

## THE USE OF GENETIC INFORMATION IN THE IMPLEMENTATION OF INSURANCE: CURRENT PROBLEMS AND PROSPECTS FOR THEIR SOLUTION

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**Abstract** Increasing the efficiency of risk assessment for the purposes of personal insurance is impossible without using the latest achievements of modern science. This translates into a growing interest in the use of genetic research results by insurers, which manifests itself not only in legislation and insurers' practices, but also in international recommendations on personal medical data processing for insurance purposes. Based on analysis of foreign practices, the authors determine priority areas of respective legislation development, in particular, legislative recognition of a ban on insurers' access to genetic data in the context of obligatory medical insurance and group insurance programs; granting insurers the right to use genetic testing results for the purposes of life insurance, personal accident and sickness insurance, voluntary medical insurance, if the sum insured exceeds a statutory threshold.

### Keywords

personal insurance,  
genetic testing,  
epigenetic changes,  
legislation,  
diagnostic and  
prognostic tests.

## **1 Introduction**

Obtaining reliable data, both on the probability of an insured event occurring and the extent of probable damage likely to result therefrom, is an important component of the relationship between the insurer and the policyholder. For personal insurance, it is key to have information on the health status of the insured person, and ideally, on the probability that the insured will develop conditions that may trigger an insured event occurrence. As a rule, such risks are detected by insurers with the help of a questionnaire completed by the insured that sometimes includes questions about medical conditions experienced by relatives. A medical checkup may be performed, if necessary, although Russian insurers are very reluctant to resort to them as they are viewed as overly intrusive and therefore a possible deterrent to attracting new business, which of course is the opposite of what insurers are hoping for. That is the reason why the use of the results of genetic testing by insurers as an underwriting tool has not gained significant traction in Western Europe, Canada, Australia and the U.S., where lawmakers are forced to seek solutions for related problems.

## **2 Discussion**

An analysis of foreign legislation shows a common trend towards abandoning the use of genetic data in obligatory medical insurance, as the goal is to ensure the universal availability of fundamental health services funded by the state, which actually assumes a significant share in the underwriting risks of each insured. In other cases, namely where persons seek medical insurance from the private sector, it is assumed that the insured can exercise freedom of choice to find an appropriate insurer that will provide the necessary coverage that will best fit that insured person's particular needs, discretion which is practically impossible in the group insurance setting. In the private insurance market, unlike the situation involving state or other group funding, the prospective insurer has more access to personal and background information on the future policyholder, in view of the fact that from a practical standpoint that within the framework of state obligatory medical insurance an insurer does not have to deal with the competitive factors that exist in the private insurance market, which in turn means such obligatory medical insurers typically do have access to genetic testing results and do not enjoy an opportunity to change insurance wording depending on the level of possible risk. However, the highly sensitive and personal nature of genetic research and resulting information makes it

necessary to introduce a set of rules that place limitations on how insurers may use such information.

The starting point of our discussion is the nature of genetic testing itself. Here, there is a need to differentiate between diagnostic and prognostic testing for insurance purposes. The former can be utilized to either confirm or refute a medical diagnosis previously made based on the person's known symptoms and physical manifestations and detected by other medical diagnostic methods, such as, for example, radiographs or routine blood testing. In this setting, the use of data obtained through genetic testing merely produces more specific data than what had already been available to the insurer. Therefore, the trend is to allow the insurer to request genetic testing data, in conjunction with more traditional medical documentation, to either confirm or refute a previously made diagnosis.

By contrast, prognostic genetic testing is aimed at detecting the risk of development of a specific condition that has either not come into existence or is latent. However, the reliability of prognostic testing is frequently questioned, as the human genome contains about 25,000 genes, and they only amount to about two percent of the total DNA sequence. The function of the remaining 98 percent of the genes that are not encoded is not fully known. That being said, the main DNA reading tool is ribonucleic acid (RNA). The sequence of DNA nucleotides is initially transcribed into mRNA (messenger RNA) and then into a protein amino acid sequence. However, most RNA molecules are not used as a code for protein sequencing but rather perform other functions in various cellular processes that play an important role in gene development, metabolism and regulation, as well as in the development of medical conditions.

It has been established that genome activity is defined by epigenetic changes that influence gene information readings without changing the actual DNA sequence. These changes begin during embryo development and are conveyed to daughter cells at every fission. Some modifications may be very stable so they would influence gene activity throughout their lifespan and even impact subsequent generations. Other epigenomic models may change under the influence of external variables, including nutritional and environmental factors and even mental stress. Therefore, the value of genetic research results in cases such as this that are impacted by a host of external factors may decrease significantly, and they may potentially impinge upon a

policyholder's rights because the insurer is basing underwriting decisions on groundless (or at least highly speculative and questionable) assumptions about an increase in the probability of a future insured event.

Genetic and epigenetic processes functioning in the organism consist of a complex network of interactions resulting in a multitude of possible conditions, some of which are perceived by the individual or his environment as a deviation from the "norm," a disorder, or a medical condition. In some cases, a genotype is the only ("monogenic") cause of an altered phenotype (e.g. a defect in the beta-globin gene that causes beta-thalassemia), while in other cases there is a plurality of causes for this, some of which are not always known. Therefore, the risk of a medical condition actually developing and leading to an actual genetic breakdown may never materialize. For this reason, in particular, specialists do not recommend making forecasts with respect to Alzheimer's disease (DeutscherEthikrat, 2013: 20-21). Therefore, it is necessary to realize that a person's susceptibility to actually developing a specific condition as a result of a genetic mutation is not synonymous with merely having an abnormal genetic condition. This, in turn, means that the actual potential for the legitimate use of prognostic testing results is very limited and dependent on the stage of scientific development. A consequence of these scientific limitations is that the insurance industry, in practice, has taken a very conservative approach in using such information. For instance, the Recommendation CM/Rec(2016)8 of the EU Committee of Ministers to the member States "On the Processing of Personal Health-Related Data for Insurance Purposes, Including Data Resulting from Genetic Tests" goes so far as to ban insurers from making any underwriting decisions, such as concluding an insurance contract or amendments thereto, based on the results of a prognostic genetic test. As to existing data that are primarily generated as a result of either perinatal diagnostics or genetic screening of newborn babies, developers of the Recommendation set forth a general ban on their use, but reserved an opportunity to have exceptions from this rule introduced by law. Typically, these exclusions are allowed in cases involving personal insurance for significant sums, though these sums are defined differently depending on the personal insurance line in question (e.g. savings life insurance, voluntary medical insurance, endowment life insurance). It is stipulated, however, that the processing of such data should only be allowed after an independent assessment is made regarding compliance with the conditions for the collection of personal data and the processing with respect to the type of testing in question and with due regard to the

insurable risk at issue. Ethical aspects of the matter in question are also dealt with from time to time.

It is obvious that the results of scientific research broaden earlier notions of the content of genetic data, which now includes not only data on hereditary conditions reflected in the genotype and transmitted from natural parents to their offspring, but also data on the epigenetic profile that is hereditary only in the sense that it is transmitted to daughter cells through fission. Accordingly, when it comes to insurance, discussions should address acquisition not only pertaining to data pertinent to hereditary conditions, but also data pertaining to genetic mutations capable of provoking the development of diseases that are atypical for family history. However, this undercuts the position of those who advocate free access to genetic data, and who advocate in favor of considering such data because it is a more advanced means of analyzing the policyholder's family history beyond less helpful and informational medical examinations.

In general, there are several distinctive approaches to using genetic data in the insurance setting. Therefore, in order to promote sound public policy in this important arena, both legislators and the insurance community must take careful notice of these developments and the possible options they provide. One possible approach is to legislatively ban the use of any genetic testing results in making underwriting decisions. This ban currently is selective in most of the countries and typically applies in situations that involve health and social insurance, as these are the areas where the state, in light of its inherent responsibility to promote social functions, considers such a ban necessary in order to guarantee all of its citizens basic levels of insurance coverage. At the same time, law makers have sometimes introduced total bans on the collection of genetic data on both already insured persons and/or persons newly applying for insurance coverage; and/or on requesting that they share tissue samples or DNA descriptions; and/or upon introducing distinct insurance conditions (such as preferential premium rates, etc.) for persons with various genetic risks (Austria, Norway, Estonia) (Human Genes Research Act, 2000: 27). However, this practice appears to have limited prospects, as the probable future improvements in genetic testing methodologies eventually will bring about qualitative improvements in their reliability. This improved reliability, which will make the testing results less open to debate, will eventually undermine the positions taken by the opponents of genetic testing. For the same

reason, the grounds for banning the use of genetic (primarily prognostic) testing results by insurers may disappear over time (e.g. France).

For this reason, the efforts to regulate both the conditions and the procedures pertaining to the actual use of genetic data results on the basis of either self-regulation (assuming that the insurance market functions relatively autonomously), or agreements between the government (which protect the interests of the policyholders in this case) and professional insurer associations (Australia, Great Britain) seems the more viable option. Another way to help foster this approach is to set a threshold for the sum the policyholder is insured for, so that genetic testing results are not taken into account if the sum insured is below that threshold (Switzerland, Sweden, the Netherlands). This threshold may be set on the legislative level, or it may be introduced by a professional insurer association.

In general, underwriting decisions that are based on the results of genetic testing are relatively rare. Global data collected by MunichRe shows that insurance companies are not as interested in the results of genetic testing as is sometimes portrayed by the media. In most of the cases, what is meant here is the desire on the part of the insurance industry to limit losses resulting from asymmetric data distribution between the applicant and the insurer. In Russia, for example, insurers frequently refrain from requesting medical checkups and limit themselves to the use of questionnaires.

At the same time, it has to be recognized that the general public has very legitimate concerns regarding insurance companies having greater access to genetic data. An opinion that a positive (i.e. unfavorable from the standpoint of the insured person or the person applying to be insured) genetic test may well in some cases equate with the insurer's decision to refuse to conclude a life insurance contract is not groundless, even though the results obtained are very often overestimated. This is the case because, from a risk assessment standpoint, genetic tests can only be interpreted probabilistically and consequently, a possible or even highly possible abnormal medical condition forecasted through the results of genetic testing cannot be viewed as an inevitable event that should automatically lead to an underwriter's decision to deny that person the conclusion of an insurance contract. In addition, with genetic data increasingly becoming more detailed and scientifically reliable, it is clear that every individual carries at least dozens of mutations that imply at least

potential risks of developing deviation in genes in the future. As a consequence, giving complete deference to the value of the insurer's awareness of an insured person's genetic dispositions will inevitably result in the loss of the personal insurance market, as the policyholder who is unable to obtain full-scale coverage for future potential medical conditions is bound to lose interest in insurance products being offered.

Moreover, to be so shortsighted would mean to totally disregard an extremely vast potential of genetics and genetic technologies such as pharmacogenetics, gene therapy, tissue engineering and preventive medicine, which may result in the expansion of (rather than the shrinking of) insurance opportunities.

In Russia, genetic testing and the use of its results for insurance purposes is largely overlooked by all insurance market players. Consequently, presently in Russia the insurance industry is not adequately regulated. As it pertains to genetic testing, and use of such data by insurance companies, we argue that Russia must address several aspects of genetic testing, ranging from general theoretical issues, connected to defining the level of legal regulation, to purely practical issues, which are driven by the need to set ground rules both for genetic research itself as well as the need to appropriately regulate the use of results obtained as a result of the testing. In establishing any such regulations, we are mindful that care must be taken to ameliorate the well-founded, reasonable concerns not only that genetic testing may be used as a prerequisite to conclude contracts of insurance, but also that the results of such testing might be used as total pretext for proposing an insured of unfavorable insurance terms and conditions where the test results uncover concerning information.

It is undisputable that the protection of policyholders' interests is possible on the basis of current legislation, taking into account that the Russian Constitution, incorporating international standards pertaining to the protection of human rights, introduces fundamental approaches to resolution of issues emerging in this field. In particular, priority is given to equality, nondiscrimination and non-interference with privacy and family matters. Moreover, these approaches assign priority to federal legislation in the legal regulation of these relations. However, this protection can hardly be called effective, as it will be based on interpretations of varying points of law. Meanwhile, foreign practices demonstrate that lawmakers have sought to enact

legal regulations that govern the grounds and procedures for the actual use of the results of genetic data by insurance companies as detailed as possible but with due regard to future developments and achievements in science, which means, among other things, foreign legislatures have also strived to review earlier legislation and to make amendments where necessary to keep abreast of such scientific advancements and otherwise.

In Russia, even though the field of genetics has developed rapidly and intensively, lawmakers unfortunately have taken a somewhat one-dimensional approach to issues arising in this field. In particular, they have tended to focus either on the individual and environmental safety aspects of the application of gene engineering for the production of genetically modified organisms and use of obtained results (Federal Law "On State Regulation in Gene Engineering," 1996), or instead on the personal identification (Federal Law "On State Genomic Registration in the Russian Federation," 2008). As a result of this either/or approach to legislating in this field, the provisions of comparable laws from related fields cannot effectively be used even by analogy. Turning to medical law provisions does not help either, as Federal Law No. 323-FZ dd. November 21, 2011 "On Public Healthcare Basics on the Russian Federation" does not regulate genetic research, instead expressly referencing only selected cases from a different medical field unrelated to the implementation of individual insurance. Correspondingly, the key issue of the potential recognition of genetic research as a component to the standard medical checkup remains unresolved, even though the results of such research may well influence the mode of access to respective information and payment for related expenses.

Of significance from the point of view of the relations emerging through implementation of personal insurance is Article 13 of the above-mentioned law, which reads that "health and diagnosis data obtained in the course of medical checkup and treatment shall constitute privileged medical information". Provisions of this article are further developed in legislation on personal data protection (Federal Law "On Personal Data," 2006).

It is no less problematic to apply civil legislation that only provides a legislative framework for general approaches to providing data relevant for the assessment of the probability of an insured event. Clause 2 of Article 945 of the RF Civil Code reads that "the subject of assessment shall be the actual health status of the insured

person", and by virtue thereof, we can drive to a conclusion that potential risks of pathological condition development are not subject to assessment and shall not influence the possibility of contract conclusion or adjustment of contract conditions.

In the absence of any specific legislation controlling the use of genetic data in the insurance industry, Russian insurers have attempted to protect their property interests through the use of available legal instruments, which include introduction into their policies of exclusions from the list of insured events or insurable persons (on the grounds of congenital anomalies or defects, hereditary and genetic conditions), as well as requesting data on selected information with the use of questionnaires pertaining to either conditions among relatives or on prior medical treatment. As a result, the insurance rules in the Russian insurance industry as they presently exist do not include a requirement for a potential or existing insured to undergo genetic testing. Furthermore, currently there are no special provisions regarding maintaining confidentiality of the results of any such testing.

### **3 Results and Takeaways**

In general, there is a worldwide tendency towards cautious recognition of insurers' rights to gain access to relevant medical information. This recognition has manifested itself both in legislation and in agreements between governments and professional insurer associations. The assessment of the opportunity to gain access to genetic data in the implementation of personal insurance varies depending on the type of insurance in question, such as whether it is group or individual, obligatory medical insurance or voluntary insurance. A fundamental unresolved matter pertains to the conditions, procedures and limits of exercising this right. Based on an analysis of foreign practices, it is possible to speak about priority trends in the development of legislation in this area.

First, there is a need for legislative recognition of a ban on insurers' access to genetic data in the implementation of obligatory medical insurance that is funded by the government, as well as in the implementation of group insurance programs, including credit life insurance. In the former case, this is justified because the government performs social functions and participates in risk distribution. In the latter cases, this is possible not only because of the participation of a large number of policyholders in insurance fund generation but also because of the necessity to

protect the interests of insured persons who effectively have no influence on the development of contract conditions.

Second, it seems possible to grant insurers the right to use genetic testing results in the implementation of life insurance, if the sum insured exceeds a statutory threshold, which the insurer will use as guaranteed protection of its property interests.

At the same time, it is critical to:

- establish different legal rules for the use of diagnostic and prognostic testing, limiting the latter with due regard to their reliability achievable in specific conditions, bearing in mind that such reliability is currently guaranteed mostly for monogenetic conditions;
- determine a source of funding for genetic research that could be included in the obligatory medical insurance program, taking into account the importance of such testing for taking timely efforts to limit the negative impact of various factors on development of medical conditions;
- provide for the means by which insured persons can avail themselves of insurance rate adjustments depending on the measures the insured person might take in the field of health support; and
- resolve ethical matters related to acquiring such information.

All of the above requires further theoretical analysis, in particular, from an underwriting standpoint.

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### **Legislation and legal documents**

Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine: 04.-4.1997. № 164/, retrieved from:<https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164> (27. 6. 2019).

- Federal law of the Russian Federation dated December 3, 2008 No. 242-ФЗ "On state genomic registration in the Russian Federation" // Collection of legislation of the Russian Federation.2008. № 49. P. 5740.
- Federal law of the Russian Federation of July 27, 2006 No. 152-ФЗ "On personal data" // Collection of legislation of the Russian Federation.2006. № 31. (Ч. 1). P. 3451.
- Federal Law of the Russian Federation of July 5, 1996 No. 86-FZ "On State Regulation in the Field of Genetic Engineering" // Collection of legislation of the Russian Federation. 1996. № 28. P. 3348.
- Federal law of the Russian Federation of November 21, 2011 No. 323-ФЗ "On the basics of protecting the health of citizens in the Russian Federation" // Collection of legislation of the Russian Federation. 2011. № 48. P. 6724.
- Human Genes Research Act: 13.12.2000 № 285, retrieved from: <https://www.riigiteataja.ee/en/eli/531102013003> (27. 6. 2019).
- Recommendation CM/Rec(2016)8 of the EU Committee of Ministers to the member States "On the Processing of Personal Health-Related Data for Insurance Purposes, Including Data Resulting from Genetic Tests" // Bulletin of the European Court of Human Rights. Russian Edition. 2017. No. 6. P. 133–144.
- The Constitution of the Russian Federation: Adopted at National Voting on December 12, 1993, retrieved from: <http://www.constitution.ru/en/10003000-01.htm> (27. 6. 2019).

## References

- Nikiforov, V. V. et al. (2019) Practical Importance of Genetic Research Results when Developing an Insurance Product for Personal Insurance: International Experience, *International Journal of Recent Technology and Engineering*, 8(2), retrieved from <https://www.ijrte.org/wp-content/uploads/papers/v8i2/B3098078219.pdf> (1. 4. 2020).
- Deutscher Ethikrat, Hrsg. (2013) *Die Zukunft der genetischen Diagnostik – von der Forschung in die klinische Anwendung* (Berlin: DeutscherEthikrat), pp. 20–21, retrieved from <https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/deutsch/stellungnahme-zukunft-der-genetischen-diagnostik.pdf> (1. 4. 2020).

