

Empowering Consumers Through Accurate Genomic Tests

Jeffrey Shuren, M.D., Director - Center for Devices and Radiological Health, FDA



We've come to recognize that almost every disease has a genetic component, and many consumers now are eager to know more about their genetic profiles. They need only send a sample of their DNA collected from their saliva or from a cheek swab to a company, and in exchange they'll get back information about their genetic risk for development of future disease.

FDA understands and supports people's interest in having access to their genetic information and believes such information can help them make more informed choices about their health - so long as that genetic information is accurate - that the results are correct, meaningful and written in a way that consumers can understand. FDA reviews genetic tests for medical conditions, whether they are intended to be ordered by a healthcare practitioner or directly by the consumer, to assure that consumers receive accurate test results.

Telling someone they are at high risk for a life-threatening cancer when they are not — or that they are at low risk for diabetes when they actually are at high risk for this chronic disease does not empower consumers. Consumers are not empowered by tests that tell them they need higher or lower doses of widely-used drugs, when the opposite is true. Moreover, some genetic tests have questionable value. Their impact on patient health is not known, and there are no guidelines for consumers or

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healthcare practitioners on how to interpret these test results, in part because the risk of getting a disease depends on a number of other factors such as age, sex, ethnicity, or environment and because genetic tests may only assess a limited number of genetic variations that only account for a small part of the risk.

Concerns about the need to demonstrate accuracy were at the heart of our five-year effort to work with the firm 23andMe that resulted last year in the company ceasing marketing its disease risk and drug dosing tests until it could demonstrate their accuracy.

These concerns were hardly theoretical ones. In 2010, at the behest of Congress, investigators from the U.S. Government Accountability Office purchased direct-to-consumer (DTC) genetic tests from four different companies — including 23andMe — and submitted two samples of their DNA to each company to receive risk predictions for 15 common diseases. The results varied across the four companies. One investigator was told that he was at below-average, average, and above-average risk for prostate cancer and hypertension. In some cases, the risk predictions conflicted with an investigator's actual medical condition.

FDA is not [standing in the way of 23andMe selling tests](#) [1]intended to help consumers trace their ancestry, identify relatives and tell them why they like or don't like the taste of cilantro. Yes, that information can be fun. But Alzheimer's disease, cancer and heart disease are serious matters. Our concern remains that genetic tests for diseases, just like other tests for medical conditions, such as hemoglobin A1C for diabetes (glucose control) should be accurate. Armed with that accurate information, consumers can take appropriate steps to take charge of their health.

Accurate information empowers. Consumers deserve no less.

This blog originally appeared at the FDA Voice blog. You can find it by [clicking here](#) [2].

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