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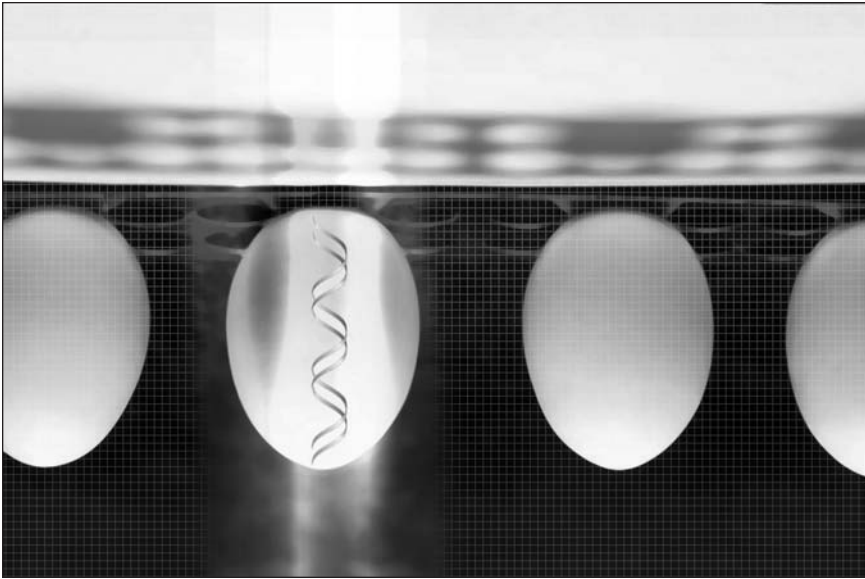
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# Genetics, Genetic Testing and Underwriting

by Thomas Ashley, M.D.



*Editor's note: This article is reprinted with permission from Insurance Issues, a publication of Gen Re LifeHealth.*

A paper published recently in *Health Affairs*, coauthored by Robert Pokorski, MD, vice president of Worldwide Research and Development for Gen Re LifeHealth, examined the consumer behavior of people who have a family history of Alzheimer's disease (AD) and tested positive for a gene linked to AD, called APOE4.<sup>1</sup> Participants in this study increased their purchase of LTC insurance, and did not change their life or DI coverage.

Anti-selection of this sort is a serious concern for insurers. While this research revealed an impact only on LTC insurance, we believe all lines will eventually be affected by genetic testing and the resulting anti-selection it can generate. Because of this, Gen Re LifeHealth wants to help our clients stay informed on this topic.

Genetics is an ever more significant aspect of medicine, and frequently the object of political regulation of life and health insurance underwriting. This report reviews important aspects of biology, summarizes the current regulatory status and concludes with Gen Re LifeHealth's opinion regarding underwriting practices.

## Definitions

### *Predictive*

The APOE4 study illustrates the predictive category of genetic information. The test subject has no clinical manifestations of the related disease, in this case AD. A positive test result confers increased risk that disease will develop at some time in the future. Another genetic test in this category is BRCA. Nongenetic information can also be predictive, such as cholesterol, BMI and blood pressure. These examples point out the difficult distinction between a disease and a risk of a disease. Is high cholesterol a disease, or is it a risk for the disease of CAD? Is BRCA1 a disease, or a risk for breast cancer?

### *Diagnostic*

When a test is used to identify the cause or confirm the presence of a disease that shows clinical signs or symptoms, it is a diagnostic test. The same test can be either predictive or diagnostic. At present, the sole licensed use of the APOE4 test is to confirm AD as the cause in a patient with dementia, which is a diagnostic use. The *Health Affairs* paper describes a predictive use of the test for APOE4.

<sup>1</sup> "Genetic Testing For Alzheimer's Disease And Its Impact On Insurance Purchasing Behavior" Zick et al. *Health Affairs* 2005; 24: 483-490 (<http://content.healthaffairs.org/cgi/content/abstract/24/2/483>).

### *Exceptionalism*

This represents a claim that some part of a greater whole is different from the rest, and special. For example, a recurring idea in American history is a form of exceptionalism: that America is different from all other countries and has a special role to play in the world. Genetic exceptionalism holds that genetic information is different from other medical information. It requires special consideration, including privileged treatment of genetic records. A growing scientific consensus maintains that it is neither appropriate nor feasible to segregate genetic information from other biological or medical knowledge. It is widely expected that genetics will become the core of medical knowledge and practice, so any distinction is meaningless and exceptionalism is untenable.

### **Politics and the Law**

Application of genetic information in underwriting is often misunderstood. Referrals to our medical department have expressed both a reluctance to act on genetic information for fear of litigation and a conviction that laws prohibit such action. The former is unrealistic, and the latter is plain false.

ACLI and its Risk Classification Issues Committee are deeply involved in the politics of genetics and insurance regulation. Over the past 10 years, nearly every state has enacted regulation of the use of genetic information. In every case, ACLI has lobbied successfully to protect the most important principle of underwriting, our freedom to consider anything that relates to mortality risk and is known by the applicant.

Most states have outlawed discrimination in employment and health insurance based on predictive genetic information. Once disease is detectable, genetic information is either permitted (diagnostic use), or it becomes unnecessary in the assessment of the disease status. A few states have extended the same prohibition on predictive genetic information to DI or LTC, or both. Every statute that regulates the use of genetic information exempts life insurance, provided that the underwriting action adheres to sound actuarial principles and reflects actual or reasonably anticipated

experience. That qualification applies to every underwriting action, so it does not add any burden.

Two states have regulated use of genetic data in life insurance—Vermont and Massachusetts. Both prohibit the insurance company from requiring or initiating a genetic test as a condition for insurance. The restriction is inconsequential, as this would be a poor underwriting strategy. If, however, genetic testing became commonplace and outside the medical record (such as mail-order screening), potential anti-selection would motivate insurance testing. Both states provide for reconsideration of the restrictions should a test become widely used in clinical medicine.

With 50 state legislatures and Congress constantly at work, the picture is complicated and can change frequently. To keep up, here are two resources.

### **National Human Genome Research Institute**

(Policy and Legislation Database)

<http://www.genome.gov/PolicyEthics/LegDatabase/pubsearch.cfm>

“This database contains Federal and State laws/statutes; Federal legislative materials; and Federal administrative and executive materials, including regulations, institutional policies, and executive orders. The database currently focuses on the following subject areas: privacy of genetic information/confidentiality; informed consent; insurance and employment discrimination; genetic testing and counseling; and commercialization and patenting.” The database supports searches by jurisdiction, by type of regulatory action (law/statute, administrative) and by topic. It appears to contain the most comprehensive and current information.

### **American Council of Life Insurers**

The ACLI has written a survey entitled “Life Insurance Law Survey: Underwriting Limitations Based on Genetic Tests and Information” which includes a listing, by state, of laws and regulations relating to

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underwriting and genetic testing. Members of the ACLI can find the survey at <http://www.acli.com/ACLI/Compliance/Law%20Surveys/LS05-LILS06>, or by typing the phrase “Underwriting Limitations Based on Genetic Tests” into the advanced search feature on the ACLI Web site.

## Conclusion

To summarize the state of underwriting, we can consider these four questions:

- Can we ask?
- Can we act?
- Will we act?
- What can we do to manage the risk of anti-selection?

Clearly, in life insurance we can ask about genetic information and we can act on genetic information, no matter how we define it, in all U.S. jurisdictions. The next question is “Will we act?” Yes, and in certain circumstances we have acted. Much genetic information is diagnostic, or else never exists without clinical disease. Examples are sickle cell anemia and cystic fibrosis.

Predictive genetic information is important to risk assessment for BRCA, APKD and Huntington’s disease. APOE4 mortality risk is smaller and more delayed, but is relevant in some cases.

Dr. Pokorski’s article demonstrates that family history and genetic test results change behavior regarding the purchase of LTC. While the impact on life insurance is smaller, the industry can act to mitigate the risk.

One thing we can address immediately is the way we inquire about family history. A typical family history question states, “Is there any history of death before age 60 from heart disease, stroke or cancer among your parents, siblings or children?” A few companies add hereditary disease to the list, or ask for age at diagnosis of disease instead of death. To counteract adverse selection related to APOE4, it is necessary to ask specifically about Alzheimer’s disease. The question should refer to diagnosis rather than death, and should not limit the age of occurrence. Inherited risk does not terminate

at any age, for Alzheimer’s or other conditions. Positive answers require a follow up question to ascertain the age at the time of each diagnosis.

When APOE4 or other tests become common, we will also need to ask about them separately. Our preference is to ask about each test, rather than about “genetic tests” as a category. Regulations vary wildly on the definition of genetic tests. All of the definitions are complicated. A dishonest applicant could successfully defend an omission. If we ask about specific tests that concern us, claims administration will be much more effective.

Framing the questions around specific diseases or tests makes regulatory filing more difficult. Each new concern requires rewording and refileing. While the time has arrived to revise the family history information, APOE4 is still rare and can wait. Perhaps there will be other tests to mention by then, such as BRCA.

The science is evolving, and the level of risk depends on the context, so Gen Re LifeHealth has not issued formal guidelines in SOURCE—Life, or any of our other underwriting manuals, on all genetic conditions. Please refer facultatively any concerns about genetic information underwriting. That will help us develop our knowledge, and improve underwriting decisions for all of us. □



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