

## OPINION SECTION

### Proposal: A Position for the Insurance Industry on Genetic Testing

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**Abstract:** Proposed legislation to limit the use of genetic test results in insurance underwriting has appeared with increasing frequency at the state and federal level. The proponents seek to protect consumers from unfair discrimination by insurers. Can we not develop a proactive approach, acknowledging that we do not need to do prospective testing while we assert that we must retain the current status of equivalency of information between the underwriter and the applicant?

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In state houses across America, in the past five years, over 70 bills have been presented that seek to limit the use of genetic tests or genetic information by insurers, employers and others. These bills are premature, anticipating widespread abuses of this new technology before it has even begun to impact on routine clinical investigation and care. With the exception of newborn screening and preconception screening, no genetic tests are widely available and no insurer is currently planning to establish prospective screening using molecular techniques.

Unfortunately, in their efforts to protect their constituents from assumed discrimination, legislators have sought strict limitations on the use of as yet unknown tests and in so doing have threatened the current practices of insurance underwriting. The problems begin with definitions of genetic testing and then lead on to prohibition of the use of genetic information that is known to the applicant. Our industry has replied with an aggressive lobbying cam-

paign to limit these threats but it is doing so after the draft legislation has been presented for public scrutiny. The legislation, because it is designed to protect consumers is usually supported across party lines. Few legislators seem to have recognized the potential impact it could have on the way we do business. It is time we took a proactive position stating when and how we will use genetic technology.

On the definition side, the legislation describes genetic tests in broad terms that would typically include any metabolite (e.g. cholesterol) or protein (e.g. transaminase) that is measured in body fluids or tissues. Some definitions include genetic information and would thus cover the simple questions on family history found on most application forms.

Because virtually all disease has a genetic component in its etiology, limitations on genetic information could be construed to prevent inquiry into past or current health status. Much of the proposed legislation would elim-

inate underwriting as we know it today.

Definitions of "genetic tests" vary with each iteration but most include all genes, human or microbiological, all gene products including all proteins, even if their alteration is a secondary effect (e.g. elevated GGT resulting from use of prescribed pharmaceuticals) and all metabolites (e.g. blood glucose in diabetes). To protect underwriting practice from limitations like these, the American Council of Life Insurance has waged an active lobbying campaign, attempting to narrow definitions to tests involving DNA and chromosome analysis.

Their efforts have been successful in most states. Legislators have modified their definitions but both lobbyists and legislators have been working in an unreal world. Geneticists have been sitting on the sidelines wondering if either of these groups understands what they are discussing. They consider most of the narrowing of definitions is hyperbole and note that screening tests for hyperphenylalaninemia (a metabolite) or hemoglobinopathies (proteins) have been performed for decades and these have always been considered "genetic tests". Many prenatal diagnoses of genetic diseases are made by measuring enzyme activity in chorionic villus samples or in cultured amniocytes. DNA and karyotyping are not the only genetic tests. It is the old "all horses are animals, but all animals are not horses" argument. I think it is time we acknowledged how inappropriate it is to argue for the narrow definition and to look to reality.

The Task Force on Genetic Testing, sponsored by the ELSI Working Group of the National Human Genome Project has recently released its final report (Holtzman NA and Watson M. 1997). The membership of the Task Force included many geneticists as well as lawyers, bioethicists, public policy specialists and representatives from various regulatory agencies of the federal government (FDA, HCFA, CDC,

etc.). They developed a definition of genetic testing which was subsequently reviewed by dozens of interested parties but in particular, it was approved by the American Society for Human Genetics, the American College of Medical Geneticists and the American Society of Genetic Counselors — the practicing professional geneticists in the country. The definition states that a genetic test is:

"The analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect heritable disease-related genotypes, mutations, phenotypes or karyotypes for clinical purposes. Such purposes include predicting risk of disease, identifying carriers and establishing prenatal and clinical diagnosis or prognosis. Prenatal, newborn and carrier screening, as well as testing in high risk families, are included.

Tests for metabolites are covered only when they are undertaken with a high probability that an excess or deficiency of the metabolite indicates the presence of heritable mutations in single genes.

Tests conducted purely for research are excluded from the definition, as are tests for somatic (as opposed to heritable) mutations, and testing for forensic purposes."

This definition is admirable because it truly defines a genetic test, it is limited to human test materials and to diseases which are inherited and, from the insurer's point of view, it excludes those screening tests that we currently carry out on our applicants. Furthermore it is a definition that is acceptable to practicing geneticists and thus does not bring our lobbyists into conflict on a point where they are arguing a position that has no factual basis — that genetic tests really only involve DNA testing.

The ELSI Task Force report clearly adopts a position to limit the use of genetic tests until they have been proven of value in the fields described in their definition. Insurers would be using the results for "predicting the risk of disease" and provided the information obtained was used to discriminate in a fair manner, the Task Force was not opposed to genetic testing by insurers.

Fair discrimination in underwriting requires actuarial support, which will not be available for these tests for decades or it requires adherence to "reasonably anticipated clinical experience." Until thousands of tests have been performed on a wide variety of test subjects, it is not possible to predict the outcome for an individual with most of the presently known genetic mutations. It is unfair, however, to deny insurers access to the results of tests that have been done in the past, if the applicant has been informed of the results. The principle of equality of information must remain in a private insurance market.

I believe that insurers should adopt the following positions:

1. Support the use of the ELSI Task Force definition in legislation.
2. Insist on access to the results of all genetic tests that have been conducted by others prior to the application.
3. Perform no prospective genetic screening tests on applicants until such time as each specific test becomes standard of care in clinical practice.

These positions leave insurers with the same information we have today. Genetic diseases are not a new human plague, like HIV was a dozen years ago. We have priced our products knowing that some people will become ill or die early and, to protect our companies, what we need is equality of information with our applicants.

#### Reference

1. Holtzman NA, Watson M, Eds (1997) Promoting safe and effective genetic testing in the United States. Final report of the ELSI Task Force on Genetic Testing.