Achieving Genetic Data Privacy Through Enforcement of Property Rights

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To protect genetic privacy, state legislatures have begun to invoke the language of property rights, declaring the information derived from DNA, and even genetic material itself, the "exclusive property" of its source. A few recent judicial decisions also recognize an individual's property interest in the information derived from genetic material, with one state court denying a motion to dismiss a plaintiff's conversion claim. The use of property rights to protect genetic privacy is due in part to the rise of direct-to-consumer genetic testing (DTC-GT), which has decoupled the receipt of genetic information from medical care, allowing third parties to access and use private genetic information without consent.

Notwithstanding their invocation of the language of property rights, however, legislatures and courts are circumspect in their application of property law principles to genetic data. Even those state genetic privacy statutes that designate genetic materials and information as property either lack a private right of action; impose criminal law penalties that establish a high burden of proof; and/or set forth statutory damages that are quite small in comparison with the profits earned by DTC-GT companies. Courts hearing cases regarding the misuse of DTC-GT have denied plaintiffs' requests for class action certification, even as they acknowledge the challenges of determining the appropriate measure of actual damages given that genetic material and information are more valuable in the aggregate than severally.

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This article offers a perspective on how to enhance state legislation regulating DTC-GT. Part I of this article discusses the rise in the U.S. of DTC-GT and its associated risks of privacy loss and discrimination. Part II examines the seminal judicial decisions from two to three decades ago holding that individuals lack property rights in their genetic material and the data derived from it. Part III considers U.S federal laws enacted in the last two decades relating to medical and genetic privacy, which are inadequate to protect consumers from the risks of genetic privacy violations associated with DTC-GT. Part IV explores the increase in state legislation relating to genetic data privacy, with a specific focus on state legislation referring to property rights. Part V analyzes two recent judicial decisions that demonstrate courts' willingness to uphold plaintiffs' rights under statutes that recognize their ownership of their genetic material and/or the information derived from it, even as these courts struggle to establish clear and effective redress of violations. Part VI concludes by suggesting methods to enhance state genetic privacy statutes, which reflect the continuing impact of normative views denying property rights in genetic material and its associated data.

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INTRODUCTION

All of us discard genetic material each day, when, for example, we touch objects or drink from a glass. As noted by one scholar, "It seems strange to say that we own all of that."[1] On the other hand, direct-to-consumer genetic testing ("DTC-GT") companies, which sell test kits directly to consumers who provide a saliva sample to receive information about their genetic makeup, such as ancestry and some health traits,[2] nod to their customers' ownership of their genetic material[3] and the information derived from it.[4] For example, Ancestry, a publicly traded genealogy and consumer genomics company, declares in its privacy policy, "You always maintain ownership of your DNA and DNA Data."[5]

State legislatures have begun to invoke the language of property rights, declaring the information derived from DNA, and even the DNA

[1] Jessica L. Roberts, *Progressive Genetic Ownership*, 93 NOTRE DAME L. REV. 1105, 1123 (2018).

[2] *Direct-to-Consumer Genetic Testing FAQ*, NAT'L HUM. GENOME RSCH. INST., https://www.genome.gov/For-Health-Professionals/Provider-Genomics-Education-Resources/Healthcare-Provider-Direct-to-Consumer-Genetic-Testing-FAQ (last visited July 2, 2023) [https://perma.cc/3KN7-7M9Y] [hereinafter *Direct-to-Consumer Genetic Testing*].

[3] *See* Roberts, *supra* note 1, at 1123.

[4] Genetic data, which is gleaned from genetic material, is intangible information about a person's genetic makeup, often stored in a database with information from other individuals. This information can be sold and mined. *Id.*

[5] *Privacy Statement*, ANCESTRY, https://www.ancestry.com/c/legal/privacystatement_2019_7_25 (last visited July 2, 2023) [https://perma.cc/T8E6-DZDN].

materials themselves, to be the "exclusive property" of its source.[6] Recent judicial decisions also recognize an individual's property interest in the genetic information derived from genetic material, with one state court denying a motion to dismiss a plaintiff's conversion claim.[7]

The law certainly seems to have changed vastly in the decades since the seminal cases of *Moore v. Regents of the University of California*[8] and *Greenberg v. Miami Children's Hospital Research Institute, Inc.*[9] declared that individuals lack property rights in their genetic material to support a conversion claim. When courts protected genetic privacy at all, it was generally through the law of informed consent.[10] The rise of DTC-GT,[11]

[6] *See, e.g.*, ALASKA STAT. ANN. § 18.13.010(a)(2) (2017) (providing that both "a DNA sample" and "the results of a DNA analysis" are "the exclusive property of the person sampled or analyzed"); FLA. STAT. ANN. § 760.40(1)(c) (2021) (defining "exclusive property" as the "right of the person whose DNA has been extracted or analyzed to exercise control over his or her DNA sample and any results of his or her DNA analysis with regard to the collection, use, retention, maintenance, disclosure, or destruction of such sample or analysis results").

[7] *See* Order Granting in Part and Denying in Part the Counter-Def's. Mots. to Dismiss the Countercl. and Dismissing the Countercl. in Part at *14, Peerenboom v. Perlmutter, No. 2013-CA-015257, 2017 Fla. Cir. LEXIS 14957 (Fla. Cir. Ct. Jan. 23, 2017) [hereinafter Perlmutter Order].

[8] Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 497 (Cal. 1990) (denying plaintiff's conversion claim for the tissue removed from his body and used in research without his informed consent).

[9] Greenberg v. Mia. Child.'s Hosp. Rsch. Inst., Inc., 264 F. Supp. 2d 1064, 1074 (S.D. Fla. 2003) (denying plaintiff's conversion claim in genetic material donated for research without knowledge of its commercialization).

[10] *See, e.g.*, *Moore*, 793 P.2d at 496 (finding that an injury to the right to make an informed decision "remains actionable through the . . . informed-consent theories").

[11] DTC-GT is distinct from two other types of genetic testing: clinic-based genetic testing and provider-mediated genetic testing ("PM-GT"). Clinic-based genetic testing is "ordered, interpreted[,] and disclosed by a physician or other healthcare professional" in the context of a conventional healthcare professional-patient relationship. *Direct-to-Consumer Genetic Testing*, *supra* note 2. The National Human Genome Research Institute notes that typical standard-of-care norms for clinic-based genetic testing include a pre-test consultation to review possible genetic risk factors, identify the appropriate tests, and discuss the advantages and limitations of testing as part of the process of obtaining informed consent from the patient. The healthcare professional also arranges a post-test visit to disclose and explain the results. Recently, genetic testing companies have marketed to consumers PM-GT, which involves a healthcare professional "in a non-traditional role as part of the testing process." *Id.* As noted by one researcher, who used the term consumer-directed physician-mediated ("CDPM") genetic testing to refer to

however, has decoupled the receipt of genetic information from medical care, allowing third parties to access and use private genetic information without consent.[12] For example, in 2021, Marvel Entertainment chairman Isaac Perlmutter and his wife sued their neighbor, Harold Peerenboom, and Chubb Insurance for alleged DNA theft.[13] The Perlmutters maintained that the defendants had subpoenaed them to a deposition with the goal of secretly collecting their DNA during that meeting, because Chubb was the insurer of Peerenboom, who pursued a defamation claim against them and sought to connect the Perlmutters to alleged illegal acts.[14]

In the absence of effective federal legislation protecting people from misuse of their genetic specimens and information, state legislatures are crafting legislation that seems to confer property rights in this material,

such testing, "Mandatory physician involvement in CDPM genetic testing is at least partially motivated by company aims to avoid regulatory scrutiny." Tenny R. Zhang, Reframing Physician Oversight in the Era of Consumer-Directed Genetic Testing 2 (Apr. 18, 2019) (Ph.D. Dissertation, Harvard Medical School), https://dash.harvard.edu/bitstream/handle/1/41971512/ZHANG-SCHOLARLYPROJECT-2019.pdf?sequence=1&isAllowed=y [https://perma.cc/953G-NNGX]. CDPM avoids regulation since physician-ordered tests fall outside the FDA's purview. *Id.* at 9. With PM-GT, the healthcare professional, who may be employed by the company and not know the consumer, or, alternatively, who may already have a professional relationship with the consumer, may order the test or approve the order for the test with minimal interaction or discussion of the test with the consumer. *Direct-to-Consumer Genetic Testing*, *supra* note 2. Clinic-based genetic testing methods are typically more thorough than DTC-GT techniques; involve clinical labs that interpret results according to published medical guidelines and healthcare professionals who consider the patient's family and health history; and employ only labs that meet established quality standards. *Id.* In this article, the term DTC-GT includes PM-GT as well.

[12] Fay Shaulson, *How Florida is Protecting the DNA Privacy Rights You Didn't Know Need Protection*, U. MIA. L. REV. (Nov. 28, 2021), https://lawreview.law.miami.edu/florida-protecting-dna-privacy-rights-didnt-protection/ [https://perma.cc/N646-5VVC].

[13] Counter-Plaintiffs' Motion to Amend the Counterclaims to Assert Punitive Damages Against Fed. Ins. Co. at 1, Peerenboom v. Perlmutter, No. 2018-CA-001996 (Fla. Cir. Ct. 2021), https://www.scribd.com/document/496707616/Isaac-Ike-Perlmutter-Motion-Part-1#fullscreen&from_embed [https://perma.cc/E6Y9-XB68] [hereinafter Perlmutter Counter-Plaintiff's Motion].

[14] Debra Cassens Weiss, *Marvel CEO Seeks Punitive Damages for Alleged Theft of His DNA During a Deposition*, ABA J. (Mar. 3, 2021, 3:30 PM CST), https://www.abajournal.com/news/article/former-marvel-chairman-seeks-punitive-damages-for-alleged-theft-of-his-dna-during-a-deposition [https://perma.cc/K2PK-AGYA].

but also continues to conceive of the issue as one of privacy and antidiscrimination law.[15] The close connection between property and privacy was noted by a scholar who observed "[a]t common law, property rights are often founded in privacy interests," and offered the examples of trespass and nuisance law as demonstrating the link between privacy and property interests.[16] Genetic privacy posits "everyone should enjoy protection of his or her genetic information from unauthorized collection, processing, use and distribution, and that certain uses of genomic data must be forbidden because they impact data subjects in ways that are considered unjust, unfair, or outright discriminatory."[17] In this sense, the right to control one's genetic material and the data derived from it raises antidiscrimination law, illustrating what one scholar referred to as a "privacy/antidiscrimination symbiosis."[18]

Notions of privacy and antidiscrimination predominate in legal theories relating to genetic material and information such that, notwithstanding the invocation of the language of property rights, legislatures and courts are circumspect in their application of property law principles.[19] Even those state genetic privacy statutes that designate genetic materials and information as property either lack a private right of action; impose criminal law penalties that establish a high burden of proof; and/or set forth statutory damages that are quite small in comparison with the profits earned by DTC-GT companies.[20] Courts hearing cases regarding the misuse of DTC-GT have denied plaintiffs' requests for class action certification, even as they acknowledge the challenges of determining the appropriate measure of actual damages given that genetic material and information are more valuable in the

[15] *See infra* Part IV.

[16] Ayesha Rasheed, *'Personal' Property: Fourth Amendment Protection for Genetic Information*, 23 U. PA. J. CONST. L. 547, 553 (2021).

[17] Tobias Haeusermann, Marta Fadda, Alessandro Blasimme, Bastian Greshake Tzovaras & Effy Vayena, *Genes Wide Open: Data Sharing and the Social Gradient of Genomic Privacy*, 9 AJOB EMPIRICAL BIOETHICS 207, 208 (2018).

[18] Jessica L. Roberts, *Protecting Privacy to Prevent Discrimination*, 56 WM. & MARY L. REV. 2097, 2135 (2015).

[19] *See infra* Parts IV, V.

[20] *See infra* Part IV.

aggregate than severally.[21] Analysis of genetic privacy legislation and jurisprudence reveals that courts and legislatures remain cautious in implementing the notion of property rights they have to some degree recognized in an individual's genetic material and data.[22] The number of judicial decisions taking seriously the notion of property rights is likely to increase, however, as the current trickle of cases relating to DTC-GT privacy violations increases.

Part I of this article discusses the rise in the U.S. of DTC-GT and its associated risks of privacy loss and discrimination. Part II examines the seminal judicial decisions from two to three decades ago holding that individuals lack property rights in their genetic material and the data derived from it. Part III considers U.S federal laws enacted in the last two decades relating to medical and genetic privacy, which are inadequate to protect consumers from the risks of genetic privacy violations associated with DTC-GT. Part IV explores the increase in state legislation relating to genetic data privacy, with a specific focus on state legislation invoking the language of property rights. Part V analyzes two recent judicial decisions demonstrating courts' willingness to uphold plaintiffs' rights under statutes that recognize their ownership of their genetic material and/or the information derived from it, even as these courts struggle to establish clear and effective redress of violations. Part VI concludes by suggesting methods to enhance state genetic privacy statutes, which reflect the continuing impact of normative views denying property rights in genetic material and its associated data.

[21] *See infra* Part V.

[22] *See infra* Parts IV, V.

I. DIRECT-TO-CONSUMER GENETIC TESTING IN THE U.S. AND THE ASSOCIATED RISKS OF PRIVACY LOSS AND DISCRIMINATION

The first sequencing of the human genome, completed in 2003,[23] cost between $500 million and $1 billion over thirteen years[24] and required the efforts of several international institutes and hundreds of researchers.[25] By 2016, for approximately $1,000, a high-quality whole-genome sequence could be completed in a day.[26] Today, U.S. consumers can access DTC-GT at prices ranging from under one hundred dollars to several thousand dollars.[27] According to a national survey conducted by Consumer Reports in 2020, approximately twenty per cent of U.S. adults have taken home genetic tests from companies such as 23andMe, AncestryDNA, and MyHeritageDNA.[28] The genetic data revealed by such tests is deeply personal and can reveal a person's likelihood of developing particular diseases as well as their genealogical information.[29] Employers and insurance companies may use such information to discriminate against individuals with genetic

[23] *Human Genome Project*, NAT'L HUM. GENOME RSCH. INST. (Aug. 24, 2022), https://www.genome.gov/about-genomics/educational-resources/fact-sheets/human-genome-project [https://perma.cc/7UHK-GYTS].

[24] *The Cost of Sequencing a Human Genome*, NAT'L HUM. GENOME RSCH. INST. (Nov. 1, 2021), https://www.genome.gov/about-genomics/fact-sheets/Sequencing-Human-Genome-cost [https://perma.cc/5TNF-4MF7] [hereinafter *The Cost of Sequencing*].

[25] Andrea Sboner, Xinmeng Jasmine Mu, Dov Greenbaum, Raymond K. Auerbach & Mark B. Gerstein, *The Real Cost of Sequencing: Higher than You Think!*, 12 GENOME BIOLOGY 125, 125 (2011).

[26] *The Cost of Sequencing*, *supra* note 24.

[27] Nat'l Libr. Of Med., *How Much Does Direct-to-Consumer Genetic Testing Cost, and is It Covered by Health Insurance?*, MEDLINE PLUS, https://medlineplus.gov/genetics/understanding/dtcgenetictesting/dtccost/ (last updated June 21, 2022) [https://perma.cc/2J2X-86RE]. The costs depend on how many genetic variations are analyzed, whether more advanced and comprehensive sequencing techniques are used, the extent to which the results are interpreted, and whether the testing includes consultation with a healthcare provider, such as a genetic counselor. *Id.*

[28] CONSUMER REPS., HOME GENETIC TESTING: A NATIONALLY REPRESENTATIVE MULTI-MODE SURVEY 2 (2020), https://article.images.consumerreports.org/prod/content/dam/surveys/Consumer%20Reports%20Home%20Genetic%20Testing%20October%202020 [https://perma.cc/HQ4W-4KKX] (October 2020 Results).

[29] Rachele M. Hendricks-Sturrup & Christine Y. Lu, *Direct-to-Consumer Genetic Testing Data Privacy: Key Concerns and Recommendations Based on Consumer Perspectives*, 9 J. PERSONALIZED MED. 25, 25 (2019).

predisposition to disease.[30] Moreover, the availability of DTC-GT may even allow more distant third parties to improperly access and use private genetic information.[31] For example, in 2021, Marvel Entertainment chairman Isaac Perlmutter and his wife sued Chubb Insurance for alleged DNA theft.[32] The Perlmutters maintained that Chubb had subpoenaed them to a deposition with the goal of secretly collecting their DNA during that meeting, because Chubb was the insurer of a neighbor of the Perlmutters who pursued a defamation claim against them and sought to connect the Perlmutters to alleged illegal acts.[33]

Given the risks associated with DTC-GT, some state legislatures have begun to regulate providers of home genetic tests by recognizing an individual's property rights in their genetic material and the data derived from it,[34] and courts have recognized such rights.[35] This approach represents a departure from case law denying individuals' property rights in their genetic materials and information.

II. COURTS HAVE TRADITIONALLY HELD THAT INDIVIDUALS LACK PROPERTY RIGHTS IN THEIR GENETIC MATERIAL AND THE DATA DERIVED FROM IT

The seminal decision establishing the principle that individuals do not possess property interests in their genetic material or the information derived from it is the California Supreme Court's 1990 decision in *Moore v. Regents of the University of California*.[36] This case represents an earlier era in genetic research, when most instances of misuse of genetic material and the information derived from it arose in the context of a doctor-patient relationship. The plaintiff's doctor extracted bodily

[30] *See* Haeusermann et al., *supra* note 17, at 208 ("Since genetic data provide information on key characteristics of individuals, disclosure or misuse of data can lead to serious harm, ranging from embarrassment to stigmatization, abuse, and potential discrimination in employment, insurance, or education.").

[31] Shaulson, *supra* note 12.

[32] *See* Perlmutter Counter-Plaintiff's Motion, *supra* note 13, at 1.

[33] Weiss, *supra* note 14.

[34] *See infra* Part IV.

[35] *See infra* Part V.

[36] Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 497 (Cal. 1990).

tissue for curative medical purposes but ultimately conducted for-profit biomedical research without informed consent.[37]

Plaintiff John Moore first sought treatment at the Medical Center at the University of California at Los Angeles (UCLA Medical Center) in 1976, shortly after he was diagnosed with hairy-cell leukemia.[38] Although the splenectomy recommended by Mr. Moore's attending physician, Dr. David W. Golde,[39] did improve Moore's condition,[40] Golde never informed Moore that Golde and a UCLA researcher, Ms. Shirley Quan, intended to study the excised spleen tissue.[41] Moore's tissue interested the researchers because of its tendency to overproduce certain proteins called lymphokines, some of which have a therapeutic value.[42] The research team hoped the tissue would help them locate the gene responsible for creating those proteins, thereby enabling them to produce large quantities of lymphokines in the lab.[43]

The researchers continued their research on Moore from 1976 to 1983, all the while maintaining that it was for his own health that they had him visit UCLA from his home in Seattle every year or two, for the purpose of drawing additional samples of blood, blood serum, skin, bone marrow aspirate, and sperm.[44] Golde developed a cell line from Moore's tissue,[45] and in January 1981, Golde's employer, the Regents of the University of California, applied for a patent on the cell line.[46] The patent issued in March 1984, naming Golde and Quan as the inventors of the cell line and the Regents as the assignee of the patent, with all of them sharing in any royalties or profits.[47] With the Regents' assistance, Golde negotiated license agreements for commercial development of the cell line and

[37] *Id.* at 481.

[38] *Id.*

[39] *Id.* at 480-81.

[40] *Id.* at 486 n.11.

[41] *Id.* at 481.

[42] *Id.* at 481-82.

[43] *Id.* at 481 n.2.

[44] *Id.* at 481.

[45] *Id.*

[46] *Id.* at 482.

[47] *Id.*

corresponding products with two pharmaceutical firms, Genetics Institute, Inc. and Sandoz Pharmaceuticals Corporation.[48]

Moore learned in 1983, two years after researchers filed the patent application, of the experimentation on his tissue. Even then, the researchers claimed falsely that their work was scientific rather than commercial.[49] In response to Moore's express inquiries, the researchers repeatedly denied that his tissue possessed any commercial value.[50] Suspicious of Golde's insistence on conducting so many tests after the splenectomy and also of the doctor's refusal to have a medical professional in Seattle perform any supposedly necessary tests, Moore hired a lawyer who located online a scholarly scientific article in which the coauthors, including Golde, described their research upon the tissue of an unnamed "37-year-old white male from Seattle, Washington,"[51] who proved to be John Moore.[52] The researchers had in fact initially named the cell line Mo,[53] ultimately changing the name to avoid detection by plaintiff.[54]

In September 1984, Moore filed a lawsuit against Golde, Quan, the Regents of the University of California, Genetics Institute, and Sandoz, alleging, among other things, conversion,[55] which the California Supreme Court defined as "interference with possessory and ownership

[48] *Id.*

[49] Donna M. Gitter, *Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material*, 61 WASH. & LEE L. REV. 257, 272 (2004).

[50] *Moore*, 793 P.2d at 485-86.

[51] V. S. Kalyanaraman, M. G. Sarngadharan, Marjorie Robert-Guroff, Isao Miyoshi, Douglas Blayney, David Golde & Robert C. Gallo, *A New Subtype of Human T-Cell Leukemia Virus (HTLV-II) Associated with a T-Cell Variant of Hairy Cell Leukemia*, 218 SCI. 571, 572 (1982).

[52] LORI ANDREWS & DOROTHY NELKIN, BODY BAZAAR: THE MARKET FOR HUMAN TISSUE IN THE BIOTECHNOLOGY AGE 27-28 (2001).

[53] Laura M. Ivey, Comment, Moore v. Regents of the University of California*: Insufficient Protection of Patients' Rights in the Biotechnological Market*, 25 GA. L. REV. 489, 492 n.27 (1991).

[54] Moore v. Regents of the Univ. of Cal., 249 Cal. Rptr. 494, 500 (Cal. Ct. App. 1988).

[55] *Moore*, 793 P.2d at 482 n.4 (noting plaintiff alleged causes of action for conversion, lack of informed consent, breach of fiduciary duty, fraud and deceit, and unjust enrichment, among others).

interests in personal property."[56] For his conversion claim, plaintiff's theory of recovery was that the tissue removed from his body was his tangible personal property, at least in the sense that he was entitled to direct its use, and that he never consented to its inclusion in commercial research.[57] Moore alleged that the unauthorized use of his cells constituted conversion, and he therefore claimed a proprietary interest in each of the products the defendants had developed from his cells or the patented cell line.[58] In his complaint, Mr. Moore sought a share in the proceeds of the products from that cell line, which he estimated at over three billion dollars by 1990.[59] Even today, Fisher Scientific, a U.S. purveyor of laboratory equipment and supplies, continues to sell the ATCC MO-MO T CRL-8066 cell line for $844.40 per unit.[60]

In its five-to-two majority opinion in *Moore*, the Supreme Court of California denied plaintiff's conversion claim under California law.[61] In deciding this issue of first impression, the court prioritized companies' need for certainty in the ownership of biological materials removed from individuals, or else the fledgling biotechnology industry would suffer.[62] Moreover, the court stated it did not need to expand the tort doctrine of conversion because the legal theories of breach of fiduciary duty and lack of informed consent adequately protected the plaintiff's interests.[63] Specifically, the court recognized a duty on the part of a physician-researcher to "disclose personal interests unrelated to the

[56] *Id.* at 487.

[57] *Moore*, 249 Cal. Rptr. 2d. at 501.

[58] *Moore*, 793 P.2d at 487.

[59] *Id.* at 482.

[60] *ATCC MO-MO T CRL-8066*, FISHER SCI., https://www.fishersci.com/shop/products/NC1953094/NC1953094 (last visited July 31, 2023) [https://perma.cc/AL9M-QNXR]

[61] *Moore*, 793 P.2d at 506.

[62] *Id.* at 495-96 (warning that "[i]f the use of cells in research is a conversion, then with every cell sample a researcher purchases a ticket in a litigation lottery," and also predicting that "companies are unlikely to invest heavily in developing, manufacturing, or marketing a product when uncertainty about clear title exists." (quoting OFF. TECH. ASSESS., OTA-BA-337, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS 27 (1987))).

[63] *Id.* at 496 ("Any injury to [plaintiff's] right to make . . . informed decision[s] remains actionable through the fiduciary-duty and informed-consent theories.").

patient's health, whether research or economic, that may affect his medical judgment" in connection with procedures he recommends to patients.[64]

The *Moore* decision is inapposite in the context of DTC-GT, since it addresses only the duties of physician-researchers, not researchers who do not provide medical care to a patient, much less any other third parties. The court acknowledged that since the Regents, Quan, the Genetic Institute, and Sandoz were not physicians, they owed neither a fiduciary duty nor a duty of informed consent to Moore.[65] They could, however, face liability through Golde's act via a theory of secondary liability, such as respondeat superior, an issue the court did not decide in its ruling.[66]

The decision in *Moore* was based, in large part, on the justices' concern that the conversion theory relied on by Moore is a strict liability tort. Application of the strict liability doctrine would attach liability to every party in possession of the cells, even those who had no responsibility for or knowledge of the deception.[67] The court declared "[i]f the scientific users of human cells are to be held liable for failing to investigate the consensual pedigree of their raw materials, we believe the Legislature should make that decision."[68] As discussed below, three decades later, some states legislatures now indeed use the term "exclusive property" to describe the right of individuals to exercise control over their DNA samples and/or any results of the DNA analysis.[69] Such an approach reflects the view propounded in Justice Mosk's vigorous dissent in *Moore*, in which he urged "no one can question Moore's crucial contribution to the invention — an invention named, ironically, after

[64] *Id.* at 485.

[65] *Id.* at 486.

[66] *Id.* at 486-87.

[67] *Id.* at 494 ("Since conversion is a strict liability tort, it would impose liability on all those into whose hands the cells come, whether or not the particular defendant participated in, or knew of, the inadequate disclosures that violated the patient's right to make an informed decision.").

[68] *Id.* at 496 (emphasizing that legislatures "have the ability to gather empirical evidence, solicit the advice of experts, and hold hearings at which all interested parties present evidence and express their views" (quoting *Foley v. Interactive Data Corp.*, 765 P.2d 373, 397 n.31)).

[69] *See infra* Part IV.

him: but for the cells of Moore's body taken by defendants, there would have been no Mo cell line" and emphasized that "for all their expertise, defendants do not claim they could have extracted the Mo cell line out of thin air."[70]

Just over a dozen years after the California Supreme Court's holding in *Moore*, a federal district court in Florida invoked that decision in the case *Greenberg v. Miami Children's Hospital Research Institute, Incorporated*, ruling that the "[p]laintiffs have no cognizable property interest in body tissue and genetic matter donated for research under a theory of conversion."[71] Like the plaintiff in *Moore*, the *Greenberg* plaintiffs had ceded tissue, blood, and other pathology samples to researchers. Unlike Moore, however, the *Greenberg* plaintiffs had consented to research, though they had believed it would remain in the public domain and did not consent to its commercialization.[72]

The *Greenberg* case arose from the efforts of several families to help develop carrier and prenatal testing for Canavan disease,[73] the fatal neurological disorder that afflicted their children,[74] in conjunction with three nonprofit organizations that had developed a confidential database and Canavan disease registry.[75] The Greenberg plaintiffs located a doctor, Reuben Matalon, who had not previously researched Canavan disease,[76] and organized to supply him with a combination of blood, tissue, autopsy, and other samples, confidential medical

[70] *Moore*, 793 P.2d at 511 (Mosk, J., dissenting).

[71] Greenberg v. Mia. Child.'s Hosp. Rsch. Inst., Inc., 264 F. Supp. 2d 1064, 1074 (S.D. Fla. 2003) (citing *Moore*, 793 P.2d at 488).

[72] Complaint at ¶¶ 21–22, 34–36, Greenberg v. Mia. Child.'s Hosp. Rsch. Inst., Inc., 208 F. Supp. 2d 918 (N.D. Ill. 2000) (No. 00C-6779), http://graphics8.nytimes.com/packages/pdf/business/20070128_FRAMING.pdf [https://perma.cc/DR3R-CTZ6] [hereinafter Greenberg Complaint].

[73] *See generally* Reuben Matalon, Kimberlee Michals, & Rajinder Kaul, *Canavan Disease: From Spongy Degeneration to Molecular Analysis*, 127 J. PEDIATRICS 511, 511 (1995) (describing Canavan disease as a progressive disease that often leads to death in the first ten years of life and is especially prevalent among Jews of Eastern Europe descent).

[74] Greenberg Complaint, *supra* note 72, ¶¶ 4–7, 14–22.

[75] *Id.* ¶¶ 19–21.

[76] Jon F. Merz, *Discoveries: Are There Limits on What May Be Patented?*, *in* WHO OWNS LIFE? 99, 102 (David Magnus et al. eds., 2002).

information, and funding, in what they viewed as a "partnership" to establish "affordable and accessible" carrier and prenatal testing.[77]

Unbeknownst to plaintiffs, however, Matalon's employer, the Miami Children's Hospital ("MCH"), which had recruited him to establish and direct a center for research on genetic diseases,[78] had filed in September 1994 a patent application for the gene associated with Canavan disease and related applications, including carrier and prenatal testing.[79] The plaintiffs alleged it was around 1994 that the defendants first presented them with a written consent form, at the plaintiffs' suggestion.[80] They contended this form was legally inadequate, for its description of the defendants' purpose, "identify[ing] mutations in the Canavan gene which may lead to carrier detection within my family," failed to reveal the researchers' commercial aims.[81] In October 1997, the United States Patent and Trademark Office issued U.S. Patent No. 5,679,635 to the MCH Research Institute in October 1997.[82]

In late 1998, MCH began sending letters to clinical laboratories engaged in Canavan testing and to the plaintiffs, informing them of the patent and the hospital's plans for commercializing the test.[83] These letters indicated defendants' intent "to enforce vigorously [their] intellectual property rights relating to carrier and patient DNA tests for Canavan Disease mutations."[84] Through these letters, the plaintiffs learned for the first time, indirectly, of the defendants' patent and their plans to earn royalties from the research in which the plaintiffs had participated with the goal of ensuring affordable and accessible carrier

[77] Greenberg Complaint, *supra* note 72, ¶ 26; Merz, *supra* note 76, at 102.

[78] Gina Kolata, *Sharing of Profits Is Debated as the Value of Tissue Rises*, N.Y. TIMES, May 15, 2000, at A1.

[79] Greenberg Complaint, *supra* note 72, ¶ 28. Dr. Matalon did not hold patent rights in the Canavan gene, as his contract with MCH required him to cede to MCH any marketable intellectual property that he developed in return for $1 million of research funding annually. Eliot Marshall, *Families Sue Hospital, Scientist for Control of Canavan Gene*, 290 SCI. 1062, 1062 (2000).

[80] Greenberg Complaint, *supra* note 72, ¶ 37; Merz, *supra* note 76, at 108.

[81] Greenberg Complaint, *supra* note 72, ¶ 37.

[82] Merz, *supra* note 76, at 103.

[83] Greenberg Complaint, supra note 72, ¶ 30; Merz, *supra* note 76, at 103.

[84] Greenberg Complaint, *supra* note 72, ¶ 30 (referring to Exhibit A of the Complaint).

and prenatal screening and, ultimately, contributing to a treatment or cure for Canavan disease.[85]

In October 2002, the Greenberg plaintiffs filed a federal lawsuit against defendants MCH, MCH Research Institute, and Dr. Reuben Matalon, which was ultimately transferred to a Florida federal district court.[86] The plaintiffs alleged conversion among the six counts of the complaint.[87] They claimed a "property interest in their blood, tissue, urine and autopsy samples and those of their minor children, and in the genetic information contained therein,"[88] as well as in the "Canavan Registry," a compendium compiled by plaintiffs of contact information and medical data about families worldwide afflicted with Canavan Disease.[89] In dismissing with prejudice defendants' motion to dismiss, the *Greenberg* court held "[p]laintiffs have no cognizable property interest in body tissue and genetic matter donated for research under a theory of conversion."[90] The court also emphasized that, under Florida law, a research participant cedes property rights in blood and tissue samples once the sample is voluntarily given to a third party.[91] Furthermore, the court held a property right inheres in *the information contained in the plaintiffs' tissue, not the tissue itself*, and that this information was developed through the efforts of the defendants, not

[85] *Id.* (alleging that the plaintiffs first learned of MCH's patent of the gene and the screening test from the enforcement letters to testing centers).

[86] *See generally id.* (setting forth the Greenberg plaintiffs' suit against the defendants). The Illinois court transferred the case to United States District Court for the Southern District of Florida, on the grounds that the Illinois court lacked jurisdiction and venue over all of the defendants. Greenberg v. Mia. Child.'s Hosp. Rsch. Inst., Inc., 208 F. Supp. 2d 918, 928-29 (N.D. Ill. 2002).

[87] Greenberg Complaint, *supra* note 72, ¶¶ 61–67. The other causes of action were lack of informed consent, breach of fiduciary duty, unjust enrichment, fraudulent concealment, and misappropriation of trade secrets. *See id.* ¶¶ 33–60, 69–75.

[88] Greenberg Complaint, *supra* note 72, ¶ 62.

[89] *Id.* ¶ 63.

[90] Greenberg v. Mia. Child.'s Hosp. Rsch. Inst., Inc., 264 F. Supp. 2d 1064, 1074 (S.D. Fla. 2003) (citing Moore v. Regents of Univ. of Cal., 793 P.2d 479, 488 (Cal. 1990)).

[91] *Id.* at 1075 (stating that "limits to the property rights that attach to body tissue have been recognized in Florida state courts" and that "the property right in blood and tissue samples also evaporates once the sample is voluntarily given to a third party").

the plaintiffs.[92] According to the court, "[i]f adopted, the expansive theory championed by Plaintiffs would cripple medical research as it would bestow a continuing right for donors to possess the results of any research conducted by the hospital."[93]

The *Moore* and *Greenberg* cases occurred in an era when access to individuals' genetic materials and information usually was limited to their medical team and the third-party researchers with whom they shared it, which indicates why those courts refused to recognize an individual's property right in her genetic material and related information. Because the plaintiff in *Moore* was not even aware he was participating in medical research, the *Moore* court declared it could protect him through legal theories arising from the doctor-patient relationship, such as breach of fiduciary duty and lack of informed consent,[94] and potentially theories of secondary liability with respect to third party researchers.[95] As stated by the court, it was not "necessary to force the round pegs of 'privacy' and 'dignity' into the square hole of 'property' in order to protect the patient, since the fiduciary-duty and informed-consent theories protect these interests directly by requiring full disclosure."[96] In contrast, the *Greenberg* case involved plaintiffs who knowingly participated in medical research. That court refused to extend the concept of informed consent to cover researchers' economic interests.[97] Presently, however, DTC-GT enables a wider array of individuals to access one's genetic materials and data. Federal law has not stayed abreast of these technological advancements that threaten individual privacy.

[92] *Id.* (citing Pioneer Hi-Bred Int'l, Inc. v. Holden Found. Seeds, Inc., 1987 WL 341211 (S.D. Iowa 1987), *aff'd*, 35 F.3d 1226 (8th Cir. 1994)) (supporting the proposition that defendants' efforts in gathering and arranging the genetic information entitled them, and not the plaintiffs, to property rights therein).

[93] *Id.* at 1076.

[94] *See supra* note 63 and accompanying text.

[95] *See supra* note 66 and accompanying text.

[96] Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 491 (Cal. 1990).

[97] *Greenberg*, 264 F. Supp. 2d at 1070.

III. EXISTING U.S. FEDERAL LAWS DO NOT PROTECT CONSUMERS FROM THE RISKS OF GENETIC PRIVACY VIOLATIONS ASSOCIATED WITH DTC-GT

Congress has enacted two federal statutes dealing with genetic privacy that are relevant to the DTC-GT industry, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA")[98] and the Genetic Information Nondiscrimination Act of 2008.[99] However, neither protects consumers of DTC-GT from privacy violations or discrimination.

Pursuant to HIPAA's requirement of national standards to protect sensitive patient health information, the U.S. Department of Health and Human Services ("HHS") issued the HIPAA Privacy Rule in 2003.[100] The Privacy Rule regulates the use and disclosure of individuals' health information, known as protected health information ("PHI"), to permit the flow of data necessary for high-quality healthcare while protecting patient privacy.[101] Only certain entities, called "covered entities," are subject to the Privacy Rule, however, namely, healthcare providers, health plans, and their business associates, including companies that conduct claims processing, data analysis, and billing for healthcare providers and health plans.[102]

In 2008 Congress amended HIPAA and the Privacy Rule by enacting the Genetic Information Nondiscrimination Act ("GINA"), which ensures that genetic information qualifies as health information protected by HIPAA.[103] GINA prohibits only employers and health insurers,

[98] Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1938 (codified as amended in scattered sections of 18, 26, 29 & 42 U.S.C.).

[99] Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (codified as amended in scattered sections of 26, 29 & 42 U.S.C.).

[100] Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82462 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164).

[101] 45 C.F.R. § 164.502 (providing that "[a] covered entity or business associate may not use or disclose protected health information, except as permitted or required").

[102] CTRS. FOR DISEASE CONTROL & PREVENTION, PUBLIC HEALTH PROFESSIONALS GATEWAY: HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA), https://www.cdc.gov/phlp/publications/topic/hipaa.html (last updated June 27, 2022) [https://perma.cc/9H6C-KC4W].

[103] Genetic Information Nondiscrimination Act § 105(a); *see* Bradley A. Areheart & Jessica L. Roberts, *GINA, Big Data, and the Future of Employee Privacy*, 128 Yale L.J. 710, 714 (2019) (stating Congress enacted GINA "primarily as a safeguard against

however, from treating an individual unfavorably based on genetic information,[104] including information derived from DTC-GT.[105]

Congress enacted GINA during the rise of the burgeoning predictive genetics era.[106] GINA was especially important before the 2010 Patient Protection and Affordable Care Act ("PPACA")[107] limited to some degree the extent to which the private, for-profit health insurance industry could use risk analysis to deny or price policies.[108]

discrimination based on genetic-test results"). Specifically, employers and health insurers cannot request or use (1) a person's genetic tests, (2) the genetic tests of her family members, and (3) manifested conditions in her family members. Genetic Information Nondiscrimination Act, § 201(4)(A)(i)–(iii). GINA does, however, allow employers and health insurers to request and consider information about an individual's gender, age, and personally manifested health conditions, specifically excluding this information from its definition of statutorily protected genetic information. *Id.* §§ 201(4)(C), 210. Congress permitted health insurers to use such information because it is integral to the risk assessment performed by health insurance companies. *See* Areheart & Roberts, *supra*, at 727. In addition, individuals with manifested conditions may receive protection pursuant to the Americans with Disabilities Act ("ADA"). Americans with Disabilities Act of 1990, Pub. L. No. 101-336, 104 Stat. 327, 329 (codified as amended at 42 U.S.C. §§ 12112, 12132, 12182).

[104] Genetic Information Nondiscrimination Act §§ 102(a), 202(a); Mark A. Rothstein, *GINA, the ADA, and Genetic Discrimination in Employment*, 36 J.L. MED. & ETHICS 837, 837 (2008).

[105] *Direct-to-Consumer Genetic Testing*, *supra* note 2 ("The genetic information protected by the law includes family health history, the results of genetic tests (including direct-to-consumer genetic tests), the use of genetic counseling and other genetic services and participation in genetic research.").

[106] Areheart & Roberts, *supra* note 103, at 722.

[107] PPACA, Pub. L. No. 111-148, 124 Stat. 119 (2010). On March 30, 2010, the PPACA was amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 125 Stat. 1029 (2010).

[108] *See* Areheart & Roberts, *supra* note 103, at 721. The PPACA created the Pre-Existing Condition Insurance Plan ("PCIP"), which has been effective in making health insurance available to people who were denied coverage by private insurance companies due to a pre-existing condition. Before the PPACA, in most states Americans with pre-existing conditions who did not receive health coverage through their employers faced barriers to accessing affordable care. Insurance companies could deny them coverage, charge higher premiums, or offer them coverage that excluded benefits for their health conditions. *About the New Pre-existing Health Insurance Plan*, CTRS. FOR MEDICARE & MEDICAID SERVS. (last updated July 23, 2012), https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/preexistingconditioninsuranceplan [https://perma.cc/BXM8-YDNJ]. At present, the PPACA prohibits most individual and group health insurers from

Commentators note GINA's legislative history makes clear that the statute aimed to allay the public's concerns about taking medical genetic tests,[109] and that because health insurance and employment were the most significant topics of concern, more expansive legislation covering additional industries would not have received adequate congressional support.[110]

GINA is not effective as a privacy statute, especially in light of the wide availability of DTC-GT. GINA's limitation to only employers and health insurers fails to prevent other entities, such as disability insurers, life insurers, and long-term-care insurers, from denying services based upon genetic information, whether derived from genetic testing or family history.[111] There is presently no federal legislation limiting the use of genetic information by these insurers.[112] Moreover, numerous other private entities can also demand and discriminate based on genetic information. In most states, for example, it is lawful for banks, landlords, and schools to make decisions based on genetic

denying coverage to or otherwise discriminating against people with pre-existing or complex health conditions. Moreover, the law prohibits health plans from using most forms of medical underwriting, which insurers had previously used to make the cost and availability of health insurance dependent upon personal health status. Aside from a person's age and tobacco use, the PPACA forbids insurers from considering virtually all other underwriting information in setting insurance premiums. STAFF OF FLA. H. COMM. ON HEALTH & HUM. SRVCS., COMM. ON COM., STAFF ANALYSIS FOR HB 1189, at 4 (Jan. 23, 2020), https://www.flsenate.gov/Session/Bill/2020/1189/Analyses/h1189c.COM.PDF [https://perma.cc/YWE8-T2X4] [hereinafter FLORIDA HOUSE OF REPRESENTATIVES STAFF ANALYSIS].

[109] Areheart & Roberts, *supra* note 103, at 722-23.

[110] *Id.* at 725.

[111] *See* Mark A. Rothstein, *GINA at Ten and the Future of Genetic Nondiscrimination Law*, 48 HASTINGS CTR. REP. 5, 5 (2018) (observing that "GINA does not prohibit genetic discrimination in life insurance, disability insurance, long-term care insurance, mortgage insurance, educational opportunities, or commercial and real property transactions"); Zhiyu Wan, James W. Hazel Ellen Wright Clayton, Yevgeniy Vorobeychik, Murat Kantarcioglu & Bradley A. Malin, *Sociotechnical Safeguards for Genomic Data Privacy*, 23 NATURE REVS. GENETICS 429, 437 (2022) (critiquing GINA, which "nominally prohibits genetic-based discrimination in the context of health insurance and employment" as "limited in its scope" because it applies "only to asymptomatic individuals and offers no protection regarding other types of insurance (for example, life and long-term disability)").

[112] FLORIDA HOUSE OF REPRESENTATIVES STAFF ANALYSIS, *supra* note 108.

information.[113] Indeed, one journalist posited that a condominium association in a retirement community could require potential residents to submit DNA test results revealing their genetic predisposition to Alzheimer's, and that this would be legal throughout most of the United States.[114]

Many commentators have deemed GINA a failure in practical terms.[115] Although Congress designed it as a protection against discrimination based on genetic test results, no plaintiffs have brought such claims pursuant to GINA. Instead, most of the successful cases under GINA have involved impermissible requests for protected data.[116] Thus, some commentators have described GINA as effective in that it prohibits employers from even requesting or purchasing genetic information, much less acting on it,[117] and have noted the statute is atypical in combining both privacy and antidiscrimination protections, representing a "privacy/antidiscrimination symbiosis."[118] As noted previously, however, the statute's application to only health insurers and employers[119] limits its effectiveness in protecting individuals from invasion of their genetic privacy and genetic discrimination.

Paradoxically, GINA protects the privacy of people whose genetic tests were ordered by their doctors, but not those who purchased them

[113] Areheart & Roberts, *supra* note 103, at 725. California has enacted significant legislative protection from genetic discrimination with its 2011 California Genetic Information Nondiscrimination Act ("CalGINA"). CalGINA enhanced the protection offered by the federal GINA statute by prohibiting under California law genetic discrimination in various types of insurance other than health insurance, as well as in emergency medical services, housing, mortgage lending, education, and other state-funded programs. CalGINA, ch. 261, 2011 Cal. Stat. 2774 (codified in scattered sections of the California Codes).

[114] Megan Molteni, *The U.S. Urgently Needs New Genetic Privacy Laws*, WIRED (May 1, 2019), https://www.wired.com/story/the-us-urgently-needs-new-genetic-privacy-laws/ [https://perma.cc/J8ZW-FC97].

[115] Areheart & Roberts, *supra* note 103, at 745 (explaining that "from the moment GINA passed, it garnered significant criticism" and "scholarly reaction to GINA has been almost entirely negative").

[116] *Id.* at 714.

[117] *Id.* at 718.

[118] Roberts, *supra* note 18.

[119] *See supra* note 103 and accompanying text.

from 23andMe and Ancestry.[120] DTC-GT companies create their own privacy policies, which they can alter at any time, and have demonstrated their willingness to exchange consumer information with third parties.[121] For example, in 2015, AncestryDNA announced its collaboration with Google subsidiary Calico, for the purpose of researching aging by evaluating "anonymized data from millions of public family trees and a growing database of over one million genetic samples," adding that financial terms had not been disclosed.[122] This

[120] Korey Clark, *State Lawmakers Find Success with Genetic Privacy*, LEXISNEXIS (June 17, 2022), https://www.lexisnexis.com/community/insights/legal/capitol-journal/b/state-net/posts/state-lawmakers-find-success-with-genetic-privacy [https://perma.cc/L9MM-WRQX].

[121] *See* JILLIAN SLAIGHT, GENETIC PRIVACY IN THE AGE OF COMMERCIAL DNA TESTING, WISCONSIN LEGISLATIVE REFERENCE BUREAU 7 (2020), https://docs.legis.wisconsin.gov/misc/lrb/wisconsin_policy_project/dna_testing_privacy_3_1.pdf [https://perma.cc/5WHU-XK9F] (noting that "company policies have changed frequently and, sometimes, imperceptibly," allowing the unconsented sharing of data with third parties); Hendricks-Sturrup & Lu, *supra* note 29, at 2 (referencing varying privacy policies and terms of use agreements of DTC-GT companies).

[122] Press Release, Ancestry DNA and Calico to Research the Genetics of Human Lifespan, ANCESTRY CORP. (July 21, 2015), https://www.ancestry.com/corporate/newsroom/press-releases/ancestrydna-and-calico-research-genetics-human-lifespan [https://perma.cc/LB82-22RU]. Ancestry Corporate refers to "anonymized data," which is a term subject to many interpretations. It is often used to refer to samples for which a code links the sample to its donor. U.S. regulations deem such samples non-identifiable, provided that an agreement prohibits the release to the investigators of the key to the code, and therefore federal funding is available for research on such samples even in the absence of informed consent. Bernice S. Elger & Arthur L. Caplan, *Consent and Anonymization in Research Involving Biobanks: Differing Terms and Norms Present Serious Barriers to an International Framework*, 7 EMBO REP. 661, 664 (2006) (noting how U.S. regulations, in contrast to those in Europe, do not require informed consent for coded samples); *see also* Harald Schmidt and Shawneequa Callier, *How Anonymous Is 'Anonymous'? Some Suggestions Towards a Coherent Universal Coding System for Genetic Samples*, 38 J. MED. ETHICS 304, 304 (2012) (noting that, according to the U.S. Office for Human Research Protections ("OHRP"), samples are not identifiable "when they cannot be linked to specific individuals by the investigator(s) either directly or through coding systems"). However, as noted by the National Human Genome Research Institute, because each human DNA sequence is unique (except for identical twins), "a DNA sample can never be truly anonymized." *Privacy in Genomics*, NAT'L HUM. GENOME RSCH. INST. (Apr. 27, 2021), https://www.genome.gov/about-genomics/policy-issues/Privacy [https://perma.cc/5SUF-D852]; *see also* Alexander Bernier, Hanshi Liu & Bartha Maria Knoppers, *Computational Tools for Genomic Data De-identification: Facilitating Data*

collaboration, which lasted for three years,[123] resulted in a scientific paper concluding that longevity has a lower level of heritability than previously believed.[124] In 2018, the pharmaceutical and biotechnology firm GlaxoSmithKline ("GSK") announced it would access 23andMe's databases to identify and select pharmaceutical targets. This announcement revealed that both companies would share in the proceeds from new medicines and therapeutics arising from the collaboration, and that GSK made a $300 million equity investment in 23andMe.[125] In early 2022, GSK announced its exercise of the option to extend its collaboration with 23andMe until July 2023, in exchange for $50 million and a share in the royalties of the products of the research.[126]

Given the lack of federal legislation in this area, states are enacting their own legislation, whether omnibus or more narrowly tailored, to protect their citizens from adverse treatment based on their genetic information. Several states have invoked a property rights approach to

Protection Law Compliance, 12 NATURE COMMC'NS 6949, 6950 (2021) (explaining that experimental results demonstrate that a small amount of genetic information from an individual is "sufficient to establish a positive match between a known individual's genetic information and that same individual's genetic information held or published in a presumptively anonymised format"); Ellen Wright Clayton, Barbara J. Evans, James W. Hazel & Mark A. Rothstein, *The Law of Genetic Privacy: Applications, Implications, and Limitations*, 6 J.L. & BIOSCI. 1, 6 (2019) (noting that "technical methods may not be completely effective in preventing the reidentification of genetic information").

[123] *See Calico Purring Right Along with Life Extension Research*, NANALYZE (Jan. 25, 2021), https://www.nanalyze.com/2021/01/calico-life-extension-research/ [https://perma.cc/T9W3-43U6].

[124] *See* J. Graham Ruby, Kevin M. Wright, Kristin A. Rand, Amir Kermany, Keith Noto, Don Curtis, Neal Varner, Daniel Garrigan, Dmitri Slinkov, Ilya Dorfman, Julie M. Granka, Jake Byrnes, Natalie Myres & Catherine Ball, *Estimates of the Heritability of Human Longevity Are Substantially Inflated Due to Assortative Mating*, 210 GENETICS 1109, 1109 (2018).

[125] Press Release, GSK and 23andMe Sign Agreement to Leverage Genetic Insights for the Development of Novel Medicines, GLAXOSMITHKLINE (July 25, 2018), https://www.gsk.com/en-gb/media/press-releases/gsk-and-23andme-sign-agreement-to-leverage-genetic-insights-for-the-development-of-novel-medicines/ [https://perma.cc/92BL-XVZ7].

[126] Press Release, 23andMe Announces Extension of GSK Collaboration and Update on Joint Immuno-oncology Program, 23ANDME (Jan. 18, 2022), https://investors.23andme.com/news-releases/news-release-details/23andme-announces-extension-gsk-collaboration-and-update-joint [https://perma.cc/6XZ9-GEYU].

ensure individual's control of their genetic material and the information derived from it.

IV. SOME STATE GENETIC PRIVACY LEGISLATION INVOKES A PROPERTY RIGHTS APPROACH

State legislatures have long enacted legislation to ensure the privacy of personal information of all kinds, including medical information,[127] social security numbers,[128] and student information.[129] Increasingly, state legislatures seek to protect consumer privacy through regulation. In 2022, at least thirty-five states and the District of Columbia introduced or considered almost two hundred consumer privacy bills.[130] These bills were most often comprehensive in scope, which the National Conference of State Legislatures ("NCSL") describes as "broadly regulating the collection, use and disclosure of personal information and providing an express set of consumer rights with regard to collected data, such as the right to access, correct and delete personal information collected by businesses."[131] Such broad bills, often termed omnibus bills, accounted for almost seventy bills in at least twenty-five states and the District of Columbia.[132] Of the approximately seventy omnibus bills proposed in 2022, five achieved enactment in as many states, for a passage rate of roughly seven percent.[133] Similarly, in 2021, legislators introduced comprehensive data privacy bills in twenty-five states, two of which enacted them, for a passage rate of about eight percent.[134]

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[127] N.Y. PUB. HEALTH LAW § 2782 (2014) (protecting the privacy of individuals with respect to HIV status).

[128] CAL. CIV. CODE tit. 1.81.1 (2001) (ensuring the protection of individuals' social security numbers).

[129] Illinois School Student Records Act, 105 ILL. COMP. STAT 10/1 (1975) (allowing for a private right of action if a student's private records are improperly released by a school or district).

[130] *2022 Consumer Privacy Legislation*, NAT'L CONF. OF STATE LEGISLATURES (June 10, 2022), https://www.ncsl.org/research/telecommunications-and-information-technology/2022-consumer-privacy-legislation.aspx#:~:text=At%20least%2034%20states%20and,and%20the%20District%20of%20Columbia [https://perma.cc/H5M3-B8QL].

[131] Clark, *supra* note 120.

[132] *2022 Consumer Privacy Legislation*, *supra* note 130.

[133] *Id.*

[134] Clark, *supra* note 120.

Given the low passage rate of comprehensive data privacy bills, another approach pursued by some state legislators is to propose bills relating to specific areas of consumer privacy, such as website privacy or children's privacy on the internet, internet service provider and information/data broker regulation, and direct-to-consumer genetic testing regulation.[135] Bills focusing specifically on genetic privacy have a much higher rate of enactment as compared to those relating to other forms of consumer privacy. Bills dealing exclusively with the protection of consumer genetic information were introduced in nine states in 2021. As noted by the NCSL, seven of these nine states enacted such bills, making genetic privacy bills, with a passage rate of nearly seventy-eight per cent, "the type of consumer data privacy legislation with the highest passage rate among the dozen categories tracked by NCSL."[136]

Some states, most notably California, have implemented an anti-discrimination approach to genetic privacy, analogous to GINA.[137] California's Genetic Information Privacy Act ("Cal GIPA")[138] was one of the seven genetic privacy statutes enacted in 2021.[139] Consumers can notify the California Attorney General or a district attorney if they believe a DTC-GT company has violated the law[140] by using, disclosing, or even retaining consumers' identifiable genetic material or data without a separate and express consent for each instance.[141] Cal GIPA applies specifically to DTC-GT companies[142] because the California Genetic Information Nondiscrimination Act ("CalGINA"), which took effect on January 1, 2012, had already included genetic discrimination as a protected category, analogous to race, gender, age, and religion, for the purpose of prohibiting discrimination in areas such as housing, mortgage lending, employment, education, and public

[135] *2022 Consumer Privacy Legislation*, *supra* note 130.

[136] Clark, *supra* note 120.

[137] *See supra* note 113.

[138] S.B. 41, 2021-2022 Reg. Sess. (Cal. 2021), https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202120220SB41 [https://perma.cc/QGG3-GWXX].

[139] Clark, *supra* note 120.

[140] CAL. CIV. CODE § 56.182 (2021).

[141] *Id.* § 56.181(2) (2021).

[142] *Id.*§ 56.18(b)(5) (2021).

accommodations.[143] Currently, five states, Alaska, Colorado, Florida, Georgia, and Louisiana, add heft to this antidiscrimination approach with language declaring that genetic specimens and/or information are the property of the individual.[144] The property rights model, which is likely to grow more common as other states increasingly enact genetic privacy legislation,[145] bears further examination.

A. Florida's Civil Rights Anti-discrimination Law Defines Genetic Information as the "Exclusive Property" of Its Source

In 2021, less than two decades after a Florida federal district court held in *Greenberg* that individuals possessed no property rights in tissue donated to researchers,[146] Florida enacted the Protecting DNA Privacy Act ("PDPA"). The PDPA defines genetic information as "exclusive property" of the person whose DNA has been extracted or analyzed, granting that individual the right "to exercise control over his or her DNA sample or the results of his or her DNA analysis with regard to the collection, use, retention, maintenance, disclosure, or destruction of

[143] CAL. GOV'T CODE §§ 11135, 12920 (2018).

[144] ALASKA STAT. ANN. § 18.13.010 (2017) (providing that both "a DNA sample" and "the results of a DNA analysis" are "the exclusive property of the person sampled or analyzed"); COLO. REV. STAT. ANN. §§ 10-3-1104.6, 10-3-1104.7(1)(a) (2017) (stating that "[g]enetic information is the unique property of the individual to whom the information pertains"); FLA. STAT. ANN. § 760.40 (2021) (providing that the results of DNA analysis are the "exclusive property" of the person tested); GA. CODE ANN. § 33-54-1 *et seq*. (2017) (stating that "[g]enetic information is the unique property of the individual tested"); LA. STAT. ANN. § 22:1023(E) (2017); LA. ADMIN CODE tit. 37, § 4515 (providing that in the context of insurance "[a]n insured's or enrollee's genetic information is the property of the insured or enrollee"); *see also* Leslie E. Wolf, Erin Fuse Brown, Ryan Kerr, Genevieve Razick, Gregory Tanner, Brett Duvall, Sakinah Jones, Jack Brackney & Tatiana Posada, *The Web of Legal Protections for Participants in Genomic Research*, 29 HEALTH MATRIX 3, 44 (2019) (setting forth the five states that provide that genetic information is the property of the individual); *State Genetic Privacy Laws*, NAT'L CONF. OF STATE LEGISLATURES, http://pierce.wesleyancollege.edu/faculty/hboettger-tong/docs/hbt%20public%20folder/FYS/State%20Genetic%20Summary%20Table%20on%20Privacy%20Laws.htm (last visited July 10, 2023) [https://perma.cc/RG26-7343].

[145] *Cf.* Wolf et al., *supra* note 144 (explaining that "the legal status of genetic property ownership is unsettled and may be shifting to a broader recognition of an individual property interest in their genetic information").

[146] *See supra* note 71.

such sample or analysis results."[147] While this enactment uses the language of property, it forms part of a statutory chapter relating to civil rights and prohibiting discrimination.[148] The statute achieves its antidiscrimination goal by requiring express consent for any person to collect, use, retain, maintain, disclose, sell, or transfer another person's DNA sample or results of a DNA analysis.[149]

Significantly, Florida imposes criminal, as opposed to civil, penalties for willful violations of genetic privacy.[150] Florida's PDPA expanded Florida's existing criminal penalties for improper use of genetic data. Florida had already enacted in 2018 a law making it a first degree misdemeanor to analyze DNA or share the analysis without the informed consent of the person tested.[151] In 2020, Florida enacted the Genetic Information for Insurance Purposes Act ("GIIPA"),[152] prohibiting life, disability, and long-term care insurance companies from requiring, soliciting, or considering for any insurance purpose an individual's private genetic information, or his or her decision not to undergo genetic testing.[153] Florida's GIIPA made it the first U.S. state to extend to life, disability, and long-term care insurers the existing protections against health insurers' use of genetic information.[154] GIIPA also provided that, in the absence of a diagnosis of a condition related to genetic information, companies providing life, disability, and long-term care insurance "may not cancel, limit, or deny coverage, or

[147] Fla. H.B. No. 833, 123rd Gen. Assemb. Reg. Sess. (Fla. 2021), § 2(1)(c).

[148] Fla. H.R. Staff Analysis, CS/HB 833 Unlawful Use of DNA (March 24, 2021), https://flsenate.gov/Session/Bill/2021/833/Analyses/h0833c.JDC.PDF, at 4 [https://perma.cc/96C8-T7HX].

[149] Fla. H.B. No. 833, §§ 3(2)-(5).

[150] *Id.* §§ 3(1)-(5).

[151] Libbie Canter, *Newly Effective Florida Law Imposing Criminal Sanctions Adds to Developing Nationwide Patchwork of State Genetic Privacy Laws*, COVINGTON (Oct. 6, 2021), https://www.insideprivacy.com/health-privacy/newly-effective-florida-law-imposing-criminal-sanctions-adds-to-developing-nationwide-patchwork-of-state-genetic-privacy-laws/ [https://perma.cc/8SR3-NY9Q].

[152] H.B. 1189, 122nd Gen. Assemb., Reg. Sess. (Fla. 2020).

[153] *Id.* §1(2)(b).

[154] *Florida Enacts Sweeping Genetic Protection Law*, FORCE (July 1, 2020), https://www.facingourrisk.org/privacy-policy-legal/advocacy/florida-enacts-sweeping-genetic-protection-law [https://perma.cc/8ZPD-DBNR].

establish differentials in premium rates, based on such information."[155] Violations of the law were punishable as a first-degree misdemeanor.[156]

The 2021 PDPA increased Florida's criminal penalties for some violations of genetic privacy from misdemeanors to potential felonies. Willful and unconsented collection or retention of an individual's DNA sample or analysis constitute a misdemeanor in the first degree; willful and unconsented submission for analysis or analysis and also unconsented disclosure, constitute a felony in the third degree; and willful and unconsented sale of a DNA sample or its analysis are considered a second degree felony.[157] Third-degree felonies in Florida are punishable by up to five years in prison, a $5,000 fine, and five years of probation, while second-degree felonies are punishable by up to fifteen years in prison, fifteen years of probation, and a $10,000 fine.[158] The PDPA must be enforced by the state, as it provides no private right of action.[159]

B. Alaska's Human Rights Law Considers Both DNA Samples and the Analysis of Those Samples to Be the "Exclusive Property" of Their Source

Among the five states that consider genetic information to be the private property of the individual, Alaska is unique in that it also considers DNA samples themselves to be personal property, declaring

[155] Fla. H.B. 1189, § 1(2)(a).

[156] Shaulson, *supra* note 12.

[157] Fla. H.B. 833, 123rd Gen. Assemb. Reg. Sess. (Fla. 2021), §§ 3(3)–(5). It should be noted that the PDPA does not apply to DNA samples collected and analysis performed for criminal investigations; subpoena compliance; compliance with federal law; medical diagnosis and treatment of a patient who consented to have a health care practitioner collect the DNA sample; newborn screening; paternity testing; research using deidentified data and conducted in compliance with protections for human research subjects; or to any DNA samples collected outside of Florida or before the date of the Act. *Id.*, §§ 3(7)–(8).

[158] Shaulson, *supra* note 12.

[159] *See* Perlmutter Order, *supra* note 7, at n.6 (noting the statute does not allow a private right of action); Theodore Claypoole, Taylor Ey & Christine Xiao, *California and Florida Introduce Two More Genetic Privacy Laws into the Mix*, JD SUPRA (Oct. 20, 2021), https://www.jdsupra.com/legalnews/california-and-florida-introduce-two-1188777/ [https://perma.cc/EP6F-7C6U] ("The Protecting DNA Privacy Act does not include a private right of action.").

that "a DNA sample and the results of a DNA analysis performed on the sample are the exclusive property of the person sampled or analyzed."[160] The Alaska Genetic Privacy Act ("AGPA"), which appears in Title 18 dealing with health, safety, housing, and human rights, provides that no one can collect, analyze, retain, or disclose a DNA sample or an analysis of another without the "informed and written" consent of the individual.[161] Unlike the Florida genetic privacy statute, the AGPA contains a private right of action, which permits an individual plaintiff to bring a civil action and recover actual damages, along with statutory damages of either $5,000 or, if the violation resulted in profit or gain to the violator, $100,000.[162] Similarly to the Florida statute, the AGPA imposes criminal penalties for knowing violations of the Act. Alaska classifies them as Class A misdemeanors,[163] however, unlike Florida, which sets forth both misdemeanor and felony classifications.[164] In Alaska, a Class A misdemeanor may invoke a maximum punishment of up to one year in a jail, and/or a $25,000 fine.[165]

C. Pennsylvania's Proposed Genetic Materials Privacy and Compensation Act Is Unique in Proposing Payment to Individuals Based on the Monetary Value of Their Genetic Material

A property rights approach to genetic privacy has also been embraced by a bipartisan group of Pennsylvania legislators who introduced the Genetic Materials Privacy and Compensation Act ("GMPCA") in January 2022.[166] The GMPCA seeks not only to address privacy concerns raised by genetic testing, including DTC-GT, but goes even further by seeking damages for individuals based on the amount of compensation

[160] ALASKA STAT. ANN. § 18.13.010(2) (2017).

[161] *Id.* § 18.13.010(a)(1) (2017).

[162] *Id.* § 18.13.020 (2017).

[163] *Id.* § 18.13.030(c) (2017).

[164] *See supra* notes 147–147.

[165] *Background About Criminal Cases*, ALASKA CT. SYS., https://courts.alaska.gov/shc/criminal/background.htm#kinds (last visited July 14, 2023) [https://perma.cc/8FR6-M5YJ].

[166] H.B. 2283, 2022 Reg. Sess. (Pa. 2022), https://custom.statenet.com/public/resources.cgi?id=ID:bill:PA2021000H2283&ciq=urn:user:PA6792530&client_md=a36aec5214fa12540ee768f19c8ad629&mode=current_text [https://perma.cc/GZ8P-9BR6].

received for their genetic material.[167] In introducing the legislation, Democratic state representative Emily Kinkead expressed concern that individuals using DTC-GT tests often were not aware that their data would be sold for use in for-profit research, and likened the situation to the exploitation of Henrietta Lacks,[168] an African-American woman whose medical team exploited her genetic material without her consent and developed a cell line that is still in use today, over half a century after her death.[169]

Pennsylvania's proposed GMPCA recognizes and inextricably links both property and privacy interests in genetic material itself, which it defines as DNA, genes, and chromosomes that may be tested for medical and/or ancestry purposes.[170] The GMPCA declares that "[i]ndividuals shall have inherent ownership rights for their genetic material and a privacy interest in it, even when voluntarily providing their genetic material to a for-profit company."[171]

Pennsylvania's proposed GMPCA aims to regulate a broad swath of entities, imposing disclosure and compensation requirements on all "genetic material testing entities." The statute defines such entities as any engaged in "collecting, testing or otherwise analyzing the genetic material of individuals," including not only medical facilities and companies that provide "genealogy services," but even law enforcement officials.[172]

The GMPCA distinguishes between and sets forth separate rules for physical genetic material and "data," which it defines as information from the tested material.[173] The statute then establishes several disclosure requirements to which either genetic material and/or data would be subject. First, genetic material testing entities may not

[167] *Id.* § 4.

[168] Rep. Emily Kinkead, *Kinkead Introduces Legislation to Protect DNA Privacy*, PA HOUSE DEMOCRATS (Jan. 25, 2022), https://www.pahouse.com/InTheNews/NewsRelease/?id=122461 [https://perma.cc/XL2U-RKNX].

[169] Editorial, *Science Must Right a Historical Wrong*, 585 NATURE 7, 7 (2020).

[170] *See* Pa. H.B. 2283, § 2.

[171] *Id.* § 8.

[172] *Id.* § 2. The statute notes that, in the absence of express consent, law enforcement officials must present a warrant to access the genetic data of an individual. *Id.* § 3(b)(3).

[173] *Id.* § 2.

misrepresent, expressly or by implication, the extent to which genetic data is collected, used, or maintained, nor the confidentiality and security measures instituted for its protection.[174] As for genetic material, entities may not misrepresent the purpose of the collection, use, or disclosure of genetic material.[175] Second, genetic material testing entities must, prior to collection of the genetic material, give notice and obtain express consent.[176] They must "prominently disclose,"[177] completely "separate and apart from a privacy policy, terms of use page or other similar documents" the following information:

> the type of genetic material that will be collected and used; the type of genetic material that will be shared with a third party; the identity of the third party; the purpose for any genetic testing entity sharing of the data collected; a data sharing agreement between the genetic testing entity or third party and a Federal, State, or local law enforcement agency or other government agency.[178]

Furthermore, in a special effort to prevent discrimination in the particularly salient areas of insurance and employment, Pennsylvania H.B. 2283 would also bar insurance companies and employers from requesting genetic material or related data about any individual.[179]

The GMPCA seeks to impose on DTC-GT companies, not only the requirement to comply with all disclosure rules and obtain consent for the collection of genetic material, but also an ongoing obligation to obtain new consent if any of the disclosed information were to change, and to offer information about how to revoke consent to the genetic material collection and sharing.[180] The GMPCA takes a retrospective approach, calling for the destruction of any genetic material collected

[174] *Id.* § 3(a)(1).

[175] *Id.* § 3(a)(2).

[176] *Id.* § 3(b).

[177] The statute sets forth detailed requirements for prominent disclosure, even establishing heightened standards for children, the elderly, and terminally ill people. *Id.* §§ 2, 3(b).

[178] *Id.* § 3(b)(1).

[179] *Id.* § 5.

[180] *Id.* §§ 3(b)(1)(ii)–(iii).

before the enactment of this proposed statute, within 120 days or within thirty days of the request from the individual from whom it was collected, whichever were to come first, unless that individual consents to its retention.[181]

Pennsylvania H.B. 2283 is unique among state genetic privacy statutes in proposing direct financial payment to plaintiffs for their genetic material, based upon the amount of compensation the seller received for their genetic material.[182] Research did not reveal any other proposed or enacted statute in the U.S. that provides for compensation to individuals for the sale of their genetic material. The statute states that any genetic material testing entity or third party must first obtain "express authorization" to sell or donate the genetic material of another and must also compensate that person by paying at least ninety percent of the amount received for the sale of the person's genetic material.[183] The statute offers a private right of action by deeming violations of the GMPCA unfair trade practices[184] and incorporating by reference Pennsylvania's consumer protection statute, which allows consumers to sue for compensation,[185] even while there is enforcement by the Attorney General or a local district attorney.[186]

In the five states that have enacted statutes recognizing individuals' property rights and/or the genetic material derived from it, courts have decided only two cases pursuant to these statutes.[187] Although in both cases the courts upheld the plaintiffs' rights under the legislation, both decisions reflect the uncertainty the courts face in terms of establishing and enforcing property rights in genetic material and its associated data.

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[181] *Id.* § 6.

[182] *Id.* § 4(a).

[183] *Id.*

[184] *Id.* § 9.

[185] Unfair Trade Practices and Consumer Protection Law, 73 PA. STAT. AND CONST. STAT. § 201-9.2 (1976).

[186] Pa. H.B. 2283, § 10.

[187] *See infra* Part V.

V. TWO RECENT JUDICIAL DECISIONS DEMONSTRATE COURTS' WILLINGNESS, WITH SOME RESERVATIONS, TO RECOGNIZE INDIVIDUALS' OWNERSHIP OF THEIR GENETIC MATERIAL

A 2017 judicial decision of a Florida state court judge in the *Perlmutter* case[188] demonstrates the challenges facing courts as they consider individuals' privacy and property rights in their genetic information and samples.[189] Ike and Laura Perlmutter sued Harold Peerenboom for conversion, among other claims, alleging he conspired to obtain their genetic material to implicate them in an unlawful hate mail campaign directed at Peerenboom.[190] The Perlmutters' conversion claim rested on their assertion that Peerenboom exercised "wrongful dominion 'of the genetic information encoded in [the Perlmutters'] genetic material'" by collecting it without consent.[191] In denying the motion to dismiss the Perlmutters' conversion claim, the court acknowledged that "[t]hough examined with less frequency than in the context of privacy, courts have also observed that a property right exists in genetic information" and "at the very least, one possesses important privacy interests in such information."[192] The court cited an earlier version of Florida's Protecting DNA Privacy Act for the principle that DNA test results, "whether held by a public or private entity, are exclusive property of the person tested."[193] According to the court, while it recognized that the statute at issue "deals with civil rights and disclosure of DNA test results — not conversion — the Court finds it significant that the legislature has recognized *some* property right exists in genetic information."[194] The qualifying language "some property right" used by the court indicates that the legislature's use of a civil rights statute to address genetic privacy contributes to judicial reluctance to rely on a traditional tort theory of conversion notwithstanding the legislature's use of the term "property" to refer to a person's interest in their genetic information.

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[188] *See* Perlmutter Counter-Plaintiffs' Motion, *supra* note 13, at *1; Weiss, *supra* note 14, at 3.

[189] *See* Perlmutter Order, *supra* note 7, at *8-14.

[190] *Id.* at *12-13.

[191] *Id.* at *9.

[192] *Id.* at *10.

[193] *Id.* at *11.

[194] *Id.*

Ultimately, the *Perlmutter* court's refusal to dismiss the plaintiff's conversion claim indicates its openness to a property rights approach.

The *Perlmutter* court also explicitly distinguished earlier cases denying individuals' property rights in their genetic material. The court noted that although the *Moore* court had declared that individuals lack a property interest in genetic material, the *Moore* court had not addressed ownership of genetic data.[195] The *Perlmutter* court also distinguished the *Greenberg* case on the grounds that it involved voluntary donations to medical research.[196] Thus, the *Perlmutter* court recognized a potential property interest in genetic information not shared voluntarily as part of commercial medical research, a holding that is applicable to research arising from DTC-GT genetic testing.

In another ongoing case brought pursuant to a genetic privacy statute that mentions individuals' property rights in their genetic information, the U.S. District Court in Alaska recognized a plaintiff's property right in his DNA sample and the analysis performed on it, in the context of denying a DTC-GT company's motion to dismiss the case.[197] The plaintiff, Alaska resident Michael Cole, bought a DTC-GT test online from the company Gene by Gene and sent in a sample. Cole wished to obtain from the company the web link where he could locate genetic matches and research his ancestry.[198] As it did with other customers, Gene by Gene offered Cole the option to join projects, which are online fora run by unpaid third-party volunteers, often through independent websites.[199] Cole alleged that he signed up for nine projects and understood that the project administrators would have access to his name, contact information, and testing kit number, but that the company did not inform him that some project administrators had separate websites and that his full DNA test results would be disclosed

[195] *Id.* (declaring *Moore* "inapplicable to the question of whether genetic *information* constitutes property for purposes of conversion").

[196] *Id.* at *12 ("*Greenberg* is also factually distinct from the one at bar in that there, the plaintiffs voluntarily provided tissue to a researcher to find a cure for Canavan disease and sued when the researcher commercialized its findings for profit against plaintiffs' wishes.").

[197] Cole v. Gene by Gene, Ltd. (*Cole I*), No. 1:14-cv-00004, 2017 U.S. Dist. LEXIS 101761, at *4-8 (D. Alaska June 30, 2017).

[198] *Id.* at *2-3.

[199] *Id.*

publicly on those sites.[200] Months later, Cole searched the internet for his email address and found it on a public website called "Rootsweb," leading him to initiate an action against Gene by Gene alleging that its sharing of his DNA test results violated Alaska's Genetic Privacy Act,[201] which provides that a DNA sample and the results of a DNA analysis performed on the sample are the "exclusive property" of the person who provided the sample.[202]

In addressing the defendant's motion to dismiss based on plaintiff's lack of standing to bring a federal suit, the *Cole* court considered whether violation of the Alaska Genetic Privacy Act is an injury sufficient to grant standing in federal court.[203] Applying a two-factor test to determine whether the plaintiff demonstrated a "concrete harm" sufficient to support standing in federal court, the court first considered whether the alleged intangible harm caused by violation of the AGPA "bears a 'close relationship to a harm that has traditionally been regarded as providing a basis for a lawsuit in English or American courts.'"[204] The court held that because the Act recognizes an exclusive property interest in one's DNA and prohibits the unauthorized disclosure of DNA information, these "statutory entitlements bear a close relationship to the common law torts of conversion of property and invasion of privacy, which have each historically provided a basis for a lawsuit in American courts."[205] As to the second factor, the *Cole* court stated that, in deciding whether a statute entitles a plaintiff to judicial relief, courts must consider the provision of a private right of action, the availability of statutory damages, and the substantive nature of the statutory right.[206] The court held that each of those factors supported plaintiff's standing in federal court, as the AGPA expressly grants a private right of action, provides for the recovery of statutory damages in addition to any actual damages suffered, and "creates a property

[200] *Id.*

[201] *Id.* at *3.

[202] ALASKA STAT. ANN. § 18.13.010(a)(2) (2017).

[203] *Cole I*, 2017 U.S. Dist. LEXIS 101761, at *4-5.

[204] *Id.* at *7.

[205] *Id.* at *8.

[206] *Id.* at *8-9.

interest in one's DNA and the results of any DNA analysis."[207] Thus, the court concluded "the unauthorized disclosure of an individual's DNA" satisfied the standing requirement because it "is not hypothetical or uncertain" but rather "a concrete harm."[208]

Plaintiff Cole did not prevail on this motion for class certification, however, which the Alaska federal district court denied, on the grounds that customers signed dissimilar informed consent forms and faced varying disclosures of their genetic information,[209] which necessitated individualized measures of damages.[210] In addition, the court held the available remedy was not too small to make Cole's individual suit viable and there were no similar suits pending that necessitated a class action.[211] By denying class certification, the court encouraged DTC-GT companies to use non-standardized consent forms to avoid class certification, even where the underlying issues regarding violation of genetic privacy are in fact quite similar.

CONCLUSION

State statutory law evinces a trend towards protecting genetic privacy. Some states have begun to include language that recognizes individuals' property rights in their genetic material and/or the data derived from it, a departure from prior case law rejecting this approach. The language of property rights is undercut however, in instances where the legislature fails to offer a private right of action; imposes criminal penalties that may contravene the plaintiff's goals; and prescribes an inadequate measure of statutory damages. In addition, courts require more legislative clarity as they grapple with whether to recognize a cause of action for conversion. Moreover, an Alaskan federal court decision signals the barriers plaintiffs will face in achieving class certification in DTC-GT cases, even as the court acknowledged the challenges of determining the appropriate measure of actual damages

[207] *Id.* at *9.

[208] *Id.*

[209] Cole v. Gene by Gene, Ltd. (*Cole II*), 322 F.R.D. 500, 505-06 (D. Alaska 2017), *aff'd*, 735 Fed. Appx. 368 (2018).

[210] *Id.* at 507.

[211] *Id.* at 508.

and the fact that genetic material and information are more valuable in the aggregate than severally.

State legislation regulating DTC-GT ought to be improved in five ways. First, a private right of action is necessary to enable individuals whose privacy was violated to serve as private attorneys general. While industry typically opposes such measures due to concerns about meritless nuisance lawsuits, many federal and state statutes already provide for individual lawsuits for privacy violations,[212] including genetic privacy.[213] Given the especially personal nature of the violation of one's genetic privacy, which implicates misuse of one's own bodily tissue, a private right of action is particularly apposite. Moreover, as demonstrated by the *Cole* case, a private right of action is instrumental in establishing standing in federal court.[214]

Second, while the imposition of criminal penalties, as in Florida, treats genetic privacy violations as deserving of the most serious attention, this approach may prove counterproductive. It removes the case from the control of the plaintiff and establishes a high burden of proof for "willful" violations that may prove insurmountable at trial.

Third, the statutory damages afforded by current genetic privacy statutes, ranging from $5,000 to $100,000,[215] are arguably inadequate. Such sums neither compensate plaintiffs for the harms suffered nor deter violations by companies earning annual revenue of hundreds of millions of dollars.

Fourth, clear legislative language as to the extent of individuals' property interest in their tissue is necessary to guide courts as they consider plaintiffs' claims of conversion against DTC-GT companies and those who use their services to violate the privacy of others. One

[212] Cameron F. Kerry & John B. Morris, *In Privacy Legislation, a Private Right of Action Is Not an All-or-Nothing Proposition*, BROOKINGS (July 7, 2020), https://www.brookings.edu/blog/techtank/2020/07/07/in-privacy-legislation-a-private-right-of-action-is-not-an-all-or-nothing-proposition [https://perma.cc/5AUY-RVVY] (setting forth several federal and state laws that offer a private right of action).

[213] *See* ALASKA STAT. ANN. § 18.13.020 (2017) (regarding the private right of action provided by the Alaska Genetic Privacy Act).

[214] *See Cole I*, No. 1:14-cv-00004-SLG, 2017 U.S. Dist. LEXIS 101761, at *4-8 (D. Alaska June 30, 2017).

[215] See supra notes 159–63 and accompanying text relating to the statutory damages provided pursuant to genetic privacy statutes.

Florida court has signaled its willingness to consider, in the context of a future full discussion on the merits, a conversion claim against a DTC-GT, yet also expressed confusion about the extent to which state legislation truly ensures an individual's "exclusive property" interest in genetic information.[216] For a conversion claim, a plaintiff need only allege: "(1) plaintiffs' ownership or right to possession of the property at the time of the conversion; (2) defendants' conversion by a wrongful act or disposition of plaintiffs' property rights; and (3) damages."[217] As Justice Mosk noted in his dissenting opinion in *Moore*, the notion that a plaintiff "cannot own his tissue, but that [defendants] can, is fraught with irony."[218] Justice Mosk further explained that the fact that a defendant, such as a researcher, enhanced the value of the tissue with their ingenuity should not negate the conversion claim, but merely impact the amount of damages if plaintiff were to prevail at trial.[219] Justice Mosk emphasized that if science has become science for profit, then there is no "justification for excluding the patient from participation in those profits."[220] Indeed, the PXE International patient group illustrates the potential for individual or group ownership rights in tissue and the information derived from it. This group negotiated with researchers for co-ownership status on patent filings in exchange for access to the group's tissue bank. The gene patent issued in 2004 lists the group as co-owner, ensuring their role in making decisions about the use of the gene in testing and research.[221] Surely if individuals can negotiate in exchange for their genetic specimens and the data

[216] *See* Perlmutter Order, *supra* note 7, at 11.

[217] Baldwin v. Marina City Properties, Inc., 145 Cal. Rptr. 406, 416 (1978).

[218] Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 507 (1990) (Mosk, J., dissenting). *See also* Radhika Rao, *Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body?*, 35 J.L. MED. & ETHICS 371, 371 (2007) (stating that "even courts that reject ownership claims on the part of those who supply body parts appear willing to grant property rights to scientists, universities, and others who use those body parts to conduct research and create products").

[219] *Moore*, 793 P.2d at 517 (Mosk, J., dissenting) ("'Recognizing a donor's property rights would prevent unjust enrichment by giving monetary rewards to the donor and researcher proportionate to the value of their respective contributions.'").

[220] *Id.* (Mosk, J., dissenting).

[221] Gitter, *supra* note 49, at 315-19.

derived from them, this material and information has a determinable value.

Finally, courts ought to offer class action certification to plaintiffs pursuing cases against DTC-GT companies. Class action status is especially important given that plaintiffs are likely to face difficulties in proving actual damages and may need to rely on statutory damages.[222] Class action status permits a multiplier effect given the relatively modest amounts of statutory damages.

Our legal system increasingly expresses the notion that individuals possess property rights in their genetic material. State legislatures must expand and clarify those rights as plaintiffs become more sophisticated in their awareness of genetic privacy violations, particularly those facilitated via DTC-GT; demand more robust legislative protection; and pursue actions against these companies and those who use their services to obtain information about others without consent.

[222] *See* Wolf et al., *supra* note 144, at 40.