



CONNECTIONS

News from the Underwriting Department
of Munich American Reassurance Company



A message from the chief underwriter

From time to time, we experience technological changes that are so significant that they are difficult to understand or put in perspective.

In-home genetic testing is surely one of those changes. Not too many years ago, the thought of any genetic testing, let alone a simple and inexpensive test that can be done at home, was the stuff of science fiction. Well, science fiction is now science fact.

What are these new tests? How do they work? What do they tell the consumer? And, what significance do these tests have for the insurance industry?

The following article examines the new tests and their potential impact on underwriting for all types of life and living benefits insurance products.

I hope you find it to be informative and helpful.

Bill Moore



In the headlines: in-home genetic testing

Mark E. Skillan, MD
VP & Medical Director

The announcement this week that Walgreens was preparing to offer customers an in-home genetic test kit created quite a stir in both the medical and business communities. It was also revealed that CVS planned to offer the same test kit by the end of the summer.

The FDA, which had not been asked to approve the distribution of this test kit to consumers, promptly declared that FDA approval was required because the FDA is responsible for

review of medical and clinical materials sold to consumers. The test kit manufacturer maintains that its product is for “research and educational” use only rather than for “medical or clinical” use.

Walgreens and CVS have both announced a delay in the offering of this test kit until the jurisdictional and any potential legal matters can be resolved.

The test kit in question is known as “Insight” and is manufactured by Pathway Genomics, a San Diego, California biotech firm.

Direct to consumer genetic testing

Direct to consumer (DTC) genetic testing, primarily via internet offerings, has been around for well over two years. Consumer genomics pioneers, 23andMe and deCODEme, were the first to offer such testing, with Insight’s developer, Pathway Genomics, following suit in mid-2009. Navigenics is another player in this arena. Of note, deCODE Genetics, parent company of deCODEme, filed for bankruptcy protection in November 2009 suggesting that the DTC market at that juncture may have

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been less robust than was initially anticipated.

Pathway's decision to market its test kit to the general public through major pharmacy chains brought on the likely inevitable attention of the FDA and raised the interest of other stakeholders including geneticists, genetics counselors and consumer watchdogs. Pathway's marketing literature asserts that their testing is the least expensive "full genome" consumer genomics test kit currently on the market.

What it costs

Early reports indicate that Insight buyers will pay the retailer about \$30.00 to purchase the test kit and then pay Pathway to receive one of three DNA report types: (1) the "Ancestry Report," which traces maternal and paternal lineages (providing one's genetic genealogy), for \$249.00, (2) the "Health Report," which reports presence or absence of markers for



over 70 health conditions or diseases with a known genetic component for \$399.00 or (3) a "Combo Package" of both reports for \$449.00. And since this is America, internet coupons for reduced pricing on these already exist. Gift certificates for testing are available as well.

What you get

The typical test kit consists of instructions for collecting a saliva specimen, a preservative/activator additive for the specimen, a specimen container, labeling and a pre-addressed and prepaid overnight mailer.

Once the specimen is received and processed in Pathway's CLIA-approved lab, a formal report is generated and provided to the consumer via a password protected secure website.

For an additional fee, the consumer's specimen may be stored for re-testing if genetic information or treatment advances for select conditions occur over pre-determined intervals.

For an additional fee, counselors are also available to discuss results with the consumer.

DTC genetic testing is marketed primarily for adults. A more limited spectrum of tests and a report are available to parents for their children who, at age 18, can subsequently request the full spectrum of testing be performed.

What you really get

Not having seen an actual consumer genotype report, one presumes that, based on today's technology, it is likely that the "Health Report" option provides a report of any of over 70 disorders for which the individual may have a predisposition—based on the presence of a genetic marker known to be associated with that disorder.

In addition, the Health Report reportedly documents the presence or absence of a single gene ("carrier status") for any of 37 or so disorders which may be of interest in pre-pregnancy planning in families with

certain known heritable disorders.

Also provided is a list of any of up to nine medications which might adversely affect, or be ineffective in, that individual based on genetic factors.

Limitations of in-home genetic testing

One should keep in mind a few things regarding the genetic testing currently being offered direct to consumers: (1) The test being offered targets select disorders and is not the equivalent of mapping one's entire genome, which would cost many thousands of dollars and require a team of scientists to decipher, (2) few diseases in man are mono-genic, i.e., involve an abnormality of a single gene. Those which are monogenic are relatively uncommon diseases, (3) most disorders in man are polygenic, i.e., involve an interplay between a number of genetic factors (e.g., CAD, etc), (4) most common disorders are likely also highly influenced by environmental factors (e.g., smoking and CAD) and (5) the degree of expression of a genetic disorder can vary significantly from person to person, i.e., one person with a disorder may express the abnormality with major symptoms or signs and, possibly, early mortality, while another may not fully express the abnormality and may remain asymptomatic or minimally affected and live a relatively normal lifespan.

Although there are exceptions, at this juncture, a genotype report may provide little more information of underwriting value for the most important causes of early mortality than do the personal medical history, family history, social history, routine insurance lab work and an attending physician's statement. As an example,



there currently is no established lab test of any kind to diagnose Alzheimer's disease. The fact that an individual discovers from a genetic test that they may have a predisposition to develop late onset Alzheimer's may similarly be indicated by a family history of older relatives with that diagnosis.

Concerns

Any testing methodology which provides a proposed insured with potentially significant medical information that is not being disclosed to the insurer puts the insurer at risk for under-pricing the risk and incurring larger-than-actuarially-anticipated losses.

Though the limitations noted above suggest that in-home genetic testing may not significantly adversely affect fully underwritten cases in its current form, this may not be the case for simplified issue products. In addition, advances in science and/or testing methodologies will no doubt improve the predictive value of DTC genetic

testing. For instance, algorithms will be developed (if they are not already developed) whereby the odds of developing a particular disorder become more precise rather than primarily speculative.

Family history is an aspect of underwriting that, with recent privacy rules, etc., has become a topic of regulatory interest in some jurisdictions. Some carriers, in fact, have eliminated family history questions from their applications. Loss of this underwriting tool could be catastrophic if coupled with the advent of effective and affordable home genetic testing, particularly since insurers are currently proscribed from asking if genetic testing has been performed or requesting that genetic testing be performed.

For these and other reasons we are very concerned over the potential implications of this developing issue.

On the horizon

With the FDA's entry into the matter, we anticipate a period of time—perhaps a number of months—for the matter to be vetted before home genetic testing becomes more widely available. The current media hoopla may, however, spur some increased interest in the internet offerings of such testing in the meantime.

It seems logical that the FDA will establish jurisdiction over the regulation of the marketing of these home test kits. It remains uncertain how things will play out at this point. It is likely that more will be heard from the scientific community as well as from consumer groups on both sides of the equation.

Interestingly, in Germany and likely the EU, "diagnostic" or "predictive" genetic tests must be ordered and interpreted by medical doctors and results disclosed to the individual by the ordering doctor, which would seem to limit DTC marketing of such kits there. It is possible that the FDA or others will consider this a reasonable precedent and look to limit such widespread availability. Absent such action, our industry may be faced with a real challenge in risk selection going forward.

We expect that the ACLI Risk Classification Committee will take up this issue and represent the industry well going forward. We plan to follow developments on this matter independently and with ACLI over the coming weeks and beyond.

Some links of interest:

www.pathway.com

www.genomicslawreport.com

www.bioit-world.com