



**ASSOCIATION FOR MOLECULAR PATHOLOGY**  
*Education. Innovation & Improved Patient Care. Advocacy.*  
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## **FOR IMMEDIATE RELEASE**

### **AMP Issues Position Statement on Direct-to-Consumer Genetic Testing; Supports DTC Testing When Information is Actionable for Patients**

**Bethesda, MD, February 10, 2015:**

The Association for Molecular Pathology (AMP), the premier global, non-profit organization serving molecular laboratory professionals today released its updated position statement on Direct Access Genetic Testing, concluding that clinically meaningful tests could benefit patients and consumers and should be made available directly to the public, but only if certain conditions are met. Conversely, AMP opposes direct access to genetic tests that are performed for the purpose of selling additional health-related products or services and do not provide clinically meaningful or actionable information. For recreational or novelty genetic testing, such as ancestry testing, AMP maintains a neutral position as these reports typically do not include health information. The AMP Direct Access Genetic Testing position statement is now available online at: <http://bit.ly/1A96OQQ>

“Direct access to genetic testing has been much debated. As a result, we spent several months examining the current DTC genetic testing landscape before amending our position on the subject,” said Roger D. Klein, MD, JD, Chair of the AMP Professional Relations Committee. “When clinically meaningful genetic information can motivate patients to make lifestyle changes that could prevent disease, or to encourage them to seek professional care that could prove beneficial or even lifesaving, we support DTC testing. However, this information should come from high-quality tests, and DTC services should meet the conditions we have outlined in our statement.”

As a result of the evolving healthcare environment, which allows people direct access to genetic test results from the servicing laboratory, the Direct Access Genetic Testing position statement developed by AMP identifies and addresses four categories of genetic testing: clinically meaningful, business interest, ancestry, and recreational/novelty.

“In his recent announcement to launch a Precision Medicine Initiative, President Obama called for tools to enable every American to be able to securely access and analyze their own health data, which prompted us to release this statement at this time,” said AMP President, Janina Longtine, MD. “AMP supports the goals of this ambitious program, but cautions that FDA’s recent proposal to apply medical device regulations intended for manufacturers to laboratory professionals and laboratories, combined with the broad non-coverage decisions from payers, which could ultimately hamper the clinical implementation of the very goals of the initiative. The Administration should work to ensure that all HHS policies support this investment in precision medicine.”

#### **About the Association for Molecular Pathology**

The Association for Molecular Pathology (AMP) was founded in 1995 to provide structure and leadership to the emerging field of molecular diagnostics. Through the efforts of its Board of Directors, Committees, Working Groups, and members, AMP is the primary resource for expertise, education, and collaboration on the fastest growing fields in healthcare. AMP members influence policy and regulation on the national and international levels, ultimately serving to advance innovation in the field and protect patient access to high quality, appropriate testing. More information about AMP is available at [www.amp.org](http://www.amp.org).

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