



Michael D. Maves, MD, MBA, Executive Vice President, CEO

February 23, 2011

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee;  
Notice of Meeting [Docket No. FDA-2011-N-0066]

The American Medical Association (AMA) is pleased to offer its comments to the Molecular and Clinical Genetics Panel (Panel) regarding direct to consumer (DTC) genetic tests that make medical claims. Our comments are based on AMA policy and rooted in the AMA's dedication to the advancement of patient care and public health by supporting the nation's physicians and physicians-in-training. The AMA has consistently supported efforts to realize the full potential of personalized medicine and the great promise it offers to the delivery of individualized care that meets the particular needs of each patient. However, we have concerns that the unfettered and unregulated growth of genetic tests marketed directly to consumers will have a significant adverse impact on consumers and undermine the physician-patient relationship. In many cases, it also represents the unauthorized practice of medicine.

**We urge the Panel to offer clear findings and recommendations that genetic testing, except under the most limited circumstances, should be carried out under the personal supervision of a qualified health care professional, and provide individuals interested in obtaining genetic testing access to qualified health care professionals for further information.** While DTC genetic tests may offer some benefits to consumers, such as promoting awareness of the genetic bases of disease and increasing attention to healthy behaviors that prevent the onset of disease, the AMA is concerned about the potential of DTC genetic tests to cause harm to consumers and over time increase health care costs. Without the guidance of a physician, genetic counselor, or other genetics specialist, test results could be misinterpreted, risks miscalculated, and incorrect health and lifestyle changes pursued. At the very least, consumers will waste money purchasing tests with little value. A 2010 report issued by the Government Accountability Office (GAO) included startling findings from an undercover audit of commercial entities offering genetic testing, including inconsistent and conflicting test results, invalid scientific claims, and, in a clear violation of rules governing who may practice medicine, unqualified company employees providing misleading and inaccurate diagnostic information concerning a customer's genetic test results. These finding underscore the

importance of regulatory standards by which these commercial entities should be required to abide.

Of the several types of genetic testing available directly to consumers, the AMA is most concerned by those that may lead consumers to pursue inappropriate therapies or interventions. For example, patients will make important reproductive decisions based on the results of carrier screening for hereditary diseases. These decisions require careful consideration of both the screening results and other factors, and it is essential that a physician or other genetics professional ensure that patients are well-informed before making such decisions. Similarly, some DTC tests report the risks for developing serious diseases such as breast or ovarian cancer. Although many of these tests can only predict small increases or decreases in risk, we strongly believe that physicians should act as an intermediary to ensure that patients understand the results and the limitations of the tests, and what type of management or intervention should occur based on results. Still other tests predict response to certain drugs. While these tests are often accurate in predicting adverse reactions, effectiveness, or specific dose, the test results are usually one factor of many used to determine therapeutic options, and require the experience of a health care professional to apply to clinical practice. Even in cases in which DTC genetic test may not lead consumers to make inappropriate health care decisions, the involvement of a physician is essential in achieving benefit from test results. A recent study (Bloss et al., 2011, *NEJM*) found that consumers who shared the results of DTC genetic tests with their physicians were more likely to pursue healthier behavior, such as lowering fat intake and increasing the intensity of exercise.

In addition to establishing clear requirements for the involvement of physicians, genetic counselors, or other genetics specialists in all stages of genetic testing, **we urge the Panel to recommend strong oversight measures.** Companies marketing DTC genetic tests tout the potential benefits of their tests, but almost never explain the limitations. For example, genetic tests often require a complete clinical context to be meaningful. A positive result does not necessarily indicate a clinical diagnosis; instead, it may indicate an increased risk for developing a disease or condition, the phenotypic manifestations of which are variable in individuals. Conversely, since only a fraction of testable mutations are identified for genetically based diseases, a genetic test with a negative result is not indicative of the absence of disease risk. These concepts are seldom, if ever, communicated to consumers. The 2010 GAO report found examples of fraudulent and deceptive marketing practices, with companies making misleading claims about the reliability and capabilities of tests. **We encourage this Panel to make a recommendation that the FDA work with the U.S. Federal Trade Commission to require that DTC companies include all relevant information regarding capabilities and limitations of the tests directly to consumers who utilize their services as well as on their websites and in other literature advertising the tests.** These statements should be communicated in a meaningful fashion and should be readily apparent to consumers, not hidden in small text that consumers are not likely to read or understand. **We also recommend that such language contain a statement referring patients to physicians or other health care professionals not employed by the testing company to obtain further information.**

The AMA believes that properly regulating DTC genetic tests will reduce harm to consumers. **We believe that the most logical regulatory framework is a risk-based approach, similar to that used for regulation of medical devices, so that tests that carry the highest risk of harming consumers if misinterpreted have the strictest regulatory requirements. We also urge that for tests placed in the higher risk categories, results be reported directly to the consumer's designated physician or genetic counselor (neither of whom should also be employed by the company).** The GAO investigation revealed cases of unqualified personnel interpreting test results and providing what amounted to medical advice. Companies have stated that their tests are not intended to be diagnostic in nature, yet results are presented to patients as an increase/decrease in risk for developing certain conditions. We argue that this is in fact, diagnostic, especially to consumers seeing these results without the benefit of a health care professional to explain what they mean. This is the unauthorized practice of medicine and should be prohibited. We are pleased that some DTC companies have begun to involve patients' physicians when reporting results, but believe this should be standard and mandatory.

We support the FDA and its partners, the National Institutes of Health and the Centers for Medicare and Medicaid Services, in their initiative to create the Genetic Testing Registry (GTR), and encourage the inclusion of DTC genetic tests claiming to provide medical information (as opposed to non disease tests such as ancestry testing) in the GTR. **We also encourage the GTR to include information about the clinical validity and utility, or lack thereof, for each DTC test.** Physicians are increasingly demanding evidence that supports clinical validity and utility before routinely using genetic tests, and we believe that patients would be well-served if DTC companies reported such information on the GTR. The AMA has previously commented that participation in the GTR should be mandatory, not voluntary as it is planned to be.

The number of genetic tests available directly to consumers has proliferated rapidly, and several studies have reported that physicians find it difficult to keep up with the pace of genetic technology. Physicians are beginning to encounter patients who have taken DTC genetic tests, and realize that they must be prepared to interpret the results and explain the capabilities and limitations of the tests. The AMA has worked to educate physicians on advances in genetic testing, including the availability of these tests directly to consumers. **Therefore, we urge this Panel to recommend that the FDA prioritize provider education as it continues its exploration of regulatory issues.** We stand ready to work with the FDA to ensure that the physician workforce is well-informed on the risks and benefits of DTC genetic testing.

Sincerely

A handwritten signature in black ink, appearing to read "Mike Maves". The signature is written in a cursive, flowing style.

Michael D. Maves, MD, MBA