

# Genetic testing, insurance discrimination and medical research: what the United States can learn from peer countries

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**While genetic testing may be the gateway to the future of medicine, it also poses challenges for individuals, especially in terms of differentiated treatments on the basis of their genetic characteristics. The fear of unwanted disclosure to insurers and the possibility of genetic discrimination can hamper the recruitment of individuals for clinical research that involves genetic testing. Precision medicine initiatives, such as All of Us, are proliferating in the United States. In order to succeed, however, they must ensure that the millions of Americans recruited to share their genetic data are not penalized with regard to life, disability and long-term insurance coverage. In this Perspective, we discuss several initiatives adopted by countries around the world, such as the United Kingdom and France, that better balance the interests of insurers and research subjects, and explain how the United States might learn from them. We call for regulatory and industry leadership to come together to establish a voluntary moratorium on insurance pricing with the aim of protecting research participants.**

Genetic testing is becoming an increasingly important part of everyday life, be it for diagnostic or predictive health information, for therapeutic guidance (for example, about cancer treatments), for helping to understand the ancestry of individuals, for illuminating prehistorical human migration, for elucidating biological filiation (parentality, family reunification) and even for criminal investigations<sup>1–7</sup> (Box 1). The analysis of an individual's genes to identify specific traits may benefit the individual by permitting the diagnosis of genetic conditions, in the process known as diagnostic testing, or by identifying a predisposition to genetic diseases, in the process known as predictive testing. This information can help individuals in making lifestyle or other changes to mitigate possible harms (physical or social) and symptoms associated with genetic conditions, and, in some cases, can help to initiate treatment earlier. These potential benefits are so great that the US National Institutes of Health (NIH), as part of the All of Us Research Program, is allocating millions of dollars to collect health data and biospecimens so as to identify individual variation in genes, environment and lifestyle to help develop new means for disease prevention and therapy<sup>8</sup>. The recruitment of 1 million Americans began in early May 2018, with a special focus on populations that have traditionally been under-represented in biomedical research<sup>9</sup>.

Despite all of these developments, many people are concerned about the risk that genetic information may be used for discriminatory purposes, potentially affecting the insurance options available both to the underwritees and to their family members<sup>10,11</sup>. If the law permitted them to do so, many employers might like to know whether a prospective or current employee had a higher risk of a late-onset condition: for example, to know if an illness will in the future be likely to affect a worker's productivity or, in systems in which the employer pays for some of the health care costs of the employee (directly or indirectly), whether the employee is likely to prove expensive in this regard. All things being equal, insurers

might prefer to use genetic information known to its insured to set premiums (in the name of achieving 'actuarial fairness')<sup>12</sup> and/or to restrict coverage of individuals who are at high genetic risk of developing conditions under some circumstances. Insurers and employers might seek to obtain genetic information from testing done in the clinical setting or with direct-to-consumer (DTC) genetic tests, and in some instances, those results—whether accurate or not—could be subject to mandatory disclosure<sup>13</sup>.

The fear of unwanted disclosure and possible genetic discrimination looms large in the public imagination<sup>14</sup>, and empirical data suggest that this holds people back from undergoing testing<sup>15–18</sup>. For instance, in the MedSeq Project, the first randomized trials of whole-genome sequencing in clinical care, 28% of declining participants invoked the 'fear of insurance discrimination'<sup>15</sup>, and a majority of respondents in a study about breast cancer genetics tests expressed reluctance to participate in research if the results could be disclosed to insurers<sup>19</sup>.

Public fear is particularly problematic in the context of research: unless the fear is quelled it will be difficult to recruit individuals for clinical research requiring genetic testing, especially if the goal is to include a representative sample of the population. This issue may bedevil precision medicine initiatives, such as All of Us, the US government's program to gather data from at least 1 million people living in the United States to help improve health, and end up being an important obstacle to fulfilling their recruitment goals. It is also ethically problematic to ask patients to help contribute to the social good by getting genetic testing as part of research, when that participation may also subject them to increased risks of genetic discrimination. This is especially problematic for insurance markets less well protected by law, such as the US life, disability and long-term care insurance markets.

These risks are more than theoretical, in that we see insurers clamoring for other kinds of personal data in order to determine which customers to serve and how to price their policies. Recently,

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**Box 1 | Genetic tests: implications for individuals and insurers**

'Genetic tests' largely refers to germline (not somatic) DNA changes that are discovered in apparently healthy individuals, through direct-to-consumer genetic testing, consumer-facing but physician-mediated genetic testing over the internet or the rare but growing phenomenon of predictive genomics clinics in conventional medical environments. This testing may result in the identification of disease risk information through either the presence of monogenic risk variants<sup>47</sup> or extremes in polygenic risk scores<sup>48</sup>. DNA testing is not fully accurate at predicting disease, and this inaccuracy can arise in two ways. The techniques used (generally next-generation sequencing) can have analytic errors, producing incorrect 'calls' such that the variants identified are simply wrong. These types of errors are increasingly rare as the technology improves. However, simply carrying a pathogenic variant or a high polygenic risk score does not mean that someone will eventually get the disease, as genetic markers have variable 'penetrance'<sup>49</sup>. Thus, genetic markers, even well-accepted pathogenic variants, may occur in individuals who will never develop the disease in question. While these points are true, the presence of both pathogenic variants for monogenic diseases and very high polygenic risk scores may increase the probability that an individual will develop the disease in question and thus can form the basis of the discrimination concerns. While there is an ongoing debate about the clinical utility of this information in the individual patient, there is no question that such information can predict risk on a population basis and is thus of great interest to life insurance companies and others that are in the business of estimating and monetizing risk.

the US insurance company John Hancock announced a decision to move to interactive life insurance policies by providing discounts to customers who share fitness data from monitoring devices<sup>20,21</sup>. The move was framed as being beneficial to both the company and insurance policyholders, because it will provide incentives to adopt healthier habits and may lead to paying less in claims. Nevertheless, it raises questions similar to the ones we discuss in this article about genetic information—questions about the privacy of policyholders and whether the information will be used in discriminatory ways<sup>22</sup>. Although such data sharing frequently begins as a 'voluntary' measure, along the way it may become mandatory. Moreover, policyholder decisions on whether to share such data may be treated by insurers as signals in pricing and other decisions.

When it comes to genetic data, though, there are ways of protecting policyholders' interests. An examination of international perspectives on this topic reveals a number of potential solutions. Several countries, most notably France, Switzerland, Canada, Australia and the United Kingdom, have implemented antidiscrimination protections for genetic information ranging from restrictive legislation to laissez-faire approaches. In this article, we discuss several of these initiatives adopted by countries around the world<sup>23,24</sup> and how the United States might learn from them. This is not meant as a comprehensive review of policies related to insurance around the world, which can be found elsewhere<sup>11,25</sup>, but rather as a comparison of several examples that may inform on the topic. We will begin, however, with an account of the current status of protection against genetic discrimination in the United States.

**United States**

In the United States, where there is not universal health insurance, 13 years elapsed between the first introduction of legislation against genetic discrimination in Congress in 1995 and the adoption of

the Genetic Information Nondiscrimination Act (GINA) in 2008. GINA was, in fact, actually supported by health insurers<sup>26</sup>.

Title II of GINA prohibits both the acquisition and the use of genetic information for employment and health insurance purposes<sup>27</sup>. The law applies to various types of employers covered by other federal statutes, such as Title VII, a US federal law prohibiting employment discrimination based on race, color, religion, sex and national origin, which also applies to employment agencies, labor organizations and training programs. Employers are prohibited from discriminating against individuals on the basis of genetic information in a way that would adversely affect their employment opportunities (for example, hiring, firing, pay or promotion). Health insurers are prohibited from using genetic information to determine eligibility or adjust premiums, to require applicants to undergo genetic testing or to impose pre-existing condition exclusions.

The statute adopts an expansive definition of genetic information, by including "information about (i) such individual's genetic tests, (ii) the genetic tests of family members of such individual and (iii) the manifestation of a disease or disorder in family members of such individual"<sup>28</sup>. Importantly, although the statute covers the manifested conditions of a person's relatives, it does *not* cover an individual's own manifested genetic conditions. The law's primary focus is therefore individuals who are presymptomatic or asymptomatic. The Equal Employment Opportunity Commission (EEOC) regulations define the terms 'manifestation' or 'manifested' to mean "that an individual has been or could reasonably be diagnosed with the disease, disorder or pathological condition by a health care professional with appropriate training and expertise in the field of medicine involved" and specifies that "a disease, disorder or pathological condition is not manifested if the diagnosis is based principally on genetic information"<sup>29</sup>.

Importantly for our purposes, GINA does not protect against genetic discrimination for life, disability and long-term care insurance, nor does it apply to small businesses, military healthcare providers and some other groups subject to exceptions. Thus, under GINA, participants in research involving genomic testing could end up having to disclose any genetic findings as part of the underwriting process for these kinds of insurance.

There is currently a legal gap in the protection of human research participants in the United States in regard to any protocols involving genetic testing<sup>30,31</sup>. Other jurisdictions have tried to plug this gap, and although their approaches are quite different both from the US approach and from each other, there are important things to be learned in regard to the US system by understanding the approaches taken by peer countries to balance the business interests of insurers with legitimate fears of genetic discrimination.

**France**

France, where health coverage is universal and mostly publicly financed, strictly limits the use of genetic information; in basic terms, genetic test results are allowed to be used only for medical and scientific endeavors<sup>32</sup>. Under the Penal Code (art. 226-26), using genetic information for other purposes (for example, employment, insurance) represents a diversion of their medico-scientific purposes and is punishable with 1 year of imprisonment and a €15,000 fine<sup>33</sup>. The French approach represents one extreme of the continuum—it is maximally protective of patients, and also maximally disruptive of insurers' business interests, by completely prohibiting them from using any genetic information.

**Switzerland**

In 2004, Switzerland, which requires universal coverage by mandating its residents to purchase statutory health insurance from insurers and partially subsidizes the costs for some individuals, adopted the Federal Act on Human Genetic Testing<sup>34</sup>, a statute to

**Box 2 | Canadian Genetic Non-Discrimination Act**

The Canadian Act prohibits employers or insurers from requiring an individual to undergo a genetic test or disclose the results of a genetic test. The law explicitly provides two exceptions: 1) for “research in respect of an individual who is a participant in the research” and 2) for healthcare practitioners providing health service. Thus, the law permits asking individuals to undergo genetic tests and the disclosure, either to researchers or healthcare practitioners, of genetic testing for providing care and conducting research. However, these exceptions cannot be used by insurers or employers; the law forbids them from making any use of these results even if the results are made available to them.

Those who violate the law may be fined up to CAD\$1,000,000 or imprisoned for up to 5 years. Canadian insurers opposed the law<sup>50</sup>. A few months before its enactment, the Canadian Association of Insurers added provisions to their industry code prohibiting the use of genetic test results for life insurance coverage of CAD\$250,000 or less<sup>51</sup>. However, these changes were superseded by the more protective law when it went to effect<sup>42</sup>. It is worth noting that the Québec government challenged the constitutionality of the law on the basis that the insurance industry is a provincial competency and that the federal government does not have the power to enact such law (since the law is regulating property and civil rights). In December 2018, a court concluded that the law was unconstitutional and a month later the Canadian Coalition of Genetic Fairness filed a notice of appeal to the Supreme Court of Canada. Some authors are afraid that the overturn may put Canadians at-risk of genetic discrimination<sup>52</sup>.

prohibit genetic discrimination against individuals in health, life and disability insurance. Insurers must obtain individuals’ consent to perform a test. The results of such tests (or results from prior tests the individual may have taken) cannot be used to determine health or life insurance policy under CHF400,000 or for disability coverage under CHF40,000 annually. The Swiss regulation therefore prohibits the use of test results only under a certain financial limit (regardless of the type of genetic information and of the disease), which distinguishes it from the French more maximalist approach. However, during a recent revision of the Federal Act, significant lobbying efforts aimed, although unsuccessfully, to eliminate this limit and allow access to genetic data for insurance of any amount<sup>35</sup>.

**Canada**

Canada provides publicly funded universal healthcare to its population. Over roughly two decades, many proposals were made to tackle genetic discrimination in Canada by explicitly including genetic characteristics as a prohibited ground of discrimination<sup>36</sup>. Until 2017, no legislation was enacted, making Canada the only remaining country of the G7 not having explicit genetic discrimination protection. A new law<sup>37</sup>, entitled the Genetic Non-Discrimination Act, recently went into effect. It prohibits requiring individuals to undergo genetic testing or requiring the disclosure of results as a contractual conditions of the supplying of goods or services<sup>38</sup>. Under the new Canadian law, employment and *all* forms of insurance are subject to the law, including life and long-term insurance (which are left out of the US GINA) (Box 2).

The Canadian law, like the French one discussed above, is much more protective of patient rights than insurer interests. Interestingly, it also shows how the threat of legislation can sometimes galvanize industry self-regulation. If the US insurance industry or the law imposed a rule similar to the one Canadian insurers self-imposed—a prohibition on the use of genetic test results for life insurance

**Box 3 | United Kingdom’s Code on Genetic Testing and Insurance (previously called the Concordat and Moratorium on Genetics and Insurance)**

ABI’s members are prevented from requiring the disclosure of predictive test results unless they are pre-approved by the government after consultation with independent experts according to the use of ‘higher standards of evidence’. In addition, to qualify for this pre-approval, the tests may apply only to monogenic (single-gene) disorders and late-onset and high-penetrance conditions (with a high probability that a specific gene is expressed). Currently, only Huntington’s disease is considered to meet this criterion and must be disclosed. In addition, for requiring the disclosure of a patient’s predictive genetic test results: 1) the applicant (that is, the patient) must be seeking coverage for life, critical illness or income protections above a specific limit (£500,000, £300,000 and £30,000 annually, respectively), and 2) the insurer must ask the applicant for the results. Both the government and the industry must stay updated with new medical knowledge and ensure that insurance underwriting is based on sound evidence.

The Code states that results cannot be used for underwriting one-off, annual (such as travel or private medical insurance) or long-term-care insurance policies. ABI members “will not require or pressure an applicant to undertake a predictive or diagnostic genetic test in order to obtain insurance,” and after the coverage has started, genetic test results (including those ascertained as part of a research activity) from insured individuals or their relatives are not required to be disclosed. Insurers cannot make use of non-required predictive genetic test results for coverage or risk-factor decisions, unless “it is to the applicant’s benefit.” Therefore, the results of predictive genetic testing (including those acquired as part of research) represent an exception to the principle of disclosure; this allows customers to obtain insurance coverage without the need to disclose such information (unless it is related to a condition subject to mandatory disclosure).

coverage of CAD\$250,000 or less—that would be a major step forward in protecting patients willing to engage in genetic testing for the sake of the public good or research.

**United Kingdom**

The United Kingdom provides publicly funded universal health care to its population. In 2001, the United Kingdom adopted a different approach to issues of genetic discrimination in insurance, a hybrid of government regulation and industry self-regulation. The government adopted a non-legislative approach to genetic discrimination by negotiating with the Association of British Insurers (ABI) and signing the Concordat and Moratorium on Genetics and Insurance<sup>39</sup> (Box 3). The Concordat was based on “fair rights of access” to substantial amounts of cover for life, critical illness or income protections without the need for providing genetic test results and for insurers to obtain relevant information for assessing and pricing risk. It aimed to balance consumers’ need for fair access to insurance with the sustainability and profitability of the insurance industry. The Concordat has been renewed several times since its inception.

In October 2018, the Concordat was replaced by the Code on Genetic Testing and Insurance<sup>40</sup>. The Code retains the scope and the provisions (for example, the financial limits) set out in the Concordat, but with several changes. First, the new Code has no end date. This is claimed to be advantageous by the UK Government and the ABI, because it provides longer-term certainty in insurance. Second, the Code will now be reviewed every 3 years to keep it up to

#### Box 4 | Australian genetic discrimination dispositions (Standard no. 11)

In Australia, the industry started to regulate its practices around the same time that the government began to inquire about addressing genetic discrimination, underwriting and privacy issues in insurance<sup>45</sup>. The Financial Services Council (FSC) Standard No. 11 Genetic Testing Policy (the Standard) took effect in 2002. It provides standards to all Council members in the conduct of their life insurance operations on the handling of genetic test results, recognizing the “potentially significant impact on customers who receive adverse results”<sup>53</sup>. The Standard has three aims: facilitating an “efficiently functioning life insurance industry,” recognizing the industry’s social responsibility to avoid inhibiting medical knowledge, and improving technology development and adoption aiming to improve health outcomes. FSC members need to abide by a set of principles ranging from ensuring that standard premium rates are available and affordable to a majority of the insurable population, that risk classification reflects the current state of medical knowledge and that the industry remains sustainable, to maintain consumer confidence and avoid dissuading the population from undertaking genetic testing.

date and to ensure that its provisions remain relevant and efficient. Third, a joint annual report published by the UK Government and the ABI will comment on genomic medicine’s market and developments and on Code compliance. Finally, it has been made more consumer friendly and simplified.

The UK approach requires that the industry remain committed to the Code’s provisions and in return that the government refrain from introducing (more demanding) legislation on the use of genetic test results. The Code seeks to reach an equilibrium between protecting commercial and consumer interests. Many consider such a negotiated agreement to be much more flexible than other approaches. One important strength of this approach is that it can be easily updated and renegotiated in light of ongoing scientific developments<sup>41</sup>. The corresponding disadvantages are that it is more difficult to prosecute violators than it would be with a law and that industry practice and willingness could change over time, causing the end of a mutually supported Code. However, terminating consumer-protection provisions will be more burdensome to achieve with the new Code than it was with a Corcordat with an expiry date, and wider public debate may be required<sup>40</sup>. This scenario remains possible and would leave an important regulatory vacuum, rendering the approach much less stable than it would be with a legislative commitment.

#### Australia

Australia provides universal health coverage for citizens and permanent residents. Its approach has been to consider genetic discrimination as a disability-based discrimination (implying that genetic predisposition is a form of disability)<sup>42</sup>, which is thus prohibited under the more general provisions of the Disability Discrimination Act (1992). The law does have exemptions in Section 46 limiting discrimination protection for actuarial and statistical-based decision-making, which implies that the use of genetic information for risk evaluation for underwriting life insurance is allowed<sup>41</sup>. There is no genetic-discrimination-specific law in Australia. Therefore, since 2002, Australia relied on industry self-regulation.

A central requirement of the policy is that “Under no circumstances will a Member ask an Applicant to undergo a Genetic Test to support an application for insurance” (10.1.1) (Box 4). However, insurers can ask for existing genetic test results for risk classification purposes (10.2), as required by the Insurance Contracts Act (1984),

which states that applicants must disclose all relevant information to the insurer. Recently, Australia’s Financial Services Council (FSC) announced that, starting in July 2019, a moratorium will prevent the use of genetic test results for insurance applications. Invoking its commitment to genetic inclusion, FSC will enable Australians to get insurance, without the need for disclosing adverse test results, for up to AUD\$500,000 for death and permanent disability, AUD\$200,000 for trauma and AUD\$4,000 a month for income protection; these limits are comparable to Swiss coverage limits but below the UK ones. The moratorium still allows the insured to choose to disclose favorable genetic test results to prove that they do not possess an illness-associated gene pattern that may run in their family. The moratorium will be valid for 5 years and reviewed in 2022 to assess its actual impacts.

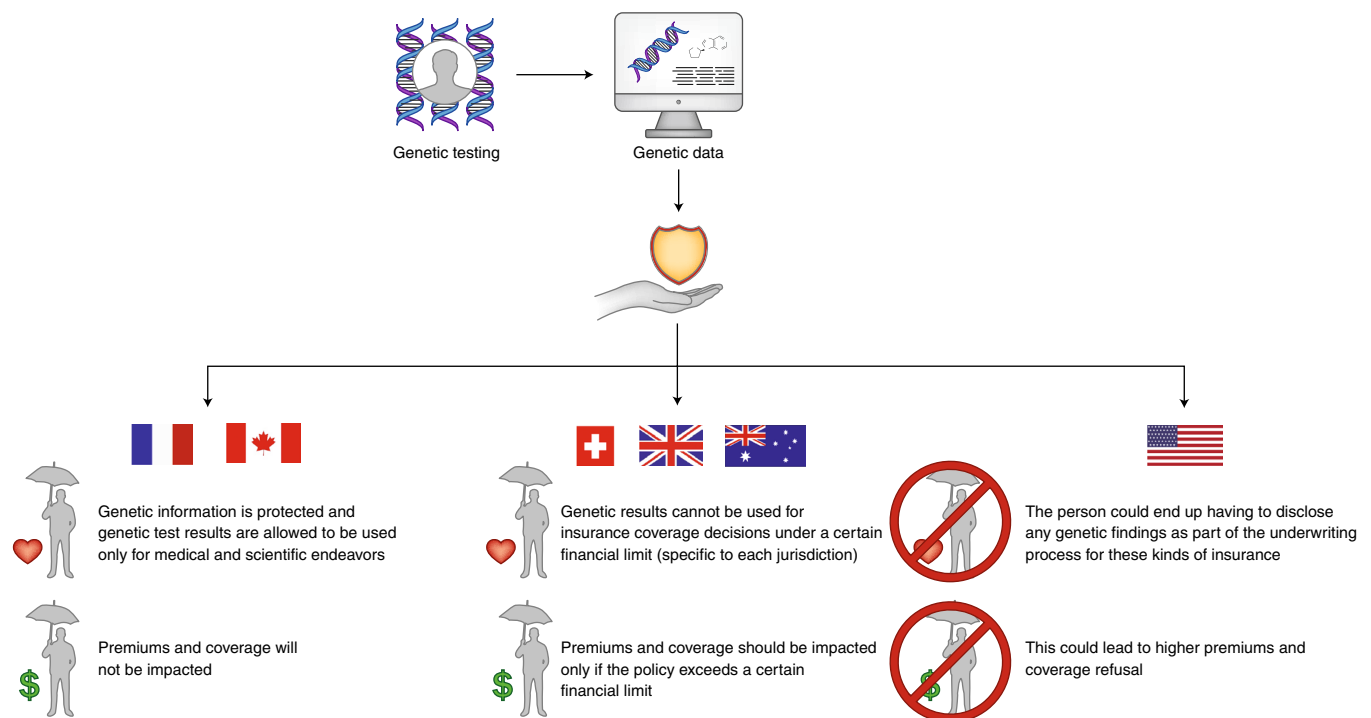
#### Analysis of peer-country approaches and recommendations for the United States

While genetic testing may be the gateway to the future of medicine, it also poses challenges for individuals for whom being treated differently can be positive (medicine adapted to each individual) or negative (limited access to certain services on the basis of genetic profile). Soon after human genome sequencing became a commercial reality, policy-makers acted to try to protect individuals from these challenges<sup>43</sup>. In 1997, the United Nations Educational, Scientific and Cultural Organization (UNESCO) Declaration on the Human Genome and Human Rights, sought to address genetic discrimination by stressing that fundamental freedoms and human dignity should not be infringed upon on the basis of genetic characteristics<sup>44</sup>. Since then, many countries have adopted national legislation reaching a different balance between patient and industry protection.

Our examples from peer countries show a spectrum of approaches, from strict and law-based (in France and Canada, and to a lesser extent Switzerland) to industry self-regulation (in Australia, which recently moved from a permissive to a more stringent model, and the United Kingdom). One commonality between all of these approaches, absent from the US approach, is that they all explicitly seek to avoid deterring individuals from participating in medical research (see Fig. 1). Moreover, unlike the US approach in GINA, all of these peer countries’ approaches have addressed forms of non-health insurance, such as life insurance.

While GINA was an important improvement in encouraging genetic testing and protecting individuals, at a moment when the next generation of research is trying to amass huge swaths of genetic data, the current US approach may be inadequate regarding the goal of reassuring patients and research participants. The examples described from our peer countries show where the United States might go next.

While France and Canada’s restrictive approach or even the Swiss prohibition under a certain limit might be challenging to adopt in the United States given some of the difficulties associated with the passage of GINA itself (and indeed talk of repealing parts of GINA as part of the Republican ‘repeal and replace’ Obamacare efforts of 2017), the Australian and British models might be more promising because they are based on greater regulation of insurers’ practices. Both the Australian self-regulated Standards and the British Code seek to balance consumers’ interests and commercial sustainability. The Code, however, because it is negotiated by the government and the industry, has the advantage of considering both public and commercial needs, while being flexible and responsive of new medical developments. In contrast, the Australian Standard leaves it to insurers to regulate their practices with little to no government oversight, and consumers may only rely on industry-accepted practices<sup>45</sup>. For instance, while the Code imposes independent mechanisms for resolving complaints, the Standard relies on corporate dispute resolution services, which may be subject to conflicts of interest. In our



**Fig. 1** | Potential impact of genetic data for insurance by jurisdiction.

view, the substantive provisions of the British Code also reflect a better balance between industry interests and patient protection.

A different feature worth considering, shared by the Swiss, British and now Australian models, is a monetary cap for policies above which genetic information may be used. Such caps allow insurers to hedge against risk for their most expensive policies and distribute risk on high-net-worth individuals rather than the vulnerable. If one is convinced that genetic information is not fair to use for rate setting, it may seem to be an unacceptable compromise to create exceptions above a certain monetary threshold. But pragmatically, such limits may be an effective way of aligning ethical goals with the needs of the insurance industry. It also helps mitigate a concern of insurance companies of information asymmetry favoring underwriters who have access to their own genetic testing results.

While the US healthcare system is clearly different from those of these peer countries because of its much more pronounced privatization and fragmentation, this does not mean that the United States cannot learn from these peer countries' protection from genetic discrimination, especially regarding long-term care and life-insurance markets. Indeed, one might think that the anti-regulatory bent of the United States (at least relative to these peers), is very well-suited to industry self-regulation in this domain.

Precision-medicine initiatives are proliferating in the United States (ranging from small size projects to the All of Us Research Program, at a scale never seen before) and make it essential to ensure that the millions of Americans recruited are not penalized with regard to life insurance coverage by agreeing to contribute to the advancement of biomedical knowledge and research<sup>46</sup>. There will also be increased genetic data coming from clinical tests. The approaches presented represent a number of possible avenues; however, some are more likely than others to be adopted in the United States, considering the history that led to the enactment of GINA and the Affordable Care Act. While we have focused on genetic information, insurance companies are also attempting to get other types of personal information, such as that from wearable devices.

While such information has not been our focus, some of the solutions we have discussed here may be relevant in that context as well. An initiative from insurers to self-regulate their practice, perhaps making use of a coverage cap, may not be the ideal solution for the United States, but incremental improvements may be more desirable than waiting for complete reform.

## Conclusion

If the goal is to foster personalized medicine to ensure that individuals undergo the most appropriate treatment for each specific genetic profile, this requires that patients not be deterred from participating in the necessary research; it is essential to develop both the knowledge for diagnosis and treatment, as well as to evaluate the cost-efficiency of interventions. Across the globe there is currently momentum to increase anti-discrimination protections for those who seek life, disability and long-term insurance coverage. The recent developments in Australia are particularly heartening—the industry has recognized that certain practices could unduly affect its customers and have social consequences, especially on the development of research.

In the United States, two avenues for change seem quite plausible: forming an agreement between the insurance industry and the government (such as occurred with the British Code) or following the example of the Australian industry, which agreed to alter its business model to address citizens' fears, foster medical knowledge and genetic research, and meet insurers' financial obligations. An important advantage to each of these paths toward a voluntary moratorium is their flexibility: they can serve as a transitory approach to finding a more stable solution, and be adapted and renegotiated according to evolution of genomic knowledge and medical interventions.

This is a moment for public and industry leadership in the United States to come together to try to establish a voluntary moratorium. We argue that it is time that the United States become a country where patients and research participants are not afraid that their genetic information may be used against them.

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