THE COLUMBIA
SCIENCE & TECHNOLOGY
LAW REVIEW

VOLUME XXV STLR.ORG FALL 2023

ARTICLE

GENE-CENTRIC LAWS IN THE POSTGENOMIC ERA: THE NEED FOR PROTECTION OF EPIGENETIC INFORMATION

EMILY DAVIDSON*

In recent decades, special attention has been given to the privacy and discrimination risks associated with genetic information. Federal, state, and international laws all contain specific protections for the use of genetic information in a variety of contexts, including insurance and employment. Yet the very considerations motivating special protections for genetic information extend beyond mere genetics. Epigenetics involves the study of heritable changes in gene function that do not involve changes in the DNA sequence. Epigenetic data shares a number of normative similarities and policy concerns with genetic data, and in some ways, presents an even greater privacy and nondiscrimination risk than genetic data. However, epigenetic information remains unprotected by existing genetic privacy and nondiscrimination laws, which are based on an outdated conception of health and disease, focused narrowly on genes and genetic information. This Note argues that epigenetic information warrants the same protections as genetic information and calls for an amendment of existing genetic privacy and nondiscrimination laws to broaden the definitions of the data at stake to encompass epigenetic and other postgenomic information.

* J.D. 2024, Columbia Law School. The author thanks Professor Mala Chatterjee for her valuable guidance and Lily Emerson and Elizabeth Tanner for their thoughtful comments. The author would also like to thank the wonderful staff of the Columbia Science and Technology Law Review for their editing and for awarding this Note the Julius Silver Prize.

I. INTRODUCTION

In the past decade, researchers have made great progress toward understanding how social and environmental factors influence human health. These developments are largely a result of the expansive field known as epigenetics. The science of epigenetics—the study of heritable changes in gene function that *do not involve changes in the DNA sequence*—has revealed how environmental factors contribute to human aging and the development of disease through the modification of different biomolecules. Epigenetic research has the potential to lead to improved disease prevention by better understanding how environment and age contribute to disease. Epigenetics has also provided for new drug treatments that target epigenetic changes. Scientists have even considered the potential for epigenetic research to uncover the key to the reversal of aging and disease.

At the center of epigenetic research has been the development of epigenetic clocks. Epigenetic clocks use DNA methylation biomarkers,[1] one form of epigenetic data, to estimate age, disease, and mortality. Epigenetic clocks have already captured the attention of insurers, law enforcement, and immigration authorities. For instance, FOXO Technologies has an exclusive license for a set of epigenetic clocks to be used in life insurance underwriting.[2] In the field of law enforcement, some have imagined the establishment of an "epigenomic fingerprint," using epigenetic information to profile individuals' age and lifestyle for forensic purposes.[3] Immigration authorities in Europe have proposed the use of

[1]DNA methylation entails the addition of methyl groups (structural units consisting of three hydrogen atoms bonded to a carbon atom) to the DNA molecule, resulting in a change in gene expression.

[2] FOXO Life, https://perma.cc/C337-QFCV (last visited Jan. 14, 2023).

[3] *See* Athina Vidaki & Manfred Kayser, *From Forensic Epigenetics to Forensic Epigenomics: Broadening DNA Investigative Intelligence*, GENOME BIOLOGY, Dec. 21, 2017, at 1, 1-2.

epigenetic clocks to confirm the age of minors seeking asylum.[4] The availability of direct-to-consumer epigenetic tests has made epigenetic clock technology widespread, helping consumers better understand their health and well-being by providing information about health indicators such as smoke exposure, biological age, and skin type.

Despite the many promises of epigenetic information, these nonmedical uses of epigenetic data present numerous legal and ethical concerns. While genetic information has been safeguarded through a variety of legal mechanisms, epigenetic information remains unprotected. The nonmedical uses of epigenetic information necessitate a reevaluation of the normative justifications underlying the adoption of federal, state, and international laws that exclusively cover genetic information.

This Note argues that the same policy concerns underpinning the adoption of genetic-specific laws demand similar protections for epigenetic information as well. Challenging the myth of genetic exceptionalism, this Note demonstrates that the same reasoning used to argue that genetic information holds distinctive qualities warranting special protections also applies to epigenetic information. Yet existing privacy and nondiscrimination laws covering genetic information fail to account for epigenetic information. These existing laws focus narrowly on an outdated heredity paradigm based on *genetic* tests and *genes*, ignorant of postgenomic conceptions of health and disease.[5] This gene-centric terminology is prevalent across federal, state, and international nondiscrimination and privacy law. The novel use of epigenetic technology in insurance, forensics, and other industries underlines an urgent need to reassess existing laws in the context of epigenetic information.

This Note proceeds as follows: Part II provides an overview of the science of epigenetics and the medical and nonmedical applications of epigenetic technology. Part III presents a framework for assessing the need for epigenetic protections, demonstrating that the qualities and policy concerns animating genetic-focused protections also apply to epigenetic information. Part IV describes the failure of existing genetic-focused state and federal statutes and international declarations to provide protections for epigenetic information. Lastly, Part V proposes an intervention: to revise existing laws to include epigenetic and other postgenomic information, noting the limitations of existing legal structures to adequately protect sensitive health information in all circumstances.

---

[4] Alison Abbott, *Can Epigenetics Help Verify the Age Claims of Refugees?*, 561 NATURE 15 (2018).

[5] "Postgenomic" refers to the time period following the completion of the Human Genome Project. It also encompasses a paradigm shift entailing "a new material understanding of the genome." Maurizio Meloni, *A Postgenomic Body: Histories, Genealogy, Politics*, 24 BODY & SOCIETY 3, 20 (2018). Postgenomic studies have embraced epigenetics, proteomics, microbiomics, metabolomics, metatranscriptomics, and other fields to understand the complicated nature in which various systems and biomolecules affect gene expression.

II. THE EPIGENETIC LANDSCAPE

A. Epigenetics: A Definition

In the early 1940s, Conrad Waddington defined epigenetics as "the branch of biology which studies the causal interactions between genes and their products, which bring the phenotype into being."[6] While the study of epigenetics has evolved considerably since Waddington introduced the term, a recognition of the causal interplay between genes and environment is at the heart of its meaning.[7] The modern definition recognizes epigenetics as the study of heritable changes in gene function that do not involve changes in the DNA sequence.[8] Whereas the study of genetics focuses on the sequence of DNA itself, the study of epigenetics is concerned with chemical modifications to DNA and proteins that result in genes being turned "on" or "off."[9] Together, the set of epigenetic changes modifying the genome of a given cell constitutes the epigenome.[10]

When epigenomic compounds attach to DNA and modify its function, they are said to have "marked" the genome. One useful metaphor is that of an instruction manual. Imagine that DNA is an instruction manual for the functioning of cells. The various bookmarks and annotations covering the pages of the manual represent epigenetic marks. The instruction manual, along with its many bookmarks and annotations, is read by the complex machinery for gene expression, thus resulting in genes being turned "on" or "off."

The main forms of epigenetic marks include DNA methylation, histone post-translational modifications, and RNA-based modifications.[11] DNA methylation refers to the addition of a small methyl group to DNA, most commonly to cytosines in CpG dinucleotides.[12] Histone post-translational modifications involve the addition of chemical groups to histones, which are proteins that provide structural support for chromosomes. RNA-based modifications include the binding of noncoding RNA to DNA, proteins, and other RNA molecules, regulating various levels of gene expression. These different marks can be passed on across cell

---

[6] Aaron D. Goldberg, C. David Allis & Emily Bernstein, *Epigenetics: A Landscape Takes Shape*, 128 CELL 635, 635 (2007).

[7] *Id.*

[8] VINCENZO E.A. RUSSO, ROBERT A. MARTIENSSEN & ARTHUR D. RIGGS, EPIGENETIC MECHANISMS OF GENE REGUL. 1-3 (1996).

[9] *What is Epigenetics*?, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://perma.cc/3FNT-23LH (Aug. 15, 2022).

[10] Adele Murrell et al., *From Genome to Epigenome*, 14 HUM. MOLECULAR GENETICS (ISSUE SUPPL_1) R3, R3 (2005).

[11] Eileen R. Gibney & Catherine M. Nolan, *Epigenetics and Gene Expression*, 105 HEREDITY 4, 4 (2010).

[12] CpG dinucleotides are regions of DNA where a cytosine nucleotide is followed by a guanine nucleotide, separated by a phosphodiester bond, in the 5' → 3' direction.

divisions and sometimes across generations, having significant implications for health and disease.[13]

Epigenetic modifications, or variants, are highly influenced by the environment. The environmental factors of nutrition, behavior, stress, toxins, and stochasticity work independently and jointly to cause changes to the epigenome.[14] For example, environmental toxins including metals, air pollutants, and endocrine-disrupting chemicals have been shown to modify epigenetic marks.[15] Lifestyle factors such as diet, obesity, physical activity, tobacco smoking, alcohol consumption, psychological stress, and working night shifts have also been associated with epigenetic changes.[16]

B. Epigenetics: A Definition

Epigenetic information has found new applications in recent years. Epigenetics is particularly promising for its potential applications in the prevention, diagnosis, and treatment of disease. The analysis of epigenetic variants associated with particular diseases may lead to better tools for disease risk evaluation and diagnosis. For instance, DNA methylation cancer biomarkers can be used for early detection of cancer.[17] Epigenetic variants associated with disease also have great potential for drug development. For example, researchers have found promise in pharmaceuticals that rely on epigenetic mechanisms to treat colorectal cancer,[18] heart failure,[19] schizophrenia,[20] and many other diseases. Associations between epigenetic variants and disease may also lead to advances in personalized medicine to better assess individual disease risk, treatment, and medication dosage.[21] It has also been suggested that epigenetic changes could eventually be manipulated to reverse aging and age-related diseases.[22]

---

[13] Irene Lacal & Rossella Ventura, *Epigenetic Inheritance: Concepts, Mechanisms and Perspectives*, FRONTIERS IN MOLECULAR NEUROSCIENCE, Sept. 28, 2018, at 1.

[14] Christopher Faulk & Dana C Dolinoy, *Timing is Everything*, 6 EPIGENETICS 791, 793 (2011).

[15] Andrea Baccarelli & Valentina Bollati, *Epigenetics and Environmental Chemicals*, 21 CURRENT OP. IN PEDIATRICS 243, 243 (2009).

[16] Jorge Alejandro Alegría-Torres et al., *Epigenetics and Lifestyle*, 3 EPIGENOMICS 267, 267 (2011).

[17] Warwick J. Locke et al., *DNA Methylation Cancer Biomarkers: Translation to the Clinic*, FRONTIERS IN GENETICS, Nov. 14, 2019, at 1, 17.

[18] *See, e.g.*, Srinivas Patnaik & Anupriya Sinha, *Drugs Targeting Epigenetic Modifications and Plausible Therapeutic Strategies Against Colorectal Cancer*, FRONTIERS IN PHARMACOLOGY, June 6, 2019, at 1.

[19] *See, e.g.*, *Vivien Ngo et al., Histone Deacetylase 6 Inhibitor JS28 Prevents Pathological Gene Expression in Cardiac Myocytes*, J. AM. HEART ASS'N, June 21, 2022, at 1.

[20] *See, e.g.*, Jacob Peedicayil, Epigenetic Management of Major Psychosis, 2 Clinical Epigenetics 249, 249 (2011).

[21] *See, e.g.*, Mahmood Rasool et al., *The role of Epigenetics in Personalized Medicine: Challenges and Opportunities*, BMC MED. GENOMICS, 15 Jan. 2015, at 1, 3.

[22] *See* Alejandra Manjarrez, *Epigenetic Manipulations Can Accelerate or Reverse Aging in Mice*, THE SCIENTIST (Jan. 12, 2023), https://perma.cc/DZ36-EY55.

Epigenetic information has also found widespread nonmedical use in recent years. Epigenetic clocks, which estimate biological age through algorithmic analysis of DNA methylation at specific regions of DNA across the genome, have been used in a variety of industries.[23] By comparing biological age, an age estimation dependent on the biological state of the individual, to chronological age, or the actual amount of time a person has been alive, these technologies can produce measures of aging acceleration or deceleration. Epigenetic clocks can also predict life expectancy and risk of age-related diseases. Notably, life insurance companies like FOXO Technologies are using epigenetic clocks in actuarial predictive modeling and underwriting.[24] FOXO Technologies has an exclusive license over two epigenetic clocks, PhenoAge and GrimAge, originally developed by UCLA researcher Dr. Steve Horvath.[25] These epigenetic clocks purport to predict mortality and aging outcomes, such as cancers, physical functioning, and Alzheimer's disease, using saliva samples from policy owners.[26] It has also been suggested that insurance companies may use epigenetic tests to detect alcohol and drug use, as well as diet and exercise.[27]

In addition to use by insurers, epigenetic clocks and other types of epigenetic tests have been proposed as promising technologies for law enforcement. Just as information at a crime scene undergoes genetic testing, it could undergo epigenetic testing to uncover both physiological and socio-cultural characteristics of individuals who may be involved in the crime.[28] In particular, forensic epigenomics may be useful in determining the age of the trace donor,[29] distinguishing between monozygotic twins, determining whether the trace donor is a smoker or illicit drug user, providing information about the trace donor's geographic region, and even providing clues as to the socioeconomic status of the trace donor.[30]

Epigenetic clocks have also been considered for use by immigration authorities. In particular, it has been proposed that epigenetic clocks could replace existing methods, which rely on an imprecise assessment of the maturity of bones or teeth, to determine whether migrants are minors, which has important implications for how migrants are treated by authorities.[31] In Germany, scientists

---

[23] Steve Horvath & Kenneth Raj, *DNA Methylation-based Biomarkers and the Epigenetic Clock Theory of Ageing*, 19 NATURE REVIEWS GENETICS 371, 372 (2018).

[24] *See* Life Insurance, Reimagined, FOXO Technologies, https://perma.cc/F2R4-MBC7(last visited Jan 15, 2023).

[25] *FOXO Technologies Exclusively Licenses Epigenetic Clocks PhenoAge and GrimAge from UCLA*, FOXO TECHNOLOGIES (May 5, 2021), https://perma.cc/S5YG-XBYQ.

[26] Life Insurance, Reimagined, *supra* note 24.

[27] Nat Shapo & Martin S. Masar III, *Modern Regulatory Frameworks for the Use of Genetic and Epigenetic Underwriting Technology in Life Insurance*, 39 J. INS. REGUL. 1, 2-3 (2020).

[28] Charles Dupras et al., *Potential (Mis)use of Epigenetic Age Estimators by Private Companies and Public Agencies: Human Rights Law Should Provide Ethical Guidance*, ENV'T EPIGENETICS, Sept. 17, 2019, at 1, 5.

[29] "Trace donor" refers to someone who leaves forensic traces, such as hair or blood, at the scene of a crime.

[30] Vidaki & Kayser, *supra* note 3, at 1, 3-8.

[31] Abbott, *supra* note 4.

expressed concerns over the accuracy and scientific validity of epigenetic clocks for forensic purposes when authorities commissioned an American company, Zymo Research, to estimate the age of a young migrant based on DNA methylation.[32] Despite these concerns, scientists across Europe have moved forward in collaboration to make epigenetic clocks more accurate for future use in determining the age of refugees, asylum seekers, and migrants.[33]

Following the success of direct-to-consumer genetic testing, private companies have begun to offer direct-to-consumer epigenetic testing. Companies like Chronomics, Elysium Health, TruDiagnostic, HKG Epitherapeutics, Muhdo, and others offer simple test kits that can be ordered online, allegedly enabling consumers to understand their biological age and other health indicators, such as smoker status and skin type. Many of these companies make claims that their epigenetic tests provide medically relevant results that consumers can act upon to make health interventions, despite the fact that the U.S. Food and Drug Administration and other regulatory bodies have not validated the accuracy or utility of such tests.[34]

III. THE NEED FOR EPIGENETIC PROTECTIONS

Legal protections for genetic information have been motivated by a belief in genetic exceptionalism, or the idea that genetic information holds distinctive qualities warranting special protections.[35] However, the view that genetics deserves a special epistemic, moral, and legal status has been called into question, especially as epigenetic and other postgenomic sciences have emerged.[36] In fact, the reasoning behind the adoption of genetic protections is not unique to genetics. Epigenetic information entails the same interests and concerns, thereby necessitating a reevaluation of genetic-specific legislation. This Part presents a framework for assessing the need for the protection of epigenetic information based on the very characteristics and concerns that animated gene-centric laws. Part III.A provides an overview of how epigenetic information shares the qualities that are commonly used to support an exceptionalist view of genetic information, challenging the idea

---

[32] *See* S. Ritz-Timme et al., *Altersschätzung auf Basis der DNA-Methylierung*, 28 RECHTSMEDIZIN 202, 202 (2018); Abbott, *supra* note 4, at 15.

[33] Abbott, *supra* note 4, at 15.

[34] *See* Charles Dupras et al., *Selling Direct-to-Consumer Epigenetic Tests: Are We Ready*?, 21 NATURE REVIEWS GENETICS 335, 335 (2020).

[35] *See* Mark A. Rothstein, *Genetic Exceptionalism and Legislative Pragmatism*, 35 J. L. MED. & ETHICS 59, 59 (2007).

[36] *See e.g.*, Sonia M. Suter, *The Allure and Peril of Genetics Exceptionalism: Do We Need Special Genetics Legislation*, 79 WASH. U. L. Q. 669, 705 (2001) ("[T]here is a grossly imperfect fit between the justifications for carving out special protections for genetic information and the category of genetic information because genetic information is both over and under-inclusive with respect to its legislative purposes."); Rothstein, *supra* note 35, at 62 ("[G]enetic-specific laws have limited value in preventing or redressing harms caused by the uses and disclosures of genetic information. Genetic specific laws also reinforce the stigma of genetic disorders (by treating them differently from nongenetic conditions) and ignore the underlying social problems that genetic privacy and discrimination exemplify.").

that such qualities are unique to genetic information. Part III.B describes how epigenetic information raises the same policy concerns used to advance genetic protections, particularly in the context of employment and insurance.

A. Similarities to Genetic Information

Genetic information's sensitivity, predictive qualities, and potential use for individual and familial identification have commonly been used to support a view of genetic exceptionalism. However, these same qualities also apply to epigenetic information, suggesting that epigenetic information also warrants legal protections. Stability is another one of the bases for genetic exceptionalism, but it is an unpersuasive ground to distinguish genetic information for two reasons. First, stability is characteristic of not only genetic information, but also epigenetic information. Second, there is reason to question the defensibility of the stability factor as a basis for genetic exceptionalism, suggesting that it should be given less weight in the determination of whether epigenetic information deserves legal protections.

1. Deeply sensitive information

Genetic data contains information that is deeply personal. One's genetic code is unique to each individual and can reveal information about disease susceptibility, ancestry, and other sensitive information. For instance, genetic information can reveal an individual's risk of developing breast cancer,[37] vulnerability to developing drug addiction,[38] and from where their ancient ancestors originated.[39] From the genetic exceptionalist point of view, the sensitivity of this information warrants heightened protection for genetic information.

Like genetic data, epigenetic data also reveals deeply sensitive information about an individual. Epigenetic information raises substantial concerns about the ability to impute personal information due to the fact that epigenetic information reflects not only disease predispositions but also lifestyle factors, or what Charles Dupras and Eline M. Bunnik have called "life-intrusive information."[40] For example, epigenetic data may be associated with education level, BMI, and alcohol consumption, which can shed light on lifestyle choices made by individuals.[41] This "life-intrusive information" may in some cases be just as, if not more, sensitive than the biological data contained in genetic information, particularly because such

---

[37] A. Surbone, *Social and Ethical Implications of BRCA Testing*, 22 ANNALS OF ONCOLOGY i60, i60 (2011).

[38] Mary Jeanne Kreek et al., *Genetic Influences on Impulsivity, Risk Taking, Stress Responsivity and Vulnerability to Drug Abuse and Addiction*, 8 NATURE NEUROSCIENCE 1450, 1450 (2005).

[39] Mark D. Shriver & Rick A. Kittles, *Genetic Ancestry and the Search for Personalized Genetic Histories*, 5 NATURE REVS. GENETICS 611, 611 (2004).

[40] Charles Dupras & Eline M. Bunnik, *Toward a Framework for Assessing Privacy Risks in Multi-Omic Research and Databases*, 21 AM. J. BIOETHICS 46, 47 (2021).

[41] *See* Daniel L. McCartney et al., *Epigenetic Prediction of Complex Traits and Death*, GENOME BIOLOGY, Sept. 27, 2018, *passim*.

information may be seen as a result of individual choice and as potentially reversible through intervention.[42] Therefore epigenetic information may be even more sensitive than genetic information, which does not reflect lifestyle and environmental exposures, thereby increasing the need for epigenetic protections.[43]

2. Predictive qualities

While genetic information is often viewed as being capable of predicting whether an individual will develop a specific disease, the predictive nature of genetic information is more nuanced.[44] The expression of one's genetic code is influenced by a number of factors, including lifestyle and environment. Given that genetic predictions contain a degree of uncertainty about whether a condition will materialize, it is more accurate to describe genetic information as probabilistic. The inherent risk that decisions will be made on the basis of genetic predispositions rather than manifestations of disease has been said to warrant legal protections.[45]

Similar to genetic data, epigenetic information is also viewed as a predictor of disease risk, such as the development of cardiovascular disease or the onset of age-related conditions.[46] Furthermore, like genetic-based predictions, predictions based on epigenetic data are not certainties. Epigenetic clocks, for example, have been shown to systematically underestimate age in older samples.[47] In addition, predictions made from epigenetic clocks are less precise when used in older tissue samples or tissue types that the predictive models were not trained on.[48] Researchers have also encountered statistical outliers in epigenetic clock data that could be a result of undiagnosed illnesses distorting the clock's predictions or technical errors.[49] Moreover, there is a great need for further study of how population and group differences affect the accuracy of epigenetic predictions.[50] As

---

[42] Dupras & Bunnik, *supra* note 40, at 51-52.

[43] *See* Charles Dupras et al., *Epigenetics, Ethics, Law and Society: A Multidisciplinary Review of Descriptive, Instrumental, Dialectical and Reflexive Analyses*, 49 SOC. STUD. SCI. 785, 799 (2019) ("[I]ndividual epigenetic data could prove to be even more ethically sensitive than genetic data, considering that it can provide information not only about an individual's disease risk profile – and sometimes on the current disease status – but also on the individual's previous exposures and lifestyle.").

[44] Amy L. McGuire et al., *Confidentiality, Privacy, and Security of Genetic and Genomic Test Information in Electronic Health Records: Points to Consider*, 10 GENETICS IN MED. 495, 497 (2008).

[45] *Id*. at 497-98.

[46] Ake T. Lu et al., *DNA Methylation GrimAge Strongly Predicts Lifespan and Healthspan*, 11 AGING 303, 304 (2019); Kenneth Westerman et al., *Epigenomic Assessment of Cardiovascular Disease Risk and Interactions With Traditional Risk Metrics*, 9 J. AM. HEART ASS'N 1, 10 (2020).

[47] Gemma L Shireby et al., *Recalibrating the Epigenetic Clock: Implications for Assessing Biological Age in the Human Cortex*, 143 BRAIN 3763, 3767 (2020).

[48] *Id*. at 3763.

[49] Alison Abbott, *Can Epigenetics Help Verify the Age Claims of Refugees?*, NATURE (Sept. 4, 2018), https://perma.cc/QT8G-74RY.

[50] *See* Sarah Holmes Watkins et al., *Epigenetic Clocks and Research Implications of the Lack of Data on Whom They Have Been Developed: A Review of Reported and Missing Sociodemographic Characteristics*, ENV'T EPIGENETICS, July 15, 2023, at 1, 1.

with genetic information, the probabilistic nature of epigenetic information creates a risk of classification or decision-making on the basis of predictive uncertainties.

Additionally, the potential reversibility and instability of some epigenetic variants may add further uncertainty to the predictive nature of epigenetic information.[51] Indeed, the fact that epigenetic changes may in some cases be reversed by various interventions, such as lifestyle changes or drugs targeting epigenetic marks, makes it more dangerous to make predictive decisions on the basis of epigenetic information. This potential for reversibility creates a different kind of probabilistic uncertainty that is not typically associated with genetic information, risking the formation of predictions on the basis of information that no longer holds true.

Given the intricate interplay between genetics and epigenetics, it would be a mistake to ignore the probabilistic nature of the two in concert. Because epigenetic and genetic variations both play an important role in determining health outcomes, genetic and epigenetic information must be considered together to determine a higher-order probability that conditions will materialize. While the genetic subpart of this predictive combination is often covered by legal protections, the epigenetic portion is without protections, despite its role in conveying the full probabilistic picture. The interaction between epigenetics and genetics further underscores the need for epigenetic protections based on the normative concern for the predictive qualities of these kinds of information.

3. Potential use for individual and familial identification

The concern of re-identification associated with genetic data is another basis for genetic privacy protections. Re-identification occurs when anonymized or de-identified genetic data is matched with publicly available information to identify the individual source of the genetic data. One method of genetic data re-identification occurs when genetic datasets contain other types of information, such as demographic details, pedigree structure, and health conditions, which can then be used to identify who the corresponding genetic information belongs to.[52] For example, scholars have re-identified individuals by linking demographic information associated with genomic data to public records such as voter lists.[53] Moreover, phenotypic information, or the observable characteristics of an individual, can be deduced from genetic information and then used for re-identification.[54] For example, researchers have predicted human biometric data such as height and eye color from whole-genome sequencing data to re-identify

[51] *See* Dupras et al., *supra* note 28, at 1, 7.

[52] Yaniv Erlich & Arvind Narayanan, *Routes for Breaching and Protecting Genetic Privacy*, 15 NATURE REVS. GENETICS 409, 410 (2014).

[53] *See* Latanya Sweeney et al., IDENTIFYING PARTICIPANTS IN THE PERSONAL GENOME PROJECT BY NAME 1 (2013), https://perma.cc/53U7-J3SS.

[54] Zhiyu Wan et al., *Sociotechnical Safeguards for Genomic Data Privacy*, 23 NATURE REVS. GENETICS 429, 431 (2022).

individuals.[55] Re-identification could also occur by the inference of genomic attributes from phenotypic data, such as physically-observable disorders or visual traits.[56]

Epigenetic data can be re-identified using similar methods. Various combinations of epigenetic variants at different locations of the genome are unique to an individual and can therefore be linked to corresponding identifying data.[57] For instance, researchers have already found that personally identifying information and substance-use histories, including information about alcohol and smoking consumption, can be simultaneously inferred from DNA methylation data.[58] The fact that characteristics such as living environment, social life, lifestyle, and life choices can be inferred from epigenetic data increases its risk of re-identification.[59] Because epigenetic data can reveal such information about an individual's lifestyle, these characteristics may be used to re-identify individuals.

In addition to individual risks associated with re-identification, both genetic and epigenetic data can reveal information about relatives. Genetic data can reveal information about disease susceptibility of family members, who share some amount of genetic information with the primary individual. Epigenetic data can also reveal information about relatives because some epigenetic modifications may be directly or indirectly passed on between generations, associated with particular backgrounds and lifestyles, or common among those in the same family.[60] In addition, both genetic and epigenetic information concern future generations, given that epigenetic and genetic information may both be inherited.[61]

4. Stability

Some scholars have noted that genetic information warrants special protection due to the fact that genes are stable and immutable, making them beyond individual control.[62] The immutability argument has been used to support nondiscrimination laws for the protection of many characteristics, such as race and

---

[55] Christoph Lippert et al., *Identification of Individuals by Trait Prediction Using Whole-Genome Sequencing Data*, 114 PROC. OF THE NAT'L ACAD. OF SCIS. 10166, 10168 (2017).

[56] Wan et al., *supra* note 54, at 431.

[57] Dupras & Bunnik, *supra* note 40, at 50.

[58] Robert A. Philibert et al., *Methylation Array Data Can Simultaneously Identify Individuals and Convey Protected Health Information: An Unrecognized Ethical Concern*, 6 CLINICAL EPIGENETICS 28, 28 (2014).

[59] Dupras & Bunnik, *supra* note 40, at 51-52.

[60] Lacal & Ventura *supra* note 13, at 1.

[61] Mark A. Rothstein et al., *The Ghost in Our Genes: Legal and Ethical Implications of Epigenetics*, 19 HEALTH MATRIX 1, 50-51 (2009) ("Epigenetics could create a wealth of sensitive information about an individual's likelihood of developing health problems in the future and possibly transmitting the risk to his or her offspring.").

[62] In fact, this reasoning was made explicit in Senate considerations about the Genetic Information Nondiscrimination Act: "We do not determine our own DNA. We are born with it. We cannot allow discrimination on the basis of such a fundamental aspect of life and one in which we had no choice." 154 CONG. REC. S3372 (daily ed. Apr. 24, 2008) (statement of Sen. Levin).

disability. The intuition behind this argument is that it is unfair to penalize individuals for factors beyond their control. Since individuals are born with a unique genetic code, this argument suggests that it is unfair to penalize them based on their genetics.

Epigenetic modifications, on the other hand, are reversible and can be inherited or accumulated over the course of one's lifetime.[63] In contrast to the stable and predetermined nature of genetics, epigenetics is influenced by environment and lifestyle. This would seem to suggest that epigenetics is not beyond individual control, and therefore does not warrant the same level of protection as genetic information.

However, such a conclusion is overly simplistic. As noted by Charles Dupras, et. al., it is "important to remain cautious about the interpretation that epigenetic modifications, in contrast with genetic mutations, are the result of free and voluntary decisions on the part of at-risk individuals."[64] Researchers have yet to determine whether most epigenetic modifications have been acquired over the course of one's life or were inherited, and therefore beyond individual control.[65] Moreover, it has been proposed that an individual's epigenetic information may to a large extent reflect inherited biological predispositions rather than acquired environmental influences.[66] Given that individuals do not have absolute control over their epigenetics, the same normative reasoning for the protection of genetic information should apply to epigenetic information.

Even if epigenetics reflects changes acquired over the course of one's life as a result of environmental and lifestyle factors, such influences are often the result of external factors that are outside an individual's control. Many lifestyle factors, such as socioeconomic background and physical environment, are much less "choices" than circumstantial differences beyond individual control. Epigenetic changes may also reflect social inequalities that are historically linked to discrimination or exclusion, often rooted in systemic and institutional causes. Accordingly, it is not clear that the reasoning for the protection of genetic information based on the normative unfairness of penalizing individuals for factors beyond their control does not at least sometimes apply to acquired epigenetic traits as well.

Even if it is accepted that epigenetic changes are reversible and therefore within individual control, the logic that characteristics beyond individual control deserve special consideration has been widely criticized. Basing legal protections in stability or immutability may create problematic moral conceptions of individual responsibility and blameworthiness, seeming to suggest that traits for which an individual does have control are acceptable bases for discrimination.[67]

---

[63] Jessica Wright, *Epigenetics: Reversible Tags*, 498 NATURE S10, S10 (2013).

[64] Charles Dupras et al., *Epigenetic Discrimination: Emerging Applications of Epigenetics Pointing to the Limitations of Policies Against Genetic Discrimination*, FRONTIERS IN GENETICS, June 8, 2018, at 1, 3.

[65] *Id*.

[66] *Id*. at 3.

[67] *See* Jessica A. Clarke, *Against Immutability*, 125 YALE L. J. 2, 9-10, 51-52 (2015).

Additionally, there is much complexity as to what qualities are indeed a result of individual control. Consider the example of a smoker, whose habit leads to changes in a variety of epigenetic marks. A simplistic notion of individual control would suggest that the smoker should be responsible for their increased likelihood of disease. However, this understanding is complicated by the addictive quality of nicotine and the fact that genetic predispositions make individuals more or less susceptible to nicotine addiction and its resulting health risks.[68] Therefore, epigenetic signatures of smoking may represent individual control over smoking habits to varying degrees. Genetic and epigenetic characteristics are inextricably linked, such that any attempt to separate those qualities that are within control from those beyond control is misguided.

Even the immutability of genetic changes is called into question by the availability of genetic modification technologies.[69] Technologies such as the CRISPR/Cas9 platform have shifted the potential for therapeutic gene editing from concept to clinical practice, with a number of gene editing therapeutics currently progressing through clinical trials.[70] With advancements in genetic technology and the possibility of genetic modification, the difference in immutability between epigenetic and genetic information is likely to become hard to discern, as the latter will become a matter of "choice" in some sense as well. Accordingly, basing legal protections in individual control results in illogical line-drawing. Greater weight should be placed on other factors in determining the need for legal protections.

B. Policy concerns shared between genetic and epigenetic information

In addition to the distinctive features of genetic information, the policy concerns of discrimination, entrenchment of existing disparities, and public health consequences of fear of discrimination have been advanced to support genetic privacy and nondiscrimination laws, particularly in the context of employment and insurance. Epigenetic information ignites the same policy concerns, evidencing the immense need for epigenetic protections.

1. Discrimination

An important motivation for genetic data protections is the concern that individuals might face discrimination on the basis of genetic information.[71] Before the passage of the Genetic Information Nondiscrimination Act ("GINA"), there were fears that a "biological underclass" would take shape, facing discrimination

---

[68] Deborah Hellman, *What Makes Genetic Discrimination Exceptional?,* 29 AM. J. L. & MED. 77, 87 (2003).

[69] Jeffrey S. Morrow, *Insuring Fairness: The Popular Creation of Genetic Antidiscrimination*, 98 GEO. L. J. 215, 242 (2009).

[70] Hongyi Li et al., *Applications of Genome Editing Technology in the Targeted Therapy of Human Diseases: Mechanisms*, ADVANCES AND PROSPECTS, SIGNAL TRANSDUCTION & TARGETED THERAPY, Jan. 3, 2020, at 1, 1.

[71] Sonia M. Suter, *Disentangling Privacy from Property: Toward a Deeper Understanding of Genetic Privacy*, 72 GEO. WASH. L. REV. 737, 776 (2004).

in employment and health insurance based on a genetic predisposition to disease.[72] Such fears were not without merit. Two high-profile lawsuits revealed that employers were conducting genetic tests of employees without their consent. In the first of these two cases, the court ruled that Lawrence-Berkeley Laboratories violated its employees' right to privacy by performing genetic tests on its employees for sensitive medical information, including syphilis and sickle cell disease, without their knowledge or consent.[73] In the second case, the U.S. Equal Employment Opportunity Commission reached a settlement in court with the Burlington Northern Santa Fe Railway Company over the company's use of diagnostic blood testing for a genetic marker for carpal tunnel predisposition on employees.[74] After its enactment, GINA has been asserted to prohibit companies from requiring job applicants to provide health history information which might entail disclosure of genetic information related to family history or disease risk factors.[75]

The unbridled use of epigenetic information also raises the concern of pernicious discrimination. Epigenetic testing of variants associated with disease susceptibility and lifestyle choices presents issues for the use of epigenetic information in settings such as insurance and employment.[76] It is easily conceivable that an individual might face discrimination on the basis of their epigenetic information, not only for disease indications, but also for epigenetic indications of certain behaviors and lifestyles.

For example, epigenetic clocks are already being used by life insurance companies in underwriting, presenting a concern of epigenetic discrimination.[77] While life insurers commonly underwrite on the basis of lifestyle and medical factors, they may not make risk classifications that are unsupported by actuarial justification.[78] Given that some experts have raised concerns about the validity of epigenetic clocks, using such non-scientifically validated technology might itself constitute unfair discrimination.[79] Additionally, given the potential reversibility of

---

[72] *See* Ashley M. Ellis, *Genetic Justice: Discrimination by Employers and Insurance Companies Based on Predictive Genetic Information*, 34 TEX. TECH L. REV. 1071, 1072 (2003).

[73] *See Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260, 1264 (9th Cir. 1998).

[74] *See E.E.O.C. v. Burlington N. and Santa Fe Ry. Co.*, 02-C-0456, 2002 WL 32155386, at *1 (E.D. Wis. May 8, 2002).

[75] *See, e.g., Equal Empl. Opportunity Comm'n. v. Grisham Farm Products, Inc*., 191 F. Supp. 3d 994, 998 (W.D. Mo. 2016) ("This Court holds that Grisham Farm's action of requiring job applicants to fill out the three-page health history form violated GINA").

[76] Luca Chiapperino, *Epigenetics: Ethics, Politics, Biosociality*, 128 BRITISH MED. BULL. 49, 51 (2018).

[77] *See* Dupras et al., *supra* note 64, at 1, 2 ("The collection by GWG Life of saliva samples from life insurance policy owners, for subsequent analysis of DNA methylation levels, suggests the possibility that some insurers might stratify their clients based on their epigenetic information.").

[78] Dupras et al., *supra* note 28, at 1, 3-4 ("Life insurers often uncontroversially underwrite on the basis of lifestyle, medical, and environmental factors. . . . In the USA, as in many other countries, fair trade practice laws require actuarial justification for medical underwriting in all forms of insurance, including life insurance.").

[79] Epidemiologists have raised concerns related to technological, biological, and methodological issues. *See, e.g.*, Louis Y. El Khoury et al., *Systematic Underestimation of the*

epigenetic changes, data that is collected might be outdated in ways that would make it erroneous to use. Furthermore, even though the practice of underwriting on the basis of epigenetic information may constitute actuarial fairness, there must also be moral fairness.[80] For instance, it may be possible in the future to infer socioeconomic status from epigenetic information,[81] which could then be used as a basis for discrimination. While it may satisfy actuarial fairness to make insurance decisions on the basis of socioeconomic status, it would be unacceptable to do so based on moral principles.

Epigenetic discrimination might also involve discrimination on the basis of certain protected classes, such as race, gender, and disability, as epigenetic variants track those class distinctions. Since various environmental and social disparities, often reflected in discrimination against protected classes, may contribute to epigenetic changes, groups exposed to those disparities might have similar epigenetic patterns. For instance, scientists have found various associations between epigenetics and race or ethnicity, reflecting the complex interplay between the social construction of race and ethnicity and the biological construct of genetic ancestry.[82] Epigenetic information that reflects these racial and ethnic distinctions could be used on a discriminatory basis. Another potential for discrimination could arise where a protected class uses a specific prescription medication, which becomes reflected in epigenetic information. For example, medications frequently prescribed to gay men to prevent the contraction of HIV could be reflected in epigenetic changes.[83] New York financial regulators are already investigating denials of life, disability, and long-term care insurance policies due to individuals'

Epigenetic Clock and Age Acceleration in Older Subjects, 20 GENOME BIOLOGY 283, 283 (2019). *See also*, Liam Drew, *Turning Back Time With Epigenetic Clocks*, 601 NATURE S20, S20 (2022) ("The US Food and Drug Administration does not currently recognize epigenetic-clock scores as surrogate end points for clinical trials. It wants their mechanistic basis to be better defined. And it wants an answer to the crucial question of whether a short-term decrease in someone's epigenetic-clock score definitively lowers their chances of developing age-related ill health.").

[80] *See* Dupras et al., *supra* note 28, at 1, 4.

[81] There is a great deal of evidence showing a strong association between socioeconomic status and adverse health outcomes, including cardiovascular, immune, stress response, and behavioral pathologies. Many scholars hypothesize that epigenetic mechanisms might explain this phenomenon. In particular, scientists suggest that various socioeconomic circumstances might lead to the alteration of gene expression through changes in DNA methylation, leading to long-term health consequences. While studies have thus far demonstrated a link between socioeconomic position and epigenetic patterns, there is still a need for studies investigating the causal and time-dependent effects of socioeconomic position on DNA methylation and other epigenetic marks. See Janine Cerutti et al., *Associations Between Indicators of Socioeconomic Position and DNA Methylation: A Scoping Review*, 13 CLINICAL EPIGENETICS 221, 221 (2021).

[82] See Joshua M Galanter et al., *Differential Methylation Between Ethnic Sub-groups Reflects the Effect of Genetic Ancestry and Environmental Exposures*, 6 ELIFE, Jan. 3, 2017, at 1, 1. *See also* Lucas A Salas et al., *A Transdisciplinary Approach to Understand the Epigenetic Basis of Race/Ethnicity Health Disparities*, 13 EPIGENOMICS 1761, 1762 (2021).

[83] It should be noted that this example was posed at the Association of Life Insurance Counsel (ALIC) Annual Meeting. Michael J Miller & Paige Freeman, *Legal Issues Relating to Epigenetics in Life Insurance* 7-8 (2018), https://perma.cc/LLR2-W9CQ.

use of the medication Truvada,[84] which is used for pre-exposure prophylaxis ("PrEP").[85] Regulators have noted that denial of insurance on such a basis would amount to illegal discrimination based on sexual orientation.[86] Given that epigenetic changes can reflect the use of medications,[87] there is a potential risk that such information could be used to discriminate against classes taking particular medications. These examples suggest that discrimination on the basis of epigenetic information that reflects protected class identities could result in protected class discrimination.

2. Entrenchment of existing disparities

A related but somewhat different argument advanced to support genetic privacy and nondiscrimination laws is that the use of genetic variants to police access and distribute resources could entrench already existing racial, health, and economic disparities. Many genetic variants associated with disease risk are shared by groups that have faced historical discrimination. Restricting access to insurance or employment on the basis of such genetic variants would increase the already disproportionate burden faced by those groups.[88] For example, in the 1970s, state legislatures enacted discriminatory laws mandating screening for sickle cell anemia, a disease which primarily afflicts the Black population.[89] This practice led to the discrimination of Black individuals in health insurance and employment, ultimately leading Congress to pass the National Sickle Cell Anemia Control Act in 1972.[90]

The use of epigenetic information by insurers, employers, or others could disproportionately burden groups that have faced historical discrimination.[91] Indeed, while epigenetics has at times been seen as a postgenomic paradigm that transcends deterministic conceptions of genetics and race, some scholars have noted how epigenetics offers a new form of racialization which is itself rooted in eugenic logic.[92] Some epigenetic variants may reflect discrimination and its effects

---

[84] Note that while Truvada is frequently prescribed to gay men due to the historical prevalence of HIV, many people take Truvada regardless of gender or sexuality. The discrimination complaints investigated by New York regulators specifically concerned gay men.

[85] Donald G. McNeil Jr, *New York Will Investigate Reports of Gay Men Denied Insurance*, N.Y. TIMES (Feb. 14, 2018), https://perma.cc/55LP-DGKK .

[86] *Id*.

[87] *See generally* Antonei B. Csoka & Moshe Szyf, *Epigenetic Side-effects of Common Pharmaceuticals: a Potential New Field in Medicine and Pharmacology*, 73 MED. HYPOTHESES 770 (2009).

[88] *See* Dupras et al., *supra* note 28, at 1, 3.

[89] Eric A. Feldman, *The Genetic Information Nondiscrimination Act (GINA): Public Policy and Medical Practice in the Age of Personalized Medicine*, 27 J. GEN. INTERNAL MED. 743, 744 (2012).

[90] *Id*.

[91] *Supra* note 28, at 1, 3.

[92] Becky Mansfield & Julie Guthman, *Epigenetic Life: Biological Plasticity, Abnormality, and New Configurations of Race and Reproduction*, 22 CULTURAL GEOGRAPHIES 3, 6 (2015) ("In short, the argument is that in this focus on abnormality and optimization, epigenetics is tied to a eugenic logic, even as it rejects notions of genetic determinism. That is, epigenetics not only ties

and may be shared between certain racial, socioeconomic, geographic, or other groups.

Epigenetic marks, which can be modified by the environment, may also reflect the disproportionate environments individuals live in. Health disparities across groups defined by class, race, and ethnicity may be both causes and results of epigenetic changes resulting from environmental exposures.[93] Consider, for example, an individual who grows up neighboring a freeway or a coal power plant in a primarily minority community with limited access to health insurance. This individual's disproportionate exposure to air pollution results in decreased DNA methylation levels.[94] When this individual attempts to obtain health insurance,[95] they are charged a high premium after undergoing an epigenetic test that analyzes DNA methylation levels. Others in this individual's community are also charged higher insurance prices based on epigenetic test results. As areas with higher-than-average Black, Asian, and Hispanic or Latino populations have consistently been exposed to higher levels of particulate matter,[96] these disparities become reinforced through epigenetic changes caused by pollution. Nutrition, stress, and other environmental factors can lead to the reflection of societal disparities in epigenetic changes.[97] In these ways, the social effects of racism are made physiological through epigenetics, leading to intergenerational health effects.[98]

Others have raised concern over the potential misuse of epigenetic information for forensic purposes, arguing that it may further the disproportionate policing of

---

difference to the biological body through molecular mechanisms but also uses those molecular mechanisms to diagnose 'abnormalities' and seeks to intervene in those molecular mechanisms to eliminate those variations deemed 'abnormal'"). *See also* Maurizio Meloni, *Race in an Epigenetic Time: Thinking Biology in the Plural*, 68 BRIT. J. SOCIOL. 389, 390 (2017).

[93] *See* Zaneta M. Thayer & Christopher W. Kuzawa, *Biological Memories of Past Environments: Epigenetic Pathways to Health Disparities*, 6 EPIGENETICS 798, 798 (2011).

[94] *See, e.g.*, Christopher F. Rider & Chris Carlsten, *Air Pollution and DNA Methylation: Effects of Exposure in Humans*, 11 CLINICAL EPIGENETICS 131, 132 (2019) (describing how traffic-related air pollution components modulates the epigenetic mark of DNA methylation).

[95] Note that this is a hypothetical scenario. At the time of publication of this Note, there has not been any record of epigenetic testing being used to determine health insurance premiums. However, it has been suggested that in the future, health insurers might discriminate on the basis of epigenetic information, necessitating legal protections. *See, e.g.*, Crystal Grant, *It's Time for Congress to Update Our Genetic Nondiscrimination Law*, ACLU (May 24, 2023) (suggesting that epigenetic discrimination may lead to disparate impacts), https://perma.cc/BB3D-GZXE.

[96] Abdulrahman Jbaily et al., *Air Pollution Exposure Disparities Across US Population and Income Groups*, 601 NATURE 228, 228 (2022).

[97] Thayer & Kuzawa, *supra* note 93.

[98] *See* Shannon Sullivan, *Inheriting Racist Disparities in Health: Epigenetics and the Transgenerational Effects of White Racism*, 1 CRITICAL PHIL. RACE 190, 210 (2013) ("[T]he stress and trauma of Jim Crow continue to live even though Jim Crow formally ended in the 1960s. Its health effects likely persist physiologically, not only in the biochemistry of African American people who were adolescents in the 1950s, but also in the biochemistry of their children and grandchildren. Of course, ongoing racism after Jim Crow also can be blamed for contributing to the high rates of infant mortality and cardiovascular disease experienced by African Americans. But it is not just the racist present that is harming contemporary African Americans.").

certain groups.[99] This concern exemplifies how existing discriminatory practices, such as the overrepresentation of minorities in law enforcement databases, may exacerbate epigenetic discrimination.[100] The use of epigenetic testing on migrants also raises significant concerns related to discrimination and the entrenchment of existing disparities.

3. Public health consequences of fear of discrimination

Another important rationale for laws protecting genetic information is the need to ensure that individuals do not forgo beneficial genetic testing out of fear that genetic information will be used against them.[101] Indeed, this motivation was made clear in GINA's congressional findings: GINA would be instrumental in "allay[ing] [the public's] concerns about the potential for discrimination, thereby allowing individuals to take advantage of genetic testing, technologies, research, and new therapies."[102]

Genetic testing has beneficial public health outcomes on both individual and societal levels. Individuals may learn through genetic testing about disease predispositions that can be ameliorated through lifestyle changes.[103] On a societal level, more widespread genetic testing can lead to the identification of genetic variants affecting disease and drug response, leading to advances in genetic research and the development of better treatments.[104] In addition to the failure to undergo genetic testing, fear of genetic discrimination may discourage individuals from partaking in the health benefits available as a result of genetic science.[105] Given that studies have shown real concern for genetic discrimination,[106] the policy concern for the public health consequences resulting from the failure to undergo genetic testing is legitimate.

Fear of epigenetic discrimination could also lead to consequences for public health and medical research.[107] Like genetics, the field of epigenetics has an enormous potential to be used to improve population health.[108] Epigenetics may

---

[99] *See* Dupras et al., *supra* note 28, at 6.

[100] *Id*.

[101] Mary R. Anderlik & Mark A. Rothstein, *Privacy and Confidentiality of Genetic Information: What Rules for the New Science*?, 2 ANN. REV. GENOMICS & HUM. GENETICS 401, 405 (2001).

[102] Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, § 2, 122 Stat. 881, 882-83.

[103] Anderlik & Rothstein, *supra* note 101

[104] *See* id.*; see also* Henry T. Greely, *Genotype Discrimination: The Complex Case for Some Legislative Protection*, 149 U. PA. L. REV. 1483, 1501 (2001) (addressing public concern regarding genetic discrimination).

[105] Hellman, *supra* note 68, at 94.

[106] *See, e.g.*, Annet Wauters & Ine Van Hoyweghen, *Global trends on fears and concerns of genetic discrimination: a systematic literature review*, 61 J. HUM. GENETICS 275, 279 (2016) (analyzing public sentiment concerning genetic discrimination).

[107] Dupras et al., *supra* note 28, at 4.

[108] Laura S. Rozek et al., *Epigenetics: Relevance and Implications for Public Health*, 35 ANN. REV. PUB. HEALTH 105, 116 (2014).

help to uncover environmental, nutritional, and other risk factors for human disease.[109] However, in order to realize this potential, it is critical that individuals do not forgo epigenetic testing out of fear of epigenetic discrimination. It is therefore necessary to ensure that adequate protections are imposed on uses of epigenetic information that could potentially be discriminatory.

IV. EXISTING PRIVACY AND ANTIDISCRIMINATION LAWS FAIL TO PROTECT EPIGENETIC INFORMATION

Existing laws that aim to protect against the privacy risks of genetic information fail to protect against the potential misuse of epigenetic information because they narrowly focus on an outdated conception of biological inheritance based on genetics.[110] While previous work has exposed the inadequacies of specific genetic privacy and antidiscrimination laws in covering epigenetic information,[111] this Note shows that such failures occur across the board: federal, state, and international laws are incapable of protecting epigenetic information. These existing statutes and international declarations often protect only a limited set of information including genetic sequences, the results of genetic tests, and chromosomal or single-gene diseases. This focus on genetics excludes epigenetic information, necessitating amendments to state and federal genetic privacy and nondiscrimination laws to protect individual epigenetic information.[112]

A. Federal Law

At the federal level, GINA and HIPAA have played a large role in shaping the landscape of genetic privacy regulation.

1. GINA

GINA protects individuals against discrimination on the basis of their genetic information in healthcare coverage and employment. Title I of GINA prohibits health insurers from discriminating on the basis of genetic information.[113] Title II

---

[109] *Id*.

[110] *See* Rothstein et al., *Ethical implications of epigenetics research*, 10 NATURE REVIEWS GENETICS 224 (2009). ("Several genetic privacy laws, particularly the State Genetic Privacy Laws enacted in the United States, contain definitions of 'genetic' that do not include privacy protection for epigenetic data. Therefore, new privacy legislation may be required to protect this sensitive information.").

[111] *See, e.g.*, Mark A. Rothstein, *Epigenetic Exceptionalism: Currents in Contemporary Bioethics*, 41 J.L. MED. & ETHICS 733, 735 (2013) (discussing the Genetic Information Nondiscrimination Act); *see also* Dupras et al., *Human Rights in the Postgenomic Era: Challenges and Opportunities Arising with Epigenetics*, 59 SOC. SCI. INFO. 12, 16-19 (2020) (discussing the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data).

[112] Rothstein et al., *supra* note 61, at 45-46.

[113] *See* Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, §§ 101-106, 122 Stat. 881, 883-905 (codified as amended in scattered sections of 29 U.S.C. and 42 U.S.C.).

of GINA prohibits the use of genetic information in making employment decisions, restricts employers from obtaining genetic information, and strictly limits the disclosure of genetic information in the employment context.[114] As defined by the statute, "genetic information" means, "with respect to any individual, information about—(i) such individual's genetic tests, (ii) the genetic tests of family members of such individuals, and (iii) the manifestation of a disease or disorder in family members of such individual."[115] The statute defines "genetic test" as "an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes."[116] An important limitation on this definition is that GINA only provides protections at the individual's pre-symptomatic or asymptomatic stage, or up until the point when the individual's disease has manifested.[117]

GINA likely fails to protect epigenetic information from use by employers and health insurance providers.[118] As Mark A. Rothstein has noted, the statute's definition of genetic information "strongly suggests that GINA does not apply to epigenetic information, unless 'an analysis of human DNA' is broadly interpreted to include epigenetic marks associated with DNA."[119] The definition's requirement that such an analysis "detect[] genotypes, mutations, or chromosomal changes," all traditional indicators of genetic disorders, indicates that it was not intended to cover epigenetic marks. This is reinforced by the fact that several federal statutes explicitly list genetics and epigenetics separately.[120] While it is possible that epigenetic marks could be considered "manifestations" of a disease, if this understanding was accepted, epigenetic marks still would not be covered by GINA when discovered in the individual seeking protection because they would fall within the limitation that manifested conditions are not protected.[121]

---

[114] *See* Genetic Information Nondiscrimination Act, §§ 201-213.

[115] 29 U.S.C. § 1191b(d)(6); 42 U.S.C. § 2000ff(4)(A).

[116] 29 U.S.C. § 1191b(d)(7); 42 U.S.C. § 2000ff(7)(A).

[117] 29 U.S.C. § 1182(b)(3)(B); 42 U.S.C. § 2000ff-9.

[118] Courts would likely be hesitant to expand GINA's coverage to epigenetic information. Some courts have even construed the definition of "genetic information" narrowly when the information at hand is indeed genetic. *See, e.g.*, *Poore v. Peterbilt of Bristol, L.L.C.*, 852 F. Supp. 2d 727 (W.D. Va. 2012) (finding that employment termination based on information about an employee's wife's diagnosis with multiple sclerosis did not constitute discrimination under GINA because it did not have any predictive value with respect to the employee's genetic propensity to acquire the disease, even though such information would fall under the plain meaning of "the manifestation of a disease or disorder in family members of such individual").

[119] Rothstein, *supra* note 111.

[120] *See*, *e.g.*, 42 U.S.C. § 280i(b)(2)(B) (requiring for CDC funding or cooperative agreements pertaining to autism spectrum disorder and other developmental disabilities that "[t]he center will develop or extend an area of special research expertise (including genetics, epigenetics, and epidemiological research related to environmental exposures), immunology, and other relevant research specialty areas").

[121] Mark A. Rothstein, *HIPAA privacy rule 2.0: currents in contemporary bioethics*, 41 J.L. MED. & ETHICS 525, 527 (2013).

2. HIPAA

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created national standards to protect sensitive patient health information.[122] The HIPAA Privacy Rule regulates the use and disclosure of protected health information ("PHI") by "covered entities" which are health plans, health care clearinghouses, and health care providers who transmit health information in electronic form.[123] PHI is defined as "individually identifiable health information" that is held or transmitted by a covered entity in any form, paper or electronic.[124] "Individually identifiable health information" is defined as:

> information that is a subset of health information, including demographic information collected from an individual, and: . . . (2) Relates 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.[125]

In 2013, the Department of Health and Human Services (HHS) issued the Omnibus Rule, which implemented various obligations under the Health Information Technology for Economic and Clinical Health Act and GINA to strengthen privacy and security protections under the HIPAA Privacy Rule and other HIPAA regulations.[126] As required by GINA, the Omnibus Rule makes HIPAA's protection of genetic information explicit by incorporating genetic information into the definition of PHI.[127] The Omnibus Rule defines "genetic information" as information about:

> (i) The individual's genetic tests; (ii) The genetic tests of family members of the individual; (iii) The manifestation of a disease or disorder in family members of such individual; or (iv) Any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by the individual or any family member of the individual.[128]

---

[122] Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 100 Stat. 2548 (codified as amended in scattered sections of 42 U.S.C.).

[123] 45 C.F.R. § 160.103 (2023).

[124] *Id*.

[125] *Id*.

[126] Modifications to the HIPAA Privacy, Security, Enforcement, and Breach-Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, 78 Fed. Reg. 5566, 5566 (Jan. 25, 2013) (codified at 45 C.F.R. pts. 160, 164).

[127] *See* Genetic Information Nondiscrimination Act of 2008 § 105(a), 42 U.S.C. § 1320d-9.

[128] 45 C.F.R. § 160.103 (2023).

HIPAA's definition of genetic information is unlikely to cover epigenetic information. Like GINA, HIPAA defines genetic information with a focus on genetic testing, genetic services, and manifestation of disease. This narrow definition excludes information that is not based on a traditional conception of genetics, such as epigenetic information.

However, HIPAA, unlike other statutes, rejects a genetic-exceptionalist view of genetic information, treating genetic information like other protected health information. While epigenetic information is likely not covered by HIPAA's narrow definition of genetic information, there is an argument to be made that epigenetic information is covered by HIPAA's broader definition of protected health information. Epigenetic information may be considered "individually identifiable health information" because it can provide predictions of an individual's disease onset or risk, thus "[r]elat[ing] to the past, present, or future physical or mental health or condition of an individual."[129] As described in Section III.A.3, epigenetic information is also capable of providing at least "a reasonable basis to believe the information can be used to identify the individual."[130] Therefore, epigenetic information would arguably fall under HIPAA when used by covered entities.

Even if epigenetic information is protected under HIPAA, its protection is limited. Partly owing to its relatively broad definition of covered data, HIPAA's protections are quite narrow in scope. Indeed, Congress did not intend for HIPAA's Privacy Rule to act as comprehensive privacy protection for health data or genetic data.[131] When protected health information, including genetic and epigenetic data, is used outside of a covered entity, it is no longer subject to HIPAA's protections. Furthermore, the HIPAA Privacy Rule has been criticized for containing extensive exclusions and exemptions and limited rights for individuals.[132]

B. State Law

Various state statutes and regulations prohibit genetic discrimination in the areas of health insurance, disability insurance, life insurance, and employment to supplement and reinforce the previously described federal protections. While all fifty U.S. states have addressed genetic discrimination in health insurance, the

[129] *Id*.; *see* discussion *supra* Section III.A.2.

[130] *Id*.

[131] Congress had initially intended to enact a broad national health privacy legislation after HIPAA's enactment but provided the U.S. Department of Health & Human Services (HHS) authority to enact the HIPAA Privacy Rule should it fail to do so. As a result of Congress's failure to enact sweeping health privacy legislation, the HIPAA Privacy Rule has assumed a larger role than intended, despite the limited jurisdiction provided to HHS by HIPAA. Ellen Wright Clayton et al., *The Law of Genetic Privacy: Applications, Implications, and Limitations*, 6 J.L. & BIOSCIENCES 1, 10–11 (2019).

[132] *See* Mark A. Rothstein, *The End of the HIPAA Privacy Rule*, 44 J.L. MED. & ETHICS 352 PASSIM (2016).

scope of these laws varies greatly from state to state.[133] Over 25% of states have enacted genetic nondiscrimination protections in the area of disability insurance, and more than 20% have enacted genetic nondiscrimination protections in the area of life insurance.[134] In the employment context, more than two-thirds of states have prohibited genetic discrimination.[135] A much smaller number of states have enacted statutes and regulations to address genetic discrimination in housing, lending, land use, and other contexts.[136] A growing number of states have sought to address genetic privacy in the context of direct-to-consumer genetic testing, with seven states enacting bills to address the protection of consumer genetic information in 2021 alone.[137] This Section will provide a brief overview of some of the existing genetic protections in California, Florida, and New Jersey. These three states have enacted some of the most influential genetic privacy legislation at the state level.[138]

1. California

The California Genetic Information Nondiscrimination Act ("CalGINA") is California's expanded version of the federal GINA. CalGINA prohibits genetic discrimination in employment, housing, provision of emergency services, education, mortgage lending, and elections.[139] Under CalGINA, "genetic information" means:

> with respect to any individual, information about any of the following: (i) The individual's genetic tests. (ii) The genetic tests of family members of the individual. (iii) The manifestation of a disease or disorder in family members of the individual.[140]

CalGINA fails to cover epigenetic information. CalGINA's definition of "genetic information" is nearly identical to that provided in GINA. Because, as described above in Section IV.A.I, GINA likely does not cover epigenetic

---

[133] *See* Yann Joly et al., *Looking Beyond GINA: Policy Approaches to Address Genetic Discrimination*, 21 ANN. REV. GENOMICS & HUM. GENETICS 491, 495–496 (2020).

[134] *Id*. at 495.

[135] *Id*. at 496.

[136] *Id*.

[137] Korey Clark, *State Lawmakers Find Success with Genetic Privacy*, Lexisnexis: State Net Insights (June 17, 2022), https://perma.cc/4JBN-QT4Y.

[138] *See* generally Jarrod O. Anderson et al., *The Problems with Patchwork: State Approaches to Regulating Insurer Use of Genetic Information*, 23 DEPAUL J. HEALTH CARE L. 1, 16 (2022) (noting that Florida is one of the first states to bar the use of genetic information in life, long-term care, and disability insurance); Anya E. R. Prince, *Comprehensive Protection of Genetic Information: One Size Privacy of Property Models May Not Fit All*, 79 BROOK. L. REV. 175, 199, 211 (2013) (discussing the broad protection of genetic information provided by New Jersey and California statutes).

[139] CalGINA, ch. 261, 2011 Cal. Stat. 2774 (codified in scattered sections of the California Codes).

[140] *Id*.

information, it can be inferred that CalGINA also fails to cover epigenetic information.

California recently enacted another law pertaining to genetic privacy, the California Genetic Information Privacy Act ("GIPA"). GIPA imposes specific requirements for the use, maintenance, and disclosure of genetic data by direct-to-consumer genetic testing companies.[141] GIPA defines "genetic data" as:

> any data . . . that results from the analysis of a biological sample from a consumer, or from another element enabling equivalent information to be obtained, and concerns genetic material. Genetic material includes, but is not limited to, deoxyribonucleic acids (DNA), ribonucleic acids (RNA), genes, chromosomes, alleles, genomes, alterations or modifications to DNA or RNA, single nucleotide polymorphisms (SNPs), uninterpreted data that results from the analysis of the biological sample, and any information extrapolated, derived, or inferred therefrom.[142]

It is uncertain whether GIPA includes epigenetic data within its definition of "genetic data." While epigenetic information would satisfy the requirement that genetic data "result[] from the analysis of a biological sample," it does not "concern[] genetic material." The statute then provides a non-exhaustive list of examples that are considered "genetic material."[143] It is possible that epigenetic data could be construed to fall under "alterations or modifications to DNA or RNA."[144] While epigenetic information does not involve alterations to the DNA or RNA sequence itself, epigenetic marks are often described as "modifying" DNA or RNA by changing their expression.[145] The statute's explicit acknowledgement that genetic material is not limited to the examples provided may cut in favor of including epigenetic data within the definition. However, the gene-centric list, focused on DNA, RNA, genes, chromosomes, and alleles, would seem to suggest that the statute is based on a traditional understanding of genetic data. Furthermore, the statute does not cover epigenetic modifications relating to the modification of proteins. Therefore, even if epigenetic information was found to fall within GIPA's definition of genetic data, it would cover only a partial set of epigenetic information. This genetics-focused approach is concerning given the recency of this statute and the growing availability of direct-to-consumer epigenetic testing.

---

[141] Cal. Civ. Code §§ 56.18–.186 (West 2023).
[142] Civ. § 56.18(b)(7)(A).
[143] *Id.*
[144] *Id*.
[145] *See*, *e.g.*, Vichithra R. B. Liyanage et al., *DNA Modifications: Function and Applications in Normal and Disease States*, 3 BIOLOGY 670 PASSIM (2014).

2. Florida

In 2020, Florida enacted a law called Genetic Information for Insurance Purposes ("GIIP"). GIIP provides that health insurers, life insurers, disability insurers, and long-term care insurers may not cancel, limit, or deny coverage, or establish differentials in premium rates based on genetic information.[146] The statute also prohibits the same insurers from requiring or soliciting genetic information or using genetic test results for any insurance purpose.[147] GIIP defines "genetic information" as:

> information derived from genetic testing to determine the presence or absence of variations or mutations, including carrier status, in an individual's genetic material or genes that are scientifically or medically believed to cause a disease, disorder, or syndrome, or are associated with a statistically increased risk of developing a disease, disorder, or syndrome, which is asymptomatic at the time of testing.[148]

Florida's GIIP excludes from its scope the protection of epigenetic information. The plain meaning of the definition of "genetic information," namely "information derived from genetic testing," does not include epigenetic information, which is fundamentally different from genetic information.[149] The definition also refers to variations or mutations in an individual's genetic material or genes, reinforcing the strictly genetic nature of the statute. That GIIP is limited to information of a genetic nature is reinforced by the intention of the bill's sponsor, Chris Sprowls: "You exercise, eat healthy and are the picture of good health. Yet you carry a genetic marker that says you may develop a disease or are even prone to obesity, so your life insurance premiums increase . . . . Seem unfair?"[150] This rhetoric evokes notions of the immutable and predictive qualities of genetic data, often used to support genetic exceptionalism.[151]

In 2021, Florida enacted the Protecting DNA Privacy Act. The Protecting DNA Privacy Act prohibits DNA analysis and disclosure of DNA analysis results without express consent.[152] It also creates criminal penalties for the willful collection, retention, maintenance, disclosure, submission, analysis, or sale of an individual's DNA sample and results of DNA analysis without express consent.[153] The statute defines "DNA analysis" as "the medical and biological examination and analysis of a person's DNA to identify the presence and composition of genes in that

---

[146] Fla. Stat. § 627.4301(2)(a) (2023).
[147] § 627.4301(2)(b).
[148] § 627.4301(1)(a).
[149] *See* discussion *supra* Section II.A.
[150] Chris Sprowls, *Life insurers should not get your DNA*, Tampa Bay Times (Jan. 12, 2020), https://perma.cc/ALB2-DEEM.
[151] *See* discussion *supra* Part VII.
[152] Fla. Stat. § 760.40(2) (2023).
[153] *Id*. § 817.5655.

person's body."[154] "DNA sample" is defined as "any human biological specimen from which DNA can be extracted or the DNA extracted from such specimen."[155]

The Protecting DNA Privacy Act provides another example of a gene-focused approach to genetic legislation that fails to account for epigenetic information. The statute's definition of DNA analysis limits the examination of DNA to the narrow purpose of identifying the presence and composition of genes in that person's body.[156] Therefore, while an analysis of DNA might conceivably include information about gene expression, such information is strictly excluded from the narrower definition the statute provides. While the definition of "DNA sample" is broad enough to include "any human biological specimen from which DNA can be extracted,"[157] it is clearly meant to limit the statute's scope to those cases where such samples could be used for DNA analysis, and "DNA analysis" has a more limited definition. This is evidenced by the fact that the statute makes it unlawful to collect or retain another person's DNA sample with the intent to perform DNA analysis or to submit another person's DNA sample for DNA analysis.[158]

3. New Jersey

New Jersey's Law Against Discrimination ("LAD") prohibits discrimination on the basis of genetic information or the refusal to submit to or share the results of a genetic test in the context of employment.[159] Additionally, New Jersey prohibits discrimination on the basis of genetic information or the refusal to submit to or share the results of a genetic test in hospital confinement or other supplemental limited benefit insurance, life insurance, or disability insurance.[160] LAD and prohibitions on genetic discrimination in insurance define "genetic information," "genetic test," and "genetic characteristic" in the same way. The statutes define "genetic information" as "the information about genes, gene products, or inherited characteristics that may derive from an individual or family member."[161] "Genetic test" is defined as "a test for determining the presence or absence of an inherited genetic characteristic in an individual, including tests of nucleic acids such as DNA, RNA, and mitochondrial DNA, chromosomes, or proteins in order to identify a predisposing genetic characteristic."[162] The statutes define "genetic characteristic" as "any inherited gene or chromosome, or alteration thereof, that is scientifically or medically believed to predispose an individual to a disease, disorder, or syndrome, or to be associated with a statistically significant increased risk of development of a disease, disorder, or syndrome."[163]

---

[154] *Id*. § 760.40(1)(a).
[155] *Id*. § 760.40(1)(b).
[156] *See id*. § 760.40(1)(a).
[157] *Id*. § 760.40(1)(b).
[158] *See id*. § 817.5655(2)–(3).
[159] N.J. Stat. Ann. § 10:5-12(a) (West 2023).
[160] *Id*. § 17B:30-12(e)–(f).
[161] *Id*. § 10:5-5(oo), § 17B:30-12(e)(2).
[162] *Id*. § 10:5-5(pp), § 17B:30-12(e)(2).
[163] *Id*. § 10:5-5(nn), § 17B:30-12(e)(2).

New Jersey's prohibitions against discrimination in employment and insurance fail to cover epigenetic information in their definition of "genetic information." The statute includes information about "inherited characteristics" as a form of "genetic information." It is possible that epigenetics could be considered to fall under this definition, given that some epigenetic modifications which result in observable characteristics are heritable across generations.[164] However, it is important to note that this is not true of all epigenetic information. The fact that the statute uses the words "inherited genetic characteristic" in its definition of "genetic test" but refers to "inherited characteristics" in its definition of "genetic information" might further seem to reinforce that "genetic information" could include non-genetic inherited characteristics, such as epigenetically inherited characteristics.[165] However, this does not seem to be the intention of the statute. In listing inherited characteristics after "genes" and "gene products," it is likely intended that inherited characteristics refer only to those of a genetic nature.[166]

LAD's definition of "genetic test" also excludes epigenetic information from LAD's protections. The definition only includes tests to assess the existence of an inherited genetic characteristic or a predisposing genetic characteristic, and epigenetic characteristics are fundamentally different from genetic characteristics. While the definition of "genetic characteristics" encompasses alterations of genes and chromosomes, epigenetics cannot be considered genetic alterations because epigenetics does not entail actual changes, or alterations, to the genetic code itself.[167]

C. International Law

International law has provided a different approach to genetic protections, establishing ethical principles that can serve as guidelines for nations, researchers, and the public in order to protect human dignity and human rights. The Universal Declaration on the Human Genome and Human Rights was the first ethical

---

[164] *See* discussion *supra* Section II.A.

[165] *See Keene Corp. v. United States*, 508 U.S. 200, 208 (1993) ("[W]here Congress includes particular language in one section of a statute but omits it in another . . . it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion" (quoting Russello v. United States, 464 U.S. 16, 23 (1983))).

[166] *See Yates v. United States*, 574 U.S. 528, 543 (2015) (Under the canon of *noscitur a sociis*,"a word is known by the company it keeps" in order "to 'avoid ascribing to one word a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to [a statute].'" (quoting *Gustafson v. Alloyd Co*., 513 U.S. 561, 575 (1995))).

[167] "Alteration" of the genetic code is distinct from genetic "modification." While genetic modification generally refers to epigenetic changes, genetic alteration generally refers to genetic mutations. *See, e.g.*, James P. Hamilton, *Epigenetics: Principles and Practice*, 29 DIGESTIVE DISEASES 130, 130 (2011) ("Epigenetics is defined as heritable changes in gene expression that are, unlike mutations, not attributable to alterations in the sequence of DNA. . . . An important feature of epigenetic modifications is that they are heritable between mother and daughter cells . . . .").

framework for genetics at the international level.[168] It was followed by the International Declaration on Human Genetic Data, a global response to concerns from governments, non-governmental organizations, and the academic community regarding the need for principles to govern the collection and use of genetic data to prevent human rights abuses.[169]

1. Universal Declaration on the Human Genome and Human Rights

The Universal Declaration on the Human Genome and Human Rights ("Universal Declaration") was adopted by UNESCO in 1997 and endorsed by the United Nations General Assembly in 1998 to provide a framework for navigating the then-burgeoning field of human genomic research and technologies based on the principle of respect for equal human dignity.[170] Under Article 2 of the Universal Declaration, "[e]veryone has a right to respect for their dignity and for their rights regardless of their genetic characteristics," and "[t]hat dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity."[171] Article 6 elaborates on this right, declaring that "[n]o one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity."[172] Article 7 provides for the confidentiality of genetic data associated with individuals that is stored and processed for any purpose.[173]

The Universal Declaration likely does not encompass protections of epigenetic information.[174] The Universal Declaration does not define "genetic characteristics" or "genetic data." Without further indication, "genetic characteristics" and "genetic data" are unlikely to be interpreted to cover non-genetic types of biological variants, such as epigenetics. The absence of consideration for epigenetic protection is reinforced by the fact that the fields of environmental and social epigenetics, which inspired conversations about the ethical and legal aspects of epigenetics, did not emerge until around 2005.[175]

---

[168]Noelle Lenoir, *Universal Declaration on the Human Genome and Human Rights: The First Legal and Ethical Framework at the Global Level*, 30 COLUM. HUM. RTS. L. Rev. 537, 538 (1999).

[169]Jasper A. Bovenberg, *Towards an International System of Ethics and Governance of Biobanks: A 'Special Status' for Genetic Data?*, 15 CRITICAL PUB. HEALTH 369, 372 (2005).

[170] *See* UNESCO 29 C/Res. 16, Universal Declaration of Human Rights (Nov. 11, 1997); G.A. Res. 53/152, (Dec. 9, 1998) (endorsing the Universal Declaration on the Human Genome and Human Rights adopted by the General Conference of the UNESCO).

[171] *Id*. ¶ 2.

[172] *Id*. ¶ 6.

[173] *Id*. ¶ 7.

[174] *See* Dupras et al. supra note 111, at 17 ("While these provisions of the DHG provide important safeguards in the context of genetics, their focus on 'genetic characteristics' raises questions about the applicability of human rights law to human dignity infringements based on other types of biological differences between persons.").

[175] *Id*. at 19.

2. International Declaration on Human Genetic Data

The International Declaration on Human Genetic Data ("International Declaration") provides ethical principles to govern the collection, processing, storage, and use of human genetic data, human proteomic data, and the biological samples from which they are derived.[176] The International Declaration begins by calling out the "special status" of genetic information, explicitly upholding an exceptionalist view of genetics.[177] Article 7(a) of the International Declaration contains a nondiscrimination provision, requiring that human genetic data and human proteomic data may not be "used for purposes that discriminate in a way that is intended to infringe, or has the effect of infringing human rights, fundamental freedoms or human dignity of an individual or for purposes that lead to the stigmatization of an individual, a family, a group or communities."[178] Article 14(b) contains a privacy provision, requiring that "[h]uman genetic data, human proteomic data and biological samples linked to an identifiable person should not be disclosed or made accessible to third parties, in particular, employers, insurance companies, educational institutions and the family," except for important public interest reasons or where prior informed consent has been obtained.[179] Human genetic data is defined as "[i]nformation about heritable characteristics of individuals obtained by analysis of nucleic acids or by other scientific analysis."[180] Human proteomic data is defined as "information pertaining to an individual's proteins including their expression, modification and interaction."[181]

The International Declaration's protections for human genetic data only cover some types of epigenetic data, if any. In particular, the protections for human proteomic data could be construed to include epigenetic data which are related to the modification of histone proteins and are therefore considered "information pertaining to an individual's proteins including their expression, modification and interaction."[182] However, other types of epigenetic data which do not concern proteins are not covered by the International Declaration, at least not explicitly.[183] For example, DNA methylation data, which involves the modification of DNA by the addition of methyl groups, would likely not fall under the definition of "human genetic data" or other kinds of data protected by the International Declaration. By the International Declaration's own championing of the "special status" of genetic data, it is clear that it was drafted with a view towards the unique harms of genetic

---

[176] *See* Economic and Social Council Res. 32/22, Universal Declaration on Human Genetic Data (Oct. 16, 2003).

[177] *Id*.

[178] *Id*. ¶ 7(a).

[179] *Id*. ¶ 14(b).

[180] *Id*. ¶ 2(i).

[181] *Id*. ¶ 2(ii).

[182] Dupras et al., *supra* note 111, at 18; *see Economic and Social Council Res*. 32/22, *supra* note 176, ¶ 2(ii).

[183] Dupras et al. *supra* note 111, at 18.

information, to the exclusion of other types of biological information, such as epigenetic information.

V. A CALL FOR EPIGENETIC PROTECTIONS

There is an urgent need to expand the scope of existing gene-centric laws to cover epigenetic information.[184] As described in Part IV, existing laws fail to protect against discrimination on the basis of epigenetic data. However, epigenetic data poses the same normative concerns as genetic data, challenging the genetic exceptionalism model that has motivated existing genetic-focused privacy and nondiscrimination protections. Concerning applications of epigenetic technologies, such as epigenetic clocks for use in life insurance underwriting, have already taken hold, necessitating swift action by legislators and international leaders.

Legislators and international leaders should revise existing protections for genetic data to include protections for epigenetic data and other postgenomic sciences that raise similar ethical and moral concerns.[185] Protections for genetic information should be expanded to include protections for information about gene function, gene expression, and epigenetics. It is important that lawmakers explicitly identify the categories of information that are protected to avoid ambiguity. Legislators and international leaders might also consider including other biomarkers and sensitive information critical to our current understanding of health and disease, including information relating to metabolomics, metatranscriptomics, microbiomics, and proteomics, which likely raise similar normative and policy concerns to both genetic and epigenetic information.

It is important to note several limitations following a proposal to expand the scope of existing law. There is concern that existing legislation fails in respects other than its limited definition of the information it protects, particularly in the United States, where the prevailing system of privacy protections is a patchwork of

[184] Dupras et al., *supra* note 28, at 8 ("[U]rgent is the need for guidance geared towards decision-makers and stakeholders on responsible epigenetic data governance and use of individual epigenetic information for non-medical reasons (e.g., in the case of epigenetic age and aging estimators, or other epigenetic markers of at-risk exposures and lifestyles)."). *See also* Florida Doci et al., *A Quest for Justice, in Epigenetics in Society* 257, 274 (Michael Crawford ed., 2015) ("Privacy laws should be adapted and clearly define how epigenetics is encompassed, and how the privacy of individuals should be protected."); Rothstein, *supra* note 111, at 735 ("[A]n amendment to add epigenetics or new legislation is needed to prevent epigenetic discrimination."); Grant, *supra* note 95 ("GINA is 15 years old and needs to be updated to reflect a new threat of abuse of biological information — epigenetic discrimination.").

[185] Note that, in calling for a revision of genetic-specific laws to encompass epigenetic information an irony exists: "The most likely way of enacting legislation protecting epigenetic privacy and prohibiting epigenetic discrimination is by adding epigenetics to existing genetic-specific laws. Thus, in rejecting epigenetic exceptionalism, policymakers might find it necessary to amend laws previously enacted under the theory of genetic exceptionalism." Rothstein, *supra* note 111, at 735.

sectoral legislation focused on individual liberty.[186] This has resulted in a privacy paradigm that is both overinclusive and underinclusive.[187]

An important criticism is that existing genetic nondiscrimination and privacy laws do not provide protections in many contexts that give rise to discrimination and privacy risks. While existing laws generally focus on insurance and employment, there is a need to expand their scope to other contexts such as education, law enforcement, public accommodations, mortgage-lending, and housing.[188] This gap was made visible in a Ninth Circuit case involving a student's removal from his neighborhood school on the basis of a genetic marker for cystic fibrosis.[189] While the plaintiffs prevailed on their claim of violation of the Americans with Disabilities Act, laws specifically aimed to cover instances of genetic discrimination failed to provide any protection.[190] In the realm of law enforcement, police have broad access to genetic databases. The use of such databases, especially without privacy and discrimination protections, has been widely criticized for violating privacy rights and resulting in the disproportionate surveillance of Black individuals, reinforcing discriminatory policing practices.[191] Other examples suggest the need for expanded international human rights protections. For instance, the Chinese government has used genetic information as a means of identifying Uighur persons, a predominantly Muslim ethnic group, to force them into "re-education camps."[192]

Furthermore, GINA fails to cover non-health insurance, such as life, disability, and long-term care insurance, leaving it up to states to fill in these gaps. Peer countries have struck a different balance between patient and industry protections, providing for greater protections against genetic discrimination in all types of insurance in order to adequately address policy concerns.[193] In order for laws

---

[186] Avner Levin & Mary Jo Nicholson, *Privacy Law in the United States, the EU and Canada: The Allure of the Middle Ground*, 2 U. OTTAWA L. & TECH. J. 357, 360 (2005).

[187] Woodrow Hartzog, *What Is Privacy? That's the Wrong Question*, 88 U. CHI. L. REV. 1677, 1679 (2021).

[188] Many experts have called for such expansions. *See* AM. MED. ASS'N COUNCIL ON SCI. & PUB. HEALTH, GENETIC DISCRIMINATION 12 (2013), https://perma.cc/H4HJ-MLKG.. *See also Aparna Choudhury, The Privacy of Your Genetic Data: Must Anti-Discrimination Laws Be Genetic or Generic?*, 54 U.S.F. L. REV. 189, 196-207 (2019); Anikka Hoidal, *Genetic Discrimination: Why We Should Expand GINA*, BiolawToday.org. (Apr. 5, 2016), https://perma.cc/ZQ37-VPM5.

[189] *Chadam v. Palo Alto Unified Sch. Dist.*, 666 Fed. App'x. 615, 616 (9th Cir. 2016) (unpublished).

[190] *Id*. at 618.

[191] Dorothy Roberts, *Collateral Consequences, Genetic Surveillance, and the New Biopolitics of Race*, HOWARD L. J. 567 *passim* (2011); Erin Murphy & Jun H. Tong, *The Racial Composition of Forensic DNA Databases*, 108 CALIF. L. REV. 1847 *passim* (2020).

[192] Sui-Lee Wee, *China Uses DNA to Track Its People, With the Help of American Expertise*, N.Y. TIMES (Feb. 21, 2019), https://www.nytimes.com/2019/02/21/business/china-xinjiang-uighur-dna-thermo-fisher.html.

[193] Jean-Christophe Bélisle-Pipon et al., *Genetic Testing, Insurance Discrimination and Medical Research: What the United States Can Learn from Peer Countries*, 25 NATURE MED. 1198, 1201 (2019).

covering epigenetic information to be effective, legislators may need to consider expanding the application of existing laws to new contexts.

Additionally, scholars have criticized the limited protections contained in existing genetic discrimination laws. In particular, GINA has been denounced as ill-conceived and ineffective as a nondiscrimination provision, evidenced by the fact that there were no successful claims filed for genetic discrimination under GINA in the statute's first ten years.[194] Despite these shortcomings, it has been suggested that GINA may serve as a "blueprint for preventing employers from breaching employee privacy."[195] Claims brought under GINA regarding unlawful requests for protected data have been successful.[196] While the existing genetic discrimination statutes may fail as nondiscrimination provisions, they may instead provide valuable privacy protections.

While epigenetics has revolutionized scientific understandings of health and disease as the products of an ongoing interplay between biology and environment, it has also reconfigured conceptions of biological identity as constitutive of environmental and social processes.[197] Given that epigenetic information is dependent on environmental and social contexts, such data is inherently the subject of population-level interests grounded in networks of relations. Accordingly, existing genetic privacy and nondiscrimination frameworks, focused on individual rather than relational harms, may need to be reevaluated. One theory reconceptualizes data as a democratic medium "that materializes population-level, social interests."[198] This theory might be particularly useful in the realm of epigenetic information, which requires relational networks to be realized in order to fulfill its tremendous promise for health and disease research.

There is ongoing debate about whether privacy laws should control the data itself or restrict its use in certain scenarios, acknowledging that data also has many beneficial uses. The need to balance the harms of certain uses of epigenetic data with its potential positive applications may call for an overhaul of the sectoral nature of privacy law in favor of comprehensive privacy schemes or ethics-based frameworks.[199]

Despite these limitations, the failure of existing laws to protect epigenetic information constitutes an enormous gap in the existing privacy framework. In order to address this disparity, privacy laws must be updated to reflect the harms at stake in the use of epigenetic information.

---

[194] Bradley A. Areheart & Jessica L. Roberts, *GINA, Big Data, and the Future of Employee Privacy*, 128 YALE L. J. 710, 714 (2019).

[195] *Id*. at 710.

[196] *Id*. at 714.

[197] Dupras et al., *supra* note 111, at 25.

[198] Salome Viljoen, *A Relational Theory of Data Governance*, 131 YALE L. J. 573, 638 (2021).

[199] *See* Elizabeth R. Pike, *Defending Data: Toward Ethical Protections and Comprehensive Data Governance*, 69 EMORY L.J. 687, 736 (2020).

VI. CONCLUSION

Our postgenomic understanding of health and disease demands a reconsideration of the genetic-focused biological understanding that has captivated lawmakers for decades. As new understandings of science, including not only epigenetics, but also microbiomics, proteomics, and other fields, take hold, the deterministic notion of DNA is unraveled. This postgenomic era disrupts our existing conceptions of biological causality, responsibility, identity, and justice, necessitating a reassessment of the existing laws and principles that guide how such information is governed.

As this Note has described, epigenetic information invokes the same normative concerns as genetic information, challenging the exceptionalism model of genetics that has inspired past genetic legislation and international declarations. Existing gene-centric laws are discrepant with both our existing technology and our current scientific understanding. As epigenetic technologies become widespread in insurance and direct-to-consumer testing, there is an urgent need to adapt existing privacy and nondiscrimination laws to meet the needs of a postgenomic era.