

2018

## Insurance Risk Classification in an Era of Genomics: Is a Rational Discrimination Policy Rational?

Anya E.R. Prince

*University of Iowa College of Law*, [anya-prince@uiowa.edu](mailto:anya-prince@uiowa.edu)

Follow this and additional works at: <https://digitalcommons.unl.edu/nlr>

---

### Recommended Citation

Anya E.R. Prince, *Insurance Risk Classification in an Era of Genomics: Is a Rational Discrimination Policy Rational?*, 96 Neb. L. Rev. 624 (2017)

Available at: <https://digitalcommons.unl.edu/nlr/vol96/iss3/4>

This Article is brought to you for free and open access by the Law, College of at DigitalCommons@University of Nebraska - Lincoln. It has been accepted for inclusion in Nebraska Law Review by an authorized administrator of DigitalCommons@University of Nebraska - Lincoln.

Anya E.R. Prince\*

# Insurance Risk Classification in an Era of Genomics: Is a Rational Discrimination Policy Rational?

## TABLE OF CONTENTS

I. Introduction .....	625
II. Theoretical Underpinnings and Foundation of Insurance Regulation .....	630
III. Policy Approaches.....	634
A. Prohibitive Approach .....	635
B. Status Quo Approach .....	638
C. Rational Discrimination Approach .....	641
1. United Kingdom Moratorium and Concordat ...	642
2. Australian Guidance .....	643
3. U.S. Uniform Law Commission Proposal .....	644
IV. Risk Classification and Economic Efficiency .....	645
A. Classifying Risk .....	645
B. Why Insurers Classify Risks .....	647
C. Choosing a Risk Characteristic .....	649
1. Statistical Considerations .....	650
2. Operational Considerations .....	651
3. Social Considerations .....	652
V. Genetic Test Results and Insurance .....	655
A. Genetic Test Results as Risk Characteristics .....	655
B. Current Use of Genetic Test Results .....	660
1. Insurer Access to Genetic Test Results .....	661

---

© Copyright held by the NEBRASKA LAW REVIEW. If you would like to submit a response to this Article in the *Nebraska Law Review Bulletin*, contact our Online Editor at lawrev@unl.edu.

\* Associate Professor, University of Iowa College of Law. Research reported in this publication was supported by the National Human Genome Research Institute of the National Institutes of Health (NIH) under Award Number K99HG008819. The content is solely the responsibility of the author and does not necessarily represent the official views of the NIH. I thank Gail Henderson, Jim Evans, Debra Skinner, John Conley, Joan Krause, Rich Saver, and Rick Sanders for feedback throughout this project and the faculty at Saint Louis University Law School for workshopping a draft. Additionally, I wish to thank Nicholas Georgakopoulos for the use of his macros and templates.

2018]	INSURANCE RISK CLASSIFICATION	625
	2. Insurer Use of Genetic Test Results . . . . .	662
VI.	Are Transparency and Oversight Necessary? . . . . .	663
	A. Insurer Misuse of Genetic Test Results . . . . .	664
	B. Transparency of the Insurance Market . . . . .	665
	C. The Arms Race of Risk Classification . . . . .	666
	D. Fear of Genetic Discrimination . . . . .	668
VII.	Standards of Evidence . . . . .	671
	A. Uniform Law Commission Draft . . . . .	671
	B. U.K. Moratorium . . . . .	673
	C. Australian Guidance . . . . .	674
	D. Additional Considerations . . . . .	675
	1. What Types of Evidence Are Sufficient? . . . . .	675
	2. How Should the Context of Genetic Tests Come into Play? . . . . .	676
	3. Should Relevance Be Measured by Marginal Added Value? . . . . .	678
	4. How Should Preventive and Treatment Measures Be Taken into Account? . . . . .	679
	5. How Should Variants Within a Gene Be Considered? . . . . .	680
VIII.	The Case for a Rational Discrimination Approach . . . . .	682
	A. Prohibitive Approach Comparison . . . . .	683
	B. Status Quo Consideration . . . . .	684
IX.	Conclusion . . . . .	686

## I. INTRODUCTION

There is continuing societal debate about whether insurers should be able to collect, access, or use genetic test results when considering applications or setting premium and coverage levels.<sup>1</sup> This debate cen-

---

1. See, e.g., Robert Klitzman et al., *Should Life Insurers Have Access to Genetic Test Results?*, 312 JAMA 1855 (2014); Kira Peikoff, *Fearing Punishment for Bad Genes*, N.Y. TIMES, Apr. 7, 2014, at D1, [http://www.nytimes.com/2014/04/08/science/fearing-punishment-for-bad-genes.html?\\_r=0](http://www.nytimes.com/2014/04/08/science/fearing-punishment-for-bad-genes.html?_r=0); Francis S. Collins, *Questions on Genetic Tests Remain; Some Rules Should Be Clear*, N.Y. TIMES (Apr. 14, 2014), <http://www.nytimes.com/roomfordebate/2014/04/14/dna-and-insurance-fate-and-risk/questions-on-genetic-tests-remain-some-rules-should-be-clear> [https://perma.unl.edu/6W8S-X9CE]; Jeremy Gruber, *Guarantee Privacy to Ensure Proper Genetic Treatment*, N.Y. TIMES (Apr. 14, 2014), <http://www.nytimes.com/roomfordebate/2014/04/14/dna-and-insurance-fate-and-risk/guarantee-privacy-to-ensure-proper-genetic-treatment>; Joy Larsen Haidle, *Genetic Test Results Are Not Always What They Seem*, N.Y. TIMES (Apr. 14, 2014), <http://www.nytimes.com/roomfordebate/2014/04/14/dna-and-insurance-fate-and-risk/genetic-test-results-are-not-always-what-they-seem> [https://perma.unl.edu/4H9X-E58Y]; Shawn Hausman, *Let Insurers Have Data and Trust to Get It Right*, N.Y. TIMES (Apr. 14, 2014), <http://www.nytimes.com/roomfordebate/2014/04/14/dna-and-insurance-fate-and-risk/let-insurers-have-data-and-trust-to-get-it-right> [https://perma.unl.edu/54GP-M27R]; Bartha Maria Knoppers, *It's Yet to Be Shown that Ge-*

ters around deeply rooted beliefs over the privacy and personal nature of genetic information on the one hand and the financial necessities and economic considerations of the insurance industry on the other. Insurers argue access to applicants' genetic test results is essential for the industry's financial security. However, public distrust of insurance companies, coupled with anecdotal evidence of individuals unable to secure insurance, led to calls for barring insurers from considering genetic test results and, in the context of health insurance, the realization of this goal.<sup>2</sup> In 2008, Congress passed the Genetic Information Nondiscrimination Act (GINA), which bars covered health insurers and employers from collecting and using genetic information.<sup>3</sup> Other insurers, such as life, long-term care, and disability insurers, are exempt from the law.<sup>4</sup> Since GINA's passage, continued suggestions have been raised to expand legislation to these other insurances, but to date regulation has been limited, variable, and confined to the state level.<sup>5</sup> It remains an open question whether and how the use of genetic test results by life, long-term care, and disability insurers should be circumscribed.

Across the globe, countries similarly struggle to balance public and insurance industry concerns. In many countries, especially those that have universal or national health care and insurance systems, the debate has focused on the types of insurances excluded from GINA, such as life, disability income, and critical illness insurance.<sup>6</sup> In a survey of

---

*netic Discrimination Exists*, N.Y. TIMES (Apr. 14, 2014), <http://www.nytimes.com/roomfordebate/2014/04/14/dna-and-insurance-fate-and-risk/its-yet-to-be-shown-that-genetic-discrimination-exists> [<https://perma.unl.edu/PH6Y-KN82>]; Angus S. MacDonald, *Risks Are Too Small for Insurers to Worry*, N.Y. TIMES (Apr. 14, 2014) [hereinafter MacDonald, *Risks Are Too Small*], <http://www.nytimes.com/roomfordebate/2014/04/14/dna-and-insurance-fate-and-risk/risks-are-too-small-for-insurers-to-worry> [<https://perma.unl.edu/D2A5-56EA>].

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

3. *Id.*

4. *Id.* This Article primarily discusses life, long-term care, and disability insurers, the three types of insurance lines where information about increased risk for morbidity and mortality are most likely to be relevant. However, as genetic testing becomes more pervasive in society, other lines of insurance, such as homeowners or travel insurance, could integrate genetic test results into underwriting. In the international context, these types of insurances covering morbidity or mortality have varying names, such as critical illness insurance.

5. See, e.g., Amy L. McGuire & Mary Anderlik Majumder, *Two Cheers for GINA?*, 1 GENOME MED. 6 (2009); Anya E.R. Prince, *Comprehensive Protection of Genetic Information: One Size Privacy or Property Models May Not Fit All*, 79 BROOK. L. REV. 175 (2013); Mark A. Rothstein, *Genetic Exceptionalism and Legislative Pragmatism*, 35 J.L. MED. & ETHICS 59 (2007).

6. See, e.g., Yann Joly et al., *Genetic Discrimination in Private Insurance: Global Perspectives*, 29 NEW GENETICS & SOC'Y 351, 351 (2010) (noting that the public nature of many countries' health insurance programs has moved focus of the debate to private insurances, such as life insurance).

international policy approaches addressing insurer use of genetic information, Yann Joly and colleagues identified six intersecting and overlapping approaches often employed.<sup>7</sup> Three of these approaches relate specifically to whether insurers can access all, some, or no genetic test results—labeled status quo, rational discrimination, and prohibitive approaches, respectively.<sup>8</sup>

Under a status quo approach, insurers set their own standards for which genetic tests they will gather and use.<sup>9</sup> This approach is premised on the fact that the overarching goal of the insurance market is to assess applicants' risks in order to offer a premium that is commensurate with risk level and is economically viable.<sup>10</sup> Additionally, since insurance companies are in the business of attracting customers, they have an incentive to assess risk as accurately as possible.<sup>11</sup> For these two reasons, a status quo approach allows insurers to create their own rules for use of risk characteristics,<sup>12</sup> implicitly trusting the insurers to use available data responsibly. In contrast, under a prohibitive approach, insurers are barred from accessing or using genetic test results.<sup>13</sup> Such legislation prioritizes social arguments that insurer use of genetic information is unfair, may violate privacy concerns, or may discourage individuals from undertaking medically recommended genetic testing.

The rational discrimination approach stands as a middle ground between the status quo and prohibitive approaches. Here, insurers are allowed to use a subset of genetic tests that meet established standards of scientific, clinical, and actuarial significance.<sup>14</sup> Given current scientific knowledge, this subset of tests may actually be quite small.

Overwhelmingly, genetic test results do not provide insurers with helpful risk information. Despite promises, current clinical understanding of genetics is, for the most part, lackluster at best in its ability to accurately predict risk.<sup>15</sup> Although some genetic tests can identify individuals at high risk for conditions such as cancer or neurodegenerative diseases, this is a small subset of overall genetic

---

7. *Id.* at 355–56 (labeling the approaches as fair limits, human rights, prohibitive, moratorium, rational discrimination, and status quo).

8. *Id.* at 356.

9. *Id.*

10. Hausman, *supra* note 1.

11. See *infra* section VI.C.

12. Joly et al., *supra* note 6, at 356.

13. *Id.*

14. *Id.*

15. James P. Evans et al., *Deflating the Genomic Bubble*, 331 *SCIENCE* 861, 861 (2011); Angus S. MacDonald, *Genetic Factors in Life Insurance: Actuarial Basis 1*, in *ENCYCLOPEDIA OF LIFE SCIENCES* (2009) [hereinafter MacDonald, *Genetic Factors*].

information.<sup>16</sup> Much of the information arising from genetic tests is vulnerable to misinterpretation<sup>17</sup> and will arguably have a small effect on aggregate health<sup>18</sup> and insurance markets.<sup>19</sup> Therefore, a rational discrimination approach narrows insurer use to only those tests that meet established criteria and are helpful in risk prediction.

A rational discrimination approach was implemented in the United Kingdom in the early 2000s, and versions of the approach have been proposed in the United States and Australia.<sup>20</sup> Additionally, United Kingdom and Australia policies place an independent body as a mediator in actuarial decisions, and an external committee must approve the genetic tests before insurer use is permitted. This Article examines the merits and drawbacks of a rational discrimination approach to address life, long-term care, and disability insurer use of genetic test results. It argues a rational discrimination approach should be adopted as a necessary baseline protection against misuse of genetic test results, while allowing insurers access to and use of genetic test results that have met sufficient scientific, clinical, and actuarial evidence.

Part II begins with an overview of two theoretical underpinnings of insurance—social fairness and actuarial fairness—and examines how these theories have been employed in U.S. insurance law. Social fairness focuses on insurance as solidarity; ensuring access to insurance coverage is a paramount goal. In contrast, actuarial fairness, also called fair discrimination, seeks to treat equal risks equally and unequal risks unequally. Part III applies these theoretical frameworks to genetic test results. It discusses in greater depth the three policy approaches employed to address insurer use of genetic test results—a prohibitive approach, a rational discrimination approach, and the status quo.

Part IV discusses the economic considerations that motivate risk classification. Risk classification is the process of gathering information, referred to as “characteristics,” about an applicant, assessing how these characteristics affect risk, and placing applicants into risk classes that dictate premium and coverage levels. Historically, insurers used data for a relatively small number of characteristics, such as age, gender, and occupation, to assess individuals’ risk and assign pre-

---

16. See *infra* section V.A (discussing the vast variety of types of genetic tests and information stemming from sequencing).

17. Haidle, *supra* note 1.

18. Evans et al., *supra* note 15.

19. Gruber, *supra* note 1; MacDonald, *Risks Are Too Small*, *supra* note 1.

20. This guidance was drafted by the National Conference of Commissioners on Uniform Laws, the Australian Law Reform Commission (ALRC), and the Australian Health Ethics Committee of the National Health and Medical Research Council (AHEC), respectively. They will be discussed in further detail *infra* subsection III.C.2.

miums; however, over time, this process of risk classification became more refined as increasing information from medical exams and lifestyle are factored into risk assessment.<sup>21</sup> The technical realm of risk classification is imbued with subjectivity. Thus, this Part foreshadows areas where a rational discrimination approach can ensure appropriate standards are met. The following Part discusses how insurers currently access and use genetic test results. Precision medicine and advancing genetic technologies further expand the possible information available to insurers challenging existing regulatory frameworks and bounds of fair use of data.

Some have argued that because it is in the insurers' best interests to avoid misuse of genetic test results, market forces should obviate the need for additional oversight. Part VI responds by arguing the market is an insufficient check on the system due to the burden placed on consumers, the competitive pressures insurers face to more narrowly refine risk classes and capture low-risk customers, the differences between insurance markets and other competitive markets, and the failure of the market to address fear of genetic discrimination. Finding the rational discrimination approach provides a balanced mechanism to address these concerns, Part VII delineates the standards for determining scientific, clinical, and actuarial relevance used or recommended by the United States, the United Kingdom, and Australia. Part VII proposes five additional areas of inquiry necessary in any determination of actuarial relevance for genetic test results. As discussed in Part VIII, the rational discrimination approach is a compromise that does not address all concerns of the public or of insurers. This Part, however, maintains this approach is an appropriate balance between the two positions and may in fact be beneficial for both.

A rational discrimination approach balances the economic needs of insurers with the social concerns of the public. As one regulator quipped, "The math of correlation can be so lovely. Because math is blind and so the math must be fair. The math can't be biased because it doesn't know who you are, but it does know all about you."<sup>22</sup> Assessing risk can be a highly technical determination, but the math of statistical correlation and actuarial relevance is not an exact science—it is not blind, and it is certainly not guaranteed to be fair.<sup>23</sup> Instead, the

---

21. See FED. INS. OFFICE, U.S. DEP'T OF THE TREASURY, HOW TO MODERNIZE AND IMPROVE THE SYSTEM OF INSURANCE REGULATION IN THE UNITED STATES 56 (2013) [hereinafter FIO Report] (using the example of "insurance scores" to illustrate the increasing amount of data available to insurers); *infra* section VI.C.

22. Joel Laucher, *Big Data Working Group Public Hearing*, NAT'L ASS'N INS. COMMISSIONERS (Apr. 3, 2016), [http://www.naic.org/audio/committees\\_d\\_big\\_data\\_wg\\_160403\\_4.mp3](http://www.naic.org/audio/committees_d_big_data_wg_160403_4.mp3).

23. See Thomas A. Moultrie & R. Guy Thomas, *The Right to Underwrite? An Actuarial Perspective with a Difference*, 5 J. ACTUARIAL PRAC. 125, 134 (1997) (noting some of the subjective decisions made by actuaries within the "scientific" process

underlying assumptions, evidence, and inputs that go into actuarial calculations affect the outcome. Genetic tests that lack predictive precision may be useful for parents weighing subjective risks or patients considering alternative treatments, but they are generally not economically feasible for use in insurance risk classification. A rational discrimination approach has the potential to level the playing field across insurance companies nationally, enhance the economic efficiency of the insurance system, increase public understanding and trust in insurance risk classification, and dampen fears of genetic discrimination. Therefore, it is a necessary baseline policy for countries grappling with insurer use of genetic-test results.

## II. THEORETICAL UNDERPINNINGS AND FOUNDATIONS OF INSURANCE REGULATION

Insurance risk classification rests on the theoretical foundation of actuarial fairness. Actuarial fairness commands equal risks be treated equally and unequal risks be treated unequally.<sup>24</sup> When pricing is actuarially fair, individuals with lower risks of harm are not unfairly subsidizing those at higher risk. As the quintessential example holds, it is unfair for nonsmokers to pay the same premiums as smokers for a life insurance policy since smokers are more likely to pass away within the policy term. The insurance industry and state laws often refer to actuarial fairness as “fair discrimination.”<sup>25</sup> Fair discrimination is a neutral term that refers to the act of differentiating between unequal risks.<sup>26</sup> Thus, in the insurance industry, unfair discrimination occurs if an insurer makes an insurance decision without actuarial justification. Therefore, if insurers have statistical evidence to

---

of underwriting); see also Deborah A. Stone, *The Struggle for the Soul of Health Insurance*, 18 J. HEALTH POL. POL'Y & L. 287, 296–300 (1993) (noting how, historically, social stereotypes have appeared in insurance rating manuals alongside empirical evidence); *id.* at 299 (“Insurance underwriting, far from being a dry statistical exercise, is a political exercise in drawing the boundaries of community membership.”).

24. See RISK CLASSIFICATION WORK GRP., AM. ACAD. OF ACTUARIES, ON RISK CLASSIFICATION 61 (2011) [hereinafter ON RISK CLASSIFICATION], [http://www.actuary.org/pdf/finreport/RCWG\\_RiskMonograph\\_Nov2011.pdf](http://www.actuary.org/pdf/finreport/RCWG_RiskMonograph_Nov2011.pdf) [<https://perma.unl.edu/5Q4B-GDFM>] (“[E]quality of treatment may be denied as much by requiring apparently identical benefits be provided to persons unequally situated as by requiring different benefits to be provided to persons equally situated.” (quoting 1973 Wash. Op. Att’y Gen. No. 21)).
25. Leah Wortham, *Insurance Classification: Too Important to Be Left to the Actuaries*, 19 U. MICH. J.L. REFORM 349, 361 (1985); see Eric Mills Holmes, *Solving the Insurance/Genetic Fair/Unfair Discrimination Dilemma in Light of the Human Genome Project*, 85 KY. L.J. 503, 549 (1996); John V. Jacobi, *Genetic Discrimination in a Time of False Hopes*, 30 FLA. ST. U. L. REV. 363, 374 (2002). Similar principles also applied in the context of health insurance prior to the Affordable Care Act. See, e.g., Stone, *supra* note 23, at 292–93.
26. Wortham, *supra* note 25, at 361.

substantiate charging a set premium for an associated risk, they should do so to maintain fairness.

As a first step to prove actuarial justification, insurers must determine how risky a particular characteristic is; they must have evidence of a statistical correlation between a risk characteristic—such as smoking status, body mass index (BMI), or a genetic test result—and expected loss. There are two aspects of this statistical evidence. First, the Actuarial Standards Board, a group that defines standards of practice for the actuarial profession states, “The actuary should select risk characteristics that are related to expected outcomes. A relationship between a risk characteristic and an expected outcome, such as cost, is demonstrated if it can be shown that the variation in actual or reasonably anticipated experience correlates to the risk characteristic.”<sup>27</sup> Therefore, there must be a statistical correlation between the risk characteristic, such as BMI, and the expected outcome, such as death. Second, an insurer should show a statistical difference between expected losses across groups to prove risks are unequal and may be assigned different premium rates.<sup>28</sup> “Rates within a risk classification system would be considered equitable if differences in rates reflect material differences in expected cost for risk characteristics.”<sup>29</sup> For example, insurers must show a statistical difference between expected outcomes of smokers and nonsmokers in order to charge the two groups different premium amounts.

Fair discrimination is a concept quite distinct from social notions of unfair discrimination, referred to here as antidiscrimination. While treating unequal risks unequally is the underpinning of fair discrimination, antidiscrimination is based upon principles of solidarity.<sup>30</sup> The

---

27. ACTUARIAL STANDARD OF PRACTICE NO. 12 § 3.2.1 (ACTUARIAL STANDARDS Bd. 2005), [http://www.actuarialstandardsboard.org/pdf/asops/asop012\\_101.pdf](http://www.actuarialstandardsboard.org/pdf/asops/asop012_101.pdf) [<https://perma.unl.edu/EVA2-EPXR>].

28. See Wortham, *supra* note 25, at 372 (generally describing the requirements and noting the requirement that risk characteristics “reasonably reflect differences in loss experience and that the data be credible” (quoting U.S. GEN. ACCOUNTING OFFICE, ISSUES AND NEEDED IMPROVEMENTS IN STATE REGULATION OF THE INSURANCE BUSINESS 127 (1979)).

29. ACTUARIAL STANDARD OF PRACTICE NO. 12 § 3.2.1 (ACTUARIAL STANDARDS Bd. 2005), [http://www.actuarialstandardsboard.org/pdf/asops/asop012\\_101.pdf](http://www.actuarialstandardsboard.org/pdf/asops/asop012_101.pdf) [<https://perma.unl.edu/EVA2-EPXR>] (noting that “equitable” and “fair” can be used interchangeably for this principle).

30. See, e.g., Regina Austin, *The Insurance Classification Controversy*, 131 U. PA. L. REV. 517 (1983); C.D. Daykin et al., *Genetics and Insurance—Some Social Policy Issues*, 9 BRIT. ACTUARIAL J. 787 (2003); Jyri Liukko, *Genetic Discrimination, Insurance, and Solidarity: An Analysis of the Argumentation for Fair Risk Classification*, NEW GENETICS & SOC’Y 457, 467–69 (2010) (referring to this form of solidarity specifically as “subsidizing risk solidarity,” in contrast to “chance solidarity”); Stone, *supra* note 23; Ine Van Hoyweghen & Lisa Rebert, *Your Genes in Insurance: From Genetic Discrimination to Genomic Solidarity*, 9 PERSONALIZED MED. 871 (2012).

solidarity view holds that insurance is a mechanism of distributive justice and mutual aid whereby individuals come together to increase access to social goods and economic security through redistribution from the lucky to the unlucky—from those who pay insurance premiums, but never face a loss, to those who experience sickness, death, or other insured harm and must file claims.<sup>31</sup> Under this framework, some risk factors are seen as inappropriate to use in the insurance decision-making process no matter how statistically accurate they are in informing risk classification.<sup>32</sup> These traits range from commonly protected traits such as gender, race, and religion to more specific traits such as human-immunodeficiency-virus (HIV) status or history of intimate-partner violence.<sup>33</sup> Although insurance companies are not barred from using these traits in all states or across all lines of insurance, legislatures turn to this option when they feel values of social fairness override any business considerations.<sup>34</sup>

While insurers could employ countless potential risk characteristics in their risk classification systems beyond those specifically banned due to social fairness, in the United States, state law establishes the bounds of fair use of these remaining possibilities.<sup>35</sup> All fifty states have some form of fair discrimination, actuarial fairness, or actuarial justification statutes, with many employing standardized language from model law.<sup>36</sup> For example, one such model law, developed

- 
31. See Stone, *supra* note 23, at 290. See generally INE VAN HOYWEGHEN, RISKS IN THE MAKING: TRAVELS IN LIFE INSURANCE AND GENETICS (Amsterdam Univ. Press 2007) (2006); Holmes, *supra* note 25, at 563 (describing the social concepts of fairness as “fair redistribution” in contrast to the use of “fair discrimination” from the language of insurance); Liukko, *supra* note 30; Moultrie & Thomas, *supra* note 23, at 129 (noting social fairness focuses on equality of outcome in contrast to actuarial fairness that focuses on equality of assessment).
  32. See KENNETH S. ABRAHAM, DISTRIBUTING RISK: INSURANCE, LEGAL THEORY, AND PUBLIC POLICY 66 (1986) [hereinafter DISTRIBUTING RISK] (identifying concerns of social or moral connotations, among other values, as “sacrifices in risk-distributional fairness”). See generally Ronen Avraham et al., *Understanding Insurance Anti-Discrimination Laws*, 87 S. CAL. L. REV. 195 (2014) [hereinafter *Understanding Insurance*] (analyzing state insurance-antidiscrimination laws in regards to race, national origin, religion, gender, age, credit score, genetics, sexual orientation, and zip code).
  33. DISTRIBUTING RISK, *supra* note 32, at 66 (identifying concerns of social or moral connotations, among other values, as “sacrifices in risk-distributional fairness”); Tom Baker, *Containing the Promise of Insurance: Adverse Selection and Risk Classification*, 9 CONN. INS. L.J. 371, 392 (2002).
  34. See generally *Understanding Insurance*, *supra* note 32, for a comprehensive assessment of which characteristics are barred under which lines of insurance in which states.
  35. See *infra* section IV.C for a discussion of the actuarial considerations insurers take into account when choosing risk characteristics within the bounds of fair use.
  36. UNFAIR TRADE PRACTICES ACT (UTPA) § 4(G) (NAT’L ASS’N INS. COMM’RS 2004). For examples of state versions of the UTPA, see ALA. CODE § 27-12-11(a) (1971);

by the National Association of Insurance Commissioners (NAIC), bars insurers from “making or permitting any unfair discrimination between individuals of the same class and equal expectation of life in the rates charged for any life insurance policy or annuity or in the dividends or other benefits payable thereon, or in any other of the terms and conditions of such policy.”<sup>37</sup> Every state imposes these requirements on life insurers, and many have also extended similar requirements to long-term care and disability insurers.<sup>38</sup>

One of the most salient aspects of the history of fair discrimination statutes is they were created as an effort to avoid federal regulation of the insurance industry.<sup>39</sup> Couched as unfair trade practices, these laws originally enshrined actuarial principles and risk classification as status quo. State regulation since the McCarran–Ferguson Act has been largely deferential to the insurance industry and varies greatly among states.<sup>40</sup> Although states have the power to regulate pricing

---

ARIZ. REV. STAT. ANN. § 20-448(A) (2009); CONN. GEN. STAT. § 38a-446 (1996); MICH. COMP. LAWS § 500.2019 (1957); N.J. STAT. ANN. § 17:29B-4(7) (West 2001); S.D. CODIFIED LAWS § 58-33-12 (1978); VA. CODE ANN. § 38.2-508 (2014); WYO. STAT. ANN. § 26-13-109(a) (1983); *see also* UTAH CODE ANN. § 31A-23a-402(3)(a) (West 2017) (allowing differentiation only on “the basis of classifications related to the nature and the degree of the risk covered or the expenses involved”); WIS. STAT. § 628.34(3) (2012) (same).

37. UNFAIR TRADE PRACTICES ACT (UTPA) § 4(G) (NAT’L ASS’N INS. COMM’RS 2004).
38. *See* MD. CODE ANN., INS. § 18-120 (West 2008); LONG-TERM CARE INSURANCE MODEL REGULATION (NAT’L ASS’N INS. COMM’RS 2017); Rothstein, *supra* note 5, at 63.
39. The pervasiveness of state fair discrimination statutes and the development of the model law stem from the federalist history of insurance regulation. In the 1800s, an ongoing tension simmered regarding whether insurance regulation should occur at the state or federal level. In 1868, the Supreme Court held insurance was not a transaction of commerce and therefore was left to the jurisdiction of the states. *Paul v. Virginia*, 75 U.S. (1 Wall.) 168 (1868). However, in 1944 the Court overturned this decision, *United States v. S.-E. Underwriters Ass’n*, 322 U.S. 533 (1944), causing confusion and a lack of regulatory oversight. Congress settled this debate in favor of state oversight through the McCarran–Ferguson Insurance Regulation Act (McCarran–Ferguson Act) of 1945, ch. 20, 59 Stat. 33 (1945) (codified as amended at 15 U.S.C. §§ 1011–1015 (2012)), albeit allowing for future federal regulation of the business of insurance. The McCarran–Ferguson Act cautioned that if states did not regulate insurance, the industry would be subject to federal antitrust and unfair trade practice acts. *Id.* In order to avoid federal sanction, the insurance industry and the states scrambled to establish sufficient state oversight of the business of insurance. Holmes, *supra* note 25, at 548–50. The NAIC, a private association of state insurance commissioners seeking to create uniform regulation of insurance across states, played a major role in this process. *Id.* Shortly after Congress passed the McCarran–Ferguson Act, NAIC and industry partners formulated one of the first post-McCarran model laws, the Unfair Trade Practices Act (UTPA), which includes provisions regarding fair discrimination. UNFAIR TRADE PRACTICES ACT (UTPA) § 4(G) (NAT’L ASS’N INS. COMM’RS 2004).
40. *See* U.S. GOV’T ACCOUNTABILITY OFF., PAD-79-72, ISSUES AND NEEDED IMPROVEMENTS IN STATE REGULATION OF THE INSURANCE BUSINESS (1979) [hereinafter

and risk classification systems of insurance companies, there is variability in how thoroughly and adequately they oversee and protect against unfair trade practices.<sup>41</sup> Resource pressures also affect states' abilities to oversee all aspects of the market. It is questionable whether state insurance regulators initiate detailed investigations into the actuarial sufficiency of each risk characteristic and whether they would currently have sufficient resources to undertake this even if they so desired.<sup>42</sup>

### III. POLICY APPROACHES

The debate over insurer use of genetic test results falls squarely into the dialogue regarding fair discrimination or antidiscrimination. Genetic testing involves the sequencing of an individual's genes to look for changes, called "variants," that are associated with increased risk of disease.<sup>43</sup> This predictive risk information can stem from many different types of tests, such as genetic tests that look at only one gene, a panel of genes, or sequencing that may unearth findings in any number of genes.<sup>44</sup> Here, it can be helpful to distinguish between *genetics*, which identifies changes, or variants, within one single gene and examines how these contribute to health and disease, and *genomics*, which investigates the entire genetic makeup and considers

---

GAO Report], <https://www.gao.gov/assets/130/127863.pdf> [https://perma.unl.edu/P2RS-WMUB]. See generally FIO Report, *supra* note 21, at 46 (historically, this has been an ongoing concern.).

41. FIO Report, *supra* note 21, at 46.

42. See GAO Report, *supra* note 40; Leah Wortham, *The Economics of Insurance Classification: The Sound of One Invisible Hand Clapping*, 47 OHIO ST. L.J. 835 (1986).

43. There are many different types of testing and a range of information that can arise from such testing and sequencing. See *infra* section V.A. This description sets a cursory baseline understanding, which will be further extrapolated. See *infra* section V.A. One particular testing distinction of importance is that between diagnostic and predictive genetic testing. In the first, genetic testing is used to assist in the diagnosis or treatment of existing symptoms, such as tumor testing for cancer. *E.g.*, ASS'N OF BRITISH INSURERS, CONCORDAT AND MORATORIUM ON GENETICS AND INSURANCE 12 (2014), <https://www.abi.org.uk/globalassets/sitecore/files/documents/publications/public/2014/genetics/concordat-and-moratorium-on-genetics-and-insurance.pdf> [https://perma.unl.edu/BYR4-7S7C]. In the latter, genetic testing is performed in asymptomatic individuals in order to assess their risk of developing disease in the future. *Id.* It is this type of predictive testing discussed in this Article. The line between these two types of testing is not always clear. Despite grey area, predictive testing is a helpful lens through which to assess insurer use of genetic testing and one that is often used. See *infra* subsection III.C.1. (discussing the insurer moratorium on the use of genetic test results in the UK).

44. See generally PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, PRIVACY AND PROGRESS IN WHOLE GENOME SEQUENCING (2012) [hereinafter PRIVACY AND PROGRESS], <http://bioethics.gov/sites/default/files/PrivacyProgress508.pdf> [https://perma.unl.edu/Z6R9-8TF2] (discussing various types of genetic testing).

how genes interact with each other, the environment, and lifestyle.<sup>45</sup> Early genetic research and the Human Genome Project focused on understanding the basic biology of genes and establishing how single genes were associated with disease.<sup>46</sup> Today, research is increasingly focused on the genome and assessing gene and environment interactions through projects like the Precision Medicine Initiative (PMI), now called the All of Us Research Program.<sup>47</sup> These projects are amassing significantly more information and data and are unearthing more complex links between genetic variation, environmental impacts, and disease. The nuances and complications of this will be discussed at greater length below.<sup>48</sup> Suffice it to say, from this basic perspective, it is clear why genetic test results are intriguing and attractive to insurers—during risk classification, insurers are calculating an individual's likelihood to get sick or pass away; thus, information linked to propensity for disease would be highly relevant.

#### A. Prohibitive Approach

Despite this basic premise, several points are consistently raised to argue insurers should be banned from considering any genetic test result.<sup>49</sup> First, there is an unfortunate history of stigmatization against

---

45. *Frequently Asked Questions About Genetic and Genomic Science*, NAT'L HUM. GENOME RES. INST., <https://www.genome.gov/19016904/faq-about-genetic-and-genomic-science/#al-1> [<https://perma.unl.edu/TB2P-FDCP>] (last updated Mar. 2, 2016).

46. The Human Genome Project (HGP) was a thirteen-year international project that successfully mapped the human genome for the first time. See Francis S. Collins & Victor A. McKusick, *Implications of the Human Genome Project for Medical Science*, 285 JAMA 540, 541 (2001). Ever since completion of the HGP in 2003, researchers, physicians, and the media have heralded the promise of genomics to revolutionize medicine and our understanding of treatment and risk for disease. See Eric D. Green et al., *Charting a Course for Genomic Medicine from Base Pairs to Bedside*, 470 NATURE 204 (2011); Alan E. Guttmacher & Francis S. Collins, *Realizing the Promise of Genomics in Biomedical Research*, 294 JAMA 1399 (2005).

47. The PMI is a \$215 million federal project designed to harness big data through electronic medical records, mobile health technologies, and genomic sequencing. Press Release, Office of the Press Sec'y, President Obama's Precision Medicine Initiative (Jan. 30, 2015), <https://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative> [<https://perma.unl.edu/6V4E-FVMU>]; President Barack Obama, State of the Union Address (Jan. 20, 2015); *All of Us Research Program*, NAT'L INST. HEALTH, <https://allofus.nih.gov> [<https://perma.unl.edu/GPV2-E29J>]. It plans to recruit one million research participants in order to develop and discover individualized treatment and prevention for clinical care. Press Release, Office of the Press Sec'y, *supra*.

48. See *infra* section V.A.

49. See *Understanding Insurance*, *supra* note 32, at 214–21 (delineating arguments raised for why genetic information should not be used by insurers, especially surrounding five fairness-related considerations including control and social solidar-

individuals with certain genetic traits.<sup>50</sup> Taken to the extreme, this stigmatization led to practices of eugenics and forced sterilization in the United States and abroad.<sup>51</sup> Such discriminatory and reprehensible practices reinforce arguments that genetic information is a trait that raises civil rights concerns and that harm based on being part of a stigmatized group despite the immutable nature of one's genetic code is unfair and unwarranted in society. Second, genetic tests have the potential to disclose highly personal information about one's self and family, such as a predisposition to a mental illness or an incurable, degenerative disease. It is only natural that individuals desire a right to privacy and feel they should not be required to disclose test results or have surreptitious testing done without their consent.

In addition to intangible harms, insurer use of genetic test results may lead to tangible economic and medical harm. For example, individuals who have genetic predispositions to diseases such as early-onset Alzheimer's Disease or a hereditary cancer syndrome may be more likely to be denied insurance given their risk for increased morbidity and mortality.<sup>52</sup> Even absent an outright denial, those with higher risk are more likely to be charged higher premiums or to be offered insurance policies that do not cover certain conditions. Such insurance actions risk the creation of a "genetic underclass" of individuals who will never be able to secure or afford insurance, especially at the moments that they need it most.<sup>53</sup> Tangible harms stemming from adverse insurer decisions based on one's genetic information has been labeled "genetic discrimination."<sup>54</sup>

Genetic testing can provide guidance relevant for treatment options and prevention, potentially minimizing the occurrence and burden of disease in society. Yet, evidence showed fear of genetic discrimination discouraged individuals from undergoing medically

---

ity, socially suspect classifications, differential inaccuracy, correlation and causation, and privacy); Gruber, *supra* note 1; Haidle, *supra* note 1.

50. See Neil A. Holtzman & Mark A. Rothstein, *Eugenics and Genetic Discrimination*, 50 AM. J. HUM. GENETICS 457, 457-59 (1992).

51. See *id.*

52. See Yann Joly et al., *Genetic Discrimination and Life Insurance: A Systematic Review of the Evidence*, 11 BMC MED. 1, 11 (2013); Wendy McKinnon et al., *Survey of Unaffected BRCA and Mismatch Repair (MMR) Mutation Positive Individuals*, 8 FAMILIAL CANCER 363, 367 (2009).

53. James P. Evans, *Health Care in the Age of Genetic Medicine*, 10 GENETICS MED. 1, 2 (2008); Krupa Subramanian et al., *Estimating Adverse Selection Costs from Genetic Testing for Breast and Ovarian Cancer: The Case of Life Insurance*, 66 J. RISK & INS. 531, 532 (1999).

54. Larry Gostin, *Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers*, 17 AM. J.L. & MED. 109, 109-10 (1991).

recommended testing or participating in research.<sup>55</sup> Widespread fear of genetic discrimination was a primary motivator for GINA's passage.<sup>56</sup> Congress worried this fear could diminish the potential medical impact of the technology and adopted a prohibitive approach in the context of health insurance to encourage broad uptake across society.<sup>57</sup> Therefore, GINA prohibits covered health insurers and employers from collecting, asking for, or using a person's genetic information, including family medical history, in insurance or employment decisions.<sup>58</sup> However, due to compromises in the legislative process, life, long-term care, and disability insurers were not included.<sup>59</sup> Absent legislation at the federal level, any restrictions on life, long-term care, and disability insurer use of genetic test results come at the state level, leaving fair discrimination as the primary regulatory framework.<sup>60</sup>

---

55. *E.g.*, Alicia A. Parkman et al., *Public Awareness of Genetic Nondiscrimination Laws in Four States and Perceived Importance of Life Insurance Protections*, 24 J. GENETIC COUNSELING 512, 512 (2014).

56. *E.g.*, Press Release, Representative Lousie M. Slaughter, Slaughter Testifies in Support of GINA (Jan. 30, 2007), <https://louisie.house.gov/media-center/press-releases/january-30-2007-slaughter-testifies-support-gina> [<https://perma.unl.edu/6JHQ-F63W>].

57. *Id.*

58. Genetic Information Nondiscrimination Act (GINA) of 2008, pmb., Pub. L. No. 110-233, 122 Stat. 881 (codified as amended in scattered sections of 26, 29, and 42 U.S.C) (noting potential avoidance of genetic testing as a reason for passing legislation).

59. Robert C. Green et al., *GINA, Genetic Discrimination, and Genomic Medicine*, 372 NEW ENG. J. MED. 397, 397 (2015).

60. Some states also have laws that regulate how insurance companies can use genetic test results, but the statutes generally do not ban the use overall. For example, some states require insurers to obtain informed consent prior to undertaking genetic testing on an individual's sample. CAL. INS. CODE § 10148(a) (West 1998); DEL. CODE ANN. tit. 16, § 1202(a) (West 2012); ME. STAT. tit. 24-a, § 2159-C(2)(B)(2)(a) (1990); OR. REV. STAT. § 746.135(1) (1991). Other statutes prohibit insurers from requiring an applicant to take a genetic test. KAN. STAT. ANN. § 40-2259 (2010); MASS. GEN. LAWS ch. 175, § 108I (2006); VT. STAT. ANN. tit. 18, § 9334(a)(1) (1997). In states with these types of statutes, as long as consent is received or an insurer does not require genetic testing, they can use genetic test results within the bounds of fair use and fair discrimination. 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. See Klitzman et al., *supra* note 1; Peikoff, *supra* note 1. However, it is unclear whether these statutes offer protections as extensive as cited in the literature and popular press. For example, California previously had a statute that prevented long-term care insurers from using genetic test results, but it had a sunset provision that expired. CAL. INS. CODE § 10233.1 (West 2003) (expired Jan. 1, 2008). More recently, the California legislature passed Cal-GINA that added genetic information to the state civil rights act. Unruh Civil Rights Act, CAL. CIV. CODE § 51 (West 2016). However, although the civil rights act arguably applies to insurance, see CAL. INS. CODE § 1861.03 (West 2016), case law regarding a life insurance applicant's disability holds that pricing differentials do not violate

Internationally, most notably in Europe, countries have restricted insurer use of genetic test results beyond just health insurance through legislative bans. For example, Austria, France, and Sweden all bar life insurers from using genetic test results in risk classification.<sup>61</sup> These laws place genetic test results squarely in the realm of social fairness, recognizing that societal concerns override the economic and actuarial arguments of the insurance companies.

## B. Status Quo Approach

On the other side of the debate, there are also strong arguments for why insurers should be allowed to use information from genetic test results in risk classification. Indeed, insurer nonuse of genetic test results can lead to several tangible harms. First, the inability to properly classify risk may lead to adverse selection and spiraling insurance costs. Adverse selection is the incidence, and its sequelae, where indi-

---

the act as long as they are actuarially justified. *Chabner v. United of Omaha Life Ins. Co.*, 225 F.3d 1042, 1050 (9th Cir. 2000). It remains to be seen whether CALGINA will be interpreted to ban all pricing differentials or only those without actuarial justification. Vermont law prohibits covered insurance to be “underwritten or conditioned on the basis of . . . the results of genetic testing of a member of the individual’s family.” VT. STAT. ANN. tit. 18, § 9334(a)(2) (1997). The law does not speak to the results of the genetic testing of the individual themselves. *Id.* Oregon law states that “[a] person may not use genetic information about a blood relative to reject, deny, limit, cancel, refuse to renew, increase the rates of, affect the terms and conditions of or otherwise affect any policy of insurance.” OR. REV. STAT. § 746.135(4) (2001). The statutory language includes “blood relative,” indicating that, similar to Vermont law, it is intended to prohibit only the use of a family member’s genetic test. However, genetic information is defined as “information about an individual or the individual’s blood relatives obtained from a genetic test.” OR. REV. STAT. § 192.531(11) (2007). This allows for a circular statutory interpretation whereby the genetic information of a blood relative includes one’s own genetic test results—an interpretation that may be suspect given that this would make the inclusion of blood relative superfluous in the statute. To further complicate the situation, three states have limitations on underwriting on the basis of genetic test results that are not often cited in the literature: Colorado in connection to group-disability and long-term care insurers, COLO. REV. STAT. § 10-3-1104.7(3)(b) (2009), Arizona related to unmanifested conditions in disability and long-term care, ARIZ. REV. STAT. ANN. § 20-448(F) (2009), and Kansas in connection with disability and long-term care. KAN. STAT. ANN. § 40-2259(d) (2010); see also DRAFT UNIFORM PROTECTION OF GENETIC INFORMATION IN EMPLOYMENT AND INSURANCE ACT (NAT’L CONFERENCE OF COMM’RS ON UNIF. LAWS 2010). Overall, it is beyond the scope of this Article to settle the question of the extent to which these states truly ban life, long-term care, or disability insurer use of genetic test results—for all six states it appears that the statutes have not been extensively discussed nor tested in court; therefore, it is unclear how they will be interpreted in practice. However, even if they do ban such use, the majority of the states remain within a fair discrimination framework.

61. Joly et al., *supra* note 6, at 362.

viduals hold information about their risk not known to insurers.<sup>62</sup> If adverse selection materializes, there may be a greater proportion of high-risk individuals in the risk class than the insurer originally anticipated and likely greater claims expenses.<sup>63</sup> To pay for these unexpected claims, the insurers must increase the premiums of the class, potentially causing more low-risk individuals to decline insurance, which would perpetuate a spiraling pattern of increasing premiums and departure of low-risk individuals from the insurance pool.<sup>64</sup>

Adverse selection has the potential to impact a larger portion of the population than use of genetic test results. While charging individuals higher premiums based on genetic risk would likely affect the small segment of the population at high risk of genetic conditions, adverse selection and increased premiums could potentially harm individuals across the entire population.

[There is a] danger that by concentrating just on “unfairness” on the basis of genetics and worrying about a “genetic underclass”, [sic] [policies] will end up discriminating against the rest of the population, or force insurers to withdraw some insurance products. This could create a much larger “financial underclass” (of which the “genetic underclass” would be a subset) as premiums could increase beyond the reach of many more people.<sup>65</sup>

- 
62. See Ronen Avraham, *The Economics of Insurance Law—A Primer*, 19 CONN. INS. L.J. 29, 45 (2012) [hereinafter *The Economics of Insurance Law*] (noting that risk classification is a tool to mitigate the threat of adverse selection); *Understanding Insurance*, *supra* note 32; Baker, *supra* note 33.
63. *E.g.*, NAT'L ASS'N OF INS. COMM'RS, REPORT OF THE NAIC GENETIC TESTING WORKING GROUP 6–7 (1996) [hereinafter GENETIC TESTING WORKING GROUP REPORT], <http://www.naic.org/store/free/GTR-OP.pdf> [<https://perma.unl.edu/CZA4-6G8N>]; Baker, *supra* note 33, at 375 (defining adverse selection as “the theoretical tendency for low risk individuals to avoid or drop out of voluntary insurance pools, with the result that, absent countervailing efforts by administrators, insurance pools can be expected to contain a disproportionate percentage of high-risk individuals”). *But see* Ronen Avraham et al., *Towards a Universal Framework for Insurance Anti-Discrimination Laws*, 21 CONN. INS. L.J. 1, 10–14 (2014) (finding that the risk of adverse selection based on the percentage of high-risk individuals in the potential pool, expected cost, the elasticity of demand, the presence of secondary markets and penalties for leaving policies, extent of consumer knowledge, and whether overinsurance is possible or whether insurance policies are mandatory); Alma Cohen & Peter Siegelman, *Testing for Adverse Selection in Insurance Markets*, 77 J. RISK & INS. 39 (2010) (the extent to which adverse selection is actually a threat to insurance systems is dependent on many factors including the insurance market and insurance line).
64. *E.g.*, *Understanding Insurance*, *supra* note 32, at 204 n.28; Krupa S. Viswanathan et al., *Adverse Selection in Term Life Insurance Purchasing Due to the BRCA1/2 Genetic Test and Elastic Demand*, 74 J. RISK & INS. 65, 66 (2007). *But see* Peter Siegelman, *Adverse Selection in Insurance Markets: An Exaggerated Threat*, 113 YALE L.J. 1223, 1254–58 (2004) (finding that the threat of death spirals in insurance is unusual).
65. U.K. DEP'T OF HEALTH, SECOND REPORT FROM SEPTEMBER 2002 TO DECEMBER 2003, at 1, 65 (2004) [hereinafter GAIC SECOND REPORT], [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/AnnualReports/DH\\_4070357?ssSourceSiteId=ab](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/AnnualReports/DH_4070357?ssSourceSiteId=ab) [<https://perma.unl.edu/9WH7-UWFS>].

Overall increased premiums or, at the extreme, failure of the insurance company or system, are obviously harms to everyone in society. Thus, the extent to which adverse selection will affect premiums and individuals' propensities to enter and exit the market greatly affects the extent of harm due to nonuse of genetic test results.<sup>66</sup>

Second, any limits on insurer use of a risk characteristic introduce actuarial unfairness into the system. If actuarial data indicates individuals with a specific genetic variant are at greater risk for disease, it would be arguably unfair for those without the variant to pay the same premiums as those with the variant.<sup>67</sup> Lower risk individuals are thus financially disadvantaged if insurers fail to take into account their genetic risk. Based on these principles, some states have fair discrimination laws that specifically reference genetic information,<sup>68</sup> genetic conditions,<sup>69</sup> or genetic test results.<sup>70</sup> However, these laws may not provide any further protection beyond the general fair discrimination requirements because the general statutes are likely sufficiently broad to encompass genetic test results.<sup>71</sup>

The statutes do illustrate the range of language and evidence states use to legislate in this area. For example, Maryland law allows long-term care insurers to use genetic information in coverage and rating decisions if based on sound actuarial principles.<sup>72</sup> Similarly, Massachusetts law prohibits unfair discrimination by allowing use of genetic test results only when "such action is taken pursuant to reliable information relating to the insured's mortality or morbidity, based

---

66. See Avraham et al., *supra* note 63, at 10–12 (noting a similar trend across insurance lines and protective traits, and listing eight factors that affect the risk of adverse selection, including the percentage of high-risk individuals, the difference in expected costs, whether policies are mandatory, the elasticity of demand, the ability of individuals to overinsure, the availability of a secondary market, the ability of policyholders and insurers to cancel policies, and the transparency of the policy design); Robert C. Green et al., *GINA, Genetic Discrimination, and Genomic Medicine*, 372 *NEW ENG. J. MED.* 397, 398–99 (2015). Many scholars argue adverse selection is not as great a concern as is often portrayed. Baker, *supra* note 33; Angus Macdonald & Fei Yu, *The Impact of Genetic Information on the Insurance Industry: Conclusions from the "Bottom-Up" Modelling Programme*, 41 *ASTIN BULL.* 343 (2011) (finding adverse selection specific to genetic information is unlikely to greatly affect the insurance market); Siegelman, *supra* note 64; R. Guy Thomas, *Some Novel Perspectives on Risk Classification*, 32 *GENEVA PAPERS ON RISK & INS. ISSUES & PRAC.* 105, 129 (2007).

67. *AM. COUNCIL OF LIFE INS., THE POTENTIAL ROLE OF GENETIC TESTING IN RISK CLASSIFICATION* 10 (1989).

68. *ME. STAT. tit. 24, § 2159-C(3)* (2009). Genetic information is defined as "the information concerning genes, gene products or inherited characteristics that may be obtained from an individual or family member." § 2159-C(1)(B).

69. *ARIZ. REV. STAT. ANN. § 20-448(E)* (2009). Genetic condition is defined as "a specific chromosomal or single-gene genetic condition." § 20-448(L)(5).

70. *KAN. STAT. ANN. § 40-2259(d)(2)* (2010).

71. Rothstein, *supra* note 5, at 63.

72. *MD. CODE ANN., INS. § 18-120* (West 2008).

on sound actuarial principles or actual or reasonably anticipated claim experience.”<sup>73</sup> Under Montana law, life and disability insurers are similarly allowed to use evidence from either actuarial projections or claims experience to “establish that substantial differences in claims are likely to result from the genetic condition.”<sup>74</sup> In the Montana law, however, genetic conditions are limited to chromosomal or single-gene conditions.<sup>75</sup> As a final example, Wisconsin law restricts life and disability insurers from using genetic information that is “not reasonably related to the risk involved.”<sup>76</sup> Overall, the potentially duplicative state laws specific to genetics highlight tensions between the desire for legislative action in the this area and the entrenched principles of fair discrimination as the regulatory framework in the insurance industry.

Internationally, countries that follow a status quo approach include South Africa and New Zealand.<sup>77</sup> Prior to 2017, Canada had a status quo approach until Parliament passed a bill that prohibits insurers, including life insurers, from using genetic test results.<sup>78</sup> The bill is currently undergoing judicial review to determine the constitutionality of the legislation and may eventually be reviewed by the Supreme Court of Canada.<sup>79</sup>

### C. Rational Discrimination Approach

Although social and actuarial fairness seem squarely at odds, several policy recommendations provide insight into a middle ground between the two positions.<sup>80</sup> Under the framework proposed by these policies, insurers are allowed to use genetic test results that meet scientific, clinical, and actuarial standards. The label employed by Joly of *rational discrimination* mirrors the insurance industry concepts of fair and unfair discrimination.<sup>81</sup> It would be irrational for insurers to use a risk characteristic that has no actuarial relevance; thus, the ra-

---

73. MASS. GEN. LAWS ch. 175, § 120E (2006).

74. MONT. CODE ANN. § 33-18-206(4) (2017).

75. § 33-18-206(5c).

76. WIS. STAT. § 631.89 (2009).

77. Joly et al., *supra* note 6, at 352.

78. Genetic Non-Discrimination Act, S.C. 2017, c 3 (Can.).

79. Press Release, Quebec Court of Appeal, Reference to the Court of Appeal of Quebec Concerning the Genetic Non-Discrimination Act Enacted by Sections 1 to 7 of the Act to Prohibit and Prevent Genetic Discrimination (July 7, 2017), [http://cour.dappelduquebec.ca/fileadmin/Fichiers\\_client/Actualites/SANS\\_SIGNATURE\\_-\\_Press\\_release\\_-\\_Reference\\_-\\_Genetic\\_Non-Dis.pdf](http://cour.dappelduquebec.ca/fileadmin/Fichiers_client/Actualites/SANS_SIGNATURE_-_Press_release_-_Reference_-_Genetic_Non-Dis.pdf) [<https://perma.unl.edu/3ASM-CAGH>]; Victoria Gibson, *Genetic Testing Back on Radar for Parents*, STAR (Aug. 9, 2017), <https://www.thestar.com/news/gta/2017/08/09/genetic-testing-back-on-radar-for-parents.html> [<https://perma.unl.edu/4R6G-3AJV>].

80. See Joly et al., *supra* note 6, at 356 (labeling this policy mechanism the “rational discrimination approach”).

81. See *supra* Part II.

tional discrimination approach limits insurer use to risk characteristics that have actuarial justification. In other words, insurers are only allowed to practice fair discrimination, not unfair discrimination.

So far, this approach appears to be the same as the status quo at the state level. The distinction, however, is the rational discrimination approach adds an additional requirement of transparency or oversight to the system. Under the Joly conception, the rational discrimination approach accepts the premise that it is important for insurers to have access to and the ability to utilize actuarially relevant information but removes the final determination of what constitutes sufficient actuarial evidence from the insurance industry itself.<sup>82</sup> Independent review adds some social fairness concerns back into the actuarial picture by ensuring that information used by insurers is scientifically valid and supported by actuarial evidence. This policy mechanism does not address all societal concerns regarding fairness since insurers would still be allowed to deny insurance or charge higher premiums for individuals with genetic test results that meet actuarial standards. Thus, it targets only irrational discrimination or misuse of genetic test results rather than broadly prohibiting all discrimination.<sup>83</sup>

Three policies based in varying degrees upon this mechanism, one implemented in the United Kingdom and two proposed in the United States and Australia, are presented below. They raise a myriad of questions, such as whether independent review of genetic test results is needed when this is not required of insurers for other types of medical information, why the United States and Australian examples were never fully implemented, and what standards such independent bodies would use to find actuarial relevance. After a brief presentation of the three policies, the remainder of the Article will examine these normative questions regarding whether the rational discrimination approach is sound policy and whether it should be recommended and implemented in the future.

### 1. *United Kingdom Moratorium and Concordat*

The United Kingdom has one of the longest standing policies regulating insurer use of genetic test results. Since 2001, the Association of British Insurers (ABI) has voluntarily agreed to a moratorium on the use of most predictive genetic test results.<sup>84</sup> This moratorium is supported by a Concordat between the government and the ABI.<sup>85</sup> The Concordat sets out the terms of cooperation between the government

---

82. See Joly et al., *supra* note 6, at 356.

83. *Id.* See *infra* sections VI.D and VIII.A for further discussion.

84. The U.K. moratorium is specifically narrowed to predictive genetic test results and does not consider the diagnostic testing. ASS'N OF BRITISH INSURERS, *supra* note 43, at 1.

85. *Id.*

and ABI to ensure that “insurers’ use of genetic information is transparent, fair and subject to regular reviews.”<sup>86</sup> Under the agreement and moratorium, insurers will not require disclosure of predictive genetic test results up to specific policy limits.<sup>87</sup> Thus, for policies under the set limits, insurers agreed to a prohibitive ban on the use of all predictive genetic test results. These limits are set for life insurance (£500,000), critical illness (£300,000), and income protection (£30,000 annually). For policies with amounts greater than the agreed limits, insurers can collect and use the results of those predictive genetic tests that have been approved by an established governmental body, the Genetics and Insurance Committee (GAIC).<sup>88</sup> To date, GAIC has only approved the use of a genetic test for Huntington’s Disease in life insurance applications over £500,000.<sup>89</sup> Although more applications were initially submitted to the GAIC, after procedure clarification, no new applications have been submitted in over a decade.<sup>90</sup>

## 2. Australian Guidance

In 2003, the Australian Law Reform Commission and the Australian Health Ethics Committee (AHEC) of the National Health and Medical Research Council undertook an extensive analysis regarding protection of genetic test results across many sectors of society.<sup>91</sup> In their analysis of insurance, they focused on standards of actuarial justification.<sup>92</sup> The Australia Disability Discrimination Act bans discrimination on the basis of a disability but has an exception for insurers as long as any differentiation is “based upon actuarial or statistical data” or “in a case where no such actuarial or statistical data is available and cannot reasonably be obtained—the discrimination is reasonable having regard to any other relevant factors.”<sup>93</sup> After inquiry and review, the working group determined there was no present need to alter the fundamental principles of the insurance market and impose any bans on insurer use of genetic test results.<sup>94</sup> Therefore, the working group opted towards a status quo approach to insurer use of genetic test results.

---

86. *Id.* at 1.

87. *Id.* at 7.

88. *Id.*

89. GAIC SECOND REPORT, *supra* note 65, at 7.

90. *See infra* section VII.B.

91. AUSTRALIAN LAW REFORM COMM’N & AUSTRALIAN HEALTH ETHICS COMM., ESSENTIALLY YOURS: THE PROTECTION OF HUMAN GENETIC INFORMATION IN AUSTRALIA 667–733 (2003) [hereinafter ESSENTIALLY YOURS].

92. *Id.*

93. *Disability Discrimination Act 1992* (Cth) s 46(1)(f), (g) (Austl.); ESSENTIALLY YOURS, *supra* note 91, at 671–72.

94. ESSENTIALLY YOURS, *supra* note 91, at 693.

However, the working group did suggest a number of improvements to insurance risk classification systems.<sup>95</sup> Given the complexities and rapidly developing science behind genetic testing, the working group ultimately suggested there be independent oversight to determine which genetic tests are appropriate for insurer use. The working group believed “independent oversight would help to build public confidence that genetic test information is being used to discriminate only in the limited circumstances permitted by law and that insurers’ use of genetic test information is transparent and based on objective information.”<sup>96</sup> Thus, although the working group initially followed a status quo approach, it proposed implementation of a rational discrimination approach. Following the recommendations, the government established the Australian Human Genetics Commission to examine issues related to genetics and insurance, among other roles, although it has since been disbanded without implementing the independent review.<sup>97</sup>

### 3. *U.S. Uniform Law Commission Proposal*

In 2010, the Uniform Law Commission developed a draft document titled the “Uniform Protection of Genetic Information in Employment and Insurance Act.”<sup>98</sup> While the Commission eventually approved a modified version of the employment section of this draft, the insurance section was never adopted and remained only in draft form. Under the draft language, unless a genetic test meets certain delineated standards, life, long-term care, and disability insurers are prohibited from “knowingly obtain[ing] or directly or indirectly inquir[ing] about, request[ing] or requir[ing] an insured to provide the insured’s genetic information based on a genetic test.”<sup>99</sup> These standards require the insurer to file with the state commissioner of insurance “the test and documentation supporting to a reasonable degree of scientific certainty the test’s analytical validity, clinical validity, and a scientific association between the test and an increased risk of morbidity and mortality.”<sup>100</sup>

---

95. *Id.* at 699.

96. *Id.* at 707.

97. *Human Genetics Advisory Committee (HGAC)*, AUSTRALIAN GOV’T NAT’L HEALTH & MED. RES. COUNCIL, <https://www.nhmrc.gov.au/about/nhmrc-committees/previous-committees-and-advisory-groups/human-genetics-advisory-committee-hga> [<https://perma.unl.edu/HY4X-8SHM>] (last updated June 30, 2016).

98. DRAFT UNIFORM PROTECTION OF GENETIC INFORMATION IN EMPLOYMENT AND INSURANCE ACT (NAT’L CONFERENCE OF COMM’RS ON UNIF. LAWS 2010).

99. *Id.* § 304(a). Section 301(7) defines genetic information in the context of life insurance, disability income insurance, and long-term care insurance as “(A) the results of a genetic test; (B) information based on the genetic test of an individual or an individual’s family member; or (C) information that an individual or an individual’s family requested or received genetic services.”

100. *Id.* § 306.

The Commission's draft is, therefore, a softer version of the rational discrimination policy approach because it requires documentation to be filed with, but not approved by, an independent organization. This was a calculated decision by the drafting committee—it notes it considered requiring insurance regulators or geneticists to make a prior finding of scientific evidence before a genetic test could be used but ultimately left the determinations in the hand of the insurers:

The approach selected by the Committee requires an insurance company to identify genetic tests that it plans to use and to file documentation supporting the validity of the test with the state insurance commissioner. This documentation would then be open to public scrutiny, creating transparency that can provide a check on a company's determination.<sup>101</sup>

#### IV. RISK CLASSIFICATION AND ECONOMIC EFFICIENCY

The rational discrimination approach to regulating insurer use of genetic test results has been successful in the United Kingdom, but the proposals in the United States and Australia were never adopted. Should such proposals be reexamined or implemented in the United States or Australia, or was failure to implement the proposals sound public policy? To answer this question, this Article turns to an in-depth analysis and understanding of the insurance risk classification process.<sup>102</sup>

##### A. Classifying Risk

A core function of insurance companies is to convert information about potential applicants, called risk characteristics, into calculations of the likelihood that a covered event will occur at a specified time and the potential severity of the event.<sup>103</sup> Life insurers gauge the life expectancy of particular population cohorts.<sup>104</sup> Disability and long-term care insurers evaluate the probability that a subgroup of individuals will, respectively, become unable to work or develop a disease or condition that requires extended care.<sup>105</sup> In life insurance, the maximum claim paid is the predetermined benefit amount payable upon death; the only uncertainty is the individual's life expectancy. If death is expected to be imminent, the insurer is less likely to gather

---

101. *Id.* (reporter's notes).

102. The background on risk classification comes predominately from the American regulatory and professional perspective, although the underlying principles and practices will be similar in the United Kingdom and Australia.

103. ON RISK CLASSIFICATION, *supra* note 24, at 71.

104. *Id.* at 4.

105. AM. ACAD. OF ACTUARIES, RISK CLASSIFICATION IN VOLUNTARY INDIVIDUAL DISABILITY INCOME AND LONG-TERM CARE INSURANCE 1, 3 (2001) [hereinafter RISK CLASSIFICATION IN DI AND LTC INSURANCE], [http://www.actuary.org/pdf/health/issue\\_genetic\\_021601.pdf](http://www.actuary.org/pdf/health/issue_genetic_021601.pdf) [<https://perma.unl.edu/Z4GC-RQE5>].

sufficient premium amounts in the short time, unless the premiums are exorbitantly high. If applicants' life expectancies are projected to be longer, the insurer is more likely to recoup the value of total expected costs in aggregated premiums.<sup>106</sup> Beyond the timing of the event, disability and long-term care insurers must additionally assess the potential severity of a claim in order to estimate the potential claim payout. The severity of these claims depends not only on the likelihood of the person developing a covered condition or disease but also on other factors, such as how long the condition is expected to last, the likelihood of recovery or recurrence, and the extent or nature of care needed.<sup>107</sup>

Taken together, insurers leverage information about both timing and severity of claims to establish risk classes based upon similar levels of risk.<sup>108</sup> Applicants in the same risk class may have quite different reasons for their assessed risk but will nevertheless be grouped together given their comparable likelihoods of covered events. For example, applicants in remission for cancer and those who are obese may be placed in the same risk class despite the distinct underlying causes of their increased risk.<sup>109</sup>

Risk classification is the process of establishing classes for the entire population of insureds.<sup>110</sup> The related concept of underwriting is the process of reviewing an individual's application and characteristics and placing him or her into a pre-defined risk class.<sup>111</sup> Three in-

---

106. Different types of life insurance policies would affect this balance between premiums and life expectancy. In term life insurance, for example, a policy holder is only insured for a set period of time, often ten years. Wortham, *supra* note 42, at 847–48. If applicants' life expectancies are generally greater than the policy term, the insurer can charge lower premiums across the group as long as premiums sufficiently account for the chances that some individuals will die during the term, despite risk predictions. *Id.* In contrast, whole life insurance provides coverage for an individual's life span, which guarantees an eventual payout assuming the policy remains in effect and premiums are paid. *Id.*

107. *See generally* RISK CLASSIFICATION IN DI AND LTC INSURANCE, *supra* note 105, at 6; COMM. ON RISK, AM. ACAD. OF ACTUARIES, RISK CLASSIFICATION: STATEMENT OF PRINCIPLES 1 (2014) [hereinafter STATEMENT OF PRINCIPLES], <http://www.actuarialstandardsboard.org/wp-content/uploads/2014/07/riskclassificationSOP.pdf> [<https://perma.unl.edu/AA3Q-8R7G>].

108. *See* ON RISK CLASSIFICATION, *supra* note 24, at 4, 71; Stone, *supra* note 23, at 293 (defining risk class as “a group of people with similar probabilities of becoming sick or, perhaps more accurately, with similar probabilities of generating costs to a company”).

109. *See* ON RISK CLASSIFICATION, *supra* note 24, at 33 (using the example of homeowners insurance and noting that while different geographic territories will have different population densities or proximities to fire departments, they could still be grouped together based on their overall risk probabilities).

110. *See generally id.*

111. STATEMENT OF PRINCIPLES, *supra* note 107, at 7 (“Development of an appropriate risk classification system is done without specific regard to any of the individual risks to be assumed. It is done a priori and establishes the framework within

surer determinations, based on risk classification and expected cost, greatly affect individuals and their policies: decisions regarding whether to accept or deny an applicant, coverage decisions regarding the level of benefits included in the policy, and rating decisions regarding the premium level of the policy.<sup>112</sup> An individual with high risk may be placed in a risk class with particularly high premiums or with exclusions for certain conditions, such as a disability insurance policy that excludes coverage for cancer. For cases with extremely high expected costs or preexisting conditions, the insurer may deny an application.<sup>113</sup>

## B. Why Insurers Classify Risks

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.<sup>114</sup> For example, to avoid increased insurance premiums, individuals may adopt safer driving habits minimizing tickets or accidents.

---

which underwriting can be performed. Underwriting is the process of determining the acceptability of a risk based on its own merits. In contrast to the assignment of a risk to a class based on general criteria, the underwriting process involves an evaluation of the individual and possibly unique characteristics of each risk.”); Kenneth S. Abraham, *Efficiency and Fairness in Insurance Risk Classification*, 71 VA. L. REV. 403, 408 (1985) [hereinafter *Efficiency and Fairness*]. In group policies, such as those offered by employers, individual employees do not go through extensive underwriting—that is, insurers do not collect information about risk characteristics at the individual level. See Susan M. Wolf & Jeffrey P. Kahn, *Genetic Testing and the Future of Disability Insurance: Ethics, Law & Policy*, 35 J.L. MED. & ETHICS 6, 14 (2007). But see AM. COUNCIL OF LIFE INS., *supra* note 67, at 12 (noting there are some occasions where individuals in group policies may go through underwriting). Instead, the insurer bases expected costs on historical data or broader population estimates. Wolf & Kahn, *supra*, at 14.

112. Jill Gaubling, *Race, Sex, and Genetic Discrimination in Insurance: What's Fair*, 80 CORNELL L. REV. 1646, 1651 (1994); Wortham, *supra* note 42, at 844–45.
113. Rejection of an application is less likely than an offer of limited coverage or of full coverage with a high premium. Historically, greater percentages of the population were deemed to be uninsurable, but life insurance companies realized that they could create a market for insuring these so-called substandard risks. Stone, *supra* note 23, at 295–96. However, despite increased willingness to insure those with substandard risk, there still remain some occasions where insurers opt for an outright denial. AM. COUNCIL OF LIFE INS., *supra* note 67, at 46 (noting insurers may deny insurance when the anticipated mortality is above five hundred percent of standard); Stone, *supra* note 23, at 295–96.
114. *Efficiency and Fairness*, *supra* note 111, at 431; Maria O'Brien Hylton, *Insurance Risk Classifications After McGann: Managing Risk Efficiently in the Shadow of the ADA*, 47 BAYLOR L. REV. 59, 94 (1995). The flip side of this argument is the oft-referenced concern of moral hazard. See *Understanding Insurance*, *supra* note 32, at 206–07. Failure of insurers to consider certain risk factors may cause individuals to take less care of themselves or pay less attention to mitigating their risk. See *id.*

Similarly, 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. To motivate risk reduction, individuals must know both why they were charged increased rates and that future rates could be adjusted given changes in behavior.<sup>115</sup>

Second, risk classification facilitates pricing that is actuarially fair, where an individual's premiums are proportional to his or her expected risks.<sup>116</sup> Some level of redistribution and subsidization is inherent in any insurance system. Given the statistical nature of grouping risks, even in risk classes with very similar risks, half the group members will fall below the average risk and half above.<sup>117</sup> Ideally, however, risk classification limits the redistribution to differences among the group that are unknown, unmeasurable, too costly or impractical to measure, or based on chance.

Pricing individuals proportional to their risk also minimizes adverse selection. When insurers have incomplete risk information about an applicant, they will be unable to accurately assess expected costs and appropriate premiums leading to two events, depending upon the direction of the disproportionality. Premiums more expensive than the expected cost or loss, as perceived by the applicant, may lead applicants to forgo insurance. Alternatively, premiums perceived to be a bargain given expected risk are more likely to induce the purchase of insurance.

The asymmetry of information inherent to the problem of adverse selection can stem from both external and internal causes.<sup>118</sup> Internally, adverse selection can arise if insurance companies do not properly classify risk<sup>119</sup> or fail to ask for all relevant information,<sup>120</sup>

---

115. Additionally, the original risk classifications have to be accurate and based upon experience rating. Holmes, *supra* note 25. Similarly, for moral hazard to be a risk, the individual must control at least some part of the characteristic and there must be a causal link between the characteristic and the risk. *Understanding Insurance*, *supra* note 32, at 207.

116. See STATEMENT OF PRINCIPLES, *supra* note 107, at 6.; Holmes, *supra* note 25, at 539; *supra* Part II. Absent fairness arguments, others argue efficient pricing is the only way that insurance will function. See Peter Siegelman, *Information & Equilibrium in Insurance Markets with Big Data*, 21 CONN. INS. L.J. 317, 332 n.42 (2014).

117. STATEMENT OF PRINCIPLES, *supra* note 107, at 10 (“The occurrence, timing and magnitude of an unforeseen event for a specific risk cannot be predicted in advance. Thus, it is inevitable that not all risks in a class will have identical actuarial claim experience. Instead, the individual risk's claim experience will be statistically distributed around the average experience for the class.”).

118. See Avraham et al., *supra* note 63.

119. See ON RISK CLASSIFICATION, *supra* note 24, at 27 (noting there is risk of adverse selection if prices do not accurately reflect costs).

causing pricing that is disproportionate to expected risk. Internal adverse selection is especially hazardous in competitive insurance markets where lower risk individuals can apply for an insurance policy with a company that calculates risk differently<sup>121</sup> or can opt to go without insurance.<sup>122</sup> Externally, applicants can cause information asymmetry if they intentionally withhold risk information from insurers.<sup>123</sup> Additionally, adverse selection occurs when legislation limits insurers' ability to collect or use risk characteristics, such as prohibitions on insurer use of gender or race, or, as relevant here, in the prohibitive approach to genetic test results. Sometimes referred to as regulatory adverse selection, this legislation externally forces asymmetric information between insurers and applicants.<sup>124</sup>

### C. Choosing a Risk Characteristic

An individual's expected cost determines whether an applicant is accepted, at what premium level, and with what covered benefits. Expected costs are determined from data on risk classes, which are grouped by levels of risk depending upon the risk characteristics chosen by insurers.<sup>125</sup> There are countless potential risk characteristics, but insurers choose a limited set when establishing their systems. Several considerations, including statistical, operational, and social, assist actuaries with determining which characteristics to employ.<sup>126</sup>

- 
120. As a contract of good faith, or *uberrimae fidei*, there is an argument an insurance applicant has a duty to disclose all relevant information regarding risk to the insurer. *Stipcich v. Metro. Life Ins. Co.*, 277 U.S. 311, 316 (1928). However, there is legal precedent that insureds do not have a duty to disclose unrequested information. *Id.* at 316–17 (finding that information is immaterial if it is not asked for on insurance applications); see also Siegelman, *supra* note 64, at 1261–63 (discussing times when insurers fail to collect information from applicants). See generally Anya E.R. Prince, *Tantamount to Fraud: Exploring Non-Disclosure of Genetic Information in Life Insurance Applications as Grounds for Policy Rescission*, 26 HEALTH MATRIX 255 (2016).
121. STATEMENT OF PRINCIPLES, *supra* note 107; Rick Swedloff, *Risk Classification's Big Data (R)Evolution*, 21 CONN. INS. L.J. 339, 345 (2014).
122. Swedloff, *supra* note 121, at 346; see also Baker, *supra* note 33, at 380 (noting that mandating universal insurance would avoid concerns of adverse selection).
123. See ON RISK CLASSIFICATION, *supra* note 24, at 4.
124. *E.g.*, Avraham et al., *supra* note 63; Michael Hoy & Michael Ruse, *Regulating Genetic Information in Insurance Markets*, 8 RISK MGMT. & INS. REV. 211, 214 (2005).
125. See generally *Understanding Insurance*, *supra* note 32.
126. There is no set way of presenting these considerations in the literature. This Article chooses three categories—statistical, operational, and social—as overarching frameworks for the multiple considerations discussed in the literature. See generally STATEMENT OF PRINCIPLES, *supra* note 107, at 9–15 (discussing considerations in designing risk-classification systems); ON RISK CLASSIFICATION, *supra* note 24, at 32–37 (generally discussing factors that go into choosing a risk classification system); *Efficacy and Fairness*, *supra* note 111, at 409–20 (discussing five features of a fair risk-classification system); Robert J. Finger, *Risk Classifi-*

### 1. *Statistical Considerations*

The process of selecting risk characteristics is not an exact science, and each risk classification system may be different.<sup>127</sup> At the most basic level, insurers will, quite intuitively, not use information about an individual that does nothing to help predict risk. “Since not every observable quality of a risk subject provides information that is sufficiently useful . . . , not every observable quality is a risk characteristic.”<sup>128</sup> Instead, insurers employ risk characteristics that promote actuarially fair pricing. Insurers begin with the baseline ideals that risk characteristics and their effects on risk should be accurate, reliable, and have predictive stability over time.<sup>129</sup> However, there are many qualities, observable and unobservable, that affect risk but cannot be accounted for in a risk classification system.<sup>130</sup> Thus, completely accurate risk measurement is a goal that can be approached but never fully achieved.<sup>131</sup>

Overall, insurers want to make risk classes as homogeneous as possible in their risk probabilities and expected cost.<sup>132</sup> Calculating expected costs uses tools of actuarial science that are based upon statistical analysis, which requires large enough groups to add credibility to the analysis. Thus, actuaries must balance between considerations of refined and homogenous risk classes with sufficiently large, and therefore credible, risk classes.<sup>133</sup> For example, the Actuarial Standards Board, the organization that develops standards and guidance

---

*cation*, in FOUNDATIONS OF CASUALTY ACTUARIAL SCIENCE 287, 292–301 (1st ed. 1990); Michael A. Walters, *Risk Classification Standards*, 68 PROCEEDINGS CASUALTY ACTUARIAL SOC’Y 1, 7–9 (1981) (delineating seven standards that promote homogeneity, reasonable relationships between characteristics and risk, and characteristics that are well-defined and practical).

127. STATEMENT OF PRINCIPLES, *supra* note 107, at 11.

128. ON RISK CLASSIFICATION, *supra* note 24, at 4.

129. See STATEMENT OF PRINCIPLES, *supra* note 107, at 11 (discussing the need for predictive stability); *Efficiency and Fairness*, *supra* note 111, at 412 (noting the need for risk characteristics to be reliable); Wortham, *supra* note 42, at 846 (noting that risk characteristics should be stable, reliable, and administratively convenient).

130. ON RISK CLASSIFICATION, *supra* note 24, at 32.

131. Soc’y of Actuaries, *Principles of Actuarial Science*, 44 TRANSACTIONS SOC’Y ACTUARIES 565, 599 (1992) (arguing “accuracy” is a poor principle because of the tendency to mislead). Additionally, the risk characteristics employed are also likely not completely accurate, thus introducing further uncertainty into the model.

132. See generally ACTUARIAL STANDARD OF PRACTICE NO. 12 (ACTUARIAL STANDARDS BD. 2005), [http://www.actuarialstandardsboard.org/pdf/asops/asop012\\_101.pdf](http://www.actuarialstandardsboard.org/pdf/asops/asop012_101.pdf) [<https://perma.unl.edu/EVA2-EPXR>]; ON RISK CLASSIFICATION, *supra* note 24; STATEMENT OF PRINCIPLES, *supra* note 107; *Efficiency and Fairness*, *supra* note 111.

133. See ON RISK CLASSIFICATION, *supra* note 24, at 51 (“Achieving a balance between homogeneity and credibility is a major consideration in the establishment of risk classes.”).

for actuaries involved in developing and updating risk classification systems, notes: “It is desirable that risk classes in a risk classification system be large enough to allow credible statistical inferences regarding expected outcomes. When the available data are not sufficient for this purpose, the actuary should balance considerations of predictability with considerations of homogeneity.”<sup>134</sup>

Occupation provides an illustrative example of this concept. Suppose a disability insurer takes into account a person’s occupation in his or her risk classification and therefore utilizes *physician* as a risk characteristic. However, based on historical data, the insurer finds that certain sub-specialties are riskier than others. For example, emergency room physicians may be more likely to submit insurance claims than others. The insurer may consider refining the risk class by physician specialty. However, if there are a limited number of people in certain physician specialties, there may not be sufficient historical data to produce credible estimates of risk across all sub-specialties.<sup>135</sup> Thus, the actuaries establishing this risk classification system would have to balance the increased homogeneity of physician sub-specialties with the potential decreased statistical accuracy.

## 2. Operational Considerations

If statistical considerations push actuaries to strive for the most efficient and ideal risk classification system, operational considerations pull the actuaries back to earth and ground them in the realities. For example, a primary operational consideration is the administrative burden of employing a risk characteristic. Insurers will not use a risk characteristic if the administrative expense is more than the value it provides in differentiating individuals into separate risk classes, even when the characteristic improves prediction of risk.<sup>136</sup> Operational considerations encourage the use of risk characteristics that ease the burden on underwriters. Desirable risk characteristics have objective definitions and are measurable and verifiable.<sup>137</sup>

It is inexpensive and easy to determine an insured’s sex; it is expensive and difficult to determine his or her habits and character. Some variables are made on the basis of risk classes, then, not because they are more accurate or

---

134. ACTUARIAL STANDARD OF PRACTICE NO. 12 § 3.3.2 (ACTUARIAL STANDARDS Bd. 2005), [http://www.actuarialstandardsboard.org/pdf/asops/asop012\\_101.pdf](http://www.actuarialstandardsboard.org/pdf/asops/asop012_101.pdf) [<https://perma.unl.edu/EVA2-EPXR>].

135. See ON RISK CLASSIFICATION, *supra* note 24, at 51 (explaining the credibility of data for an occupation as a whole will be greater than the credibility of the data for each specialty).

136. STATEMENT OF PRINCIPLES, *supra* note 107, at 7.

137. *Id.* at 13. Some view this as an operational consideration since measurability and verifiability streamline the underwriting process. See *id.*

preferable to others in any ultimate sense, but because they are available and useful.<sup>138</sup>

Another common operational goal is to minimize applicants' abilities and desires to manipulate their apparent risk. Actuaries aim for risk characteristics that are difficult to misrepresent on applications.<sup>139</sup> For example, if asked about the number of cigarettes or alcoholic beverages one has each week, an applicant could easily disclose a deflated amount. An applicant's ability to manipulate his or her application is directly tied to the measurability or verifiability of a characteristic. Individuals could similarly try to manipulate information about their weight, but this is more likely to be reported in medical records and thus subject to insurer follow-up and evaluation if the information in medical records and the application conflict.<sup>140</sup>

### 3. *Social Considerations*

Ultimately, an insurer could develop an extremely efficient and accurate risk classification system but be left without consumers to join the pool if the criteria it uses are objectionable to the public. Thus, when establishing a risk classification system, insurers weigh societal views of acceptability.<sup>141</sup> Four common factors affect the public's tolerance for use of a risk characteristic. While the mathematical modeling and actuarial science do not require consideration of any of these factors when designing a theoretically efficient risk classification system, insurers may end up considering them due to the economic impact of consumer preferences or objections.

First, from the consumer perspective, the degree to which an individual can control a characteristic alters perceptions of fairness.<sup>142</sup> Arguably, it is patently unfair to deny someone insurance or charge higher premiums based on a risk factor that is not a choice. Under this logic, characteristics such as race and gender are more likely proscribed from use in risk classification than factors within the individual's control such as smoking or an individual's geographic area.<sup>143</sup>

---

138. DISTRIBUTING RISK, *supra* note 32, at 85.

139. STATEMENT OF PRINCIPLES, *supra* note 107, at 13.

140. An applicant's motivation to manipulate his data is minimized if insurers avoid extreme discontinuities between risk classes. ON RISK CLASSIFICATION, *supra* note 24, at 47–48. When a risk characteristic is a continuous variable, such as age or blood pressure, setting cutoff thresholds for each risk class can lead to large jumps in premium as one moves along the continuum. *Id.*

141. STATEMENT OF PRINCIPLES, *supra* note 107, at 14. Although similar, Abraham classifies this as "admissibility." See *Efficiency and Fairness*, *supra* note 111, at 419–20.

142. See *Understanding Insurance*, *supra* note 32, at 214–15 (noting individual control is possibly the most frequently cited social fairness argument); Holmes, *supra* note 25, at 563.

143. Gaulding, *supra* note 112, at 1674.

This argument's underpinnings stem from egalitarian theories of distributive justice such as from John Rawls and Norman Daniels.<sup>144</sup> Drawing from Rawls's veil of ignorance, a professor discussing actuarial versus social fairness notes:

If an individual does not know that he would be born into a set of circumstances that would lead to diabetes and hypertension or to healthy longevity, how would he set the insurance premiums from the position of uncertainty? Behind a veil of ignorance, any rational, risk-averse person would choose community rating, that is, charging everyone the same price, regardless of risk, except when that risk is significantly within our control.<sup>145</sup>

Of course, individual control is a conceptual distinction fraught with controversy.<sup>146</sup> For example, behaviors such as smoking or drinking that are outwardly personal choices may in fact be less controllable for individuals with tobacco addiction or alcohol dependency.<sup>147</sup> Similarly, geographic ratings are commonly used risk factors in home and auto insurance, but where one lives may be less a matter of choice than of economic, familial, or professional necessity or, most problematic, of societal discrimination.<sup>148</sup> Normatively, it seems that social objections to using involuntary risk characteristics depend in part on how they are framed. For example, taking family history into account raises fewer hackles than other uncontrollable traits.

Second, fair discrimination and actuarial justification require only statistical correlation, not causation.<sup>149</sup> However, the social acceptability of the use of a characteristic increases if the trait is intuitively related to cost.<sup>150</sup> For example, while age is clearly linked to expected costs for life insurers, the use of credit scores in auto insurance may raise eyebrows given the tenuous relationship between the characteristic and expected cost. The further removed a characteristic is from the actual cause of loss, the more questionable its use becomes.<sup>151</sup> In

---

144. DISTRIBUTING RISK, *supra* note 32; Holmes, *supra* note 25, at 577.

145. Saurabh Jha, *Punishing the Lemon: The Ethics of Actuarial Fairness*, 9 J. AM. C. RADIOLOGY 887, 888 (2012).

146. *See Understanding Insurance*, *supra* note 32, at 215 (noting characteristics that ostensibly are matters of choice, such as smoking, eating, or working out, may be the result of habit, addiction, or socioeconomic factors beyond the control of the individual).

147. DISTRIBUTING RISK, *supra* note 32, at 29.

148. *See id.* (calling an individual's choice of where they live "semidetermined" and noting that classification in fire and auto insurance should account for this lack of complete control when setting rates).

149. ACTUARIAL STANDARD OF PRACTICE NO. 12 §§ 3.2.1, 3.2.2 (ACTUARIAL STANDARDS Bd. 2005), [http://www.actuarialstandardsboard.org/pdf/asops/asop012\\_101.pdf](http://www.actuarialstandardsboard.org/pdf/asops/asop012_101.pdf) [<https://perma.unl.edu/EVA2-EPXR>]; Gaulding, *supra* note 112, at 1658; Jha, *supra* note 145, at 887 ("Yet for insurers seeking to slice and dice the population into a profitable mix, correlation is sufficient.").

150. Finger, *supra* note 126, at 296.

151. Austin, *supra* note 30, at 559–63; Gaulding, *supra* note 112.

these cases, either a characteristic is a proxy factor for a variable that is much harder to identify or measure<sup>152</sup> or insurers are using a characteristic as a measure of risk simply for convenience,<sup>153</sup> both of which are problematic motivations from a social acceptability perspective.

Third, an insurance classification system is less likely to be acceptable to consumers if it leads to unaffordable premiums. As insurance classification systems become more refined, groups in the highest risk classifications could face steep premiums, which may effectively bar them from entering the market. For example, insurer use of genetic test results raises the specter of a genetic underclass.<sup>154</sup> Even absent fears of alienating portions of society, insurers may strive for increased affordability to avoid public perceptions that the system is inaccessible to some and therefore unjust.<sup>155</sup>

Finally, the use of a risk characteristic may be socially unacceptable if it is viewed as a violation of privacy. An insurance applicant may not bat an eye at providing information regarding occupation, age, or marital status but may view questions about psychological disorders, genetic test results, or sexual orientation as unacceptable invasions of privacy. Additionally, insurer access to information about the public without its knowledge or consent may violate notions of privacy and therefore acceptability.<sup>156</sup>

---

152. *Hartford Accident & Indem. v. Ins. Comm'r*, 482 A.2d 542, 550 (Pa. 1984) (Hutchinson, J., concurring) (“What does appear is only a statistical correlation between sex and the incidence of auto accidents. This correlation simply provides a convenient measuring rod for setting rate differentials occasioned by other factors not so easily identified or quantified.”)

153. *Id.*; *Nondiscrimination in Insurance: Hearing on H.R. 100 Before the H. Comm. on Interstate & Foreign Commerce*, 96th Cong. (1980) (statement of Hon. Barbara Mikulski); Austin, *supra* note 30, at 534 (“However much the companies plead happenstance, insurance ‘risk’ classifications correlate with a fairly simplistic and static notion of social stratification that is familiar to everyone.”).

154. See Holmes, *supra* note 25, at 569; Subramanian et al., *supra* note 53, at 532.

155. See ON RISK CLASSIFICATION, *supra* note 24, at 59 (noting an insurance system may consider questions of affordability due to public perceptions, even if this makes it more difficult to attain other criteria).

156. For example, in 2014 there was an uproar in the United Kingdom when it was publicized that insurers were accessing aggregate, anonymous patient data from the National Health System (NHS). See Amie Keeley, *The Society Which Used Data on Every NHS Patient—And Used It to Guide Insurance Companies on Premiums*, DAILYMAIL (Feb. 23, 2014), <http://www.dailymail.co.uk/news/article-2566397/The-insurance-firms-buy-data-NHS-patient.html>; Randeep Ramesh, *NHS Patient Data to Be Made Available for Sale to Drug and Insurance Firms*, GUARDIAN (Jan. 19, 2014), <https://www.theguardian.com/society/2014/jan/19/nhs-patient-data-available-companies-buy> [<https://perma.unl.edu/4TBS-CAYS>].

## V. GENETIC TEST RESULTS AND INSURANCE

## A. Genetic Test Results as Risk Characteristics

Although insurer use of predictive genetic test results is a recent possibility, insurers have long employed family history as an imperfect proxy for genetic risk.<sup>157</sup> Family history, however, is a notoriously inaccurate and imprecise risk prediction tool due, in part, to patients' potentially incomplete knowledge or misunderstanding of diagnoses.<sup>158</sup> Furthermore, family history is self-reported, making manipulation conceivable and verification nearly impossible. Especially when compared with family history, genetic test results meet many of the statistical and operational considerations important for risk classification because genetic test results can be verified and may be more accurate than family history in specific contexts.

Precise knowledge of hereditary risk also allows insurers to refine risk classes into more homogeneous groups. Huntington's Disease (HD), a fatal, neurodegenerative genetic condition,<sup>159</sup> can be used as an example. If one has a deleterious variant associated with HD, there is essentially a one hundred percent likelihood she will develop the disease, unless she dies prior to onset.<sup>160</sup> If an individual's parent has HD, he has a fifty percent chance of inheriting the HD variant and thus a fifty percent chance of developing the disease.<sup>161</sup> When only family history is available to an insurer, it may deny a policy or charge higher premiums to every individual with a family history of the disease.<sup>162</sup> However, if allowed to use both family history and genetic-test results, the insurer can accept those fifty percent who did not inherit the deleterious variant from their parent.<sup>163</sup> Here, use of genetic test results is arguably beneficial because insurance access expands due to the availability of more accurate risk predictors.

---

157. See AM. COUNCIL OF LIFE INS., *supra* note 67, at 26.

158. Elissa M. Ozanne et al., *Bias in the Reporting of Family History: Implications for Clinical Care*, 21 J. GENETIC COUNSELING 547, 547 (2012) (finding that accuracy of family history can depend upon whether the information is from the maternal or paternal side of the family); see R.J. Mitchell et al., *Accuracy of Reporting of Family History of Colorectal Cancer*, 53 GUT 291, 292 (2004). *But see* Harvey J. Murff et al., *Does This Patient Have a Family History of Cancer?: An Evidence-Based Analysis of the Accuracy of Family Cancer History*, 292 JAMA 1480, 1480 (2004) (finding that family history of some cancers in first-degree relatives is generally accurate but that other types of family history reporting are less accurate). See generally Eugene C. Rich et al., *Reconsidering the Family History in Primary Care*, 19 J. GEN. INTERNAL MED. 273 (2004).

159. Simon C. Warby et al., *Huntington Disease*, GENEREVIEWS, <https://www.ncbi.nlm.nih.gov/books/NBK1305> (last updated Dec. 11, 2014).

160. *Id.*

161. *Id.*

162. Holmes, *supra* note 25, at 540.

163. *Id.*; see AM. COUNCIL OF LIFE INS., *supra* note 67.

However, few genetic test results are as strongly predictive as HD. In fact, given the current state of clinical knowledge, much genomic information is remarkably unpredictable.<sup>164</sup> Many genetic test results fall along the continuum of one hundred percent predictive to completely unpredictable.<sup>165</sup> Therefore, the type of condition that is tested for greatly impacts the relevance it will have for risk classification.

Test results are also often much more complicated than a simple positive or negative; instead, the relevance of a test result must be interpreted in light of the individual being tested. Take, for example, a woman who has undergone genomic sequencing and is found to have a variant in the *BRCA1* gene. Individuals with harmful changes, called pathogenic variants, in *BRCA1/2* are more likely to develop breast or ovarian cancer than individuals in the general population.<sup>166</sup> Once a woman receives this result, she must undergo further evaluation. As a first step, the testing laboratory and doctors must determine whether the change in her genetic code is pathogenic (one that puts her at an increased risk of developing breast and ovarian cancer).<sup>167</sup> There are many different changes or variants that can appear in a gene, but not all are harmful.<sup>168</sup> The laboratory's interpretation may depend on the woman's type of genetic change, ethnicity, and family history of cancer.<sup>169</sup> Recent studies highlight relatively high rates of disagreement across laboratories when interpreting the same variants.<sup>170</sup>

Even if the laboratory classifies the woman's genetic change as a pathogenic variant, it does not necessarily mean she will develop cancer. Unlike HD, individuals with pathogenic variants in *BRCA1/2* will not always develop clinical symptoms. In genetics terminology, this is referred to as "penetrance," or the probability of developing the condition if one has a pathogenic variant in the associated gene.<sup>171</sup> Estimates of the penetrance of *BRCA1/2* greatly vary depending on the

---

164. See Michael C. Adams et al., *The Promise and Peril of Genomic Screening in the General Population*, 18 GENETICS MED. 593 (2015); Evans et al., *supra* note 15.

165. See PRIVACY AND PROGRESS, *supra* note 44, at 114–15.

166. *BRCA1* and *BRCA2* are genes associated with hereditary breast and ovarian cancer (HBOC). Nancie Petrucelli et al., *BRCA1- and BRCA2-Associated Hereditary Breast and Ovarian Cancer*, GENEREVIEWS, <https://www.ncbi.nlm.nih.gov/books/NBK1247> (last updated Dec. 15, 2016).

167. See Sue Richards et al., *Standards and Guidelines for the Interpretation of Sequence Variants: A Joint Consensus Recommendation of the American College of Medical Genetics and Genomics and the Association for Molecular Pathology*, 17 GENETICS MED. 405, 411 (2015).

168. See *infra* subsection VII.D.5.

169. See generally Richards et al., *supra* note 167.

170. Laura M. Amendola et al., *Performance of ACMG-AMP Variant-Interpretation Guidelines Among Nine Laboratories in the Clinical Sequencing Exploratory Research Consortium*, 98 AM. J. HUM. GENETICS 1067, 1067 (2016) [hereinafter Amendola et al., *Performance of Interpretation Guidelines*].

171. ESSENTIALLY YOURS, *supra* note 91.

study context but generally range from approximately 45–65% for breast cancer and 10–40% for ovarian cancer.<sup>172</sup> Thus, women with pathogenic variants in *BRCA1/2* are not guaranteed to have cancer but have a much greater risk than the lifetime risk for women in the general population—12.3% and 1.4%, respectively.<sup>173</sup>

Penetrance estimates vary greatly across genetic conditions. For example, familial adenomatous polyposis (FAP), a genetic condition associated with colon cancer, has essentially a one hundred percent chance of colon polyps and subsequent cancer.<sup>174</sup> In contrast, familial hypercholesterolemia (FH), a condition associated with coronary artery disease and heart attack, has a penetrance of fifty percent by age fifty.<sup>175</sup> At the other end of the spectrum, hereditary hemochromatosis, a condition related to high absorption of iron that, if untreated, can lead to organ failure, has an estimated overall penetrance of two percent or less; however, men display clinical symptoms more often than women.<sup>176</sup> Thus, genetic test results are not uniform. The results' relevance and meaning will differ, not just across genetic tests but across gender, ethnicity, and the extent of family history of disease.

A factor of paramount interest to insurers is the positive predictive value of a risk characteristic. In genetic testing, the positive predictive value of a risk characteristic is the proportion of individuals with positive test results who will develop the disease.<sup>177</sup> While insurers will weigh additional factors,<sup>178</sup> the positive predictive value is a particularly important metric because it directly relates to the accuracy of the

---

172. *Final Recommendation Statement: BRCA-Related Cancer: Risk Assessment, Genetic Counseling, and Genetic Testing*, U.S. PREVENTIVE SERVS. TASK FORCE, <http://www.uspreventiveservicestaskforce.org/Page/Document/Recommendation-StatementFinal/brca-related-cancer-risk-assessment-genetic-counseling-and-genetic-testing> [<https://perma.unl.edu/6DM3-RL52>] (last updated Dec. 2013); Petrucelli et al., *supra* note 166, at 246–47.

173. *Final Recommendation Statement*, *supra* note 172.

174. Kory W. Jasperson, Swati G. Patel & Dennis J. Ahnen, *APC-Associated Polyposis Conditions*, GENEREVIEWS, <https://www.ncbi.nlm.nih.gov/books/NBK1345> (last updated Feb. 2, 2017).

175. Emily Youngblom, Mitchel Pariani & J.W. Knowles, *Familial Hypercholesterolemia*, GENEREVIEWS, <https://www.ncbi.nlm.nih.gov/books/NBK174884> (last updated Dec. 8, 2016).

176. Rebecca Seckington & Lawrie Powell, *HFE-Associated Hereditary Hemochromatosis*, GENEREVIEWS, <https://www.ncbi.nlm.nih.gov/books/NBK1440> (last updated Sept. 17, 2015). These penetrance estimates refer to clinically defined symptoms. *Id.* While people with pathogenic variants in the gene associated with hemochromatosis are likely to develop biochemically defined iron overload, they are unlikely to present clinical symptoms. *Id.*

177. AM. COUNCIL OF LIFE INS., *supra* note 67, at 21; ROBERT DAVID CAMPBELL BRACKENRIDGE & W. JOHN ELDER, *MEDICAL SELECTION OF LIFE RISKS* 182 (Stockton Press 1992); GENETIC TESTING WORKING GROUP REPORT, *supra* note 63;

178. *See* BRACKENRIDGE & ELDER, *supra* note 177, at 184 (highlighting a list of other questions an insurer may consider).

characteristic as an approximation of risk. For a test with a sixty percent positive predictive value, sixty out of one hundred individuals who test positive will develop the condition. For an insurance company, this equates to forty people for whom the risk is not accurately calculated. An insurer may find this level of inaccuracy perfectly acceptable if there is no better test available to determine who will develop symptoms, or if the condition is severe and likely to result in high claim payouts. However, a lower positive predictive value may be unacceptable; these are determinations that must be made in light of the context and the statistical, operational, and social considerations.<sup>179</sup>

The positive predictive value of a clinical test is a measure of three factors: sensitivity, specificity, and prevalence.<sup>180</sup> Sensitivity is the ability of the test to measure true positives—the individuals who receive a positive test result and actually have the disease.<sup>181</sup> In other words, the more false negatives a test produces, the lower the sensitivity.<sup>182</sup> For example, if a test has a sensitivity of 0.7, seventy percent of people who will develop the disease will receive a positive test result—a true positive—and thirty percent of people who will develop the disease will receive a negative test result—a false negative. Specificity, on the other hand, is the ability of a test to measure true negatives; the more false positives a test produces, the lower the specificity.<sup>183</sup> If a test has a specificity of 0.8, eighty percent of people who truly do not have the disease will receive a negative test result—a true negative—and twenty percent of people who truly do not have the disease will receive a positive test result—a false positive.

The prevalence of a condition also affects the positive predictive value. Prevalence measures the rate of a disease in the entire population.<sup>184</sup> Prevalence alters the predictive value because as the rate of disease increases, the total number of positive tests will increase

---

179. See generally AM. COUNCIL OF LIFE INS., *supra* note 67, at 21; ON RISK CLASSIFICATION, *supra* note 24.

180. See Adams et al., *supra* note 164, at 593–94. The analytic validity also measures sensitivity and specificity, but this indicates whether the test actually works. See *ACCE Model List of 44 Targeted Questions Aimed at a Comprehensive Review of Genetic Testing*, CTNS. FOR DISEASE CONTROL & PREVENTION [hereinafter *ACCE Model*], [https://www.cdc.gov/genomics/gtesting/acce/acce\\_proj.htm](https://www.cdc.gov/genomics/gtesting/acce/acce_proj.htm) [<https://perma.unl.edu/DK4E-CJRU>]. Clinical validity is whether the results from the test indicate true disease, the relevant concept in this Article. *Id.*

181. Douglas G. Altman & J. Martin Bland, *Diagnostic Tests 1: Sensitivity and Specificity*, 308 BRIT. MED. J. 1552 (1994).

182. AM. COUNCIL OF LIFE INS., *supra* note 67, at 21.

183. *Id.*

184. Douglas G. Altman & J. Martin Bland, *Statistics Notes: Diagnostic Tests 2: Predictive Values*, 309 BRIT. MED. J. 102, 102 (1994).

while the number of false positives will decrease.<sup>185</sup> Thus, other factors being equal, conditions with higher prevalence are more likely to have a higher positive predictive values.<sup>186</sup>

It is important to remember sensitivity, specificity, and prevalence of genetic conditions are estimates based on current best understanding of genomics. Many factors will affect a genetic test's sensitivity and specificity. First, incomplete penetrance will increase the number of people who receive false positives because a portion of people who test positive will never develop the disease. Similarly, for some genetic conditions, the symptoms expressed range from mild to severe<sup>187</sup> or cause different underlying conditions.<sup>188</sup> For example, in FH, symptoms of coronary heart disease can have varying severity,<sup>189</sup> and *BRCA1/2* is associated with multiple diseases from breast or ovarian cancer to pancreatic and prostate cancers.<sup>190</sup> Such variable symptoms complicate insurance calculations because some individuals may experience symptoms severe enough to trigger an insurance claim while others will have mild symptoms but never need insurance. Finally, the number of genetic changes affecting disease complicates test interpretation and performance. These changes can be either within a gene—where a range of changes within the gene can cause symptoms—or across multiple genes—where, as in the case of *BRCA1/2*, changes in different genes can result in the same disease.<sup>191</sup>

Given the variability of penetrance, symptoms, underlying genetic causes, and other factors across genetic conditions, the operational, statistical, and social considerations of risk classification will also

185. Mathematically, the total number of positives equals the true positives plus the false positives. *Id.* The true positive rate equates to  $[prevalence * sensitivity]$ , a number that will increase as prevalence increases. *Id.* The number of false positives equates to  $[(1 - prevalence) * (1 - specificity)]$ , a number that will decrease as prevalence increases. *Id.*

186. Insurers may also be interested in negative predictive value. This is a measure of the proportion of individuals with negative test results that truly do not have the disease. *Id.* For example, if an insurer is accounting for negative test results in its risk classification system, it will want to make sure a large portion of negative results are not false negatives. AM. COUNCIL OF LIFE INS., *supra* note 67, at 21 (noting both negative and positive predictive value are relevant to insurers).

187. This is called “variable expressivity.” MARK SANDERS & JOHN BOWMAN, GENETIC ANALYSIS: AN INTEGRATED APPROACH G-11, G-17 (2012) (defining the term as “variation in the degree, magnitude, or intensity of expression of” the observable physical characteristics or traits).

188. In genetics, this is referred to as “pleiotropy.” *Id.* at G-12 (defining pleiotropy as “a single gene mutation that affects multiple and seemingly unconnected properties of an organism”).

189. Youngblom et al., *supra* note 175.

190. Petrucelli et al., *supra* note 166.

191. These concepts are referred to, respectively, as allelic heterogeneity and genetic heterogeneity. Charles R. Scriver, *Allelic and Locus Heterogeneity*, in ENCYCLOPEDIA OF LIFE SCIENCES (2006) (abstract).

vary across genetic tests. In some cases, genetic test results can make risk classes more homogenous, while in others a result may be too imprecise or inaccurate to be operationally or statistically useful. Conditions with high predictive values tend to be single-gene disorders, diseases caused by specific variants in one or a few genes, such as HD, *BRCA1/2*, and FH.<sup>192</sup> Conditions with low predictive values are more likely to be caused by multiple genes,<sup>193</sup> interactions between genes and the environment,<sup>194</sup> and genes with low penetrance.<sup>195</sup> Most genetic changes that are found to contribute to common diseases, such as diabetes and heart disease, fall in the complex, low-predictive category.<sup>196</sup> Despite the differences of predictive value across genetic conditions, debates regarding insurer use of genetic test results often reference highly penetrant genes such as *BRCA1/2* or HD without fully acknowledging the breadth of information that can be produced by genetic tests.<sup>197</sup> Indeed, single-gene disorders are very rare and account for only a small portion of the genomic information available from sequencing.<sup>198</sup> Additionally, as further study occurs through efforts such as the PMI, it is much more likely researchers will unearth complex associations with multiple gene and environmental causes and generally low predictive values than discover new single-gene disorders.<sup>199</sup> Thus, although discussions of insurer use of genetic test results often collapse all results into a monolithic concept, it is clear that failure to differentiate the types of genetic tests available misses significant nuances.

## B. Current Use of Genetic Test Results

In the ongoing debate over insurer use of genetic test results, two questions naturally arise. First, To what extent are these insurers accessing genetic test results? And second, To what extent are they using the results?

---

192. See GENETICS & INS. COMM., DEP'T OF HEALTH, FIRST ANNUAL REPORT (2000), [http://webarchive.nationalarchives.gov.uk/20120503132741/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/AnnualReports/DH\\_074080?ssSourceSiteId=ab](http://webarchive.nationalarchives.gov.uk/20120503132741/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/AnnualReports/DH_074080?ssSourceSiteId=ab) (discussing the differences between single-gene disorders, multigene disorders, and chromosomal disorders).

193. These are referred to as multigene conditions. *Id.*

194. These are referred to as multifactorial conditions. SANDERS & BOWMAN, *supra* note 187, at G-10.

195. GENETICS & INS. COMM., *supra* note 192.

196. *See id.*

197. *See generally* C.D. Daykin et al., *Genetics and Insurance—Some Social Policy Issues*, 9 BRIT. ACTUARIAL J. 787 (2003); Yann Joly et al., *Genetic Discrimination and Life Insurance: A Systematic Review of the Evidence*, 11 BMC MED. 1 (2013); Robert Klitzman, *Views of Discrimination Among Individuals Confronting Genetic Disease*, 19 J. GENETIC COUNSELING 68 (2010).

198. *See* PRIVACY AND PROGRESS, *supra* note 44, at 18.

199. Evans, *supra* note 53, at 2670–71.

### 1. *Insurer Access to Genetic Test Results*

Generally, insurers do not directly inquire about genetic testing or its results in applications despite their common collection of family medical history.<sup>200</sup> Although genetic test results may be of interest, no insurer is presently willing to break the status quo norms for fear of bad press.<sup>201</sup> Some insurance applications are likely to be accepted without any further inquiry beyond the initial application questions because insurers have little motivation to search unless the marginally greater risk prediction that the characteristic provides saves more than the cost to find and measure the new risk characteristic.<sup>202</sup> However, insurers utilize medical exams, physician inquiries, and requests for medical records when further information regarding a person's risk profile is needed, and insurers could discover genetic test results through these means.<sup>203</sup> Thus, even without asking in the initial application, insurers could obtain applicants' genetic test results during later stages of the application process.

Insurance companies also gain information about applicants through the Medical Information Bureau (MIB). MIB is a nonprofit organization that compiles a database for insurance companies to share broad-level information about applicants.<sup>204</sup> When an individual applies for insurance with one company, the company can provide applicant information to the MIB, such as the name, hazardous avocations, and medical information.<sup>205</sup> Subsequent insurers are then able to cross-check new applicants against information from other insurers in order to help prevent fraud or overinsurance.<sup>206</sup>

Although there is no evidence insurers are currently doing so, they could also learn of genetic risk through direct testing of applicant samples themselves.<sup>207</sup> This practice would be fully outlawed in some states and would require permission in others because of informed

---

200. See Klitzman et al., *supra* note 1, at 1455 (noting insurers do not want to be the first to ask about genetic test results).

201. *Id.*

202. Swedloff, *supra* note 121, at 351; see also *supra* subsection IV.C.2 (discussing operational considerations).

203. Sharona Hoffman, *Medical Big Data and Big Data Quality Problems*, 21 CONN. INS. L.J. 289, 291–92 (2014); Wolf & Kahn, *supra* note 111. Thus, whether or not genetic test results are known by physicians or recorded in a medical record directly impacts the likelihood that an insurance company may gain knowledge of a person's prior testing. For this reason, genetic and other healthcare professionals sometimes advise patients to secure any desired insurance coverage prior to undergoing testing. Klitzman et al., *supra* note 1, at 1856.

204. Harry Ostrer et al., *Insurance and Genetic Testing: Where Are We Now?*, 52 AM. J. HUM. GENETICS 565, 566 (1993).

205. See generally *id.*; *The Facts About MIB*, MIB, [http://www.mib.com/facts\\_about\\_mib.html](http://www.mib.com/facts_about_mib.html) [<https://perma.unl.edu/8UYS-66CK>].

206. See Ostrer et al., *supra* note 205, at 567.

207. AM. COUNCIL OF LIFE INS., *supra* note 67, at 14.

consent laws or bans on required genetic testing.<sup>208</sup> However, in states that lack legislation, insurers could collect blood samples and perform tests directly, which may become a more realistic possibility given the decreasing cost of genomic sequencing.<sup>209</sup>

## 2. *Insurer Use of Genetic Test Results*

Despite the lack of direct inquiry, insurers maintain they need to be able to access genetic testing to defend against adverse selection. There is documentation for several genetic conditions that shows high-risk individuals are more likely to purchase insurance to protect against future loss.<sup>210</sup> To avoid information asymmetry, insurers want to have access to any information about genetic test results that might motivate individual applicants to request high levels of insurance. Thus, insurers want access to all genetic test results so they have the power to decide which are relevant to each individual's policy.

Even if insurers gain access to genetic test results, it is unclear how often they are taken into account during individual underwriting. There is evidence insurers do consider genetic test results for a select number of tests they deem relevant.<sup>211</sup> For example, insurers may incorporate results of diagnostic genetic testing or results for highly predictive genetic conditions. However, they are unlikely to find the vast majority of genetic test results helpful in the risk classification process.<sup>212</sup> Indeed, at this point in time, insurer use of genetic test results with low predictive value is theoretical. Insurers are likely only using a few types of genetic tests that are highly predictive and have a sufficient evidence base. In Canada, for example, life insurance companies generally consider thirteen highly predictive conditions when classifying risk.<sup>213</sup>

---

208. See statutes cited *supra* note 60.

209. James Evans, Bradford Powell & Jonathan Berg, *Finding the Rare Pathogenic Variants in a Human Genome*, 317 JAMA 1904, 1904 (2017).

210. See Donald H. Taylor et al., *Genetic Testing for Alzheimer's and Long-Term Care Insurance*, 2 HEALTH AFF. 102 (2010); see also Subramanian et al., *supra* note 53, at 532 (noting women with *BRCA1* or *BRCA2* mutations, associated with an increased risk for breast and ovarian cancer, may purchase more life insurance); Cathleen D. Zick et al., *Genetic Testing for Alzheimer's Disease and Its Impact on Insurance Purchasing Behavior*, 24 HEALTH AFF. 483, 486 (2005).

211. GENETIC TESTING WORKING GROUP REPORT, *supra* note 63, at 4 (“[A]lthough no insurers are now requiring genetic testing, if the results of genetic testing are in an applicant's medical record and are relevant, insurers are likely to include such results in the underwriting process.”).

212. ANGUS S. MACDONALD, THE ACTUARIAL RELEVANCE OF GENETIC INFORMATION IN THE LIFE AND HEALTH INSURANCE CONTEXT 2 (2011); MacDonald, *Genetic Factors*, *supra* note 15; MacDonald, *Risks Are Too Small*, *supra* note 1.

213. See ROBERT C.W. HOWARD, GENETIC TESTING MODEL: IF UNDERWRITERS HAD NO ACCESS TO KNOWN RESULTS (2014) (modeling the impact on the insurance indus-

As scientific understanding grows, more conditions may be taken into consideration, but given the current nascent state of genetic knowledge and rarity of most highly penetrant conditions, relatively few test results would be utilized by insurers. Under the status quo, the insurer holds the power to determine when a test crosses scientific and actuarial thresholds, despite the wide-ranging societal and scientific questions that affect the positive predictive value and validity of tests. Additionally, the decisions regarding which risk characteristics to employ, and what scientific and actuarial evidence supports these actions, are currently completed within the opaque insurance industry. Individual applicants are unlikely to know what genetic test results may be of interest to each insurer and why. A rational discrimination approach adds transparency to this system by requiring documentation, and sometimes approval, of the evidence that supports insurer use of each type of genetic test.

#### VI. ARE TRANSPARENCY AND OVERSIGHT NECESSARY?

In a competitive insurance market, companies have an incentive to accurately predict risk or face the chance of losing customers.<sup>214</sup> Competitive advantage occurs if an insurer develops a more refined classification system than other companies.<sup>215</sup> Competitive disadvantage occurs if insurers misuse genetic test results and incorrectly assign a low-risk individual to a high-risk class. Market proponents argue when insurers properly classify genetic risk, affected individuals can reapply elsewhere and likely receive a policy from a different company.<sup>216</sup> One question that arises under this theory is whether the increased oversight or documentation requirements of the rational discrimination approach are necessary. Is it enough to leave it to the market to properly classify genetic test results? These questions are especially relevant given insurers only use a handful of genetic test results. This Part argues the market alone is insufficient to address concerns of insurer use of genetic test results for four reasons: existing evidence of insurer misuse of genetic test results, the lack of transparency within the insurance industry, incentives within the industry

---

try if it is not permitted to use genetic test results in underwriting). Thirteen conditions were modeled, suggesting that these are the most likely to be used and thus the ones most likely to impact the industry if removed. *See id.* Similarly, when a list of most relevant genetic conditions was drafted in the 1990s for the United Kingdom, eight disorders were listed. Macdonald & Yu, *supra* note 66, at 346. For examples of genetic tests that are highly predictive, see *supra* section V.A.

214. Furthermore, insurers have incentives to offer as many policies as possible without denying large portions of their risk pool. *See* AM. COUNCIL OF LIFE INS., *supra* note 67, at 15.

215. *See infra* section VI.C.

216. GENETIC TESTING WORKING GROUP REPORT, *supra* note 63.

to adopt use of new risk characteristics as early as possible, and the societal effects of fear of genetic discrimination.

### A. Insurer Misuse of Genetic Test Results

The market may eventually sort out how genetic test results should be efficiently and fairly utilized by insurers as measured by economic pricing. However, clinical and technological understanding of genetics and genomics is still developing. There has long been discussion in the medical field regarding the appropriate standards to determine whether and when genetic tests should be utilized in clinical care.<sup>217</sup> Transitioning the standards and challenges from the clinical realm to insurance will likely prove equally, if not more, challenging. Therefore, during the time of flux in the creation of accurate actuarial models, there is likely to be misapplication of genetic test results. Anecdotal evidence supports this concern. For example, insurers have denied individuals when they carry one variant for a condition but not the two needed to be affected. In genetics terminology, insurers have denied carriers even though they will never develop the condition.<sup>218</sup> An insurer also denied a policy for an individual who tested negative for Huntington's Disease because he "could get Huntington's Disease" in the future—a statement that is unequivocally false.<sup>219</sup>

Anecdotal stories such as these are often raised by proponents of a prohibitive approach. They argue insurers should be disallowed from considering genetic test results because the dangers of misuse are just too great.<sup>220</sup> However, it is in an insurer's best interest to correctly assess risk.<sup>221</sup> The insurance company who denied the individual based on his HD-carrier status lost a customer and the monetary value of the premiums he should have been offered given his true expected risk. Thus, misuse of genetic test results creates economic harms for both insurers and applicants. Competitive insurance markets may eventually address these misuses and mistakes, but harm ensues in the interim.

---

217. See James E. Haddow & Glenn E. Palomaki, *ACCE: A Model Process for Evaluating Data on Emerging Genetic Tests*, in HUMAN GENOME EPIDEMIOLOGY 217 (Muir J. Khoury et al. eds., 2004).

218. Ostrer et al., *supra* note 205.

219. Bev Heim-Meyers, Chair, Canadian Coal. for Genetic Fairness, Chief Exec. Officer, Huntington Soc'y of Can., Testimony to the Canadian Parliament Proceedings of the Standing Senate Committee on Human Rights (Dec. 10, 2014).

220. *Id.*

221. See *supra* section IV.B.

## B. Transparency of the Insurance Market

The theoretical possibility that the market will adjust to the most efficient outcome implies a level of transparency in the system that simply does not exist. If an individual is unfairly, under actuarial standards, denied a life insurance policy by one company, he or she may be able to secure a policy from a different insurer. This, however, requires the individual to know the reason for his or her denial; understand the nature of insurance risk classification; have the knowledge, time, and resources to compare other insurance offerings; and apply to a different insurer or insurers.<sup>222</sup> In reality, the nature of the insurance market does not support transparent practices for consumers.<sup>223</sup> Consumers are often expected to shop around for the best price in other competitive markets, and it is not seen as unfair to require them to have the wherewithal to do so. However, given unfair discrimination is an illegal unfair trade practice under many states' UTPAs,<sup>224</sup> it is inappropriate to place the burden on individuals to do the work to find a company that is following the law—especially in an environment where transparency is wanting.

Additionally, the MIB distorts this market competition when insurers transfer information about applicants between one another. Proponents of the market argue that insurance companies have different appetites for risk and that where one may deny a woman with a positive BRCA test result, another may accept her. Therefore, as discussed above, individuals are encouraged to shop around for insurance policies even after a denial. However, the centralized database of the MIB collects information about applicants.<sup>225</sup> Once a company denies an applicant, medical information may appear in the MIB system. This distorts the market because an underwriter who sees medical information from another company may be more likely to scrutinize the application and charge a higher premium or deny the policy, even in a situation where the company's risk appetite would have originally accepted the individual's risk level. Additionally, many applicants are likely unaware of the MIB, so they may not know the underlying reason for any denials or premium increases.

---

222. See GAO Report, *supra* note 40, at 12 (“When sufficient information is not available to compare products and prices, or when the consumer is not able to judge product quality before purchase, consumers are unable to choose the best product for themselves. Not being able to choose limits the consumer impact on the market and reduces the competitive incentive to improve product quality and to lower prices.”).

223. See Wortham, *supra* note 42, at 861 (noting other reasons consumers may fail to find the lowest price, such as irrational behavior and inelastic consumer demand).

224. See *supra* Part II.

225. See *supra* subsection V.B.1.

A rational discrimination approach places the burden on insurance companies to show they are justified in using information in risk classification. In contrast, the status quo places the burden on individuals to shop for an insurance company that will consider their risk, to identify mistakes or misunderstandings made by insurers, and to appeal these decisions or go elsewhere. Additionally, those choosing to undergo clinical genetic testing or to participate in genomics research must do so without a clear understanding of how such a test will impact their insurability, leading to the patterns of avoidance of genetic testing that were a concern prior to GINA's passage.

### C. The Arms Race of Risk Classification

Insurers are economically motivated to accurately classify risk or jeopardize losing consumers to their competition, leaving risk classification models susceptible to an arms-race mentality between insurers.<sup>226</sup> To increase their bottom line, insurers vie to attract as many low-risk individuals to their pool as possible.<sup>227</sup> The first insurer to employ a new risk characteristic has a momentary competitive advantage over its rival insurers when it can offer lower prices to those individuals in the new low-risk category.<sup>228</sup> For example, historically, insurers did not classify risk on the basis of smoking; however, the first insurer to offer different tiers of policies for smokers and nonsmokers attracted the lower risk nonsmokers to its plan and deterred smokers, who would be offered a lower premium from those insurers still pooling risk across the broader risk class.<sup>229</sup> Just as in weapons arms races, the brief economic advantage is lost as soon as the competition employs the same new refined risk class, which leads to a renewed search for the next classification refinement and the next competitive edge.

Meanwhile, the entire industry is spending increased resources collecting data and verifying new risk classes. Early insurance policies underwrote on three to four risk classes, such as age, gender, and geography; the system now operates complicated applications and medi-

---

226. Baker, *supra* note 33, at 377.

227. Stone, *supra* note 23, at 294–95.

228. See Baker, *supra* note 33, at 377; Thomas, *supra* note 66, at 121. However, Leah Wortham notes possible reasons that insurers may not act in this manner at all times: that income comes predominately from investments, that insurers do not scrutinize cost of classification, and that insurers may be hesitant to introduce new classifications. She ultimately concludes: “I agree with the economists’ prediction . . . that once some insurers introduce a new classifier, other insurers are pressured to follow suit from fear of adverse selection. At the same time, the pressure on a company to first introduce the new classification may not be as strong as posited.” Wortham, *supra* note 42, at 864–66.

229. See Allen M. Klein, *Life Insurance Underwriting in the United States—Yesterday, Today and Tomorrow*, 18 BRIT. ACTUARIAL J. 486, 488–89 (2013).

cal exams, involving actuaries and underwriters to assess the numerous risk characteristics.<sup>230</sup> All the while, the aggregate level of risk across the population of insured individuals has probably changed little.

Genomic data feeds directly into the frenzy of the risk classification arms race, foreshadowing a potential transformation of how insurers classify risk.<sup>231</sup> The promise of genomics and precision medicine is far from being realized. However, competitive pressures and incremental improvements in clinical understanding of genetic risk could lead insurers to bifurcate risk classes into smaller and smaller refinements. Suppose, for example, scientists discover a genetic variant that protects individuals against heart disease even when they have high blood pressure. Insurers could use this information to refine the risk class for those with high blood pressure into two smaller classes depending on genetic risk. While this may increase the accuracy of risk prediction and make the class more homogenous, increasingly smaller risk classes may have less statistical credibility.<sup>232</sup> On the other hand, large genomic epidemiology studies may provide sufficient evidentiary grounds to justify assumptions even for rare differences. Genetic sequencing and big data thus invite questions over whether small risk classes are really a threat to the system in the way actuaries have previously predicted.<sup>233</sup>

Auto insurance provides an apt illustration of how developing technology can vastly alter the process of risk classification. Traditionally, auto insurers utilized factors such as age, gender, past traffic violations, occupation, and zip code as risk characteristics.<sup>234</sup> Past traffic violations and the number of miles driven have a fairly clear causal path between the risk characteristic and expected cost—both the more reckless a driver is, as measured by tickets, and the more miles a car is on the road, as measured by mileage, directly increase the chances of an accident. Ticket violations, although measurable, are an imperfect proxy for reckless behavior since not all reckless drivers will get tickets while some safe drivers may get tickets. Mileage is also measurable; however, it requires self-reporting or incurs added costs associated with having an insurance representative collect and verify this information.

---

230. *Id.* at 487–89.

231. For a discussion of the potential for other forms of big data to alter risk classification, see generally Swedloff, *supra* note 121.

232. *See supra* subsection IV.C.1.

233. *See* Swedloff, *supra* note 121, at 344–45.

234. DIMITRIS KARAPIPERIS ET AL., USAGE-BASED INSURANCE AND VEHICLE TELEMATICS: INSURANCE MARKET AND REGULATORY IMPLICATIONS 2 (Ctr. for Ins. Policy & Research ed., 2015).

Given advances in big data, tracking technology, and algorithms, auto insurers are increasingly turning to usage-based insurance.<sup>235</sup> Under usage-based insurance, auto insurance companies use telematics (in-vehicle telecommunication devices) to collect data, such as a consumer's location, miles driven, driving speed, and propensity to make fast turns or hard brakes.<sup>236</sup> The companies then input combinations of these measured factors into algorithms to more narrowly define risk classes based on individualized data.<sup>237</sup> The lure of this phenomenon to more precisely classify risk without the need to group individuals into large risk classes is strong. Uptake of telematics is rapid, and it is estimated by 2020, thirty-six percent of auto insurers will utilize the software, showing the desire and trend for insurance companies to rapidly adopt technology in risk classification, at first to gain a competitive edge over other insurers but then just to remain as competitive.<sup>238</sup>

The extent to which genomic sequencing will alter risk classification remains to be seen; however, an arms-race mentality of risk classification creates insurer incentives to incorporate risk characteristics before the competition. This could cause insurers to utilize a genetic test as a risk characteristic before there is sufficient scientific evidence of its predictive value.<sup>239</sup> As scientific understanding of genetic test results increases, when does misuse transition to acceptable use? What was once a genetic test result with no predictive power may develop into one that can be clinically used to assess risk. What level of scientific knowledge is sufficient to push a genetic test result from uncertain and unhelpful to a potential risk characteristic? Once clinically relevant, does this automatically equate to relevance for insurers? Different insurance companies have different appetites for risk; some insurers may employ a genetic test result as a risk characteristic before there is concrete scientific evidence in order to avoid unexpected costs in the future, leading to arguable misuse of genetic test results.<sup>240</sup> The rational discrimination approach combats this potential misuse by requiring documentation or oversight of scientific and clinical validity before insurer use.

#### D. Fear of Genetic Discrimination

The greater transparency and oversight of the rational discrimination approach is also beneficial because it can dampen fears of genetic

---

235. *See generally id.*

236. *Id.* at 19.

237. *Id.* at 21.

238. *Id.* at 20.

239. *See* AM. COUNCIL OF LIFE INS., *supra* note 67, at 14–15.

240. Klitzman et al., *supra* note 1, at 1856 (“[C]onservative business decisions may lead [insurers] to overestimate risks.”).

discrimination in ways the market alone cannot. When genetic counselors, health care professionals, or researchers are discussing issues of genetic discrimination with patients and potential research subjects, they must use broad language to describe the ability of life, long-term care, and disability insurance companies to access and use genetic test results. For example, an informed consent document for a genomic-sequencing research project describes:

The Genetic Information Non-Discrimination Act of 2008 (GINA) is a federal law that provides additional protection against genetic discrimination, specifically in the areas of employment and health insurance coverage. It does not specifically cover long-term care insurance, life insurance and disability insurance. Despite GINA and the legal protections it offers, the results generated in this research could affect your future insurance eligibility or insurance premiums. Before enrolling in this study you may wish to review your current insurance coverage and explore life, long-term care and disability insurance options.<sup>241</sup>

Although it would be difficult to narrow any statement, because it is unclear when and how insurers are using genetic test results, this type of broad language in consent documents and discussions potentially leads individuals to believe insurers are using more genetic test information than they actually are. In contrast, under the rational discrimination framework of the United Kingdom, genetic counselors can provide a succinct and clear message to patients and research participants: insurers will not use your predictive genetic test results unless it is for HD and the policy is over £500,000.<sup>242</sup> Even under the system created by the Uniform Law Commission's draft legislation, medical professionals could direct patients and research subjects to the state insurance commissioner's office to examine which genetic tests insurers filed documentation for and therefore which tests they are allowed to consider.<sup>243</sup> Greater transparency and clarity in the system could ease fears of genetic discrimination among the general public and remove this commonly cited barrier to genetic testing and participation in genetic research.<sup>244</sup>

This diminished fear of genetic discrimination is beneficial not only for the public and research but also for insurance companies. Genomic technologies are likely to lead to decreased mortality and morbidity as

---

241. CLINICAL SEQUENCING EXPLORATORY RESEARCH, PARTNERS HEALTHCARE SYSTEM RESEARCH CONSENT FORM: THE MEDSEQ PILOT PROJECT: INTEGRATING WHOLE GENOME SEQUENCING INTO CLINICAL MEDICINE, [https://cser1.cser-consortium.org/system/files/attachments/bwh\\_consentform\\_medseq\\_patients\\_cardiology\\_6.18.14.pdf](https://cser1.cser-consortium.org/system/files/attachments/bwh_consentform_medseq_patients_cardiology_6.18.14.pdf) [<https://perma.unl.edu/F49N-69C4>].

242. *See supra* subsection III.C.1.

243. DRAFT UNIFORM PROTECTION OF GENETIC INFORMATION IN EMPLOYMENT AND INSURANCE ACT (NAT'L CONFERENCE OF COMM'RS ON UNIF. LAWS 2010).

244. This system, of course, fails to address the fears and concerns of individuals with positive test results for the conditions that have been approved. This gap will be discussed in further detail *infra* section VIII.A.

disease causes and pathways are understood, and preventive and mitigating strategies are developed.<sup>245</sup> A healthier and longer living public is also usually in insurers' interests since it limits the number and severity of claims.<sup>246</sup> Insurers should have an interest in supporting a regulatory framework that clarifies practices in this area. It will foster good will towards the insurance industry and assuage fear of discrimination, which in turn can lead to not only socially desirable goals but also better financial outcomes for insurers.

Turning back to the example of the woman with a pathogenic variant in *BRCA1*, suppose she has a sister who is unwilling to be tested for fear of genetic discrimination. Based on her family history, the sister is at risk for ovarian cancer, but without testing there is little clinical prevention she can undertake since screening for ovarian cancer is not as effective as screening for other cancers like breast or colon cancer.<sup>247</sup> If she receives such testing and is found to have a pathogenic *BRCA1* variant, she could undergo a prophylactic oophorectomy.<sup>248</sup> If this woman develops ovarian cancer and passes away, it is not only a tragic death that could have potentially been avoided but also leads to financial loss to her disability and life insurers.<sup>249</sup> Thus, both parties lose when fear of discrimination leads to avoidance of testing.

Whether this situation could have been avoided and whether the rational discrimination approach would have helped the situation or led to denial depends on the scientific, clinical, and actuarial requirements established through the rational discrimination approach.

---

245. James P. Evans et al., *We Screen Newborns, Don't We?: Realizing the Promise of Public Health Genomics*, 15 *GENETICS MED.* 332, 332–33 (2013).

246. In some situations, increased longevity may place a financial strain on some benefit mechanisms, such as pension plans. Similarly, if increased knowledge about genetic causes of diseases allows us to prolong death, but not necessarily disease, this could place a strain on long-term care and disability insurances. Overall, however, a healthier society uses less insurance and therefore lowers claims and financial burdens on the system.

247. See Susan M. Domchek et al., *Association of Risk-Reducing Surgery in BRCA1 or BRCA2 Mutation Carriers with Cancer Risk and Mortality*, 304 *JAMA* 967, 967 (2010).

248. *See id.*

249. In some cases, the sister may have been charged an increased premium or been denied insurance based on her family medical history alone. *See Holmes, supra* note 25, at 565–66. However, insurers may fail to discover individuals with a limited family history. For example, many insurers ask about the medical history of grandparents, parents, and siblings but do not necessarily collect information regarding great aunts, cousins, or other extended family. Baopeng Lu et al., *The Genetics of Breast and Ovarian Cancer IV: A Model of Breast Cancer Progression*, 2011 *SCANDINAVIAN ACTUARIAL J.* 239.

## VII. STANDARDS OF EVIDENCE

The threshold levels of scientific, clinical, and actuarial evidence required through a rational discrimination approach will greatly affect the number and scope of genetic test results available for insurer use. The United States and Australian proposals and the United Kingdom Moratorium each use similar frameworks for assessing whether there is sufficient evidence for a genetic test to be used by an insurance company. However, the details of these frameworks could drastically alter the scope of genetic information available to insurers.

## A. Uniform Law Commission Draft

The Uniform Law Commission's draft legislation "contemplates the type of evidence-based review of genetic tests conducted by the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Working Group."<sup>250</sup> EGAPP, a working group established to provide evidence-based assessment of genetic tests and genomic technologies, employs the ACCE model as its evidentiary-assessment framework.<sup>251</sup> The ACCE model was developed based on recognition that in an age of rapidly developing genomic technologies, there is a danger of introducing under-researched and unsubstantiated genetic tests into clinical practice to the harm of patients.<sup>252</sup> Four criteria—analytical validity, clinical validity, clinical utility, and ELSI (ethical, legal, and social considerations)—comprise the elements of the ACCE framework.<sup>253</sup> The analytical validity measures how well the genetic test works on a technical level, such as if the test will find a variant that is present in a gene or whether the results are reliable and reproducible.<sup>254</sup> Clinical validity refers to the predictive value of the test, including consideration of the sensitivity and specificity.<sup>255</sup> Clinical utility examines whether the test measurably changes clinical outcomes in terms of treatment or prevention, that is, whether it is help-

---

250. Draft Uniform Protection of Genetic Information in Employment and Insurance Act (NAT'L CONFERENCE OF COMM'RS ON UNIF. LAWS 2010).

251. Steven M. Teutsch et al., *The Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Initiative: Methods of the EGAPP Working Group*, 11 GENETICS MED. 3 (2009). The ACCE Model was developed by the Centers for Disease Control and Prevention (CDC), based on recommendations by the Secretary's Advisory Committee on Genetic Testing and other groups, as a framework for assessing the risks and benefits of genetic tests. SEC'Y'S ADVISORY COMM. ON GENETIC TESTING, ENHANCING THE OVERSIGHT OF GENETIC TESTS: RECOMMENDATIONS OF THE SACGT (2000); Haddow & Palomaki, *supra* note 217, at 217.

252. See Muin. J. Khoury et al., *The Evidence Dilemma in Genomic Medicine*, 27 HEALTH AFF. 1600 (2008).

253. *ACCE Model*, *supra* note 180.

254. SEC'Y'S ADVISORY COMM. ON GENETIC TESTING, *supra* note 251, at 15.

255. *Id.* at 16; see text accompanying note 180.

ful to the person taking the genetic test.<sup>256</sup> Finally, the ACCE model takes into account ELSI considerations of a test, such as whether the test can lead to discrimination or stigmatization.<sup>257</sup> The ACCE framework is comprised of forty-four questions within the four criteria that help to assess whether a genetic test should be implemented into clinical care.<sup>258</sup> Therefore, under a rational discrimination approach mirroring the Uniform Law Commission, when providing documentation for each genetic test, insurers could utilize these questions as a valuable starting point.

In the ACCE model, clinical utility is generally narrowed to only clinical outcomes, although critics have argued that individuals may obtain other types of personal utility from a test even if it does not lead to clinical improvement.<sup>259</sup> For example, a genetic test may end a diagnostic odyssey or may allow individuals to make financial or other life decisions in light of their genetic risk.<sup>260</sup> Furthermore, increasing dialogue has focused on the potential public health benefits of preventive genetic screening, where individuals can learn about their risk and prevent or mitigate future disease based on this knowledge.<sup>261</sup> The EGAPP Working Group recently issued a recommendation that the tumors of all newly diagnosed colorectal-cancer patients should be sequenced for Lynch Syndrome, a genetic condition associated with an increased risk of colon and endometrial cancer.<sup>262</sup> EGAPP recommends this testing not necessarily for the clinical benefit of the patient but for the benefit to relatives in the form of discovering familial risk.<sup>263</sup> As the scope of utility expands from clinical utility to personal and familial utility, there may be more patients with genetic test re-

---

256. See Scott D. Grosse & Muin J. Khoury, *What Is the Clinical Utility of Genetic Testing?*, 8 GENETICS MED. 448, 448 (2006).

257. SEC'Y'S ADVISORY COMM. ON GENETIC TESTING, *supra* note 251, at 20.

258. *ACCE Model*, *supra* note 180.

259. Wylie Burke, *Genetic Tests: Clinical Validity and Clinical Utility of Genetic Tests*, 81 CURRENT PROTOCOLS HUM. GENETICS 9.15 (2014); Morris W. Foster et al., *Evaluating the Utility of Personal Genomic Information*, 11 GENETICS MED. 570 (2009); Grosse & Khoury, *supra* note 256; M.J. Khoury, *Dealing with the Evidence Dilemma in Genomics and Personalized Medicine*, 87 CLINICAL PHARMACOLOGY & THERAPEUTICS 635 (2010).

260. Evans et al., *supra* note 15, at 862; Foster et al., *supra* note 259, at 571;

261. See, e.g., Evans et al., *supra* note 245; Robert C. Green et al., *ACMG Recommendations for Reporting of Incidental Findings in Clinical Exome and Genome Sequencing*, 15 GENETICS MED. 565, 565-66 (2013); Muin J. Khoury et al., *Population Screening in the Age of Genomic Medicine*, 348 NEW ENG. J. MED. 50, 50 (2003); Mary-Claire King et al., *Population-Based Screening for BRCA1 and BRCA2: 2014 Lasker Award*, 312 JAMA 1091 (2014).

262. Alfred O. Berg et al., *Recommendations from the EGAPP Working Group: Genetic Testing Strategies in Newly Diagnosed Individuals with Colorectal Cancer Aimed at Reducing Morbidity and Mortality from Lynch Syndrome in Relatives*, 11 GENETICS MED. 35, 35 (2009).

263. *Id.*

sults in their medical records that do not directly affect their clinical care.

Although the Uniform Law Commission refers to the EGAPP assessment for the type of documentation it envisioned, the ACCE model was developed for recommendations in the clinical setting and misses an essential aspect of evidence relevant in the insurance realm—actuarial calculations. While the ACCE model provides an excellent baseline, since clinical validity and utility are essential aspects of fair use of genetic test results by insurers, insurers should also consider and prove how the genetic test results affect their actuarial calculations and their business. For example, clinical care is enhanced by encouraging innovation and the introduction of new genetic tests to the market while simultaneously balancing considerations of patient safety. It is not beneficial to have such a restrictive application of the ACCE model that genetic tests cannot be brought to market and industry incentives for research are diminished.<sup>264</sup> Thus, there are policy motivations for easing the evidentiary threshold for incorporation into clinical care. However, just because a genetic test reaches evidentiary thresholds for clinical care does not automatically ensure the satisfaction of actuarial thresholds. The experiences of the United Kingdom and Australia highlight other factors that should be considered to determine actuarial relevance.

## B. U.K. Moratorium

Under the United Kingdom Moratorium and Concordat, in order to gain approval for use of a genetic test, the ABI must submit an application to GAIC proving three elements—technical, clinical, and actuarial relevance.<sup>265</sup> In 2000, GAIC received eighteen applications regarding the use of predictive genes for Huntington’s Disease, early-onset Alzheimer’s Disease, and *BRCA1/2* in life, critical illness, income-protection, and long-term care insurance lines.<sup>266</sup> However, between 2002 and 2003, GAIC updated its application standards, approved the use of Huntington’s Disease in life insurance under these standards, and asked the ABI to resubmit the remaining seventeen applications under the new standards.<sup>267</sup> No revised or additional applications were ever submitted, and eventually GAIC was

---

264. See Khoury et al., *supra* note 252, at 1606 (“[A] high evidence threshold could become a major disincentive for industry and academe to develop genomic technology.”).

265. GAIC SECOND REPORT, *supra* note 65, at 6.

266. *Id.* at 7.

267. R.G. Thomas, *Genetics and Insurance in the United Kingdom 1995–2010: The Rise and Fall of “Scientific” Discrimination*, 31 *NEW GENETICS & Soc’y* 203, 206 (2012).

disbanded in 2009.<sup>268</sup> Although GAIC was disbanded, the application process remains in effect; in order to use a predictive genetic test result, the insurance industry still needs to submit an application to the government.

The first two standards of GAIC somewhat mirror the analytical validity, clinical validity, and clinical utility standards of the ACCE model. Under technical relevance, the ABI must disclose the number of variants that occur across individuals affected with the condition, the ability of the test to detect variants, the analytic precision, the effect of family history on the interpretive value, and the extent of “inherent weakness or technical imperfections” of the test and its interpretation.<sup>269</sup> Under clinical relevance, the GAIC application requires disclosure of differential diagnoses; the clinical effects and expected course of the condition; and the penetrance, prevalence, and number of genes associated with the condition.<sup>270</sup> Many of these requirements speak directly to the factors that influence the positive predictive value of the test.<sup>271</sup>

Unlike the Uniform Law Commission suggestion, the United Kingdom Moratorium explicitly adds a requirement of actuarial relevance. To prove actuarial relevance, insurers must “[q]uantify the extra risk justifying revised terms, for example the need to increase premiums (or decline applications)” and demonstrate the methods and evidence used in these calculations.<sup>272</sup> Additionally, the insurers must illustrate how test results would affect insurance coverage and premium amounts, and demonstrate how the availability of preventive interventions was considered in calculations.<sup>273</sup> The lack of further applications by the ABI limits evidence of how these standards can and will be applied to other genetic tests. It is unclear whether the ABI has failed to resubmit applications because it does not think it is cost-effective to do so or because it does not have adequate evidence to prove relevance under the strict GAIC standards. The GAIC experience, however, shows how threshold standards can impact the number of tests determined to have actuarial relevance.

### C. Australian Guidance

In its report on insurance and genetics, the Australian Law Reform working group highlighted two primary factors to establish relevance

---

268. GAIC SECOND REPORT, *supra* note 65, at 7; Thomas, *supra* note 267, at 206.

269. GAIC SECOND REPORT, *supra* note 65, at 21.

270. *Id.* at 22.

271. *See supra* section V.A.

272. GAIC SECOND REPORT *supra* note 65, at 23.

273. *Id.*

for use by insurers—scientific reliability and actuarial relevance.<sup>274</sup> “The first factor relates to the link between the existence of a genetic mutation and the expression of a particular disorder; the second relates to the link between the expression of disease and increased morbidity or mortality.”<sup>275</sup> Several of the factors the working group considered relevant to scientific reliability are similar to GAIC’s inquiries into both technical and clinical relevance in the United Kingdom. For example, the Australian working group cited concerns of low penetrance, available prevention and treatment, and variability of the severity of symptoms associated with a gene.<sup>276</sup>

#### D. Additional Considerations

Although the specific overarching labels—such as technical relevance or scientific reliability, clinical utility or relevance, and actuarial relevance—may change across countries, the underlying criteria are similar. However, this Article argues that any requirement of documentation or standards of approval by an external body should include discussion of five specific considerations. These considerations affect the clinical and technical relevance of genetic tests; they do not necessarily need to be stand-alone considerations. However, they are worth highlighting to ensure these factors are incorporated into the larger criteria frameworks.

##### 1. *What Types of Evidence Are Sufficient?*

Genetics is a rapidly developing field; therefore, the scientific certainty regarding the factors that affect the positive predictive value are constantly evolving. At this point, the ability to collect and sequence genetic and genomic information is greater than the understanding of its clinical significance.<sup>277</sup> For example, there are approximately nineteen thousand genes in the human genome, only a portion of which have known clinical relevance.<sup>278</sup> Historically, evidence for actuarial justification came from data collected by the insurance company regarding the specific claims of those with certain risk criteria—that is, calculations based on actual experience of the insurer.<sup>279</sup> However, with rapid technological developments and discov-

---

274. ESSENTIALLY YOURS, *supra* note 91, at 700; HUMAN GENETICS COMM’N, INSIDE INFORMATION: BALANCING INTERESTS IN THE USE OF PERSONAL GENETIC DATA (2002); GAIC SECOND REPORT, *supra* note 65, at 23.

275. See GAIC SECOND REPORT, *supra* note 65, at 23.

276. ESSENTIALLY YOURS, *supra* note 91, at 700–01.

277. Evans et al., *supra* note 15.

278. See *id.* at 861; Green et al., *supra* note 261, at 566–67.

279. See ON RISK CLASSIFICATION, *supra* note 24, at 32, 38 (noting risk classification determinations are often based on historical data). See generally ACTUARIAL STANDARD OF PRACTICE NO. 23 (ACTUARIAL STANDARDS BD. 2011), [http://www.actuarialstandardsboard.org/wp-content/uploads/2014/02/asop023\\_141.pdf](http://www.actuarialstandardsboard.org/wp-content/uploads/2014/02/asop023_141.pdf) [<https://per>

ery, this data will not be available for quite some time for many genetic tests.<sup>280</sup> With the lack of data, it is unclear what type of evidence insurers will use—they may rely on published epidemiological studies, or they may rely on the opinions of researchers or health care professionals. Reliance solely on epidemiological studies is potentially problematic, even if they are done with scientific rigor.<sup>281</sup>

We must accept that epidemiological work is aimed largely at medical questions, and so the methods of medical statistics will figure largely. These may have a basis in common with actuarial science, for example in survival analysis, but there are differences of practice and emphasis. Actuarial models, even the ordinary life table, are in fact exceptionally demanding of the data, by requiring detailed, age-dependent risk estimates. Not many medical studies, especially into rare disorders in respect of which samples may be small, meet these demands.<sup>282</sup>

Beyond published studies, the Actuarial Standards Board allows expert opinions to be considered: “In demonstrating [an actuarial] relationship, the actuary may use relevant information from any reliable source, including statistical or other mathematical analysis of available data. The actuary may also use clinical experience and expert opinion.”<sup>283</sup> Guidance should delineate the bounds of such expert advice, such as necessary independence, number of opinions required, and credentials of the expert.<sup>284</sup>

## 2. *How Should the Context of Genetic Tests Come into Play?*

There are three primary contexts in which individuals may have undergone medical genetic testing: clinical testing, research testing, and direct-to-consumer (DTC) testing.<sup>285</sup> Insurance companies are most likely to gather information regarding clinical testing through

---

ma.unl.edu/HV9W-PDEF] (discussing standards of practice for actuaries when using data provided by others).

280. J. LEMAIRE & A.S. MACDONALD, GENETICS, FAMILY HISTORY, AND INSURANCE UNDERWRITING: AN EXPENSIVE COMBINATION? 8–9 (2003).

281. *E.g.*, Li Lu et al., *Premium Rates Based on Genetic Studies: How Reliable Are They?*, 42 INSURANCE 319, 329 (2008) (finding the reliability of premiums based on epidemiological studies varied depending on the number of cases within age brackets of interest).

282. LEMAIRE & MACDONALD, *supra* note 280.

283. ACTUARIAL STANDARD OF PRACTICE NO. 12 § 3.2.1 (ACTUARIAL STANDARDS Bd. 2005), [http://www.actuarialstandardsboard.org/pdf/asops/asop012\\_101.pdf](http://www.actuarialstandardsboard.org/pdf/asops/asop012_101.pdf) [<https://perma.unl.edu/EVA2-EPXR>].

284. These discussions can benefit from the growing use of evidence-based underwriting. *See generally* Ine Van Hoyweghen & Klasien Horstman, *Evidence-Based Underwriting in the Molecular Age: The Politics of Reinsurance Companies Towards the Genetics Issue*, 28 NEW GENETICS & SOC’Y 317 (2009).

285. Given the ties to insurance, this Article focuses on medical genetic testing and not genetic testing for other purposes such as paternity, criminal investigation, newborn screening, or ancestry testing. These types of genetic tests could be conducted in settings and contexts different than those discussed here for medical testing.

direct questions of medical professionals and medical records. Individuals are most likely to undergo clinical genetic testing when they have some symptoms or family history that indicates possible increased risk, making these results simultaneously of interest to insurers but also less relevant if the insurers can gather the same information through family history or other clinical information. However, just because genetic or genomic testing is conducted in a clinical setting does not guarantee its clinical relevance.<sup>286</sup>

Insurers are also likely to be interested in any genetic testing done in a research setting. There is ongoing debate about whether genetic research results should be used by insurers for two primary reasons: testing done in the research setting does not always conform to the same laboratory standards as for those conducted in the clinical setting, and potential insurer use of research results deters individuals from enrolling in research studies.<sup>287</sup> In some countries, insurers are prohibited from using or have agreed not to use research results in risk classification.<sup>288</sup> The boundaries between research and clinical care, however, are increasingly blurring. Today, genetic research results, even those that are incidental or secondary to the primary research question, are often returned to participants.<sup>289</sup> Thus, genetic research results may be just as valuable as clinical results for insurers. For example, in Canada, prior to the latest bill, insurers would not seek information about genetic research results that were not returned to participants; if the individual or physicians had access to the results, however, the Canadian insurers wanted equal access to the information.<sup>290</sup>

In the United States, arguments concerning differential standards are likely less relevant for recent research results. The Clinical Laboratory Improvement Act of 1988 (CLIA), an act that promulgates and enforces standards for laboratories performing genetic testing, generally exempts research testing laboratories from regulations.<sup>291</sup> However, it requires any research results returned to participants for “diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients” be certified in a

---

286. *See supra* section VII.A. Another example of this could be genetic testing for pregnant women or for those considering pregnancy.

287. Yann Joly et al., *Life Insurance: Genomic Stratification and Risk Classification*, 22 EUR. J. HUM. GENETICS 575, 577 (2014).

288. *Id.*; Margaret Otlowski et al., *Genetic Discrimination: International Perspectives*, 13 ANN. REV. GENOMICS & HUM. GENETICS 433, 441 (2012).

289. *See* Gail P. Jarvik et al., *Return of Genomic Results to Research Participants: The Floor, the Ceiling, and the Choices in Between*, 94 AM. J. HUM. GENETICS 818 (2014).

290. CANADIAN LIFE & HEALTH INS. ASS'N, INDUSTRY CODE: GENETIC TESTING INFORMATION FOR INSURANCE UNDERWRITING § 4.3 (2017).

291. 42 C.F.R. § 493.3(b)(2) (2013).

laboratory that meets clinical standards.<sup>292</sup> Therefore, returned research results will most likely have gone through the same rigorous requirements of clinical validity as genetic tests conducted through clinical care. Although this minimizes the arguments related to standards and quality of results, concerns remain regarding potential deterrence from participating in the research.

In addition to testing through research or clinical care, individuals may also have genetic test results through DTC testing. In 2013, the Food and Drug Administration (FDA) began regulating health-related DTC tests.<sup>293</sup> Companies must now obtain authorization from the FDA by proving the analytic and clinical validity of each test in order to market it directly to consumers.<sup>294</sup> This requirement essentially halted the health-related DTC market in the United States, and the markets have not fully reformulated, although they are beginning to.<sup>295</sup> In the meantime, DTC results from prior to the FDA crackdown may remain of interest to insurers. DTC test results raise greater concerns of adverse selection because the information is less likely to be housed in the medical record and, indeed, the individual may have even sought this type of testing to avoid insurer discovery.

### 3. *Should Relevance Be Measured by Marginal Added Value?*

Actuarial relevance requires insurers to demonstrate a risk characteristic is associated with an increased risk for disease. However, when assessing the strength of this association, a baseline question is: An increased risk as compared to what? Insurers already employ information about individuals' family history and clinical information to determine one's risk of genetic conditions. In the United Kingdom, GAIC asked insurers to show not just that a genetic test result was correlated with increased risk but how the risk compared with the insurer's current ability to assess risk.<sup>296</sup> If actuarial relevance is defined by the marginal benefit a risk characteristic provides over characteristics currently in use, this would significantly lower the im-

---

292. *Id.*

293. Patricia J. Zettler et al., *23andMe, the Food and Drug Administration, and the Future of Genetic Testing*, 174 JAMA INTERNAL MED. 493, 493 (2014). There is still an ongoing DTC market for other purposes such as ancestry testing.

294. *Id.*

295. See Kayte Spector-Bagdady, "The Google of Healthcare": *Enabling the Privatization of Genetic Bio/Databanking*, 26 ANNALS EPIDEMIOLOGY 515 (2016).

296. GAIC SECOND REPORT, *supra* note 65, at 23 (requiring insurers to show "how the use of normal/abnormal test results may affect the ratio of people accepted for insurance and the additional premiums they may be asked to pay in comparison with those for whom the only indicator of risk would previously have been an adverse family history").

pact of the characteristic being assessed.<sup>297</sup> For example, many genetic conditions will develop at ages earlier than most individuals get insurance or could be identified through clinical means other than genetic testing; thus, the marginal benefit of genetic test results will be limited.<sup>298</sup> If the potential to learn of hereditary risk through family history is removed, then the impact genetic testing will have on actuarial relevance is much greater.

#### 4. *How Should Preventive and Treatment Measures Be Taken into Account?*

The extent to which preventive and treatment measures are available to mitigate risk by definition alters the original risk assessment of insurers. The availability of preventive measures is an important component of clinical utility and was specifically considered in both the United Kingdom and Australian contexts.<sup>299</sup> The genomics literature refers to “medically actionable” genetic conditions—that is, those with preventive measures, treatment measures, or both available to lower one’s risk of developing the condition or ameliorate its impact.<sup>300</sup> There is a growing consensus that information about medically actionable genetic conditions should be returned to individuals in both the clinical and research settings.<sup>301</sup> For example, in 2013 the American College of Medical Genetics and Genomics (ACMG) issued guidance suggesting the results of fifty-six predetermined, medically actionable genetic conditions should be returned to the patient any time whole-genome or whole-exome sequencing is conducted.<sup>302</sup> The ACMG believed that genetic and genomic testing can lead to preven-

---

297. See Macdonald & Yu, *supra* note 66, at 345–46 (noting only a limited number of genetic conditions will have marginal benefit for insurance because there are few that are late onset, will not be discovered through symptoms or family history, will not have effective treatment once discovered, and will have sufficient predictive value).

298. See AM. COUNCIL OF LIFE INS., *supra* note 67, at 26.

299. See *supra* sections VII.B–C.

300. Jonathan S. Berg et al., *An Informatics Approach to Analyzing the Incidentalome*, 15 *GENETICS MED.* 36 (2012); Green et al., *supra* note 261.

301. Jarvik et al., *supra* note 289.

302. Green et al., *supra* note 261. This position garnered heated debate over the next several years regarding consent, the right not to know genetic information, and return of results. See Wylie Burke et al., *Recommendations for Returning Genomic Incidental Findings? We Need to Talk!*, 15 *GENETICS MED.* 854 (2013); Thomas May, *On the Justifiability of ACMG Recommendations for Reporting of Incidental Findings in Clinical Exome and Genome Sequencing*, 43 *J.L. MED. & ETHICS* 134 (2015); Susan M. Wolf et al., *Patient Autonomy and Incidental Findings in Clinical Genomics*, 340 *SCIENCE* 1049 (2013). Despite ultimate changes to the form of consent, the underlying motivation and principle behind the recommendation stands. ACMG Bd. of Dirs., *ACMG Policy Statement: Updated Recommendations Regarding Analysis and Reporting of Secondary Findings in Clinical Genome-scale Sequencing*, 17 *GENETICS MED.* 68 (2014).

tion or mitigation of disease and that individuals and their families should be given this information to lessen the burden of disease in our society.<sup>303</sup>

Medically advisable prevention of genetic conditions is one of the primary societal reasons to encourage increased genetic testing and is why fear of genetic discrimination minimizing uptake of testing is bemoaned. If insurers classify risk on the basis of a genetic condition but do not fully consider the impact of potential preventive measures, this will only add to the entrenched problems of fear of genetic discrimination and mistrust of the insurance system. To return to the example above of the woman with a pathogenic *BRCA1* variant, suppose she is now considering a prophylactic oophorectomy, a preventive removal of ovaries, to minimize the risk of ovarian and breast cancer. This procedure lowers the woman's risks of ovarian and breast cancer by ninety-six percent and fifty-three percent.<sup>304</sup> If insurers learn of the woman's genetic risk and deny her insurance despite the availability of preventive measures, is this actuarially justified or fair? Requiring insurers to fully consider the actuarial impact of preventive measures is a necessary component in order to meet societal goals of disease prevention and ensure actuarial fairness. In some situations, the preventive measure will not be as effective as the case of a preventive surgery for *BRCA1/2*; in such cases, the individual may still face an increased premium, but insurers should still be required to have actuarially sufficient evidence to raise premiums based on conditions with the preventive measures available.

##### 5. *How Should Variants Within a Gene Be Considered?*

The thresholds of actuarial relevance must address not only which genetic tests insurers can use to classify risk but also how insurers should use specific results from a genetic test or condition. Actuarial relevance should be measured not just across genes but across variants and subpopulations.

For most genetic tests, the molecular analysis is not looking for one simple on-off switch that indicates whether a person either has or does not have the genetic predisposition. Instead, genetic testing ana-

---

303. For a discussion of the changes to the consent procedures, see *Updated ACMG Recommendations to Allow Patient Opt Out of Incidental Findings*, GENOMEWEB (Apr. 1, 2014), <http://www.genomeweb.com/clinical-genomics/updated-acmg-recommendations-allow-patient-opt-out-incident- findings>. But see Anya E.R. Prince, *Prevention for Those Who Can Pay: Insurance Reimbursement of Genetic-Based Preventive Interventions in the Liminal State Between Health and Disease*, 2 J.L. & BIOSCIENCES 365 (2015), for a critique of the assumption that knowledge of genetic risk equates to ability to prevent disease.

304. R.I. Olivier et al., *Clinical Outcome of Prophylactic Oophorectomy in BRCA1/BRCA2 Mutation Carriers and Events During Follow-Up*, 90 BRIT. J. CANCER 1492, 1492 (2004).

lyzes individuals' specific sequences of chemical base pairs in the gene of interest, and then testing laboratories compare this to a reference genome to identify variants (permanent changes in the genetic sequence).<sup>305</sup> Variants in all genes are very, very common, but very few variants will indicate an increased risk of disease, even if they occur in a gene that is known to be associated with a certain disease.<sup>306</sup> Thus, determining the results of a genetic test requires complex variant interpretation, which often involves individualized assessment based on race, ethnicity, age, symptoms, and family history of disease.<sup>307</sup>

The ACMG recently issued guidance for the interpretation of variants in single-gene conditions.<sup>308</sup> It established five categories of classification for variants—pathogenic, likely pathogenic, uncertain significance, likely benign, and benign—and delineated the types of evidence that could be used for laboratories to place each variant into each classification.<sup>309</sup> Other types of genetic tests require different variant interpretation, such as the test for Huntington's Disease, which identifies the number of times a certain genetic sequence repeats, called copy-number variants.<sup>310</sup> Variant interpretation will be even more complicated in multigene conditions.

Given the complexities of interpreting the clinical significance of variants, there is often disagreement across laboratories regarding the appropriate label for identified variants.<sup>311</sup> Efforts to increase consistency, like the ACMG standards, and centralized variant databases where researchers report their interpretations, will improve inter-laboratory consistency.<sup>312</sup> However, the extent of laboratory disagree-

---

305. Richards et al., *supra* note 167, at 406.

306. *Id.*

307. See generally D.G. MacArthur et al., *Guidelines for Investigating Causality of Sequence Variants in Human Disease*, 508 *NATURE* 469 (2014); Richards et al., *supra* note 167; Steven Benowitz, *Genomics' Daunting Challenge: Identifying Variants that Matter*, NAT'L HUM. GENOME RES. INST. (Apr. 23, 2014), <https://www.genome.gov/27556983/genomics-daunting-challenge-identifying-variants-that-matter> [https://perma.unl.edu/7LHY-LB6C].

308. Richards et al., *supra* note 167, at 406. The ACMG refers to these conditions as Mendelian disorders.

309. *Id.*

310. *Id.* at 407.

311. Laura M. Amendola et al., *Actionable Exomic Incidental Findings in 6503 Participants: Challenges of Variant Classification*, 25 *GENOME RES.* 305, 306 (2015); Amendola et al., *Performance of Interpretation Guidelines*, *supra* note 170, at 1070 (finding prior to consensus talks there was only thirty-four percent concordance across labs in variant classification); Sara L. Van Driest et al., *Association of Arrhythmia-Related Genetic Variants with Phenotypes Documented in Electronic Medical Records*, 315 *JAMA* 47, 50–51, 55 (2016).

312. Amendola et al., *Performance of Interpretation Guidelines*, *supra* note 170, at 1070–71, 1075 (finding laboratory consensus increased after discussion about the ACMG guidelines).

ment should be considered when assessing the technical credibility of actuarial relevance.<sup>313</sup>

The complications of variant interpretation raise important considerations as to how specific test results should be used by insurance companies. For example: Should insurers use variants of uncertain significance (VUS)? Must insurers use the variant classification that was reported from the patient's laboratory, or can the insurer curate its own list of variant classifications? If insurers ever begin to undertake their own genetic testing, what standards of variant interpretation must they employ? How individualized must their assessment be with regard to the symptoms and familial evidence from the individual applicant? These and other similar questions must be considered and debated from the perspectives of insurers, scientists, and consumers alike. However, it is clear insurer use of genetic test results cannot simply end at an inquiry into which tests have sufficient data. For example, perhaps sufficient actuarial data could support insurer use of the woman's *BRCA1* test; however, further clarification is needed regarding whether insurers can charge a higher rate to those with a VUS or another given variant.

#### VIII. THE CASE FOR A RATIONAL DISCRIMINATION APPROACH

A rational discrimination approach recognizes the complexities and potential for misunderstanding and misuse of emerging genetic test results but balances this with the need of insurers to access and use information that is actuarially relevant. The additional documentation and, in the case of Australia and United Kingdom, external approval depart from the traditional deferential oversight of the insurance industry. However,

[g]one are the days when applicants had a deferential attitude towards highly respected financial institutions. In these days of openness, transparency and accountability there will be pressure for insurers to develop and to demonstrate the scientific basis for all of their underwriting policies and decisions and to disclose much more to prospective policyholders on how they are viewed by the underwriting process, especially when they are rated up or refused cover.<sup>314</sup>

Indeed, deference to the insurance industry is a problematic means of controlling use of genetic test results since insurers may have the incentive to set low thresholds of evidence, especially in a competitive market where each insurer desires to be the first to incorporate new,

---

313. Indeed, this is already incorporated in the ACCE forty-four questions. Under analytic validity, the CDC asks reviewers to consider the within-and-between laboratory precision. *ACCE Model*, *supra* note 180.

314. Daykin et al., *supra* note 30, at 824.

more accurately refined risk classes.<sup>315</sup> To counter these incentives, necessary evidence levels are best defined externally, ideally through incorporation of independent approval.

### A. Prohibitive Approach Comparison

Regulating insurer use of genetic test results through a rational discrimination approach is by no means a panacea. Given the ability of genetic and genomic tests to provide information about individuals' predisposition to certain conditions, an increasing number of genetic tests may provide useful and actuarially relevant information to insurers as scientific understanding improves. Depending on the standards of actuarial relevance that are chosen, an actuarial model may not prevent individuals with pathogenic variants in these genes from being charged higher premiums or from being denied insurance outright. Some may critique this as minimizing the social solidarity goals of insurance and leaving the groups at the highest risk without protection. Yet, public debate about standards of actuarial relevance increases the chances thresholds are set in a fair and unbiased way and are beneficial to many across society.

This is not to say that a prohibitive approach is the wrong approach. Indeed, this Article has not attempted to assess which approach, prohibitive or rational discrimination, would be preferable. It does, however, argue a rational discrimination approach is preferable to the status quo approach because the status quo fails to adequately address fear of discrimination, places burdens on insurance applicants in an opaque insurance market, and leaves insurers vulnerable to incentives to use risk characteristics before sufficient scientific and actuarial evidence is established.<sup>316</sup>

It is in the interest of both insurers and society as a whole to limit misuse of genetic test results—and indeed all risk characteristics—in risk classification. While insurer use of the highly penetrant genetic conditions that would be most likely to satisfy evidence standards can and should be debated regarding social fairness concerns, such as access to insurance, privacy, and stigmatization, these are distinct from concerns of misuse leading to economic efficiencies.

There is a difference . . . between that which is undesirable because it is economically irrational and that which is undesirable because, despite its economic logic, it offends our common understanding of fairness. In the former

---

315. Similarly, insurers are incentivized to make more conservative decisions, especially for new diseases with little historical and actuarial data. John H. Dodge, *Predictive Medical Information and Underwriting*, 35 J.L. MED. & ETHICS 36, 38 (2007) (noting because life insurance policies can not be altered in the future to raise rates, but can be altered to lower rates, prudent insurers will make conservative decisions in cases of limited evidence).

316. See *supra* Part VI.

case, the government simply acts to correct the market; in the latter, it accepts a deliberate market distortion in order to reinforce a moral stance.<sup>317</sup>

The rational discrimination approach is one that seeks to correct the market but does not overstep into distorting the market out of social fairness concerns. It may be the case that, given the rarity of highly predictive single-gene conditions, adopting a prohibitive approach will have limited financial impact on the insurance industry. However, this is something that will be easier and clearer to measure when focusing on those conditions that are actuarially relevant rather than on *all* genetic test results—in other words, targeting only rational discrimination, not irrational discrimination. Social fairness arguments that combine both actuarially justified and actuarially unjustified genetic test results may inadvertently suggest a larger impact on insurers than actually exists.

### B. Status Quo Comparison

Any policy to increase oversight of the risk classification systems of insurers is likely to be met with opposition from the insurance industry itself. Indeed, the failure of the recommendations in both the United States and Australia suggests successful pushback to increased oversight. The question is what specific concerns the industry may have over such an approach. Several possibilities are immediately apparent: (1) the worry that providing increased documentation will result in administrative expense; (2) a concern that public disclosure of internal calculations and the risk characteristics employed would cause insurers to lose their competitive edge against other insurance companies; and (3) the fear that limited use of genetic test results would create regulatory adverse selection. While each of these have some validity, the concerns can be limited and in the end do not outweigh the social concerns of fear of genetic discrimination and fairness in insurance risk classification.

A worry of increased administrative expense should be minimal for insurance companies. Unfair trade practice acts in all fifty states already require life insurers, and often other insurers, to have actuarial justification for use of risk characteristics.<sup>318</sup> Therefore, a rational discrimination approach in the United States would require documentation of a standard that is already in place. Depending on the nature of the documentation required, there will, of course, be administrative costs added in order to convert internal decisions into external documents, but the actuarial calculations and considerations legally should have already been conducted. Additionally, these administrative costs to the insurers can be minimized if the rational discrimina-

---

317. Jeffrey S. Morrow, *Insuring Fairness: The Popular Creation of Genetic Antidiscrimination*, 98 GEO. L.J. 215, 227 (2009).

318. *See supra* Part II.

tion approach includes oversight and review by an external or independent committee. This could remove the administrative costs of collecting information about each genetic test and determining whether it meets set standards for each insurance company separately and replace it with a streamlined, centralized process.

Due to the competitive nature of insurance, companies may not want public disclosure of their actuarial calculations and the specific genetic tests they employ in their risk classification. Proposals, such as the draft by the Uniform Law Commission, do add an element of public disclosure to the insurance process. Depending on the nature of the required disclosure, the amount of information made public could vary. For example, a system could be created to disclose more to the insurance commissioner than is made public. Here too, an external advisory body could actually benefit companies by leveling the playing field across insurers. Risk classification is an expensive process; insurers need to invest resources to collect data, interpret the risk associated with this data, and set premium levels appropriately.<sup>319</sup> While insurers are incentivized to create ever-more-refined classifications in competitive markets,<sup>320</sup> setting standards across all insurance companies may decrease costs of the risk classification process.

Finally, insurer concerns over adverse selection can and should be minimized by the process as well. For example, under the United Kingdom Moratorium and Concordat, insurers provide evidence of how a genetic test would affect premiums and insurance coverage.<sup>321</sup> This provides an opportunity to demonstrate whether adverse selection would result if insurers cannot gather information about a genetic test result. Adverse selection, if it does occur, is most likely to occur with highly predictive and scientifically valid tests; the very tests that could be approved under a rational discrimination approach. Minimizing insurer use of tests that are scientifically unfounded or have minimal predictive value will hardly lead to the spiraling insurance costs and collapse of the system forewarned by adverse selection.

The United Kingdom provides an example of how even restrictions on the use of highly predictive genetic tests has not led to substantially increased cost or evidence of adverse selection. The United Kingdom Moratorium was instituted in 2001 for a five-year period and has been repeatedly extended since that time.<sup>322</sup> While it is difficult, if not impossible, to concretely measure adverse selection in the market, the fact that United Kingdom insurers voluntarily agreed to continue the moratorium for over fifteen years indicates they have not seen evidence of an increase in unexpected costs from their insurance pools

---

319. See, e.g., *The Economics of Insurance Law*, *supra* note 62, at 45–46.

320. Thomas, *supra* note 66, at 121; see *supra* section VI.C.

321. See *supra* section VII.B.

322. Thomas, *supra* note 267, at 206.

despite their inability to collect and use the vast majority of predictive genetic tests.

The United Kingdom also provides an illustration of a political calculation by insurers. In the late 1990s, the United Kingdom government considered a prohibitive ban on insurer use of genetic test results.<sup>323</sup> The insurance industry was adamantly opposed to such legislation, citing concerns such as the need to access genetic test results and adverse selection.<sup>324</sup> Eventually, however, the industry realized it was likely to face a prohibitive ban on using a broad range of genetic test results and agreed to the Moratorium and Concordat under a rational discrimination approach as a compromise.<sup>325</sup> Therefore, it may be in the interest of insurers to accept a rational discrimination approach as a flexible option that allows continued reassessment of scientific advances in genetics in lieu of a potential prohibitive approach in the future.<sup>326</sup>

## IX. CONCLUSION

Much of the controversy and difficulty of using genetic test results during risk classification stems from the nascent state of genetic science. Although the science has greatly advanced since the completion of the Human Genome Project in 2003, there is still much that is not understood about the clinical implications of genes. One prominent question is how to combine the use of information with potentially mercurial implications into the framework of insurance risk classification. A common trope employed by those advocating for a prohibitive approach on insurer use of genetic test results is that “all of us have something bad in our genes.”<sup>327</sup> The statement, although perhaps an effective discursive tactic, is incomplete. It draws on the fear of genetic discrimination and encourages everyone to feel they are just one genetic test away from the inability to secure insurance. From a social fairness perspective, this is an understandably persuasive tactic. It draws people behind Rawls’s veil of ignorance and asks them to develop policy without knowing what their genetic lottery may be. However, from an actuarial perspective, it is not helpful to condense all genetic conditions into one discussion. The average person will have approximately three to four million genetic variants that are different

---

323. *Id.* at 205.

324. *Id.* at 206–10.

325. *Id.* at 206.

326. Canada also provides an illustration. Until recently, the country followed a status quo approach, but a bill was passed by Parliament in 2017 that adopted an expansive prohibitive approach despite industry disapproval. *See Genetic Non-Discrimination Act*, S.C. 2017, c 3 (Can.). If the industry had accepted or advocated for a rational discrimination approach, as in the United Kingdom, the political dynamics could be quite different.

327. *See* Wolf & Kahn, *supra* note 111, at 13.

than the reference genome—at least one of these, and likely many more, will increase an individual’s risk for disease.<sup>328</sup> Others may be protective or lower one’s risk.<sup>329</sup> Most will have no effect on risk at all.<sup>330</sup> Additionally, while all of us will have some “bad” genes, very few will have genetic predispositions to the highly penetrant, single-gene conditions so often cited as the poster children of insurer use.

A rational discrimination approach creates a regulatory-enforcement system that is transparent, clear, and flexible. This approach finds common ground between societal concerns over unfair misuse of genetic test results and insurer acknowledgement of the lack of actuarial evidence for the use of most results. Through continuing genomic research efforts, there will be a more robust understanding of the clinical implications across the entire human genome and the associated possible preventive measures and treatments. When this day comes, insurer use of genetic test results may become less worrisome and controversial, and more like the current use of family history or other common medical information. After all, we all have a genetic risk for something, and hopefully in the future we will be able to return to a model of broad risk pooling across genetic conditions rather than strong differentiation between those with known bad genetic luck and those whose genetic misfortune is yet to be discovered. Until that time, to minimize misuse and ease societal concerns, the additional transparency and oversight of a rational discrimination approach should be adopted as a baseline policy.

---

328. Evans et al., *supra* note 209.

329. *Id.*

330. *Id.*