



# Statement on Direct-to-Consumer Marketing of Genetic Tests

January 13, 2010

The Ohio Department of Health

## A Message for All Ohioans

We believe that Ohioans should have access to high-quality genetic<sup>(1)</sup> services. For that reason, we strongly advise that an expert, trained in genetics, be involved in ordering and interpreting genetic tests.

Genetic Centers are staffed with Medical Geneticists<sup>(2)</sup>, Genetic Counselors<sup>(3)</sup>, and Genetic Nurses. They are specially trained to:

- Assess if people have or are at risk for having a condition that is hereditary<sup>(4)</sup>.
- Assess the need for genetic testing.

- Explain genetic test results and talk about what the results mean to the patient and family.
- Answer questions that other healthcare providers have about genetic conditions and the testing process.

All Ohioans have genetic services in the region where they live. Many health plans cover genetic testing and services. The GINA<sup>5</sup> law was passed to help protect against unfair treatment from health plans or in the work place based on genetic tests or family health history.

---

<sup>1</sup> Genetic (ge-net-ic): involving, resulting from, or relating to genes or genetics

<sup>2</sup> Medical Geneticist (ge-net-i-cist): a doctor who has special training in diagnosing and treating patients with medical conditions that have a genetic basis.

<sup>3</sup> Genetic Counselor: a health professional with a graduate degree and experience with medical genetics and counseling. They provide information, counseling and support to families with birth defects or other genetic conditions. Medical Geneticists and Genetic Counselors often work closely together while performing genetic evaluations or genetic counseling for patients and families.

<sup>4</sup> Hereditary (he-red-i-tar-y): passed genetically, or capable of being passed genetically, from one generation to the next.

<sup>5</sup> GINA stands for Genetics Information Nondiscrimination Act. This is a federal law that prohibits the improper disclosure and use of genetic information in health insurance and employment.

<http://www.genome.gov/24519581>

## **Goal:**

Ohioans with an increased risk for hereditary conditions will make informed decisions about genetic testing and treatment by accessing a knowledgeable professional who is involved in the process of ordering and interpreting genetic tests.

## **Background Information:**

With the current explosion of genetic discoveries and ongoing improvements in technology, more genetic tests are available than ever before. Along with this availability comes increased consumer demand for genetic tests and expansion of Direct-to-Consumer (DTC) marketing of these tests. Private companies and laboratories that offer genetic tests are increasing their marketing efforts in Ohio and throughout the United States. As a result, consumer requests for genetic testing through Ohio physicians and other healthcare providers are expected to rise. Some of these tests must be ordered by a healthcare provider and others can be ordered directly by the patient without any involvement of a healthcare provider. The latter is referred to as DTC genetic testing and is not addressed in this statement.

The benefits of DTC marketing of genetic tests include:

- increased consumer and physician awareness of genetics and genetic testing as components of disease, and
- increased consumer access to testing.

Concerns that have been raised about DTC marketing of genetic testing include:

- lack of oversight of these tests;
- inappropriate testing of low-risk individuals;
- increased healthcare spending; and
- difficulty interpreting the results of these tests, particularly when they are ordered in the absence of a healthcare provider who is knowledgeable about genetic testing.

Experts agree that genetic testing is only one part of a complex process with potential for both positive and negative effects on health and well-being. It is important to ensure that proper risk assessment and genetic counseling occur prior to and following genetic testing in order for consumers to make informed decisions about the appropriateness of testing and to understand the test results.

To date, familial cancers have been the focus of DTC marketing of genetic tests. The number/variety of genetic tests are expected to rapidly expand in the future. Therefore, this statement is meant to apply broadly to all DTC marketing of genetic testing.

## **Strategies**

Ensuring the correct use of genetic tests is an important challenge. To promote the proper use of genetic tests in Ohio we support efforts to:

1. Educate healthcare providers about the role and value of genetic counseling to identify patients appropriate for genetic testing.
2. Educate healthcare providers about the role and value of genetic counseling to interpret and communicate genetic test results.
3. Assist community physicians in responding to their patients' concerns by increasing awareness about the availability of genetic counseling services.

4. Promote public awareness about the significance and impact of hereditary diseases and the availability of qualified genetics professionals to assess risks and coordinate testing when appropriate.
5. Develop and promote policies that support access to genetic services throughout our state.

**To locate a genetic professional in your area visit:**

[www.odh.ohio.gov/odhPrograms/cmh/genserv/genserv1.aspx](http://www.odh.ohio.gov/odhPrograms/cmh/genserv/genserv1.aspx) or  
[www.nsgc.org/resource/link.cfm](http://www.nsgc.org/resource/link.cfm)

**Institutions, organizations and groups that endorse this statement include:**

- The Ohio Regional Comprehensive Genetic Center Directors
- The Ohio Cancer Genetics Network



**References**

- American College of Medical Genetics. Statement on direct-to-consumer genetic testing. Published September 24, 2007.
- American College of Obstetricians and Gynecologists. ACOG Practice Bulletin: Clinical Guidelines for Obstetrician-Gynecologists, Number 103, April, 2009.
- ASHG Statement on Direct-to-Consumer Genetic Testing in the United States. *The American Journal of Human Genetics*, Volume 81, September, 2007.
- Direct-to-Consumer Marketing of Genetic Testing. ACOG Committee Opinion. No. 409. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2008; 111:1493-4.
- Ethical Issues in Genetic Testing. ACOG Committee Opinion. No. 410. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2008; pp. 1-7.
- Matloff E. Direct to Confusion: Lessons learned from Marketing BRCA Testing. *American Journal of Bioethics*, 8(6): 5-8, 2008.
- Myers MF, Chang MH, Jorgensen C, et.al. Genetic testing for susceptibility to breast and ovarian cancer: Evaluating the impact of a direct-to-consumer marketing campaign on physicians' knowledge and practices. *Genetics In Medicine* June 2006, Vol. 8, No. 6, 361-370.
- National Society of Genetic Counselors, Statement on direct-to-consumer genetic testing, adopted 2007.
- Offit K. Genomic Profiles for Disease Risk: Predictive or Premature?. *Journal of the American Medical Association*. Vol. no. 11, 2008;299(11):1353-1355.
- U.S. Preventive Services Task Force. Genetic Risk Assessment and BRCA Mutation Testing for Breast and Ovarian Cancer Susceptibility: Recommendation Statement. *Annals of Internal Medicine*. September 2005, Volume 143, Issue 5, pp 355-361.