



Special section: GINA at 10 years

Political economy, stakeholder voices, and saliency: lessons from international policies regulating insurer use of genetic information

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ABSTRACT

A decade ago, Congress passed the Genetic Information Nondiscrimination Act (GINA), with the goals to address fear of genetic discrimination and prevent adverse health insurance and employment decisions on the basis of one's genetic information. Yet, fear of discrimination remains because other insurers, notably life, long-term care, and disability insurers, are not covered by the law. Therefore, there have been persistent murmurings for a 'GINA 2.0' to extend the protections of the original law. Although it is plausible to assume that the insurance industry has the political economy to control future regulation, given the saliency of genetic discrimination, other stakeholders and bureaucrats may have greater influence. This paper explores the history of policy in four countries—the United Kingdom, Sweden, Australia, and Canada. Each country provides examples of continued policy debate and change following an initial period of reliance on insurance industry self-regulation, with change generally occurring over the objection of the insurance industry. This article argues that US insurers, regulators, and stakeholders should negotiate a consensus solution for insurer use of genetic information that balances between social and economic considerations. Without compromise, continued saliency and a weakened political economy of insurers will foster continued entrenched debate on the issue.

KEYWORDS: genetic testing, genetic discrimination, insurance, ELSI, political economy, moratorium

I. INTRODUCTION

Ever since the earliest mapping of the human genome, people have worried about the prospects of adverse societal outcomes and genetic discrimination. Since then, genetic discrimination has continued to capture the imagination and focus of society and the media. “Within the past 30 years or so, [genetic discrimination]... has become one of the most pervasive and mediatised issues associated with genetic research and its implementation in developed countries.”¹ Yet, there has been relatively little empirical evidence of widespread genetic discrimination actually occurring.²

Likely in part due to media amplification of the issue, fear of genetic discrimination is quite common across the globe.³ Concerns of potential discrimination have dire negative consequences as some individuals forego genetic testing and research due to the potential for misuse of information.⁴ In order to assuage these fears and mitigate any ill health effects from avoidance of genetic testing, governments throughout the world have regulated insurer use of genetic information.⁵ The policies range from outright bans on insurer use to a variety of regulatory mechanisms that restrict insurers, but do not ban use outright.

In 2008, the US Congress tackled this issue and passed the Genetic Information Nondiscrimination Act (GINA). GINA prohibits covered health insurers and

¹ Yann Joly et al., *Comparative Approaches to Genetic Discrimination: Chasing Shadows?*, 33 *TRENDS GENET.* 299, 299 (2017). Many examples of the potential negative consequences of genetic testing have been highlighted across the globe, such as women being denied critical illness, life, or disability insurance for having a genetic risk of breast and ovarian cancer, (Sarah Zhang, *The Loopholes in the Law Prohibiting Genetic Discrimination*, *THE ATLANTIC*, 2017, <https://www.theatlantic.com/health/archive/2017/03/genetic-discrimination-law-gina/519216/> (last visited Feb. 12, 2019); Wendy McKinnon et al., *Survey of Unaffected BRCA and Mismatch Repair (MMR) Mutation Positive Individuals*, 8 *FAMILIAL CANCER* 363 (2009); Angie Seth, *Genetics Discrimination Impacts Cancer Patients without Insurance Coverage*, *GLOBAL NEWS*, Nov. 14, 2014, 2014, <https://globalnews.ca/news/1671371/genetic-discrimination-impacts-cancer-patients-without-insurance-coverage/> (last visited Feb. 12, 2019)), life insurance discrimination for those with predispositions to Huntington’s Disease (Cheryl Erwin et al., *Perception, Experience, and Response to Genetic Discrimination in Huntington Disease: The International Responed-HD Study*, 153 *AM. J. MED. GENET. B: NEUROPSYCHIATR. GENET.* 1081 (2010)), or someone being denied life insurance based on a genetic predisposition to colon cancer (Louise A. Keogh & Margaret F. A. Otlowksi, *Life Insurance and Genetic Test Results: A Mutation Carrier’s Fight to Achieve Full Cover*, 199 *MED. J. AUSTR.* 363 (2013)).

² Yann Joly et al., *Genetic Discrimination and Life Insurance: A Systematic Review of the Evidence*, 11 *BMC MED.* 25 (2013).

³ Annet Wauters & Ine Van Hoyweghen, *Global Trends on Fears and Concerns of Genetic Discrimination: A Systematic Literature Review*, 61 *J. HUM. GENET.* 275 (2016).

⁴ *Id.* at 275.

⁵ See eg Trudo Lemmens, *Genetics and Insurance Discrimination: Comparative Legislative, Regulatory and Policy Developments and Canadian Options*, *HEALTH L. J.* 41, 55 (2003) (discussing Jurgen Simon, *Gendiagnostik und Versicherung: Die Internationale Lage im Vergleich* (Lüneberg: Universität Lüneberg (2000)); Julie-Anne Tarr, *Regulatory Approaches to Genetic Testing in Insurance*, 24 *SYDNEY L. REV.* 189, 200 (2002) (relatedly arguing that regulation of genetic discrimination fell into three primary categories: restricted access to test results, restricted use of genetic tests, and imposition of a monetary limit); Bartha Maria Knoppers et al., *A Comparative International Overview*, in *GENETICS AND LIFE INSURANCE: MEDICAL UNDERWRITING AND SOCIAL POLICY* (M. A. Rothstein ed. 2004); Joly et al., *supra* note 1; Yann Joly et al., *Genetic Discrimination in Private Insurance: Global Perspectives*, 29 *NEW GENET. & SOC.* 351 (2010). This article uses the term genetic information to encompass a range of information related to heredity and risk; however, as discussed, *infra* Section III.A.4., different policies use different definitions of genetic information—most often it includes at least some type of genetic testing, but sometimes also includes family medical history. This paper generally uses genetic information and genetic test results interchangeably but highlights those policies that define genetic information in a specific way.

employers from discriminating on the basis of genetic information, including genetic test results, family medical history, and use of genetic services.⁶ Though heralded as the ‘first civil rights law of the 21st century,’ GINA was by no means a comprehensive solution to all concerns of genetic discrimination. Indeed, one of the most frequently cited gaps is that it does not address use of genetic information beyond health insurance. Since 2008, there have been persistent murmurings for additional legislation to expand coverage to other types of insurance—such as life, long-term care, and disability insurance. GINA provides the primary model available at the federal level for potential legislation in these insurance contexts—a strong ban on insurer use of and access to genetic information.⁷ Yet, the life, long-term care, and disability industries serve different social purposes, have different market conditions, and exist within differing social safety net frameworks.⁸ Additionally, unless the federal government steps in with uniform legislation, there will likely be a patchwork of policies because regulation of these insurances rests primarily at the state level.⁹ Whether a GINA 2.0 could pass at the state or federal level—and what such legislation would look like—will depend on which stakeholder voices gain influence and how much weight is given to the social versus economic arguments surrounding this issue.

Although the insurance industry is often thought of as a powerful lobby with significant influence, the political economy of insurance regulation is complex. Often, multiple stakeholders are able to shape insurance-related legislation, especially when the issues in question are salient to the public.¹⁰ For example, in their extensive analysis of US insurance anti-discrimination laws, Ronan Avraham, Kyle Logue, and Daniel Schwarcz argued that both industry and diverse stakeholders can hold sway on anti-discrimination regulation.¹¹ Genetic discrimination in insurance is no different. It is particularly salient as exemplified by the continued discussion in society and media.

The complex political economy of the insurance realm may explain why countries have implemented policies that prioritize social concerns over economic concerns—or at least attempt to balance between these two considerations that so often pull in

⁶ Genetic Information Nondiscrimination Act of 2008 (GINA), Pub. L. No. 110–233, 122 Stat. 881 (codified as amended in scattered sections of 26, 29, and 42 U.S.C.).

⁷ Congress was by no means the only legislative actor in this arena during this time. Amid growing use of genetic testing, continued concerns over use of genetic tests, and stalled federal action, many states had stepped in to add protections. In 2004, for example, 47 states had non-discrimination legislation in health insurance and 32 states had protections in employment. Secretary’s Advisory Committee on Genetics, Health and Society, an Analysis of the Adequacy of Current law in Protecting Against Genetic Discrimination in Health Insurance and Employment, May 2005, https://osp.od.nih.gov/wp-content/uploads/2014/01/ulegal_analysis_May2005_0.pdf (last visited Feb. 12, 2019).

⁸ See *infra* Section IV.B.

⁹ In the USA in general, insurance is regulated at the state level. Although Congress can regulate insurance through laws explicitly targeting the industry (McCarren Ferguson), such as GINA and the Affordable Care Act (ACA), it has primarily left insurance regulation to the states—particularly in the realms of life, long-term care, and disability insurance. There has been some movement at the state level to regulate the use of genetic information by these insurers, but states that do have legislation in this area generally tend to regulate the use, not ban the use.

¹⁰ See generally KENNETH J. MEIER, *THE POLITICAL ECONOMY OF REGULATION: THE CASE OF INSURANCE* (State University of New York Press 1988); see also Ronen Avraham et al., *Understanding Insurance Anti-Discrimination Laws*, 87 S. CAL. L. REV. 195, 221–23 (2014).

¹¹ Avraham et al., *supra* note 10.

opposite directions.¹² This article offers a descriptive analysis of policy motivations and the policies adopted across several countries. It argues that US insurers will face similar problems controlling the debate regarding use of genetic information by insurers. Therefore, US governments, advocates, and insurers should work together to find workable compromises, such as those implemented internationally.

Section II highlights the economic and social arguments for and against insurer use of genetic information. It then introduces in greater depth how GINA prioritized the social concerns to completely ban insurer use of genetic information in health insurance. The question becomes: will policy regarding non-health insurer use of genetic information mirror GINA or will different political economies affect what legislation looks like or whether it is passed?

To provide insight on how the social and economic considerations play out in different insurance lines, Section III examines the development of policy regarding non-health insurer use of genetic information in four countries—the United Kingdom (UK), Sweden, Australia, and Canada.¹³ Each country was chosen to represent a different type of policy mechanism—the UK has a moratorium, Australia has guidance, and both Canada and Sweden have legislation, one recent and one more long-standing. Additionally, these countries provide apt comparison for the USA because they have relatively similar systems of private insurance, such as life insurance. A comparative analysis of health insurance across countries is difficult given the vast differences between delivery and financing of health care between the USA and countries with national health services or national insurance. However, the market in private, individually underwritten insurance industries, such as life, critical illness, long-term care, and disability insurance, is much more comparable. Thus, the policies employed across the globe in private, individual insurance may provide insight for future US legislation and debate.

The social and economic arguments related to insurer use of genetic information vary depending on the nature of insurance, the market, and the availability of social safety nets. Despite this, perhaps due to the influence of social stakeholders, policies do not always carefully differentiate across insurance lines. Thus, Section IV discusses how, given the saliency of the issue of genetic discrimination in insurance, multiple stakeholders and motivated regulators are able to influence dialogue in a field against a powerful industry lobby. The insurance industry in the case study countries adopted shifting strategies to address public concern. However, if such response is too little too late, policies may be adopted that are worse for the economic interest of the insurers.

In the USA, calls for a GINA 2.0 will likely endure until social concerns are at least somewhat satisfied. The solution sought could be a ban on life, long-term care, and disability use of genetic information. However, a full-scale adoption of GINA's policy framework plopped down in the context of these other insurances may not necessarily be the best fit. In order to avoid unnecessary economic consequences while still addressing fear of genetic discrimination, the insurance industry, regulators, and stakeholders should come together to find a compromise solution that effectively balances

¹² *Id.* at 221–23.

¹³ These four case studies are part of the broader grant research. Between 2016 and 2017, I conducted empirical research, including interviews with key stakeholders in each of the four case study countries. For a write-up of the qualitative findings, see Anya E.R. Prince, *Comparative Perspectives: Regulating Insurer Use of Genetic Information*, 27 EUR. J. HUMAN GENET. 340–348 (2019).

concerns on both sides of the debate and provides flexibility for the future as the science of genetics progresses.

II. BALANCING ECONOMIC VS. SOCIAL CONSIDERATIONS

Insurance anti-discrimination laws reside at the intersection of economic and social arguments. Should insurers be allowed to use a certain characteristic, such as race or gender, for underwriting because it provides some information about risk or should they be barred from using the characteristic because it is socially unacceptable to do so?¹⁴ Genetic information falls squarely within these competing frameworks.¹⁵ The complete prioritization of economic concerns over social concerns, and vice versa, has led to regulatory policies at the extremes—permissive use versus a complete ban on insurer use. This section highlights the primary economic and social arguments and provides examples of policies under these extremes.

A. Economic Considerations and Permissive Use

Insurance rests on an important economic industry norm—actuarial justification.¹⁶ In order for insurers to use a risk factor in underwriting, they must be able to show a correlation between the risk factor and increased cost to the insurer.¹⁷ For example, outdoor rock-climbing likely increases one's risk of accidental death. All else being equal, policyholders who rock climb can be reasonably expected to have earlier claims payouts than other policyholders, so life insurers can use information about an applicant's recreational sport to set premiums.¹⁸ Similarly, insurers consider medical history, smoking status, and other lifestyle factors to set rates that are commensurate with risk, and therefore actuarially justified.¹⁹

From the insurer perspective, this status quo allows them to control two important and interrelated economic considerations:²⁰ actuarial fairness and adverse selection. First, under actuarial fairness, insurers must assess premiums based on the risk one brings to the insurance pool. For example, it would be 'unfair' to charge smokers the same as non-smokers, since their differing levels of risk are known.²¹ Actuarial fairness thus builds on principles of actuarial justification—under *actuarial justification* insurers should have an evidence-based reason to charge a premium and under *actuarial fairness* it would be unfair for insurers to fail to take risk status into account. Thus, in the context

¹⁴ See generally Kenneth S. Abraham, *Efficiency and Fairness in Insurance Risk Classification*, 71 VA. L. REV. 403 (1985); Ronen Avraham et al., *Towards a Universal Framework for Insurance Anti-Discrimination Laws*, 21 CONN. INS. L.J. 1 (2014); Avraham et al., *supra* note 10; Xavier Landes, *How Fair Is Actuarial Fairness?*, 128 J. BUS. ETHICS, 519 (2014).

¹⁵ Anya E.R. Prince, *Insurance Risk Classification in an Era of Genomics: Is a 'Rational Discrimination' Policy Rational?*, 96 NEB. L. REV. 624, 634 (2017).

¹⁶ *Id.*

¹⁷ For an explanation of some of the standards behind actuarial justification, see Actuarial Standard of Practice (ASOP) No. 12: Risk Classification (for All Practice Areas) (2005), 3.

¹⁸ *Id.*

¹⁹ Something that has no correlation to risk will both fail to meet actuarial standards and will be of little use to insurers. There are, however, potential gray areas where there can be differences of opinion regarding whether risk information meets actuarial standards and what these standards should be. Prince, *supra* note 15, 663-68.

²⁰ There are other efficiency and economic concerns that also come into play, such as moral hazard, efficient redistribution, and limiting socially wasteful expenditures, see Avraham et al., *supra* note 10, 204-13, but this section highlights two primary overarching concerns of actuarial fairness and adverse selection.

²¹ Landes, *supra* note 14, at 520.

of genetics, insurance companies need access to genetic information to accurately classify an applicant's risk—failure to do so would result in actuarially unfair rates, where an individual who is known to be at high risk for a genetic condition is charged the same as an individual without such a genetic marker.²²

Second, and relatedly, insurance companies want to have the same information about an applicant's risk level as the applicant. Asymmetrical information, where an applicant knows more about his or her risk than the insurer, can lead to adverse selection.²³ Adverse selection can occur when a high-risk applicant with knowledge of his risk applies for a policy and the insurance company, unaware of the heightened risk, rates him as a standard risk.²⁴ This may result in higher claims payouts than the insurance company expected, leading to a resultant increase in premiums. Skyrocketing premiums may induce low-risk individuals to leave the insurance market, leaving greater proportions of high-risk individuals in standard plans—causing the cycle to repeat itself. The potential cyclical pattern of rising premiums, low-risk individuals leaving market, and high-risk individuals staying is called a 'death spiral'.²⁵ A death spiral can cause increased premiums or, at the extreme, a collapse of the insurance industry.²⁶ For insurers, therefore, adverse selection is an ever-present concern.

One option for any policy-making body assessing potential regulation of the insurance industry is, of course, maintaining the status quo and not implementing any new policy. In general, however, because actuarial justification is the baseline for the insurance industry for using all risk-factor information, not just genetic information, then the absence of any overarching policy essentially means that the principles of actuarial justification will apply to genetics. This is a principle that arises out of insurance practice, but has sometimes been codified into law, such as in US insurance unfair trade practices acts.²⁷ Thus, maintaining the status quo prioritizes the economic concerns of the insurance industry.

B. Social Considerations and the Full Ban

In contrast to the economic concerns in a status quo approach, a ban on insurer use of genetic test results focuses on social arguments and concepts of solidarity.²⁸ Under solidarity principles, insurance is a tool that pools risk together and provides for those

²² For definitions and critiques of concepts of actuarial fairness, see Saurabh Jha, *Punishing the Lemon: The Ethics of Actuarial Fairness*, 9 J. AM. COLL. RADIAL. 887 (2012); Landes, *supra* note 14.

²³ See Ronen Avraham, *The Economics of Insurance Law—a Primer*, 19 CONN. INS. L. J. 29 (2012); Michael Hoy & Mattias Polborn, *The Value of Genetic Information in the Life Insurance Market*, 78 J. PUB. ECON. 235 (2000); see also Tom Baker, *Containing the Promise of Insurance: Adverse Selection and Risk Classification*, 9 CONN. INS. L. J. 371 (2002) (laying out the general principles of adverse selection and arguing that insurer practices can also create adverse selection); but see Peter Siegelman, *Adverse Selection in Insurance Markets: An Exaggerated Threat*, 113 YALE L. J. 1223 (2004) (arguing that adverse selection is not as great of a threat to insurers as they state).

²⁴ Siegelman, *supra* note 23, at 1223-24. There are other ways that adverse selection can manifest, such as when laws prevent insurers from accessing some information about an applicant. See *infra* note 56.

²⁵ *Id.* at 1254.

²⁶ Avraham, *supra* note 23, at 204; Siegelman, *supra* note 23, at 1254 (discussing the evidence of death spirals and explaining why they are not necessarily a guaranteed outcome of informational asymmetry).

²⁷ See eg Unfair Trade Practices Act (UTPA), Model Law Nat'l Ass'n of Ins. Commissioners (2004).

²⁸ This concept has been particularly salient in Europe where there are deep-rooted cultural norms of solidarity. Ine Van Hoyweghen & Lisa Rebert, *Your Genes in Insurance: From Genetic Discrimination to Genomic Solidarity*, 9 PERS. MED. 871, 872 (2012).

unlucky in society who have gotten sick or incurred costs.²⁹ Denying access to insurance based on certain uniquely personal or immutable traits that cannot be controlled goes against the solidarity principles of insurance and is often seen as ‘unfair’ from a social perspective.³⁰

Insurer use of genetic information raises social concerns in two primary ways. First, if individuals with certain genetic markers are unable to obtain insurance due to their elevated risk levels, they will form a so-called ‘genetic underclass’.³¹ Second, empirical evidence shows that fear of genetic discrimination has led individuals across the globe to refuse to participate in genetic research projects or to fail to undergo recommended clinical testing.³² Therefore, restricting insurer use of genetic information could contribute to genetic research and help to save lives by encouraging medically necessary preventive genetic testing while preserving access to insurance.³³

A strong stance against insurer use of genetic test results has been supported by international groups and is especially common in Europe.³⁴ For example, Belgium was the first country to implement a ban on insurer use of genetic information and many European countries have followed suit.³⁵ One overarching international example is the United Nations Educational, Scientific, and Cultural Organization (UNESCO) Universal Declaration on the Human Genome and Human Rights.³⁶ This 1997 declaration states that, ‘no one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity.’³⁷ Since human dignity and fundamental freedoms are closely aligned with privacy and security of the person, discrimination based on genetic characteristics is of concern. Indeed, in a 2003 declaration regarding genetic data, UNESCO went further to argue that genetic data and biological samples should not

²⁹ See eg Baker, *supra* note 23, at 371–72.

³⁰ See eg Eric Mills Holmes, *Solving the Insurance/Genetic Fair/Unfair Discrimination Dilemma in Light of the Human Genome Project*, 85 KY. L. J. 503, 509 (1996); this is a very different type of unfairness than the actuarial unfairness discussed above, which sometimes leads to a problematic overlap of the use of the term in both contexts in the literature.

³¹ See eg *id.* at 568; see also Lemmens, *supra* note 5, at 53 (referring to concerns of a ‘genetic proletariat’); Ine Van Hoyweghen, *Taming the Wild Life of Genes by Law? Genes Reconfiguring Solidarity in Private Insurance*, 29 NEW GENET. & SOC. 431 (2010).

³² Robert Klitzman, *Views of Discrimination among Individuals Confronting Genetic Disease*, 19 J. GENET. COUNSEL. 68–83 (2010); Wauters & Van Hoyweghen, *supra* note 3, at 279–80; Louise A. Keogh et al., *Choosing Not to Undergo Predictive Genetic Testing for Hereditary Colorectal Cancer Syndromes: Expanding Our Understanding of Decliners and Declining*, 40 J. BEHAV. MED. 583 (2017); for example, a 2007 study conducted by the Genetics and Public Policy Center documented the public’s levels of trust for those who had access to and control of their genetic information. While 86% and 66% of individuals surveyed trusted their doctor and researchers respectively to access genetic test results, only 24% trusted their health insurer and only 16% trusted their employer. U.S. Public Opinion on Uses of Genetic Information and Genetic Discrimination, Genetics and Public Policy Center (2007).

³³ Louise M. Slaughter, *The Genetic Information Nondiscrimination Act: Why Your Personal Genetics Are Still Vulnerable to Discrimination*, 88 SURG. CLIN. 723 (2008).

³⁴ Van Hoyweghen, *supra* note 31, at 436.

³⁵ Margaret Otlowski et al., *Genetic Discrimination: International Perspectives*, 13 ANNU. REV. GENOMICS & HUM. GENET. 433, 444 (2012); see also Joly et al., *supra* note 5, at 362.

³⁶ UNESCO, Universal Declaration on the Human Genome and Human Rights (1997); Joly et al., *supra* note 1, at 299.

³⁷ UNESCO, *supra* note 36.

be accessible by insurance companies, among other actors.³⁸ While the USA has recently withdrawn from UNESCO, effective December 31, 2018,³⁹ the other countries in this comparative study remain member states. The overarching principles of the UNESCO declaration have been similarly adopted by other international bodies, such as the World Health Organization (WHO), the Human Genome Organisation (HUGO), and the World Medical Association.⁴⁰

Although the USA does not have such a strong tradition of solidarity in insurance that is common in Europe and elsewhere, it too has prohibited insurers from using genetic information—at least in the context of health insurance. In 2008, Congress passed GINA, which bars covered health insurers and employers from using genetic information and, absent a handful of exceptions, from collecting genetic information from a policyholder or employee.⁴¹ GINA had two primary motivations, both prioritizing social considerations: 1) to assuage fears of genetic discrimination, and thus promote public support for genetic testing and research, and 2) to prevent discrimination that may occur in the future.⁴² These forward-looking goals stem from the limited evidence of genetic discrimination, but the more robust evidence of fear of genetic discrimination. They also made GINA unique among other US nondiscrimination statutes, making it ‘the first preemptive antidiscrimination statute in American legal history’.⁴³

Opponents argued that the fear of genetic discrimination was irrational and unfounded given the absence of widespread evidence of genetic discrimination. Therefore, the solution was not to pass anti-discrimination legislation, but to properly educate the public regarding the lack of evidence of genetic discrimination. In the end, however, the concern that fear of discrimination, ‘whether based on reality or perception’, would stymie uptake of genetic testing and research was more palpable than concerns of superfluous legislation.⁴⁴

C. GINA 2.0: Which Priority?

Due to the sustained fear of discrimination in contexts broader than health insurance, there have been murmurings that Congress should broaden GINA to include other insurances. For example, Congresswoman Louise Slaughter, the original author of GINA, had considered bringing new legislation to encompass life, long-term care, and disability insurers.⁴⁵ The question is whether such legislation could come to pass and, if it does, what it might look like. Would this legislation follow GINA’s model of a complete ban

³⁸ *Id.*; Joly et al., *supra* note 5, at 357.

³⁹ Press Statement of Heather Nauert, US Department of State Spokesperson, ‘The United States Withdraws From UNESCO’, Oct. 12, 2017, <https://www.state.gov/t/pa/prs/ps/2017/10/274748.htm> (last visited Feb. 12, 2019).

⁴⁰ Joly et al., *supra* note 5, at 357.

⁴¹ GINA, *supra* note 6.

⁴² Robert C. Green et al., *GINA, Genetic Discrimination, and Genomic Medicine*, 372 *NEW ENG. J. MED.* 397, 397 (2015); Mark A. Rothstein et al., *Limiting Occupational Medical Evaluations under the Americans with Disabilities Act and the Genetic Information Nondiscrimination Act*, 41 *AM. J. L. & MED.* 523, 547 (2015).

⁴³ Jessica L. Roberts, *Preempting Discrimination: Lessons from the Genetic Information Nondiscrimination Act*, 63 *VAND. L. REV.* 437 (2010).

⁴⁴ Secretary’s Advisory Committee on Genetics, Health and Society: A roadmap for the integration of genetics and genomics into health and society. Washington, DC, Department of Human Health & Services, 2004.

⁴⁵ David Schultz, *It’s Legal for Some Insurers to Discriminate Based on Genes*, NPR, Jan. 17, 2013, <http://www.npr.org/blogs/health/2013/01/17/169634045/some-types-of-insurance-can-discriminate-based-on-genes> (last visited Feb. 12, 2019); Congresswoman Slaughter has recently passed away, but her vision for a more expansive GINA-type legislation remains pertinent.

or would another form of regulation arise? Would it be a national bill or will change occur at the state level?

At the state level, legislatures have placed some restrictions on insurer use of genetic information in life, long-term care, and disability insurance. However, they are generally not wholesale bans of use across multiple lines of insurance. Some state legislation prohibits insurers from using a specific trait or predisposition in underwriting. For example, states have restricted insurer use of sickle cell trait⁴⁶ and carrier status for recessive genes.⁴⁷ Sometimes, restrictions may apply to one particular type of insurance but leave genetic information available for underwriting in other insurance lines. For example, in Colorado, *group* disability and long-term care insurers are not allowed to use genetic information, although *individual* policies or life insurance policies do not have a similar restriction.⁴⁸

There have been other state efforts to introduce complete bans in insurance. For example, in 2011, a comprehensive genetic privacy bill was introduced in Massachusetts.⁴⁹ This bill would have restricted the use of genetics in life, long-term care, and disability insurances,⁵⁰ but it was never passed. In Florida in 2017, a bill was introduced in the state legislature to bar life, disability, and long-term care insurer use of genetic information, the bill was passed unanimously by the House and voted, also unanimously, out of two Senate committees, but died in a third committee.⁵¹

Although there is some legislative movement at the state level, it is currently fairly limited. As Section IV discusses further, it is no surprise that we continue to see state movement in this arena a decade after GINA was passed. Examining the history of genetic information regulation in private, non-health insurance lines gives valuable insight into what factors and stakeholders can influence the shape of policy. The following section will detail the policy in four case studies—UK, Sweden, Australia, and Canada.

III. CASE STUDIES

Given that many policies adopted in the case study countries have overlapping principles, this part begins with an overview of four common policy constraints used internationally.⁵² It then continues with an in-depth discussion of the policy in each of the

⁴⁶ F.S.A. § 626.9706 (West, Westlaw through 2018 Second Regular Session of the 25th Legislature).

⁴⁷ Cal. Ins. Code §10143 (West, Westlaw current through Ch. 1016 of 2018 Reg.Sess.).

⁴⁸ C.R.S.A. § 10-3-1104.7 (West, Westlaw through end of the Second Regular Session of the 71st General Assembly (2018)).

⁴⁹ S.1080, An Act to Create A Genetic Bill of Rights, 187th General Court of the Commonwealth of Massachusetts.

⁵⁰ Jaclyn G Ambriscoe, *Massachusetts Genetic Bill of Rights: Chipping Away at Genetic Privacy*, 45 SUFFOLK U. L. REV. 1177, 1195 (2011).

⁵¹ HB 855: Genetic Information Used for Insurance; CS/SB 1106: Genetic Information Used for Insurance. <https://www.flsenate.gov/Session/Bill/2018/00855> (last visited Feb. 12, 2019).

⁵² There are other examples of policy constraints highlighted in the literature that are not employed in the four comparison countries and therefore will not be included in this paper. For example, another policy constraint is a therapeutic limit. A therapeutic limit policy constraint restricts actors from using genetic test results for purposes other than health or research. Thus, this constraint attaches to the data itself, rather than places any limits on a particular set of actors. The goal of such a limit, presumably, is to promote the use of genetic testing for research and health purposes, while simultaneously deterring the use by actors outside of the medical realm. Joly et al., *supra* note 5, at 356. Policy constraints such as these—that attach to the data—are also perhaps less likely to be implemented in the USA where genetic information is already commonly available and used outside a therapeutic realm.

four countries, the UK, Sweden, Australia, and Canada, covering a brief description of the country's insurance landscape, including their health insurance or health care system; the countries' policy or policies as it relates to non-health insurer use of genetic information; and the impact of the policy or policies highlighted in each country.

A. Common Policy Constraints

Policy constraint refers to some element of a policy that narrows the effect of a bar on insurer use of genetic information, thus creating a scenario where insurers are allowed to use genetic information under certain conditions but restricted under other conditions. This paper will highlight four policy constraints, labeled as monetary limits,⁵³ regulatory review,⁵⁴ information symmetry, and breadth of genetic information.

1. Monetary Limits

Under a monetary limits approach, insurers are barred from using genetic test results when an applicant applies for a policy under a certain monetary amount but are allowed to take test results into account for policies over the monetary threshold.⁵⁵ For example, a threshold could be set at \$500,000 for a life insurance policy. This balances between the competing social and economic concerns related to insurer use of genetic information. As discussed above, insurance companies are concerned, among other things, about adverse selection where they will not be able to accurately assess premiums if they are not permitted to collect full information about an applicant's risk.⁵⁶ The detrimental economic effects of these concerns are heightened for insurance policies with high payouts. Thus, allowing insurers to review and consider genetic test results for high-value policies minimizes the potential economic impact of a regulatory ban. Under monetary limits, insurers would no longer need to worry about high-risk individuals flooding an insurance company with multi-million dollar policies without having to disclose their genetic risk. Instead, high-risk individuals wishing to purchase insurance without underwriting on the basis of their genetic risk would be limited to lower-value policies.

From a social perspective, however, this policy option limits the creation of a genetic underclass because high-risk individuals are more likely to be able to access at least some level of insurance. Additionally, if this policy constraint adequately assuages fear of genetic discrimination, it may increase participation in genetic research and use of genetic testing for clinical care.

2. Regulatory Review

A policy constraint of regulatory review begins with the general premise that insurance companies should be able to use actuarially relevant genetic information in risk classification. However, these policies create a level of independent review to assess which genetic tests will be allowed.⁵⁷ Thus, principles of actuarial justification remain, but the power to determine which genetic tests reach actuarial evidentiary thresholds is housed

⁵³ This has also been labeled the fair limits approach. *Id.*

⁵⁴ This has also been labeled the rational discrimination approach. *Id.*; see also Prince, *supra* note 15, 641-45.

⁵⁵ Joly et al., *supra* note 5, at 355-56.

⁵⁶ In the context where the informational asymmetry that leads to adverse selection is imposed through law, it is referred to as regulatory adverse selection. Michael Hoy & Michael Ruse, *Regulating Genetic Information in Insurance Markets*, 8 RISK MANAGEMENT & INSURANCE REV. 211, 214 (2005).

⁵⁷ For an extensive review of this policy constraint, see Prince, *supra* note 15.

within a group independent from the insurance company, such as a government appointed review committee. This adds a level of oversight, but also flexibility, to insurer use of genetic information. Unlike an inflexible legislative ban, regulatory review allows for continued reassessment of developing genetic technologies, albeit by an independent reviewer, not the insurance industry itself. The goal is to increase trust and transparency in the insurance industry and therefore lower fears of genetic discrimination among the public. It also addresses the economic needs of insurers while increasing the clarity and public trust in the system.

3. Symmetrical Information

One of the insurance mantras related to concerns of adverse selection is that insurers need access to the same information about an applicant's risk that the applicant has.⁵⁸ If an applicant has taken a genetic test, and has knowledge about the test results, the insurers want access to the test results as well. In order to appease some privacy concerns, policies sometimes state that insurers will not or cannot actively undertake genetic testing on applicants or require an applicant to undergo testing.⁵⁹ Through this, information asymmetry is preserved without forcing an applicant to learn more about her future risk than she wishes. Indeed, if insurers undertake genetic testing themselves, this would create a system where now the insurer has more information about an applicant's risk than the applicant himself. The policy constraint of symmetrical information is often implemented through industry self-regulation.⁶⁰ While no US states have utilized a monetary limit or independent review,⁶¹ the symmetrical information requirement has been codified into US law. For example, Vermont prohibits insurers from requiring an applicant to take a genetic test in order to qualify for coverage.⁶² Therefore, insurers can collect existing test results or other relevant information, such as family medical history, but cannot require more risk information to be produced.

4. Breadth of Genetic Information

For any policy affecting insurer use of genetics, one of the most salient definitional questions is what constitutes genetic information. GINA defines genetic information

⁵⁸ 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, 266 (2016); Ine Van Hoyweghen et al., 'Genetics Is Not the Issue': Insurers on Genetics and Life Insurance, 24 NEW GENET. & SOC. 81 (2005).

⁵⁹ See eg Canadian Life and Health Insurance Association (CLHIA), Industry Code: Genetic Testing Information for Insurance Underwriting, Jan. 11, 2017, §4.1, 4.3 (discussing the principle of 'equal information'); Financial Services Council, FSC Standard No. 11 Genetic Testing Policy, Dec. 7, 2016, §10.2 (discussing Australian disclosure rules); there has been some controversy over the years regarding whether insurance companies should have information about an applicant's participation in genomic research. See eg Yann Joly et al., *Life Insurance: Genomic Stratification and Risk Classification*, 22 EUR. J. HUM. GENET. 575, 577 (2014); the industry codes sometimes address this by stating that they will not seek information about participation in genetic research unless any research results have been returned to the applicant or his or her physician.

⁶⁰ *Id.* Additionally, in those countries where insurers are prohibited from requiring applicants to disclose genetic information, they often are not allowed to undertake testing themselves. However, it is important for policies to address both possible sources of genetic information.

⁶¹ Independent review has been discussed by the Uniform Law Commission in the US, but never fully recommended. National Conference of Commissioners on Uniform Laws, Draft Uniform Protection of Genetic Information in Employment and Insurance Act (2010).

⁶² V. S. A. tit. 8 § 4724(22) (West, Westlaw through all acts of the Adjourned Session of the 2017-2018 Vermont General Assembly).

to include information beyond just genetic test results, such as family medical history.⁶³ Other policies differentiate between predictive and diagnostic genetic tests.⁶⁴ The definition of genetic information or genetic test in a policy will greatly alter the economic impact the policy has on the insurance industry and the number of people whose information may be protected. Although most if not all of the policies described below will have a definitions section, this paper will flag those policies that have particularly notable definitional constraints or breadth around ‘genetic information’.⁶⁵

B. United Kingdom

1. UK System

The UK has a robust National Health Service (NHS), providing comprehensive health care to the population generally free of cost.⁶⁶ NHS coverage is universal, but some residents supplement coverage with private health insurance to access additional services and obtain more rapid access to care.⁶⁷ There is also a private insurance market for non-health insurances. Three common types of insurance in the UK are relevant for this discussion: life, income protection, and critical illness.⁶⁸ Notably, mortgages and life insurance in the UK interconnect, meaning that inability to access a life insurance policy may affect the ability to fully secure one’s mortgage policy.⁶⁹ There are approximately 25.7 million individual life, income protection, and critical illness insurance policies in force.⁷⁰

2. UK Genetics and Insurance

In the UK, insurer use of genetic information was, until recently, governed by a moratorium—a voluntary agreement between the Association of British Insurers (ABI) and the UK government. A new 2018 agreement, the Code on Genetic Testing and Insurance (the Code), maintains similar provisions.⁷¹ The agreement employs several policy constraints—monetary limits, regulatory review, and a limited definition of genetic test.⁷² Notably, the original voluntary agreement was established at a time when the insurance industry feared the implementation of a more permanent policy solution—legislation.

⁶³ GINA, *supra* note 6.

⁶⁴ For example, HM Government and ABI, *Concordat and Moratorium on Genetics and Insurance* (2014).

⁶⁵ See Table 1.

⁶⁶ ELIAS MOSSIALOS ET AL., *INTERNATIONAL PROFILES OF HEALTH CARE SYSTEMS* 49–50 (The Commonwealth Fund 2017).

⁶⁷ *Id.* at 49.

⁶⁸ Genetics and Insurance Committee (GAIC), *Second Report from September 2002 to December 2003* (2004).

⁶⁹ See generally A. S. Macdonald, *Moratoria on the Use of Genetic Tests and Family History for Mortgage-Related Life Insurance*, 9 *BRIT. ACTUARIAL J.* 217 (2003) (discussing the importance of life insurance to mortgages in the UK); GAIC 2nd Report, *supra* note 68, at 26; Chief Medical Officer, *Generation Genome: Annual Report of the Chief Medical Officer* at ch. 15, p. 3 (2016) [hereinafter *Generation Genome*].

⁷⁰ Association of British Insurers (ABI), *UK Insurance & Long-Term Savings: Key Facts* (2017).

⁷¹ HM Government and ABI, *Code on Genetic Testing and Insurance* (2018), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/751230/code-on-genetic-testing-and-insurance.pdf (last visited Feb. 12, 2019).

⁷² See *supra* Section III.A.

Table 1. Case Study Policies Regarding Insurer Use of Genetic Information.

<i>Country</i>	<i>Policy</i>	<i>Policy Constraint(s)</i>	<i>Legal Regime</i>
UK	Concordant and Moratorium (now the Code on Genetic Testing and Insurance)	Monetary limit Regulatory review Definition	Insurance
Sweden	Moratorium	Monetary limit Symmetrical information Definition	Insurance
Sweden	Genetic Integrity Act	Monetary limit	Insurance
Australia	Disability Discrimination Act		Anti-discrimination
Australia	FSC Industry Code	Symmetrical information	Insurance
Australia	Essentially Yours	Regulatory review*	Insurance
Canada	Canadian Charter of Rights and Freedoms & Human Rights Act		Anti-discrimination
Canada	Personal Information Protection and Electronic Documents Act (PIPEDA)		Privacy
Canada	CLHIA Industry Code	Symmetrical information Monetary limit	Insurance
Canada	Genetic Nondiscrimination Act	Monetary limit*	Criminal

*Proposed, but never fully implemented.

In the 1990s, the UK Parliament began to take an interest in the possibility of insurer use of genetic information and early committee work recommended legislation if the insurance industry did not fully address concerns of the integration of genetic tests into underwriting.⁷³ Initially, the UK government created several committees to review the issues, make recommendations, and provide oversight for insurer use of the tests, although the insurance industry was ultimately left to self-regulate.⁷⁴ By 2001, government committees were pushing for legislation, arguing that the industry's attempts at

⁷³ R. Guy Thomas, *Genetics and Insurance in the United Kingdom 1995–2010: The Rise and Fall of 'Scientific' Discrimination*, 31 *NEW GENET. & SOC.* 203, 205 (2012).

⁷⁴ *Id.* at 205–06.

self-regulation had failed.⁷⁵ Fearing potential legislation that could create a permanent restriction on insurers, the industry opted for a voluntary agreement with the government.⁷⁶ This led to the creation of the Concordat and Moratorium. Although the agreement has been modified over the years, the primary structure of the policy continues to this day.⁷⁷

Under the Concordat and Moratorium, the UK insurers voluntarily agreed to a ban on the use of predictive genetic test results. The moratorium applied to life, long-term care, income protection, and critical illness insurance. The first Concordat in 2001 was set to expire in 2006, with a mandatory review of the agreement set for three to four years after implementation. At each review in 2005, 2008, 2011, and 2014, the ABI and government renewed the agreement with few changes.⁷⁸ The latest iteration, the Code on Genetic Testing and Insurance, was announced in October 2018. It builds on the previous Concordats, with only slight changes.⁷⁹ This structure has created a long-lasting and stable policy. With the Concordats there was the possibility that the agreement could end after each review period; however, in the newest code the government and insurance industry 'have agreed to make this Code open-ended, to provide longer term certainty to customers'.⁸⁰ The Code retains a review for potential updates every three years.⁸¹

The agreement is subject to three policy constraints. First, the agreement created a monetary limit where insurers would not collect or consider predictive genetic test results under the set thresholds. These thresholds were set at £500,000 for life insurance, £300,000 for critical illness, and £30,000 for annual income protection insurance benefits⁸² and have not been changed since the policy was implemented.⁸³ Due to the thresholds, it is estimated that approximately 95% of applicants for life insurance will not have to disclose any possible genetic test results.⁸⁴ Second, for policies above the thresholds, insurers can only use those genetic tests approved by a government body. Originally, the Genetics and Insurance Commission (GAIC) served this role.⁸⁵ In 2000, GAIC approved the use of the genetic test for Huntington's disease for use in life insurance policies above £500,000, but has not approved any other genetic tests since then.⁸⁶ Indeed, after some initial applications and clarification of standards,

⁷⁵ *Id.* at 206 (citing the Human Genetics Commission 2001); see also C. D. Daykin et al., *Genetics and Insurance—Some Social Policy Issues*, 9 BRIT. ACTUARIAL J. 787, 815 (2003) (indicating that the insurance industry's practices increased the likelihood of threatened legislation).

⁷⁶ Thomas, *supra* note 73, at 206; indeed, this has successfully avoided the introduction of new legislation, see eg House of Lords Science and Technology Committee, *Genomic Medicine*, 2nd Report of Session 2008–09, p. 62, noting that in 2008 the Government looked into the matter, but decided that no insurance anti-discrimination legislation was necessary given the success of the Concordat and Moratorium.

⁷⁷ Code on Genetic Testing and Insurance, *supra* note 71.

⁷⁸ Generation Genome, *supra* note 69, at ch.15, pp. 3–4 (discussing the changes made across the agreements, such as clarifying definitions and noting that research results were not to be used by insurers).

⁷⁹ Code on Genetic Testing and Insurance, *supra* note 71.

⁸⁰ *Id.* at 4.

⁸¹ *Id.* at 11.

⁸² *Id.* at 7.

⁸³ GAIC 2nd Report, *supra* note 68, at 8; Concordat and Moratorium, *supra* note 64, at 7.

⁸⁴ Generation Genome, *supra* note 69, at ch. 15, p. 7; Genomics and Genome Editing in the NHS: Third Report of Session 2017–19 (2018) [hereinafter *Genomics in the NHS*].

⁸⁵ Thomas, *supra* note 73, at 205–6.

⁸⁶ Daykin et al., *supra* note 75, at 815.

no applications for use of tests have been submitted by the insurance industry.⁸⁷ Without any applications to approve, the GAIC was soon disbanded. However, a process still exists if insurers desire to submit an application in the future.⁸⁸

Finally, the moratorium is limited due to the definitional bounds of the agreement. Most notably, the agreement only applies to *predictive* genetic tests. ‘A predictive genetic test is taken prior to the appearance of any symptoms, signs or abnormal non-genetic tests results which indicate that the condition in question is present.’⁸⁹ Thus, insurers can still consider family medical history and diagnostic genetic tests that are used to assess someone’s current symptoms of disease.⁹⁰

3. Impact of Policy

As indicated by the continued renewal of the agreement by both the ABI and the government, the UK’s policy has created a stable solution that appears to balance between economic and social concerns. For example, on the consumer side, the moratorium appears to have quelled some of the fears of genetic discrimination that were present prior to the policy.⁹¹ This is notable since diagnostic genetic tests and family medical history remain fair game for insurers to use in underwriting. From the insurer perspective, there has not been evidence of adverse selection stemming from insurers inability to collect predictive genetic test results.⁹² While it is difficult to measure adverse selection, those looking into the issue have not reported notable changes to the insurance markets or premiums as a result of the moratorium.⁹³ Additionally, the regular review of the moratorium is beneficial because there is flexibility to adjust the agreement if and when there are major scientific advances in genetic risk prediction.⁹⁴

C. Sweden

1. Swedish System

Sweden has a universal health care system with automatic coverage.⁹⁵ The national government oversees health care policy, while regional governments handle health care financing and delivery.⁹⁶ In addition to the universal coverage, Sweden has a very small private health insurance system with fewer than 700,000 members, primarily used to provide access to elective treatments on a faster timeline than through the national

⁸⁷ Thomas, *supra* note 73, at 205–06; GAIC 2nd Report, *supra* note 68 (detailing the new application standards and indicating approval for the use of Huntington’s disease for life insurance policies); see also Prince, *supra* note 15, 673–74 (providing a detailed discussion of the actuarial standards employed by the GAIC).

⁸⁸ Code on Genetic Testing and Insurance, *supra* note 71, at 12.

⁸⁹ Concordat and Moratorium, *supra* note 64, at Annex 2.

⁹⁰ Generation Genome, *supra* note 69, at ch. 15, p. 3.

⁹¹ Genomics in the NHS, *supra* note 84, at 36 (noting that consumers’ concerns of insurer use of genetic information should continue to be monitored as the Concordat comes under pressure from increased population participation in whole genome sequencing); Generation Genome, *supra* note 69, at ch. 15, p. 7.

⁹² Third Report from January 2004 to December 2004 at 8 (2005) (indicating that GAIC had not seen evidence of adverse selection since the implementation of the moratorium); Thomas, *supra* note 73, at 210; Genomics in the NHS, *supra* note 84, at 36.

⁹³ Australian Law Reform Commission (ALRC), *Essentially Yours—the Protection of Human Genetic Information in Australia*, Volume 1 and Volume 2. Report 96 at 681 (2003).

⁹⁴ Van Hoyweghen et al., *supra* note 58, at 92; Genomics in the NHS, *supra* note 84.

⁹⁵ MOSSIALOS ET AL., *supra* note 66, at 147.

⁹⁶ *Id.*

system.⁹⁷ Sweden also guarantees adults access to long-term care services, including nursing home and hospice care.⁹⁸ The country has a small life insurance industry and a non-life insurance industry that includes sickness and accident insurance.⁹⁹ The sickness and accident insurance includes products for child insurance, rehabilitation insurance, and accident insurance—however, fewer than 25 million policies are sold overall and fewer than 5 million of these are individual policies.¹⁰⁰

2. *Swedish Genetics and Insurance*

Like the UK, Sweden policy in the area of insurer use of genetic information began with an agreement between the insurance industry and the government. The first agreement, developed in 1999, applied to individual life and health insurance policies and employed two policy constraints—symmetrical information and monetary limits.¹⁰¹ First, the agreement determined that no one should be required to undergo a genetic test for insurance purposes.¹⁰² Second, the parties agreed to a monetary threshold based on a percentage of base amount utilized in Swedish social welfare systems, for example to calculate pensions—in today's US dollars, this equates to approximately \$71,000 for lump sum policies.¹⁰³ An annual limit was also set for insurances paying yearly benefits, such as income replacement schemes.¹⁰⁴ The advantage of linking the policy to the base amount is that it automatically adjusts annually for price inflation. For example, the agreement was renewed in 2004 and the threshold amount had more than doubled since the original formation.¹⁰⁵ Under this threshold amount, life and health insurers agreed not to take into account genetic test results. Notably, this agreement also applied to family medical history—a much broader definitional bound than the UK moratorium.¹⁰⁶ Because the moratorium only applied to life and health insurers, the agreement did not cover children's insurance, which under Swedish regulation is considered non-life insurance.¹⁰⁷

In 2004, a government commission produced a report on a range of issues regarding genetics, including genetics and insurance.¹⁰⁸ The commission recommended that insurers not be allowed to require an applicant to undergo testing and should only be allowed to ask about genetic test results for policies with high monetary values.¹⁰⁹ This led to the passage of the Genetic Integrity Act in 2006.¹¹⁰ The Act codifies the monetary threshold into law and prohibits 'risk-rated personal insurers' from using genetic

⁹⁷ *Id.*; Svensk Försäkring, Insurance in Sweden Statistics (2016).

⁹⁸ MOSSIALOS ET AL., *supra* note 66, at 149.

⁹⁹ Svensk Försäkring, *supra* note 97.

¹⁰⁰ *Id.* at 7.

¹⁰¹ GAIC 2nd Report, *supra* note 68, at Appendix.

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ Jon Lambert, 'International Comparisons of the Use of Genetic Information in the Life and Health Insurance Markets' in the Geneva Associations Working Papers Series.

¹⁰⁶ Angus Macdonald & Fei Yu, *The Impact of Genetic Information on the Insurance Industry: Conclusions from the 'Bottom-up' Modelling Programme*, 41 ASTIN BULLETIN 343, 347 (2011).

¹⁰⁷ Svensk Försäkring, *supra* note 97, at 7.

¹⁰⁸ Genetik, Integritet Och Etik [Genetics, Integrity, and Ethics] Sou 2004:20 (2004).

¹⁰⁹ *Id.*

¹¹⁰ The Genetic Integrity Act (2006:351), Swedish Code of Statutes no 2006:351.

information for policies over a certain monetary amount, as calculated by a base amount formula.¹¹¹ The commission also recommended that those insurers underwriting children's policies should not be able to use genetic information; therefore, the Act's monetary threshold exception only applies to adults.¹¹²

3. Impact of Policy

Given the robust welfare system in Sweden, the private insurance market is very small. Therefore, the prohibition of insurer use of genetic information under certain threshold amounts only affects a small segment of the population. Although it is difficult to determine the full impact of the policy due to language, there does not appear to have been any extensive review or government reports indicating unintended consequences or concerns of the policy.¹¹³ Additionally, while the Swedish insurance industry was an early adopter of a voluntary moratorium, gaps in this policy—such as the continued ability for insurers to use genetic information in children's insurance—led the commission to recommend broader legislation despite the moratorium.

D. Australia

1. Australian System

Australia has a federalist system of government, where the power to regulate the insurance industry rests within the federal jurisdiction, rather than in state or territory jurisdiction.¹¹⁴ The country has approximately 30 life insurers which sell a range of products such as term life, disability, critical illness, and income protection insurance.¹¹⁵ There is a robust system of group life insurance through an employment system called a superannuation fund. Superannuation is a retirement scheme made up by both compulsory employer contributions and voluntary individual contributions.¹¹⁶ These retirement schemes are paired with various types of insurance coverage and, as a result, most Australians obtain limited levels of life insurance and disability cover through their superannuation.¹¹⁷ For example, of the approximately 21.9 million life insurance policies, 14 million are group policies through superannuation.¹¹⁸ Although superannuation comprises a major portion of life insurance in Australia, the private individual life insurance market is still important.

In the health care arena, Australia has a national health insurance, called Medicare.¹¹⁹ This is funded by the federal government and covers a broad range of services from hospital care, medical services, and pharmaceuticals.¹²⁰ Australians can also

¹¹¹ This formula is 30 price base amounts for lump sum and 4 price base amounts for annual policies. The Genetic Integrity Act (2006:351), Swedish Code of Statutes no 2006:351, ch. 2, Section 2.

¹¹² Genetik, Integritet Och Etik [Genetics, Integrity, and Ethics] Sou 2004:20, *supra* note 108.

¹¹³ This is also based on speaking to individuals as part of this NHGRI-sponsored research. See the Acknowledgment section.

¹¹⁴ Parliamentary Joint Committee on Corporations and Financial Services, Life Insurance Industry at 10 (2018) [hereinafter Parliamentary Report] (noting that regulation is overseen by the Australian Securities and Investments Commission (ASIC) and the Australian Prudential Regulatory Authority (APRA)).

¹¹⁵ *Id.* at 5

¹¹⁶ Commonwealth of Australia, Super System Review Final Report at Appendix B (2010).

¹¹⁷ *Id.* at 142

¹¹⁸ Statistic from 2005; Parliamentary Report, *supra* note 114, at 7.

¹¹⁹ MOSSIALOS ET AL., *supra* note 66, at 11.

¹²⁰ *Id.* at 11–12

purchase community-rated private health insurance supplements, meaning that they do not go through individual underwriting to access this supplemental insurance.¹²¹ Approximately half of Australians have private hospital coverage that covers additional services and a choice of providers.¹²²

2. Australian Genetics and Insurance

The UK and Swedish policies regarding insurer use of genetic information are fairly comprehensive. They apply directly to the insurance industry and have created stable systems to regulate insurer use of genetic information. Australia, on the other hand, provides an illustration of how an anti-discrimination approach creates potential gaps and concerns in society and how regulatory attempts to fill these gaps can fail to effect change.

In 2003, the Australian Law Reform Commission and the Australian Health Ethics Committee of the National Health and Medical Research Council completed an extensive report on how genetic testing affects society.¹²³ In the report, *Essentially Yours*, the Inquiry laid out its recommendations for protecting privacy and protecting against unfair discrimination across a variety of sectors, including insurance.¹²⁴ This Section discusses three intertwined Australian policies: the Disability Discrimination Act, *Essentially Yours*, and insurance industry self-regulation.

a. Disability Discrimination Act. The most salient Australian anti-discrimination law in this context is the Disability Discrimination Act (DDA).¹²⁵ The DDA, similar to the Americans with Disabilities Act (ADA) in the USA, prohibits discrimination on the basis of a disability. *Essentially Yours* recommended that the DDA should be amended to make clear that the law covers genetic discrimination in addition to disability discrimination.¹²⁶ In 2009, the Disability Discrimination and Other Human Rights Legislation Amendment Act followed this recommendation and clarified that the act made it unlawful to discriminate based on a genetic predisposition.¹²⁷

While this clarification ensures protections for individuals with genetic predispositions in the context of employment and other jurisdictions of the DDA, the effect on insurance is limited. Australia's anti-discrimination legislation has an explicit exception for insurance—as long as they have actuarial justification, insurers can use genetic and

¹²¹ Jane Tiller et al., *Should Australia Ban the Use of Genetic Test Results in Life Insurance?*, 5 FRONT. PUB. HEALTH, 330 (2017).

¹²² MOSSIALOS ET AL., *supra* note 66, at 11; Australians are incentivized to get private insurance through levied taxes on higher income Australians. <https://www.ato.gov.au/individuals/medicare-levy/medicare-levy-surcharge/> (last visited Feb. 12, 2019).

¹²³ *Essentially Yours*, *supra* note 93.

¹²⁴ The report details how the existing regulatory legal regimes in anti-discrimination law covers genetic discrimination in addition to disability discrimination. It also discusses the country's privacy regime and generally finds that the privacy regime is adequate to address health information broadly and genetic information specifically. *Id.* at 33, chs 7, 8, and 28. They did, however, make some small recommendations regarding consent to gather genetic information data from insurance applicants.

¹²⁵ *Id.* at 297; Disability Discrimination Act, Act No. 135 of 1992 (DDA).

¹²⁶ *Essentially Yours*, *supra* note 93, at 305–12.

¹²⁷ *Disability Discrimination and Other Human Rights Legislation Amendment Act 2009* (amending the definition of disability in the DDA §4 to read, 'includes a disability that... may exist in the future (including because of a genetic predisposition to that disability)').

other health information to set different premium levels.¹²⁸ This is a common exception to human rights and anti-discrimination laws because insurance is built on a system of discrimination.¹²⁹ That is, in order to assess premiums that reflect an applicant's expected cost to the system, insurers must treat people differently based on health and social factors.¹³⁰ Thus, although Australia employs an anti-discrimination legal regime that specifically covers genetic discrimination, the only policy constraint that relates to insurers is that they must have actuarial justification to use genetic information or other health data—a constraint that is essentially no different than the insurance status quo.

b. Essentially Yours. After examining the insurance and anti-discrimination landscape of Australia, the Essentially Yours Inquiry concluded, 'there is insufficient evidence to justify a departure from the fundamental principle underlying the market in voluntary, mutually rated insurance in Australia, namely, equality of information between the applicant and the insurer.'¹³¹ They considered five options for reform, including maintaining the status quo, prohibiting use, imposing a monetary limit, developing new insurance products, and cross-subsidizing high risks.¹³² However, they ultimately concluded that insurers should continue to legally access genetic test results to avoid negative impact on insurance premiums.

Instead, the Inquiry felt the focus of concern should be on using the information properly, not whether or not the industry should have access to the information.¹³³ To this end, they recommended that a policy constraint of regulatory review should be developed, similar to the GAIC model in the UK.¹³⁴ Unlike the UK, the recommendation explicitly covered review of both predictive and diagnostic tests.¹³⁵ A Human Genetics Advisory Committee was created address many of the societal concerns raised in the Essentially Yours report; however, the recommendation of external review in insurance was never implemented by this committee or another, and the committee was ultimately disbanded.¹³⁶ Thus, although more in-depth oversight has been proposed in Australia, insurer use of genetic information remains regulated by the DDA and insurance self-regulation.

c. Industry Genetic Testing Policy. The first industry guidance on genetic testing was developed in 1997.¹³⁷ Today, industry self-regulation continues with the Financial Services Council (FSC).¹³⁸ The FSC first approved their Genetic Testing Policy

¹²⁸ DDA § 46 (insurance discrimination (ie treating people differently based on their disability or genetic status) is not unlawful if '(f) the discrimination: (i) is based upon actuarial or statistical data on which it is reasonable for the first-mentioned person to rely; and (ii) is reasonable having regard to the matter of the data and other relevant factors; or (g) 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.').

¹²⁹ Trudo Lemmens, *Selective Justice, Genetic Discrimination, and Insurance: Should We Single out Genes in Our Laws?*, 45 MCGILL L. J. 347, 405 (2000).

¹³⁰ See *supra* Section II.A.

¹³¹ Essentially Yours, *supra* note 93, at 668.

¹³² *Id.* at 682.

¹³³ *Id.* at 691–92.

¹³⁴ *Id.* at 707.

¹³⁵ *Id.* at 708, 27.37.

¹³⁶ Tiller et al., *supra* note 121, at 2; Australian Genetic Non-Discrimination Working Group, Submission Regarding Inquiry into the Life Insurance Industry (2016).

¹³⁷ Essentially Yours, *supra* note 93, at 663–64.

¹³⁸ The FSC was previously the International Financial Services Association (IFSA). The IFSA first created an industry standard for genetic testing in the late 1990s. *Id.* at 664.

(Standard No. 11) in 2001 and updated to the current policy in 2016.¹³⁹ This industry self-regulation guidance employs a policy constraint of symmetrical information. That is, while insurance companies are explicitly allowed to ask applicants about genetic tests they have taken in the past, the companies are prohibited from asking or requiring an applicant to undergo genetic testing as a condition of his or her insurance application.¹⁴⁰ Insurance applicants are also not required to provide information about genetic testing completed in a research setting, as long as test results are not provided to the applicant nor has the applicant requested to receive the research results.¹⁴¹

3. *Impact of policies*

Since the regulatory review suggestion from Essentially Yours was never implemented, the primary policies in Australia are the anti-discrimination framework of the DDA and the self-regulation of the FSC policies. Therefore, insurers can continue to use applicants' existing genetic test results in underwriting as long as there is actuarial justification or other evidence that justifies this use. The insurance industry itself determines what meets these evidentiary thresholds, although applicants can submit a complaint to the Australian Human Rights Commission if they believe that there has been a violation of the DDA.¹⁴² However, this complaint system is seen as ineffective and inaccessible to applicants.¹⁴³

Unlike in the UK, where the moratorium has created a relatively stable policy environment despite initial concerns of the temporary nature of the policy, the debate over insurer use of genetic information in Australia continues to this day.¹⁴⁴ The Australian insurance community continues to warn of the economic impact on the industry if insurers are not able to address adverse selection through information symmetry.¹⁴⁵ The insurance industry has participated in some oversight to ensure that they are properly using genetic test results in underwriting. The precursor organization to the FSC collected data from member insurers regarding the use of genetic testing in underwriting and agreed to share this data with independent Australian researchers.¹⁴⁶ The researchers found that, for the most part, the insurers' use of genetic tests in

¹³⁹ Although legally non-binding, the industry group has the possibility of disciplinary measures if a member insurer does not comply with the policy. *Id.* at 665(25.59). Thus, the policy is binding 'upon FSC Members'. Other life insurers are encouraged to follow the recommendations. FSC No. 11, *supra* note 59.

¹⁴⁰ FSC No. 11, *supra* note 59, at 10.1–10.2 (2016); the recommendations also state that this information should not be acquired or purchased through third parties. Essentially Yours, *supra* note 93, at 10.6.1.

¹⁴¹ FSC No. 11, *supra* note 59, at 10.3 (2016).

¹⁴² See eg Keogh & Otlowski, *supra* note 1 (describing how one man with a predisposition to colon cancer navigated insurance appeals following a denial of insurance).

¹⁴³ Non-Discrimination Working Group Submission, *supra* note 136.

¹⁴⁴ See eg Ainsley J. Newson et al., *Genetics and Insurance in Australia: Concerns around a Self-Regulated Industry*, 20 PUB. HEALTH GENOMICS 247 (2017); Tiller et al., *supra* note 121; Human Genetics Society of Australasia, *Position Statement Genetic Testing and Personal Insurance Products in Australia* (2018).

¹⁴⁵ Damjan Vukcevic & Jessica Chen, *Thinking About Life Insurance through a Genetic Lens*, ACTUARIES INSTITUTE (2017); Parliamentary Report, *supra* note 114, at 147–50.

¹⁴⁶ Margaret Otlowski et al., *Investigating Genetic Discrimination in the Australian Life Insurance Sector: The Use of Genetic Test Results in Underwriting, 1999-2003*, 14 J. L. MED. 367 (2007); Parliamentary Report, *supra* note 114, at 147.

underwriting has been reasonable.¹⁴⁷ Despite this, there has been continued empirical findings documenting that fear of genetic discrimination is limiting uptake of genetic testing in both the research and clinical contexts.¹⁴⁸

Researchers and advocates continue to encourage greater restrictions on insurer use of genetic information. For example, an interdisciplinary group of Australia researchers—called the Australian Genetic Non-Discrimination Working Group—submitted comments to a public inquiry of the life insurance industry related to use of genetic information.¹⁴⁹ Of particular concern to the group is the self-regulatory nature of the policies to date.¹⁵⁰

In March 2018, the Parliamentary Joint Committee on Corporations and Financial Services released a wide-ranging report on the life insurance industry. The report recommends that Australia should have a moratorium similar to the UK.¹⁵¹ Additionally, the report recommends that the government continue to monitor whether more stringent bans are needed in the future.¹⁵² Finally, the report recommends a system of co-regulation where the federal government would have enforcement authority over the FCS's self-regulatory policies.¹⁵³ Although these currently are recommendations, they could feasibly lead to legislative action or industry change due to the increased threat of legislation.

After the Parliamentary Report, the FSC announced a moratorium that will begin in July 2019 and last at least five years.¹⁵⁴ The moratorium adopts several of the policy constraints of the UK system. It sets a monetary limit of \$500,000 Australian dollars. For policies under this amount, applicants would not be required to disclose genetic test results. However, unlike the UK, there is no government review and all genetic test results can be considered over the threshold.

E. Canada

1. Canadian System

Like Australia, Canada has a federalist system of government. The health care system is publicly funded and administered through the provinces, with national standards

¹⁴⁷ Otlowski et al., *supra* note 146; this study was recreated for the years 2010–2013 with similar findings. M. Liepins et al., *Australian Life Insurers Use of Genetic Test Results in Underwriting Decisions*, ESHG PRESENTATION ABSTRACT (2017)

¹⁴⁸ Tiller et al., *supra* note 121, at 2 (summarizing current research in genetic discrimination); Keogh et al., *supra* note 32, at 592; Keogh & Otlowski, *supra* note 1, at 363.

¹⁴⁹ Tiller et al., *supra* note 121, at 2; Non-Discrimination Working Group Submission, *supra* note 136.

¹⁵⁰ Newson et al., *supra* note 144, at 12 (noting that, “The Australian status quo of self-regulation for the insurance industry’s use of genetic test information is at the extreme laissez-faire end of the regulatory spectrum. This is in contrast to the growing number of countries internationally with state-led regulation or co-regulation. While we accept that companies offering life insurance are for-profit entities, we claim that a self-regulating industry body as the sole overseer for this complex area arguably represents a conflict of interest and does not protect consumers, especially as the role of genomics in the healthcare system continues to expand.”); Parliamentary Report, *supra* note 114, at 150–51.

¹⁵¹ Parliamentary Report, *supra* note 114, at Recommendation 9.1; this recommendation includes an exception for consumers providing genetic information to demonstrate that they are not at risk of developing a disease.

¹⁵² *Id.* at Recommendation 9.3, 9.4.

¹⁵³ *Id.* at Recommendation 155–56.

¹⁵⁴ FSC, *FSC Announces Moratorium on Genetic Tests for Life Insurance to Start in July 2019*, Oct. 2018, https://www.fsc.org.au/_entity/annotation/c5cbac97-9fdc-e811-8165-480cff12ac1 (last visited Feb. 12, 2019).

dictated by the federal Canada Health Act.¹⁵⁵ Most health care provision is overseen by the provinces, but the federal government plays a role in setting uniform standards, providing a portion of the funding, and ensuring the provision of health care to specific populations, such as military personnel and veterans.¹⁵⁶ Private health insurance policies cover services not provided through the government health care, such as prescription drug coverage and dental or vision care.¹⁵⁷ There are approximately 150 life and supplemental health insurance companies operating in Canada.¹⁵⁸

Unlike in the Australian federalist system, primary regulation of other insurances rests with the provinces rather than the federal government. Thus, insurance regulation of private insurance markets, such as life, can vary across the country. In 2016, 22 million individuals were covered by Canadian life insurance policies for a total coverage of \$4.5 trillion dollars—60% of which are individual policies.¹⁵⁹ The markets for other insurances are smaller, although still robust. For example, 12 million people have disability coverage contributing 9.1 billion in premiums in 2016.¹⁶⁰ Another 20 million Canadians have other medical-related insurances, such as accidental death and dismemberment, long-term care, and critical illness.¹⁶¹

2. *Canadian Genetics and Insurance*

Canada's regulation of insurer use of genetic information just went through intensive debate and ultimate change. In 2017, Parliament passed the Genetic Nondiscrimination Act (GNA), a bill that makes it illegal for genetic information to be used in contract formation, including insurance contracts.¹⁶² Prior to this legislation, there were several other policies in play, including anti-discrimination laws, privacy laws, and industry codes. However, the ultimate impact of the GNA is up in the air because of constitutional challenges.¹⁶³ Therefore, these precursor policies remain important beyond just their illustration of the trajectory of debate in the country.

a. Canadian Human Rights. Canadian human rights protections, such as the Canadian Charter of Rights and Freedoms, the Canadian Human Rights Act, and analogous provisions at the provincial level, protect against discrimination on the basis of enumerated traits.¹⁶⁴ As in the case of the DDA in Australia and the ADA in the USA, there are two potential problems in relying on anti-discrimination and human rights frameworks for regulating insurer use of genetic information. First, there was some question over whether discrimination on the basis of genetic information falls into an enumerated protected trait under the law.¹⁶⁵ There were arguments and case law that indicated that

¹⁵⁵ Government of Canada, *Canada's Health Care System* (2018), <https://www.canada.ca/en/health-canada/services/health-care-system/reports-publications/health-care-system/canada.html> (last visited Feb. 12, 2019); Lemmens, *supra* note 129, at 399.

¹⁵⁶ MOSSIALOS ET AL., *supra* note 66, at 21.

¹⁵⁷ *Canada's Health Care System*, *supra* note 155.

¹⁵⁸ CLHIA-ACCAP, *Canadian Life and Health Insurance Facts* (2017).

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² Genetic Nondiscrimination Act: An Act to Prohibit and Prevent Genetic Discrimination, BILL S201§9–10 (2017).

¹⁶³ See *infra* section III.E.2.d.

¹⁶⁴ Lemmens, *supra* note 5, at 50.

¹⁶⁵ *Id.*

asymptomatic individuals with genetic predispositions would be protected.¹⁶⁶ However, any lingering doubt has been put to rest with the passage of the GNA which specifically added genetic characteristics as a protected class.¹⁶⁷ Second, as is common in anti-discrimination legislation around the world, many of the human rights laws in Canada have exceptions for insurance.¹⁶⁸ For example, the Québec Charter of Human Rights and Freedoms allows insurers to use various protected traits as long as it is based on actuarial data.¹⁶⁹ Thus, like in Australia with the DDA, adding genetic characteristics to protected traits may be important for other areas of law, but does not necessarily prohibit insurer use of genetic information.

b. Personal Information Protection and Electronic Documents Act. In the 2010s, the Office of the Privacy Commissioner of Canada undertook an interesting and extensive analysis of the collection of genetic information in the insurance industry.¹⁷⁰ Canada's privacy law, the Personal Information Protection and Electronic Documents Act (PIPEDA), restricts the collection of personal information in order to supply a product or service 'beyond that required for an explicitly specified and legitimate purpose'.¹⁷¹ There is a four-part test to determine whether collection of information would violate this requirement: '1) Are the collection and the use of this personal information necessary to achieve a legitimate business purpose; 2) Is the personal information likely to be effective in achieving that purpose; 3) Are the collection and the use proportionate to the benefits gained; and, 4) Are there less privacy-invasive alternatives?'.¹⁷² After commissioning papers to assess the economic and actuarial impact of a ban on insurer use of genetic information,¹⁷³ the Privacy Commission determined that genetic information was unlikely to satisfy this four-part test and recommended that the industry adopt a moratorium on the use of genetic information.¹⁷⁴ The industry did not take this approach and did not alter their industry code to significantly restrict the collection of genetic information. No case law ever tested the Privacy Commissioner's position that collection of genetic information could violate PIPEDA.

c. Industry Guidance. Like in Australia, the insurance industry in Canada utilized industry codes to self-regulate in the area of insurer use of genetic information. The Canadian Life and Health Insurance Industry Association (CLHIA) has an industry code, 'Genetic Testing Information for Insurance Underwriting', that has gone through changes as the policy arguments have developed. Prior to the GNA, the code utilized symmetrical information as its policy constraint. Under the guidance, insurers will not

¹⁶⁶ *Id.*

¹⁶⁷ GNA, BILL S201 §9–10.

¹⁶⁸ Lemmens, *supra* note 5, at 50–51.

¹⁶⁹ The Québec Charter of Human Rights and Freedoms, R.S.Q. chapter C-12, Section 20.

¹⁷⁰ Office of the Privacy Commissioner of Canada, Genetic Information, the Life and Health Insurance Industry and the Protection of Personal Information: Framing the Debate (2012).

¹⁷¹ *Id.* at 2

¹⁷² Office of the Privacy Commissioner of Canada, Statement on the use of genetic test results by life and health insurance companies, July 9, 2014, <https://www.priv.gc.ca/en/opc-news/news-and-announcements/2014/s-d.140709/> (citing *Eastmond v. Canadian Pacific Railway*, 2004 FC 852 at para. 127) (last visited Feb. 12, 2019).

¹⁷³ Angus Macdonald, The Actuarial Relevance of Genetic Information in the Life and Health Insurance Context (2011); Michael Hoy & Maureen Durnin, *The Potential Economic Impact of a Ban on the Use of Genetic Information for Life and Health Insurance* (2011).

¹⁷⁴ Privacy Commissioner Statement, *supra* note 172.

require that genetic testing be undertaken as part of an insurance application.¹⁷⁵ It also indicates that insurers may ask individuals to disclose test results already taken, but that these results will be kept confidential and that they will be used to the individual's benefit if the test indicates lower genetic risk.¹⁷⁶ Finally, for those individuals who are denied insurance based on their genetic test results, the guidance provides that insurers will distribute additional information that may assist these applicants to find coverage through other means.¹⁷⁷ Just before the GNA was passed, the insurance industry updated their code. This change will be discussed following the introduction of the GNA.

d. Genetic Nondiscrimination Act. The GNA—also referred to as S201, the name of the bill in Parliament—was passed in 2017. The bill has three main components. First, the law amends the Canada Labour Code to protect against genetic discrimination in employment.¹⁷⁸ Second, as discussed above, it adds genetic characteristics as a protected class under the federal human rights act.¹⁷⁹ Third, and most relevant for this discussion, it makes it a criminal offence to require an individual to undergo genetic testing or to disclose the results of a genetic test as a condition of accessing a good or service, entering into a contract, or offering a specific contract term.¹⁸⁰ Violation of this may result in a fine, imprisonment, or both.¹⁸¹ There are exceptions for health care and research, but not for insurance. Therefore, insurers are not allowed to require individuals to disclose their genetic test results nor undergo genetic testing as the insurance contract is formed. One controversial aspect of the bill from the insurers perspective is that it defines genetic testing to include both predictive and diagnostic test results—thus, it will have a greater impact on the insurance industry than a policy like the UK moratorium that has definitional constraints.

The insurance industry was highly involved in the debates surrounding the bill, through testimony and active public debate.¹⁸² They argued that it would prevent them from setting actuarially fair rates, increase adverse selection, and increase premium rates for the insured population overall.¹⁸³ On the other side of the debate, researchers and community advocacy groups also actively published papers and participated in committee hearings and debates.

Although the legislation was passed by both houses of Parliament and given Royal Assent, its ultimate fate remains uncertain because of ongoing constitutional review. The insurance industry argued that the bill was unconstitutional—specifically that the federal government did not have jurisdiction to pass the law given that insurance regulation is the realm of the provinces. In June 2017, a question of constitutionality was

¹⁷⁵ CHLIA-ACCAP, 'Industry code: Genetic Testing Information for Insurance Underwriting' § 5.1; additionally, as in Australia, the code addresses research findings by noting that insurers will not ask for genetic test results from a research study as long as the individual also did not receive the results. §5.2.

¹⁷⁶ *Id.* §5.3, S.10, 5.4.

¹⁷⁷ *Id.* § 5.13.

¹⁷⁸ GNA, BILL S201 §8.

¹⁷⁹ *Id.* at §9.

¹⁸⁰ *Id.* at §3–4.

¹⁸¹ *Id.* at §6.

¹⁸² See eg Standing Senate Committee on Human Rights - Evidence S-201 (Sept. 29, 2014), testimonies of Jacques Boudreau, Chair, Committee on Genetic Testing, Canadian Institute of Actuaries, Bob Howard, Past President, Canadian Institute of Actuaries, and Frank Swedlove, President of the Canadian Life and Health Insurance Association.

¹⁸³ *Id.*

submitted to the Court of Appeal of Quebec.¹⁸⁴ The court issued an advisory opinion finding that the law was unconstitutional, putting the ultimate fate of the law ‘at risk’.¹⁸⁵

This constitutional debate highlights two of the most notable quirks of the Canadian bill and its legislative process, as compared to Australia, Sweden, and the UK. First, the legal regime utilized by the GNA is criminal law. This is distinct from the regimes used across other countries, but is relatively easily explained by Canada’s federalist system. The position of Senator Cowen, the sponsor of the bill, is that the law is not regulating acts of insurance, but rather is addressing criminal action—criminal action that insurers just happen to participate in.¹⁸⁶ Thus, by targeting an unlawful action rather than a specific industry, the bill is within the federal government’s purview. A consequence of this is that individuals are protected from the use of genetics more broadly, not just through a siloed approach to insurance.

The insurance industry countered that the bill, even if written in broader criminal law language, has the intention of targeting the insurance industry. As evidence of this, the insurers cited a provision that was included in a prior version of the bill. This is the second notable quirk. The original provision provided for a monetary cap for insurance contracts; life insurance contracts over \$1 million Canadian and insurance that paid over \$75,000 Canadian per annum in benefits were exempt from criminal liability for asking for disclosure of genetic tests.¹⁸⁷ Senator Cowen explained in testimony to the Standing Committee on Human Rights:

One provision in the previous bill referenced the insurance industry. That was actually an exemption from the prohibitions, which I included to try to assuage the concerns of the insurance industry regarding large insurance policies. It became clear last time that the inclusion of that provision was taken as evidence that the bill somehow in pith and substance was about the insurance industry. As I say, that was never my intention. So as to be very clear that the bill is not about the insurance industry or any industry for that matter, I’ve removed that provision. Now the word ‘insurance’ does not appear anywhere in this bill.¹⁸⁸

Thus, there is an irony that if the GNA is ultimately found constitutional, it will have a greater impact on the insurance industry than if the original version of the act with the monetary cap had been passed.¹⁸⁹

The monetary limit is exactly the policy constraint that the insurance industry self-imposed right before the GNA passed in Parliament. In the latest version of their industry code, CHLIA added a provision stating that, ‘insurers will not ask for, or use, the results of any genetic test an individual has taken for underwriting life insurance

¹⁸⁴ Yvonne Bombard & Bev Heim-Myers, *The Genetic Non-Discrimination Act: Critical for Promoting Health and Science in Canada*, 190 CMAJ E579 (2018); 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*, 2017, http://courdappellduquebec.ca/fileadmin/Fichiers_client/Actualites/SANS_SIGNATURE_-_Press_release_-_Reference_-_Genetic_Non-Dis.pdf (last visited Feb. 12, 2019).

¹⁸⁵ <http://ccgf-cccg.ca/en/recent-updates/> (last visited Feb. 12, 2019).

¹⁸⁶ Julian Walker, Publication No. 42-1-S201-E - Bill S-201: An Act to Prohibit and Prevent Genetic Discrimination (2016).

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

policies (term or permanent) of \$250,000 or less, effective January 1, 2018¹⁹⁰ It is likely that the insurance industry added this provision into their code in an attempt to show Parliament that passing the more restrictive GNA was not necessary. While this strategy perhaps may have worked at an earlier stage, it did not have the desired effect of derailing the bill.

3. *Impact of Policies*

It is unclear what the lasting impact of Canada's policies are given that they are so new and are still undergoing constitutional review. Some have argued that it is beginning to assuage patient's fears and encouraging participation in research, although this is based on anecdotes and will need to be empirically studied in the future.¹⁹¹ What is clear is that the Canadian policy prior to the GNA—including human rights laws and privacy laws—left gaps that some wanted to address. For example, as explained in a report written for S201,

[i]t is possible that, if a genetic discrimination case were to proceed in court, the CHRA, Privacy Act, PIPEDA or a provincial human rights law would be interpreted as already providing some protection from genetic discrimination and some protection of the privacy of genetic information. However, since such a case has yet to be adjudicated in Canada, uncertainty remains.¹⁹²

Therefore, if the GNA is ruled unconstitutional, there may be sustained fears of genetic discrimination due to the patchwork of laws prior to the GNA.

F. Policy Impact Across Insurance Lines

Policy discussions often treat different insurance lines as sets. In Canada, the GNA applies to all insurers—indeed to all contracts formed across the country. In the USA, discussion often lumps life, long-term care, and disability insurance together, although some legislation has applied more narrowly.¹⁹³ Yet, lumping all insurances together prevents specific consideration of the impact of policy across insurance lines. This is problematic since the impact of a policy and the strength of the social and economic arguments varies by three primary factors: (1) the nature of insurance; (2) the market conditions; and (3) the availability of social safety nets.

First, the strength of social arguments varies with the nature of insurance. The impact of social arguments, such as the creation of a genetic underclass, changes depending on the purpose of that insurance and whether it is seen as a social good versus an economic commodity.¹⁹⁴ This categorization may change based on the societal goals and norms of each country.¹⁹⁵ While access to economic goods is important, it is not necessarily seen as the role of the government to ensure equitable access. For example, although fancy cars may be desirable, the inability for all citizens to afford them does not create an imperative for government intervention. In contrast, there is a need for a

¹⁹⁰ CHLIA-ACCAP, 'Industry code: Genetic Testing Information for Insurance Underwriting' § 4.2 (2017).

¹⁹¹ Bombard & Heim-Myers, *supra* note 184, at 2.

¹⁹² Walker S-201 Overview, *supra* note 186.

¹⁹³ See *supra* Section II.C.

¹⁹⁴ Prince, *supra* note 58, at 262-66.

¹⁹⁵ Joly et al., *supra* note 55, at 355.

public-school system so that all children are able to access affordable education. Similarly, if a type of insurance is seen as an economic tool, not a social good, it is less likely to need government intervention to ensure broad access.

Broadly, health insurance is much more likely to be seen as a social good, even in a country like the USA which generally has taken longer to improve access to health care than other countries.¹⁹⁶ The four case study countries all have some form of national health insurance or national health care system; therefore, access irrespective of one's genetic information was already guaranteed. The USA, on the other hand, had to pass GINA in order to ensure greater access to health insurance—a loss that could have significant impacts on one's life.

Life insurance is more often seen as a commercial product,¹⁹⁷ although it has sometimes been categorized as a quasi-social good that falls between a social good and an economic commodity.¹⁹⁸ Unlike health insurance, life insurance is generally an investment tool that provides family members or other beneficiaries with a monetary payout after death. Despite the economic nature of life insurance, European countries, like Sweden, have legislated bans on life insurer use of genetic information. Approximately 30 European countries have regulated life insurer use of genetic information in some way.¹⁹⁹ '[European laws] highlight the fact that even life and additional health insurance may be very important goods. While such insurance may not be as important as basic health care, particular societies may value it in such a way as to command some form of equitable distribution.'²⁰⁰ However, these countries have not always opted for a legislative ban. Thus, the spectrum between a social good and an economic commodity may help to explain why other case study countries, such as the UK and Australia, have opted for policy constraints that limit use, rather than for implementation of a full ban.

Other insurance lines from critical illness to long-term care to disability insurance arguably fall on the spectrum between social and economic good. For example, long-term care is closer to health insurance and a social good than an economic commodity—as shown in part by the fact that Sweden covers it as part of their general welfare state. Thus, the strength of social concerns over access to an insurance line or the role of the government in regulating the industry could vary across lines.

Second, each line of insurance exists with diverse market conditions that vary across countries. Different market conditions may mean that the implementation of the same policy constraint could lead to different levels of economic harm.²⁰¹ For example, in committee debate over the GNA, the insurance industry in Canada specifically noted two market differences between the UK and Canada. First, in the UK life insurance and mortgages are linked in a way not seen in Canada. Second, Canada has viatical settlements available and the UK does not. These differences could create distinctive market effects due to adverse selection.²⁰² 'The danger of adverse selection fluctuates by reference to the size and origin of the risk pool at stake, the amount of coverage offered

¹⁹⁶ *Id.*

¹⁹⁷ *Id.* at 353–54; *Essentially Yours*, *supra* note 93, at 26.97.

¹⁹⁸ For an in-depth analysis of whether life insurance is a social good or an economic commodity, see Prince, *supra* note 58, at 262–67.

¹⁹⁹ Joly et al., *supra* note 5, at 361; Lemmens, *supra* note 129, at 389–91.

²⁰⁰ Lemmens, *supra* note 129, at 393.

²⁰¹ Standing Senate Committee on Human Rights - Evidence S-201 (Sept. 29, 2014), testimony of Bob Howard.

²⁰² *Id.*

and the type of insurance sought.²⁰³ In the USA, the life insurance market is more robust than the long-term care insurance market. Therefore, the risk of adverse selection is likely greater in the long-term care market since fluctuations in premium amounts will have a greater impact on a smaller market.²⁰⁴

Third, the existence of social safety nets also impacts the social and economic effect of restrictions on insurer use of genetic information. When there is a robust social safety net available in lieu of a private insurance line, the pool of those seeking private insurance is smaller, as in the case of life insurance and superannuation in Australia or Medicaid and Medicare coverage of long-term care in the USA. A smaller insurance market could be more susceptible to adverse selection and may have greater increases in premiums if insurers are restricted from using genetic information.

A social safety net can cut both ways in terms of whether this strengthens or weakens social arguments in favor of regulating the private version of the insurance. A social safety net may have been created precisely because the insurance is viewed as a social good. Alternatively, the existence of the safety net may mean that loss of access to the private good is not as detrimental. For example, since Australia provides national health insurance, a private health insurance policy may be more likely to be seen as an economic tool available to supplement the social system. In contrast, since the USA does not provide broad access to health insurance across the population, private health insurance is arguably standing in as a social good in lieu of a robust government system.

Due to three main factors—the nature of insurance, market conditions, and social safety nets—policies regulating insurer use of genetic information could have very different impacts across insurance lines and across countries. Thus, insurers likely have an interest in ensuring that each insurance line and market is considered individually. UK insurers were able to negotiate a policy that acknowledges some differences between insurance lines. The UK moratorium is designed to take into consideration differences between insurance lines in two ways. First, the monetary threshold is set at a different amount for life, critical illness, and income protection insurance. Therefore, if adverse selection is seen in one insurance versus another, the industry and government could agree to lower the limit on one of the insurance lines in their renewal negotiations. Second, the regulatory review is designed to assess the genetic tests that can be used insurance line by insurance line. For example, GAIC approved the industry's application to use Huntington's disease in *life* insurance. The industry had prepared other applications for other genetic tests in different lines of insurance, but these were never approved.²⁰⁵ Despite this, if the industry feels the need to broaden the number of genetic tests they consider, they could submit applications with evidence specific to each line of insurance. Therefore, the application process itself takes into consideration the differing insurance markets and risk of adverse selection across insurance lines.

Yet, in other countries, the policy solutions lump various types of insurance together. Although the strength of arguments surrounding access and impacts of adverse selection vary across insurance lines and markets, fear of genetic discrimination applies more evenly. If the complaint is that third parties should not be able to use one's genetic

²⁰³ Tarr, *supra* note 5, at 197.

²⁰⁴ See also Avraham et al., *supra* note 14, at 10 (listing eight factors that could affect the level of adverse selection in an insurance line).

²⁰⁵ Prince, *supra* note 15, at 643.

information outside of the medical sphere, then this argument holds true across insurance lines. One indicator of this is that concern of insurance discrimination sometimes migrates to different insurance lines depending on what is most socially important and currently least protected. For example, in the UK after the moratorium, the topic of genetic discrimination has moved from those typically discussed, such as life insurance, to concerns about use of genetics in travel insurance—a line that was not regulated by the moratorium, although is covered by the new Code.²⁰⁶ Therefore, as in the USA where the fear of genetic discrimination has moved to the least regulated area insurance lines that are likely to use medical underwriting (life, long-term care, and disability insurance), fear of discrimination in the UK had relocated from life and critical illness insurance to travel insurance. This may indicate that individuals are broadly fearful of many types of genetic discrimination, but that the focus and dialogue are concentrated on one set of insurances at a time. In this way, fear of genetic discrimination and regulation may be a game of cat and mouse—once one line of insurance becomes adequately protected, the focus will turn to any other line that could use genetic information in a negative way. This also helps to explain why insurances are often lumped together in policy discussions despite the varying nature of economic and social arguments across insurance lines.

IV. STAKEHOLDER INFLUENCE AND SALIENCY

The regulation of insurer use of genetic information balances between social and economic concerns—the more privacy and protection given to insureds, the greater economic risk the insurance companies will be required to take on. Conversely, the more leeway insurers have to use genetic information, the more society risks discouraging participation in clinical genetic testing and genetic research or creating a group of individuals unable to access insurance. One could imagine, under a political economy theory, that the insurance industry is a powerful interest group that has captured regulators. If so, we would expect that the economic principles of actuarial justification would be the predominate policy in regulating insurer use of genetic information.²⁰⁷ For the most part, this is the current case regarding US state regulation of life, long-term care, and disability insurers. Yet, there are examples around the world where complete bans on insurer use of genetic information have been implemented. Additionally, as the case studies show, the international landscape provides many examples of policies implemented shy of a complete ban, but still controlling insurer use in meaningful ways.²⁰⁸

So, what might explain this political economy conundrum? It is plausible that market differences create varying policies across countries and insurance lines. Yet, as shown above, this is not a complete explanation since insurances are often lumped together and there is not always prioritization of economic arguments. Instead, this article argues that stakeholder influence and saliency greatly contribute to the changing policy landscape across the globe. Additionally, these aspects of the debate will not dissipate until social concerns of insurance discrimination are adequately addressed.

²⁰⁶ GAIC, Sixth Report from January 2007 to December 2007 at 7 (2008); Code on Genetic Testing, *supra* note 71; for a discussion of the concerns of travel insurance discrimination, see also Prince, *supra* note 13, at 2.

²⁰⁷ Avraham, *supra* note 10, at 221-23; MEIER, *supra* note 10.

²⁰⁸ See eg Lemmens, *supra* note 5, at 55; Tarr, *supra* note 5, at 200; Knoppers et al., *supra* note 5; Joly et al., *supra* note 1; Joly et al., *supra* note 5; there are also US state laws that provide examples of regulation shy of a ban.

In his seminal work on political economy of insurance regulation, Kenneth Meier illustrates how multifaceted the issue is—that multiple stakeholders can influence regulation, particularly when a policy issue is salient.²⁰⁹ As an example, Meier discusses the history of unisex insurance rating to illustrate that because the issue was salient, the insurance industry was unable to control the political dialogue. He argues that the insurers attempted to work within a scope of arguments outside their forte and were ultimately ineffective.²¹⁰ Similarly, Avraham et al. argue that both insurers and other stakeholders can influence insurance anti-discrimination regulation.²¹¹ Insurance underwriting on the basis of genetic information is no less salient to the public than unisex insurance rating or other forms of discrimination. ‘The rise of genetic technologies... has turned private insurers’ medical risk selection into a major public issue again and this seems to be the catalyst that has drawn state regulators to intervene into private insurance markets.’²¹²

The interplay of insurance and genetics resonates with many different stakeholder groups.²¹³ Patient rights’ groups are engaged with the issue in order to ensure that their members have access to insurance. Medical professionals, geneticists, and researchers are similarly engaged out of concern that fear of genetic discrimination will dissuade uptake of genetic testing and participation in research.²¹⁴ Perhaps most notably, the discourse has been spun to make genetic discrimination a concern for the entire public through arguments that ‘all of us have something bad in our genes.’²¹⁵ For the public, genetic information is also seen as immutable and uniquely personal, so use that results in negative outcomes is seen as particularly pernicious.

Given the wide-ranging proponents for regulation of insurer use of genetic information, it is perhaps no surprise that insurers are not always able to steer regulation toward economic priorities or avoid regulation completely. Instead, insurers have had to adjust strategies over time. Overall, the case studies bolster the assertion by Avraham and coauthors that ‘highly motivated regulators or “bureaucrats” can effectively advocate for their own vision of the public interest’.²¹⁶

Globally, insurers have had to adjust strategies as public discourse and threats of legislation have changed over time. Van Hoyweghen and colleagues have described the transformation of insurer perspectives on regulation of genetic information as comprising three phases.²¹⁷ First, insurers treated genetics and insurance as a public relations problem, where the industry felt that it was a victim due to the public not understanding long-standing insurance principles.²¹⁸ Second, the industry turned toward a defensive approach citing the dire economic impacts that would befall the industry if they could

²⁰⁹ See generally MEIER, *supra* note 10.

²¹⁰ *Id.* at 122–26, 135–36.

²¹¹ Avraham, *supra* note 10, at 221–23.

²¹² Van Hoyweghen, *supra* note 31, at 433.

²¹³ Van Hoyweghen & Rebert, *supra* note 28, at 872–73 (discussing how ‘various social groups mobilized around the discourse of ‘genetic discrimination’, translating the issue of genetics and insurance from a problem originally affecting a small group (the ‘genetically at risk’) into a major public issue.’).

²¹⁴ See eg Lemmens, *supra* note 129, at 365.

²¹⁵ Susan M. Wolf & Jeffrey P. Kahn, *Genetic Testing and the Future of Disability Insurance: Ethics, Law & Policy*, 35 J. L. MED. & ETHICS 6, 13 (2007); Van Hoyweghen & Rebert, *supra* note 28, at 873.

²¹⁶ Avraham et al., *supra* note 10, at 222–23.

²¹⁷ See generally Van Hoyweghen, *supra* note 58.

²¹⁸ *Id.* at 80–82.

not underwrite accurately and combat adverse selection.²¹⁹ Finally, some insurance industries developed ‘an acceptance that science did not provide robust justification for insurers’ ideological preference for implementing any technically feasible discrimination, and that politically negotiated solutions between that preference and wider social preferences were unavoidable.’²²⁰ In other words, in the third phase, the insurance industry decided that a compromise position was the most advantageous. This final transformation was often propelled by a meaningful threat of legislation and resulted in either negotiation of voluntary moratoriums or the creation of industry codes of practice.²²¹ This article argues that the case studies suggest that a fourth phase is emerging where even attempts at industry compromise do not necessarily quiet the debate if the industry compromise is too little too late or fails to fully address societal concerns.

For example, in Sweden, the government commission successfully recommended new legislation, the Genetic Integrity Act, even after the industry developed a voluntary moratorium with the government.²²² The moratorium, however, did not include children’s insurance and was thus seen as incomplete. In Australia, debate continues about whether the system of anti-discrimination protections with an exception for the insurance industry—an exception that is for the most part regulated by the insurance industry itself—is appropriate policy.²²³ Although the insurance industry prefers these policies, there are perceived gaps in policy due to the DDA’s anti-discrimination legal regime and the resultant reliance on self-regulation from the insurance industry. For example, after the recommendations of the Essentially Yours report failed to be implemented, the Australian Genetic Non-Discrimination Working Group formed to continue to advocate for more robust policy change.²²⁴ By teaming together as a working group, concerned researchers have kept momentum in the debate and, most recently, successfully lobbied a Parliamentary commission to recommend a moratorium and ban on insurer use of genetic information.

In Canada, early legislation, such as PIPEDA and human rights laws, had fairly substantial gaps in protection.²²⁵ The initial laws and industry self-regulation did not adequately address societal fear of genetic discrimination; thus, the issue remained salient to consumers, researchers, and legislators—leading to the GNA. It remains to be seen whether the industry strategy in actively lobbying against the bill will be good for insurers. By so voraciously arguing against the constitutionality of the GNA, the insurance industry may have inadvertently tanked efforts at compromise between consumer privacy concerns and industry economic concerns, such as through the monetary limit originally in the bill. Of course, if the act is found unconstitutional, then this insurance lobbying strategy will have paid off from their perspective. Additionally, if found unconstitutional, the monetary limit in the new industry code could remain in place, thus perhaps dissuading the provinces from passing their own versions of the GNA—legislation which is well within their jurisdictional purview of regulating insurers. However, the

²¹⁹ *Id.* at 82–83.

²²⁰ R. Guy Thomas, *supra* note 73 (discussing Van Hoyweghen’s article on insurer perspectives); Van Hoyweghen et al., *supra* note 58, at 83–84.

²²¹ Van Hoyweghen et al., *supra* note 58, at 86.

²²² See *supra* Section III.C.

²²³ See *supra* Section III.D.

²²⁴ See *supra* Section III.D.

²²⁵ See *supra* Section III.E.

insurance industry is not controlling the debate in Canada, rather they have made reactionary changes to strategies throughout the legislative process given the persistence and success of other stakeholders and bureaucrats.

Indeed, only the UK provides an example where the insurance industry has more effectively controlled the debate and developed a lasting policy solution that is beneficial for both insurers and the public.²²⁶ Early on, the UK had a system of self-regulation similar to other case study countries. Similarly, dissatisfaction with insurance self-regulation led to calls for stricter regulation. Faced with potential for legislation, the insurance industry readjusted its strategy and agreed to the moratorium, allowing them to secure important protections, such as the ability to reassess the policy on a regular basis and the narrowing of the restriction to predictive genetic test results—concessions that are not present in Canadian or Swedish policies.²²⁷

Therefore, one lesson from the case studies is that there is staying power in the saliency of the issue of genetic discrimination. Fear of genetic discrimination, and therefore pressure to pass legislation, may continue despite industry's best efforts at explaining their positions until consumers and other stakeholders feel that their concerns are adequately addressed. In the USA, continued fear of genetic discrimination is well documented.²²⁸ Therefore, it is reasonable to believe that regulators and legislators will continue to face questions over the need to bar the use of genetic information by insurers in lines beyond just health insurance.

Given the saliency and the likelihood of sustained debate, US insurers should not wait to see what GINA 2.0 may look like, nor should they trust that they will always be able to control the debate and successfully lobby against legislation state by state. Nor should regulators imagine that limited past action or legislative inaction will quiet stakeholder calls for new policy. Instead regulators and insurers should heed lessons from abroad and seek compromise with a broad range of stakeholders. A moratorium or other agreement at the national level between the insurance industry and the government would allow insurers to set a compromise that best accounts for the economic interest across insurance lines, such as through monetary limits, regulatory review, and flexible policy.

V. CONCLUSION

Although GINA was proclaimed an important civil rights statute, legislative compromise during the bill's long journey through Congress resulted in a fairly narrow application to only health insurers and employers.²²⁹ This occurred despite evidence that people were also concerned with genetic discrimination in broader contexts, especially in other insurances, such as life, long-term care, and disability insurance.²³⁰ Perhaps unsurprisingly then, despite GINA, fear of genetic discrimination by insurance

²²⁶ See *supra* Section III.B.

²²⁷ Australia's policies are still in flux, so it remains to be seen whether these types of concessions will be adopted.

²²⁸ See *supra* Section II.B.

²²⁹ Green et al., *supra* note 42, at 397.

²³⁰ GINA, *supra* note 16; Dawn C. Allain et al., *Consumer Awareness and Attitudes About Insurance Discrimination Post Enactment of the Genetic Information Nondiscrimination Act*, 11 *FAMILIAL CANCER* 637, 639 (2012); Klitzman, *supra* note 32.

companies remains a barrier to participation in genomic research projects.²³¹ This continues to be a concern in an era of large-scale, government-funded genomics research projects, such as the All of Us Precision Medicine Initiative,²³² where full-scale participation in genomic research continues to satisfy an important social goal.

Should US regulators adopt a ban on insurer use of genetic information or add policy constraints such as those discussed and implemented in other countries? The ultimate choice depends on how policymakers choose to prioritize the social and economic arguments on each side of the debate. If regulators prioritize insurers' economic arguments, such as fear of adverse selection, they will be less likely to create new legislation. However, if they worry about social arguments, such as the impact that fear of genetic discrimination may have on the health of their citizenry, then they will be more likely to adopt policy constraints or a ban.

This article argues that legislation is necessary to mitigate fear of genetic discrimination and encourage genetic testing and that insurers, stakeholders, and regulators should work together to find a consensus solution that works best for the insurance line and market conditions. Given the general power of insurance industries, it would be plausible to suspect that insurers can protect their economic concerns, including adverse selection and actuarial fairness. However, in the four case studies—UK, Sweden, Australia, and Canada—we see a more dynamic interplay between the insurance industry, stakeholders, and changing regulation. One possible explanation for the power of diverse stakeholders to influence policy is that the issue of genetic discrimination is salient.²³³

The regulated industry will of necessity participate in regulatory policy regardless of whether issues are salient or non-salient, complex or noncomplex. Because regulated interests have to compete with consumer groups, bureaucratic actors, and politicians when salience is high, the regulated industry will be unable to control the process in this situation.²³⁴

Indeed, amongst these case studies, only the UK insurance industry changed strategy based on fear of legislation and found a compromise that was beneficial for all. In this way, the UK insurers were able to control the process—or at least quell the movement for more restrictive legislation.

Given saliency of the issue and continued fear of genetic discrimination, the USA could face a situation similar to these four case studies, where initial reliance at insurance industry self-regulation does not adequately address social concerns. Thus, the issue will remain salient, shifting the power to influence regulation from insurers to a broader range of stakeholders. Rather than wait for the threat of stringent legislation, either at the state or federal level, the insurance industry should seek to compromise with the government and other stakeholders to adopt a policy that adequately balances

²³¹ Jill Oliver Robinson et al., *Participants and Study Decliners' Perspectives About the Risks of Participating in a Clinical Trial of Whole Genome Sequencing*, 11 J. EMPIR. RES. HUM. RES. ETHICS 21 (2016); Laura M Amendola et al., *Why Patients Decline Genomic Sequencing Studies: Experiences from the CSER Consortium*, 27 J. GENET. COUNS. 1220–27 (2018).

²³² *All of Us Research Program*, NAT'L INST. OF HEALTH, <https://allofus.nih.gov> (last visited Feb. 12, 2019).

²³³ MEIER, *supra* note 10, at 30–31.

²³⁴ *Id.* at 31.

between the competing economic and social arguments on both sides of the issue. Similarly, governments should consider what legislation would work best for their jurisdiction as introduction of legislation may spur the opportunity for compromise with the industry. Without such a compromise, the insurance industry risks passage of a GINA 2.0 that mirrors the framework of the initial bill passed 10 years ago—a welcome solution for many advocates, regulators, and stakeholders, but one that fails to consider economic factors across insurance lines and may be inflexible to future advances in technology.

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