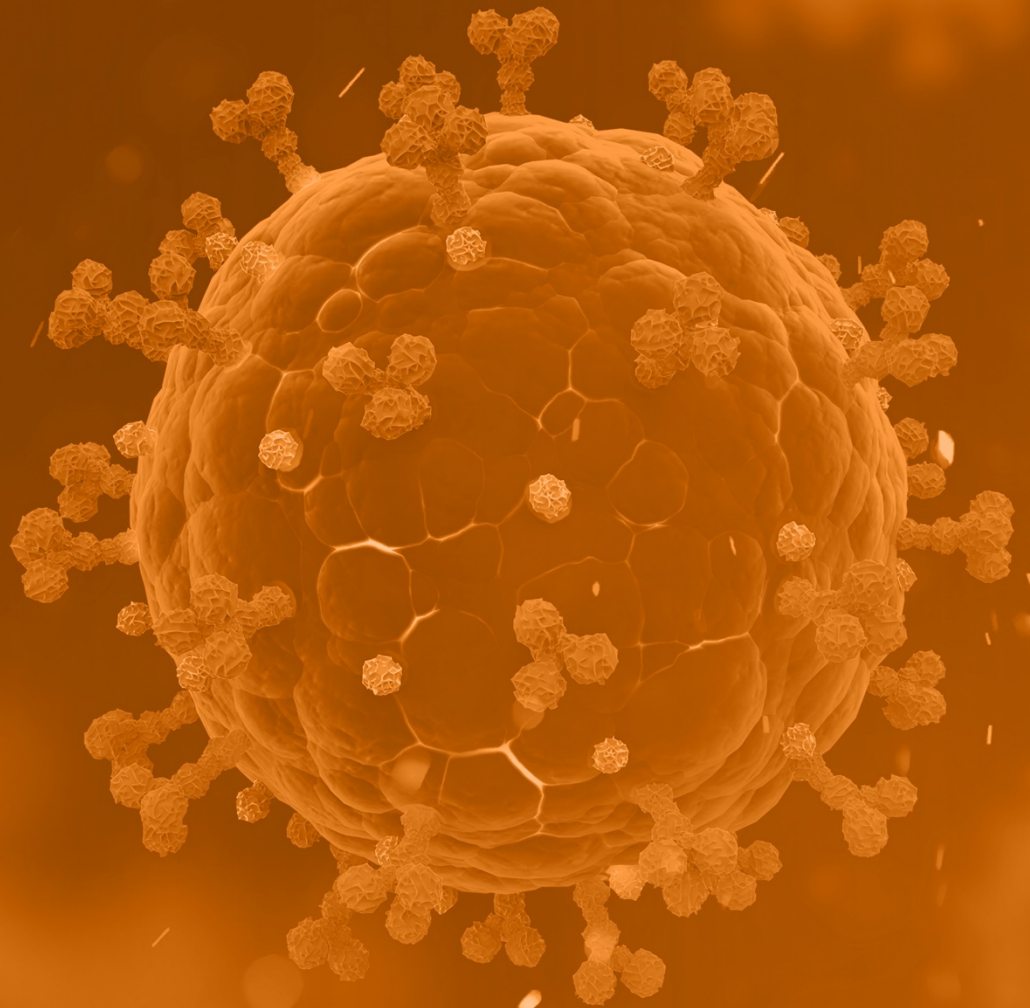


A Primer on Insurance Policies and Genetics





A Primer on Insurance Policies and Genetics

Regulation is Likely but Options Exist: Definitions, Impacts, Resources

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Introduction

The marriage of massive analytical power and human genome sequences – consisting of three billion DNA data points *for each person* – is accelerating rapidly and generating a trove of data correlating our fixed genetic blueprints with disease risk. Unlike environmental or behavioral factors – e.g., tobacco, alcohol, and physical and chemical exposures – the core heritable genetics of an insured are otherwise unchangeable or ‘immutable.’

In parallel, tremendous consumer interest – and launch of large government, university, and private genetics (e.g., 23andMe, Ancestry) initiatives – has surged and now has generated valuable published genetic risk data.

Because of this, certain legal efforts are underway or in place to prevent societal and insurance discrimination in this area. These regulations are firmly in place for healthcare insurers in the United States under the Affordable Care Act, or ACA, and now broadened for all types of insurance lines in Canada.

This building genetic database is of interest to insurers to maintain informational symmetry (as opposed to ‘asymmetry’) between the insured and the insurer. A founding principle of insurance is a balance between the accurate assessment of risk and the fair offering of insurance protection. At minimum, this new genetic knowledge can help insurers consider sponsoring early intervention programs to minimize major future claims (and attendant suffering) for individuals and their families.

It is now clear, however, that the use of many types of genetic data will continue to be restricted by law, and the insurance industry needs to be aware of legislation that may unduly enhance asymmetry – for example, an insured’s awareness of a severe genetic risk that can play against the insurance company due to these regulations.

This primer paper seeks to introduce and update the actuarial profession to this overall topic and study the impacts on insurance and potential responses. The goals of this primer are to:

- i. Describe the landscape of how human genetics increasingly affects insurance industry function and regulatory policies.
- ii. Define the types of genetic information (e.g., germline or hereditary ‘blueprint’ data versus somatic and epigenetic ‘non-blueprint’ data) and rank their current and forecasted utility to actuaries.
- iii. Consider data gaps that negatively impact actuarial access, and compare policies that maximally aggregate this data and minimize risk for the insurance industry and actuaries.
- iv. Compile a user-friendly bibliography of references, web resources, and charts/exhibits.

The scope of this paper is largely focused on the U.S. market, and also recently Canada; however, the principles addressed can be applied more broadly in other territories. Topics for follow-on research will be suggested in the summary statement.

Section 1: Human Genetics and the Insurance Industry in 2021

The insurance industry has been under restrictions on the use of genetic data, starting with the ACA healthcare legislation over a decade ago that makes it illegal for insurers to deny health coverage in the United States based on the genetics of the insured, via the Genetic Information Nondiscrimination Act or GINA. (1)

It is important to note the GINA definition of Genetic Information that is codified by federal law:

“The term **genetic information** means, with respect to any individual, information about (i) such individual’s genetic tests, (ii) the genetic tests of family members of such individual, and (iii) the manifestation of a disease or disorder in family members of such individual. Such term includes, with respect to any individual, any request for, or receipt of, genetic services or participation in clinical research, which includes genetic services by such individual or any family member of such individual. The term ‘genetic test’ means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes.”

GINA prohibits plans from collecting genetic information (including family medical history) from an individual prior to, or in connection with, enrollment in the plan or at any time for underwriting purposes. Thus, under GINA, plans and issuers are also generally prohibited from offering rewards in return for the provision of genetic information, including family medical history information collected as part of a Health Risk Assessment (HRA).

While this was set in stone in the U.S. for healthcare insurers, and is extremely broad, genetic data restrictions were **not** regulated for life, disability, and long-term care insurance under ACA (2). These latter policies are generally governed by state law in the U.S. and have largely remained free of regulations as onerous as GINA.

Over the past year, however, increased restrictions in states and beyond the U.S. border have also been codified, notably in Canada and most recently (July 2020) via passage of a major regulation in Florida (HB 1189) (3).

Now, in 2021, it is again instructive to review the codified definitions of regulated genetic information (i.e., now disallowed for use in life, disability, and long-term lines), that are more specific than GINA. For example, in the Florida law (with an emphasis on the underlined phrases below):

“**Genetic information** means information derived from genetic testing to determine the presence or absence of variations or mutations, including carrier status, in an individual's genetic material or genes that are scientifically or medically believed to cause a disease, disorder, or syndrome, or are associated with a statistically increased risk of developing a disease, disorder, or syndrome, which is asymptomatic at the time of testing. Such testing does not include routine physical examinations or chemical, blood, or urine analysis unless conducted purposefully to obtain genetic information, or questions regarding family history.”

Thus, in Florida, the presence of symptoms – however mild – allows genetic information to be used in underwriting of life, disability, and long-term care. Florida law also limits regulation to variations and mutations which are ostensibly heritable in nature.

Apart from Florida, below are summaries of other current state laws regulating genetic information in the U.S., split between limitations on use in life insurance risk classification. (4)

State Laws Regulating Genetic Information in Life Insurance That Are Procedural – but Do Not Restrict Use in Risk Classification (24):

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

State Laws Regulating Genetic Information in Life Insurance That Do Regulate Use in Risk Classification (16):

- Restricted to specific disease populations (6): California, Florida, Louisiana, Maryland, North Carolina, and Tennessee.
- Consistent with current anti-discrimination laws (10): Arizona, California, Kansas, Maine, Massachusetts, Montana, New Jersey, New Mexico, Vermont, and Wisconsin.

Canada Genetic Non-Discrimination Act (enacted on rejection of court appeals):

- All Provinces – any business or contractual transaction covered.

Specifically for insurers and actuaries, there are three excellent articles shown below – two of which cite SOA involvement – that were published since 2018 with detailed analyses of the economic impacts of regulations of genetics and insurance at the state level and can be found at these links:

<https://content.naic.org/sites/default/files/inline-files/JIR-ZA-38-05-EL.pdf>

<https://www.soa.org/globalassets/assets/Files/resources/research-report/2018/2018-impact-genetic-testing-report.pdf>

<https://content.naic.org/sites/default/files/inline-files/JIR-ZA-39-10-EL.pdf>

In parallel, a full list of genetic data-related laws – by State – for non-healthcare lines of insurance is also maintained at the below link, compiled by NIH (note: choose ‘enacted’ for bill status):

https://www.genome.gov/about-genomics/policy-issues/Genome-Statute-Legislation-Database?field_content_type_value=State%20Statute&field_topic_value=Other%20Lines%20of%20Insurance%20Nondiscrimination

Outside the U.S., another law of importance survived appeal and is now fully enacted in Canada also as of July 2020. This far-reaching national law (5), summarized below by Robinson, Sheppard, & Shapiro, goes beyond insurers.

“No one will be able to compel a person to undergo a genetic test or to report the results of such a test as a precondition for any of the following activities: providing goods or services to that individual; entering into or continuing a contract or agreement with that individual; or offering or continuing specific terms or conditions in a contract or agreement with that individual...”

The Act provides for severe penalties for offenders, including fines on indictment or summary conviction of up to \$1,000,000 and maximum imprisonment terms of five years. “(The) Act... provides certain exceptions, particularly for healthcare practitioners and scientific researchers... and the voluntary submission (of results) by any individual.”

A 2014 report for the Canadian Institute of Actuaries (6) predicted a minimum 35% life insurance premium increase (males, ages 20-60) driven by anti-selection claims under the new law, based on a set of market assumptions.

Section 2: Defining the Types of Genetic Information, and Their Utility for Insurers

There are two main categories of genetic information – **Germline and Somatic** – as depicted below with respect to cancer testing. Germline genetic data is clearly-regulated heritable genetic information (left) and, conversely, Somatic genetic data is (believed) non-regulated, non-heritable information (right):

Figure 1

GERMLINE VS. SOMATIC GENETIC INFORMATION - IN ONCOLOGY AS AN EXAMPLE

Germline Testing	Somatic Testing
Conducted on blood or saliva	Conducted on tissue or circulating tumor DNA in the blood
Identifies inherited gene mutations present in every cell of the body	Identifies gene mutations that exist only in the tumor
Provides eligibility for targeted therapies if cancer progresses	Provides eligibility for targeted therapies if cancer progresses
Provides risk of additional cancers	
Offers information regarding family member’s risk of developing cancer	

Examples of **Germline** information are X- and Y-chromosome linked sequences that determine gender at birth, and substantially all the DNA that a person is born with – and passes on to progeny. There are roughly three billion fixed base pairs or ‘letters’ in every person’s genome in this category, and much of the societal concern and legal and commercial landscape is dealing with this category.

A subset of Germline information that is currently unrelated to biological function in most cases is the subcategory of *Single Nucleotide Polymorphisms, or SNPs* (pronounced ‘snips’), commonly referred to as variants. SNPs are the core genetic feature of individuality, are not considered themselves to be a mutation, and are not necessarily connected to a disease. One interesting example of a SNP is a single genomic position that could either be a T, or an A, genetic base readout – the FTO gene. Through studies of tens of thousands of subjects over the past 20 years, the presence of a T naturally predisposes the individual to obesity (7). [Note: Genetic traits that are visible – or biochemical – driven by our Germline are termed phenotype. Phenotype examples include the color of your hair, blood type, and other measurable traits. In genetic diseases, observable traits and/or symptoms are not a subject of regulation.]

Medical science – and especially genomics companies – can identify differences in an individual’s SNPs from those of others. No individual SNP profile is ‘normalized’ to a master genome, however, i.e., there is no ‘perfect genome’ for comparison. Scientists can still correlate sets of variants to disease, which is important as shown below. But, unless the SNP or variant is known to interfere in a key functional gene’s actions biochemically, it remains a simply statistical correlation without medical proof in diseased populations.

An army of scientists are processing and publishing these SNPs for tens of thousands of patients with chronic diseases. These statistical studies, called *Genome Wide Association Studies, or GWAS*, are important for actuaries to monitor for diseases of high interest to insurers (8). A searchable weblink for this enormous database is shown below:

<https://www.ebi.ac.uk/gwas/docs/file-downloads>

As these studies mature, they should be a valuable indirect genetic data source for the actuarial profession, as there will increasingly be a clear connection between SNPs and disease phenotype, at least statistically.

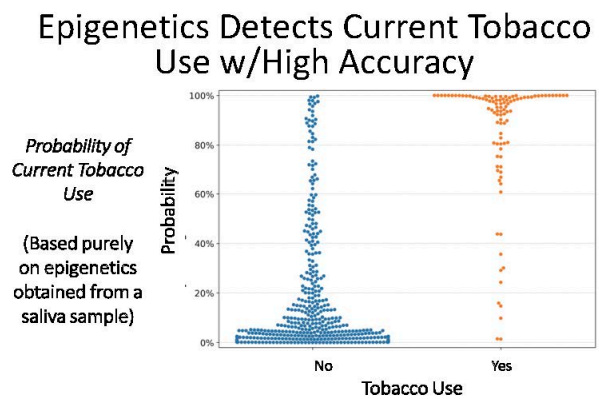
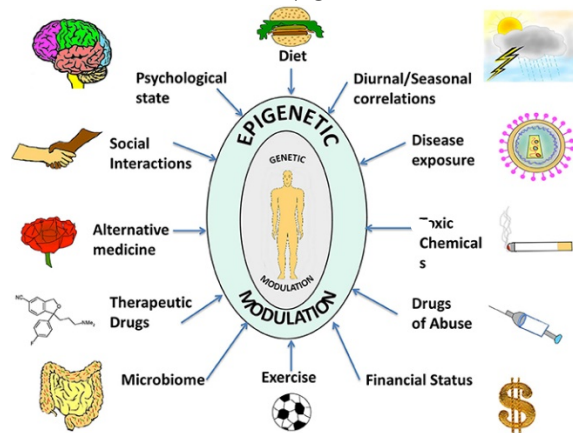
Conversely, Somatic Genetic Information is non-heritable genetic data found in matured or maturing cells that have been exposed to the environment in the living person (‘soma’ meaning of the body only, in Greek). Disease or

environmental impacts – such as virus infection, radiation, runaway tumor DNA mutations, and other insults – change DNA and are, thus, within the realm of diagnostic and treatment-eligible genetic information that is ‘non-blueprint’ and generally is accompanied by symptoms as well.

A new subset of Somatic non-blueprint information is the growing field of Epigenetics, defined as changes ‘above the genetics,’ where it has recently been found that lifestyle choices also induce non-heritable physical or chemical changes directly on a person’s DNA after birth, and can be measured by isolating the DNA and revealing these features. The U.S. Center for Disease Control states: “Epigenetics is the study of how your behaviors and environment can cause changes that affect the way your genes work. Unlike genetic changes, epigenetic changes are reversible and do not change your DNA sequence.” (9)

An example of the latter is a finding that the tips of our chromosomes – called telomeres – can shorten or lengthen in correlation with health status and ‘biological aging,’ a finding that was the subject of a 2009 Nobel Prize (10). An additional example of epigenetics is in tobacco use, shown below, and generally discussed at the 2020 SOA Health Conference by Dr. Brian Chen at this link https://webcasts.soa.org/products/actuarial-innovation-and-technology-update-on-recent-research#tab-product_tab_speaker_s.

Figure 2
Breadth of Influences on Epigenetics - Tobacco Use Data as an Example



An excellent review article on the entire topic of regulation and genetics, with a focus on epigenetics, can be found in a 2020 review article for the Journal of Insurance Regulation (with thanks to Dr. Chen for his referral).

<https://content.naic.org/sites/default/files/inline-files/JIR-ZA-39-10-EL.pdf>

Utility of each category to the Insurance Industry, given regulatory pressures.

Germline genetic information subject to GINA restrictions, ironically, are likely the least impactful near-term for the insurance industry. Most heritable gene defects are found in rare diseases at low incidence in the population and are usually quite visible. Those that are less visible are increasingly being found to be countered by known and unknown 'corrective' genes (e.g., DNA repair mechanisms) or related multifactorial biological processes such as compensatory nerve regeneration.

Schizophrenia, diabetes, and cholesterol-driven heart disease are examples of diseases where dozens of genes remain under study, as well as in Alzheimer's, Parkinson's disease, and common depression. An enormous amount of medical research has been invested in these disease genes, with no blockbuster findings to date – which is notable as it is estimated that medical knowledge has been doubling every 90 days (11). While rare genetic afflictions are indeed important for insurers, they generally are revealed by prenatal or non-genetic diagnostics at early stages.

Even in one of the most-studied heritable disease genes affecting a larger population – BRCA for breast cancer – at least 4,000 variants have been exhaustively characterized by hundreds of labs. Of these, 72.5% were deemed functionally pathogenic (in theory), and 21.1% non-functional (12). However, most of the functional group had mutations that were difficult to define for medical impact. While a deadly mutation for women into old age, only 0.2% of the female population carry any mutation at all for BRCA. Thus, at present, most of the diseases attributed to a single gene mutation reside in relatively small, targeted populations, and it is logical that insurers will be increasingly pursuing coverage for related preventive measures (based on consumer or medical tests).

In summary, Somatic and Epigenetic information are 'non-blueprint,' such as changes found in the sequencing of tumor cells, virus infected cells, and also in the determination of telomere length and other post-birth DNA modifications. This information is observable – and not heritable – data and, thus, their genetic tests may be permissible and fall outside Florida law and GINA.

While epigenetics is attractive, it admittedly remains a relatively new area without significant population data. The greatest data cache for insurers to mine – and the easiest for the application of statistical science apart from medical science – is the compendium of SNPs being found in GWAS studies at the earlier link: <https://www.ebi.ac.uk/gwas/docs/file-downloads> . While this data is publicly available, it technically remains in the realm of Germline genetic information. However, when tied to the appearance of symptoms, it would be:

Figure 3
TWO MAIN GENETIC DATA CATEGORIES FOR ACTUARIES TO REMEMBER

Heritable Genetic Data	Non-Heritable Genetic Data
Fixed in chromosomes	Changeable by stressors
Environment – independent	Environment – dependent
Passes to progeny	Affects only the individual
Ex: 23andMe, Whole Genome Sequencing (WGS), GWAS	Ex: tumor DNA, methylated DNA, virus inserts, telomere length

Separately, it is worthwhile to note that the federal HIPAA Privacy Rule contains at least 10 ‘public purpose’ exceptions, which permit covered entities to disclose personal health information – including genetic information – without the authorization or consent of the individual. Access to genetic information is permitted for the following uses (underlined for emphasis) and disclosures:

(1) as required by law; (2) for public health activities; (3) for health oversight activities; (4) for judicial and administrative proceedings; (5) for law enforcement; (6) about decedents; (7) for cadaveric organ, eye, or tissue donation; (8) for some types of research; (9) to avert a serious threat to health or safety; and (10) for workers’ compensation. Some of these sources could provide actuaries an additional avenue to collect and consider data.

According to Barbara Evans, a noted privacy expert at the University of Florida: “Beyond the HIPAA public purpose exceptions, there are numerous instances in which genetic information may be required as a lawful condition of a transaction or an application for benefits; in these cases, the information is no longer protected under federal law once disclosed to an entity not covered under the Privacy Rule. Technically, wherever individuals are compelled to provide unlimited access to their health information, the extent that these data become available outside healthcare institutions results in a loss of HIPAA protection.” (13).

On a final note, regarding government actions: early statements thus far within the Biden administration remain uncertain as to initiatives that may be launched by the new president or his advisors. However, the newly created Cabinet-level post of Scientific Advisor was filled by Dr. Eric Lander, a leading MIT genomics scientist and a key proponent of the Innocents Project (for wrongful imprisonment based on DNA evidence). His deputy is a social scientist that is also published in racial disparities in genomics. Greater attention to genetic information and society is likely, at least in most social programs (14).

Section 3: Data Gaps and Policies that Impact Actuarial Access and Utility

Clearly, there is a growing asymmetry of genetic data access for North American insurers within the fixed heritable germline category – both at the federal level and also now at the state level. Further legal restrictions on life, disability, and long-term care insurers' use of genetic information appear inevitable in coming months in the U.S. and is firmly in place in Canada. However, based on some of the details within this paper, actuaries can begin to develop tools to counter existing and future asymmetric regulations.

Among others, three strategies to consider in evaluating growing regulations are offered below for consideration:

1. Educate members and industry colleagues on the differences between heritable (fixed) genetic information, and somatic (changeable) genetic information – especially tumor genetics and epigenetics.
2. Analyze the growing public databases of GWAS studies and, perhaps, engage volunteer donors for cross-confirmation to establish sound statistical risk correlations and stratifications.
3. Consider partnerships with epigenetics leaders, and possibly support the launch of nonprofits, with the purpose of filling in data gaps for priority diseases with a genetic basis and parallel studies of early intervention programs that could minimize both disease suffering and healthcare outlays.

Since states continue to regulate life insurance, the above and other alternatives should allow actuaries to be better prepared to minimize data gaps.

Legal access to non-heritable genetic information appears justifiable and within regulations. As an example, nearly all biopsies can or do undergo a genetic sequencing (including collateral sequences that are germline), and viral sequencing is clearly widespread currently during the COVID crisis.

Epigenetics is not far behind as a useful data resource, especially focused on tobacco use detection, biological aging, and additive chemical modifications brought on by ill health (e.g., methylation). Alliances with groups in these scientific fields, such as Dr. Chen's company, FOXO Technologies, would be another avenue to data (15).

In summary, there is still time for insurers and actuaries to educate lawmakers of the differences in genetic data and, in parallel, invest in novel genetic data-gathering initiatives. Once statistical power is reached conclusively in large populations using non-heritable Somatic information – and possibly through private confirmations of SNP/Variant information from GWAS studies – regulatory oversight may not be as feared or uncertain.



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Section 4: Acknowledgments

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Section 5: Quick Reference Bibliography and Web Resources to Monitor

Within the Primer Text:

- (1) <https://www.eeoc.gov/statutes/genetic-information-nondiscrimination-act-2008>
- (2) <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-genetic-information-nondiscrimination-act/index.html>
- (3) <https://legiscan.com/FL/text/H1189/id/2088560>
- (4) <https://content.naic.org/sites/default/files/inline-files/JIR-ZA-39-10-EL.pdf>
- (5) <https://www.canlii.org/en/ca/laws/stat/sc-2017-c-3/latest/sc-2017-c-3.html>
- (6) <https://www.cia-ica.ca/docs/default-source/2014/214082e.pdf>
- (7) <https://foodgenesandme.com/en/blog/post/4-yes-virginia-there-really-is-a-fat-gene.html>
- (8) <https://www.nature.com/articles/s41467-020-20188-y>
- (9) <https://www.cdc.gov/genomics/disease/epigenetics.htm>
- (10) <https://www.nobelprize.org/prizes/medicine/2009/press-release/>
- (11) <https://www.elsevier.com/connect/medical-knowledge-doubles-every-few-months-how-can-clinicians-keep-up>
- (12) <https://jeccr.biomedcentral.com/track/pdf/10.1186/s13046-020-01554-6.pdf>
- (13) Journal of Law and the Biosciences, 1–36; 14 May 2019
- (14) <https://www.statnews.com/2021/02/01/eric-lander-connected-controversial-biden-pick/>
- (15) <https://foxotechnologies.com/>

State Law Databases:

https://www.genome.gov/about-genomics/policy-issues/Genome-Statute-Legislation-Database?field_content_type_value=State%20Statute&field_topic_value=Other%20Lines%20of%20Insurance%20Nondiscrimination

Raw Data Sources for Genetic Variants and High-Incidence Diseases:

<https://www.ebi.ac.uk/gwas/docs/file-downloads>

Insurance Industry Articles and Podcasts:

<https://content.naic.org/sites/default/files/inline-files/JIR-ZA-38-05-EL.pdf>

<https://www.soa.org/globalassets/assets/Files/resources/research-report/2018/2018-impact-genetic-testing-report.pdf>

<https://webcasts.soa.org/products/actuarial-innovation-and-technology-update-on-recent-research#tab-product%20tab%20speaker%20s>

<https://content.naic.org/sites/default/files/inline-files/JIR-ZA-39-10-EL.pdf>

About The Society of Actuaries

With roots dating back to 1889, the Society of Actuaries (SOA) is the world's largest actuarial professional organization with more than 31,000 members. Through research and education, the SOA's mission is to advance actuarial knowledge and to enhance the ability of actuaries to provide expert advice and relevant solutions for financial, business and societal challenges. The SOA's vision is for actuaries to be the leading professionals in the measurement and management of risk.

The SOA supports actuaries and advances knowledge through research and education. As part of its work, the SOA seeks to inform public policy development and public understanding through research. The SOA aspires to be a trusted source of objective, data-driven research and analysis with an actuarial perspective for its members, industry, policymakers and the public. This distinct perspective comes from the SOA as an association of actuaries, who have a rigorous formal education and direct experience as practitioners as they perform applied research. The SOA also welcomes the opportunity to partner with other organizations in our work where appropriate.

The SOA has a history of working with public policymakers and regulators in developing historical experience studies and projection techniques as well as individual reports on health care, retirement and other topics. The SOA's research is intended to aid the work of policymakers and regulators and follow certain core principles:

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