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Modern Regulatory Frameworks for the Use of Genetic and Epigenetic Underwriting Technology in Life Insurance

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Abstract

Following Florida's recent prohibition on the use of genetic information in life insurance risk classification, this paper analyzes insurance regulatory law and policy pertaining to the use of modern molecular biotechnology and InsurTech—particularly in the developing field of epigenetics, which studies the area above and around a human cell's immutable DNA, and the changes in gene expression brought about by a person's behavior and experiences. Public policy to date, from the health insurance prohibitions in the 2008 federal Genetic Information Nondiscrimination Act (GINA) to the 2020 GINA-like Florida prohibitions for life insurance, seeks to redress concerns that genetic information identifying pre-dispositional risk of disease could be used to penalize otherwise healthy insureds who have not manifested a diagnosable health condition. In contrast, epigenetic information,

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derived from a noninvasive saliva specimen, can be used to identify current health and wellness statuses, both negative and positive, that result from behavioral choice (such as tobacco, alcohol and drug use, as well as diet and exercise), with more precision than traditional, incumbent paramedical testing methods. By providing more accurate information about insureds' current and changeable health status, while avoiding the perceived unfairness of immutable genetic information, the use of epigenetic testing in life insurance underwriting would conform to the fundamental regulatory norms of information transparency and symmetry; accurate risk classification; sound risk pool construction; and a resulting alignment of interests between insurers and insureds.

Introduction

The individual life underwriting landscape is experiencing rapid InsurTech-driven change. Characterized as a "paradigm shift" (Seeman and Schaber, 2019), more and more companies are implementing automated or "accelerated" underwriting programs that forgo biological specimen collection in favor of predictive models that use analytics and third-party datasets to underwrite and classify the risk of life insurance applicants.[1]

This trend has only been hastened by insurers' inability to collect biological specimens through on-site paramedical testing during the COVID-19 pandemic (Adriano, 2020). Regulators, however, have previously warned that such techniques could be unfairly discriminatory or lack a sufficient actuarial basis (Regalbuto, 2019).[2]

At the same time, new biotechnologies—such as epigenetic testing that detects tobacco, alcohol and drug use, as well as diet, exercise and other health risk factors—promises to more accurately measure traditional states of health and wellness.[3] Moreover, because epigenetic testing is obtained from noninvasive saliva specimens rather than blood and urine collected by paramedical nurses, its use can improve customer convenience and experience.[4]

In this paper, we discuss the epigenome found above, not in the immutable DNA sequence of the genome. Rather than revealing preordained hereditary statuses, epigenetic information identifies chemical changes occurring along the epigenome that are linked to gene expression and behavioral conduct or environment. Such expressions accurately correlate, either negatively or positively, with health and wellness and, therefore, underwriting risk.

Insurers studying InsurTech are thus considering whether using epigenetic information as a biotechnology innovation could improve underwriting and product personalization, as well as enhance consumer engagement and experience.[5] This

1. *See* Cook, 2020 ("According to LIMRA, nearly 90% of life insurers are currently using or are planning to use automated underwriting techniques.").

2. *See also* Cook, 2020 (a new NAIC Accelerated Underwriting (A) Working Group is "charged with considering the use of external data and data analytics in accelerated life underwriting" and is "currently … identifying key regulatory and consumer issues to be addressed").

3. Sabes, Chen and Juang (2020) provide substantial practical insight into the methods and mechanics of how epigenetic information can be gathered and analyzed for use in life insurance risk classification and underwriting.

4. Applicants could produce a saliva sample in front of a company representative or neutral witness, with the specimen being mailed to the laboratory. Epigenetic tests, the expense of which would be borne by the insurer just as with traditional paramedical techniques, are similar in cost to direct-to-consumer genetic testing, currently starting at around $200.

5. *See* Swaraj and Vishwakarma, 2020 ("Trend 8: Insurers are exploring epigenetics as an alternative data source to enhance product personalization and improve underwriting."); Lefebre et al, 2019 ("It is believed that the study of epigenetics or of the epigenome, as it is now called, may be able to predict all-cause mortality risk as well as qualify and quantify the use of tobacco and consumption of alcohol. Many factors emerging as having potential epigenetic influence are

could facilitate much-needed greater availability of coverage[6] and foster healthy consumer behavior—while reducing information asymmetries between, and aligning the interests of, both parties to a life insurance contract.

Genetic testing, life insurance and insurance regulation has been the subject of robust discussion for some time. Recently, Born (2019) analyzed 2019 Florida legislation that proposed to ban the use of genetic information in life insurance.[7] While that legislation, like prior similar bills nationally, was initially thwarted, a similar bill passed both chambers and was signed by the governor in 2020[8]—without an ameliorating amendment that would have allowed insurers to use actuarially justified genetic information, as Born previously suggested.

Carriers' longstanding fear of an information asymmetry developing between them and applicants who obtain, but do not share, their genetic information is now a tangible reality under the Florida law. But a different biotechnology, epigenetics, might counter this new risk by closing other substantial, existing information asymmetries in underwriting—such as what consumers know, but do not reveal, about their tobacco smoking and other risky behaviors.

Seeking to contribute to a modern regulatory framework for the beneficial use of emerging biotechnologies and InsurTech, this paper supplements prior scholarship regarding genetic information in life insurance underwriting with a detailed review of regulatory law and policy pertaining to the use of both genetic and epigenetic information. Part I provides background regarding molecular biotechnology, including those features relevant to public policy that distinguish epigenetics from genetics. Part II then presents and analyzes applicable law and public policy governing the use of genetic information in life insurance and considers their applicability to epigenetics. Part III delves further into the fundamental insurance regulatory concepts of information asymmetry, adverse

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not captured in either the traditional medical record or underwriting processes. Thus, epigenetics may have the potential to offer truly novel information."); Miller and Freeman, 2018 ("Now, a new type of testing based on 'epigenetics' has emerged with the potential to either even the playing field or to expand the asymmetry of information, depending on the industry's willingness and ability to utilize it."); Nabholz, 2018 ("Epigenetics is the adaptive response system of our genome to deal with environmental exposure ... . Will the insurance industry start incentivizing healthy behavior and measure outcome by epigenetic monitoring?").

6. Addressing the need identified by Abrokwah et al, 2018: "[T]he aggregate mortality gap in the U.S., a measure of life underinsurance, was close to USD 25 trillion in 2016."

7. *See* Born, 2019 ("In the spring of 2019, the Florida legislature considered two proposals (S. 258 and H.R. 879) that would amend s. 627.4301 of the Florida statutes. The current statute imposes a ban on the use of genetic test results by health insurers; the proposed amendments would extend the ban to underwriting in life insurance and long-term care insurance [LTCI]. If passed, the proposed amendment would make Florida the first state to ban the use of genetic test information for underwriting purposes in life insurance.").

8. *See* Haughey, 2020 ("Florida on Wednesday became the nation's first state to enact a DNA privacy law, prohibiting life, disability and long-term care insurance companies from using genetic tests for coverage purposes. Gov. Ron DeSantis signed House Bill 1189 … . It extends federal prohibitions against health insurance providers accessing results from DNA tests, such as those offered by 23andMe or AncestryDNA, to the three other insurers.").

selection and matching price with risk, particularly as they pertain to biotechnologies that assess health, wellness and associated longevity.

The Epigenome Above Immutable DNA Reflects the Cellular Changes Caused by Human Behavior

Molecular biotechnology innovation is transforming the science of medicine, health and wellness. A review of the basics of molecular biology starts with our genes, which serve as the blueprint instructions that ultimately direct the function and activity of all cells.

Genes are the fundamental working unit of every biological function and are made up of DNA. From the time we are conceived with a single cell until we become adults with more than 40 trillion cells, each cell maintains an exact copy of the same DNA from that single cell.

Our genes are comprised of four fundamental chemical bases: adenine, cytosine, guanine and thymine, commonly abbreviated as A, C, G and T. The DNA strand within the nucleus of each cell, commonly known as the double helix, is made up of base pairs or combinations of As, Cs, Gs and Ts.

The specific groupings, order and frequency of these base pairs of As, Cs, Gs and Ts within the double helix serve as the base DNA sequence instructions of our biological life. Our DNA sequence is comprised of approximately 3 billion base pairs that selectively express to each cell how to manufacture the functional proteins that support and operate our biological system.

How and why our genes express themselves to make proteins is the subject of substantial research encompassing many aspects of genetics, bioinformatics and system biology. A growing area of scientific research in this field is epigenetics, which, among other things, seeks to discern how external or environmental factors drive gene expression.

"Epi," a Greek prefix, means over, above or upon. The epigenome is a biological region found above the genome, or DNA. Epigenetic research, as discussed in this paper, is focused on DNA methylation (DNAm), which refers to chemical methyl groups that change as a result of external factors that affect *genetic expression*, without changing the *DNA sequence*.

Research demonstrates that the presence, or absence, of identifiable patterns of DNAm along the epigenome (epigenetic biomarkers) directly correlates to the same types of health risk factors—such as diabetes (Willmer et al., 2019), cardiovascular disease (Lorenzen, Martino and Thum, 2012) or tobacco use (Joehanes, 2016)—underwritten by life insurers today with the aid of blood and urine analyses.

The fundamental differences between epigenetics and genetics are well documented.[9] The classic example illustrating the diverging paths of genetics and epigenetics is the study of identical twins, who, born with the same DNA, experience material differences to their health and mortality as they engage in different behaviors throughout life. Research shows that exposure to different environmental factors, such as smoking tobacco, drinking alcohol, using illegal drugs, and exercise and diet will cause two people with identical, immutable DNA to diverge substantially in their health and mortality as a result of the differing gene expression driven by their individual behavioral choices. Epigenetics seeks to detect and measure the effects of such voluntary conduct on gene expression and their related impact on health, wellness and ultimate mortality (Gruber, 2012).

Because genes, received at birth, are permanent instructions that insureds are powerless to change, life and health insurance policymakers—consistent with the American ethos that opportunity should not be limited by circumstances at birth—have shown particular concern that genetic information not be used to disadvantage otherwise healthy individuals who have increased risks of developing a future disease based only on their inherited DNA (Sprowls, 2020; Peikoff, 2014). As discussed further below, this policy concern is codified in the federal GINA law that prohibits use of genetic information in health insurance. Similarly, some states prohibit discrimination in life insurance based on certain DNA factors, such as sickle cell anemia genetic traits.[10]

By contrast, the policy ramifications of using epigenetic information to verify behavior such as tobacco use, or assessing current disease states such as diabetes, are qualitatively different. Epigenetic biomarkers, which capture current health and wellness status, are materially different than latent, immutable genetic instructions. Epigenetic biomarkers are dynamic, working both ways—identifying not only health risks caused by behavior such as smoking, but also the health benefits resulting from good diet and exercise.[11] Importantly, epigenetic biomarkers have been shown to be reversible as an individual adopts healthy habits.

9. Wei, 2017, summarizes: "Epigenetics is a discipline that studies heritable changes in gene expression that do not involve altering the DNA sequence. Over the past decade, researchers have shown that epigenetic regulation plays a momentous role in cell growth, differentiation, autoimmune diseases, and cancer … . Epigenetics is the study of inherited changes in phenotype (appearance) or gene expression that are caused by mechanisms other than changes in the underlying DNA sequence." Aboud, Simpson, and Jialal, 2020, explained: "As people age, the biggest influence on the epigenome is the environment. Direct influences such as diet can affect one's epigenome. A person who has a healthy diet will have different epigenetic pattern[s] than somebody who has an unhealthy diet. The epigenome can also be influenced by indirect environmental changes, for example, stress."

10. *See* Sect. II(A)(2)(b).

11. *See* Woelfel at al., 2018 ("the epigenome may be one of the most powerful systems through which exercise exerts its beneficial effects on health and longevity"); Zhang, 2017 ("prevention of or intervention on smoking-related DNAm changes may provide major improvement in premature death prevention, given the reversibility of smoking-induced methylomic aberrations").

Since, like traditional paramedical exams, epigenetic testing can be used to detect actual, physiologically developed manifestations of health and wellness that affect mortality, its use would satisfy core insurance underwriting and regulatory norms—incentivizing and rewarding safer, healthier conduct; eliminating fraud; and closing informational symmetries in underwriting.

Law and Public Policy Pertaining to Genetic and Epigenetic Information

Current Law and Legislation Applying to Genetic Information

The emergence of modern molecular biotechnology has led to frequent legislation governing the use of genetic information in insurance. GINA,[12] preceded by[13] several similar state laws,[14] prohibits the use of genetic information by health insurers, but it does not regulate life insurance.

Florida this year became the first state to adopt a GINA-like framework, essentially prohibiting the use of genetic information for life insurance underwriting and risk classification. Several other states have considered but not yet passed such GINA-like prohibitions for life insurance.[15] At least 29 other states have laws regulating, though not prohibiting, use of genetic information in life insurance.

12. *See* Public Law 110-233 ("A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require an individual or a family member of such individual to undergo a genetic test."); 45 CFR § 164.502(a)(5) ("a health plan … shall not use or disclose protected health information that is genetic information for underwriting purposes"); Federal Register, Vol. 78, No. 17, Jan. 25, 2013, p. 5666 ("The final rule adopts the proposed prohibition on a health plan's use or disclosure of genetic information for underwriting purposes, except with regard to health plans that are issuers of long term care policies … . This prohibition, located in this final rule at § 164.502(a)(5), applies to all genetic information from the compliance date of these modifications forward, regardless of when or where the genetic information originated.").

13. *See* Rothstein, 2008 ("During the 1990s, almost every state enacted one or more laws to prohibit genetic discrimination. By the time GINA was enacted in 2008, 47 states had laws banning genetic discrimination in health insurance … . State health insurance laws prohibit the use of predictive genetic information in medical underwriting for individual health insurance.").

14. *See, e.g.*, New Mexico Statute 24-1-4(A); New Hampshire Statute 141-H:4(IV); North Carolina Statute 58-3-215(c); South Carolina Statute 38-93-30(A); Montana Statute 33-18-903(1); Minnesota Statute 72A.139(3).

15. In 2019, North Carolina H.B. 514, Maine L.D. 1314 and Illinois H.B. 2189 all proposed banning the use of genetic information in life insurance. North Carolina's bill did not pass. The Maine and Illinois proposals were both amended down to prohibit requesting or using information from direct-to-consumer testing without consent, and both passed as such. *See* Maine Statute 24-A-2159-C(4) ("an insurer may not request … or use information obtained from an entity providing direct-to-consumer genetic testing without … informed written consent."); 410 ILCS 513/20(e) ("A company providing direct-to-consumer commercial genetic testing is prohibited from sharing any genetic test information … with any health or life insurance company without written

These laws are further discussed below, and they are fully categorized, both by type of statute and by jurisdiction, in Appendices A and B.

State Laws Regulating Genetic Information in Life Insurance That Are Procedural but Do Not Restrict Use in Risk Classification

At least 24 states have laws imposing procedural restrictions on the use of genetic information in life insurance.[16] Most of these states require informed consent whereby consumers must agree to genetic testing, frequently pursuant to disclosures that explain how and why testing will be done and results will be used, and often imposing confidentiality restrictions or requirements that results be shared with the subject.

A few states impose additional procedural requirements. These include requiring insurers to pay for genetic tests (the same way insurers pay for paramedical exams today); reciting that genetic information is the property of the insured; requiring destruction of specimens; and requiring testing to be performed in an accredited laboratory.

State Laws Regulating Genetic Information in Life Insurance That Regulate Use in Risk Classification

The New Florida Law Banning Use of Genetic Information – On June 30, 2020, Gov.Ron DeSantis signed into law, "effect[ive] July 1, 2020," and "appli[cable] to policies entered into or renewed on or after January 1, 2021," Florida H.B. 1189, pertaining to "Genetic Information for Insurance Purposes."

H.B. 1189 adds life/disability and long-term care (LTC) to the strictures of Florida Statute 627.4301(2)(a) and (2)(b)—previously limited to health—under which an insurer may "not cancel, limit, or deny coverage, or establish differentials in premium rates, based on ... genetic information"[17]; and "may not require or solicit genetic information, use genetic test results, or consider a person's decisions or actions relating to genetic testing in any manner for any insurance purpose."

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consent."). Connecticut H.B. 7262 from 2019 would have prohibited life insurers from requiring applicants to take genetic tests but has not passed.

16. Alaska, Arizona, California, Colorado, Connecticut, Delaware, Florida, Illinois, Maine, Massachusetts, Minnesota, Missouri, Michigan, Nebraska, Nevada, New Jersey, New Mexico, New York, Oregon, South Carolina, South Dakota, Vermont, Tennessee and Wyoming.

17. This prohibition in Sect. 627.4301(2)(a) would have two exemptions. The first, already found in the existing Subsection 2(a) itself, uses limiting language, common in many states' prohibitions on the use of genetic information in health insurance: "In the absence of a diagnosis of a condition related to genetic information … ." The second exemption was added to H.B. 1189 in the Senate as a new Subsection 2(d): "Nothing in this section shall be construed as preventing a life insurer or long-term care insurer from accessing an individual's medical record as part of an application exam. Nothing in this section prohibits a life insurer or long-term care insurer from considering a medical diagnosis included in an individual's medical record, even if a diagnosis was made based on the results of a genetic test." The new, second exception appears to be largely a restatement of the original one, and thus not a significant impediment to the sponsors' intent to ban the use of genetic information in the covered lines of insurance.

Florida's law is the first of its kind to extend GINA-like prohibitions to life insurance.[18] The statute as enacted did not contain a previously proposed amendment that would have prevented the creation of informational asymmetries—arising when insureds take consumer genetic tests and do not share the results with insurance underwriters—by "restrict[ing] the use of genetic test information without imposing a ban" (Born, 2019)[19].

Insurers have successfully promoted such compromise amendments, which in essence reiterate the general insurance unfair discrimination principle's applicability to the use of genetic information[20] in other states considering similar proposals. But the 2020 Florida measure codified a functional ban—prohibiting underwriting and rating "based on ... genetic information," Florida Statute 627.4301(2)(a)—of the sort that "necessarily complicate[s] insurers' ability to perform statistical analysis of genetics information and the impact on mortality experience" (Born, 2019).

Because passage of such legislation in a major state could prove influential elsewhere, the genesis of the Florida law is instructive. The powerful Speaker-Designate wrote the bill after "discovering the issue … when he was applying for life insurance. While he was on hold on the telephone … he said he was struck by commercials from companies such as 23andMe and AncestryDNA encouraging people to buy genetic tests." This triggered a potent political reaction, as echoed by the Senate sponsor: "While countless Floridians have used DNA testing kits to learn

18. California and Oregon have been described by some as "hav[ing] broad regulations prohibiting the use of genetic information in life, long-term care and disability insurance" (Peikoff, 2014), but this is not accurate. California Insurance Code §10148 instructs that "[n]o insurer shall require a test for the presence of a genetic characteristic for the purpose of determining insurability other than for those policies that are contingent on review or testing for other diseases or medical conditions." The California Department of Insurance explains that "[i]f you test positive for HIV antibodies, the life or disability income insurance company can deny your application for insurance. It can also deny coverage if you refuse to provide your written informed consent to take an HIV antibody test." *https://www.insurance.ca.gov/01-consumers/105-type/95-guides/05-health/hiv-aids.cfm#disability*, placing life policies among "those policies that are contingent on review or testing for other diseases or medical conditions" under §10148. Further, §10149 states that "[n]o life or disability insurer shall require a genetic characteristic test if the results of the test would be used exclusively or nonexclusively for the purpose of determining eligibility for hospital, medical, or surgical insurance coverage or eligibility for coverage under a nonprofit hospital service plan or health care service plan"—implying that insurers may require such testing for life insurance. Oregon Statute § 746.135 instructs that a "person may not use favorable genetic information to induce the purchase of insurance," but it does not pertain to requiring or rejecting coverage; it also explicitly prohibits genetic testing in health insurance, thus by implication allowing it for life insurance. *See also* Prince, 2018 ("Three states are commonly cited as having stronger protections that limit life, long-term care, and disability insurers from using genetic test results—California, Oregon, and Vermont. [Citing to Klitzman et al (2014) and Peikoff (2014).] However, it is unclear whether these statutes offer protections as extensive as cited in the literature and popular press.").

19. As described by Born (2019), the 2019 amendment would have "put[ ] the burden on life insurers to justify underwriting decisions with objective statistical evidence related to actual or anticipated loss experience, and thus allow[ed] for, and even encourage[d] further study on the statistical accuracy of this information for underwriting."

20. *See* notes 22–25, and accompanying text.

more about their background or identify potential health risks, they didn't sign up in order for insurers to access this personal information and then base their policies on it." (Downey, 2020.)

With this potential dynamic becoming commonplace—more than 26 million consumers have purchased ancestry tests (Regalado, 2019), many of which reveal individual pre-disposition of risk of deadly diseases (Lombardo, 2018)—lawmakers' concern about insurers' use of consumer test results is likely to spread beyond Florida. This means, in turn, that insurers' ongoing worries about economic threats resulting from information asymmetries around genetic information are well founded, as further discussed in Section III, below.

Other States' Laws Regulating Genetic Information in Life Insurance Risk Classification – Six states prohibit or restrict underwriting decisions based on discrete genetic traits usually associated with a particular protected social class, such as sickle-cell anemia, Hemoglobin C disorder and Tay-Sachs disease.[21]

Ten states prohibit life insurers' use of genetic testing in an unfairly discriminatory manner.[22] These statutes equate unfair discrimination with lack of actuarial justification and classification of insureds in a manner not reasonably related to risk,[23] thus essentially restating their (and all) states' general unfair discrimination standards,[24] which require that like risks be treated alike according to actuarial justification.[25]

Two states (Massachusetts and Vermont) prohibit insurers from requiring mandatory genetic tests (but allow voluntary testing) as a condition of obtaining life insurance. Two states (Arizona and Montana) prohibit an insurer from refusing to

21. California, Florida, Louisiana, Maryland, North Carolina and Tennessee. Maryland's prohibition, though, is qualified by the caveat "unless there is actuarial justification," meaning that it essentially just restates the unfair discrimination prohibition already applicable to all insurance risk classification, as discussed herein.

22. Arizona, California, Kansas, Maine, Massachusetts, Montana, New Jersey, New Mexico, Vermont and Wisconsin.

23. *See, e.g.*, Massachusetts Statute 175-120E ("No insurer … shall practice unfair discrimination against persons because of the results of a genetic test. … [U]nfair discrimination means … in any way practicing discrimination against persons unless such action is taken pursuant to reliable information relating to the insured's mortality or morbidity, based on sound actuarial principles or actual or reasonably anticipated claim experience.").

24. Consistent with the National Association of Insurance Commissioners' Model *Unfair Trade Practices Act* (#880) (prohibiting "any unfair discrimination between individuals of the same class and equal expectation of life in the rates charged for any life insurance policy … or in the … benefits payable thereon, or in any of the terms and conditions").

25. *See, e.g., Gunter v. ISO*, 434 So.2d 908, 912-913 (Fla. App. 1 Dist. 1983) ("[T]he most equitable classification factors are those that are the most actuarially sound … . Historically, the Department has measured the equitableness of a rating factor by its predictive accuracy."); *Telles v. Cmmsr. of Ins*., 574 N.E.2d 359, 361 (Mass. 1991) ("The statutory pattern which deals with insurance regulation authorizes insurers to 'discriminate fairly.' [Citation omitted.] … 'The intended result … is that persons of substantially the same risk will be grouped together, paying the same premiums, and will not be subsidizing insureds who present a significantly greater hazard.'").

consider an applicant in the first place based on a genetic condition, but they do not prohibit risk classification of the applicant using actuarially justified genetic test results.

Laws Regulating Use of Genetic Information Do Not Apply to Epigenetic Information

Epigenetics' distinguishable features exempt it from the text of, and rationale behind, current laws regulating use of genetic information in life insurance.

Use of Epigenetic Information in Current Authority and Scholarship

No statutes specifically regulate the use of epigenetic information in life insurance. No laws regulating use of genetic information in life insurance specifically reference epigenetic information, and extensive relevant guidance demonstrates that epigenetic information is not covered by laws regulating use of genetic information.

Several federal statutes treat genetics and epigenetics as different, separate areas,[26] strongly implying that epigenetics is a separate category from genetics. Scholarship reflects the same understanding. Rothstein et al. (2009), in an early and influential article, explained that, "Scientifically, epigenetic information is not genetic information, and therefore it probably would be necessary to amend state and federal nondiscrimination laws to prohibit discrimination based on epigenetic factors."

The widely held view[27] that statutes regulating use of genetic information do not capture epigenetic information is rooted in the fundamental differences between genetics and epigenetics. Rothstein in 2013 reiterated that "neither the ADA nor GINA would appear to apply to discrimination based on epigenetic information." Diemer and Woghiren (2015) explained that expanding genetic statutes to cover epigenetics "would require broad consultation with diverse stakeholders and experts," because the "structure [of] GINA and the distinguishing reversibility of epigenetic changes" exempt them from regulation under genetic oversight statutes.[28]

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26. *See, e.g.,* 42 USC §284g (requiring NIH Director to expand autism activities "including…research in fields including pathology, developmental neurobiology, genetics, epigenetics, pharmacology, nutrition, immunology, neuroimmunology, neurobehavioral development, endocrinology, gastroenterology, and toxicology"); 42 USC §280i (limiting CDC funding if "[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").

27. *See also* Diemer and Woghiren, 2015 (arguing that "GINA's disregard for phenotype … will have greater bearing in epigenetic protection considering the wider range of variation … that can result from epigenetic alterations"); Dyke et al, 2015 (concluding that "GINA probably would not apply to epigenetic information").

28. *See also* Dupras, 2018 (explaining that the authors of laws regulating genetics in insurance "do not seem to have considered the potential implications of this emerging discipline. Instead,

The Florida Law Applies Only to Genetics

Florida's new law prohibiting life insurers' use of genetics on its face does not apply to epigenetic information—as intended. The bill's sponsor explained his purpose: "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 based on these genetic possibilities from either an at-home genetic testing kit, like ones you purchase from AncestryDNA or 23andMe, or even genetic testing that may be conducted at your doctor's office. Sound unfair?" (Sprowls, 2020.)

The Florida statute was thus passed to ban the use of immutable DNA characteristics, not behaviors of choice, in life insurance risk classification, just as Dupras et al. (2018) explained was the rationale for GINA with respect to health insurance: "to provide greater protection to asymptomatic individuals against denial of … insurance … based on a genetic predisposition to diseases." This political choice tracks the fundamental divergence between genetics and epigenetics; as Rothstein et al (2009) explained, "Genetic mutations tend to be irreversible … but epigenetic changes are intrinsically reversible."

Textual interpretation yields the same result. The Florida law's operative prohibitions apply to "genetic information," "genetic test results" and "genetic testing."[29] "Genetic information" is a defined term that "means information derived from genetic testing."[30] Because "genetic test results" and "genetic testing" are not defined, "the most common understanding of the terms"[31]—which does not include epigenetic information, nor other biomarkers that better measure changes to individual health and wellness, as discussed extensively above—controls their application.

Policy Considerations Regarding Information Asymmetry and the Use of Genetic and Epigenetic Information

Since symmetry of information—whereby carriers learn and can analyze the same information that applicants know about their own health—is the foundation of a stable insurance marketplace, life insurers have, with respect to genetic

they privileged narrowly framed, short-sighted approaches regulating only the use of genetic components—and specifically when revealed through genetic testing.").

29. Florida Statute § 627.4301(2).

30. Florida Statute § 627.4301(1)(a).

31. *See, e.g., Bryant v. State*, 712 So.2d 781, 783 (Fla. 1998) (utilizing "ordinary meaning or common understanding" when "the statute does not define the term"); *Bryan v. Butterworth*, 692 So.2d 878, 880 (Fla. 1997) (applying the meaning "consistent with the most common understanding of the term").

information, struck a balance of not requiring genetic testing while protecting their access to the results of consumers' own tests.

By upending this status quo, the recent Florida law creates a new financial vulnerability for insurers. At the same time, however, new technologies are emerging that could counterbalance these losses by identifying politically palatable methods of closing other, existing information asymmetries. Epigenetics, for example, promises to rectify a longstanding, significant underwriting distortion: Tobacco smokers who conceal their status on applications and then elude detection by current verification tests.

Insurers Do Not Require Genetic Testing, but Stress Their Need to Have the Same Information That Insureds Have Regarding Their Health and Wellness

Despite relatively permissive rules governing the use of genetic information, its substantial potential predictive value (Lombardo, 2018) and their historical utilization of substitutes for immutable genetic characteristics (such as gender and family history), no life insurers are known to have required or requested genetic testing from their applicants (Prince, 2018). This is a longstanding choice: The National Association of Insurance Commissioners' (NAIC) Genetic Testing Working Group found in 1996 that "insurers are not requiring genetic testing as a prerequisite to coverage."

While this NAIC report included an American Council of Life Insurers (ACLI) paper correctly forecasting that "DNA-based tests are widely expected to become the standard of practice in clinical medicine in connection with common conditions many of which have significant mortality and morbidity implications," the ACLI's further prediction that "it is likely that life and disability income insurers will wish and in some cases need to use some of these tests in underwriting," has not come to fruition. (NAIC, 1996.) As Prince (2018) explains: "Although genetic test results may be of interest, no insurer is presently willing to break the status quo norms for fear of bad press."

Under this détente, insurers do not require genetic test information, but they lobby to preserve their right to receive and analyze genetic testing results initiated by consumers.[32] Carriers' business decision not to proactively use a powerful, actuarially valid risk classification tool was strategically designed to protect them from legislation, like Florida's, that creates a potential material underwriting information gap—whereby applicants can factor the results of their genetic tests into

32. *See* Peikoff (2014) ("At least for now … companies ask no explicit question about genetic testing. But when Dr. Green asked company executives why not, he said, 'at least one of them has told me, "We would do this, but we don't want to be the first."' Still, he added, 'you can imagine a world where millions of people have this information, and that would reach a tipping point that the insurance companies can no longer ignore.' Even if most insurers are not asking now, they do seek out medical records and can use genetic test results listed there.").

their purchase decisions, but their insurers cannot use the same relevant information in their risk classification decisions.

The stakes are high. Information asymmetries cause better risks to subsidize worse risks. The resulting mispricing can drive better risks out of an insurance pool, leading to adversely selected pools of worse risks—the most dangerous consequence of which is a death spiral for the insurance carrier. (Donnelly, 2011; Avraham, 2012; NAIC 1996; Prince, 2018.) Even short of that worst case scenario, any material separation of price from risk has "significant and sizable" effects on carrier solvency (Born, 2019), which is ultimately borne by consumers in the form of diminished accessibility and affordability of coverages.

Stakeholder response to a 2019 Maine proposal to ban use of genetic information in life insurance highlights this concern. The lead life insurer witness warned against the "adverse selection [that] occurs when there is an information asymmetry between the insurer and the applicant." Insurers' need to "access … and … consider the same information the applicant possesses" crystallized when the industry witness expressed "support [for] legislation that prohibits the requiring of genetic testing" by life insurers, so long as carriers were allowed to continue receiving and risk-assessing "genetic testing … voluntarily taken by an individual seeking insurance."[33] (Kilmartin, 2019).

This "insurance mantra" of "need[ing] access to the same information about an applicant's risk that the applicant has" (Prince, 2018)—"especially pronounced in life insurance underwriting" (Born, 2019)—has driven the carriers' thoughtful, balanced de facto policy of not requiring genetic testing in exchange for full transparency regarding an applicant's health and wellness status, including genetic information derived from consumer tests.

With this carefully crafted center, designed to preserve information symmetry, frayed by the new Florida law, carriers stand at a crossroads created by the advent of the molecular biology revolution and direct-to-consumer testing. If legislation prohibiting life insurers from accessing what applicants know about their genetic information continues, new informational asymmetries could drive adverse selection. At the same time, different molecular biotechnologies, such as epigenetics, offer a means to ameliorate this trend by reducing other, chronic insurance asymmetries through more precise measurement of traditional risk factors.

Epigenetics Can Reduce Existing Information Asymmetry Through Better Assessment of Insureds' Current Health and Wellness

Epigenetic analysis, if used by life insurers, could provide more precise measures of an insured's current health and wellness around relevant controllable and dynamic behaviors for which carriers underwrite today. As a result, individuals

33. The offer turned out to be unnecessary, as the proposal was amended to prohibit requesting or using information from direct-to-consumer testing without consent. *See* note 15.

in good physical condition (due to healthy habits such as moderate diet and regular exercise)[34] would have better access to affordable, accurately priced coverage, while individuals who are less healthy as a result of engaging in risky activities (such as smoking tobacco)[35] would face higher rates that better reflect their increased mortality risk.

The ability of epigenetic technology to better measure tobacco smoking best illustrates[36] how molecular biotechnology might improve the effectiveness of the well-established and necessary insurance risk underwriting practice of verifying consumer health risk profiles. Because smoking history is a leading indicator of mortality risk—"the leading preventable cause of death in the world, accounting for nearly 6 million deaths each year" (Joehanes, 2016)—insureds "not reporting that they smoke" represent "the quintessential example" (Prince, 2018) of "asymmetric information [that] brings with it strategic behavior … when high-risk insureds pretend to be low risk" (Avraham, 2012).[37]

The materiality of the tobacco smoking information gap is substantial. A leading life insurance industry cotinine study concluded that 22.9% of tobacco smokers claimed not to be smokers on their applications (Palmier and Lanzrath, 2016). This results in major financial consequences for insurers, and ultimately their policyholders, whose premiums must support the risk pool. Because "tobacco users will typically pay 2 to 4 times the premiums of their non-user peers for comparable levels of coverage … even mid-market tobacco users who are able to successfully conceal their habit … typically realize annual premium savings of over $1,000" (Palmier et al, 2014). Thus, the one-fifth of applicants who inaccurately report negative tobacco status constitute a "large minority of false-negative self-reporting

34. *See* Rea, 2017 ("discuss[ing] how physical activity and exercise is understood to produce changes in the human epigenome, which have the potential to … lead to better ageing" and "helps make us fitter … and reduces our risk of developing illnesses such as diabetes and heart disease"); Woelfel et al., 2018 ("The epigenome may be one of the most powerful systems through which exercise exerts its benefical effects on health and longevity."); Bishop and Ferguson, 2015 ("It is thought that many of these dietary compounds provide a protective effect against cancer by influencing epigenetic modifications.").

35. *See* Zong et al., 2019 ("Several epigenome-wide association studies … have confirmed that the altered DNA methylation at multiple CpG sites is induced by CS [cigarette smoke]."); Nielsen et al, 2012 ("The interactions of environmental and genetic factors indicate the significance of epigenetic mechanisms, which have been found to occur in response to illicit drug use or as underlying factors in chronic substance abuse and relapse").

36. Tobacco is just one form of behavior relevant to risk that can be detected by epigenetic testing, as discussed throughout this paper. *See also* Shenker et al., 2013

37. *See also* ACLI, 2019 ("A basic example of adverse selection is if a smoker claims to be a non-smoker on their application and receives the non-smoking risk classification… . If enough smokers get added to the nonsmoking risk pool, adverse selection could occur because the premiums charged to the pool are too low to account for the increased mortality and morbidity of the smokers. The pool eventually becomes unsound because the insurer is not collecting enough premiums to pay the higher rate of claims."); Donnelly, 2011 ("Anti-selection occurs when an underwriting information deficit allows a higher-risk group (such as smokers) to purchase life or health insurance at the same price as a lower-risk group (non-smokers).").

cases … more than sufficient to undermine the pricing assumptions of most life insurance products if accepted as truthful by underwriters" (Palmier et al., 2014).

To combat this substantial informational asymmetry, life insurers rely on verifying tobacco use by testing for "cotinine, a major metabolite of nicotine in tobacco smoke" (Zhang, 2016), via a urine specimen usually collected from the applicant by a paramedical nurse. Palmier et al. (2014), however, found that the cotinine test may be accurate less than half the time. Their research indicated that 15.2% of those studied self-reported their status as a tobacco "user"; 8.1% were cotinine negative, while 7.1% were cotinine positive. Thus, 53% of self-reported smokers tested negative in their cotinine test. The finding that a majority of cotinine tests were incorrect is plausible, given Zhang's (2017) explanation that, although "cotinine objectively reflects the actual uptake … it only reflects short-term exposure due to short residence in the body."

Assessing tobacco use with epigenetics may also better answer two key questions essential to assessing the health risk posed by smoking status: How much, and how long? Shenker (2013) explained that "[a]ny biomarker of tobacco exposure should reflect the degree of exposure, including the intensity and duration of smoking"; that cotinine "fails to estimate long-term past exposure, which is particularly useful for assessing health risks accumulated through tobacco smoking"; and that epigenetics "measure[s] long-term smoking exposure with high accuracy, which is a major advantage when assessing health risks resulting from cumulative smoking exposure." Wan et al (2012) found epigenetic markers were able to provide measures "associated with cumulative smoke exposure, and … associated with time since quitting cigarettes."[38]

The ability—currently unavailable to insurers—to scientifically verify the pertinent specific details of "how much and how long" the insured smoked would be of substantial underwriting predictive value for carriers: Jha et al. (2013) found that "adults who had quit smoking at 25 to 34, 35 to 44, or 45 to 54 years of age gained about 10, 9 and 6 years of life, respectively, as compared with those who continued to smoke."

Conclusion

Epigenetic tests, which identify individual behaviors and lifestyle choices—rather than a set of immutable instructions obtained at birth—should not engender the same political objections that recently triggered Florida's GINA-like prohibitions on the use of genetic information in life insurance.

Therefore, at this difficult time—with a pandemic increasing the public's concern about mortality protection while at the same time impeding carriers' ability

38. *See also* Guida et al., 2015 ("historical signatures are promising biomarkers to refine individual risk profiling of smoking-induced chronic disease"; Zeilinger et al, 2013 (finding "wide-spread differences in the degree of site-specific methylation").

to collect blood and urine specimens through paramedical nurses—emerging biotechnologies like epigenetics[39] merit study and consideration as a potentially useful bridge between the goals of traditional underwriting and the possibilities of modern InsurTech.

Innovation, a necessary component of a healthy and vibrant life insurance marketplace, is best supervised under a regulatory framework that applies the fundamental norms of information transparency, symmetry and avoidance of adverse selection; carrier solvency through accurate risk pool construction; and consumer fairness (rewarding safe behavior by charging insureds based on their risk) and public well-being (incentivizing good health). Because, properly understood, they meet these standards, epigenetic technologies that identify risky consumer behaviors hold the promise of aligning the interests of insureds and their insurers—thus, harnessing revolutions in molecular biology to the traditional policy goals of life insurance regulation.[40]

39. For identification of tobacco use and other risky conduct, many, including Shenker (2013), have noted the potential use of epigenetics as "a biological indicator of lifetime accumulation of environmental exposures," including "ionizing radiation, alcohol, smoking, and perhaps many others."

40. *See Life Ins. Ass'n of Mass. v. Com. Of Ins*., 530 N.E.2d 168, 171 (Mass. 1988) ("The basic principle underlying statutes governing underwriting practices is that insurers have the right to classify risks and to elect not to insure risks if the discrimination is fair ... The intended result … is that persons of substantially the same risk will be grouped together, paying the same premiums, and will not be subsidizing insureds who present a significantly greater hazard."); Prince (2018) ("Risk classification, when done well, bolsters the economic efficiency of the insurance systems by creating incentives and optimal pricing. First, risk classification encourages individuals to minimize risk. For example … a smoker charged more for his or her term life insurance policy may quit smoking to reduce costs in the next term. Both scenarios not only benefit the individuals themselves, but also ultimately save insurers money as lower risks equate to fewer overall claims and payouts… . Second, risk classification facilitates pricing that is actuarially fair, where an individual's premiums are proportional to his or her expected risks… . Pricing individuals proportional to their risk also minimizes adverse selection… . The asymmetry of information inherent to the problem of adverse selection can stem from both external and internal causes. Internally, adverse selection can arise if insurance companies do not properly classify risk or fail to ask for all relevant information, causing pricing that is disproportionate to expected risk. Externally, applicants can cause information asymmetry if they intentionally withhold risk information from insurers.").

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