conducted differently by different courts, and is largely a subjective evaluation that depends on how important and fundamental the right is that has been deprived.<sup>101</sup> Is informed consent itself enough "due process" to deprive the participant of her own property?

What is clear is that the right being sought is extremely important. A right of control over your own being, bodily integrity, and autonomy is a right that has been enumerated in many court cases throughout different types of disciplines and issues.<sup>102</sup> Access to information about your genetic code is not as directly related to bodily integrity as some other concerns, particularly control over medical treatment and procedures. But, notably,

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otherwise misusing an individual's genetic information without the express consent of the owner").

<sup>98</sup> *Id.* at 617.

<sup>99</sup> *Id.* at 661–62.

<sup>100</sup> Sonia M. Suter, *Disentangling Privacy from Property: Toward a Deeper Understanding of Genetic Privacy*, 72 GEO. WASH. L. REV. 737, 798 (2004).

<sup>101</sup> See *Washington v. Glucksberg*, 521 U.S. 702, 720–21 (1997) ("[W]e have regularly observed that the Due Process Clause specially protects those fundamental rights and liberties which are, objectively, deeply rooted in this Nation's history and tradition . . . ." (internal quotation marks omitted)).

<sup>102</sup> See, e.g., *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 278 (1990) (recognizing that a competent person holds a liberty interest in refusing unwanted medical treatment under the Due Process Clause of Fourteenth Amendment).

the information is one step on the way to better control over your body. Without all of the relevant information, how can we make the best and most informed personal choices? Some people would argue that, even with all of the information that genetic testing could offer, people's behaviors and practices will hardly change. Art Caplan, for instance, writes that people *know* they should not smoke, and they *know* they should bring their weight down, but ultimately not much has changed.<sup>103</sup> It is not our place, though, as lawmakers and policymakers, to decide whether people will do the right thing with the information we give them. We place a high value on allowing people to make their own decisions. Whenever government tries to paternalistically prevent information from being disseminated, courts frown upon the practice and strike down laws that tend toward such a result.<sup>104</sup> Ultimately, whether a person should be allowed to completely waive his right to genetic information about himself should depend on how important that information might be. And the truth is: the information could be the difference between life and death.

If a court were to hear a right of access to genetic information case, in a state where genetic information was considered property, they would be hard pressed to hold that informed consent is enough due process to deprive a person of that property. The biggest hurdle for such a plaintiff to overcome would be the simple designation of genetic information as property. But there is one other avenue of Fourteenth Amendment analysis that a plaintiff could ask the court to employ: the new fundamental right.

### C. *New Fundamental Right*

Plaintiffs in several cases have attempted to create a new fundamental right in something, where no property right or other claim can be articulated.<sup>105</sup> This type of claim is a long shot, to say the least. A plaintiff using this reasoning would have to argue that the right to information that could change the course of medical treatment, resulting in the difference between life and death, is so fundamental as to deserve the independent protection of the Constitution. In accepting this logic, a court would be happy to avoid the messy and controversial issue of calling genetic information property, which may have unintended consequences, as the

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<sup>103</sup> Art Caplan, *Will knowing your DNA motivate you to lose weight?*, VITALS (Jan. 10, 2012, 7:00 PM), [http://vitals.nbcnews.com/\\_news/2012/01/10/10098646-will-knowing-your-dna-motivate-you-to-lose-weight?](http://vitals.nbcnews.com/_news/2012/01/10/10098646-will-knowing-your-dna-motivate-you-to-lose-weight?)

<sup>104</sup> *See* Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 764–65 (1976) (characterizing the free flow of information as indispensable).

<sup>105</sup> *See, e.g., Glucksberg*, 521 U.S. at 705–06, 708 (refusing to recognize a liberty interest in assisted suicide).

Governor of New Jersey articulated.<sup>106</sup> But courts are extremely reluctant to recognize new fundamental rights. The most analogous case in which a plaintiff attempted to argue this logic was *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*.<sup>107</sup> In this case, the court ruled that terminally ill adult patients have no fundamental due process right of access to investigational drugs not yet approved by the FDA *regardless of the drug's potential life-saving properties*.<sup>108</sup>

On the one hand, it seems at first glance that if a court refused to create a fundamental right of access to life-saving drugs, it would be even less apt to create one for potentially life-saving information. However, in looking more closely at the court's analysis in *Abigail Alliance*, it becomes clear that the primary focus was on whether this country has a long history of protecting the right now claimed to be fundamental. The court in *Abigail Alliance* explains that the government has expressed a strong interest in regulating drugs and access to them in the interest of the overall safety of its citizens.<sup>109</sup> In other words, the government's interest in regulating drug use and in assuring safety before any drug is released to the market trumps the right of one person's access to a potentially life-saving drug that has not yet been approved. In the instant case, there is no evidence that the government has a long history of expressed interest in withholding information from its citizens. It certainly does not have a history of expressed interest in withholding information from citizens *about themselves*. In fact, we are an information nation. Our society is centered around providing information and maintaining transparency, allowing citizens to make autonomous well-informed decisions. There is a potential that, despite the contradictory holding in *Abigail Alliance*, a court would find a new fundamental right of access to genetic information. However, it is more likely that a court will find a property interest in genetic information and proceed with the above-outlined Fourteenth Amendment analysis.

## XI. COUNTERARGUMENTS AND OBJECTIONS

One major concern about this proposed right to receive the results of genetic research is the burden it places on the (usually state-based, and therefore potentially under-budgeted) institutions that possess the information. With the disclosure of any medical information, there are

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<sup>106</sup> Letter from Governor Christine Todd Whitman to N.J. Senate, *supra* note 85.

<sup>107</sup> *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 697 (D.C. Cir. 2007) (en banc).

<sup>108</sup> *Id.* at 697, 712.

<sup>109</sup> *See id.* at 711 (“[O]ur Nation’s history evidences increasing regulation of drugs as both the ability of government to address these risks has increased and the risks associated with drugs have become apparent.”).

certain safeguards that must be in place. For example, research institutions will likely grapple with whether or not specific geneticists, internists, or genetic counselors would need to be assigned to do the notifying. If new staff needs to be hired simply for the purpose of notifying participants of research findings, that requirement could place a significant burden on hospitals and research institutes. In addition, systems must be in place to re-identify DNA and match it up accurately with its “owner.” Such administrative and structural concerns, while not overly burdensome, would certainly be a consideration for those who conduct genetic research.

In addition, if the road towards establishing this kind of right of access proceeds in the most likely manner, by classifying genetic information as the property of its donor, several unintended consequences might result. The New Jersey Governor who vetoed such a genetic property bill elucidated a few of these concerns.<sup>110</sup> But it is impossible to conceive of all of the potential consequences of such a statute. One benefit of the alternative to establishing a right of access, the new fundamental right, is that it avoids classifying genetic information as property in an absolute sense, and focuses instead on the issue at hand in the described situation.

Of the utmost importance is maintaining the ease and wide participation of large-scale genetic research studies<sup>111</sup>, because personalizing diagnosis and treatment and individually assessing disease risk are the future of medicine. If establishing a right of access to research results would unnecessarily bog down research efforts or burden hospitals or state research institutions, then doing so may be ultimately counterproductive.

Finally, should it become the common practice of researchers and institutions to return genetic research results, it is likely that they will find a legal basis for such a practice *not* in the Constitution, but instead in federal and state regulation which could center around privacy doctrine, contract law, or another legal theory. The Constitution could be a powerful tool in court to argue for such a right, however, it is unlikely to be the ultimate driver of change in the practice of returning genetic research results.

## XII. CONCLUSION

It is probable that a change in the landscape of genetic research is on the horizon. There is a strong sense, driven by ethics, justice, and American societal norms, that withholding potentially life-saving information from voluntary research participants is wrong. Up until now, the researchers who work on large-scale genetic research have been hesitant to see it as a project

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<sup>110</sup> Letter from Gov. Christine Todd Whitman to N.J. Senate, *supra* note 85.

<sup>111</sup> See PRIVACY AND PROGRESS IN WHOLE GENOME SEQUENCING, *supra* note 24.

focusing on the individual patient. While dreams of personalized genomic medicine have been in our minds since watching movies like *GATTACA* over fifteen years ago, scientists have always known that such dreams are decades away from becoming a reality. Accordingly, they have viewed their research as pertinent only to large groups of people. They are statisticians, driven by the largest possible numbers to find broad sweeping correlations that might direct further study. And they are right, in some sense. We don't know enough, yet, about how genetics works to use it as a part of individual diagnostic processes. We are not prepared to say exactly how much more often a woman with a BRCA mutation should go in for a mammogram, or exactly how much value exists in the knowledge of the mutation. But hesitation on the part of scientists amounts to paternalism and withholding of information with which people might make important life-altering decisions.

In short, genetic researchers' hesitancy to disclose research results to participants is understandable, and to do so now would be a little bit premature. But it will not be long before one of the plaintiffs described in this Comment starts filing his lawsuit. Americans demand information from their government. The Constitution is meant to protect our most fundamental civil liberties. What could be more fundamental than the right to choose how to live; the right to choose the information we gather, how we process that information, and what we do with it; the right to direct our medical treatment using the absolute best resources we have at our disposal?

So the question is: how will a court react when this case reaches its docket? Hopefully, the analysis provided above gives a taste for the claims likely to be considered. Ultimately, the constitutional claim on which a plaintiff is most likely to succeed is a claim arising out of the Fourteenth Amendment's Due Process Clause. Failure to disclose the results of a genetic test in the course of research amounts to a deprivation of property without due process of law.