

Genetics and Life Insurance

A View Into the Microscope of Regulation

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The Geneva Association

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The Geneva Association

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Foreword



Anna Maria D'Hulster

*Secretary General,
The Geneva Association*

Genetic testing is becoming increasingly available at ever lower prices. People who know they have a gene associated with a type of cancer, for example, may look for treatments which could minimise the risk of developing the disease. What are the implications of this for life insurance underwriting? Should genetic information be a requirement by life insurers?

Such questions represent the tip of the iceberg of the many complex implications of genetics in life insurance. In addition to the economic aspects, there are many other social, ethical and regulatory considerations to address.

This paper focuses specifically on the regulatory implications of genetic testing. The report, produced by The Geneva Association's Global Ageing research programme, finds that for life, disability, critical illness and long-term care insurance, regulations typically fall into five categories. Thus, there is a whole spectrum ranging from countries that have no genetic-specific regulatory framework; to countries with a clear-cut prohibition or moratorium to the use of genetic information. Each scenario—including the ones in-between—has different consequences.

The use of genetic information for life, disability, critical illness and long-term care insurance is likely to increase in relevance. Whilst this hardly comes as a surprise, only recently has the topic started to attract the attention of regulators, policymakers and the general public. This report represents an attempt to understand key aspects of genetics, as well as limitations and controversies of its utilisation in life insurance.

Kind regards,
Anna Maria D'Hulster

Executive Summary

The use of genetic information for life, disability, critical illness and long-term care insurance is likely to increase in relevance as testing becomes more widespread and better clinical data emerges. Existing regulations generally apply to employment and health insurance.

A country having no genetic-specific regulation for life, disability, critical illness or long-term care insurance implies that the country considers genetic information to be included with other medical information. However, it could simply mean that the country has not yet found the time, need or support necessary to enact a specific regulation. In these countries, the fact that industry groups may have attempted to fill a regulatory void by issuing codes of conduct for their member companies implies that the industry would prefer its own codes rather than sometimes unpredictable broader regulation.

Prohibitions could mean that governments do not trust the insurance industry to follow non-discriminatory practices with respect to genetic testing. Those countries that have regulations prohibiting the use of results from existing genetic tests below certain limits seem to subscribe to the theory that some level of life, disability or long-term care insurance is an inalienable human right, vis-à-vis medical insurance, but above that limit is optional.

An absolute prohibition or moratorium could simply mean that regulators in those countries are taking a wait-and-see attitude. As new testing becomes more affordable and more widespread, life and health insurance companies need to monitor the emerging trends in genetic science closely. Working with regulators, medical professionals, industry groups and genetic counsellors to agree on reasonable self-regulation in the field of genetics may be a prudent approach to staving off suboptimal restrictive regulation.

Introduction

The discovery of the gene mutation for Huntington's disease in 1993 may have been the single most important cause for the misunderstanding of genetic and genomic testing. Huntington's disease is quite rare and only affects about 1-in-10,000 people¹. Unlike most diseases, Huntington's disease is monogenic and 100% predictive. If you have the mutated gene, you contract the disease and, if you contract the disease, you have the mutated gene.

The certainty of prediction for this specific disease leads many people to believe that genetic and genomic test results are much more powerful than they really are. The vast majority of diseases cannot be predicted with any degree of certainty near the 100% certainty of predicting Huntington's disease.

A Brief History of Genes

While the concept of a gene has been around since Gregor Mendel, an Augustinian monk turned botanist, performed his now famous experiments with peas in 1865, the actual word "gene" was first used by Danish botanist Wilhelm Johannsen in 1909. Mendel, known as the father of modern genetics, realized the concept that hereditary traits were passed down from the mother and father in discrete units, that is, they do not blend. His pea experiments showed that there were recessive and dominant traits and that they remain distinct.

James Watson and Francis Crick were credited with the discovery of the structure and properties of Deoxyribonucleic acid (DNA) in 1953 and even won the Nobel Prize for their efforts in 1962. Mendel was not awarded a Nobel Prize since the first prize was awarded in 1901 and Mendel died in 1884. The Nobel Prize is not awarded posthumously².

The Human Genome Project

With over 3 billion pairs of bases, the DNA double helix structure is one of the most complicated scientific structures known³. The Department of Energy, the National Institutes of Health and other international organisations convened in 1984 and agreed to study DNA to better understand it. This led to the very ambitious goal in 1990 to map the entire human genome sequence, named the Human Genome Project. The project was initially intended to last 15 years with a budget of USD 200 million per year, or a total budget of USD 3 billion¹. Once analyzed, the data gleaned from this project was hoped to be a source book for insight into the possible treatment of approximately 7,000 rare genetic diseases that currently affect mankind⁴.

Not only was the project finalized a full two years before its planned completion date, it also came in under budget by about USD 300 million. An important element of the project, besides the purely scientific aspects, was to consider the legal and ethical ramifications involved. 5% of the budget, USD 150 million, was allocated toward this purpose⁵. While the first mapping of the human genome took 13 years at a cost of about USD 2.7 billion, prices have come down quite quickly. In fact, the decrease in cost has far exceeded that suggested by Moore's Law.

Moore's Law

Named after Gordon Moore, cofounder of Intel, who observed in 1965 that the number of transistors per square inch on integrated circuits had doubled every year since their invention, Moore's law is a commonly accepted principle that basically states that computer processing speed will double approximately every two years⁶. This principal has been used for estimating the decrease in prices of technology-related apparatus. While the cost of the entire Human Genome Project was about USD 2.7 billion, many estimated the cost of sequencing the human genome at USD 100 million in 2003. Applying Moore's Law to the cost of mapping the human genome would

1 National Human Genome Institute, 2017, genome.gov

2 *Nobel Prize Facts*, nobelprize.org

3 Rettner, Rachael, 2017: *DNA: Definition, Structure and Discovery*, Livescience.com

4 globalgenes.org 2017

5 Suter, Sonia, 2001: *The Allure and Peril of Genetic Exceptionalism—Do We Need Special Genetics Legislation*, 79 Wash ULQ 699

6 mooreslaw.org

yield a reduction in price in 2017 to about USD 800,000. The significant reduction of price became possible after the 2007 introduction of next generation sequencing technologies. By 2006, whole genome sequencing (WGS) cost was estimated at USD 10 million and has dropped to only a few thousand U.S. dollars currently—even as low as USD 1,000⁷.

Genetic Information: Unleash or Control it?

Direct-To-Consumer Testing

This dramatic reduction in cost has caused testing to become accessible to many people. Companies now claim to offer WGS direct to consumer⁸. However, many experts believe that direct-to-consumer WGS is still a few years away. For example, on its website 23andMe, a company that offers genotyping services (the process of determining which genetic variants an individual possesses) direct-to-consumer, states:

23andMe uses genotyping, not sequencing, to analyze your DNA. Sequencing technology has not yet progressed to the point where it is feasible to sequence an entire person's genome quickly and cheaply enough to keep costs down for consumers⁹.

With direct-to-consumer genotyping already available, WGS available at laboratories and direct-to-consumer WGS on the horizon, a whole new array of issues involving ethics and legality of data use and disclosure arises. Direct-to-consumer genotyping seems to occupy an undefined space between health and wellness. Current regulations typically address employment, health insurance and other types of insurance. Most of these regulations are relatively old and have not kept up with the rapid pace of genetic testing advancements and specifically do not address the vast possibilities offered by WGS.

Testing and Insurance

While few would disagree that an employer should not have the right to restrict work based on the results of a genetic test, a personal decision to purchase individual life and health insurance presents a different dynamic. Voluntary insurance is based upon the principle of pooling of like risks. When a potential policyholder has information about his or her health that is not shared with the insurance company, this could lead to anti-selection where poorer risks purchase more insurance and better risks purchase little or no insurance. An insurer would find it extremely difficult to cover claim payments with existing revenues for pools where there were many anti-selective risks.

However, if insurers had the right to ask for information from previous genotyping tests, this could cause an entirely different dynamic. Some doctors argue that this may cause a person to postpone or even cancel a planned genetic test that might be vital to that person's wellbeing. The fear of being denied insurance could become an obstacle in the continued health of an individual.

This could put the insurance industry in a very precarious situation. Mitigation of this problem is possible if the person purchases insurance prior to scheduling a genetic test, as suggested by many genetic counsellors¹⁰. Nevertheless, future additional insurance purchases may still be affected.

The question of anti-selection vs. the fear of being denied insurance mostly applies to life insurance rather than health insurance because most leading countries in the world offer government-provided health insurance or mandate the purchase of health insurance¹¹. If health insurance is provided to everyone, by definition, there can be no anti-selective risks. The U.S. is a notable exception with a somewhat more complex structure. There is national coverage for the elderly through Medicare and the poor through Medicaid. The Affordable Care Act

7 WGS is a method used to determine the exact sequence of a certain length of DNA. It can be used to genotype someone for known variants as well as variants unique to that individual.

8 Bhangra, Kulraj Singh: *Sure Genomics offers direct-to-consumer whole-genome sequencing*, 2016, BioNews.org.uk

9 23andMe.com, 2017

10 genetics.edu.au, 2017

11 In some countries, advanced medical treatments may have different rules and could be affected by genetic testing

(ACA) sets out minimum coverage standards for health insurance, but it has very lenient opt-out penalties causing a large number of better risks to simply pay the penalty and forego coverage. This has caused premiums to rise in many states which will undoubtedly trigger another round of opt-outs and the cycle will continue.

Before the ACA was enacted, the U.S. passed a regulation called the Genetics Information Nondiscrimination Act (GINA) in 2008. This law basically prohibits discrimination against people who have taken genetic tests with respect to employment and health insurance. Life, disability and long-term care insurances are specifically excluded from the Act¹². Prior to the enactment of GINA, many individual states passed their own genetic-specific legislation.

While many countries have specific laws covering genetic testing, most of the regulations are not very detailed. In fact, many experts continue to dispute if a good definition of a genetic test really exists. Some countries simply include genetic testing along with any other medical information, for example family history, blood pressure or cholesterol levels, with respect to regulation. Other countries attempt to define in the regulation what constitutes a genetic test. These attempts to define genetic tests will have difficulty keeping up with the rapid pace of genetic testing technology.

Genetic Exceptionalism

Before this paper presents some of the regulations governing genetic testing, it is important to discuss an interesting concept with respect to testing, namely *genetic exceptionalism*. Genetic exceptionalism is the belief that genetic information is special and must therefore be treated differently from other types of medical information.

There are five primary arguments in favor of genetic exceptionalism, namely that genetic information: 1) is unique to each individual (except for identical siblings);

2) has predictive powers; 3) may have an effect on relatives; 4) may be used for discriminatory purposes; and 5) may lead to emotional damage of the affected person¹³.

There are additional arguments that can be made about genetic tests that are shared with other medical tests. These are: 1) that a genetic test can be made from a very small sample; 2) that the information gleaned from a test can be used for completely different purposes than the original intent of the test; 3) that the information can be of interest to third parties; 4) that a test can determine susceptibility of disease or other features of the patient; and 5) that tests can be taken from biological material collected from patients in the past.

Looking through this list will cause many to say that these cited reasons are not unique to genetic testing. For example, a simple test determining that a person has high blood pressure could be hereditary and affect one's children. What is truly unique is that all of the above-mentioned arguments hold for genetic testing. It would be difficult to contend that the same can be said about any other non-genetic medical test.

Many people believe, perhaps wrongly so, that genetic information is immutable. There is a misperception that genes predetermine our health. Much of this misperception could have been initiated by genetic tests such as the test for Huntington's disease which is 100% predictive. In fact, scientists have shown that many diseases are affected by environmental factors such as smoking, obesity, air quality, diet, exercise, stress and sleep. The perceived "power" of genetics has caused some in the scientific world to reject the widely-accepted concept of genetic exceptionalism.

One of the most vocal opponents to the theory of genetic exceptionalism is Sonia Suter, a professor of law at George Washington University in the U.S. In her 95-page essay called *The Allure and Peril of Genetic Exceptionalism: Do We Need Special Genetics Legislation?*, Professor Suter

12 Robert C. Green, MD, MPH; Denise Lautenbach, MS, CGC; and Amy L. McGuire, JD, PhD: *New England Journal of Medicine*, 2015; 372:397-399 January 29, 2015. DOI: 10.1056/NEJMp1404776

13 Sarata, Amanda, 2011, *Genetic Exceptionalism: Genetic Information and Public Policy*, Congressional Research Service, 7-5700, www.crs.gov, RL34376

suggests that treating genetic information differently from other medical information discriminates against poorer classes of people¹⁴.

If genetic non-discriminatory regulations are passed, a person who acquires a disease due to a gene mutation could be treated differently from a person acquiring the very same disease without a genetic mutation. Poorer classes of people are more susceptible to acquiring diseases due to environmental causes (less access to top medical care, poorer living conditions and suboptimal diet) while genetic disease is non-discriminatory, Professor Suter argues. This leads to her belief that genetic exceptionalism is discriminatory against the poor.

Even though Professor Suter's paper was published in 2001, in a recent phone interview she stated that she continues to hold the same view as presented in her paper¹⁵. She agrees that some genetic information is indeed sensitive, but also contends that some non-genetic information is sensitive. At the heart of her argument is that genetic information is supposed to tell us everything about a person, but it doesn't. We still do not understand all the factors affecting people's health and also the interconnectivity of all factors is very complicated and still not well understood.

While the academic and medical communities continue to argue the merits of genetic exceptionalism, regulators are adapting to the influences of the media and the general public that genetic testing requires its own set of laws. One interesting discussion borders both genetic exceptionalism and current genetic regulations.

Genetic Regulation

The medical profession is highly aligned with clinical trials for new drugs and procedures. For example, the magnetic resonance imaging (MRI) machine was first built in 1977 and approved for clinical use by the Food and Drug Administration (FDA) in the U.S. in 1984. This non-invasive procedure, which identifies injuries and abnormalities,

needed clinical trials to prove that what the MRI displayed was actually occurring within the body. However, 23andMe began its direct-to-consumer campaign in 2007 for USD 99 without any FDA approvals. Its stated functions were to help build a participant's family tree using genetic material from a saliva sample and to disclose some interesting and "fun" traits such as the odds of having a certain eye color or whether the participant had wet or dry ear wax.

What quickly provoked the attention of the FDA were the additional risk factors included in the report such as the tendency to be obese, be an alcoholic or develop breast cancer, Alzheimer's disease or Parkinson's disease. Along with this information, 23andMe was offering medical advice on how to reduce the risk of developing these diseases.

In 2013, the FDA banned 23andMe from offering medical analysis in its report. This caused the company to only offer ancestry information instead of the information on the 254 possible conditions that it originally offered. 23andMe reworked its testing in conjunction with the FDA and received approval for 36 of the original conditions, although it can only tell if a person carries the gene mutation for these 36 diseases without stating the probability of actually acquiring the disease¹⁶. But, on 6 April 2017, 23andMe received FDA approval to report on the probability of developing 10 specific diseases¹⁷. The fact that genetic testing holds the allure of the general public as an exact science even before evidence-based results are available, is troubling to many physicians.

Limitations and Controversies

Experts May Disagree on the Powers of Genetics

In an extremely well-received presentation at the 2017 ReFocus Conference in Las Vegas, Nevada¹⁸, Dr J. Craig Venter (an American geneticist who was frustrated by the slow progress of the government-funded Human Genome Project and launched an effort that sequenced human DNA two years earlier than planned¹⁹) discussed the degree to which a combination of genetic and clinical

14 Suter, Sonia, 2001: *The Allure and Peril of Genetic Exceptionalism—Do We Need Special Genetics Legislation*, 79 Wash ULQ 699

15 Phone interview between Sonia Suter and Ronald Klein on Friday, 31 March 2017

16 Pollack, Andrew, 10/21/2015: *23andMe Will Resume Giving Users Health Data*, New York Times

17 Christensen, Jen, 2017, cnn.com

18 Based upon ReFocus survey results

19 Herper, Matthew, 2017: *Craig Venter Mapped the Genome. Now He is Trying to Decode Death*, forbes.com

testing could tell about a person's health. His company, Human Longevity, Inc. (HLI) performs high-end full medical checks for a price of USD 25,000. Dr Venter discussed in his presentation the spectrum of possibilities gleaned from these tests. On one end of this spectrum he spoke about identifying and curing early onset cancers. On the other end, he spoke about being able to create an accurate computer generated facial image of the patient using only genetic data.

Dr Venter strongly implied in this presentation that the genetics proved the clinical tests. In a follow-up discussion, Dr Achim Regenauer, Chief Medical Director at Partner Re had a slightly different view. Dr Regenauer held the opinion that the clinical tests proved the genetic tests and without these clinical tests, the genetic tests only give probabilities of acquiring diseases. For example, an early onset cancer can only be seen with a clinical test – the genetic test shows a susceptibility to that cancer. The exact science of the tests that Dr Venter's company offers is a bit more complicated than stated above. The tests offered may be able to identify certain tumours, for example, but diagnostic imaging is still required to confirm and locate the tumour.

While interesting to discuss, these diverse views by well-respected experts can cause confusion in both the medical and the public arenas, making regulation of genetics that much more difficult. Few in the medical profession doubt the potential of genetic tests, however many believe that clinical proof of the value of genetic tests (clinical validity) is necessary before they become more widely used and trusted.

Genetic Test Results May Be Misinterpreted

This again leads back to the anti-selective risk discussion. If the information gleaned from genetic testing, especially

from the direct-to-consumer market, does not have the level of predictive powers that some may want to imply, could this actually work in favour of life insurance companies? An analogy can be drawn to the gambling community and the game of Blackjack.

Also known as Twenty One, Blackjack is a casino card game played with a standard deck of cards in which the player attempts to beat the House by drawing a hand that is higher than the House's hand, but does not exceed twenty one. Players soon realized the value of keeping track of the cards already played so that they could better predict future cards. This is known as card counting.

Card counting was outlawed in casinos. However, it was difficult to determine if someone was counting cards so the casino industry began using multiple decks of cards making counting much more difficult. It is typical for a casino to use six decks and reshuffle the cards after only 75% of the cards have been drawn.

There are still many players that attempt to count cards, but it is no longer a banned activity. The reason is simple. For every adept card counter that creates an edge against the House's favored odds, there are multiples of players that count incorrectly increasing the House's odds. Can the same thing happen with life insurance and direct-to-consumer genetics analysis? Is it possible that consumers will misinterpret the genetic information and purchase additional insurance with little or no additional mortality risks? As with gaming establishments, the insurance industry has an excellent reputation for finding creative methods to combat anti-selective risks. Genetics legislation will play a key role in determining how costly it will be for the life insurance industry to protect itself against this emerging technology.

Conclusions

The use of genetic information for life, disability, critical illness and long-term care insurance is likely to increase in relevance as testing becomes more widespread and better clinical data emerges. Existing regulations generally apply to employment and health insurance. For life, disability, critical illness and long-term care insurance, regulations typically fall into the following categories:

1. No regulation
2. No regulation with written or unwritten codes of conduct from insurance industry groups
3. Prohibitions on insurers requiring applicants to take a genetic test and prohibitions on discrimination if the applicant refuses to take a test
4. Prohibitions or moratoriums on using results from existing tests when policies are below certain limits
5. Prohibitions or moratoriums on using results from existing tests at all, sometimes including use of family history information

No genetic-specific regulation for life, disability, critical illness or long-term care insurance (bullet point 1) implies that the country considers genetic information to be included with other medical information. However, it could simply mean that the country has not yet found the time, need or support necessary to enact a specific regulation. In these countries, the fact that industry groups may have attempted to fill a regulatory void by

issuing codes of conduct for their member companies (bullet point 2), implies that the industry would prefer its own codes rather than sometimes unpredictable broader regulation.

Prohibitions (bullet point 3) could mean that governments do not trust the insurance industry to follow non-discriminatory practices with respect to genetic testing. Those countries that have regulations prohibiting the use of results from existing genetic tests below certain limits (bullet point 4) seem to subscribe to the theory that some level of life, disability or long-term care insurance is an inalienable human right, vis-à-vis medical insurance, but above that limit is optional.

An absolute prohibition or moratorium (bullet point 5) could simply mean that regulators in those countries are taking a wait-and-see attitude. As new testing becomes more affordable and more widespread, life and health insurance companies need to monitor the emerging trends in genetic science closely. Working with regulators, medical professionals, industry groups and genetic councillors to agree on reasonable self-regulation in the field of genetics may be a prudent approach to staving off unwanted restrictive regulation.

What follows is a list of genetic-related regulation by selected country. While not an exhaustive list, the goal is to identify countries with key insurance industries. When appropriate, the list attempts to highlight the genetics regulation as it applies to life insurance.

Country by Country Regulation

Country/Regulation (if any)	Latest Effective Year	Category (Bullet Point Number)	Purpose	Comments
Australia / Financial Security Council Standard No. 11 Genetic Testing Policy and No. 16 Family Medical History Policy ²⁰	2016	3	Genetic test information must be handled with extreme care. Insurers cannot ask an applicant to take a genetic test, however insurers can ask if an applicant has taken a genetic test or is planning to take a test (unless the test was for scientific research purposes only and the applicant does not know the results). Insurers may not use genetic tests of relatives and may not ask third parties for test results. Only information with clear medical evidence can be used. The same basically applies to family history questions.	Main goals: insurance should be available and affordable to most people at standard rates, risk classification should evolve with medical advancements, the industry should be sustainable, customers should not be dissuaded from taking genetic tests and the industry should be transparent.
Austria / Austrian Gene Technology Act ²¹	2005	5	Genetic tests can only be performed in an approved facility with a competent medical specialist and with the consent of and advanced and post-test counselling of the applicant. Insurers cannot collect, demand or accept test results.	The regulation prohibits results from Types 2, 3 or 4 genetic tests to be used for insurance purposes. Type 1 identifies a current disease, Type 2 identifies a current germ-line disease and Types 3 and 4 identify the predisposition of a disease.
Belgium / Law on terrestrial insurance contracts ²²	1992	5	The regulation prohibits the use of pre-symptomatic genetic testing that enables to predict the future state of health. Insurers cannot collect, demand or accept test results.	

²⁰ FSC Standard No. 11 Genetic Testing Policy, 2016, Financial Security Council

²¹ Vibiral, Dietmar, 2010: *Legal Regulation for Genetic Testing in Austria*, European Human Genetics Conference 2010, Gothenburg

²² Nys, Herman, et al, 2002: *Genetic Testing Patients' rights, insurance and employment. A survey of regulations in the European Union*, European Commission, ISBN 92-894-4217-4

Country/Regulation (if any)	Latest Effective Year	Category (Bullet Point Number)	Purpose	Comments
Canada / Bill S-201 ²³	2017	5	The regulation (which has not yet been enacted) prohibits an insurer from requiring a person to take a genetic test, from requiring a person to disclose the results of a genetic test or discriminating against a person because he or she did not take a genetic test.	Prior versions of this bill allowed insurers to ask for prior tests if a life insurance policy face amount exceeded CAD 1 million or is annual payments exceeded CAD 75,000. These provisions were removed in the current version.
China ²⁴		1	No specific regulation exists. The government put a ban on all genetic testing for a few months in 2014 and required all medical equipment to be approved. This shut down the genetics industry for a while but the regulation was relaxed.	The biggest concern is prenatal testing. While the one-child policy is now relaxed, many families still only have one child and finding out the sex, health and even the potential mental capacity of the unborn child is a huge industry.
Denmark / Insurance Agreement Act ²⁵	1997	5	Insurers cannot ask for or use information from genetic tests but can use diagnostic tests for risk evaluation. The regulation specifically allows use of information about current or past health of the applicant or relatives.	
Finland / Federation of Finnish Insurance Companies ²⁵	1999	1	No specific genetics regulations currently exist.	Insurers follow industry convention and do not ask for or use any information (positive or negative) from genetic testing.
France / Loi N° 2004-800, Loi N° 2011-267 ²⁶	2004, 2011	5	To perform a genetic test, a facility must be approved and the test must be ordered by a qualified party. Also, the test may only be ordered for a specific medical reason, that is, not just for informational purposes. Genetic information may only be used for scientific, medical or identification (in case of death) purposes and can only be taken with the subject's consent. A doctor is obliged to disclose information to the patient, but not allowed to disclose information to relatives.	The law seems to exclude direct-to-consumer genetic tests inside of France, but some argue that a resident could order a direct-to-consumer genetic test outside of France.

23 parl.gc.ca, 2017

24 Shu-Ching, Chen (Jean), 2014: *China Cracks Down on DNA Testing*, Forbes Asia Magazine

25 Robert C. Green, MD, MPH; Denise Lautenbach, MS, CGC; and Amy L. McGuire, JD, PhD: *New England Journal of Medicine*, 2015; 372:397-399 January 29, 2015. DOI: 10.1056/NEJMp1404776

26 Soini, Sirpa, 2012: *Genetic testing legislation in Western Europe—A fluctuating regulatory target*, doi: 10.1007/s12687-012-0078-0

Country/Regulation (if any)	Latest Effective Year	Category (Bullet Point Number)	Purpose	Comments
Germany / Gendiagnostikgesetz ²⁷	2010	4	The main goal of the regulation is to prevent discrimination to genetic predispositions and it applies to all genetic tests except for pre-natal tests. All genetic testing must be performed by a licensed physician (“geneticist”) and adequate counselling is required. This prohibits direct-to-consumer tests within Germany. Insurers cannot require a genetic test, request results from a genetic test or use the information from a genetic test. However, an insurer may ask for the results of prior tests if the insurance contract exceeds EUR 300,000 or if annual annuity payments result in more than EUR 30,000.	It appears as if direct-to-consumer products purchased outside of Germany may be legal. The regulation excludes genetic testing for scientific and criminal purposes.
Greece ²⁸		2	No specific genetic regulations exist but insurers voluntarily do not ask for genetic information prior to issuing a policy.	
Japan ²⁹		2	No specific genetic regulations exist so genetic tests fall into the category of other medical tests. Any tests must be approved.	While no laws currently exist and there have been no official comments from the Financial Services Agency (FSA), no insurance products currently sold in Japan use results from genetic testing in any way. At least one company is researching how genetic information could be used in life insurance products.
India ³⁰		1	Genetic testing laboratories in India are not governed by any specific legislation. They require the same set of permissions that a diagnostic laboratory performing blood glucose tests, for example, does.	
Ireland / Part 4 of the Disability Act ³¹	2005	5	Genetic test data may only be collected with the applicant’s consent and the results cannot be used for insurance purposes.	

27 Harbuck, Benjamin, 2011: *Lessons for Germany’s Gendiagnostikgesetz from Europe’s Protocol on Genetics Testing for Health Purposes*, Washington University Global Studies Law Review 371

28 Robert C. Green, MD, MPH; Denise Lautenbach, MS, CGC; and Amy L. McGuire, JD, PhD: *New England Journal of Medicine*, 2015; 372:397-399 January 29, 2015. DOI: 10.1056/NEJMp1404776

29 Conwill, Stephen, Email exchange, 2017

30 Vora, Priyanka, 2017: *More Indians are taking home DNA tests but do they understand what their genes are telling them?*, Scroll.in

31 *Guide to the Disability Act 2005*, 2005, Department of Justice, Equality and Law Reform

Country/Regulation (if any)	Latest Effective Year	Category (Bullet Point Number)	Purpose	Comments
Netherlands / Wet op het bevolking-sonderzoek ³²	1998	4	Genetic testing is allowable for consumers by this regulation (for example direct-to-consumer) but certain tests (for example tests for incurable diseases) can only be made by a licensed individual. The test can only be made if it benefits the person, for the stated purpose only and with his or her consent. The Dutch Insurance Association states that no company can require an applicant to take a test and it cannot ask for the results of a previously taken test unless the insurance face amount exceeds NLG 300,000 (approximately EUR 150,000) or annual payments of EUR 30,000 (year 1)/ 20,000 (year 2+) for disability insurance. Hereditary questions may only be asked if a disease has already manifested itself if the policy is under the above limits.	There was a moratorium on genetic testing imposed by the government in 1990 for five years. The Dutch Insurance Association decided to impose its own voluntary regulation at the end of the moratorium to supersede a new regulation. The regulation described must be renewed every two years. Before the regulation, the law stated that an insurance applicant must disclose all material information regardless of being asked. Now the courts conclude that the insurer must ask and the applicant need only answer the questions.
Poland / Ustawa o dzialalnosci ubezpieczeniowej ³³	2015	5	Insurers cannot request results from genetic tests of applicants.	
Portugal / Law 12/2005 ³⁴	2005	5	Insurers cannot ask for a genetic test or use test results or any other kind of genetic information already available, including family history, to deny insurance or establish higher premiums.	
Singapore / Genetic Testing and Genetic Research – Bioethics Advisory Committee (BAC) ³⁵	2007	5	A moratorium on insurer's being able to request data from genetic tests continues to be in place since May, 2007. Singapore regulation is against genetic exceptionalism. Genetic information should be treated as other medical information. Genetic testing should generally be conducted through a qualified healthcare professional. Tests that provide predictive health information should not be offered directly to the public.	The Life Insurance Association in Singapore agreed to the moratorium of the BAC but the industry is still allowed to ask family history questions on applications.

32 van Hellemond, RE, et al, 2011: *Regulating the Use of Genetic Tests: Is Dutch Law an Example for Other Countries with Regard to DTC Genetic Testing?*, VU University Amsterdam

33 Dziennik Ustaw Rzeczypospolitej Polskiej, 2015, Warszawa, dnia 10 listopada 2015r., Poz 1844

34 Sequieros, Jorge, 2010: *Portugal's Genetic Information Law* (Law 12/2005 26 Jan.), IBMC Univ. Porto

35 Life Insurance Association, Singapore, 2006: *Genetics and Life Insurance*

Country/Regulation (if any)	Latest Effective Year	Category (Bullet Point Number)	Purpose	Comments
Spain / Law 14/2007, on Biomedical Research ³⁶	2007	1	An individual can take a genetic test but cannot be required to do so and must be given counselling before giving the necessary consent. A person cannot be discriminated against for refusing to take a test or on account of the results of the test.	No regulation exists that specifically affects insurance but privacy of data would apply to all insurers.
Switzerland / Federal Act on Human Genetic Testing ³⁷	2004	4	There can be no discrimination based upon genetics and a person must give consent to perform a test. Companies that perform testing must be licensed. The test must serve a medical purpose. Insurers may not require a test and cannot request the results from prior tests unless a life insurance policy exceeds CHF 400,000 or a disability policy exceeds CHF 40,000 annually.	The purpose of the act is to preserve human dignity, prevent improper testing and improper use of genetic data and to ensure the quality and interpretation of tests.
United Kingdom / Concordat and Moratorium on Genetics and Insurance ³⁸	2014	4	Insurers cannot request or require that an applicant take a genetic test. Insurance applicants do not have to disclose results of genetic tests taken after the policy is issued or of a blood relative. The only way that an insurer can request the results of a genetic test is if a life insurance policy is GBP 500,000 or above, critical illness is GBP 300,000 or above or disability is GBP 30,000 per year or above, the test is on the approved list (currently Huntington's disease is the only approved test) and the insurer asks for the test results. Family history and diagnostic test results can be used with the applicant's consent.	This is an agreement between the government and the Association of British Insurers that insurance underwriting should be based upon sound evidence and that insurers should have access to relevant medical information. This agreement extends until 2019.
United States / Genetics Information Nondiscrimination Act (GINA) HR 493 ^{39, 40}	2008	1	The regulation focuses on prohibiting genetic discrimination in employment and health insurance but does not address life, disability or long-term care insurance. Most individual U.S. states have their own regulations, but they mainly apply to health insurance. ⁴¹ Some states require actuarial justification in order to use genetic information for life, disability or long-term care insurance.	In its original form, GINA included life, disability and long-term care insurance but these were removed because of great opposition and fear that the regulation would not be enacted.

36 Law 14/2007, of 3 July, on Biomedical Research


37 Federal Act on Human Genetic Testing (HGTA), 2004, Law 810.12

38 HM Government and Association of British Insurers, 2014: *Concordat and Moratorium on Genetics and Insurance*

39 U.S. Equal Opportunity Commission, 2008: *The Genetic Information Nondiscrimination Act of 2008*

40 National Conference of State Legislatures, 2008: *Genetics and Life, Disability and Long-Term Care Insurance*, Congressional Research Service

41 NCSL, statenet, 2008



The use of genetic information for life, disability, critical illness and long-term care insurance is likely to increase in relevance. This report represents an attempt to understand key aspects of genetics, as well as limitations and controversies of its utilisation in life insurance.

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