

AMERICAN BAR ASSOCIATION
ADOPTED BY THE HOUSE OF DELEGATES
AUGUST 8-9, 2011

RESOLUTION

RESOLVED, That the American Bar Association urges federal, state and territorial governments to assure that predictive and diagnostic medical genetic testing provided on-line, via the telephone, or by any other direct-to-consumer means complies, at a minimum, with the following requirements:

1. Test samples are received and tests are performed only in licensed laboratories that are certified under the Clinical Laboratory Improvement Amendments of 1988 to perform the category of tests requested and that comply with state and territorial requirements applicable to clinical laboratories;
2. Before test reports and interpretations of test results are issued to consumers, they are reviewed and authorized by qualified health personnel acting in accordance with relevant professional standards of care;
3. Consumers are fully informed of material information about the test and the test results, including but not limited to the following: the scientific evidence on which the test is based; the clinical utility of the test results, if any; the limits of the particular kind of genetic testing, including what it can and cannot tell the consumer; an explanation of what probabilities mean, in understandable terms a statement that genes are not the only determinants of illness; a statement that genetic links to health conditions and diseases are the subject of ongoing research; and a statement that they are advised to discuss test results with a qualified health care professional before making medical decisions based upon the test results;
4. Consumers are advised regarding potential disclosure of their personal information;
5. Appropriate measures are in place to protect the security, privacy, and confidentiality of personal health information; and
6. Claims made and information provided by direct-to-consumer medical genetic testing companies are truthful, accurate, and not misleading.

FURTHER RESOLVED, That the American Bar Association urges federal, state and territorial governments to take action against companies that fail to meet applicable requirements or that make false or misleading claims about direct-to-consumer medical genetic testing.

REPORT

Direct-to-consumer genetic testing (DTCGT) can be defined as the marketing and delivery of clinical genetic tests to consumers without the involvement of an independent health care professional. There is no doubt that there are potential benefits associated with DTCGT, including increased awareness of and access to a variety of genetic tests. To the extent those tests are used for recreational purposes, such as tracing ancestry, predicting the type of ear wax an individual may develop, or selecting the most appropriate skin care product to “prevent” aging, they are likely to be relatively harmless, and this Report and Recommendation takes no position on them.

However, the marketing and delivery of direct-to-consumer *medical* genetic testing (DTCMGT) – that is, genetic tests that purport to predict adverse reactions to medications, estimate susceptibility to various genetic and multifactorial disorders, or diagnose genetic or predominantly genetic conditions -- raise myriad health and safety issues and call out for state and federal regulation.

Overview

Over the last fifty years, medical genetic testing has been limited primarily to conditions such as Tay-Sachs Disease, sickle cell anemia, and other heritable diseases caused by mutations involving single genes. New technology, however, allows the simultaneous analysis of thousands of genes. Along with greater capabilities have come increased consumer demand for genetic tests and the expansion of medical genetic testing into the commercial “direct-to-consumer” arena. A number of web-based companies now offer to provide consumers with assessments of their risk of developing more complex common diseases such as asthma, diabetes, heart disease and various types of cancer.

Whereas in the past, medical testing was firmly under the control of medical practitioners, genomic information is now increasingly available outside traditional medical settings. Patients are no longer subordinate, passive recipients of physician-initiated genetic testing; rather, patients can instigate their own testing and often know more than their clinicians about particular genetic topics.

James P. Evans, M.D., Ph.D., David C. Dale, M.D. and Cathy Fomous, Ph.D., *Preparing for a Consumer-Driven Genomic Age*. <http://healthpolicyandreform.nejm.org/?p=11933> (8/18/2010).

At prices ranging from several hundred to thousands of dollars, anyone can order a genetic test kit through the mail, collect saliva and mail it back to the company’s laboratory, and, in a few weeks, receive information describing his or her chances of developing specific diseases or conditions. But then what?

{Although the testing process may seem simple, interpreting the results is not straightforward. It is often unclear what you should do with the information you get. For example, suppose that your test result indicates that you have a 20 percent increased risk of developing a particular disease in your lifetime. Is this enough for you to be concerned and to seek follow-up care? How does this compare with the risk in the general population? Will your doctor know what to do with the information should you decide to share it with him/her? How does this information fit in with your personal and family health history or with other factors, such as diet, exercise, and environment exposures What [will happen to your] sample and genetic information after genetic testing has been completed?}

Connecticut Department of Public Health Genomics Office, *Direct to Consumer Personal Genomics Services -- Information to Consider*.
http://www.ct.gov/dph/lib/dph/state_health_planning/pdf/dtc_10_27_09.pdf (10/09).

A Silicon Valley start-up company is claiming that it can eradicate more than 100 rare genetic diseases by alerting would-be parents that they are carrying the affected genes. The company, Counsyl, calls its product the “Universal Genetic Test.” However, medical professionals know well that genetic testing is only one part of a complex process that has the potential for both positive and negative impact on the health and well-being of patients and their families.

Decisions based on genetic testing are very personal and can be difficult, emotional, costly and life-changing; they are not to be taken lightly. The causes of many conditions are complex and include a combination of genetic, lifestyle and environmental factors. The potential benefits to mankind are tremendous but there are a great many questions still to be answered and more research needs to be done to better understand how genetic and non-genetic factors influence many conditions.

Godfrey on GeneForum, *Making Informed Decisions about Genetic Tests*.
<http://www.geneforum.org/node/661> (4/19/08).

Personal genetic information provided to individuals without interpretation by knowledgeable clinicians can cause anxiety, lead to undertaking unnecessary medical procedures or forgoing necessary ones, and use up valuable health care resources; it can cause both direct and indirect harm. As Harold Varmus, M.D., writing on the tenth anniversary of the deciphering of the human genome, recently concluded: “The direct-to-consumer marketing of genotypes . . . has been among the most visible manifestations of genomics. Yet this practice is not regulated, lacks external standards for accuracy, has not demonstrated economic viability or clinical benefit, and has the potential to mislead

consumers.” Varmus, H., *Ten Years On – The Human Genome and Medicine*, 362 New Eng. J. Med. 2028 (2010).

The Issues

Numerous medical professional organizations, commentators and government agencies have expressed serious concerns about the risks of DTCMGT, including questions such as:

Are the tests analytically valid? Do the tests accurately and reliably measure what they purport to measure? The use of high-throughput techniques to bundle a large number of medical genetic tests into microarray genomic scans raises broad quality assurance issues. For example, what, if any, criteria are used to support the inclusion of a particular test in the array? For DNA-based tests, analytical validity requires establishing the probability that a test will be positive when a particular DNA sequence is present (analytical sensitivity) and the probability that the test will be negative when the sequence is absent (analytical specificity).

Are the tests clinically valid? Do the tests actually detect risk of disease? Results from DTCMGT are not black and white. Genetic information is complex, and predictive genetic tests do not – cannot – provide a simple ‘yes’ or ‘no’ answer as to whether an individual actually will develop a particular disease in his/her lifetime. They can provide only the risk that the disease will develop – and only to the extent that the genes tested for contribute to that risk, and that other genes do not. Further, the test cannot predict when the disease may develop or how severe the symptoms will be, nor does a negative result necessarily mean that the disease will not occur.

Recent reports of *incorrect results* from DTCMGT providers have fueled this concern. This past spring, about 90 patients of the DTCMGT company 23andMe received incorrect test results:

One woman panicked when the genetic test she had ordered over the Internet concluded that her son was carrying a life-threatening disorder and, even more disturbing, that he was not – genetically – her son. Another, who always thought she was white, was flabbergasted to find her genes were mostly of African origin. A third woman’s result was still more stunning: She was a man, it said.

“I thought, ‘Oh my God, Am I really a man?’” said Denise Weinrich, 48, of St. Peters, Mo. “I thought ‘What’s the matter with me? I’m not who I thought I was. How am I going to tell my children?’ DNA doesn’t lie.”

Rob Stein, *Genetic testing mix-up reignites debate over degree of federal regulation needed*. <http://www.washingtonpost.com/wp-dyn/content/article/2010/07/16/AR2010071606246.html> (7/17/2010).

On July 22, 2010, the Subcommittee on Oversight and Investigations of the House of Representatives Committee on Energy and Commerce (the “Subcommittee”) held a hearing to examine “Direct-to-Consumer Genetic Testing and the Consequences to the Public Health.” Prior to that hearing, the Subcommittee had asked the Government Accountability Office (“GAO”) to investigate DTCMGT companies, and the results of the undercover investigations conducted by the GAO’s Forensic Audit and Special Investigations Unit were presented at the hearing. Highlights of GAO Testimony Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives, *Direct-To-Consumer Genetic Tests: Misleading Test Results Are Further Complicated by Deceptive Marketing and Other Questionable Practices* (July 22, 2010). [“GAO Report”] <http://www.genomicslawreport.com/wp-content/uploads/2010/08/Kutz.Testimony.07.22.2010.pdf>.

The GAO reported that the results of consumer genetic tests are unreliable and that the purveyors of the tests sometimes overstate their value in order to sell other products and services. “Test results from four direct-to-consumer genetic testing companies varied widely for the same person,” according to the GAO report, “indicating that identical DNA samples yield contradictory results.” For example, one 38-year-old male was informed that his risk for developing prostate cancer was below average in one company’s test, average in two other tests, and above average in the fourth. A representative of one of the companies investigated by the GAO responded that the differences in the reported test results likely were due to different methods of interpreting the genetic markers. Such a response, however, is unlikely to be helpful to patients who receive incorrect test results.

GAO also found 10 egregious examples of deceptive marketing, including claims made by four companies that a consumer’s DNA could be used to create personalized supplement to cure diseases. Two of these companies further stated that their supplements could “repair damaged DNA” or cure disease, even though experts confirmed there is no scientific basis for such claims. One company representative even fraudulently used endorsements from high-profile athletes to convince GAO’s fictitious consumer to purchase such supplements. Two other companies asserted that they could predict in which sports children would excel based on DNA analysis, claims that an expert characterized as “complete garbage.” Further, two companies told GAO’s fictitious consumer that she could secretly test her fiancé’s DNA to “surprise” him with test results—though this practice is restricted in 33 states. Perhaps most disturbing, one company told a donor that an above average risk prediction for breast cancer meant she was “in the high risk of pretty much getting” the disease, a statement that experts found to be “horrifying” because it implies the test is diagnostic. [GAO Report]

Also testifying at the July 22 Subcommittee hearing, Jeff Shuren, MD, director of the FDA's Center for Devices and Radiological Health, stated that the increasingly bolder marketing tactics of DTCMGT could lead to tighter Food and Drug Administration control over the industry. When questioned as to why the FDA had not regulated these consumer genetic testing companies more aggressively, Dr. Shuren acknowledged "We should have acted sooner." Doug Trapp, *Consumer genetic testing has little value, GAO report says*. <http://www.ama-assn.org/amednews/2010/08/02/gvsd0802.htm> (8/2/2010).

Are the tests clinically useful? Is there something that can be done to alter the predicted risk? Most of the commercially available DTCMGT rely on the occurrence of currently known genetic variants. Yet, studies of this variation have not yet explained much of the heritability of common diseases. Are the results of DTCMGT an improvement risk prediction achieved based on family health history or established risk factors? Or, can they, themselves, cause harm?

For tests of genetic mutations of genes associated with known syndromes of cancer susceptibility, a test result could lead, for example, to a risk-reducing surgery of the breast, ovaries, or colon. Genetic test results can also lead to increased screening; examples of increased screening include magnetic resonance imaging (MRI) of the breast, blood tests for markers of prostate cancer, and colonoscopy tests beginning at an early age and performed more frequently, as well as other screening strategies. Recently, specific treatments have been shown to be more effective for patients with certain genetic mutations. Currently, there are no known specific medical interventions for cancer screening or prevention based on results of DTC testing for variants for cancer risk, as provided by a number of for-profit laboratories.

Kenneth Offitt, MD, MPH, *ASCO Expert Corner: Direct-to-Consumer Genetic Testing*. <http://www.cancer.net/patient/All+About+Cancer/Cancer.Net+Feature+Articles/Cancer+Screening+and+Prevention/ASCO+Expert+Corner%3A+Direct-to-Consumer+Genetic+Testing> (1/14/2010).

How will the availability of these unregulated and often unproven tests affect our health care costs?

What should happen, for instance, when a 30-year-old man with no, relevant signs, symptoms, or family history shows his doctor a genetic test result indicating that he has an elevated risk of prostate cancer? Should his prostate-specific antigen level be measured? An ultrasound obtained? A biopsy performed? What level of risk should

trigger further testing? What are the liability risks of not pursuing a diagnostic evaluation?

McCartney, *Sense on Genetic Screening from the USA*.

<http://www.margaretmccartney.com/blog/?p=724&cpage=1> (8/18/10).

Recently, Walgreens said it will postpone selling a controversial at-home genetic test – a test that could purportedly gauge a person’s individual risk for developing a variety of diseases and other health conditions such as Alzheimer’s Disease, diabetes, heart attack, certain cancers, and the likelihood of having a child with certain genetic disorders – after the FDA challenged the legality of the test. Medical experts expressed concerns about the effects on individuals who received test results that predict diseases in the individual or his or her children or other family members without the benefit of discussion and professional counseling to help interpret the results. Amanda Gardner, “Walgreens Postpones Plans to Sell Do-It-Yourself Genetic Test.” <http://www.businessweek.com/lifestyles/content/healthday/639079.html> (5/14/10).

Similarly, the University of California at Berkeley recently modified its plan to conduct genetic testing on students in the Class of 2014. The students were asked to submit a DNA test as part of a project to look at three “innocuous” genes that help regulate the metabolism of alcohol, lactose, and folates. The students received a swab in the mail, returned it with cheek scrapings, and were to receive test results in about a week. However, a ruling by the California Department of Public Health forced the University to abandon its plans to release the personal genetic information to students because it had failed to require a physician’s order for each test and to have the samples processed at a state-approved laboratory. Although the University believed the tests were non-medical in nature, the Health Department found that the information could affect the diagnosis and treatment of disease; ergo, that it was medical information. Lisa M. Krieger, “U.C. Berkeley drops plans to release personal genetic information to incoming freshmen.” <http://www.mercurynews.com/15162462?source=email> (8/16/2010).

Recommendation:

Appropriate Regulation of Direct-to-consumer Medical Genetic Testing

In addition to being subject to many of the general issues discussed above, direct-to-consumer medical genetic testing raises additional concerns because of the serious health and safety issues that it raises. DTCMGT takes place *outside* of the traditional medical setting and has not yet been subjected to regulatory requirements that protect patient interests in traditional medical settings.

The American College of Medical Genetics (“ACMG”), the medical specialty society for clinical geneticists, believes that it is critical for the public to understand that medical genetic testing is only one part of a complex process that has the potential for both positive and negative impact on health and well-being. The College recommends that the following be considered *minimum requirements* for any medical genetic testing protocol, irrespective of the means of delivery, including those carried out by DTCMGT companies:

- **A knowledgeable professional should be involved in the process of ordering and interpreting a genetic test.** Genetic testing is highly technical and complex. A genetics expert such as a certified medical geneticist or genetic counselor can help the consumer determine, for example, whether a genetic test should be performed and how to interpret test results in light of personal and family history. A number of risks can be reduced if a genetic professional is involved in genetic testing. These risks include lack of informed consent, inappropriate testing, misinterpretation of results, testing that is inaccurate or not clinically valid, lack of follow-up care, misinformation, and other adverse consequences.
- **The consumer should be fully informed regarding what the test can and cannot say about his or her health.** Most DTC genetic tests are not diagnostic. They do not give a definitive answer as to whether an individual will develop a given condition, but provide only a risk or probability of developing a disease, which can vary widely. The interpretation of such results is often highly nuanced, and such information needs to be communicated to the consumer in the appropriate context and in an understandable fashion that is linguistically and culturally appropriate.
- **The scientific evidence on which a test is based should be clearly stated.** DTC genetic test providers should provide easy-to-understand information with primary references documenting the scientific data on which a specific test is based.
- **The clinical testing laboratory must be accredited by the Centers for Medicare and Medicaid Services under CLIA, the relevant state agency and/or other applicable accrediting agencies.** Each laboratory that performs and reports genetic test results must be appropriately accredited. This process ensures that laboratories adhere to strict standards and guidelines for clinical testing. Test result reports to consumers should indicate the specifics of the lab's accreditation.
- **Privacy concerns must be addressed.** Prior to testing, the consumer should be informed regarding who will have access to test results, what security is in place to protect these results, and how to access a complaint procedure to report breaches of privacy. Also, the issues of possible employment and insurance discrimination and the potential impact on other family members should be discussed prior to obtaining genetic testing.

ACMG Statement on Direct-to-Consumer Genetic Testing (April 7, 2008). Available at http://www.acmg.net/AM/Template.cfm?Section=Policy_Statements&Template=/CM/ContentDisplay.cfm&ContentID=2975.

While many of these recommendations can – and should – be implemented through state laws, there also is a need for federal regulation. For example, a 2008 report from The Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) recommended that “the FTC must step up its efforts to monitor promotional materials and address exaggerated and inconsistent claims. For example, some companies claim that

genetic testing allows consumers to ‘take charge of their health’ but simultaneously claim that they don’t provide medical advice. Such contradictory claims are potentially harmful.” The SACGHS report also recommended that the FDA apply its authority in this area. James P. Evans, M.D., Ph.D., David C. Dale, M.D. and Cathy Fomous, Ph.D., *Preparing for a Consumer-Driven Genomic Age*. <http://healthpolicyandreform.nejm.org/?p=11933> (8/18/2010). In addition, both federal and state governments should apply consumer protection rules more vigorously in this area. Finally, professional organizations and federal and state agencies should continue to publish materials aimed at educating consumers about the potential risks and benefits of genetic testing.

For all of the above reasons, the Section believes that the American Bar Association should urge federal, state and territorial governments to assure that medical genetic testing complies, at a minimum, with requirements discussed above, and to take action against companies that fail to meet applicable requirements or that make false or misleading claims.

Respectfully submitted,

Linda Baumann
Chair
Health Law Section
American Bar Association

August 2011

GENERAL INFORMATION FORM

Submitting Entity: Health Law Section

Submitted By: Linda Baumann, Chair

1. Summary of Resolution(s).

The resolution calls for the American Bar Association to urge all states and territories to enact legislation and promulgate regulations requiring that genetic tests must be ordered by, and the test results disclosed to, the patient's physician; patients are fully informed of the potential medical information that will and will not be provided; tests are conducted by licensed laboratories appropriately certified to perform the tests; all testing policies and procedures conform to applicable standards of medical care; and specific patient authorization is required prior to disclosure of patient test results or other personal medical information. It also calls for the Association to urge the appropriate federal agencies to develop and enforce regulations prohibiting false and misleading claims by direct-to-consumer genetic testing providers.

2. Approval by Submitting Entity.

Approved by the Health Law Section Council on December 14, 2010.

3. Has this or a similar resolution been submitted to the House or Board previously?

No.

4. What existing Association policies are relevant to this resolution and how would they be affected by its adoption?

No other relevant policies were identified.

5. What urgency exists which requires action at this meeting of the House?

A growing number of web-based companies are offering to provide consumers with medical genetic test results that "predict" their risk of developing genetic diseases as well as more common and multi-factorial disorders such as asthma, diabetes, heart disease and various types of cancer. Recent reports, however, including a report by the GAO, have documented that these test results and the predictions based on them are often unreliable, overstated, or simply wrong. Moreover, medical genetic information provided to consumers without interpretation by knowledgeable clinicians can cause anxiety, lead to undertaking unnecessary medical procedures or foregoing necessary therapy, and use up valuable health care resources.

6. Status of Legislation. (If applicable.)

No specific federal legislation is pending; various states have attempted and are considering regulatory action.

7. Cost to the Association. (Both direct and indirect costs.)

None.

8. Disclosure of Interest. (If applicable)

Not applicable.

9. Referrals.

The resolution and report were sent to: Intellectual Property Section, Science and Technology Section, Individual Rights and Responsibilities, Tort Trial & Insurance Practice Section, Young Lawyers Division, Family Law, Special Committee on Bioethics, Standing Committee on Medical Professional Liability, and the ABA Health Law Coordinating Group.

10. Contact

Tony Patterson, cell: 406/249-5671, japatterson@fulbright.com
Greg Pemberton, cell: 317/431-9013, Gregory.pemberton@icemiller.com
Linda Baumann, baumann.linda@arentfox.com

11. Presenter

Tony Patterson, cell: 406/249-5671, japatterson@fulbright.com
Greg Pemberton, cell: 317/431-9013, Gregory.pemberton@icemiller.com

EXECUTIVE SUMMARY

1. Summary of the Resolution:

The Resolution calls for the American Bar Association to urge all states and territories to enact legislation and promulgate regulations requiring that genetic tests must be ordered by, and the test results disclosed to, the patient's physician; patients are fully informed of the potential medical information that will and will not be provided; tests are conducted by licensed laboratories appropriately certified to perform the tests; all testing policies and procedures conform to applicable standards of medical care; and specific patient authorization is required prior to disclosure of patient test results or other personal medical information. It also calls for the Association to urge the appropriate federal agencies to develop and enforce regulations prohibiting false and misleading claims by direct-to-consumer genetic testing providers

2. Summary of the issue which the resolution addresses:

A growing number of web-based companies are offering to provide consumers with medical genetic test results that "predict" their risk of developing genetic diseases as well as more common and multi-factorial disorders such as asthma, diabetes, heart disease and various types of cancer. Recent reports, however, including a report by the GAO, have documented that these test results and the predictions based on them are often unreliable, overstated, or simply wrong. Moreover, medical genetic information provided to consumers without interpretation by knowledgeable clinicians can cause anxiety, lead to undertaking unnecessary medical procedures or foregoing necessary therapy, and use up valuable health care resources.

3. An explanation of how the proposed policy position will address the issue:

The proposed policy will encourage states and territories, as well as the federal government, to develop and enforce laws regulating direct to consumer medical genetic testing as the practice of medicine.

4. A summary of any minority views or opposition which have been identified:

None have been identified.