STATE OF MARYLAND
DHMH

Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

December 22, 2014

The Honorable Thomas M. Middleton
Chair, Senate Finance
Committee
3 East Miller Senate Office Building
11 Bladen Street
Annapolis, MD 21401-1991

Dear Senator Middleton,

During the 2014 session, the Finance Committee requested that the Department of Health and Mental Hygiene and the Office of the Attorney General study the issue of increasing access to medical laboratory testing by patients in Maryland. Under Maryland law, the process of accessing laboratory test results involves two questions: 1) who may order a test from a laboratory, and 2) who may receive the results of the laboratory test.

Maryland law answers the second question—who may receive test results—in favor of patient access. Section 17-202.1 of the Health – General Article provides that "[o]n written request of an individual to a medical laboratory for a copy of the results of a laboratory examination of that individual, the medical laboratory shall send a copy of those results that are sought to that individual." This section also requires the medical laboratory to notify the individual's physician before sending the results to the individual.

The first question—who may order a laboratory test—has been the subject of recent interest in Maryland. Current Maryland law provides that in general, a laboratory may not perform a test unless authorized by: 1) a court of law, 2) a doctor of medicine, osteopathy, podiatric medicine, or dentistry, or 3) another person authorized to order laboratory tests under the Annotated Code of Maryland.[1] Other individuals who are authorized to order tests include other health care providers, such as nurse practitioners and physician assistants, and employers requesting a job-related drug or alcohol test.[2]

There are exceptions to this requirement, however. Individuals may directly purchase approved tests from a temporary laboratory operating under a health awareness permit at an event such as a health fair. Tests must be approved by the Secretary of Health and Mental Hygiene and measure clinical values that the Secretary has determined are in the interest of public health, such as glucose or lipids.

[1] COMAR 10.10.06.02.A.
[2] COMAR 10.10.06.02.B.

There are also a number of medical testing products that can be purchased at local pharmacies without a prescription or order from a health care provider. The U.S. Food and Drug Administration (FDA) has approved products that can determine if the user has a condition such as Hepatitis C or HIV and products that allow the user to monitor certain health indicators, such as cholesterol or glucose. More information about FDA-approved home-use tests is available here: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/HomeUseTests/default.htm.

Two bills were introduced during the 2014 legislative session that sought to expand access to medical laboratory testing by allowing patients to directly order a test, without consultation or authorization from health care provider. This practice is known as "direct-to-consumer" (DTC) testing.

House Bill 906, sponsored by Delegate Pendergrass, would have authorized a person to advertise for, solicit business in the State for, offer, or perform direct-to-consumer genetic testing if certain conditions are met. Senate Bill 227, sponsored by Senator Reilly, would have repealed a prohibition on a medical laboratory from directly or indirectly advertising to and/or soliciting business from anyone other than a physician, hospital, medical laboratory, clinic, clinical installation, or other medical care facility. The legislative intent of SB 227 in particular sought to provide broad authority for individuals to order medical laboratory tests directly, sparking considerable interest and questions.

The Department's position for both of these bills was "support with amendments." The amendments sought by the Department, as well as amendments offered by the Consumer Protection Division of the Office of the Attorney General, provide important consumer protections, such as a requirement that companies offering laboratory tests directly to patients be subject to the privacy protections offered by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Department continues to believe that these issues should be addressed as part of any proposal to permit direct-to-consumer testing in Maryland.

To that end, we've included the following documents:

- Position papers and amendments submitted for HB 906 and SB 227 – Appendix 1; and
- A literature review of health issues related to direct-to-consumer genetic testing, conducted during the 2013 interim for Delegate Shane Pendergrass – Appendix 2

I hope this information is helpful. If you have any questions, please contact Allison Taylor, Director of Governmental Affairs, at (410) 767-6481.

Sincerely,

Joshua M. Sharfstein, MD
Secretary

THE SENATE OF MARYLAND
FINANCE COMMITTEE

February 28, 2014

The Honorable Douglas F. Gansler
Office of the Attorney General

Mr. Joshua M. Sharfstein, Secretary
Department of Health and Mental Hygiene

Dear Attorney General Gansler and Secretary Sharfstein:

During the 2014 session, the Finance Committee considered Senate Bill 227, Health – Medical Laboratories – Advertising for or Soliciting Business – Repeal of Prohibition. The bill would have repealed the prohibition on advertising or soliciting business in Maryland for a medical lab from anyone except for medical providers or facilities. The Department of Health and Mental Hygiene (DHMH) and the Office of the Attorney General (OAG) expressed concerns regarding the direct marketing of laboratory tests directly to consumers, particularly relating to "direct to consumer" genetic testing.

DHMH's testimony included amendments that would have provided consumer protections. During the hearing I requested that DHMH and OAG work with the sponsor to address consumer protection concerns. Subsequently, the sponsor indicated that the he hoped the bill would be subject to summer study. I am aware that the department studied the direct marketing of genetic tests to consumers, and as a result legislation has been introduced in the House of Delegates requiring these labs to get a license. The sponsor has indicated, however, that he favors the approach in Senate Bill 227, which simply repeals the prohibition. In lieu of a legislative solution, I would encourage DHMH and OAG to study repealing this long-standing prohibition on **all** labs directly marketing their products and procedures to consumers. The rise of the internet has greatly altered consumer behavior and access to information and health care reform may be altering the delivery of health care services, so it may be time to revisit some of these long standing statutory provisions.

We look forward to hearing the any conclusions, findings, or recommendations from the study before December 1, 2014. Thank you for your attention to this important matter.

Very truly yours,

Thomas M. Middleton

Thomas McLain Middleton

TMM/das

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Appendix 1

STATE OF MARYLAND
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Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

**2014 SESSION**
**POSITION PAPER**

**BILL NO:** **HB 906**
**COMMITTEE:** **HEALTH AND GOVERNMENT OPERATIONS**
**POSITION:** **SUPPORT WITH AMENDMENTS**

**TITLE:** Medical Laboratories – Direct–to–Consumer Genetic Testing

**BILL ANALYSIS**: House Bill 906 authorizes firms to market and offer genetic tests directly to consumers, places certain limits on the kinds of tests that may be advertised and offered, and requires firms marketing or offering these tests to disclose certain information to consumers.

**POSITION AND RATIONALE**: The Department of Health and Mental Hygiene (the Department) supports SB 227, provided that the bill is amended to ensure adequate consumer protection. Studies of the clinical validity of these products call their accuracy into serious question, and the U.S. Food and Drug Administration recently asked one company to cease marketing its products. Inaccurate or misleading testing results and interpretations, which are labeled as scientifically valid, provided by these companies can lead to consumers making decisions about their health and medical treatment that may be harmful. Moreover, these testing companies have been involved with selling the genetic information of consumers to outside companies for marketing and other purposes without consumer awareness, raising serious privacy concerns.

A 2013 study examined how three direct-to-consumer testing companies interpreted the same genotype data for 100,000 individuals.[1] The researchers assessed the tests' predicted risk for six diseases. Because the various tests assume different genomic associations for the same diseases, results on risk of the diseases were different across tests. For example, more than 27 percent of individuals would receive contradictory risk predictions for Crohn's disease from different tests. Another study found that 4 in 10 *physicians* would be uncomfortable interpreting the results of these tests and using them to guide patient care.[2]

Given these findings and others, the FDA recently sent a letter to 23andMe, the leading direct-to-consumer genetic testing company, asking them to immediately discontinue marketing their testing kits. The FDA has repeatedly asked 23andMe for proof of clinical validity to support its marketing

[1] Kalf RRJ, Mihaescu R, Kundu S, de Knijff P, Green RC, Janssens ACJW. Variations in predicted risks in personal genome testing for common complex diseases. Genet Med. 2013 Jun 27
[2] Bernhardt BA, Zayac C, Gordon ES, Wawak L, Pyeritz RE, Gollust SE. Incorporating direct-to-consumer genomic information into patient care: attitudes and experiences of primary care physicians. Pers Med. 2012 Sep;9(7):683–92.

claims, and 23andMe has not provided this information. Similar requests for proof of clinical validity have been sent to other testing companies, and these companies have also failed to provide this information. In its warning letter, the FDA said:

> "A direct-to-consumer test result may be used by a patient to self-manage… serious concerns are raised if test results are not adequately understood by patients or if incorrect test results are reported."
>
> "Some of the uses [of the test kits] are particularly concerning, such as assessments for BRCA-related genetic risk and drug responses…because of the potential health consequences that could result from false positive or false negative assessments for high-risk indications such as these.. For instance, if the BRCA-related risk assessment for breast or ovarian cancer reports a false positive, it could lead a patient to undergo prophylactic surgery, chemoprevention, intensive screening, or other morbidity-inducing actions, while a false negative could result in a failure to recognize an actual risk that may exist."

The Maryland Laboratory Advisory Committee (LAC), which is a panel of medical professionals advising the Department, has raised similar concerns about clinical validity, false claims from the companies.

To address these concerns raised by the FDA and Maryland LAC, the Department proposes that the Secretary of the Department be given authority to prohibit the marketing or offering of tests that are not approved by the FDA and are otherwise found by the Department to have a negative public health impact. This provision would help protect consumers from products that make invalid, false, or misleading claims or conclusions regarding the consumer's health.

The Department respectfully submits the following amendments.

On page 2, in line 25, before "**A**" insert "**(A)**".

On page 3, after line 26, insert:

"**(B) THE SECRETARY MAY PROHIBIT THE ADVERTISING, OFFER, AND SALE OF INDIVIDUAL DIRECT-TO-CONSUMER GENETIC TESTS IF:**

**(1) THE PRODUCT IS FOUND TO HAVE A PUBLIC HEALTH IMPACT OF CONCERN, AND**

**(2) THE PRODUCT IS NOT APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION**".

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**2014 SESSION**
**POSITION PAPER**

**BILL NO:** **SB 227**
**COMMITTEE:** **FINANCE**
**POSITION:** **SUPPORT WITH AMENDMENTS**

**TITLE:** Health – Medical Laboratories – Advertising for or Soliciting Business – Repeal of Prohibition

**BILL ANALYSIS**: Senate Bill 227 repeals a prohibition on medical laboratories from directly or indirectly advertising to and/or soliciting business from anyone other than a physician, hospital, medical laboratory, clinical, clinical installation, or other medical facility. This repeal would allow medical laboratories to market products directly to consumers.

**POSITION AND RATIONALE**: The Department of Health and Mental Hygiene (the Department) supports SB 227 provided that the bill is amended to ensure sufficient consumer protection. Several companies market genetic testing products directly to consumers in states without this prohibition. Studies of the clinical validity of these products calls their accuracy into serious question, and the U.S. Food and Drug Administration (FDA) recently asked one company to cease marketing its products. Inaccurate or misleading testing results and interpretations, which are labeled as scientifically valid, provided by these companies can lead to consumers making decisions about their health and medical treatment that may be harmful. Moreover, these testing companies have been involved with selling the genetic information of consumers to outside companies for marketing and other purposes without consumer awareness, raising serious privacy concerns.

A 2013 study examined how three direct-to consumer (DTC) testing companies interpreted the same genotype data for 100,000 individuals.[1] The researchers assessed the tests' predicted risk for six diseases. Because the various tests assume different genomic associations for the same diseases, results on risk of the diseases were different across tests. For example, more than 27 percent of individuals would receive contradictory risk predictions for Crohn's disease from different tests. Another study found that 4 in 10 *physicians* would be uncomfortable interpreting the results of these tests and using them to guide patient care.[2]

[1] Kalf RRJ, Mihaescu R, Kundu S, de Knijff P, Green RC, Janssens ACJW. Variations in predicted risks in personal genome testing for common complex diseases. Genet Med. 2013 Jun 27
[2] Bernhardt BA, Zayac C, Gordon ES, Wawak L, Pyeritz RE, Gollust SE. Incorporating direct-to-consumer genomic information into patient care: attitudes and experiences of primary care physicians. Pers Med. 2012 Sep;9(7):683–92.

Given these findings and others, the FDA recently sent a letter to 23andMe, the leading DTC genetic testing company, asking them to immediately discontinue marketing its testing kits. The FDA has repeatedly asked 23andMe for proof of clinical validity to support its marketing claims, and 23andMe has not provided this information. Similar requests for proof of clinical validity have been sent to other testing companies, and these companies have also failed to provide this information. In its warning letter, the FDA said:

> "A direct-to-consumer test result may be used by a patient to self-manage… serious concerns are raised if test results are not adequately understood by patients or if incorrect test results are reported."
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> "Some of the uses [of the test kits] are particularly concerning, such as assessments for BRCA-related genetic risk and drug responses…because of the potential health consequences that could result from false positive or false negative assessments for high-risk indications such as these.. For instance, if the BRCA-related risk assessment for breast or ovarian cancer reports a false positive, it could lead a patient to undergo prophylactic surgery, chemoprevention, intensive screening, or other morbidity-inducing actions, while a false negative could result in a failure to recognize an actual risk that may exist."

The Maryland Laboratory Advisory Committee (LAC), which is a panel of medical professionals advising the Department, has raised similar concerns about clinical validity, false claims from the companies, and other issues such as privacy. Based on the recommendations of this panel, the Department respectfully submits the following amendments.

On page 1, after line 20, insert:

"17-215.

(A) A PERSON MAY DIRECTLY OR INDIRECTLY ADVERTISE FOR OR SOLICIT BUSINESS IN THIS STATE FOR ANY MEDICAL LABORATORY, REGARDLESS OF LOCATION, ONLY IF THE FOLLOWING CONDITIONS ARE MET:

(1) ALL PRODUCTS MUST BE ACCREDITED BY THE FEDERAL CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF1988 (CLIA).

(2) ALL TESTING PROTOCOLS FOR MARKETED PRODUCTS MUST BE SUBMITTED TO THE U.S. FOOD AND DRUG ADMINISTRATION.

(3) THE PERSON SHALL:

(I) DISCLOSE RISKS ASSOCIATED WITH ALL TESTS, INCLUDING POTENTIAL PSYCHOLOGICAL RISKS OR THOSE POSED TO OTHER INDIVIDUALS;

(II) PROVIDE OR ENSURE ACCESS TO A GENETIC COUNSELOR AS PART OF RECEIVING THE PRODUCT'S RESULTS;

(III) PROVIDE SPECIFIC PRIVACY POLICIES TO CONSUMERS;

(IV) COMPLY WITH THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA);

(V) RESTRICT THE TRANSFER OF A CONSUMER'S GENETIC INFORMATION; AND

(VI) MAKE PLANS FOR THE DESTRUCTION OF PRIVATE INFORMATION WHEN ENTITIES ARE SOLD OR NO LONGER IN OPERATION, OR BOTH.

(4) A PERSON MAY NOT:

(I) MAKE CLAIMS ABOUT CLINICAL VALIDITY THAT HAVE NOT BEEN SUBMITTED AND CLEARED BY THE U.S. FOOD AND DRUG ADMINISTRATION; OR

(II) USE DATA IN RESEARCH STUDIES OR REQUIRE SPECIFIC CONSENT OF PARTICIPANTS.

(B) THE DEPARTMENT MAY TAKE LEGAL ACTION TO RESTRICT MARKETING OF SPECIFIED LABORATORIES OR PRODUCTS IF THE SECRETARY DETERMINES THERE TO BE A PUBLIC HEALTH THREAT OR THAT THE LABORATORY OR PRODUCT IS NOT IN COMPLIANCE WITH THE REQUIREMENTS OF THIS SECTION.".

Appendix 2

**Introduction**

At the request of Delegate Shane Pendergrass, Vice Chair of the Health and Government Operations Committee, the Department of Health and Mental Hygiene conducted a review of the laws and policies of other states and conducted a literature review on the potential harms and benefits of allowing direct-to-consumer genetic testing (DTC) in Maryland. Since that time, the Department has completed a review of the literature on the harms and benefits as well as the clinical utility of services offered by DTC companies. Additionally, the Department has included a review of an expanded set of state policies and laws that have been used to protect consumers in their interaction with DTC genetic testing companies.

**Review of the clinical utility of services offered by DTC genetic testing companies:**

Direct-to-Consumer genetic testing companies offer a wide range of tests, from those with little clinical utility, such as a genes determining eye color, to those that evaluate serious medical conditions, such as the BRCA breast cancer genes (1).

Validity of testing relies on two components: (a) analytic validity, whether the lab accurately analyzes the biologic sample and (b) clinical validity, whether the result from the lab is interpreted in a clinically meaningful way. In the United States, the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulates laboratories that provide testing services and helps to ensure the analytic validity of services. After some initial concerns, now most DTC companies in the U.S. are regulated by CLIA (1).

In a 2013 study by Kalf and colleagues examined how the results of genetic testing were interpreted by 3 companies. Investigators created genotypes for a hypothetical population of 100,000 individuals and then calculated the predicted risks of disease using the methods published on the websites of 23andMe, deCODEme and Navigenics. The companies used different sets of single nucleotide polymorphisms (SNPs) and different average population risks for many of the diseases tested, resulting in substantially different predictions for the risk of the disease in individuals. For example, 27.1% of the hypothetical individuals would have received opposite responses from the different companies regarding their risk of Crohn's disease (2).

Of note, the company 23andMe now offers BRCA testing, a test that is characteristically different than many of tests that were evaluated in these studies. BRCA testing evaluates genomes for a specific gene, rather than SNPs, which give less specific information about disease risk. BRCA carriers have a greatly increased risk of breast cancer and ovarian and carrying this gene has potential profound health implications, with many people recommended to undergo a prophylactic mastectomy (3). This and other high risk testing on the market, have high clinical utility, but present their own potential risks to patients.

**Literature Review:**

In our previous communication to Delegate Pendergrass, the Department reviewed several studies of actual and hypothetical users of Direct-to-Consumer genetic testing. This review demonstrated mixed

findings on the impact of DTC genetic testing on patient anxiety and healthcare utilization. Since that time, a few studies have been published that further address these issues.

*Effects on Health Status and Behaviors:*

A large long-term evaluation of users of DTC genetic testing was recently published. In this study by Bloss and colleagues, 3,416 study participants initially purchased a genomic test and 1,325 had long-term follow-up over 1 year. The authors investigated the impacts of testing participation on patient anxiety, fat intake and exercise. In the 3 month follow-up study, published in the New England Journal of Medicine, and the year-long follow-up, participation in the DTC genetic testing service had little impact on these patient outcomes. Ninety seven percent of the sample had no test related distress. Of note, the genetic testing involved in this study did not involve more specific testing such as BRCA tests (4,5)

A small exploratory study by Wasson and colleagues followed 20 patients recruited from an urban primary care clinic. These patients were offered free DTC genetic testing from 23andme and were interviewed periodically over the course of one year. The panel of testing included a broad range of test results including testing for susceptibility to diabetes and varicose veins as well as BRCA testing. Many reported no significant impact from the testing, with several unable to recall the specific results of the study after 1 year. Most patients reported feeling relieved or pleased by their results. The authors did not report what specific results patients received and in such a small sample it would unlikely for these patients to have positive results for any of the rare, serious genetic diseases that were screened (6).

*Effects on Health Utilization:*

Bloss and colleagues also evaluated participants' use of health services, in particular their increased use of screening tests. Across the entire study population, the researchers did not find an increased rate of screening test completion according to patient self report. Thirty six percent of individuals in the overall study shared their test results with their physician and the sharing test results was associated with increased screening test completion. It is unknown if this increased screening represented increased compliance with screening recommendations or unnecessary, over- testing (4). In a 2012 study by Reid colleagues, 1,599 participants were offered genetic testing (that did not include BRCA testing), with 217 (13.6%) choosing to complete the testing. Utilization of health services was determined by evaluating health records. There were no significant differences in physicians visits or utilization of medical tests or procedures in the post-test period between those who did and did not choose testing (7).

The sharing of tests results with primary care physicians may present new counseling burdens on already busy practices. In 2012 nationally representative survey of primary care physicians by Bernhardt and colleagues, 58% of respondents felt confident interpreting genetic testing and with 40% feeling that results would be helpful in disease management (8). In most surveys, few physicians encountered DTC genetic testing frequently and no studies estimate the amount of time counseling may take (9).

Overall, there appears to be little impact of genomic testing on healthcare utilization. However, no well designed studies address the impact of DTC access to testing of higher risk studies, such as BRCA tests.

**Legal Action:**

DTC genetic testing has been challenging to regulate in part because no single agency clearly oversees all aspects of regulation (10). In our last communication, we noted that 37 states and the District of Columbia allow direct to consumer genetic testing. In 23 of the states that allow this type of testing, laws are silent on the issue, rather than explictly allowing and regulating DTC genetic testing. A handful of states allow limited direct to consumer testing for a select number of specific tests. There has been varied federal and state action taken to regulate DTC testing.

*Federal Action:*

The Food and Drug Administration (FDA) has the regulatory ability to oversee genetic testing, but has not to our knowledge clarified its regulatory approach (1,11). In 2010, the FDA sent several letters to DTC genetic testing companies indicating its intention to assert regulatory authority over them and held several public meetings to discuss possible regulatory approaches (1). Further regulatory action by the FDA is expected soon (12) .

The Federal Trade Commission (FTC) has authority to regulate the marketing of DTC genetic testing. On its website, it warns consumers to take at-home genetic testing with a "healthy dose of skepticism" (13). Thus far they have limited their action to the most flagrant false claims (1).

The Secretary of Health and Human Services' Advisory Committee on Genetics, Health and Society also weighed in on the regulation of DTC genetic testing. In its April 2010 report, it recommended a stratified approach such that higher-risk results would require more oversight than lower-risk results (19). This approach has been supported by other thought leaders as well (1).

*State Action:*

In addition to regulating access to DTC genetic testing, states have also enacted legislation to address misleading advertisement. According to a 2009 survey by the Genetics and Public Policy Center, 48 states have more general provisions addressing the false representation of the benefits of services provided (17). 4 states have more specific laws that could apply to DTC genetic testing. California and Nevada specifically outlaw the presentation of false or misleading scientific or medical claims and Nebraska and Pennsylvania explicitly outlaw false or misleading claims in privacy policies(18).

**Other policies and recommendations for regulation in the literature:**

Several medical associations have weighed in on approaches to regulating DTC genetic testing. The American College of Medical Genetics and the American Medical Association recommend that testing should only be performed with the guidance of a licensed healthcare provider (1). U.K. Human Genetics Commission and the European Society of Human Genetics, allow DTC but only with the involvement of

genetic counselor (1). American College of Medical Genetics suggests that consumers be specifically informed about the benefits and risks of genetic testing (14).

Many experts have raised concerns about the privacy of the potentially sensitive data held by DTC genetic testing companies. These companies are not required to meet HIPAA requirements (1). Special concerns have arisen when companies are sold or go bankrupt, which has occurred frequently in the DTC marketplace. It is often unclear what happens to the sensitive genetic information held by the defunct companies.

The U.S. Preventive Services Task Force recommends BRCA genetic testing only for patients with previous family history of breast cancer due to the likelihood of unnecessary stress and additional testing and treatment (15).

Secretary's Advisory Committee on Genetics, Health and Society raised concerns about the use of the resources of the DTC companies for research (16).

Finally, ethicists and policy makers have urged the prohibition of using DTC testing to evaluate third parties, minors and prenatal testing of fetuses(17) .

**Bibliography:**


1. Caulfield T, McGuire AL. Direct-to-Consumer Genetic Testing: Perceptions, Problems, and Policy Responses. Annu Rev Med. 2012 Feb 18;63(1):23–33.

2. Kalf RRJ, Mihaescu R, Kundu S, de Knijff P, Green RC, Janssens ACJW. Variations in predicted risks in personal genome testing for common complex diseases. Genet Med [Internet]. 2013 Jun 27 [cited 2013 Jul 17]; Available from: http://www.nature.com/doifinder/10.1038/gim.2013.80

3. Chen S, Parmigiani G. Meta-Analysis of BRCA1 and BRCA2 Penetrance. J Clin Oncol. 2007 Apr 10;25(11):1329–33.

4. Bloss CS, Wineinger NE, Darst BF, Schork NJ, Topol EJ. Impact of direct-to-consumer genomic testing at long term follow-up. J Med Genet. 2013 Apr 4;50(6):393–400.

5. Bloss CS, Schork NJ, Topol EJ. Effect of direct-to-consumer genomewide profiling to assess disease risk. N Engl J Med. 2011;364(6):524–34.

6. Wasson K, Sanders TN, Hogan NS, Cherny S, Helzlsouer KJ. Primary care patients' views and decisions about, experience of and reactions to direct-to-consumer genetic testing: a longitudinal study. J Community Genet [Internet]. 2013 Jul 7 [cited 2013 Jul 11]; Available from: http://link.springer.com/10.1007/s12687-013-0156-y

7. Reid RJ, McBride CM, Alford SH, Price C, Baxevanis AD, Brody LC, et al. Association between health-service use and multiplex genetic testing. Genet Med. 2012 May 17;14(10):852–9.

8. Bernhardt BA, Zayac C, Gordon ES, Wawak L, Pyeritz RE, Gollust SE. Incorporating direct-to-consumer genomic information into patient care: attitudes and experiences of primary care physicians. Pers Med. 2012 Sep;9(7):683–92.

9. Goldsmith L, Jackson L, O'Connor A, Skirton H. Direct-to-consumer genomic testing from the perspective of the health professional: a systematic review of the literature. J Community Genet. 2013 Jan 16;4(2):169–80.

11. Borry P, Cornel MC, Howard HC. Where are you going, where have you been: a recent history of the direct-to-consumer genetic testing market. J Community Genet. 2010 Oct 8;1(3):101–6.

12. Bollinger JM, Green RC, Kaufman D. Attitudes About Regulation Among Direct-to-Consumer Genetic Testing Customers. Genet Test Mol Biomarkers. 2013 May;17(5):424–8.

13. Y. At-Home Genetic Tests [Internet]. -Home Genet. Tests. 2006. Available from: http://www.consumer.ftc.gov/articles/0166-home-genetic-tests

14. American College of Medical Genetics. ACMG Statement on Direct-to-Consumer Genetic Testing [Internet]. 2008 [cited 2013 Jul 8]. Available from: http://www.acmg.net/AM/Template.cfm?Section=Policy_Statements&Template=/CM/ContentDisplay.cfm&ContentID=2975

15. U.S. Preventive Services Task Force. Genetic Risk Assessment and BRCA Mutation Testing: Draft Recommendation Statement. 2013. Available from: http://www.uspreventiveservicestaskforce.org/uspstf12/brcatest/draftrecbrcatest.htm

16. Leachman BSA, MacArthur DG, Angrist M, Gray SW, Bradbury AR, Vorhaus DB. Direct-to-consumer genetic testing: personalized medicine in evolution. ASCO Educ Book. 2011;34–40.

17. The Lancet Editorial Board. Direct to Consumer Genetic Testing. 2012 Jul 14;380.

18. Schlanger SJ. Filling in the Cracks: Improving the Regulation of Direct-to-Consumer Genetic Tests. J Heal Care Pol. 2011;14:S1.

19. Teutsch S. Direct-to-Consumer Genetic Testing: Report of the Secretary's Advisotry Committee on Genetic Health and Society. 2010.

**Questions for Public Comment:**

The Department would like to receive comments from impacted stakeholders and the public on whether DTC testing should be allowed in Maryland and if so, what, if any consumer protections should be put into place. Specifically, the Department would like comments on:

**1. Whether consumers should have direct access to genetic testing.**

**2. If direct access to genetic testing is authorized, what types of consumer protections (if any) should be included, such as:**

- **Quality controls;**
- **Disclosure requirements;**
- **Requirements for access to genetic counselors as part of the testing package; and**
- **Privacy requirements for companies conducting the testing.**

**3. If direct access to genetic testing is authorized, whether and what types of testing should be prohibited (such as testing for the BRCA gene or other high risk tests with clinical significance, or for prenatal testing of fetuses).**