Gene Stewards: Rethinking Genome Governance

Shelly Simana*

Various entities, such as genetic testing and biotech companies, biobanks, research institutions, and government agencies, collect, analyze, and share human genetic material and information. When maximizing the benefits they obtain from these resources, such entities frequently employ exploitative practices that take advantage of power and information asymmetries. For example, they require individuals to waive property rights over genetic material and information, use these resources for purposes other than those for which they were obtained without the individuals' knowledge or comprehension of the implications, or collect these resources surreptitiously. Exploitative practices steer genetic material and information toward the ends of powerful entities while undermining individuals' property and privacy interests. They result in "appropriative harms."

The existing legal framework in the United States is fragmented, excessively narrow, and riddled with inconsistencies. Consequently, it falls short of effectively addressing exploitative practices and mitigating the profound power and information asymmetries in the genetic sphere. This Article addresses this gap by laying the theoretical and regulatory groundwork for future legal reform. It creates a new statutory category of "Gene Stewards," proposing to impose quasi-fiduciary duties of loyalty and care on every powerful entity in the genetic sphere, whether public or private. These duties highlight the value of trust and mandate that powerful entities act ethically and responsibly as stewards of identifiable and de-identified genetic material and information.

* Assistant Professor, Boston College Law School. For helpful conversations and invaluable comments on earlier drafts, I am profoundly grateful to Jennifer Allison, Yochai Benkler, Kathleen M. Boozang, Teneille Brown, I. Glenn Cohen, Jorge L. Contreras, Hanoch Dagan, Doron Dorfman, Evelyn Douek, Nir Eyal, Dov Fox, Henry T. Greely, Yaniv Heled, Mark A. Lemley, Myrisha S. Lewis, Michelle M. Mello, Christopher Morten, Emily R.D. Murphy, Yifat Naftali Ben Zion, Natalie Ram, D. Theodore Rave, Jessica L. Roberts, Daría Roithmayr, Jacob S. Sherkow, Joseph Singer, Sonia M. Suter, and Erez Yoeli. I would also like to thank the participants of the 7th Annual Health Law Works-in-Progress Retreat at Seton Hall Law School, the 2023 Law & Technology Workshop, the 2023 Privacy Law Scholars Conference, the 2023 Health Law Professors Conference, the Work in Progress Topics Seminar at the Stanford Center for Biomedical Ethics, and the Junior Faculty Forum for Law and STEM at Stanford Law School for constructive comments and suggestions. I am also thankful to the editors of the *UC Irvine Law Review* for their exceptional work in preparing this Article for publication.

Introduction 1106
I. Power Relations in the Genetic Sphere 1115
A. Gene Users: Who Are They? 1116
B. Exploitative Practices 1118
1. Requirement to Waive Property Rights 1118
2. Secondary Uses Without Individuals' Knowledge or Comprehension of the Potential Outcomes 1123
3. Surreptitious Collection 1127
C. Appropriative Harms 1129
II. The Existing Legal Framework and Its Limits 1133
A. Lack of Protection Against Exploitative Practices 1133
1. Requirement to Waive Property Rights 1134
a. Federal Level 1134
b. State Level 1136
2. Secondary Uses Without Individuals' Knowledge or Comprehension of the Potential Outcomes 1137
a. Federal Level 1137
b. State Level 1139
3. Surreptitious Collection 1140
a. Federal Level 1140
b. State Level 1141
B. Structural Limitations 1142
III. A Quasi-Fiduciary Framework for Genome Governance 1144
A. Fiduciary Law 1144
B. Information Fiduciaries 1147
C. Gene Stewards 1148
1. Information Fiduciaries versus Gene Stewards 1150
2. Blurring Distinctions in the Genetic Sphere 1151
3. Genetic Quasi-Fiduciary Duties 1154
4. Possible Objections to the Concept of Gene Stewards 1157
D. Gene Stewards Act 1159
Conclusion 1163

INTRODUCTION

Imagine that you suffer from a genetic disease. A clinical trial conducted by the Institute for Genetic Treatments uses an experimental treatment for this disease. Although the Food and Drug Administration (FDA) has not yet approved the treatment, you decide to participate in the clinical trial because you could benefit from the treatment. Your eligibility was approved, and you are now in the informed consent process. In the informed consent form, you notice the following provision: "By consenting to participate in this clinical trial, I give up any property rights I may have in DNA samples and results of DNA analyses obtained during this clinical trial." This provision appears unfair because you have no idea what other benefits the

Institute will gain from your genetic material and information, yet you are desperate for the treatment. Would you sign the form or withdraw your participation?

This dilemma underscores a growing trend in the fields of biomedicine and biotechnology, or the "genetic sphere," wherein a surge of entities collect, analyze, and share human genetic material and information.[1] These entities, which I classify as "Gene Users," range from direct-to-consumer (DTC) genetic testing and genetic genealogy companies to biotech companies, biobanks, laboratories, hospitals, research institutions, and government agencies. What motivates all these entities is the societal and economic value they can derive from genetic material and information.

The genetic sphere is far from being a level playing field. Gene Users enjoy significant advantages stemming from their specialized knowledge, connections to domains of public importance such as health, research, and public safety, and the ability to operate with limited oversight. Such conditions set a concerning stage for potential exploitation, transforming the dilemma presented earlier into a broader societal issue that demands careful scrutiny and resolution.

This Article is concerned with exploitive practices employed by Gene Users. It focuses on three such practices: (1) inclusion of property rights waivers in legal documents, often without ensuring people comprehend the implications of waiving their rights; (2) secondary use of genetic material and information without people's knowledge or understanding of the potential consequences; and (3) surreptitious collection of genetic material and information. A particular Gene User might employ only a subset of these practices and not necessarily all of them.

The exploitive practices enhance the power of Gene Users and amplify the vulnerability of individuals.[2] Exploitation in the genetic context arises when Gene

---

1. In this Article, human genetic material and information are defined to encompass a wide range of genetic components, including specimens, DNA samples, manipulated genetic materials, and information. In a nutshell, a *specimen* is a physical substance, like hair or saliva (for the purposes of this Article, I exclude gametes from this definition due to their reproductive potential). A *DNA sample* is DNA isolated from the nucleus of the cell, like Y-DNA, mitochondrial DNA, and autosomal DNA (Y-DNA is the DNA inherited by men from their fathers; mitochondrial DNA is a circular chromosome located within the cellular organelles known as mitochondria, which is passed unchanged from mother to child; and Autosomal DNA is a person's twenty-two pairs of non-sex chromosomes). A *manipulated genetic material* is a substance that has been manipulated by laboratory techniques, like a cell line. *Genetic information* is the information stored in genetic material. Information can be, for example, on single nucleotide polymorphism (one base pair in the DNA sequence), short tandem repeats (DNA strands with 2–7 nucleotide-long core repeat units), single genes, chromosomes, and the whole genome.

2. This Article draws upon Michel Foucault's definition of the term "power":

> [P]ower must be understood in the first instance as the multiplicity of *force relations* immanent in the sphere in which they operate and which constitute their own organization . . . [as well as] strategies in which they take effect, whose general design or institutional crystallization is embodied in the *state apparatus, in the formulation of the law, in the various social hegemonies*.

MICHEL FOUCAULT, THE HISTORY OF SEXUALITY VOLUME I: AN INTRODUCTION 76 (Robert Hurley trans., Vintage Books 1990) (1978) (emphasis added). Foucault suggested that

> [t]his form of power applies itself to immediate everyday life which categorizes the individual . . . . It is a form of power which makes individuals subjects. There are two meanings of the word "subject": subject to someone else by control and

Users unfairly take advantage of people.[3] The perception of what constitutes "unfair" can vary depending on a person's moral values. Viewed through the lens of my own moral matrix, I see Gene Users engaging in exploitative behavior by taking advantage of power and information imbalances to advance their objectives at the expense of individuals.[4] If these individuals were empowered or better informed, they might have made different choices.[5] This kind of exploitation can culminate in Gene Users distributing profits unequally, benefiting from people's lack of awareness or comprehension of the consequences of their actions, or capitalizing on individuals' dependence on essential genetic services.[6]

The Article argues that the three practices violate individuals' property and privacy interests,[7] resulting in what Professor Maureen Brady terms "appropriative

---

> dependence; and tied to his own identity by a conscience or self-knowledge.

Michel Foucault, *The Subject and Power*, 8 CRITICAL INQUIRY 777, 781 (1982).

3. ALAN WERTHEIMER, EXPLOITATION 10 (1996). As Wertheimer suggested, an exploitative act could also be mutually advantageous (i.e., the exploitee gains as well as the exploiter). *Id.* at 14. It is important to clarify that my position is not against the interactions between individuals and Gene Users. Rather, I advocate for these interactions to simply take place under fairer conditions.

4. By "power and information imbalances," I mean a "growing constellation of de jure and de facto legal immunities that predominantly bolsters . . . power, that magnifies the vulnerability of ordinary citizens to manipulation, exploitation, and political disempowerment, and that threatens profound collective harm." JULIE E. COHEN, BETWEEN TRUTH AND POWER: THE LEGAL CONSTRUCTIONS OF INFORMATIONAL CAPITALISM 76 (2019).

5. This perspective reflects an *asymmetrical* account of harms and benefits, acknowledging that enjoying a benefit does not preclude the possibility of experiencing harm as well. Applying this perspective to the genetic context suggests that, while individuals may gain benefits from interacting with Gene Users (such as receiving treatment or learning about their genetic makeup), they can also face potential harm as a result of this interaction. Seana Shiffrin discussed the intricacies associated with a *symmetrical* account of harms and benefits, highlighting that this account fails to identify harm where it exists:

> [M]any regard harms and benefits as though they represent two ends of a scale, like the scale of positive and negative numbers. Benefits are thought to be just like harms, except that harms are bad and benefits are good. . . . To evaluate whether an event has benefited or harmed a person, one compares, with respect to the fulfillment of his interests, either his beginning and his end points (historical models), or his end point and where he would have been otherwise (counterfactual models). If he has ascended the scale (either relative to his beginning point or alternative position), then he has been benefitted. If he moves down, then he has been harmed. Either way, one arrives at an all-things-considered judgment that either harm or benefit (but not both) has been bestowed. Thus, because he has been overall benefited, he has not been harmed.

Seana V. Shiffrin, *Wrongful Life, Procreative Responsibility, and the Significance of Harm*, 5 LEGAL THEORY 117, 121 (1999).

6. As previously mentioned, individuals and Gene Users can still engage in agreements concerning genetic material and information. However, those agreements should not reflect power or information asymmetries that adversely affect the individual's interests and well-being.

7. Legal scholars have engaged in vigorous debates regarding whether individuals have a *property* interest over their genetic material and information. This contentious issue has provoked divergent perspectives, with some scholars vehemently defending the existence of a property interest, and others adamantly rejecting this idea. *Compare, e.g.*, Radhika Rao, *Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body?*, 35 J.L. MED. & ETHICS 371 (2007); Natalie Ram, *DNA by the Entirety*, 115 COLUM. L. REV. 873 (2015); and Jessica L. Roberts, *Progressive Genetic Ownership*, 93 NOTRE DAME L. REV. 1105 (2018), *with* Jorge L. Contreras, *Genetic Property*, 105 GEO. L.J. 1 (2016); Jorge L. Contreras,

harms."[8] These practices are harmful because they undermine the legitimate control of individuals over their genetic material and information and instead privilege Gene Users' interests. They also infringe upon people's reasonable expectations, causing diverse types of privacy harms in the areas of psychological well-being, agency and autonomy, and personal relationships.[9] This broader understanding of harm extends beyond mere economic or physical consequences and also includes activities that common, ordinary individuals perceive as harmful, especially when they are intentionally carried out.[10]

Considering the harms caused by exploitative practices, this Article argues that the existing legal framework in the United States is insufficient and inadequate to protect individuals from such practices.[11] Laws governing the genetic sphere apply within narrow domains, subjecting only certain Gene Users to limitations. These limitations are inconsistent and diverse, leading to ambiguity and unpredictability. The Article therefore presents a new legal framework that addresses the shortcomings of that which is currently in place, providing better protection against exploitative practices.[12]

Key features of the proposed framework are the adoption of a "quasi-fiduciary" model[13] and the enactment of a new federal law[14] that would (a) designate Gene Users—private and public—as quasi-fiduciaries, (b) specify their duties, and (c) establish the option of suing Gene Users for breach of their duties, both through the authority of attorneys general and by means of a private right of action for individuals. Overall, this framework envisions a future characterized by trusting and collaborative relationships between Gene Users and individuals,[15] which better foster scientific

---

The False Promise of Health Data Ownership, 94 N.Y.U. L. REV. 624 (2019); and James Toomey, *Property's Boundaries*, 109 VA. L. REV. 131 (2023). Elsewhere I asserted that the core foundation of individuals' property interest stems from personhood and intelligible possession. Shelly Simana, *Genetic Property Governance*, 25 YALE J.L. & TECH. 144, 203–05 (2023).

8. Maureen E. Brady, *Property and Projection*, 133 HARV. L. REV. 1143, 1179–84 (2020).

9. Danielle Keats Citron & Daniel J. Solove, *Privacy Harms*, 102 B.U. L. REV. 793, 830–61 (2022).

10. Brady, *supra* note 8, at 1214.

11. *See* discussion *infra* Part II.

12. *See* discussion *infra* Part III.

13. The model is quasi-fiduciary because Gene Users' duties do not rise to the level of traditional fiduciary duties, yet they share some of the characteristics. *See* discussion *infra* Section III.C.

14. The rationale for enacting a statute, rather than solely depending on the courts, is that courts typically intervene only after a dispute arises. In other words, courts retrospectively resolve conflicts that have already emerged. However, establishing a statute provides a forward-looking approach for genome governance. This proactive approach, through the establishment of predefined rules and standards, aims to direct the actions of Gene Users. Such guidance is intended to preemptively avert the occurrence of conflicts. The statute, however, is not designed as a form of direct regulation to precisely dictate the actions Gene Users can take with genetic material and information. Instead, it establishes broad rules and standards that provide some flexibility. Given the evolving nature of uses and the varied contexts in which genetic material and information can be employed, the statute sets out general obligations rather than specific directives. The primary objective of the statute is to promote the idea that Gene Users are stewards of genetic material and information.

15. Despite potential skepticism, there are compelling reasons to believe that a genetic sphere founded on trust is achievable. First, this trust would be supported by legal safeguards. Law plays a

exploration based on the exchange of genetic material and information, with benefits for all members of society. Acknowledging the possibility of Gene Users acting opportunistically, the proposed framework also provides a legal pathway for assessing liability in cases of breaches of trust related to genetic material and information.[16] It opens up the possibility for people who have experienced harm due to the use of their genetic material and information to seek appropriate remedies.[17]

Thus far, numerous proposals have sought to address the insufficiency and inadequacy of the existing legal framework. Some proposals are narrow and context-specific: they target one domain (e.g., the criminal, scientific, insurance, clinical, or commercial domain) and a specific Gene User (e.g., the police, researchers, insurance companies, physicians, or DTC genetic testing companies).[18] Consequently, these proposals offer only a piecemeal solution and fall short of providing an overarching structural solution to the power and information asymmetries between individuals and Gene Users.

---

crucial role in preventing exploitation and would ensure that Gene Users operate within a framework that protects individual interests. Second, Gene Users would be expected to earn the trust placed in them, especially in contexts where their motives might be questioned. For trust to flourish, they would need to consistently demonstrate transparency, consistency, and reliability in their actions and communications, embodying a commitment to individual well-being. Third, people already place their trust in entities that handle sensitive information. In healthcare, for example, trust is routinely placed in professionals like doctors. Extending this trust to Gene Users is a rational next step. It is worth noting that doubts regarding the establishment of trust in powerful institutions are not limited to the genetic sphere; they challenge the very foundations of fiduciary law more broadly. These doubts question the assumption of trust that is integral to fiduciary law. However, I believe such doubts overlook the crucial role of trust in situations where there is mutual benefit.

16. On liability rule structures for health data, see Jorge L. Contreras, *Direct-to-Consumer Genomics and Personal Health Data*, *in* CONSUMER GENETIC TECHNOLOGIES: ETHICAL AND LEGAL CONSIDERATIONS 51, 61–63 (I. Glenn Cohen, Nita A. Farahany, Henry T. Greely & Carmel Shachar eds., 2021).

17. The legal framework introduced in this Article is an integral part of a comprehensive model for governing genetic material and information, which I develop in other related work. Within this model, genetic material and information are treated as a common and subjected to a common property regime. Simana, *supra* note 7. This Article explores the application of liability rules under the common property regime. By employing a combination of property rules and liability rules, an effective allocation of rights and responsibilities can be achieved. Property and liability rules can function collaboratively instead of contradictorily. In cases where exercising control over genetic material and information is not possible, providing compensation may be required. Furthermore, there might be scenarios where an injunction is issued along with accompanying compensation.

18. *See, e.g.*, Elizabeth E. Joh, *Reclaiming "Abandoned" DNA: The Fourth Amendment and Genetic Privacy*, 100 NW. U. L. REV. 857 (2006) (discussing the collection of DNA by law enforcement); Natalie Ram, *Assigning Rights and Protecting Interests: Constructing Ethical and Efficient Legal Rights in Human Tissue Research*, 23 HARV. J.L. & TECH. 119 (2009) (examining the use of genetic material and information in research); Jessica L. Roberts, *The Genetic Information Nondiscrimination Act as an Antidiscrimination Law*, 86 NOTRE DAME L. REV. 597 (2013) (addressing genetic discrimination by insurance companies and employers); Ifeoma Ajunwa, *Genetic Testing Meets Big Data: Tort and Contract Law Issues*, 75 OHIO ST. L.J. 1225 (2014) (focusing on disclosure of genetic information by DTC genetic testing companies); Divya Ramjee & Katelyn Ringrose, *The Challenges of Forensic Genealogy: Dirty Data, Electronic Evidence, and Privacy Concerns*, 98 DENV. L. REV. 157 (2020) (addressing forensic genealogy and publicly available genealogy databases); Jarrod O. Anderson, Anna C.F. Lewis & Anya E.R. Prince, *The Problems with Patchwork: State Approaches to Regulating Insurer Use of Genetic Information*, 22 DEPAUL J. HEALTH CARE L. 1 (2021) (discussing discrimination by life, long-term care, and disability insurance).

Other proposals address genome governance issues from a rights-based perspective, seeking to grant people an extensive bundle of rights over genetic material and information.[19] The main limitation of these proposals is that their dedication to expanding the *rights* of individuals hinders a comprehensive exploration of the corresponding *duties*. After all, to better protect people's rights, a legal framework should also ensure that duties are met.[20]

This Article urges a rethinking of genome governance and proposes a new legal concept, "Gene Stewards," to rebalance the relationship between individuals and Gene Users.[21] This concept takes cues from fiduciary law, which elucidates duties that foster trust. In particular, it is analogous—though not identical—to the concept of "Information Fiduciaries," proposed by Professor Jack Balkin as a response to power dynamics in the digital age.[22]

The Article also suggests the adoption of a new federal law, the "Gene Stewards Act."[23] This law would introduce a defined category of Gene Stewards and articulate the baseline duties they have toward individuals. The duties specified in the law should not be perceived as exhaustive. As new cases arise and scientific and technological advances occur, courts could identify additional duties by considering the reasonable expectations that should be imposed on Gene Stewards within the relevant context. Throughout this process, judges would diligently assess societal norms.

The concept of Gene Stewards recognizes that Gene Users have a special relationship with individuals who serve as the source of the genetic material and information.[24] This relationship is formed regardless of whether there is a contract

---

19. *See, e.g.*, Richard Cole, *Authentic Democracy: Endowing Citizens with a Human Right in Their Genetic Information*, 33 HOFSTRA L. REV. 1241 (2005) (suggesting to establish a human right in genetic information); Jaclyn G. Ambriscoe, *Massachusetts Genetic Bill of Rights: Chipping Away at Genetic Privacy*, 45 SUFFOLK U. L. REV. 1177 (2012) (proposing a Genetic Bill of Rights); Tufik Y. Shayeb, *You Are What You Own: Reopening the Discussion on Universally Recognizing a Property Right in Genetic Information and Material*, 38 WHITTIER L. REV. 181 (2017) (suggesting that a property right in genetic material and information be codified); Angela S. Gassner, *The Right to Delete: Protecting Consumer Autonomy in Direct-to-Consumer Genetic Testing*, 12 U.C. IRVINE L. REV. 267 (2021) (defending the right to delete genetic information); Yaniv Heled & Liza Vertinsky, *Genetic Paparazzi: Beyond Genetic Privacy*, 82 OHIO ST. L.J. 409 (2021) (suggesting to expand the protection afforded to identity under right of publicity laws to include genetic information).

20. On the relationship between rights and duties, see Wesley Newcomb Hohfeld, *Some Fundamental Legal Conceptions as Applied in Judicial Reasoning*, 23 YALE L.J. 16 (1913).

21. *See* discussion *infra* Section III.C.

22. Jack M. Balkin, *Information Fiduciaries and the First Amendment*, 49 U.C. DAVIS L. REV. 1183 (2016). For the parallels and differences between *Information Fiduciaries* and *Gene Stewards*, see discussion *infra* Section III.C.1.

23. *See* discussion *infra* Section III.D.

24. In the *research* context, the Maryland Court of Appeals established that a special relationship exists between researchers and their human subjects in nontherapeutic research projects. The court explicitly stated:

> [R]esearch agreements can, as a matter of law, constitute "special relationships" giving rise to duties . . . . [N]ormally, such special relationships are created between researchers and the human subjects used by the researchers. . . . [G]overnmental regulations can create duties on the part of researchers towards

or direct exchange, and it gives rise to quasi-fiduciary duties of loyalty and care. These duties "attach" at the beginning of the relationship—which is when Gene Users obtain access to genetic material and information—and remain in effect throughout the duration of Gene Users' utilization of these resources. The duties of loyalty and care underscore the critical role of trust and impose an obligation on Gene Users to act as stewards for genetic material and information.

Specifically, quasi-fiduciary duties are imposed on all entities engaged in the collection, analysis, and sharing of genetic material and information,[25] irrespective of whether these are identifiable or de-identified. In this context, the term "de-identified" refers to genetic material and information stripped of markers such as names, specific dates related to an individual, geographic locations, or Social Security numbers. The intention behind this proposal is to regulate powerful entities that aim to extract societal or economic benefits from genetic material and information, as well as encourage a more equitable power distribution. It strives to ensure that there exists a definable, basic threshold for duties within the genetic sphere.

My claim is founded on two premises. First, quasi-fiduciary duties follow genetic material and information, which means that every Gene User who has access to these resources should be subject to them.[26] Second, the significance of trust is represented in all forms of relationships between individuals and Gene Users. People should have confidence in Gene Users, trusting that their vulnerabilities will not be exploited, and Gene Users should have a duty to uphold this trust.[27]

---

human subjects out of which "special relationships" can arise.
Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 858 (Md. 2001).

25. While there are scholars who suggest the imposition of duties (not exclusively fiduciary) on entities that use genetic material and information, this Article sets itself apart from existing legal literature by advocating for special (quasi-fiduciary) duties to be imposed on *all entities*, regardless of whether they are private or public. For alternative proposals, see Sonia M. Suter, *Disentangling Privacy from Property: Toward a Deeper Understanding of Genetic Privacy*, 72 GEO. WASH. L. REV. 737 (2004) (claiming that the relationships between a research subject and a researcher and between a patient and a physician involve fiduciary duties); Benjamin T. Van Meter, *Demanding Trust in the Private Genetic Data Market*, 105 CORNELL L. REV. 1527 (2020) (imposing fiduciary duties on DTC genetic testing companies); Jessica L. Roberts & Alexandra L. Foulkes, *Genetic Duties*, 62 WM. & MARY L. REV. 143 (2020) (imposing a duty on labs or physicians to inform patients when a lab reclassifies a genetic variant); Jessica L. Roberts, *In Favor of an Action for Genetic Conversion*, *in* CONSUMER GENETIC TECHNOLOGIES: ETHICAL AND LEGAL CONSIDERATIONS 39 (I. Glenn Cohen et al. eds., 2021) (imposing duties on DTC genetic testing companies).

26. A similar approach is implemented in the General Data Protection Regulation (GDPR), which governs the use of personal data by controllers and processors established within the European Union. *See* Regulation (EU) 2016/679, of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and Repealing Directive 95/46/EC. The GDPR "has protections that 'follow the data' and establishes the 'default in Europe . . . that personal information cannot be collected or processed unless there is a specific legal justification for doing so.'" Cason Schmit, Brian Larson & Hye-Chung Kum, *Data Privacy in the Time of Plague*, 21 YALE J. HEALTH POL'Y L. & ETHICS 152, 181 (2022) (citing Anupam Chander, Margot E. Kaminski & William McGeveran, *Catalyzing Privacy Law*, 105 MINN. L. REV. 1733, 1747–48 (2021)). However, unlike this Article, the GDPR exempts the collection of personal data for law enforcement purposes.

27. On the importance of trust in relationships, see Neil Richards & Woodrow Hartzog,

Before plunging forward, one point of clarification is important. Genetic material and information warrant special consideration.[28] To be clear, while some of their features may be shared with other types of material and information, it is the combination of these features that makes genetic material and information sufficiently special. Moreover, while some of the concerns may emerge with respect to other types of material and information, this should not preclude a proper discussion on the significance of genetic material and information.

Genetic material and information possess collective, familial, and personal dimensions that are inherently interconnected, making it impossible to separate these dimensions from the genetic resources themselves. Approximately 99.9%of a person's DNA is identical among all individuals.[29] In fact, because relatives share more than 99.9% of their DNA,[30] less than 0.1% is unique to an individual.[31] Recognizing the interplay between these three dimensions is crucial. Through the study of genetic material and information, we acquire valuable knowledge that has the potential to improve the lives of all individuals. We also develop a deeper understanding of our familial connections by identifying and learning more about our relatives, unraveling the intricacies of our familial relationships. Additionally, we gain insights into our distinct genetic conditions.

Moreover, genetic material and information are rarely disconnected from the person they pertain to and can be linked to that person with only a small amount.[32]

Privacy's Trust Gap: A Review, 126 YALE L.J. 1180 (2017); Neil Richards & Woodrow Hartzog, *Trusting Big Data Research*, 66 DEPAUL L. REV. 579 (2017); ARI EZRA WALDMAN, PRIVACY AS TRUST: INFORMATION PRIVACY FOR AN INFORMATION AGE (2018).

28. This argument does not suggest that I adhere to genetic essentialism. I reject the notion that genes define the essence, or nature, of human beings. Furthermore, this argument does not imply that protection should be exclusively reserved for genetic material and information, nor does it suggest that concerns about exploitation are confined solely to these resources. It only claims that it is possible to make distinctions between genetic material and information and other types of materials and information that carry significance. On genetic exceptionalism, see Sonia M. Suter, *The Allure and Peril of Genetics Exceptionalism: Do We Need Special Genetics Legislation?*, 79 WASH. U. L. Q. 669 (2001); Amanda K. Sarata, Cong. Rsch. Serv., Genetic Exceptionalism: Genetic Information and Public Policy (2008) https://www.policyarchive.org/handle/10207/18867 [https://perma.cc/EL7K-ZEY3]; Samual A. Garner & Jiyeon Kim, *The Privacy Risks of Direct-to-Consumer Genetic Testing: A Case Study of 23andMe and Ancestry*, 96 WASH. U. L. REV. 1219, 1241–45 (2019). On the special nature of genetic material and information, see Yaniv Heled, Liza Vertinsky & Ana Santos Rutschman, *A Theory of Genetic Dimensions in the Law*, 99 IND. L.J. 1341 (2024).

29. *Human Genomic Variation*, NAT'L HUM. GENOME RSCH. INST. (Apr. 6, 2018), https://www.genome.gov/dna-day/15-ways/human-genomic-variation [https://perma.cc/W4R6-66EP].

30. As relatives become more distant in the family tree, the amount of DNA they share decreases. For example, the DNA of a mother and her child is more similar than the DNA of uncles and nephews—the mother and her child share approximately half of their DNA. ALAN MCHUGHEN, DNA DEMYSTIFIED: UNRAVELLING THE DOUBLE HELIX 200–02 (2020).

31. *Whole Genome Association Studies*, NAT'L HUM. GENOME RSCH. INST. (JUL. 15, 2011), https://www.genome.gov/17516714/2006-release-about-whole-genome-association-studies [https://perma.cc/5ABQ-CAAT].

32. Currently, the ideal amount of DNA for profiling is about 500 picograms, which is roughly equivalent to eighty diploid cells, each cell averaging approximately six picograms of DNA. Assuming there is no DNA loss during processing, a sample yielding eighty cells should be sufficient to generate a DNA profile.

Since genetic sequence is perhaps one of the most distinctive characteristics of individuals, it is difficult to "de-identify" genetic material and information.[33] Even in cases where they have been stripped of identifiable information, it remains possible to uncover the person's identity.[34] Hence, the differentiation between identifiable and de-identified becomes less relevant when it comes to genetic material and information.

Furthermore, genetic material traces can be found ubiquitously in sources ranging from discarded tissues, water bottles, cigarettes, footprints, and even the air.[35] This makes it very difficult to prevent others from collecting genetic material and processing it to obtain genetic information. Theoretically, it might be possible to avoid the loss of genetic material if an individual were to always wear gloves and carry cleaning tools to wipe down all surfaces they touch. However, if a person is not careful enough to collect all the DNA that they shed—a Herculean, if not practically impossible, task—it would be easy for someone else to do so without the person's knowledge.

Lastly, a small genetic sample can yield a variety of information for multiple uses. Genetic material can generate information about a person's ancestry and paternity, and it can also be predictive, revealing information about disease predisposition and genetic conditions that can be passed down to offspring.[36] Consequently, a Gene User can utilize the genetic sample for multiple purposes, thereby accumulating a substantial amount of information about the individual in question.

The Article proceeds in four parts. Part I describes power relations in the genetic sphere. It begins by acknowledging that, despite their many differences, Gene Users have much in common. Indeed, some Gene Users are private, while others are government or quasi-government entities; some are interested in using genetic material and information for societal purposes (e.g., creating valuable genetic databases, advancing our knowledge of how genetic variations influence the risk of genetic conditions, or promoting public safety), while others are interested in using these resources for purely economic reasons. Still, all Gene Users have at least four characteristics in common: they provide public benefits, their actions significantly affect individuals' interests, they possess the ability to retain genetic material and information for extended periods, and they are the primary beneficiaries of practices that disempower people.

Piyamas Kanokwongnuwut, Belinda Martin, Duncan Taylor, K. Paul Kirkbride & Adrian Linacre, *How Many Cells Are Required for Successful DNA Profiling?*, 51 FORENSIC SCI. INT'L: GENETICS 1 (2021).

33. Nora von Thenen, Erman Ayday & A. Ercument Cicek, *Re-Identification of Individuals in Genomic Data-Sharing Beacons via Allele Inference*, 35 BIOINFORMATICS 365 (2019); Mahsa Shabani & Luca Marelli, *Re-Identifiability of Genomic Data and the GDPR: Assessing the Re-Identifiability of Genomic Data in Light of the EU General Data Protection Regulation*, 20 EMBO REPS. e48316 (2019); 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 (2022).

34. Alexander Bernier, Hanshi Liu & Bartha Maria Knoppers, *Computational Tools for Genomic Data De-Identification: Facilitating Data Protection Law Compliance*, 12 NATURE COMMC'NS 6949 (2021).

35. *See, e.g.*, Roland A. H. van Oorschot & Maxwell K. Jones, *DNA Fingerprints from Fingerprints*, 387 NATURE 767 (1997); Chiara Fantinato, Peter Gill & Ane Elida Fonneløp, *Detection of Human DNA in the Air*, 8 FORENSIC SCI. INT'L: GENETICS SUPPL. SERIES 282 (2022).

36. Faith Lagay, *Should Genetic Information Be Treated Separately?*, 3 AMA J. ETHICS 4 (2001).

This part then provides detailed insights into three exploitative practices employed by Gene Users, deemed so because they grant Gene Users the power to use genetic material and information for their own advantage and deny individuals the respect and care they deserve. This part further asserts that these practices infringe upon individuals' property and privacy interests. As Part III will subsequently argue, these three practices constitute a violation of Gene Users' quasi-fiduciary duties.

Part II explores the legal mechanisms in place to safeguard individuals against exploitative practices. It identifies two structural gaps in the existing legal framework. First, it is narrow, covering only a few exploitative practices and Gene Users. Second, it is riddled with inconsistencies. State laws vary significantly in terms of the exploitative practices they regulate, the Gene Users they cover, and the type of genetic component they protect.

Part III introduces the concept of Gene Stewards, contrasts it with Jack Balkin's concept of Information Fiduciaries, and considers potential objections. Then, this part discusses the characteristics of the proposed federal law. The overarching objective of the legal reform suggested in this Article is to blur categorical boundaries within the genetic sphere and foster greater consistency and predictability in the governance of human genetic material and information.

I. POWER RELATIONS IN THE GENETIC SPHERE

In recent years, technological advances have increased our understanding of genomics and genetics.[37] As a result, a growing number of Gene Users seek access to human genetic material and information for various purposes. For example, DTC genetic testing companies create databases gathered from at-home DNA testing kits, as well as assist individuals in tracing their family history and establishing contact with relatives with whom they had no prior relationship.[38] Research laboratories, institutions, and programs investigate how genetic variations impact health.[39] Law enforcement and intelligence agencies identify criminal suspects and protect public safety.[40] And biotech and pharmaceutical companies develop novel medical devices and drugs.[41] Together with these societal purposes, many Gene

37. Genomics describes the study of the genes of a particular person. Genetics refers to the study of human genes and the way that certain conditions are passed down from one generation to another. *Genetics vs. Genomics Fact Sheet*, NAT'L HUM. GENOME RSCH. INST. (Sept. 7, 2018), https://www.genome.gov/about-genomics/fact-sheets/Genetics-vs-Genomics [https://perma.cc/7UP4-Z4LR].

38. James W. Hazel, Catherine Hammack-Aviran, Kathleen M. Brelsford, Bradley A. Malin, Laura M. Beskow & Ellen Wright Clayton, *Direct-to-Consumer Genetic Testing: Prospective Users' Attitudes Toward Information About Ancestry and Biological Relationships*, 16 PLOS ONE e0260340 (2021).

39. *See, e.g.*, *Impact of Genomic Variation on Function (IGVF) Consortium*, NAT'L HUM. GENOME RSCH. INST. (Dec. 10, 2023), https://www.genome.gov/Funded-Programs-Projects/Impact-of-Genomic-Variation-on-Function-Consortium [https://perma.cc/8Y37-CJ5L].

40. *See* Joh, *supra* note 18; Natalie Ram, Erin E. Murphy & Sonia M. Suter, *Regulating Forensic Genetic Genealogy*, 373 SCI. 1444 (2021).

41. Matthew R. Nelson, Toby Johnson, Liling Warren, Arlene R. Hughes, Stephanie L. Chissoe, Chun-Fang Xu & Dawn M. Waterworth, *The Genetics of Drug Efficacy: Opportunities and Challenges*, 17 NATURE REVS. GENETICS 197 (2016).

Users seek to maximize their profits from genetic material and information.

One of the major concerns is that Gene Users are powerful—their dominance stems, in part, from their scientific or technical knowledge and expertise, their connections to areas of public benefit, and their nontransparent and prone-to-exploitation behavior. Gene Users' dominance and individuals' dependency and vulnerability are not only interrelated but they also result in significant power and information asymmetries. These asymmetries demonstrate how "law, technology, and ideas have worked together to generate growing power for those in command."[42] They create a "system that amplifies power in the hands of the state and a concentrated class of private actors."[43]

This part explores three exploitative practices that manifest power and information asymmetries between Gene Users and individuals. Section I.A provides a description of Gene Users and delineates the common characteristics shared by all entities in this group. Section I.B discusses Gene Users' exploitative practices and the interests of individuals that are affected by them. Section I.C explains how exploitative practices result in what Professor Maureen Brady refers to as "appropriative harms."[44] Specifically, Gene Users steer genetic material and information toward their own ends, including using them for undesirable and unanticipated purposes, without always considering the interests of individuals. While exploitative practices characterize many market and nonmarket relationships, a higher standard of behavior should be expected from these actors. As Part III will argue, Gene Users are quasi-fiduciaries and have special duties to protect individuals from precisely these types of harms.

A. Gene Users: Who Are They?

Gene Users continuously collect, analyze, and share genetic material and information and seek to generate societal and economic value from these resources. This wide-ranging category of entities includes private, quasi-government, or government entities, such as those engaged in genetic testing, genetic genealogy, biotechnology, research, pharmaceuticals, public health, or law enforcement.

Despite their differences, Gene Users share four main characteristics. First, they provide public benefits, impacting various domains, including scientific research, medical advancements, and forensic investigations. For instance, researchers and biotech companies shed light on important biological processes. These entities use genetic material and information to unlock valuable insights into the complexities of the human body.[45] By delving into the human genome, they

42. Amy Kapczynski, *The Law of Informational Capitalism*, 129 YALE L.J. 1460, 1486 (2020) (addressing how law, ideologies, and technology interact in the context of the information economy).

43. Yochai Benkler, *Degrees of Freedom, Dimensions of Power*, 145 DAEDALUS 18, 19 (2016).

44. Brady, *supra* note 8.

45. COMMITTEE ON ASSESSING INTERACTIONS AMONG SOCIAL, BEHAVIORAL, AND GENETIC FACTORS IN HEALTH, GENES, BEHAVIOR, AND THE SOCIAL ENVIRONMENT: MOVING BEYOND THE NATURE/NURTURE DEBATE (Lyla M. Hernandez & Dan G. Blazer eds., 2006); Angela

deepen our understanding of genetic predispositions, hereditary conditions, and potential health risks. Genetic testing and genetic genealogy companies possess the ability to unravel the origins of humanity and families.[46] Through genetic testing and analysis, they uncover ancestral connections and trace lineages.[47] This knowledge not only satisfies our curiosity about our own heritage but also fosters a greater sense of belonging and interconnectedness in our society. Finally, law enforcement and intelligence agencies prevent and solve criminal cases.[48] Through their use of genetic material and information, these agencies uncover crucial evidence, identify perpetrators, and ensure public safety.

Second, Gene Users have a significant impact on individuals' interests, although they affect those interests differently depending on the activities they conduct. Some entities, such as pharmaceutical companies and research institutions, shape and impact people's interest in health. They provide essential health information to individuals and communities, and their scientific contributions impact the well-being of people around the world. Another interest is related to identity.[49] Some entities, such as DTC genetic testing and biotech companies, offer people information about their genetic traits and ancestry, which are of major importance for personal identity.[50] Two other areas of particular interest are property and privacy.[51] As Section I.C elaborates, the practices employed by Gene Users disrupt the appropriate control individuals should have over genetic material and information and undermine their expectations.[52]

Third, Gene Users tend to retain genetic material and information over extended durations, thereby establishing lasting relationships with individuals that endure even after their death. The retention of genetic material is facilitated through various means, such as cryopreservation and specialized storage solutions.[53] Moreover, digital storage methods offer efficient archiving and retrieval capabilities for genetic information.[54] The ability of Gene Users to retain genetic material and

---

Brand, Helmut Brand & Tobias Schulte in den Bäumen, *The Impact of Genetics and Genomics on Public Health*, 16 EURO. J. HUM. GENETICS 5 (2008).

46. Hazel et al., *supra* note 38.

47. *Id.*

48. Joh, *supra* note 18; Ram et al., *supra* note 40.

49. Heled & Vertinsky, *supra* note 19, at 454–55; EMILY POSTAN, EMBODIED NARRATIVES: PROTECTING IDENTITY INTERESTS THROUGH ETHICAL GOVERNANCE OF BIOINFORMATION (2022).

50. Hazel et al., *supra* note 38; Heled & Vertinsky, *supra* note 19.

51. Several scholars have recognized that property interests envelop privacy interests. *See* Brady, *supra* note 8, at 1179–84; Elizabeth G. Patterson, *Property Rights in the Balance - The Burger Court and Constitutional Property*, 43 MD. L. REV. 518, 535–48 (1984).

52. Ensuring individuals' appropriate control over genetic material and information requires Gene Users to refrain from collecting, analyzing, and sharing these resources in a disproportionate and unreasonable manner. Moreover, Gene Users must fulfill a set of quasi-fiduciary duties, demonstrating their commitment to responsible and respectful practices. *See infra* notes 135–137, 265–269 and accompanying text.

53. David Whaley, Kimia Damyar, Rafal P. Witek, Alan Mendoza, Michael Alexander & Jonathan RT Lakey, *Cryopreservation: An Overview of Principles and Cell-Specific Considerations*, 30 CELL TRANSPLANTATION 1 (2021).

54. Warren C. Lathe III, Jennfer M. Williams, Mary E. Mangan & Donna Karolchik, *Genomic*

information for a long time puts people at increased risk and raises concerns about the vulnerability of their interests.

Fourth, in most circumstances, Gene Users receive the lion's share of benefits from genetic material and information, while passing on the lion's share of risks to individuals. Indeed, although in some situations Gene Users empower people and give them a sense of control over their lives (by providing extensive information on health and ancestry, for example), they also exploit them. The power of Gene Users allows them to act in their own self-interest in ways that disadvantage individuals and result in appropriative harms. As Section I.C discusses, appropriative harms have adverse effects on individuals' property and privacy interests.

It is crucial to acknowledge that treating government agencies, particularly law enforcement and intelligence agencies, on par with private entities is not a common approach.[55] Nevertheless, I adopt this approach because I strive to establish a minimum threshold of fair and just standards for all Gene Users. My primary objective is to prevent any form of exploitation of genetic material and information, regardless of the type of entity involved. Imposing identical baseline standards on government agencies as those on other entities ensures consistent and uniform protection of people's interests across all sectors. All relevant entities are held to the same baseline standards: transparency, minimization, purpose limitation, and respect for individuals' interests. Adhering to these standards not only strengthens oversight mechanisms but also provides individuals with stronger remedies in cases where their genetic material and information are misused. I will delve deeper into this matter in Section III.C.2.

B. Exploitative Practices

Gene Users' practices grant them power and control over people's property and privacy interests. This section focuses on three practices: (1) a requirement to waive all property rights over genetic material and information; (2) secondary uses of genetic material and information without individuals' knowledge or comprehension of the ramifications; and (3) surreptitious collection of genetic material and information.

1. Requirement to Waive Property Rights

Gene Users offer an extensive selection of products and genetic testing services, including an invitation to participate in clinical trials and research studies. When interacting with individuals, Gene Users ask them to sign or acknowledge legal documents, such as terms of service, privacy policies, and informed consent forms.[56] This is frequently done without ensuring comprehension on the part of the

---

Data Resources: Challenges and Promises, 1 NATURE EDUC. 2 (2008).

55. For example, government bodies and law enforcement are exempt from the provisions of the GDPR when it comes to gathering and processing data for the purposes of preventing, investigating, detecting, or prosecuting criminal offenses, executing criminal penalties, or safeguarding public safety. Regulation (EU) 2016/679, *supra* note 26, at art. 23.

56. *Privacy in Genomics*, NAT'L HUM. GENOME RSCH. INST. (Feb. 6, 2024), https://www.geno

individuals involved.[57] In those documents, Gene Users often require individuals to waive any property rights they may have over not only their own genetic material and information but also over any research or commercial products that may be developed from these resources.[58] Those who waive their property rights cannot profit from the genetic material and information, nor can they have a say in how Gene Users utilize these resources.

For example, United Therapeutics Corporation, a biotech company that develops technologies for rare lung diseases, oncology, and organ manufacturing, includes in its informed consent form the following provision: "I give up any property rights I may have to the sample collected for this optional research, and any genomic sequencing information or other data derived research using the sample."[59]

Kailos Genetics, a genetic testing company that specializes in hereditary cancer screening, requests that individuals agree to the following terms:

> You understand that by providing any sample, having your Genetic Information processed, accessing your Genetic Information, or providing Self-Reported Information, you acquire no rights in any research or commercial products that may be developed by Kailos Genetics or its collaborating partners. You specifically understand that you will not receive compensation for any research or commercial products that include or result from your Genetic Information or Self-Reported Information.[60]

Two of the major DTC genetic testing companies in the United States, 23andMe and Ancestry, also include property rights waivers in their terms of service. For instance, 23andMe's waiver reads as follows:

> You understand that by providing any sample, having your Genetic Information processed, accessing your Genetic Information, or providing Self-Reported Information, you

---

me.gov/about-genomics/policy-issues/Privacy [https://perma.cc/Y8PD-9G54].

57. *See* Valerie Gutmann Koch, *Reimagining Informed Consent: From Disclosure to Comprehension*, 14 U.C. IRVINE L. REV. 894 (2024). *See also* Anya E.R. Prince, *Disclosing Privacy and Discrimination Protections in Informed Consent*, 33 HEALTH MATRIX 79 (2023).

58. For examples of property rights waivers, see *Terms & Conditions*, TOOLBOX GENOMICS, INC. (JAN. 20, 2023), https://www.toolboxgenomics.com/pages/terms-and-conditions/ [https://perma.cc/M472-486B]; *Terms of Service*, Juno Diagnostics (SEPT. 29, 2022), https://junodx.com/terms-of-service/ [https://perma.cc/K8DT-X6L2]; *Terms of Service*, GENE GUARD, INC. (SEPT. 27, 2021), https://geneguard.bio/legal/terms-of-service [https://perma.cc/M4U4-LVGT]; *Terms of Service*, GENEBLUEPRINT, https://geneblueprint.com/pages/terms-of-service [https://perma.cc/XKY2-GZDB]; *Terms & Conditions*, MUHDO HEALTH LTD. (OCT. 23, 2023), https://muhdo.com/terms-conditions/ [https://perma.cc/ZGL9-YBYL]; *LifeNome Terms of Service*, LIFENOME, INC., https://www.lifenome.com/terms-of-service/ [https://perma.cc/D6R6-YBHA]; *Terms of Service of EDGC in US*, GENE2ME, https://www.gene2me.global/en/policy/terms [https://perma.cc/VAR4-ZDJE].

59. *Informed Consent Form*, UNITED THERAPEUTICS CORP., https://clinicaltrials.gov/ProvidedDocs/37/NCT01560637/ICF_002.pdf [https://perma.cc/9WWJ-FKKQ].

60. *Terms & Conditions*, KAILOS GENETICS, https://www.kailosgenetics.com/sites/default/files/2021-02/Terms.pdf [https://perma.cc/WP8M-6ZBD].

> acquire no rights in any research or commercial products that may be developed by 23andMe or its collaborators. You specifically understand that you will not receive compensation for any research or commercial products that include or result from your Genetic Information or Self-Reported Information.
>
> . . .
>
> Your saliva sample, once submitted to and analyzed by us, is processed in an irreversible manner and cannot be returned to you. See our website for more information on sample processing. Any Genetic Information derived from your saliva remains your information, subject to rights we retain as set forth in these TOS [Terms of Service]. You understand that you should not expect any financial benefit from 23andMe as a result of having your Genetic Information processed; made available to you; or, as provided in our Privacy Statement and these TOS, shared with or included in Aggregated Genetic and Self-Reported Information shared with any research collaborator.[61]

The unequivocal assumption that individuals do not have property rights over genetic material and information, or the research and commercial products that result from them, has been the norm for a long time.[62] This norm holds particular significance in the U.S. judicial system, as evident in two landmark cases: *Moore v. Regents of the University of California* and *Greenberg v. Miami Children's Hospital Research Institute*. In these cases, courts ruled against individuals having property rights over their genetic material and information,[63] or any derived products.[64]

Regulatory bodies have also addressed the issue of property rights waivers. The U.S. Office for Human Research Protections (OHRP) and the FDA issued a draft of Guidance on Exculpatory Language in Informed Consent that supports the inclusion of property rights waivers within the context of research activities. The Guidance provides various examples of "acceptable language" in informed consent forms:

- Although future research that uses your samples may lead to the

---

61. *23andMe Terms of Service*, 23ANDME (DEC. 9, 2021), https://www.23andme.com/legal/terms-of-service/full-version/3.6/ [https://perma.cc/5PM2-28WH].

62. David E. Winickoff & Richard N. Winickoff, *The Charitable Trust as a Model for Genomic Biobanks*, 349 NEW ENG. J. MED. 1180 (2003); ELISA EISEMAN, GABRIELLE BLOOM, JENNIFER BROWER, NOREEN CLANCY & STUART S. OLMSTED, CASE STUDIES OF EXISTING HUMAN TISSUE REPOSITORIES: "BEST PRACTICES" FOR A BIOSPECIMEN RESOURCE FOR THE GENOMIC AND PROTEOMIC ERA 141 (2003); John C. Bear, "*What's My DNA Worth, Anyway?" A Response to the Commercialization of Individuals' DNA Information*, 47 PERSPS. BIOLOGY & MED. 273 (2004); Gary E. Marchant, *Property Rights and Benefit-Sharing for DNA Donors?*, 45 JURIMETRICS 153 (2005).

63. Greenberg v. Mia Child's Hosp. Rsch. Inst., 264 F. Supp. 2d 1064 (S.D. Fla. 2003) (in this case, the genetic sequence identified by the researcher and related inventions were patented).

64. *Id.*; Moore v. Regents of Univ. of Cal., 51 Cal. 3d 120 (1990) (in this case, the cells were used to develop and patent a cell line).

development of new products, you will not receive any payments for these new products.

- By agreeing to this use, you are giving up all claims to any money obtained by the researchers from commercial or other use of these specimens.
- I voluntarily and freely donate any and all blood, urine, and tissue samples to the [name of research institution] and hereby relinquish all property rights, title, and interest I may have in those samples.
- By consenting to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples collected during this research.
- Although the results of research, including your donated materials, may be patentable or have commercial value, you will have no legal or financial interest in any commercial development resulting from the research.
- Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. No financial compensation will be provided to you should this occur.[65]

Incorporating property rights waivers into terms of service, privacy policies, and consent forms is a practice that makes use of the unequal power distribution between Gene Users and individuals. As Part II will reveal, this practice is considered valid rather than "deceptive" or "unfair" under current law. However, considering the significant role Gene Users play in providing a service that is important—and often necessary—to the public, their substantial advantage in bargaining power over individuals, and individuals' limited comprehension of the consequences of waiving their rights, this Article deems property rights waivers exploitative.[66]

---

65. OHRP & FDA, Exculpatory Language in Informed Consent (Aug. 2011), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/exculpatory-language-informed-consent [https://perma.cc/BJ47-WZBT].

66. In a different context, the Supreme Court of California introduced a six-factor test aimed at assisting courts in determining whether a contract pertains to the "public interest." The court held:

> In placing particular contracts within or without the category of those affected with a public interest, the courts have revealed a rough outline of that type of transaction in which exculpatory provisions will be held invalid. Thus the attempted but invalid exemption involves a transaction which exhibits some or all of the following characteristics. It concerns a business of a type generally thought suitable for public regulation. The party seeking exculpation is engaged in performing a service of great importance to the public, which is often a matter of practical necessity for some members of the public. The party holds himself out as willing to perform this service for any member of the public who seeks it, or at least for any member coming within certain established standards. As a result of the essential nature of the service, in the economic setting of the transaction, the party invoking exculpation possesses a decisive advantage of bargaining strength against any member of the public who seeks his services. In exercising a superior bargaining power the party confronts the public with a standardized adhesion contract of exculpation, and makes no provision whereby a purchaser may pay additional reasonable fees and obtain protection against negligence. Finally, as a result of the transaction, the person or

People almost never find themselves in a favorable negotiating position when interacting with Gene Users. Due to the inherent power dynamics in the genetic sphere, in most cases, individuals have two options: (1) they can either sign a legal document containing a property rights waiver or (2) choose not to do so and forfeit their use of genetic testing services or participation in clinical trials and research studies. The scenario presented in the Introduction serves as an illustration of how individuals may be unable to bargain over an objectionable provision.[67]

This imbalance of negotiating power is further reflected by the fact that Gene Users can make unilateral alterations to their policies and terms of service that individuals cannot reject.[68] This means that property rights waivers could potentially be introduced *after* individuals have contributed their genetic material and information.

Finally, Gene Users typically do not offer comprehensive explanations in legal documents, and their vocabulary tends to be vague and complicated.[69] Although Gene Users may provide some explanations about what they intend to do with genetic material and information or what they are legally permitted to do with them, an average person's comprehension of the implications of property rights waivers is limited. Consequently, individuals cannot fully consider the costs and benefits of purchasing genetic testing services or participating in clinical trials and research studies, nor can they comprehend the ramifications of agreeing to property rights waivers.

Through these waivers, Gene Users not only gain greater control over genetic material and information but also take advantage of their relative power and individuals' vulnerability for financial gain.[70] In some cases, individuals have no alternative to giving up influence over what happens to the genetic material and information they provided and are denied a portion of the monetary gains resulting from the Gene Users' activities.

Given these circumstances, when individuals provide genetic material and information without receiving any compensation, it raises a prima facie case of unjust enrichment.[71] Based on this theory of liability, individuals who confer

---

> property of the purchaser is placed under the control of the seller, subject to the risk of carelessness by the seller or his agents.

Tunkl v. Regents of Univ. of Cal., 383 P.2d 441, 444–45 (Cal. 1963).

67. *See generally* Mark A. Lemley, *The Benefit of the Bargain*, 2023 WIS. L. REV. 237 (2023) (arguing that large businesses frequently impose terms and conditions on individuals in a unilateral manner, presenting them with a "take it or leave it" proposition).

68. Van Meter, *supra* note 25, at 1547–48. On unilateral amendments in the health domain, see Leah R. Fowler, Jim Hawkins & Jessica L. Roberts, *Uncertain Terms*, 97 NOTRE DAME L. REV. 1 (2021).

69. *See* Yannis Bakos, Florencia Marotta-Wurgler & David R. Trossen, *Does Anyone Read the Fine Print? Consumer Attention to Standard-Form Contracts*, 43 J. LEGAL STUDS. 1 (2014); Matthew Tokson, *Knowledge and Fourth Amendment Privacy*, 111 NW. U. L. REV. 139 (2016); Tomasz Pietrzykowski & Katarzyna Smilowska, *The Reality of Informed Consent: Empirical Studies on Patient Comprehension—Systematic Review*, 22 TRIALS 57 (2021).

70. Mary T. Danforth, *Cells, Sales, and Royalties: The Patient's Right to a Portion of the Profits*, 6 YALE L. & POL'Y REV. 179 (1988); Debra L. Greenfield, *Greenberg v. Miami Children's Hospital: Unjust Enrichment and the Patenting of Human Genetic Material*, 15 ANNALS. HEALTH L. 213 (2006); Rebecca A. Johnson & David Wendler, *Challenging the Sanctity of Donorism: Patient Tissue Providers as Payment-Worthy Contributors*, 25 KENNEDY INST. ETHICS J. 291 (2015); Roberts, *supra* note 7.

71. Section 44 states:

benefits to Gene Users deserve to retain a portion of the benefits. Because the benefits partially result from their contribution, it is unjust for Gene Users to retain benefits without sharing some of them with individuals.[72]

In fact, the family of Henrietta Lacks filed a lawsuit against Thermo Fisher Scientific alleging a similar claim.[73] Henrietta was a Black woman who received cancer treatment at Johns Hopkins Hospital in 1951. Some of her cells were collected without her knowledge or consent and have been widely used in medical research, including by Thermo Fisher Scientific.[74] The family sued the company, alleging unjust enrichment. The claim was based on wrongful conduct that not only violated the duties owed to Henrietta by her doctors but was also facilitated by a long-standing and systemic disregard for ethical and legal principles in medical experimentation, particularly concerning Black, low-income, and other marginalized groups.[75]

2. Secondary Uses Without Individuals' Knowledge or Comprehension of the Potential Outcomes

Gene Users engage in primary and secondary uses of genetic material and

---

> (1) A person who obtains a benefit by conscious interference with a claimant's legally protected interests (or in consequence of such interference by another) is liable in restitution as necessary to prevent unjust enrichment, unless competing legal objectives make such liability inappropriate. (2) For purposes of subsection (1), interference with legally protected interests includes conduct that is tortuous, or that violates another legal duty or prohibition (other than a duty imposed by contract), if the conduct constitutes an actionable wrong.

RESTATEMENT (THIRD) OF RESTITUTION & UNJUST ENRICHMENT § 44 (Am. L. Inst. 2011).

72. For an interesting example of a benefit-sharing legal framework, see Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity, U.N. Doc. UNEP/CBD/COP/DEC/X/1 (Oct. 29, 2010). *See also About the Nagoya Protocol*, Convention on Biological Diversity (June 9, 2015), https://www.cbd.int/abs/about/ [https://perma.cc/D5SB-KJW3]. The Nagoya Protocol is an interesting example, despite its focus on *non-human* genetic material and information. The Nagoya Protocol is a supplement to the Convention on Biological Diversity and provides a legal framework for implementing a fair and equitable distribution of benefits—monetary or nonmonetary—between countries that emerge from the use of genetic resources.

73. Second Amended Civ. Complaint & Request for Jury Trial, Ron L. Lacks, Pers. Representative Est. Henrietta Lacks v. Thermo Fisher Sci., Inc., No. 1:21-cv-02524-DLB (D. Md, Nov. 18, 2022). Thermo Fisher Scientific has recently reached a settlement with the Lacks family, the specifics of which remain confidential. *See* Amanda Holpuch, *Family of Henrietta Lacks Settles with Biotech Company That Used Her Cells*, N.Y. TIMES (Aug. 1, 2023), https://www.nytimes.com/2023/08/01/science/henrietta-lacks-cells-lawsuit-settlement.html [https://perma.cc/LG8D-A25H]. In addition to the lawsuit against Thermo Fisher Scientific, Henrietta Lacks' family has filed lawsuits against several other companies, including UltraGenyx, Novartis, and Viatris, for unjust enrichment. As of the time of writing this paper, the outcomes of these lawsuits remain unknown. *See* Complaint, Ron L. Lacks, Pers. Representative Est. Henrietta Lacks v. Ultragenyx Pharmaceutical, Inc., No. 1:23-cv-2171 (D. Md, Aug. 10, 2023); Complaint, Ron L. Lacks, Pers. Representative Est. Henrietta Lacks v. Novartis Pharmaceuticals Corporation, Novartis Gene Therapies Inc., Viatris Inc., and Mylan Pharmaceuticals Inc., No. 1:24-cv-02267-DLB (D. Md, Aug. 5, 2024).

74. For more information on the story of Henrietta Lacks, see REBECCA SKLOOT, THE IMMORTAL LIFE OF HENRIETTA LACKS (2010).

75. Second Amended Civ. Complaint & Request for Jury Trial, *supra* note 73.

information. Primary uses are those activities that directly relate to providing goods or services, such as producing a genetic testing report for a consumer. *Secondary uses* are those activities that involve the use of genetic material and information for purposes other than those for which they were initially obtained.[76] Examples include using genetic ancestry testing to investigate hereditary conditions, conduct research, develop new drugs, or identify suspects. Secondary uses, in general, are not unique to the genetic context—in today's society, where data is freely accessible, such uses are ubiquitous.[77]

Many secondary uses entail disclosing or transmitting genetic material and information from one entity to another.[78] Therefore, they are not limited to the original collector—third parties may also engage in secondary uses.[79] For example, the DTC genetic testing company FamilyTreeDNA granted the FBI access to its database of records.[80] In the same year, 23andMe announced its plan to share the genetic information of millions of consumers with a pharmaceutical company, GlaxoSmithKline, to help it develop new drugs.[81]

Although genetic material and information are frequently de-identified before being shared, the procedures used to do so are not always successful, and the risk of re-identification is relatively high in many circumstances.[82] To illustrate, in one study, researchers were able to infer the last names of anonymous research subjects by analyzing only a small portion of genetic information, together with additional

---

76. *See* Yeslam Al-Saggaf, *The Use of Data Mining by Private Health Insurance Companies and Customers' Privacy*, 24 CAMB. Q. HEALTHCARE ETHICS 281 (2015); Teneille R. Brown, *Why We Fear Genetic Informants: Using Genetic Genealogy to Catch Serial Killers*, 21 COLUM. SCI. & TECH. L. REV. 1 (2019); Janessa Mladucky, Bonnie Baty, Jeffrey Botkin & Rebecca Anderson, *Secondary Data Usage in Direct-to-Consumer Genetic Testing: To What Extent Are Customers Aware and Concerned?*, 24 PUB. HEALTH GENOMICS 199 (2021); Tina Hambuch, Swaroop Aradhya, Robert Nussbaum & Michael Hamilton, *Secondary Uses of Genetic Data: Practical Solutions to Address a Complex Legal Framework*, 15 J. HEALTH & LIFE SCI. L. 58 (2021).

77. Eugene E. Hutchinson, *Keeping Your Personal Information Personal: Trouble for the Modern Consumer*, 43 HOFSTRA L. REV. 1151 (2015).

78. 23andMe, for instance, indicates that a person's genetic information may be shared and hence used, by law enforcement, regulatory bodies, and other entities for their own purposes. *What You Should Know About Privacy at 23andMe*, 23ANDME, https://www.23andme.com/about/privacy/ [https://perma.cc/Q22U-SSJM]. Similarly, according to Ancestry's Terms of Service, the company is authorized to share genetic information with third parties who can ultimately use it for their own purposes. *Ancestry Terms and Conditions*, ANCESTRY, https://www.ancestry.com/c/legal/termsand conditions [https://perma.cc/382C-7Z7G].

79. James W. Hazel & Christopher Slobogin, *Who Knows What, and When?: A Survey of the Privacy Policies Proffered by U.S. Direct-to-Consumer Genetic Testing Companies*, 28 CORNELL J.L. & PUB. POL'Y 35 (2018). The authors found that 78% of the DTC genetic testing companies included in the study provide genetic information to third parties in de-identified or aggregated forms without additional consent from individuals. Moreover, 62% use genetic information for internal research and development, and 71% use genetic information internally for other purposes than providing the results to consumers.

80. Matthew Haag, *FamilyTreeDNA Admits to Sharing Genetic Data with F.B.I.*, N.Y. TIMES (Feb. 4, 2019), https://www.nytimes.com/2019/02/04/business/family-tree-dna-fbi.html [https://perma.cc/58X4-4VUF].

81. Jamie Ducharme, *A Major Drug Company Now Has Access to 23andMe's Genetic Data. Should You Be Concerned?*, TIME (July 26, 2018), https://time.com/5349896/23andme-glaxo-smith-kline/ [https://perma.cc/M25M-AQWL].

82. *See supra* sources cited note 33 and accompanying text.

information such as the subject's date of birth and home state.[83]

One of the most troubling aspects of secondary uses is that they often occur without individuals' knowledge (unlike primary uses, about which the individual typically knows). In the context of research, for instance, this practice is even actively encouraged by the Revised Federal Policy for the Protection of Human Subjects (known as the "Common Rule"), which allows obtaining "broad consent" for secondary uses.[84] In other words, researchers can store, maintain, and use identifiable biospecimens for future research without obtaining additional consent. Moreover, the Common Rule does not impose any requirements regarding consent or the provision of information in cases involving de-identified biospecimens and information.

Quite often, secondary uses are also initiated without the individuals' clear comprehension of the potential outcomes of such uses. While Gene Users may include provisions related to secondary uses in their legal documents, the language is typically vague and does not give a fair warning of how Gene Users will later use the genetic material and information. Put simply, the emphasis lies not on fostering *comprehension* but solely on conveying information.

A well-known example of this is the case of the Havasupai Tribe. Tribe members agreed to provide Arizona State University with genetic samples, handprints, and genealogy information for a diabetes research project.[85] The only reason they agreed to provide the materials was to see whether there was a genetic link to diabetes in the Tribe, thereby improving the health of their community. The Tribe members later discovered that the University used the materials for other purposes, including some that were anthropological and not medical. Consequently, the Tribe members sued the university—they felt the secondary uses violated their rights and contradicted their core beliefs.[86]

One more noteworthy example is the genetic material and information exchange agreements between pharmaceutical companies and the hospitals of Geisinger in Pennsylvania, Mount Sinai Health System in New York, and the Mayo Clinic in Minnesota.[87] Under these agreements, the companies received samples

---

83. Melissa Gymrek, Amy L. McGuire, David Golan, Eran Halperin & Yaniv Erlich, *Identifying Personal Genomes by Surname Inference*, 339 SCI. 321 (2013).

84. 45 C.F.R. § 46.116(d). In addition, the Common Rule does not require consent for secondary research if certain criteria are met, including if the information or biospecimens are either publicly available, subject to Health Insurance Portability and Accountability Act (HIPAA) protections for certain research, or government-generated or government-collected for nonresearch activities. 45 C.F.R. § 46.104(d)(4).

85. The Tribe members signed a broad consent to "study the causes of behavioral/medical disorders," yet they believed that the materials would be used solely for studying diabetes. Robyn L. Sterling, *Genetic Research Among the Havasupai: A Cautionary Tale*, 13 AMA J. ETHICS 113 (2011).

86. Katherine Drabiak-Syed, *Lessons from Havasupai Tribe v. Arizona State University Board of Regents: Recognizing Group, Cultural, and Dignitary Harms as Legitimate Risks Warranting Integration into Research Practice*, 6 J. HEALTH & BIOMEDICAL L. 175 (2010).

87. Melanie Evans, *DNA Data Shared in Ways Patients May Find Surprising*, WALL ST. J. (Aug. 12, 2019), https://www.wsj.com/articles/deals-give-drugmakers-rights-to-dna-data-11565607602 [https://perma.cc/59BM-WRVG].

from the hospitals and sequenced the DNA from those samples. They sent back copies of the DNA sequence to the hospitals, which then used the information for research. The informed consent forms failed to inform patients that the hospitals had agreements with pharmaceutical companies and that these companies had access to their genetic material and information, which the companies could use for their own purposes.

Secondary uses of genetic material and information without individuals' knowledge or clear comprehension of the potential outcomes are exploitative. Gene Users take advantage of the fact that many individuals do not understand what could happen to the genetic material and information they provide and are not aware of the plethora of secondary uses for which Gene Users could use these resources.[88] As with property rights waivers, Gene Users use obscure language and retain the right to change policies after they have been signed by an individual.[89] Relatedly, individuals expect certain limits on how Gene Users use genetic material and information.[90] However, such limits hardly exist. Once Gene Users possess these resources, they can use them in ways that individuals may find highly objectionable.

Currently, the dominant approach to regulating genetic material and information is one of "notice and choice."[91] Under this approach, as long as Gene Users provide "disclosure" of their intentions and allow individuals to make a "choice" about whether to share the genetic material and information, they are generally free to use these resources for whatever purposes they see fit. In this way, secondary uses—including those with de-identified genetic material and information, which are subject to significantly less stringent regulation and rules—thwart individuals' expectations, generating uncertainty over how one's genetic material and information are used and creating a sense of powerlessness and vulnerability. In many instances, if people were fully aware of secondary uses, they might not have provided genetic material and information in the first place (like in the case of the Havasupai Tribe).

To clarify, I do not assert that individuals must give consent for *every* secondary use of genetic material and information. Such an approach would not align with my goal of developing a genome governance framework that promotes collaboration among different stakeholders and facilitates the appropriate flow of genetic material and information within the genetic sphere. However, this perspective does not imply that we should disregard the need for safeguards to prevent the exploitation of individuals. These safeguards aim to ensure that people are not taken advantage

88. Charlotte A. Tschider, *The Consent Myth: Improving Choice for Patients of the Future*, 96 WASH. U. L. REV. 1505 (2019).

89. *See supra* sources cited note 68 and accompanying text.

90. *See* Forrest Briscoe, Ifeoma Ajunwa, Allison Gaddis & Jennifer McCormick, *Evolving Public Views on the Value of One's DNA and Expectations for Genomic Database Governance: Results from a National Survey*, 15 PLOS ONE 1 (2020); Christopher Slobogin & J. W. Hazel, *"A World of Difference"? Law Enforcement, Genetic Data, and the Fourth Amendment*, 70 DUKE L.J. 705 (2021).

91. Garner & Kim, *supra* note 28; Leslie Francis, *Health Information Beyond Pandemic Emergencies: Privacy for Social Justice*, 70 AM. U. L. REV. 1629 (2021).

of and that their interests are protected when it comes to the use of their genetic material and information. As I will argue in Part III, individuals should be informed about secondary uses of genetic material and information well enough to understand the ramifications of those uses. When applicable, they should also be able to "exit" through an opt-out mechanism if they desire to terminate the relationship with Gene Users. Finally, secondary uses should be reviewed and approved by an institutional review board (IRB) or another oversight body.

3. Surreptitious Collection

We leave behind genetic material wherever we go. Hair, fingernails, saliva, footprints, and "touch DNA"[92] are all trails of DNA that can be collected surreptitiously. The possibility of widespread government surveillance and commercial or research exploitation of shed DNA is not far-fetched and might become increasingly prevalent in the near future.

We do not know how common the surreptitious collection of genetic material and information is in the United States nowadays. However, it is well-known that law enforcement and intelligence agencies engage in this practice regularly.[93] While it has demonstrated effectiveness in solving crimes and safeguarding the interests of victims and the public,[94] the main concern is that this practice is often carried out without proper authorization, which is an issue that should not be condoned. In one case, for example, police officers collected a discarded napkin a person used while eating a hot dog at his daughter's hockey game.[95] In other cases, police officers obtained DNA from a spoon at Baskin-Robbins,[96] or from garbage that a person left outside for the garbage collector.[97] In each of these cases, police officers collected genetic material without a warrant.

Surreptitious collection of genetic material and information often goes hand in hand with investigative genetic genealogy,[98] which facilitates the identification of

---

92. This is a sample obtained through physical contact between one person and an object or another person.

93. Ram, *supra* note 7, at 881–83; Natalie Ram, *Genetic Privacy After* Carpenter, 105 VA. L. REV. 1357 (2019); Slobogin & Hazel, *supra* note 90.

94. Brown, *supra* note 76, at 7, 40; Ram, *supra* note 7; Ram, *supra* note 93; Ram et al., *supra* note 40.

95. Joel Shannon, *He Threw Away a Napkin at a Hockey Game. Police Used It to Charge Him with a 1993 Murder*, USA TODAY (Feb. 20, 2019, 9:16 PM), https://www.usatoday.com/story/news/nation/2019/02/20/cold-case-murder-charge-napkin-genealogy-site-used-police/2932656002/ [https://perma.cc/8MP9-32B9].

96. Emily Shapiro, *DNA on Baskin-Robbins Spoon Links Man to Sex Assaults from 22 Years Ago: Prosecutors*, ABC NEWS (Nov. 19, 2019, 11:33 AM), https://abcnews.go.com/US/dna-baskin-robbins-spoon-links-man-sex-assaults/story?id=67138429 [https://perma.cc/2QLE-VM9Q].

97. Jon Schuppe, *Police Lifted DNA from Her Trash and Charged Her with a Baby's 1981 Killing. She Says That Was Illegal*, NBC NEWS (Mar. 14, 2020, 2:34 AM), https://www.nbcnews.com/news/us-news/police-lifted-dna-her-trash-charged-her-baby-s-1981-n1158416 [https://perma.cc/75KW-T6JY].

98. Christi J. Guerrini, Jill O. Robinson, Devan Petersen & Amy L. McGuire, *Should Police Have Access to Genetic Genealogy Databases? Capturing the Golden State Killer and Other Criminals Using a Controversial New Forensic Technique*, 16 PLOS BIOL. 1 (2018); Natalie Ram & Jessica L. Roberts,

individuals by analyzing identity-by-descent DNA segments that suggest shared ancestry.[99] Some DTC genetic testing companies, such as AncestryDNA and 23andMe, do not currently permit law enforcement agencies to use their databases without a warrant and have promised to fight any efforts to open up their databases to searches by police. However, other companies, such as FamilyTreeDNA and GEDMatch, do permit at least some uses of their data by law enforcement agencies.[100]

Consider the Golden State Killer investigation,[101] which was conducted without a warrant or any formal oversight.[102] In this case, the police arrested Joseph James DeAngelo in 2018 because they believed he was the infamous "Golden State Killer." He was suspected of being responsible for more than a dozen murders and almost fifty rapes that occurred over more than forty years.[103] The police, stymied in their investigation for several years until they turned to genetic genealogy, started by creating a profile using genetic material from one of the crime scenes. They uploaded the profile to GEDmatch, a free genealogy database many individuals use to learn more about their family tree.[104] The investigators then searched to find similar profiles on GEDmatch and identified DeAngelo thanks to the discovery of a distant relative via genetic genealogy. After secretly collecting DNA from the door handle of DeAngelo's car and a discarded tissue, the police were able to match the evidence from the crime scene to DeAngelo, leading to his arrest.

The frequency of this practice outside of the criminal context is not entirely clear, although there have been instances of surreptitious collection of genetic material and information in other contexts as well. For instance, a prominent case in the research domain involves Henrietta Lacks, whose cells were surreptitiously

---

Forensic Genealogy and the Power of Defaults, 37 NATURE BIOTECHNOLOGY 707 (2019); Ella Lubell, *Cops Now Need a Warrant for 23andMe and AncestryDNA Searches in Maryland and Montana*, REASON (June 14, 2021, 1:45 PM), https://reason.com/2021/06/14/cops-now-need-a-warrant-for-23andme-and-ancestrydna-searches-in-maryland-and-montana/ [https://perma.cc/4B9G-XDRK].

99. Yaniv Erlich, Tal Shor & Shai Carmi., *Identity Inference of Genomic Data Using Long-Range Familial Searches*, 362 SCI. 690, 690 (2018).

100. Ram, *Genetic Privacy After* Carpenter, *supra* note 93, at 1363–64.

101. *See generally* Ray A. Wickenheiser, *Forensic Genealogy, Bioethics and the Golden State Killer Case*, 1 FORENSIC SCI. INT'L 114 (2019).

102. Sarah Zhang, *The Messy Consequences of the Golden State Killer Case*, ATLANTIC (Oct. 1, 2019), https://www.theatlantic.com/science/archive/2019/10/genetic-genealogy-dna-database-criminal-investigations/599005/ [https://perma.cc/QC79-JS2D].

103. Ram, *Genetic Privacy After* Carpenter, *supra* note 93, at 1359.

104. At least according to some reports, genetic material from the crime scene was first sent to FamilyTreeDNA, which created a DNA profile and allowed law enforcement to set up a fake account to look for matching profiles. When that failed to provide any promising results, a genetic genealogist who was assisting the investigators in this case submitted the forensic profile to MyHeritage. The search on MyHeritage led to the discovery of the distant relative. Sarah Zhang, *How a Genealogy Website Led to the Alleged Golden State Killer*, ATLANTIC (Apr. 27, 2018), https://www.theatlantic.com/science/archive/2018/04/golden-state-killer-east-area-rapist-dna-genealogy/559070/ [https://perma.cc/72BV-ETTF]; Paige St. John, *The Untold Story of How the Golden State Killer Was Found: A Covert Operation and Private DNA*, LA TIMES (Dec. 8, 2020, 5:00 AM), https://www.latimes.com/california/story/2020-12-08/man-in-the-window [https://perma.cc/HS7P-6Z9D].

collected by researchers.[105] It was customary during that period for medical institutions and researchers to collect cells and tissues from patients without their explicit knowledge or consent.[106] Therefore, the absence of reported cases in various domains does not necessarily imply that surreptitious collection of genetic material and information is nonexistent among different Gene Users, and we should remain vigilant in acknowledging, monitoring, and addressing this practice.

Surreptitious collection of genetic material and information is harmful because it allows Gene Users to abuse their power, depriving individuals and their relatives of any possible decision-making power. People have expectations regarding the use of genetic material and information by Gene Users; when Gene Users collect them surreptitiously, without restrictions, these expectations are undermined. Moreover, surreptitious collection makes it possible to collect genetic material and information from virtually *anyone*, effectively functioning as "a backdoor to population-wide data banking."[107] If Gene Users can employ this practice, then there is not much to stop them from compiling a virtually unlimited database of genetic material and information for their own benefit.

C. Appropriative Harms

Exploitative practices, such as those detailed in Section I.B, affect two types of interests whose symbiotic relationship has been neglected by many scholars and policymakers: property and privacy.[108]

Generally, property interests envelop privacy interests.[109] For example, both the "right to exclude others from physically entering property ordinarily carries with it a concomitant right to seclusion and privacy in that realm" and the right to destroy property also protect privacy interests.[110] Conversely, privacy concerns are

---

105. *See supra* notes 73–75 and accompanying text.

106. *See* Skloot, *supra* note 74. As Skloot explains:

> Like many doctors of his era, TeLinde often used patients from the public wards for research, usually without their knowledge. Many scientists believed that since patients were treated for free in the public wards, it was fair to use them as research subjects as a form of payment . . . . TeLinde began collecting samples from any woman who happened to walk into Hopkins with cervical cancer. Including Henrietta.

Id. at 29–30.

107. Joh, *supra* note 18, at 874.

108. *See* Abraham Bell & Gideon Parchomovsky, *The Privacy Interest in Property*, 167 U. PA. L. REV. 869, 871–73 (2019).

109. Brady, *supra* note 8, at 1181–84. For more on the connection between privacy and property interests, see, for example, Radhika Rao, *Property, Privacy, and the Human Body*, 80 B.U. L. REV. 359, 366–400 (2000) (exploring the connection between privacy and property in the context of the human body); Lior Jacob Strahilevitz, *The Right to Destroy*, 114 YALE L.J. 781, 786 (2005) (discussing how protecting the right to destroy one's property increases social welfare by protecting privacy); Nita A. Farahany, *Searching Secrets*, 160 U. PA. L. REV. 1239, 1243–44 (2012) (addressing how property law informs the expectations of privacy in searches of informational property); Michael C. Pollack, *Taking Data*, 86 U. CHI. L. REV. 77, 77–78 (2019) (recommending a takings-based regime for data and electronic information and claiming that it has the potential to protect privacy).

110. Brady, *supra* note 8, at 1182.

frequently framed in property terms. For instance, a violation of a person's privacy interest is referred to as an "intrusion" or an "invasion."[111] Finally, the relationship between the two interests occurs in the Fourth Amendment context, where "the Supreme Court's articulation of a new, privacy-centric framework for evaluating the constitutionality of government searches and seizures evolved out of the privacy interests threatened by intrusions on forms of property."[112] Therefore, although previous arguments have distinguished between privacy and property,[113] in action, this distinction is often superficial: privacy is one of the considerations that animate property.

At the most basic level, exploitative practices in the genetic sphere disrupt individuals' control over their own genetic material and information, while also violating individuals' expectations.[114] Such practices, however, would most likely fail to meet the requirements of the existing tort claims in the property context. Property torts traditionally pertain to real property and do not protect against harms that infringe on privacy interests.[115] Therefore, rather than conventional property torts, the harms caused by exploitative practices in the genetic sphere appear to be more consistent with what Professor Maureen Brady called "appropriative harms."[116]

Appropriative harms are caused by nontrespassory interferences with tangible or intangible property that "commandeer it to another's purposes, disrupting the owner's control over [that] property and risking other dignitary, personal, or pecuniary harm."[117] These harms not only "disrupt the owner's use and control, but they also cause dignity and privacy harms by exploiting the owner's realty toward unwanted ends."[118] While Brady discussed appropriative harms in the context of projection (i.e., using light to project unwanted messages onto buildings), appropriative harms may exist in other contexts as well.[119]

Exploitative practices in the genetic sphere result in appropriative harms. First,

---

111. *Id.* at 1183.

112. *Id.*

113. *See generally* Samuel D. Warren & Louis D. Brandeis, *The Right to Privacy*, 4 HARV. L. REV. 193 (1890). Warren and Brandeis articulated a concept of privacy that has now been commonly known as "the right to be alone." According to them, privacy protects individuals' choice whether or not to share information about their "private life, habits, deeds, and relations." *Id.* at 216.

114. Bell & Parchomovsky, *supra* note 108, at 885–91, 905.

115. *Id.* at 905–14.

116. Brady argued for the need to recognize a new cause of action for appropriative harms. She demonstrated that the existing property-tort frameworks are relatively limited regarding new technologies and that many actions are generally outside the scope of tort law. Brady, *supra* note 8 at 1184–201.

117. *Id.* at 1181.

118. *Id.* at 1144.

119. Brady explained that

> [appropriative] harms may arise outside the context of projection, in other places where new technologies permit others to modify the appearance of or communications from land, buildings, or airspace without physically traversing boundary lines, making the framework outlined here useful for reasoning about how the law might also extend to cover those circumstances.

Id. at 1147.

they interfere with individuals' *property* interests.[120] This Article does not delve into the origins of individuals' property interests, yet I explored this issue elsewhere,[121] arguing that individuals' property interest over genetic material and information is grounded in two key values: personhood and intelligible possession.[122] Personhood suggests that resources closely connected to one's identity should be legally protected. The concept of property as personhood asserts that property interests as they relate to resources are essential for an individual's self-development and fulfillment. Furthermore, according to the principle of intelligible possession, property interests should be protected irrespective of the physical location of the resources.

In that context, I also elucidated the various advantages of treating genetic material and information as property.[123] First, property forms the essential framework for establishing rights and determining their allocation. It provides a clear structure for defining ownership rights and guiding their distribution. Second, property rights do not rely on preexisting contracts or specific legal relationships to establish obligations among third parties. They are in rem, meaning they are attached to the resource itself. Third, property is a multifaceted concept that accommodates the diverse interests of numerous entities. It recognizes and safeguards the rights and interests of the various stakeholders involved. Lastly, the recognition of genetic material and information as property plays a crucial role in promoting the efficient use of resources and addressing collective action challenges. It has the potential to incentivize responsible resource management, while also providing mechanisms to resolve conflicts and foster collective cooperation.

Individuals are emotionally connected to genetic material and information and regard them as the constitutive medium of their own identity.[124] They see these resources as their own, regardless of whether they physically possess them. Individuals particularly believe they have a legally protected property interest over genetic material and information, not only due to the personal and familial aspects embedded in these resources but also because such resources enhance one's ability to exercise self-determination and carry out significant life plans. When Gene Users employ the exploitative practices discussed in the previous section, they exercise extensive control over genetic material and information, diminishing individuals' appropriate control and sense of ownership over these resources.

---

120. By "property," I mean authority—the normative power to determine to some degree what others may do with a resource—that is enforceable against the "whole world" (i.e., a right *in rem*). *See* Morris R. Cohen, *Property and Sovereignty*, 13 CORNELL L.Q. 8, 11–14 (1927); Hanoch Dagan, *Autonomy and Property*, *in* RESEARCH HANDBOOK ON PRIVATE LAW THEORY 185, 187 (Hanoch Dagan & Benjamin Zipursky eds., 2020). According to this definition, property offers different "configurations of entitlements that constitute the contents of an owner's rights vis-à-vis others, or a certain type of others, with respect to a given resource." HANOCH DAGAN, A LIBERAL THEORY OF PROPERTY 20 (2021).

121. Simana, *supra* note 7, at 203–05.

122. Margaret Jane Radin, *Property and Personhood*, 34 STAN. L. REV. 957 (1982); GREGORY S. ALEXANDER & EDUARDO M. PEÑALVER, AN INTRODUCTION TO PROPERTY THEORY 75–76 (2012).

123. Simana, *supra* note 7, at 196–97.

124. Suter, *supra* note 25, at 737, 799–800; Roberts, *supra* note 7, at 1152–53, 1158–62.

Consider the case of the Havasupai Tribe to illustrate this point.[125] Originally, the Tribe provided their genetic material and information to Arizona State University exclusively for the purpose of diabetes research, with the intent of improving their community's health. However, the university's use of these resources for undisclosed purposes infringed on the Tribe's rights and contradicted their fundamental beliefs. The Tribe members experienced a deep sense of betrayal as the university's actions strayed from the initially agreed-upon objective of exploring a potential genetic connection to diabetes within their Tribe.

The *Greenberg* case presents another example, in which a researcher received a patent for the Canavan gene sequence and its related applications concerning Canavan disease.[126] This patent allowed the researcher to enforce restrictions on activities and further developments linked to the Canavan disease gene. Families with children affected by Canavan disease had entrusted their genetic material and information to this researcher, guided by the specific understanding that their contributions would be used for research on the Canavan disease, including identifying mutations and aiding in carrier detection within their families and the broader population. Furthermore, they thought that any resulting carrier and prenatal testing from this research would be affordable and readily accessible. They also believed that the research results would remain in the public domain, encouraging the discovery of improved prevention methods, treatments, and ultimately, a cure for Canavan disease.

Alongside the property harms, the exploitative practices in the genetic sphere also intrude upon individuals' *privacy* interests.[127] Privacy is an umbrella concept that incorporates various types of harms.[128] As explained by Professors Danielle Citron and Daniel Solove, privacy harms include psychological harm ("a range of negative mental responses, such as anxiety, anguish, concern, irritation, disruption, or aggravation");[129] autonomy harm ("restricting, undermining, inhibiting, or unduly influencing people's choices");[130] and relationship harm ("damage to important relationships that are important for one's health, well-being, life activities, and functioning in society").[131]

The exploitative practices employed by Gene Users generate different forms of privacy harms. They thwart individuals' expectations regarding how genetic material and information are collected, used, and shared, and also create anxiety and

---

125. *See supra* notes 85–86 and accompanying text.

126. Greenberg v. Miami Children's Hosp. Rsch. Inst., 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

127. I acknowledge the long-standing debates over privacy as restricted access *or* control. However, I refrain from taking a position in any of these debates since the difference between conceptions of privacy does not impact the argument of this Article. On different theories of privacy, see HELEN NISSENBAUM, PRIVACY IN CONTEXT: TECHNOLOGY, POLICY, AND THE INTEGRITY OF SOCIAL LIFE 67–74 (2009).

128. Citron & Solove, *supra* note 9.

129. *Id.* at 841.

130. *Id.* at 845. This harm can be caused, for instance, by undue influence over behavior or decision-making, failure to provide sufficient information to make decisions, and activities that thwart expectations. *Id.* at 845–46.

131. *Id.* at 859.

concern. Gene Users utilize genetic material and information in ways that are not transparent to individuals, even going so far as to transfer them to other entities for the purpose of pursuing completely different objectives than those that were originally understood and agreed to. Consequently, Gene Users provoke various adverse mental responses and erode the confidence of individuals.

To clarify, I do not support *individualistic* perceptions of property and privacy in forming my arguments in this Article.[132] As I suggested elsewhere, it is necessary to pivot away from endorsing an exclusive, and thus controlling, interest over human genetic material and information.[133] Such an approach tends to disregard the concerns and interests of other significant stakeholders. Instead, I encourage an approach that considers the effects on the individual to whom the genetic material and information pertain, *as well as* those to whom the individual is genetically related and those with whom the individual has ongoing social relationships.[134]

This approach has served as the bedrock for my proposal to conceptualize genetic material and information as shared resources, governed by a common property regime.[135] Under this regime, individuals retain appropriate control over genetic material and information, allowing to simultaneously consider the interests of other stakeholders and promote the exchange of genetic material and information within the genetic sphere.[136] This implies that not every use of genetic material and information by third parties should be prohibited. The law should intervene only when third parties use genetic material and information in a *disproportionate* and *unreasonable* way, meaning, without a rationale and necessity and without carefully weighing all the relevant considerations.[137]

II. THE EXISTING LEGAL FRAMEWORK AND ITS LIMITS

This part delves into the existing legal framework related to the use of human genetic material and information, revealing its inadequacy in sufficiently protecting individuals' property and privacy interests. I begin by examining the state and federal laws that govern the practices discussed in Part I and providing a critical assessment of their shortcomings. This is followed by a description of the structural limitations of the current legal framework, in which I assert that, due to its limited scope, it covers only a limited number of Gene Users and exploitative practices and suffers from inconsistencies that introduce ambiguity and unpredictability.

A. Lack of Protection Against Exploitative Practices

Lawmakers have implemented a limited number of measures to protect

132. *See* Salomé Viljoen, *A Relational Theory of Data Governance*, 131 YALE L.J. 573, 617–34 (2021) (discussing the prevailing individualistic conceptions of property and privacy concerning personal data).

133. Simana, *supra* note 7.

134. *Id.*

135. *Id.*

136. *Id.* at 198–212.

137. *Id.* at 206–12. *See also infra* notes 265–267 and accompanying text.

individuals from exploitative practices.[138] For example, federal and state laws protect against genetic discrimination,[139] and certain state laws have allotted substantive rights related to genetic material and information, such as a property right over them, a right to seek their destruction, a right to access them, and a right to be notified about what is done with them.[140] However, these laws provide little to no protection against the exploitative practices addressed in Part I.

1. Requirement to Waive Property Rights

Neither federal nor state legislation has been passed to address the use of property rights waivers in the genetic context. The existing legal framework is designed to regulate specific concerns such as discrimination and privacy and utterly disregards the common practice among certain Gene Users to require waivers of property rights. In fact, the framework not only disregards this practice—it actively encourages it. As mentioned in Part I, the OHRP and the FDA released a proposed version of their Guidance on Exculpatory Language in Informed Consent that endorses the use of property rights waivers.[141]

a. Federal Level

One might expect that this exploitative practice would fall within the jurisdiction of the Federal Trade Commission (FTC).[142] The FTC exists to protect consumers from entities engaging in "deceptive, unfair and anticompetitive business practices."[143] According to the Federal Trade Commission Act (FTCA), the FTC has the authority to "prevent persons, partnerships, or corporations . . . from using . . . unfair or deceptive acts or practices in or affecting commerce."[144] The FTCA determines that an "unfair" practice is one that "causes or is likely to cause

---

138. *See* Anya E. R. Prince, *Comprehensive Protection of Genetic Information: One Size Privacy or Property Models May Not Fit All*, 79 BROOK. L. REV. 175, 194–201 (2013); 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 1 (2019); Simana, *supra* note 7, at 160–68.

139. Wolf et al., *supra* note 138, at 13–14, 52–62, 90–98. *See also* Sonia M. Suter, *GINA at 10 Years: The Battle Over "Genetic Information" Continues in Court*, 5 J.L. & BIOSCIENCES 495 (2018) (providing an overview of the Genetic Information Nondiscrimination Act).

140. Wolf et al., *supra* note 138, at 63–75.

141. *See supra* note 65 and accompanying text.

142. To clarify, the FDA does not have authority over this exploitative practice. According to the Federal Food, Drug, and Cosmetic Act, the FDA is responsible for exercising regulatory oversight over the development, marketing, and usage of food, drugs, devices, and cosmetics. The FDA requires informed consent for trials submitted to it, and those trials have to conform to some substantive requirements, like the right to withdraw and the absence of personal injury waivers. *See* U.S. DEP'T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., INFORMED CONSENT: GUIDANCE FOR IRBS, CLINICAL INVESTIGATORS, AND SPONSORS (Aug. 2023). However, the requirement to waive property rights over genetic material and information does not fall under the authority of the FDA.

143. *About the FTC: Mission*, FED. TRADE COMM'N, https://www.ftc.gov/about-ftc/mission [https://perma.cc/4Z92-VY59].

144. 15 U.S.C. § 45(a)(2).

substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition."[145] A "deceptive" practice involves a material representation, omission, or practice that is likely to mislead a consumer acting reasonably under the circumstances.[146] Therefore, it can be inferred that the FTC has the authority to halt unfair and deceptive practices in the genetic sphere.

However, the FTC has limited authority regarding property rights waivers over genetic material and information. First, this authority is confined to unfair and deceptive practices. For the FTC to act, Gene Users must fail to fulfill a promise (such as to protect an individual's privacy or provide a product of a certain level of quality), knowingly advertise inaccurate information, or cause severe harm that is not reasonably avoidable by individuals. Given this, it does not seem that property rights waivers would constitute an unfair or deceptive practice, even if they exploit an imbalance in power between Gene Users and individuals. This practice does not involve making promises or disseminating false information in advertising. Moreover, no one compels individuals to waive their property rights—they do so voluntarily, and in theory at least, they can avoid the adverse effects of this practice.

Second, the FTC mainly relies on its authority over deceptive rather than unfair practices.[147] It is easier to demonstrate that a Gene User failed to uphold a promise than to establish a threshold for unfairness (especially for "substantial injury"[148]). This is another reason why the FTC is unlikely to intervene when it comes to property rights waivers over genetic material and information.

Third, the FTC does not have authority over many Gene Users—it focuses solely on commerce. It does not, for example, oversee the practices of research institutions and programs, or of public health authorities. At this time, therefore, no federal law incorporates a prohibition of unfair or deceptive practices that is relevant across a wide range of Gene Users.

Overall, the FTC lacks the authority to take meaningful steps to protect individuals against the use of property rights waivers. Beyond that, the FTC fails to use its current authority effectively. To this day, the FTC has taken very few actions against Gene Users.[149] One of the most significant enforcement actions taken to

---

145. 15 U.S.C. § 45(n).

146. FED. TRADE COMM'N, FTC POLICY STATEMENT ON DECEPTION, appended to Cliffdale Assocs., Inc., 103 F.T.C. 110 (1984), https://www.ftc.gov/system/files/documents/public_statements/410531/831014deceptionstmt.pdf [https://perma.cc/9BJ7-MNYT].

147. Robert Gellman, *Can Consumers Trust the FTC to Protect Their Privacy?*, ACLU (Oct. 25, 2016), https://www.aclu.org/news/privacy-technology/can-consumers-trust-ftc-protect-their-privacy [https://perma.cc/4CR7-7QJB].

148. 15 U.S.C. § 45(n).

149. Ellen Wright Clayton, Barbara J. Evans, James W. Hazel & Mark A. Rothstein, *The Law of Genetic Privacy: Applications, Implications, and Limitations*, 6 J.L. & BIOSCIENCES 1, 19 (2019). In 2023, the Federal Trade Commission secured orders against two companies, Vitagene and CRI Genetic, for purportedly engaging in misleading trade practices. A settlement was reached with Vitagene, while the legal proceedings against CRI Genetic remain ongoing. *See In re* 1Health.io Inc., FTC File No. 1923170, Docket No. C-4798 (Sep. 6, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/1Healt

date was against GeneLink, Inc. in 2014, on the basis that the company's health-related claims of benefit were not supported and that its data security practices were inconsistent with its privacy policy.[150]

b. State Level

All states have Unfair and Deceptive Acts and Practices (UDAP) laws to supplement the FTCA.[151] Every state has a consumer protection law that broadly forbids deceptive practices;[152] many states also forbid unfair or unconscionable practices; and a few forbid abusive practices.[153] Although UDAP laws differ from state to state, all of them are guided by the idea that some business practices are unacceptable. The laws adopt certain features of the FTCA by prohibiting at least some categories of unfair or deceptive practices. Moreover, they go beyond the FTCA by empowering a state agency to enforce prohibitions and by providing remedies to individuals.[154]

Similar to the FTCA, UDAP laws do not protect against requiring an individual to waive property rights over genetic material and information. The most relevant weaknesses of these laws are that (1) they prohibit only a few types of practices (instead of a general prohibition, there is a closed list of practices, and property rights waivers are not included) and (2) they have a limited scope (only some entities are covered, and the laws are generally applicable only to consumer transactions involving products and services).[155]

---

h-DecisionandOrder.pdf [https://perma.cc/WKY2-B626]; Complaint, FTC v. CRI Genetics, Docket No. 2:23-CV-9824 (Nov. 20, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/crigeneticscomplaint.pdf [https://perma.cc/883X-789S].

150. Complaint, Genelink, Inc., FTC File No. 112-3095, Docket No. C-4456, 2014 WL 2142612 (May 8, 2014), https://www.ftc.gov/system/files/documents/cases/140512genelinkcmpt.pdf [https://perma.cc/8S6V-W7H2]. For information about the settlement between GeneLink and the FTC, see *Companies Pitching Genetically Customized Nutritional Supplements Will Drop Misleading Disease Claims*, FED. TRADE COMM'N (Jan. 7, 2014), https://www.ftc.gov/news-events/news/press-releases/2014/01/companies-pitching-genetically-customized-nutritional-supplements-will-drop-misleading-disease [https://perma.cc/C99P-CD7C].

151. Cary Silverman & Jonathan L. Wilson, *State Attorney General Enforcement of Unfair or Deceptive Acts and Practices Laws: Emerging Concerns and Solutions*, 65 U. KAN. L. REV. 209 (2016); Prentiss Cox, Mark Totten & Amy Widman, *Strategies of Public UDAP Enforcement*, 55 HARV. J. ON LEGIS. 37 (2018).

152. *State-by-State Summaries of State UDAP Statutes*, NAT'L CONSUMER L. CTR., https://www.nclc.org/wp-content/uploads/2022/08/udap-appC-1.pdf [https://perma.cc/S2VW-BBYS].

153. *Unfair, Deceptive and Abusive Practices (UDAP)*, NAT'L CONSUMER L. CTR., https://www.nclc.org/topic/unfair-deceptive-and-abusive-practices-udap/ [https://perma.cc/YE68-UR3U] (last visited Jan. 19, 2023).

154. *State-by-State Summaries of State UDAP Statutes*, *supra* note 152.

155. *Consumer Protection in the States: A 50-State Evaluation of Unfair and Deceptive Practices Laws*, NAT'L CONSUMER L. CTR. (2018), https://filearchive.nclc.org/udap/udap-report.pdf [https://perma.cc/H5GK-7H33].

2. Secondary Uses Without Individuals' Knowledge or Comprehension of the Potential Outcomes

Federal and state laws that prohibit secondary use of genetic material and information are limited to very specific domains and primarily concern *identifiable* genetic material or information. Furthermore, these laws do not establish a duty to inform individuals about secondary uses or to ensure they fully understand the implications of such uses.[156] The current laws emphasize the need for informed consent, but the emphasis should shift from consent to *comprehension*. As I previously mentioned, informed consent does not necessarily have to be obtained before every use of genetic material and information. My aim, after all, is to facilitate the appropriate flow of genetic material and information within the genetic sphere. However, this does not imply that we should neglect implementing safeguards to ensure that individuals are informed about secondary uses, comprehend their implications, and, when applicable, have the option to opt out if they wish.

a. Federal Level

The Health Insurance Portability and Accountability Act (HIPAA)[157] and the Common Rule[158] provide the main federal restrictions on secondary uses. However, both HIPAA and the Common Rule provide inadequate protection for several reasons. First, they do not protect de-identified genetic material and information at all. Second, they contain numerous exceptions. Lastly, they lack a broad requirement to inform individuals about secondary uses or ensure their comprehension of the implications associated with such uses.

Regulations promulgated by the United States Department of Health and Human Services under HIPAA that set forth the Standards for the Privacy of Individually Identifiable Health Information (known as the "Privacy Rule")[159] generally prohibit a "covered entity"[160]—a health plan, healthcare clearinghouse, healthcare provider, and their business associates—from using or disclosing *identifiable* health information, including genetic information, without an individual's authorization.[161] A central aspect of the Privacy Rule is the principle of "minimum

156. As I noted earlier, the FTC has the authority to step in when it comes to matters of commerce. As a result, it may offer protection in the event that Gene Users employ deceptive or unfair practices. However, its power is weak overall. *See* discussion *supra* Section II.A.1.

157. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 100 Stat. 1936 (codified as amended in scattered sections of 26 U.S.C., 29 U.S.C., and 42 U.S.C).

158. Codified at Subpart A of 45 C.F.R. pt. 46 (2023).

159. Codified at 45 C.F.R. pt. 160 and pt. 164, sub pts. A and E (2023).

160. 45 C.F.R. § 160.103.

161. The term "individually identifiable health information" refers to information that [r]elates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (i) That identifies the individual; or (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Id.

necessary" use and disclosure: a covered entity must make reasonable efforts to use, disclose, and request only the minimum amount of identifiable health information needed to accomplish the intended purpose of the use, disclosure, or request.[162] However, when de-identified, the Privacy Rule does not apply. Moreover, the Privacy Rule only applies to "covered entities"[163] and would not typically apply to many Gene Users such as biobanks, DTC genetic testing companies, online platforms for genetic genealogy, biotech and pharmaceutical companies, or research institutions and programs.

The Privacy Rule also includes several exceptions. It determines that a covered entity is permitted to use or disclose identifiable information without an individual's authorization for specific purposes, including public health activities, law enforcement purposes, and research.[164] In this way, Gene Users are granted the authority to engage in secondary uses for various purposes, without the obligation to inform individuals about these uses.

The Common Rule sets the conditions under which *identifiable* biospecimens and private information are used in "research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency."[165] It requires that an IRB will generally review and approve research.[166] The IRB should ensure, among other things, that appropriate consent is obtained, that risks are minimized and reasonable in relation to anticipated benefits, and that selection of subjects is conducted in an equitable manner.[167] Moreover, under the Common Rule, researchers are required to specify several aspects, including the removal of identifiers, the potential commercial use of biospecimens, the possibility of individuals receiving a share of any profits, the provision of clinically relevant findings to participants, and the inclusion of whole genome sequencing in the research.[168] However, these requirements do not extend to non-federally funded research and de-identified biospecimens and information collected for another purpose.

Moreover, similar to the Privacy Rule, the Common Rule also incorporates exceptions that effectively permit a wide range of secondary uses for genetic material and information without imposing significant limitations. Specifically, the Common Rule permits an IRB to waive or alter consent when (1) research involves public benefits or service programs[169] or (2) the research poses minimal risk, the consent waiver would not adversely affect the rights and welfare of the individual, and the research could not practicably be carried out without the waiver of consent.[170]

Lastly, the Common Rule permits obtaining "broad consent" in lieu of

162. 45 C.F.R. § 164.502(b).
163. 45 C.F.R. § 160.103.
164. 45 C.F.R § 164.512. *See also* Wolf et al., *supra* note 138, at 12, 43, 75–77.
165. 45 C.F.R §§ 46.101(a), 46.102(e).
166. 45 C.F.R § 46.109.
167. 45 C.F.R § 46.111.
168. 45 C.F.R § 46.116(c).
169. 45 C.F.R § 46.116(e)(3).
170. 45 C.F.R § 46.116(f)(3).

informed consent.[171] Broad consent is less specific about the risks of research and allows more use of identifiable biospecimens and private information for future, perhaps unforeseen, research.[172]

b. State Level

States generally have laws that limit secondary uses of genetic material and information by imposing restrictions on the obtainment, retention, transmission, or disclosure of these resources.[173] Nonetheless, like the federal laws, the protection afforded by state laws is insufficient. Most state laws cover only *identifiable* genetic material or information, do not mandate that individuals be informed about secondary uses or clearly understand their implications, and include a wide variety of exemptions.

For instance, several states require consent to obtain or retain genetic material or information.[174] This requirement may even be accompanied by a mandate to destroy these resources once the primary use for them is complete,[175] which would further hamper Gene Users' ability to engage in secondary uses. Many of these laws, however, exempt secondary uses such as paternity determinations, newborn screening, scientific research, and uses by law enforcement.[176]

Moreover, several states prohibit any person from disclosing information obtained through genetic testing without the individual's consent, making it harder for Gene Users to engage in secondary uses.[177] However, these laws also include exemptions, such as disclosure for public health and law enforcement purposes, newborn screening, research, and paternity determination.[178]

Finally, some states impose restrictions specifically on DTC genetic testing companies.[179] These include a requirement to obtain consent from individuals for

---

171. 45 C.F.R § 46.116(d).

172. Celia B. Fisher & Deborah M. Layman, *Genomics, Big Data, and Broad Consent: A New Ethics Frontier for Prevention Science*, 19 PREVENTION SCI. 871 (2018).

173. The discussion in this subsection is not comprehensive, and the main goal is to demonstrate the insufficient and inadequate protection provided to individuals. For a comprehensive analysis of laws at the state level, see Wolf et al., *supra* note 138; Hambuch et al., *supra* note 76.

174. Wolf et al., *supra* note 138, at 31. *E.g.*, IOWA CODE §§ 729.6(3)(a)–(b) (2024); N.M. STAT. ANN. §§ 24-21-3(A)–(B) (LexisNexis 2024); NEV. REV. STAT. ANN. §§ 629.151, 629.161(1) (LexisNexis 2023); OR. REV. STAT. §§ 192.537(1)–(3) (2023); FLA. STAT. ANN. §§ 817.5655(2)–(3) (LexisNexis 2024).

175. Wolf et al., *supra* note 138, at 32. *E.g.*, DEL. CODE ANN. TIT. 16, § 1203(b) (2022); N.J. STAT. ANN. §§ 10:5-46(b)–(d) (West 2023); NEV. REV. STAT. ANN. § 629.161(2) (LexisNexis 2023).

176. IOWA CODE § 729.6(3)(c); N.M. STAT. ANN. § 24-21-3(C); NEV. REV. STAT. ANN. §§ 629.151, 629.161(1); OR. REV. STAT. §§ 192.537(1)–(3); FLA. STAT. ANN. § 817.5655(7).

177. Wolf et al., *supra* note 138, at 44. *E.g.*, ALASKA STAT. § 18.13.010(a)(1) (2024); COLO. REV. STAT. § 10-3-1104.6(3) (2024); DEL. CODE ANN. TIT. 16, § 1205(a) (2022); N.J. STAT. ANN. § 10:5-48(a); ARIZ. REV. STAT. § 20-448.02 (LexisNexis 2024).

178. ALASKA STAT. § 18.13.010(b); COLO. REV. STAT. §§ 10-3-1104.6(4)–(9); DEL. CODE ANN. TIT. 16, § 1205(a); N.J. STAT. ANN. § 10:5-48(c); ARIZ. REV. STAT. § 12-2802 (LexisNexis 2024).

179. *E.g.*, CAL. CIV. CODE § 56.181 (Deering 2023); MD. CODE ANN., COM. LAW § 14-4404 (LexisNexis 2023); UTAH CODE ANN. § 13-60-104 (LexisNexis 2024); ARIZ. REV. STAT. § 44-8002 (LexisNexis 2024); MONT. CODE ANN. §§ 30-23-101–06 (2023); KY. REV. STAT. ANN. § 311.705 (West 2024). At this time, no federal law addresses DTC genetic testing companies directly.

the collection, use, and disclosure of genetic information, and for any use beyond the primary purpose of the genetic testing or service. However, like many state laws discussed so far, they exempt different secondary uses. For instance, in California, the law does not apply when genetic information is used for scientific research or educational activities.[180] In Maryland, DTC genetic testing companies are permitted to establish legal policies and procedures for disclosing genetic information to law enforcement or other government agencies without requiring explicit consent from individuals.[181] The laws in Utah, Arizona, and Montana do not apply to a "covered entity" (i.e., health plan, healthcare clearinghouse, and healthcare provider) or business associate,[182] and to institutions of higher education or an entity owned or operated by them.[183]

3. Surreptitious Collection

At the federal level, there are no formal protections against the surreptitious collection of genetic material and information;[184] such protections only appear at the state level. Additionally, in state laws, a predominant exemption permits this practice for law enforcement uses, among other permitted medical, research, and public health uses. While there may be a need to collect genetic material and information without an individual's knowledge in certain circumstances, responsible and ethical practices are an absolute must, even in those situations. It is crucial to establish transparency and accountability in the collection process, and one way to achieve this is by, as a few state laws do, requiring Gene Users to seek authorization from an oversight body, such as the courts.

a. Federal Level

Federal law does not broadly prohibit the surreptitious collection of genetic material and information. One relevant federal law is the Genetic Information Nondiscrimination Act (GINA),[185] which prohibits requesting, requiring, or

180. CAL. CIV. CODE § 56.184(c).

181. MD. CODE ANN., COM. LAW § 14-4405.

182. 45 C.F.R. § 160.103.

183. UTAH CODE ANN. § 13-60-103; ARIZ. REV. STAT. § 44-8003; MONT. CODE ANN. § 30-23-103.

184. The current Fourth Amendment jurisprudence fails to regulate the surreptitious collection of genetic material and information. Courts have been reluctant to grant Fourth Amendment protections to "abandoned" property, including any DNA it may contain. They have maintained that individuals cannot reasonably expect privacy when it comes to items they discard. Moreover, the Supreme Court has made clear that information that is "knowingly exposed" to the public is also unprotected by the Fourth Amendment. *See* Slobogin & Hazel, *supra* note 90, at 736–37, 751–52. For cases involving surreptitious collection of genetic material and information, *see, e.g.*, People v. Gallego, 190 Cal. App. 4th 388 (Cal. Ct. App. 2010); Maryland v. King, 569 U.S. 435 (2013); Guy v. State, No. 03-12-00466-CR, 2014 Tex. App. LEXIS 11577 (Tex. Ct. App. Oct. 22, 2014); People v. Moore, No. 7292/2017, 2018 NYLJ LEXIS 3520 (N.Y. Sup. Ct. Oct. 26, 2018); State of Iowa v. Jerry Lynn Burns, 988 N.W.2d 352 (Iowa 2023).

185. Genetic Information Nondiscrimination Act, Pub. L. No. 110-233, 122 STAT. 881 (2008) (codified as amended in scattered sections of 26 U.S.C., 29 U.S.C., and 42 U.S.C.).

purchasing genetic information. The most significant challenge with GINA is that it only applies in two contexts: employment and health insurance. As a result, GINA may shield individuals from surreptitious collection in a limited number of instances.

Another relevant federal law might be the FTCA, which provides the FTC with the authority to prevent unfair or deceptive practices.[186] While it is unlikely that surreptitious collection would be seen as deceptive (the definition involves misleading a consumer behaving reasonably under the circumstances[187]), this practice could potentially be viewed as unfair. It can cause substantial injury that is not reasonably avoidable by individuals and is not outweighed by countervailing benefits for them. However, the FTC has failed to actively exercise its authority thus far, and even if it were to do so, its power would be limited, since the FTC only has authority over commerce. Therefore, surreptitious collection of genetic material and information done outside of the commercial context would fall outside its purview.

b. State Level

Several states have laws that may protect individuals from this practice by prohibiting the collection of genetic material for DNA analysis and its use to perform genetic genealogy investigations without consent. However, these laws contain numerous exceptions, which differ among states, and notably lack any requirement for appropriate oversight.

For example, Alaska prohibits the collection of a DNA sample and the performance of a DNA analysis on a sample without the informed and written consent of the person to whom the sample pertains.[188] This prohibition, however, does not apply when the sample is collected for law enforcement purposes, the determination of paternity, or newborn screening.[189] In Florida, it is against the law to willfully, and without express consent, collect or submit a DNA sample belonging to another individual.[190] This prohibition does not apply if the collection is done for the following purposes: law enforcement, research, determination of paternity, and newborn screening.[191] Under Iowa law, it is illegal to perform genetic testing or collect genetic information unless the individual provides their consent.[192] These prohibitions do not apply if the collection is performed according to federal and state law or for law enforcement, medical, scientific research, or education purposes.[193]

Regarding investigative genetic genealogy, several states (e.g., Maryland, Montana, Utah, Texas, Tennessee, and Kentucky) restrict law enforcement's access to databases. Maryland determines that law enforcement agencies may use only

186. *See* discussion *supra* Section II.A.1.
187. *See supra* note 146 and accompanying text.
188. ALASKA STAT. § 18.13.010(a)(1) (2024).
189. *Id.* at § 18.13.010(a)(2)(b).
190. FLA. STAT. ANN. §§ 817.5655(2)–(3) (LexisNexis 2024).
191. *Id.* at § 817.5655(7).
192. IOWA CODE § 729.6(3)(b) (2024).
193. *Id.* at § 729.6(3)(c).

genetic databases of companies that have explicitly informed the public and their customers that law enforcement uses their databases and that have asked for their customers' consent to such use.[194] The law also requires judicial authorization to perform genetic genealogy searches[195] and determines crimes that are eligible for searches.[196] Under Montana, Texas, Tennessee, Arizona, and Kentucky laws, government entities cannot obtain DNA search results from consumer DNA databases without a warrant or a valid legal process.[197] Lastly, the law in Utah implements multiple safeguards in relation to investigative genetic genealogy.[198] For example, a law enforcement agency can request the use of investigative genetic genealogy services or a genetic genealogy database from a genetic genealogy company if ordered by a court during a post-conviction relief proceeding. When making such a request to a genetic genealogy company, the law enforcement agency must choose one that (1) notifies its customers and the public about the potential use of its services by law enforcement for investigating crimes or identifying unidentified human remains; (2) allows users to decide whether their information can be accessed by law enforcement in an investigation (opt-in or opt-out option) and grants users access to the company's services even if they choose to opt out of having their information accessible to law enforcement; and (3) has a policy in place that prohibits the compilation, sale, licensing, or transfer of any information to a third party related to a victim, crime scene, or suspect.

These safeguards implemented by Maryland, Montana, Utah, Texas, Tennessee, and Kentucky are highly commendable. However, it is problematic that such safeguards are currently limited to only a few states.

B. Structural Limitations

While Section II.A focused on particular exploitative practices, it also reveals two significant structural limitations in the existing legal framework.

First, at both the federal and state levels, laws affecting Gene Users are defined by sector. They apply only to specific domains (e.g., employment, health insurance, DTC genetic testing, or research), and only identify particular types of Gene Users that are subject to them. For example, the federal Privacy Rule only applies to "covered entities," the federal Common Rule only covers those Gene Users that conduct federally funded research, and GINA only regulates health insurance companies and employers.[199] Most state laws mirror the federal laws in that they

194. MD. CODE ANN., CRIM. PROC. §17.102(d) (West 2023).

195. *Id.* at § 17.102(a)(1).

196. *Id.* at § 17.102(b)(1).

197. MONT. CODE ANN. §§ 44-6-104(1)(2) (2023); TEX. BUS. & COM. CODE § 503A.007 (West 2023); TENN. CODE ANN. § 47-18-4904 (2023); ARIZ. REV. STAT. § 44-8002 (LexisNexis 2024); KY. REV. STAT. ANN. § 311.705(2)(c) (West 2024).

198. UTAH CODE ANN. § 53-10-403.7 (West 2024).

199. GINA only covers employers with fifteen or more employees, and it does not apply to various forms of insurance. Wolf et al., *supra* note 138, at 36.

only cover specific Gene Users.[200] Federal and state laws are therefore narrowly targeted and circumscribed in scope, resulting in a patchwork of sectoral laws.

Second, inconsistencies run rampant among state laws. Only a few states have enacted laws that require written informed consent for genetic testing,[201] limit the use of genetic information by *any* person without consent,[202] ban the retention of genetic material and information,[203] or limit law enforcement's access to genetic genealogy databases.[204] Moreover, although many states have laws that cover employers and insurance companies[205] or research institutions,[206] only a few states have adopted laws to regulate DTC genetic testing companies.[207] Lastly, some state laws set boundaries on the disclosure and use of genetic information but do not address genetic material,[208] and certain laws limit their restrictions to only identifiable genetic information.[209] Overall, states significantly differ in terms of the practices they regulate, the Gene Users they cover, and the type of genetic component they protect (i.e., genetic material versus information, identifiable versus de-identified genetic material and information).

These two structural limitations yield a concerning reality: many Gene Users do not always have to comply with requirements set by the laws. Moreover, because protection is confined to specific domains, there are many instances in which certain Gene Users must comply with one law but not another. The outcome is dismal: Gene Users not governed by a particular law are free to engage in exploitative practices without restrictions.

We need to overhaul the existing legal framework to overcome these structural limitations. This new framework should appreciate the diverse potential uses of human genetic material and information, recognizing their ability to transcend a single domain. It should also impose restrictions on *any* powerful entity that collects, analyzes, and shares genetic material and information. By enforcing uniform rules, the new framework would instill greater consistency, the benefits of which would include equal treatment for all individuals, enhanced efficiency, and the creation of a harmonious structure.[210]

---

200. For instance, some laws impose limitations solely on insurance companies (*Id.* at 54–60), law enforcement agencies (*See supra* notes 194–198 and accompanying text), and DTC genetic testing companies (*See supra* notes 179–183 and accompanying text).

201. *See supra* note 177 and accompanying text.

202. Wolf et al., *supra* note 138, at 53.

203. *See supra* note 174 and accompanying text.

204. *See supra* notes 194–198 and accompanying text.

205. Wolf et al., *supra* note 138, at 36.

206. *Id.* at 27–31.

207. *See supra* notes 179–183 and accompanying text.

208. *E.g.*, COLO. REV. STAT. ANN. § 10-3-1104.7 (West 2024); GA. CODE ANN. § 33-54-1 (West 2023); LA. STAT. ANN. § 22:1023 (2024); DEL. CODE ANN. TIT. 16, § 1204 (2024).

209. CAL. CIV. CODE § 56.181 (Deering 2023); MD. CODE ANN., COM. LAW § 14-4404 (LexisNexis 2023); UTAH CODE ANN. § 13-60-104 (LexisNexis 2024); KY. REV. STAT. ANN. § 311.705 (West 2024).

210. Eric Stein, *Uniformity and Diversity in a Divided-Power System: The United States' Experience*, 61 WASH. L. REV. 1081, 1090–91 (1986).

III. A QUASI-FIDUCIARY FRAMEWORK FOR GENOME GOVERNANCE

The genetic sphere holds the promise of empowering individuals through valuable insights into their DNA. This knowledge has the potential to profoundly impact their health and well-being, while also fostering stronger connections within families and society as a whole. However, this sphere frequently fosters a sense of disempowerment since Gene Users can and do derive economic and societal benefits from human genetic material and information at the expense of violating individuals' property and privacy interests. This leaves individuals vulnerable to exploitative practices.

What is missing is a trust-based understanding of how genetic material and information create more robust and long-lasting relationships. This understanding recognizes that when Gene Users collect, analyze, and share genetic material and information, they embark on a relationship with individuals. This relationship creates a responsibility to care for those individuals and ensure that trust, defined as "the willingness to accept vulnerability to the actions of others,"[211] is fundamental.

The core argument of this part is that we should draw upon fiduciary law to delineate appropriate regulatory boundaries in the genetic sphere, ensuring genetic material and information are not tools of exploitation. Fiduciary law would enable a better understanding of the relationship between Gene Users and individuals in terms of trust and emphasize the need to address power and information asymmetries between them.

Section III.A delves into the fiduciary concept, highlighting its objectives and the duties of a fiduciary relationship. Section III.B pivots to Jack Balkin's "Information Fiduciaries" theory, which targets the substantial power of private service providers such as Facebook and Google. Section III.C introduces the "Gene Stewards" concept, drawing parallels and distinctions with Information Fiduciaries, as well as outlining the duties this new concept carries. Lastly, Section III.D calls for new federal legislation, the "Gene Stewards Act," with the goal of imposing quasi-fiduciary duties on all Gene Users to protect against possible exploitative actions.

A. Fiduciary Law

It is widely agreed that fiduciary law addresses matters related to the power entrusted to one party, the "fiduciary," in relation to the legal or practical interests of another party, the "beneficiary."[212] This area of law applies when entities "undertake powers relative to specific individuals or groups that have an inherently fiduciary character,"[213] and it encompasses the fundamental premise that "the use

211. Neil Richards & Woodrow Hartzog, *Taking Trust Seriously in Privacy Law*, 19 STAN. TECH. L. REV. 431, 433 (2016).

212. *See* Deborah A. Demott, *Beyond Metaphor: An Analysis of Fiduciary Obligation*, 1988 DUKE L. J. 879 (1988); Scott FitzGibbon, *Fiduciary Relationships Are Not Contracts*, 82 MARQ. L. REV. 303 (1999); TAMAR T. FRANKEL, FIDUCIARY LAW 279 (2010).

213. Paul B. Miller, *The Fiduciary Relationship*, *in* PHILOSOPHICAL FOUNDATIONS OF FIDUCIARY LAW 63, 88 (Andrew S. Gold & Paul B. Miller eds., 2014).

of discretionary power over the material, practical, and legal interests of others must be constrained by obligations meant to align the interests" of fiduciaries and beneficiaries.[214] Overall, fiduciary law serves as a mechanism to establish higher standards for governing relationships characterized by power imbalances.[215]

In accordance with fiduciary law, the interests of the beneficiary must always be paramount.[216] This is a divergence from the standard legal principle of "caveat emptor," or "let the buyer beware," typically seen in private law. This traditional principle assumes that all parties have equal access to information and bargaining power, thereby enabling them to protect their own interests. However, once a relationship is classified as fiduciary,[217] the fiduciary has legal obligations to be trustworthy and act in the best interests of the beneficiary.[218]

The fiduciary's duty is bifurcated into multiple duties; the core ones are duties of loyalty and care.[219] Each of these duties may vary in content and scope, depending on the nature of the fiduciary relationship and its unique characteristics.[220] The content of the duties may also be subject to modification by agreement between the beneficiary and the fiduciary.[221]

Generally speaking, under a *duty of loyalty*, a fiduciary is prohibited from acting against the beneficiary's interests—the fiduciary is required to, among other things, avoid conflicts of interest, refrain from undertaking obligations that may conflict with their existing loyalty obligations, not retain profits made through a conflicted

---

214. Ethan J. Leib, David L. Ponet & Michael Serota, *Mapping Public Fiduciary Relationships*, *in* PHILOSOPHICAL FOUNDATIONS OF FIDUCIARY LAW, *supra* note 213, at 388, 388.

215. Andrew S. Gold & Paul B. Miller, *Introduction*, *in* PHILOSOPHICAL FOUNDATIONS OF FIDUCIARY LAW, *supra* note 213, at 1, 1 (Andrew S. Gold & Paul B. Miller eds., 2014).

216. Leonard I. Rotman, *Understanding Fiduciary Duties and Relationship Fiduciarity*, 62 MCGILL L.J. 975, 984 (2017).

217. Fiduciary relationships can be identified on the basis of status or facts. Paul B. Miller, *The Identification of Fiduciary Relationships*, *in* THE OXFORD HANDBOOK OF FIDUCIARY LAW 366 (Evan J. Criddle, Paul B. Miller, & Robert H. Sitkoff eds., 2019). Miller explained that there are disparate characterizations of fiduciary relationships:

> [T]he possession and exercise of legal authority and/or power by one person relative to another; inequality in material position, power, strength or influence between the parties; the dependence and/or vulnerability of one person upon another; a more specific susceptibility to harm, as where one's assets or person is placed at risk of conversion or exploitation; the exchange of confidential or private information; a repose of trust and/or confidence; the legal or actual incapacity of a party and/or a complete or situational inability to engage in monitoring, reporting, or other forms of self-protection; the reliance of one person upon another; or, one person's expectation of goodwill, altruism, loyalty or competent or considered advice or judgment from another.

Id. at 374.

218. Paul B. Miller, *The Morality of Fiduciary Law*, 62 WM. & MARY L. REV. 1349, 1354 (2021).

219. FRANKEL, *supra* note 212, at 106–07.

220. Andrew S. Gold, *The Fiduciary Duty of Loyalty*, *in* THE OXFORD HANDBOOK OF FIDUCIARY LAW, *supra* note 217, at 384, 386 (Evan J. Criddle et al. eds., 2019).

221. John C. P. Goldberg, *The Fiduciary Duty of Care*, *in* THE OXFORD HANDBOOK OF FIDUCIARY LAW, *supra* note 217, at 404, 408 (Evan J. Criddle et al. eds., 2019).

transaction, act in good faith, and disclose pertinent information to the beneficiary.[222] Under a *duty of care*, an objective standard of care is imposed—a fiduciary must exercise a sufficient and appropriate level of care and skill in their actions.[223]

Traditionally, fiduciary law has held significant importance in the realm of private affairs. The doctor-patient relationship, for instance, stands as an example of a fiduciary relationship that embodies the core principles of trust, loyalty, and responsibility.[224] Doctors have access to sensitive and private information about their patients. Moreover, they are knowledgeable, skilled, and experienced in medicine, a field that patients typically know very little or nothing about. Therefore, patients entrust doctors with power over their bodies and cannot avoid placing a significant amount of dependence, faith, and confidence in the doctors' judgment, advice, and actions. In return, the doctors are obligated to protect the interests of their patients, act in good faith toward them, avoid any situations that could lead to conflicts of interest, and refrain from disclosing any information that could be used against them.

A particularly noteworthy case involving the doctor-patient relationship is *Moore v. Regents of the University of California*.[225] In this case, John Moore, a person with hairy-cell leukemia, underwent surgery to remove his spleen at UCLA Medical Center. David Golde, Moore's physician, had used parts of the removed spleen for research without Moore's consent. Golde withdrew more genetic samples while Moore visited the UCLA Medical Center after the spleen removal. Seven years later, Moore discovered that his cells were used to create an extremely valuable cell line that Golde patented. The Supreme Court of California held that "(1) a physician must disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment; and (2) a physician's

---

222. Gold, *supra* note 220, at 388–89. Gold explained that

> [t]ypes of fiduciary relationship implicate distinctive concerns, and these concerns affect the content of fiduciary loyalty. For example, trust law has commonly played a role in wealth preservation and shows a strong concern for giving effect to donative intent. Corporate law, by contrast, is characteristically concerned with shareholder wealth maximization. Agency law emphasizes effective obedience to a principal's instructions. Guardianship law frequently requires decision-making on behalf of a ward who cannot make a decision for himself or herself (or whose decision-making does not meet legal standards for decision-making ability).

Id.

223. Goldberg, *supra* note 221, at 406.

224. Many courts and scholars have acknowledged the fiduciary nature of the doctor-patient relationship. *See* Frankel, *supra* note 212, at 17; Thomas L. Hafemeister & Selina Spinos, *Lean on Me: A Physician's Fiduciary Duty to Disclose an Emergent Medical Risk to the Patient*, 86 WASH. U. L. REV. 1167 (2009); Mark A. Hall, *Fiduciary Principles in Health Care*, *in* THE OXFORD HANDBOOK OF FIDUCIARY LAW, *supra* note 217, at 287 (Evan J. Criddle et al. eds., 2019); Sophie Ludewigs, Jonas Narchi, Lukas Kiefer & Eva C. Winkler, *Ethics of the Fiduciary Relationship Between Patient and Physician: The Case of Informed Consent*, 2022 J. MED. ETHICS, DEC. 2022, AT 1, 2. However, it is important to acknowledge that certain courts and scholars still express skepticism regarding the fiduciary nature of the doctor-patient relationship. For an in-depth exploration of their viewpoints, see Maxwell J. Mehlman, *Why Physicians Are Fiduciaries for Their Patients*, 12 IND. HEALTH L. REV. 1, 10–39 (2015).

225. Moore v. Regents of Univ. of Cal., 51 Cal. 3d 120 (1990).

failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent or breach of fiduciary duty."[226]

Fiduciary duties may not be limited to the private sphere, and scholars have increasingly argued for their application in the public domain as well. This expanded perspective recognizes that entities such as the state and public authorities may be potential fiduciaries, underlining not only the critical role of trust but also that these entities have a duty to act in the public's best interest.[227] These scholars astutely infer that a fiduciary relationship is established when one party places their trust and confidence in another, thereby conferring upon them power. They believe that the key factor triggering the invocation of fiduciary law is the potential for the fiduciary to exploit this power to the beneficiary's detriment. Like in the private sector, fiduciary relations in the public sector embody a complex agency issue as fiduciaries might pursue their interests at the expense of the beneficiaries.[228]

To conclude, the reach of fiduciary duties is vast, encompassing a wide variety of relationships, with the specifics of each relationship defining the respective fiduciary obligations.[229] Nevertheless, at their essence, all fiduciary duties address power imbalances and require those in fiduciary positions to adhere to a higher behavioral standard.[230] All fiduciary duties are anchored in the understanding that trust is a critical factor in relationships. This element of trust provides individuals in society with the confidence to live their lives without fearing that others will exploit their vulnerabilities. By laying the groundwork for reliance and dependence, trust serves as a catalyst for the growth of human social and economic interactions.[231]

B. Information Fiduciaries

Recognizing the impact of the digital era, some scholars have proposed extending fiduciary duties to "digital businesses," such as Facebook and Google.[232]

---

226. *Id.* at 129.

227. *See, e.g.*, Evan Fox-Decent, *The Fiduciary Nature of State Legal Authority*, 31 QUEEN'S L.J. 259 (2005); Evan J. Criddle, *Fiduciary Foundations of Administrative Law*, 54 UCLA L. REV. 117 (2006); D. Theodore Rave, *Politicians as Fiduciaries*, 126 HARV. L. REV. 671 (2013); Gary Lawson, Guy I. Seidman & Robert G. Natelson, *The Fiduciary Foundations of Federal Equal Protection*, 94 B.U. L. REV. 415 (2014); Ethan J. Leib & Stephen R. Galoob, *Fiduciary Principles and Public Offices*, *in* THE OXFORD HANDBOOK OF FIDUCIARY LAW, *supra* note 217, at 303.

228. D. Theodore Rave, *Fiduciary Voters?*, 66 DUKE L.J. 331, 335 (2016).

229. Miller, *supra* note 217.

230. Rotman, *supra* note 216, at 987–90; Tamar Frankel, *Fiduciary Law*, 71 CALIF. L. REV. 795, 798 (1983).

231. Neil Richards & Woodrow Hartzog, *A Duty of Loyalty for Privacy Law*, 99 WASH. U. L. REV. 961, 969 (2021).

232. *See, e.g.*, Kiel Brennan-Marquez, *Fourth Amendment Fiduciaries*, 84 FORDHAM L. REV. 611 (2015); Jack M. Balkin & Jonathan Zittrain, *A Grand Bargain to Make Tech Companies Trustworthy*, The Atlantic (Oct. 3, 2016), https://www.theatlantic.com/technology/archive/2016/10/information-fiduciary/502346/ [https://perma.cc/2ZLH-Z783]; Richards & Hartzog, *supra* note 211; Christopher W. Savage, *Managing the Ambient Trust Commons: The Economics of Online Consumer Information Privacy*, 22 STAN. TECH. L. REV. 95 (2019); Lindsey Barrett, *Confiding in Con Men: U.S. Privacy Law, the GDPR, and Information Fiduciaries*, 42 SEATTLE U. L. REV. 1057 (2019).

Specifically, Jack Balkin developed the concept of "Information Fiduciaries," which refers to the "many online service providers and cloud companies who collect, analyze, use, sell, and distribute personal information."[233] Balkin claimed that "[b]ecause of their special power over others and their special relationships to others, Information Fiduciaries have special duties to act in ways that do not harm the interests of the people whose information they collect, analyze, use, sell, and distribute."[234]

Compared to the classic fiduciary relationships that are designed to serve the beneficiary's interests alone, fiduciary duties in the digital context are more limited. Balkin acknowledged that "[t]he business of a social media platform or Internet service provider is quite different from the business of a doctor or a lawyer, and the degree of reasonable trust that end-users have in digital enterprises is also different."[235]

The core obligation of Information Fiduciaries is not to act like con artists, "inducing trust in their end-users to obtain personal information and then betraying end-users or working against their interests."[236] Specifically, Information Fiduciaries have three primary fiduciary duties: duty of loyalty, duty of care, and duty of confidentiality.[237] They must behave competently and diligently, keep individuals' interests in mind and act in their best interests, and avoid any conflicts of interest that could undermine their duties.[238]

Considering the foregoing, the concept of Information Fiduciaries provides three scenarios in which digital businesses act as fiduciaries:

(1) when these people or entities hold themselves out to the public as privacy-respecting organizations in order to gain the trust of those who use them;

(2) when these people or entities give individuals reason to believe that they will not disclose or misuse their personal information; and

(3) when the affected individuals reasonably believe that these people or entities will not disclose or misuse their personal information based on existing social norms of reasonable behavior, existing patterns of practice, or other objective factors that reasonably justify their trust.[239]

C. Gene Stewards

The concept of Information Fiduciaries holds significant implications within the genetic sphere, and this section expands upon it by introducing a new concept: Gene Stewards.[240] To understand this new concept, it is essential to consider two

---

233. Balkin, *supra* note 22, at 1186.

234. *Id.*

235. Jack M. Balkin, *Free Speech in the Algorithmic Society: Big Data, Private Governance, and New School Speech Regulation*, 51 U.C. DAVIS L. REV. 1149, 1162 (2018).

236. *Id.* at 1163.

237. Jack M. Balkin, *The Fiduciary Model of Privacy*, 134 HARV. L. REV. F. 11, 14 (2020).

238. Balkin, *supra* note 22, at 1207–08.

239. *Id.* at 1223–24.

240. The term "stewards" is deliberately chosen to encapsulate a specific role and responsibility that Gene Users are envisioned to fulfill. This terminology emphasizes the stewardship aspect to highlight the unique ethical obligations that come with using genetic material and information. While

key points. First, the relationships in the genetic sphere, while distinct from traditional fiduciary relationships, share key characteristics that have historically identified certain individuals and entities as fiduciaries under common law. These characteristics include an imbalance in knowledge and expertise, as well as the dependence and vulnerability of the individuals involved.[241] In this Article, Gene Users are identified as quasi-fiduciaries with special duties toward the individuals whose genetic material and information they collect, analyze, and share.[242] Gene Users have the knowledge and expertise to collect and analyze genetic material and information, while individuals generally lack the necessary resources and skills for independent engagement in such activities. Additionally, Gene Users' relationships with individuals are founded on a certain level of dependence and vulnerability. Frequently, individuals lack awareness and comprehension of the consequences of their own actions, find it challenging to oversee Gene Users' actions, and rely on an important and often necessary service or product provided by Gene Users. Trust is the cornerstone of these relationships, and to maintain it, Gene Users must responsibly wield their power.

Second, the concept of Gene Stewards is influenced by established fiduciary frameworks, particularly those from corporate law. This inspiration is not a direct adoption of corporate law fiduciary principles but rather an adaptation of its inherent flexibility to suit the unique needs of the genetic sphere. For example, corporate law employs the "best interests" standard to ensure decisions prioritize the welfare of affected parties.[243] Moreover, it approaches potential conflicts of interest not with outright prohibition but through fairness assessment and equitable scrutiny.[244] These examples highlight an adaptable approach and nuanced decision-making, which are key in shaping the duties of Gene Users.

The following subsections expand on the concept of Gene Stewards. The first subsection compares and contrasts the concept of Information Fiduciaries with Gene Stewards. The second subsection delves deeper into one of the rationales behind introducing the concept of Gene Stewards: to blur the definitive boundaries

---

fiduciaries are primarily bound by legal duties that stress formal or contractual responsibilities to their beneficiaries, stewards are guided by a broader, ethical framework that focuses on care, responsibility, and moral obligation. Using the term stewards, therefore, reflects an aspiration for Gene Users to adopt an ethical stance that transcends legal obligations.

241. *See* discussion *supra* Section III.A.

242. The relationship between Gene Users and individuals will be declared quasi-fiduciary by a specific federal law—the Gene Stewards Act. Courts would be responsible for defining additional duties by evaluating the expectations that a "reasonable person" would have from Gene Stewards. *See* discussion *infra* Section III.D. As Paul B. Miller explained, "[M]uch of the familiar landscape of fiduciary law has become familiar through status-based identification of fiduciary relationships. Status-based identification proceeds on the basis of recognition of an authoritative declaration that a kind of relationship is fiduciary." Miller, *supra* note 217, at 370–72.

243. Julian Velasco, *Fiduciary Principles in Corporate Law*, *in* THE OXFORD HANDBOOK OF FIDUCIARY LAW, *supra* note 217, at 61, 62. This is unlike the rigid "sole interest" rule in trust law, for example. *See* Robert H. Sitkoff, *Fiduciary Principles in Trust Law*, *in* THE OXFORD HANDBOOK OF FIDUCIARY LAW, *supra* note 217, at 41, 44–45.

244. Velasco, *supra* note 243, at 66–69.

between the public and private sectors and within the private sector itself. The third subsection outlines the special duties of Gene Stewards. The fourth subsection addresses potential objections to the concept of Gene Stewards.

1. Information Fiduciaries versus Gene Stewards

The concepts of Information Fiduciaries and Gene Stewards share several overlapping attributes. They both tackle the challenges of asymmetric vulnerability and dependency, recognizing the profound dependency and relative lack of agency that ordinary people experience when they enter into relationships with entities that collect, analyze, and share valuable resources to gain socio-economic advantages. At the heart of these concepts is the idea that powerful entities should not misuse personal resources in unforeseen ways or in manners that infringe upon established social norms. Moreover, these concepts propose, if not necessitate, the extension of fiduciary duties to new categories of entities, while at the same time accepting that these entities have obligations distinct from those of traditional fiduciaries. Both concepts also acknowledge that it is impossible to always align these parties' interests and that there is always the risk that powerful entities will act opportunistically and abuse their power for their own benefit at the expense of individuals. Finally, compared to traditional fiduciaries, both Information Fiduciaries and Gene Stewards are engaged in more tenuous relationships because of the large number of individuals on whose behalf they execute specific duties.

Despite these similarities, essential differences exist between the two concepts. While the Information Fiduciaries concept pertains to personal information, the Gene Stewards concept focuses on genetic material and information, which possess some special features.[245] These resources involve personal, familial, and collective aspects, and their use affects not just the individual but also their family members and society at large: they cannot be truly anonymized; it is possible to generate genetic information from one DNA sample even without the knowledge of the person to whom the sample pertains; and the same genetic material and information can be used for a variety of purposes, among them genetic research, forensic identification, and genetic genealogy.

Moreover, unlike the concept of Information Fiduciaries, which presupposes a contractual relationship,[246] the concept of Gene Stewards can be imposed regardless of whether there is a contract or direct exchange. Because protections follow the genetic material and information, simply having access to the genetic material and information suffices to impose duties on Gene Users.

The previous difference is linked to another difference between the two concepts: Information Fiduciaries have duties to only one set of dependents—customers and end-users—whereas Gene Stewards have duties to a broader set of

245. *See supra* notes 28–36 and accompanying text.
246. Balkin, *supra* note 235, at 1163.

dependents.[247] The concept of Gene Stewards acknowledges that genetic material and information are tied to family members and the wider public, rather than only a single individual. Therefore, individuals are not the only ones who merit protection; family members and the general public must also be protected.

Lastly, the concept of Information Fiduciaries focuses only on entities operating in the private sector.[248] In contrast, the concept of Gene Stewards recognizes that the private sector is not the only setting in which fiduciaries are found; entities operating in the public sector may also hold the role of fiduciary. Therefore, it imposes duties on all Gene Users, regardless of whether they are public or private. In other words, quasi-fiduciary duties underline the relationships between individuals and *any Gene User with access to genetic material and information.*

The boundary between the private and public sectors in the genetic sphere is not as clear as one might think. Indeed, the relationship between individuals and all Gene Users—be they private or public—reflects features typically used to identify fiduciary relationships. These characteristics include the wielding of power, inequality in material position, dependency, and vulnerability, the exchange of confidential and personal information, and the inability to monitor the actions of the more powerful party.[249] From this, it can be inferred that all Gene Users have a duty to act in a manner that safeguards individuals' interests and expectations. If they fail in this duty, they should be held liable. All Gene Users must therefore reflect on their privileges and the power and information imbalances that exist in the genetic sphere. They need to be cognizant of any exploitative dynamics they may be part of and carefully consider the relationships they are building with individuals.

2. Blurring Distinctions in the Genetic Sphere

The sharp categorical distinctions in the genetic sphere between the public and private sectors, as well as within the private sector itself, are problematic. These distinctions result in fragmented laws that apply only to certain Gene Users. They also make it challenging to establish baseline standards and rules that should guide the behavior of all Gene Users.

Generally, a fundamental distinction in the American legal system is between the public and private sectors.[250] The public-private distinction "is the premise which lies at the foundation of American legal thought, and it shapes the way in which we relate to each other in our daily lives."[251] It is implicitly embedded in the Constitution itself, specifically in the Bill of Rights, which, almost without

247. Balkin, *supra* note 22, at 1186.

248. Balkin, *supra* note 235, at 1162.

249. Miller, *supra* note 217, at 374.

250. Morton J. Horwitz, *The History of the Public/Private Distinction*, 130 U. PA. L. REV. 1423 (1982); Paul M. Schoenhard, *A Three-Dimensional Approach to the Public-Private Distinction*, 2008 UTAH L. REV. 635 (2008).

251. Alan Freeman & Elizabeth Mensch, *The Public-Private Distinction in American Law and Life*, 36 BUFF. L. REV. 237, 237 (1987).

exception, applies only to the federal government and states and not to private actors. This distinction holds that some standards and rules apply to vertical relationships between the government and private actors but not to horizontal relationships between private actors. The legal standards and rules that govern private actors are concerned with freedom and essentially promote competition, whereas the legal standards and rules that govern public actors are concerned with fairness and equality and are guided by the value of government loyalty to the general public interest.[252]

The delineation between the public and private sectors serves as a primary rationale for the imposition of different standards and rules on public and private Gene Users. As detailed in Part II, there are numerous restrictions on the use of genetic material and information today. Yet, public Gene Users involved in areas like law enforcement and public health are almost invariably exempt from these constraints.[253] In contrast, in other scenarios, public entities are the ones bound by constraints. For instance, the limitations imposed by the federal Common Rule only apply to entities receiving public funding.[254] Furthermore, certain rules are exclusive to private entities, such as the laws regulating the activities of DTC genetic testing companies, or employers and insurance companies.[255] Hence, the prevailing presumption is that even if private and public Gene Users are involved in *similar activities*, they are permitted to abide by *different standards and rules*.

Courts have also applied different standards and rules based on the public-private distinction. In law enforcement cases, for instance, courts have traditionally refused to grant defendants any property rights over genetic information that the police collected and analyzed from evidence found in public spaces. Many courts have held that individuals do not have reasonable expectations of privacy in such circumstances.[256] In comparison, in at least one civil case, *Peerenboom v. Perlmutter*, a Florida trial court arrived at the opposite outcome.[257] In this case, two private individuals were involved, with one being sued for conspiring to collect and test the genetic material of the other. The court recognized the property rights of the person to whom the genetic information pertained. Even though the circumstances in *Peerenboom* were quite similar to those in the criminal cases (in both types of cases,

252. John A. Powell & Stephen Menendian, *Beyond Public/Private: Understanding Excessive Corporate Prerogative*, 100 KY. L.J. 43, 51–93 (2012).

253. *See* discussion *supra* Sections II.A.2 and II.A.3.

254. *See* discussion *supra* Section II.A.2.

255. *See* discussion *supra* Sections II.A.2 and II.A.3.

256. *See supra* note 184 and accompanying text.

257. Peerenboom v. Perlmutter, No. 2013-CA-015257, 2017 Fla. Cir. LEXIS 14957 (Fla. 15th Cir. Ct. Jan. 23, 2017). As of this writing, the litigation between the Perlmutters and Peerenboom has yet to reach its conclusion. The trial court's decision to allow the Perlmutters to amend their counterclaims to seek punitive damages against Peerenboom was reversed by the District Court of Appeal of Florida, Fourth District. The appellate court found the evidence insufficient for the allowance of claims for punitive damages. In this reversal, the appellate court did not address the question of whether individuals have property interests in their genetic information. *See* Fed. Ins. Co. v. Perlmutter, Nos. 4D2022-1558, 4D2022-1560, 4D2022-1562, 48 Fla. L. Weekly D 2320 (Fla. Dist. Ct. App. Dec. 13, 2023).

genetic material was collected from a public space), the *Peerenboom* court held that individuals do have important property and privacy interests in genetic information.

The second categorical distinction in the genetic sphere is within the private sector itself. Several laws regulate only specific kinds of private Gene Users. For instance, some laws apply only to employers and health insurance companies, while other laws apply only to DTC genetic testing companies or research institutions.[258]

The distinctions between the public and private sectors and within the private sector reflect a normative assumption; they assume that different standards and rules should apply to the different types of Gene Users. However, creating distinctions between Gene Users serves no purpose. The fact that just some Gene Users are restricted or held accountable is not desirable, given the possibility that all Gene Users can engage in the same exploitative practice and that it is often hard to predict who will collect, analyze, and share genetic material and information. These resources are exposed to many risks, and one cannot possibly anticipate all the potential Gene Users that have access to genetic material and information.

In addition, the distinctions fail to reflect the underlying commitment of quasi-fiduciary duties: that of being in relationships with others that center on mutual respect and trust. These duties represent the idea that individuals are relational and vulnerable beings who rely on one another. Our commitment to one another essentially imposes limitations on practices, decisions, and behaviors that are inconsistent with the norms guiding a free and democratic society that require that each person is treated with respect.

Once we recognize that the distinctions in the genetic sphere are social constructs, we can impose the same baseline duties on all Gene Users. The concept of Gene Stewards would impose genetic quasi-fiduciary duties on all Gene Users, ensuring a consistent application of these duties irrespective of the entity's nature. In this way, the new concept would guarantee that standards and rules are broadly applicable and that the governance of genetic material and information is more consistent. That said, the concept of Gene Stewards certainly does not preclude considering *additional* relevant standards and rules that may apply to certain Gene Users; it only calls for setting a threshold or baseline applicable to *all* Gene Users.[259]

To be sure, I do not argue that the traditional distinction between private and public is theoretically meaningless or should be eliminated entirely. I merely propose that this distinction be set aside as a determinant for assigning genetic quasi-fiduciary duties. The public-private distinction as a legal tool for predetermining the level of responsibility of a particular entity for its conduct is not well-suited in the genetic sphere.[260] Because of changes in power relations in society, particularly the

258. *See* discussion *supra* Section II.B.

259. *See* discussion *infra* Section III.C.3.

260. The traditional distinction between private and public has generally been blurred. For example, public law standards have infiltrated into private law, and private entities are bound to comply with such standards. Due to their economic power, status, or public function, some private entities may abuse their power and violate the protected interests of the public. Therefore, it is often suggested that

increased power of private entities, public entities should not be considered the only entities with concentrated power that threaten the protected interests of individuals in society.[261] Therefore, insofar as it can direct their behavior, the law must impose stricter standards and rules of responsibility on both public and private Gene Users, which is the only way they can both be subject to genetic quasi-fiduciary duties.

3. Genetic Quasi-Fiduciary Duties

Given the power Gene Users have garnered through their actions, it is important to discuss the duties they owe to individuals and the broader society in exchange for the societal and economic benefits they extract. A substantial change could be effectuated if Gene Users were to perceive their relationships with individuals through the lens of fiduciary duty. Gene Users are endowed with authority over the interests of individuals who, in contrast, find themselves in a state of vulnerability and dependence. To safeguard the well-being and interests of those affected by the practices of Gene Users, it is imperative that quasi-fiduciary duties be imposed on Gene Users.

In general terms, genetic quasi-fiduciary duties would compel Gene Users to consider individuals' interests and not engage in opportunistic behavior. These duties would prohibit Gene Users from collecting, analyzing, and sharing genetic material and information in manners that erode trust, violate expectations, and enable the exploitation of vulnerabilities.

Specifically, in this proposed framework, Gene Stewards are subject to specific duties of loyalty and care. Because Gene Stewards can be either private or public entities, have multiple beneficiaries, and are not solely responsible for serving the interests of the beneficiaries alone,[262] the duties of loyalty and care cannot be directly transplanted from private law. Instead, these duties must be customized to suit the genetic context.

In this regard, the duty of loyalty imposes an obligation on Gene Stewards to act purposefully and fairly, which prohibits them from prioritizing their own interests at the expense of the individuals whose genetic material and information they collect, analyze, and share. The duty of loyalty does not prevent Gene Stewards from using genetic material and information, nor does it require them to always subordinate their interests, as a true duty of loyalty would. Instead, it sets boundaries on their actions based on the trust and expectations established with individuals,

---

they be subjected to public law standards. *See* Jody Freeman, *Extending Public Law Norms Through Privatization*, 116 HARV. L. REV. 1285 (2003).

261. Legal scholars have developed a strong critique of the public/private distinction. *See, e.g.*, Duncan Kennedy, *The Stages of the Decline of the Public/Private Distinction*, 130 U. PA. L. REV. 1349 (1982); Ruth Gavison, *Feminism and the Public/Private Distinction*, 45 STAN. L. REV. 1 (1992).

262. Elsewhere I argued that the interests of different relevant stakeholders should also be considered. I recommended adopting a liberal conception of property, which delimits the authority of individuals and insists that their authority must be consistent with the self-determination of other individuals and entities. Simana, *supra* note 7.

thereby preventing opportunistic behavior toward individuals. The duty of care entails the responsibility to exercise an appropriate level of diligence and engage in reasoned decision-making. This implies that Gene Stewards should rely only on relevant and appropriate reasons when making and justifying decisions concerning the collection, analysis, and sharing of genetic material and information.

The next step involves delving into the specifics of the duties of loyalty and care, or the "subsidiary duties" that pertain to Gene Stewards. While the duties of loyalty and care are formulated as broad principles, subsidiary duties are structured as more specific rules or standards.[263] To determine these subsidiary duties, we must identify the actions that individuals collectively entrust Gene Stewards not to undertake. Specifically, based on their need for predictability, people should be able to trust Gene Stewards to refrain from using genetic material and information in harmful ways and from exploiting power and information imbalances between them. Such trust is shattered when Gene Users exploit individuals and use genetic material and information in ways that individuals neither desire nor anticipate.

When put into action, the duties of loyalty and care require that Gene Stewards do not cause appropriative harms, which they do when any of the following take place: (1) they require individuals to waive property rights over genetic material and information, (2) they use genetic material and information for secondary purposes without explaining the possible ramifications of secondary uses and notifying individuals when such uses occur, and (3) they collect genetic material and information surreptitiously.[264]

To effectively uphold their quasi-fiduciary duties, Gene Stewards must ensure that individuals possess appropriate control over genetic material and information and must use genetic material and information in a proportionate and reasonable way.[265] A practice is considered proportionate when (1) it aligns with its intended objective, (2) there are no other appropriate means for achieving this objective, and (3) the potential harm is not significantly disproportionate to the benefits accrued from the objective's realization.[266] A practice is deemed reasonable when it involves a balanced consideration of all relevant factors, thereby avoiding arbitrary or unreasonable decisions and ensuring that the practice aligns with the principles upheld in a free and democratic society, such as justice, fairness, equality, and accountability.[267]

These principles create several duties for Gene Stewards that form the fundamental basis, or minimum core, of their responsibility.

(1) *Duty to Respect Property and Privacy Rights*: Gene Stewards have the

---

263. Robert H. Sitkoff, *Other Fiduciary Duties: Implementing Loyalty and Care*, *in* THE OXFORD HANDBOOK OF FIDUCIARY LAW, *supra* note 217, at 419, 419–20.

264. *See* discussion *supra* Section I.C.

265. On proportionality and reasonableness, see Aharon Barak, *Foreword: A Judge on Judging: The Role of a Supreme Court in a Democracy*, 116 HARV. L. REV. 19, 145, 147–48 (2002).

266. *Id.* at 147–48.

267. Joseph William Singer, *The Rule of Reason in Property Law*, 46 U.C. DAVIS L. REV. 1369, 1421–23 (2013).

responsibility to guarantee that individuals retain appropriate control over their genetic material and information.

(2) *Duty to Inform and Preserve Expectations*: Gene Stewards are obliged to inform individuals about the use of their genetic material and information and ensure that these resources are not used in a way that undermines their expectations. When applicable, Gene Stewards should provide a clear and easy-to-use opt-out mechanism.

(3) *Duty to Ensure Comprehension*: Individuals should have sufficient information to make a fully voluntary choice. Therefore, Gene Stewards must provide individuals with a meaningful opportunity to consider entering into a relationship with them. This involves providing clear information about the use of genetic material and information and ensuring that individuals comprehend this information.

(4) *Duty to Minimize Collection*: Gene Stewards have a duty to minimize the collection of genetic material and information by only collecting what is necessary for the intended purposes.

(5) *Duty of Timely Disposal*: Gene Stewards are obligated to refrain from retaining genetic material and information for extended periods beyond the necessary timeframe.

(6) *Duty to Establish Agreements*: Gene Stewards should form agreements with other entities, explicitly prohibiting uses of genetic material and information that undermine individuals' interests and expectations.

(7) *Duty to Explain Property Rights Waivers and Secondary Use*: Gene Stewards have a duty to explain all the possible consequences and risks associated with waiving property rights over genetic material and information, as well as with the secondary use of these resources.

(8) *Duty to Share Benefits*: When applicable, Gene Stewards have a duty to share benefits derived from the use of genetic material and information with the individuals involved. Failure to fulfill this duty may give rise to a viable claim for unjust enrichment.[268]

(9) *Duty to Seek Oversight Approval for Secondary Uses*: Gene Stewards must seek review and approval from an oversight body for any secondary use of genetic material and information.

(10) *Duty to Obtain Proper Authorization*: Collecting genetic material and information without the knowledge of individuals should be limited to specific circumstances and must be done only after seeking judicial authorization.

Going forward, it may become necessary to identify and incorporate additional standards and rules to ensure the responsible use of genetic material and

268. *See supra* notes 71–72 and accompanying text.

information.[269] Courts could recognize additional duties by evaluating the reasonable expectations placed upon Gene Stewards within a specific context, as new cases emerge and scientific and technological progress continues.

4. Possible Objections to the Concept of Gene Stewards

The concept of Gene Stewards may encounter opposition on several grounds. One argument against considering Gene Users as quasi-fiduciaries is based on the expectation that fiduciaries are obliged to act solely in the best interests of the beneficiaries. Since Gene Users often have self-interested motives that conflict with the interests of individuals, the case for them being quasi-fiduciaries may appear relatively weak.

Another objection pertains to the application of quasi-fiduciary duties to both private and public entities. Critics might argue that imposing the same duties and levels of trust on these entities is problematic due to inherent differences in their functions and the nature of their entrusted roles. This concern becomes significant in the context of law enforcement and intelligence agencies, especially considering that a sense of distrust exists toward these entities (at least among certain groups).

In response to the first objection, the concept of Gene Stewards draws inspiration from fiduciary law and is tailored to the genetic context. Gene Users, as quasi-fiduciaries, differ from traditional fiduciaries like lawyers, directors, and financial advisors. Unlike these fiduciaries, Gene Users are not obligated to act exclusively in the interests of individuals but rather have the flexibility to consider their own interests and other relevant factors. This may lead to conflicts of interest between Gene Users and individuals.

However, the presence of self-interested motives does not render the application of quasi-fiduciary duties inapplicable to Gene Users. On the contrary, the recognition of such motives underscores the importance of stricter duties and protections.[270] It is precisely because Gene Users have strong incentives to prioritize their own interests that the imposition of quasi-fiduciary duties becomes crucial.[271] These duties serve as safeguards to prevent Gene Users from exploiting their position and to ensure that individuals' interests are properly safeguarded.

Gene Users owe individuals special duties that impose significant limitations on their ability to act solely in their own self-interest. The purpose of these duties is to establish boundaries and prevent any potential misuse or exploitation of genetic

269. *See* Yifat Naftali Ben Zion, *Moving Along the Continuum of Loyalty From a Standard Towards Rule*, 35 CAN. J.L. & JURIS. 187 (2022). Yifat Naftali Ben Zion argued that fiduciary duties are located on a continuum of rules and standards and that they "should be realized as moving along the continuum in a pendulum-like movement, which aspires to reach the edge of rules, yet does not forsake its origin as a standard." *Id.* at 220. Generally, rules support the legitimacy of a legislative action, while standards support the legitimacy of a judicial action. *Id.* at 191 n.10.

270. Andrew F. Tuch, *A General Defense of Information Fiduciaries*, 98 WASH. U. L. REV. 1897, 1903 (2021).

271. *Id.*

material and information. While conflicts of interest may arise, the duty of Gene Users is to navigate these conflicts ethically and consider the interests and well-being of individuals.

In summary, although Gene Users have self-interested incentives that may conflict with the interests of individuals, the adaptation of fiduciary duties in the genetic context is not only possible but necessary. The presence of self-interest underscores the need for robust protections and accountability to ensure the responsible and ethical use of genetic material and information. The current state of affairs is inadequate, and the effectiveness of the existing mechanisms leaves much to be desired. There is a pressing need to transform the relationships and dynamics within the genetic sphere to eliminate exploitative practices. If Gene Users start viewing themselves as quasi-fiduciaries, such practices would be preemptively prevented.

In response to the second objection, it is important to clarify that the concept of Gene Stewards does not assume that duties are identical between private and public Gene Stewards in *all circumstances*. The concept acknowledges that there may be differences in function and entrusted roles between private and public entities.[272] However, the underlying principle that guides the duties of both private and public Gene Stewards remains the same: to prevent the misuse of entrusted power.[273]

All Gene Users, whether private or public, have relationships with dependent and vulnerable individuals. They must exercise their powers in accordance with ethical and legal parameters derived from trust-based duties. They have a responsibility to be accountable for how they use the power entrusted to them, and safeguards must be in place to prevent any potential misuse of that power.

Furthermore, the concept of Gene Stewards recognizes that levels of trust can vary among individuals and groups, including trust in government agencies, based on people's personal experiences, beliefs, and political affiliations. Also, trust in government is not a static concept and can evolve over time. Positive actions, effective governance, transparency, accountability measures, and responsive policies can contribute to restoring and enhancing trust in government agencies.

Therefore, the concept of Gene Stewards does not preclude the consideration of additional duties for different types of Gene Stewards, although providing detailed definitions of these additional duties falls outside the scope of this article.

---

272. Trust manifests differently when it pertains to private and public entities. In the case of private entities, trust is typically more of an individual matter. It hinges on one's personal experiences and direct interactions with the entity, with factors like the entity's reputation, past conduct, and apparent motives playing a significant role. Conversely, trust in public entities is typically more of a collective matter. It arises from the broader public's confidence in the entity, rooted in its role in society, its commitment to adhering to public standards and laws, and its obligation to uphold the common good. This collective trust does not necessarily mean every single individual within society trusts the public entity to the same degree.

273. *See* Richard W. Painter, *The Fiduciary Principle in Private and Public Law*, *in* GETTING THE GOVERNMENT AMERICA DESERVES: HOW ETHICS REFORM CAN MAKE A DIFFERENCE 1, 2 (2009); D. Theodore Rave, *Two Problems of Fiduciary Governance*, *in* FIDUCIARY GOVERNMENT 49, 50 (Evan J. Criddle, Virginia, Evan Fox-Decent, Andrew S. Gold, Sung Hui Kim & Paul B. Miller eds., 2018).

That said, it is possible, for example, for the law to prohibit specific secondary uses by public Gene Stewards and to provide different remedies when they breach their genetic quasi-fiduciary duties.

Lastly, it is worth noting that the notion of public entities having a trust-based relationship with individuals is not unprecedented. For instance, legal scholars have argued for treating politicians and administrative agencies as fiduciaries.[274] Such entities exercise discretionary power over the interests of individuals, who are subject to state power, and they must faithfully exercise their entrusted powers.[275] Therefore, considering public Gene Users as quasi-fiduciaries is not an exceptional proposition. Public Gene Users, such as law enforcement, intelligence, and public health agencies, are granted discretionary powers to enforce laws and provide public benefits. Individuals rely on these entities to act in the best interest of the public while being particularly vulnerable to their potential misuse of power.

In conclusion, the concept of Gene Stewards represents a departure from the current implementation of the fiduciary concept. However, considering Gene Users as quasi-fiduciaries offers a more constructive approach to fulfilling their duties and tackling the challenges posed by genetic material and information. It highlights the importance of overseeing the discretionary powers of Gene Users and the vulnerabilities inherent in their relationships with individuals. It emphasizes the need for robust oversight, transparency, and accountability to ensure responsible behavior and protect the interests of individuals. While implementing the concept of Gene Stewards may present challenges, it overall provides a comprehensive framework that acknowledges the distinct nature of genetic material and information and ensures the responsible and ethical use of these resources.

D. Gene Stewards Act

In order to successfully implement the concept of Gene Stewards, it is critical to establish a new regulatory framework. The existing framework, as elucidated in Part II, has not adequately grappled with the challenges posed by exploitative practices, underscoring the need for greater scrutiny of power relations in the genetic sphere.

This section proposes a more ambitious, cross-sectoral, and structural regulatory framework that would minimize the power and information asymmetries between Gene Users and individuals. Specifically, it proposes the adoption of a new federal law in the United States—"the Gene Stewards Act." The Act would impose genetic quasi-fiduciary duties across all Gene Users and protect against various exploitative practices.[276] This Act would achieve regulatory uniformity.

---

274. Rave, *supra* note 227, at 708; Evan J. Criddle, *Fiduciary Administration: Rethinking Popular Representation in Agency Rulemaking*, 88 TEX. L. REV. 441 (2010).

275. Evan J. Criddle & Evan Fox-Decent, *A Fiduciary Theory of Jus Cogens*, 34 YALE J. INT'L L. 331 (2009).

276. The Gene Stewards Act is inspired by the proposed Data Care Act introduced in December 2018 by Senator Schatz. Data Care Act of 2018, S. 3744, 115th Cong. (2018). The Data Care Act exemplifies the emerging school of thought among U.S. academics that favors reframing privacy

Two clarifications are necessary. First, this section does not outline the new regulatory framework in its entirety; it provides a rough sketch of what it may look like in practice. Second, the proposed regulatory reform does not intend to establish specific rights of individuals. Its main goal is to consider the broad legal structures required to ensure appropriate control over genetic material and information.

Reasonable regulatory restrictions should be imposed on how Gene Users collect, analyze, and share genetic material and information through their relationships with individuals. The Gene Stewards Act would categorize Gene Users as quasi-fiduciaries and encourage the widespread application of genetic quasi-fiduciary duties.

First, the Act would establish a general legal principle to address the concerns raised by exploitative practices employed by Gene Users.[277] In accordance with this principle, genetic material and information shall only be collected, used, and shared for proportionate and reasonable purposes, meaning, with a rationale and necessity and with carefully weighing all the relevant considerations. This principle reflects the commitment to appropriate control over genetic material and information.[278] Second, the Act would declare Gene Users as Gene Stewards and outline the set of fundamental duties they must uphold toward individuals. In the previous section, I outlined these duties, which encompass the duties of care and loyalty.

Under the proposed statutory regime, to ensure transparency, Gene Stewards must diligently inform individuals about the specific ways in which genetic material and information will be used and ensure that individuals comprehend this. When collecting genetic material and information, Gene Stewards would be limited to gathering only what is necessary and would not be permitted to retain genetic material and information for extended periods without valid reasons. Furthermore, when collaborating with other entities, Gene Stewards must establish agreements to ensure that genetic material and information are not used for harmful or exploitative purposes. Gene Stewards may also not require individuals to waive property rights over genetic material and information, and they must establish a fair and equitable system for distributing monetary and nonmonetary benefits arising from their use of genetic material and information. Additionally, Gene Stewards must seek review and approval from an appropriate oversight body before engaging in secondary uses of genetic material and information. Finally, in exceptional cases where genetic material and information are collected without individuals' knowledge, Gene

---

as a matter of "trust" or "fiduciary-like obligation" on the part of large-scale data collectors. Woodrow Hartzog & Neil Richards, *Privacy's Constitutional Moment and the Limits of Data Protection*, 61 B.C. L. REV. 1687, 1715–16 (2020).

277. *Principles* allow extensive discretion, whereas *rules* outline particular conducts and provide minimal leeway in determining what conducts are covered by the law. Louis Kaplow, *Rules Versus Standards: An Economic Analysis*, 42 DUKE. L.J. 557, 560 (1992).

278. *See supra* notes 132–137 and accompanying text. A commitment to appropriate control implies that the property and privacy interests of individuals are prima facie violated when Gene Users collect, analyze, and share genetic material and information in a disproportionate and unreasonable manner. *See also supra* notes 265–267 and accompanying text.

Stewards would be required to seek judicial authorization.[279]

The aforementioned duties should not be considered exhaustive. For instance, additional duties not addressed in this Article pertain to manipulation and discrimination: Gene Stewards are obligated to refrain from manipulating individuals to act in specific ways and from engaging in discriminatory practices, such as denying services based on factors like genetic predispositions. Anticipating and codifying all potential forms of exploitation that Gene Users may employ is challenging. Therefore, as new cases emerge, courts should establish additional duties based on what a reasonable person would expect from Gene Stewards. In doing so, judges should rely on proportionality and reasonableness as guiding principles.

Third, the Act would establish the authority of attorneys general to file a civil action against Gene Stewards, as well as a private right of action for individuals to sue Gene Stewards directly for injuries caused by appropriative harms and breaches of genetic quasi-fiduciary duties, thereby allowing injured individuals to hold Gene Stewards accountable, protect and defend their rights, and obtain redress for their injuries. Specifically, individuals would have the right to ask for compensation for damages, seek injunctive or declaratory relief when applicable, and receive other remedies that courts deem proper.

Overall, the Gene Stewards Act attempts to regulate multiple Gene Users and exploitative practices by setting uniform minimum requirements for collecting, analyzing, and sharing genetic material and information. This would result in a structural change and enable federal, state, and local agencies to better govern issues related to Gene Users' activities. To be more precise, the Act would push for greater regulatory uniformity, assisting in harmonizing the patchwork of diverse and conflicting laws in the United States.

One of the primary problems with the existing legal system is the inconsistency and substantive variations in the laws governing the genetic sphere.[280] Given the lack of comprehensive state-level legislation across all fifty states, individuals are left wondering what protections they have against exploitative practices, and Gene Users are left wondering what laws and regulations they are expected to comply with and how much it will cost them to do so.

Generally, there are essentially two routes to achieving coherence within the legal system: the enactment of federal legislation that preempts state law or the cooperative effort of states to establish and adopt uniform laws (the Uniform Law Commission is a means through which such uniformity can be achieved).[281] This Article advocates for

279. *See* discussion *supra* Section III.C.3.

280. *See* discussion *supra* Section II.B.

281. Carlyle Conwell Ring, Jr., *A New Era: Cooperative Federalism—Through the Uniform State Laws Process*, 33 HAMLINE L. REV. 375 (2010). Over the course of its 117-year history, the Uniform Law Commission has drafted hundreds of uniform laws to harmonize state laws, such as the Uniform Probate Code, the Uniform Commercial Code, and the Uniform Anatomical Gift Act. William H. Henning, *The Uniform Law Commission and Cooperative Federalism: Implementing Private International Law Conventions through Uniform State Laws*, 2 ELON L. REV. 39, 39 (2011); Gregory A. Elinson &

federal legislation over uniform law because (1) both federal and state Gene Users should be governed as Gene Stewards (an outcome not attainable under a uniform law), and (2) traditionally, uniform laws have not been broadly implemented across states.[282]

The introduction of federal legislation in the genetic sphere brings numerous significant advantages, addressing the need for clarity, effective enforcement mechanisms, and fostering a harmonious regulatory environment.[283] First, the implementation of federal legislation simplifies the task for individuals by offering clear guidelines and protection of their interests concerning genetic material and information. Rather than having to navigate the complex policies of various Gene Users and the intricate aspects of different state laws, federal legislation outlines the protections to which individuals are entitled. This not only provides them with a sense of certainty but also ensures that their rights and interests are adequately safeguarded. Moreover, federal legislation establishes effective enforcement mechanisms that enhance the protection of individuals' interests, thereby instilling confidence in the system.

Furthermore, the advantages of federal legislation extend to Gene Users as well. Currently, Gene Users face the overwhelming challenge of keeping track of fifty diverse state laws and attempting to develop compatible frameworks for each jurisdiction. This arduous process not only burdens them with excessive administrative tasks but also increases the likelihood of mistakes and inconsistencies in compliance. However, the introduction of federal legislation alleviates this burden by providing a unified framework for Gene Users to adhere to. This streamlines their legal obligations and makes it considerably easier for them to navigate the regulatory landscape. The uniformity established by federal legislation also reduces confusion among Gene Users and promotes a more harmonious regulatory environment.

Lastly, the implementation of federal legislation compels Gene Users to confront and better understand their capabilities and responsibilities. With a clear framework and legal guidelines in place, Gene Users are prompted to evaluate their internal policies and practices. This introspection allows them to ensure compliance with the law and enables them to identify areas for improvement in terms of responsible use of genetic material and information.

To conclude, the Gene Stewards Act is comprehensive legislation at the federal level that would bring uniformity and govern all U.S. states and territories. It intends to unify genome governance by ensuring that the laws pertaining to human genetic material and information are harmonized and coordinated. Greater uniformity should be promoted because, in this way, it is possible to achieve

---

Robert H. Sitkoff, *When a Statute Comes with a User's Manual: Reconciling Textualism and Uniform Acts*, 71 EMORY L.J. 1073, 1075, 1083–97 (2022).

282. Kim Quaile Hill & Patricia A. Hurley, *Uniform State Law Adoptions in the American States: An Explanatory Analysis*, 18 PUBLIUS 117, 121 (1988).

283. The intention behind introducing federal legislation is to create a national standard, while still providing room for state laws to address specific gaps or issues. This approach allows states to have a role in enforcing the federal legislation, as well as to enact additional provisions. Nevertheless, accepting a certain degree of preemption is essential for the establishment of robust protections across the United States, ensuring consistency and comprehensive coverage.

consistency, stability, certainty, and predictability.[284]

CONCLUSION

Given the ever-growing influence of Gene Users and their dominant role in the genetic sphere, concerns surrounding the collection, use, and sharing of human genetic material and information have reached a critical juncture. The need for an ambitious, cross-sectoral, and structural legal framework to regulate Gene Users has become more pronounced than ever before.

To address these pressing concerns, this Article proposed a new legal framework that imposes special duties on Gene Users. These duties draw inspiration from duties found in fiduciary law. The new framework prevents Gene Users from engaging in unpredictable and exploitative practices while designating them as stewards of both identifiable and de-identified genetic material and information. This crucial step is essential to establishing a foundation of trust within the genetic sphere.

By establishing a trust-based system, we impose structured limitations on the actions of Gene Users while facilitating the appropriate flow of genetic material and information in the genetic sphere. This system can serve as the cornerstone for enabling the immense potential of genetics to be harnessed for the betterment of humanity, all while respecting the interests and values of individuals.

284. All of these values are central components of the rule of law. Jeremy Waldron, *The Rule of Law and the Importance of Procedure*, *in* GETTING TO THE RULE OF LAW: NOMOS L 3, 5–6 (James E. Fleming ed., 2011).