

# **The Proliferation of Genetic Testing and the Rise of New Issues in Underwriting**

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## ■ Abstract

In recent years, the rapid acceleration of genetic testing, even in Japan, has breached the bounds of theory with respect to the various issues between genetic testing and insurance, and the possibility of influencing the insurance business itself is becoming a reality. Though genetic testing results are not applicable to underwriting in Japan at present, there are examples, such as in the UK, where this is being introduced, albeit in a limited fashion. In the insurance business, there are several particular factors for each individual nation, including the social security system, legal system, citizens' awareness, and others and the influence of these factors cannot be ignored; therefore, it would not be appropriate to apply scenarios from other nations to Japan. Still, it is desirable to compile data from several nations about the handling of genetic testing and other issues in underwriting and to hold proactive, concrete, and multifaceted discussions on these issues in Japan in a prompt fashion. With regard to insurance in recent years, due to more rapidly changing environments, including medical advances, it is now required more than ever before that insurers handle these issues in a swift and appropriate manner.

## ■ Keywords

genetic testing, risk classification, rate fairness

## **1. Introduction**

The Nobel Prize Dialogue<sup>1</sup> was jointly held by the Nobel Foundation and the Japan Society for the Promotion of Science at the Tokyo International Forum on March 1, 2015 (as the Nobel Prize Dialogue Tokyo 2015), the event's first occurrence outside Sweden. Under the topic of "The Genetic Revolution and Its Future Impact," the Nobel Prize

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<sup>1</sup> The Nobel Prize Dialogue is a public symposium held every year in Sweden around the time of the Nobel Prize Award Ceremony (since 2012).

Dialogue Tokyo 2015 featured lectures, panel discussions, and audience-engaged debates with the seven gathered Nobel laureates and other researchers. The discussions on that day can all be viewed on the Nobel Foundation's official website<sup>2</sup>.

On being graced with the opportunity to join this event as a panelist (in Breakout Panel Discussion 1-B: "The Promised Land of Genomic Medicine: How do we get There?"; Moderator: Goran K. Hansson; Panelists: Shinya Yamanaka, Tikki Pang, Clara Gaff, Yasuchika Hasegawa, and Tomoka Miyachi), this author provided comments on the influence exerted by the development of genetic testing technology on Japan's commercial life insurance business.

In Japan's insurance industry, both past and present, genetic testing has not been utilized in underwriting, and there is no official position on testing given by the industry<sup>3</sup>. As such, research concerning genetic testing and insurance in Japan primarily takes a theoretical approach. However, in light of the advancements in medicine, the speed of technological development in diagnosis and treatment, and the trends in several foreign nations in recent years, the day when issues surrounding genetic testing and insurance are discussed as practical matters in Japan may not be so far off.

## **2. Trends in Genetic Testing and Insurance in Europe and North America**

With the development of genetic medicine, represented in expressions like "order-made medicine,"<sup>4</sup> a negative aspect has also been noted that exerts a damaging influence on hiring, promotion, marriage, subscription to insurance, and other areas. This is, in general, called "genetic discrimination." As previously mentioned, genetic testing is not used in insurance underwriting in Japan; thus, discussions surrounding genetic testing and insurance have not progressed in Japan as they have in Europe and North America. As such, discussion of recent changes in the status of genetic testing and how the insurance business accommodates such changes in Europe and North America would

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<sup>2</sup> <http://www.nobelprize.org/events/nobel-prize-dialogue/index.html/tokyo2015/jp>

<sup>3</sup> Though there is a report titled "Genetic Testing and Life Insurance" compiled by the Genetics Research Group (a private research group composed of medical reps from insurance firms and other members), there is no official published industry position.

<sup>4</sup> "Medicine up to now has involved giving a uniform treatment (ready-made medicine) when diagnosing the same illness between patients. However, it has been known for some time that the state of the illness (its condition, treatment efficacy, side effects) varies, and it is not always appropriate to apply the same treatment (medicine/dosage) to the same illness. By contrast, it is becoming more advocated that each individual's characteristics, that is, diversity, be taken into consideration when practicing medicine (diagnosis/treatment) optimally (order-made medicine)." (Tamai, Mariko and Matsuda, Jun, eds. 2013, p. 168).

yield beneficial suggestions on future practical issues and solutions in Japan; indeed, this would also be demanded by society.

To take an example from the United States, as the problem of “genetic discrimination” in hiring, promotion, marriage, and insurance subscription became obvious, since 1991, many states have enacted legislation prohibiting the use of genetic testing results in medical insurance underwriting. At present, the use of information gained from genetic testing in hiring, promotion, or subscribing to medical insurance is prohibited by US federal law.

To provide context, it can be noted that the US, unlike Japan, does not have a comprehensive health insurance system for all citizens. Public medical insurance in the US is focused around Medicare, which is for the elderly and disabled, and Medicaid, which is for low-income persons. Both systems were established in 1965. With the ethos of self-responsibility and free-market competition as core principles, the medical system is relegated to market forces; thus, more than half the population subscribes to private health insurance either through their employer or independently. Though some of the most affluent may benefit from the finest in medical technology and services, those working in small- and medium-sized companies, or otherwise in an unstable employment situation, as well as the unemployed, may find it impossible to acquire health insurance.

In contrast to the US, the UK utilizes its national budget in providing the services of its National Health Service (NHS) to all residents. France’s system segments the population by occupation in its medical insurance system. Like these two, Japan is a nation with a well fleshed-out public security with regard to health insurance. As such, in a nation where the government provides comprehensive health services, the crucial areas concerning genetic testing are not in the health insurance arena, but instead revolve around life insurance and other insurance instruments.

Notable among the trends in life insurance and genetic testing is an October 2000 decision made by the Genetics and Insurance Committee (GAIC)<sup>5</sup>, an advisory committee to the UK’s Department of Health. This decision permits the use of an existing genetic testing result of Huntington’s disease<sup>6</sup> in risk selection for life

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<sup>5</sup> The GAIC is a third-party organization that evaluates genetic testing and reviews its applicability to insurance; in addition, it oversees trends on insurance company use of genetic testing and issues reports.

<sup>6</sup> As per the Ministry of Health, Labor and Welfare’s overview of “Huntington’s disease” in the “Specified Intractable Diseases (New), Enforced Jan. 1, 2015,” Huntington’s disease is defined as “a chronic and progressive neurodegenerative disease with autosomal dominant inheritance and primary symptoms of dementia, involuntary movement, primarily chorea, and mental disorder,” and further described as “primarily occurring in adults, with peak age of onset in the thirties, but there have been

insurance, but this decision drew attention because of its great variance from worldwide trend to restrict the use of genetic testing results.

In response to this decision, the House of Commons of the UK's Science and Technology Committee recommended a re-evaluation in April 2001 and demanded a moratorium on government and industry use of genetic testing results for at least two years. The Human Genetics Commission (HGC)<sup>7</sup> also issued a demand in May 2001 for a minimum three-year moratorium for genetic testing-based insurance contracts below £500,000, regardless of the insurance type, as well as a recommendation for legislating the said moratorium.

In response, the Association of British Insurers (ABI) altered the text in its Code of Practice from "A moratorium period shall be set for life insurance contracts connected to mortgages under £100,000" to "Genetic testing results shall not be used in insurance contracts below £300,000 regardless of the type of insurance." The ABI followed-up in October 2001 by announcing a more rigorous moratorium plan (to take effect in November 2001).

More specifically, the plan 1) enacts a five-year moratorium on the use of genetic testing results; 2) applies a moratorium for life insurance contracts under £500,000 in value and other insurance contracts under £300,000 in value; and 3) demands that the use of genetic testing results receives approval from the GAIC.

This voluntary moratorium, enacted in November 2001, will be extended until at least November 1, 2019<sup>8</sup>. An extension on the moratorium would, with the exception of income security insurance, life insurance policies above £500,000, and catastrophic illness policies above £300,000, allow subscribers not to notify their insurance companies about the genetic testing results they had already received when applying for insurance. Currently, the only scenario for using genetic testing results with GAIC approval is for Huntington's disease in life insurance policies above £500,000.

At present, there are no insurance companies, be they in the US, UK, or anywhere on the planet, that require genetic testing of their subscribers. However, there are cases

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observations of onset in a wide variety of ages from infancy to old age" (<http://www.mhlw.go.jp/file/06-Seisakujouhou-10900000-Kenkoukyoku/0000089959.pdf>). Also, as per the Japan Intractable Disease Information Center homepage of the Japan Intractable Diseases Research Foundation (<http://www.nanbyou.or.jp/entry/175>): "four to eight per 100,000 persons will suffer from the disease in Caucasoids," and it notes that "studies in our nation show that only approximately 0.5 per 100,000 will suffer from it, one-tenth of that in Europe and North America." In Japan, Huntington's disease applies for public health expenditure.

<sup>7</sup> The HGC is an independent government advisory body for genetics.

<sup>8</sup> For details on moratoria in the UK, see the "HM Government and ABI's Concordat and Moratorium on Genetics and Insurance," which is posted on the Association of British Insurers website (<https://www.abi.org.uk/~media/Files/Documents/Publications/Public/2014/Genetics/Concordat%20and%20Moratorium%20on%20Genetics%20and%20Insurance.pdf>).

whereby disclosure is requested for existing genetic testing results, depending on the type and value of the insurance policy as well as the region in question. As yet, Japanese insurers have not once elected to use genetic testing results in underwriting; however, its use is not prohibited by legislation.

### **3. Japan on Genetic Testing**

In recent years, private firms like Yahoo and DeNA have emerged in the genetic analysis services sector in Japan. However, it has been pointed out that the quality of the information presented by these widely utilized genetic testing results only allows a little understanding of one's constitution; information on risks and probabilities without adequate explanations and aftercare services is fueling people's concerns. The quality of genetic tests varies, from a trustable one such as detecting mutations in the BRCA1 and BRCA2 tumor suppressor genes at hospitals to something close to fortune-telling.

American actress Angelina Jolie underwent a double mastectomy in 2013 as a preventive measure based on results from genetic testing at a hospital; it was reported that the procedure greatly reduced her risk of breast cancer from 87% to 5%. It was also reported that she subsequently had her ovaries and fallopian tubes removed. The momentum from this coverage led to increased interest in genetic testing in Japan, and mass media outlets, such as newspapers and television broadcasters, have increasingly raised this subject. The context behind Angelina Jolie's decision to undergo the genetic testing and surgeries was her family's history of cancer<sup>9</sup>.

All illnesses arise from an improper relationship between genetic and environmental factors, including work, diet, lifestyle, smoking, drinking, and others (see Figure 1). The involvement of each of these two types of factors in the onset of a disease may be structured in various ways, but those in which genetic factors play a predominant role are called hereditary (genetic) diseases.

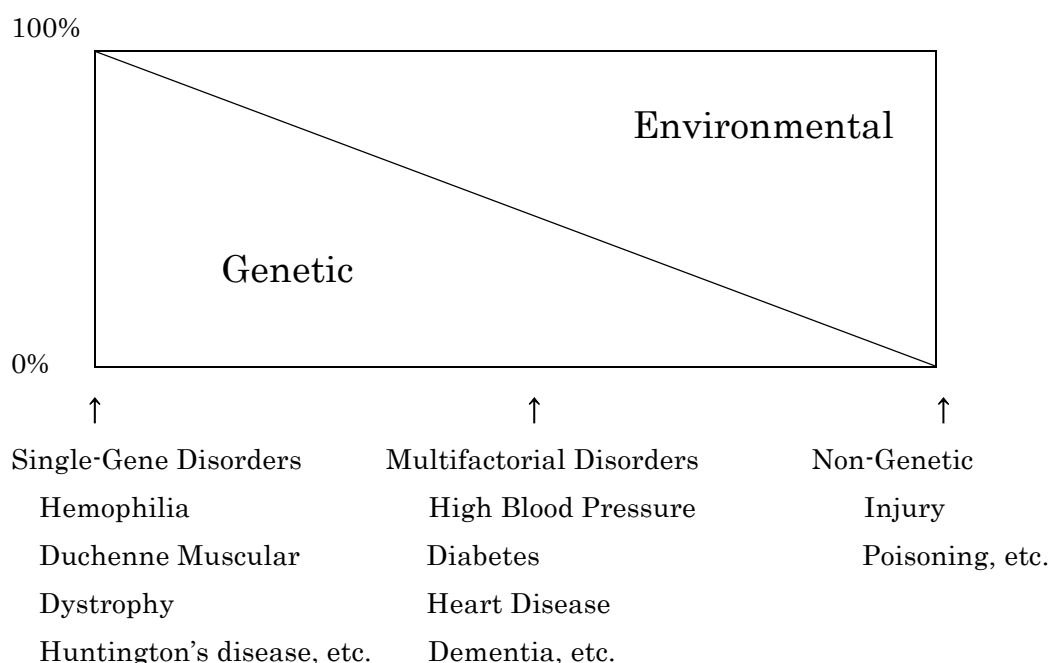
Among them is the single-gene disorder, which is caused by abnormality in a single gene, making the cause-and-effect relationship between gene mutation and disease onset relatively clear. For example, any person with a negative genetic testing result for Huntington's will never suffer from that disease in his or her lifetime. However, the onset of multifactorial disorders is the result of a complex set of effects exerted by multiple genetic and environmental factors. The vast majority of cancer is regarded as

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<sup>9</sup> Her mother and grandmother both passed away from uterine cancer at the young ages of 56 and 45, respectively. After her mastectomy, her aunt then passed away from breast cancer at the age of 61.

multifactorial rather than genetic; however, there are cases where some types of cancer are strongly influenced by genetics. To give an example, people with observed mutations in their tumor-suppressing BRCA1 and BRCA2 genes have an increased risk of developing breast and/or uterine cancer. Angelina Jolie’s circumstances apply here. She underwent genetic testing, found that she had a high risk of contracting these diseases, and conducted a preventive mastectomy operation before the cancer actually occurred. Though we cannot say that this is a conventional choice in Europe and North America as of yet, we can say that it is a more widely known procedure than it is in Japan.

Figure 1 Relationship between genetic and environmental factors



Source: Kagawa, Yasuo and Sasazuki, Takehiko, eds. 2000, "Iwanami Lecture: Foundations of Modern Medicine 9–Genetics and Disease," Iwanami Shoten, p. 123. (Modified by the author.)

Statistics published by the Ministry of Health, Labor, and Welfare for 2005 show that 5–10% of breast and ovarian cancer cases in Japan are hereditary. For these people, a suppressive effect on the chance of cancer can be expected from the appropriate application of preventive surgery and drug prescription. However, the decision to remove a mammary or uterus without any problems before a disease occurs is inferentially not an easy one for the woman herself, her spouse, or other family members. Although advances in breast reconstruction surgery techniques mean less

emotional trauma due to breast loss, changes in hormones and other factors can lead to a marked drop in the quality of life.

When taking account of autosomal recessive genetic diseases, wherein onset occurs only if mutated genes are inherited from both the mother and father (25% probability), we can see from the outset that any individual is a carrier for some diseases. Here, the term “carrier” refers to any person who carries one normal and one mutated gene in his or her homologous DNA pair (one originating from the father, and one from the mother). If the person has not inherited mutated genes from both parents, then the disease will not manifest; therefore, that person would not be aware that he or she is a carrier.

The expansion of genetic testing also brings about the opportunity for people to recognize these previously unknowable risks. Further, the increasing desire of people to control risks related to their bodies will lead to the expansion of processes like prenatal diagnoses or enhancements<sup>10</sup>. This move would get increasingly irreversible from now on.

For people who have no financial restrictions, the issues raised in this paper on insurance underwriting may not hold any serious meaning. However, for the majority of people, it would likely become a major financial issue if approval for insurance subscriptions were to hinge on the results of genetic testing. In addition, there may also be a psychological burden incurred by being unable to obtain insurance. Specifically, in a country such as the United States, where the private share of the medical insurance system is significant, it is conceivable that there is an un-ignorable financial and psychological influence. For that reason, and given the several societal and ethical issues, the use of information gained from genetic testing in hiring, promotion, and subscription to medical insurance is banned by federal law in the United States. However, if genetic testing is to be used commonly, for example in a regular checkup, one can say theoretically that failure to use genetic testing information in underwriting may lead to adverse selection<sup>11</sup>, whose negative influence may be unavoidable<sup>12</sup>.

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<sup>10</sup> “ ‘Enhancement’ is a word originally meaning to ‘make greater, make stronger’. The practice of using medical technology to go beyond ‘treating’ an illness and strengthen human attributes is dubbed ‘enhancement’.” (Tamai, Mariko and Matsuda, Jun, eds. 2013, p. 113)

<sup>11</sup> “Adverse selection” refers to an occurrence wherein one would subscribe to insurance more or increase insurance money when made aware of higher risk of loss. The existence of adverse selection leads to increased benefit claims, and is not desirable for management of an insurance company. However, there are notable perspectives present that higher risks pose insurance’s *raison d’être* and insurance companies’ role in society.

<sup>12</sup> For more on the potential negative influences from not utilizing genetic testing results in underwriting, see this author’s previous publication (Miyachi, Tomoka, 2005, pp. 109–130).

#### 4. Issues in Genetic Testing and Insurance in Underwriting

##### (1) The Changing State of Underwriting

When considering issues on genetic testing and insurance in underwriting, it may be helpful to refer to cases of non-smoker discounts and gender-based rates. In contrast to the common notion that smoking exerts a negative influence on one's health, a non-smoker discount is part of a system often used around the world to classify risk. In Japan, questions about smoking habits are asked in reporting forms since 1994. Smoker tests utilizing urine and saliva have also been in place since 1998. Conversely, race-based rates, which were formerly considered part of appropriate risk classification and adopted in some places, are now considered discriminatory worldwide and are not in use.

In Japan, gender-based rates have been introduced as part of many insurance products; however, some states view this as "discrimination." Based on a decision by the European Court of Justice on March 1, 2011, new policies came into effect in the EU that banned all kinds of insurance, including automotive, life, and pensions, from setting rates based on gender, for the new contracts made on and after December 21, 2012. This change in gender-based rate handling in the EU is a notable case of how a shift in popular opinion and people's value judgments can lead to changes in insurance business practices.

As such, once a legislation is enacted, the insurance industry must react to it; insurance itself has "limits"<sup>13</sup> by which it must handle changes in the societal landscape *ex post facto*. In actuality, the insurance industry and insurance researchers in the EU had already widely discussed the influence that would be exerted by a ban on gender-based rate-setting on insurance company management and policyholders before the legislation became effective. However, in the present day, when the legal ban on gender-based rates is set, insurers will only respond in pre-determined areas provided that the negative influence exerted on society is small enough to be overlooked. This issue would be unlikely, once again, to draw the attention of the average person.

The example cases of non-smoker discounts and gender-based rates vividly show that the state of insurance underwriting is not a fixed quantity, and may change with shifts in the environment (legislation, etc.) and people's value judgments. Similarly, we may posit that how genetic testing is handled in underwriting is also a dynamic situation.

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<sup>13</sup> Maekawa, Yutaka (1982, pp. 1-19) focuses on the "limits" that insurance products and systems naturally have.



## (2) Medical Advances and Their Influence on Underwriting

One of the most notable changes in the environment in recent years is probably the striking technological innovation in bioscience. For example, examination of urine and/or blood alone to detect even small cancers is a technology that is already in clinical use. If surgery or other treatments could be applied while tumors are still small, then it would enable low-stress treatments, like an endoscopy, which could be completed within a single day, with a good prognosis. For those with a higher risk of cancer, conducting these sorts of tests at regular short intervals would yield the benefit of being able to deal with cancer at its extremely early stages. Additionally, there is the perspective that economic burden would be eased for both insurer and consumer if procedures can be conducted in those early stages. However, for those at higher risk, what would be a single claim could be stretched across a number of claims, even if the amount of each claim is smaller in the latter case. It is conceivable that there could be influence over actuarial operations with the increase in those patients undergoing examination.

Genetic testing, the topic of this paper, has one vastly different point of distinction from other medical testing. That point is its ability to predict future risks. Even at present, some genetic tests can fairly accurately predict the risk that some disease may occur at some point in the future. For example, for those who have inherited the gene for Huntington's disease, an intractable neurological disease with onset primarily in the middle-aged and elderly, almost all will contract the disease (excluding those who die from accidents/suicide/other diseases/etc. before onset) and die within an average of ten to twenty years after that. For those who have inherited the Huntington's gene, they will surely contract the disease at some point if they continue living, even if at present they enjoy a sound physical state. However, the age at which the disease will manifest and the progression of its symptoms cannot be predicted. Though a diagnosis method does exist, there is a great ethical dilemma presented by the current lack of basic prevention and treatment methods. The potential for depression and subsequent suicide calls for ample explanation and counseling before testing, but it is sometimes impossible to keep a patient from suicide after delivering the test results.

Underwriting practices in Japan at present applies existing symptoms and medical history in its examinations, estimating future risks based on this data and calculating premiums. Genetic testing is, at present, not applicable to Japan's underwriting practices. However, there are some limited cases in the UK, such as in certain types of insurance and high-value policies as well as for testing for specific illnesses, where genetic testing is being implemented already in underwriting. It can be believed that

the presupposition of insurance underwriting—that being estimating future risk based on policy applicants’ present and past circumstances—is gradually changing.

If the proliferation of genetic testing were to continue, attention would increasingly turn to preventive medicine over time. Consequently, we may forecast an increasing number of people who take more proactive and innovative methods to prevent illness. In addition, the drastic shift in concepts of “health” and “illness” would be indicated as a potential for insurance underwriting to deal with these changes<sup>14</sup>. Change may also be needed in the design of insurance products in response to changes occurring in people’s insurance needs and the configuration (frequency/value) of claims. As such, in light of the fact that medical advances exert a great influence on insurance underwriting practices and that these advances are accelerating in recent years, it is likely that Japanese insurers and other entities will need to prepare more quickly for these environmental changes.

## 5. Conclusion

The functions and roles of insurance have transformed over time in response to various factors, including societal changes such as economic and social security systems as well as technological innovation and shifts in values. Similarly, underwriting’s form has also altered in response to popular opinions and environmental changes. Though there is already demand for the insurance business to respond to the always-present environmental changes in medical technology, social and economic systems, and legislation, etc., caution is probably necessary with respect to the recent incomparably rapid changes in this environment.

Value judgments on fairness in insurance underwriting are not only based on analysis of objective data; there are several heavily weighted subjective elements, including citizen awareness and the degree of social acceptance<sup>15</sup>. For that reason, there is demand for underwriting practices to take note of changes in the societal environment and popular opinion, taking into ample consideration the consumers’ perspective. The various issues in insurance underwriting and genetic testing can be given as observations for how insurers can rapidly and appropriately respond to changes in the societal environment. Therefore, insurers must be more sensitive than ever to citizen

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<sup>14</sup> See Sasaki, Mitsunobu (2013, pp. 31–48) for more on the influence exerted by medical advances on the insurance business.

<sup>15</sup> See this author’s previous publishing (Miyachi, Tomoka, 2011, pp. 41–57) for more on value judgments on fairness in underwriting.

awareness and value judgments; so too with underwriting, they may well have a social responsibility to collect broadly opinions and information from those with many different attributes and contexts for the status of underwriting and the individual issues that face underwriting practices.

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