

Trick or Treat? FDA Approves A New 23andMe Report



By Chuck Dinerstein, MD, MBA — November 2, 2018



Courtesy of Pedro Ferreira [1]

This Halloween, with much fanfare the FDA and 23AndMe simultaneously announced a new service, genomic testing for an individuals ability to metabolize 50 commonly used prescribed and over the counter medications.

“The decision allows 23andMe to report directly to customers, without a prescription, the influence their genetics have on how well they metabolize certain medications.” [1]

A word from science.

Our response to medications is based in part on their “bioavailability” – how much of the medicine is active in our body and how long it hangs around. It is influenced by how it is administered (“Take on an empty or full stomach, do not take with grapefruit juice”) and by how quickly our body metabolizes the medication. This chemical breakdown can be more rapid or slow and become clinically significant based upon our genetic profile. Alcohol dehydrogenase which breaks down alcohol has several genetic variants influencing the rate of alcohol’s breakdown; some are associated with causing increasing flushing, nausea, and an increased heart rate all of which make you uncomfortable and decreases the likelihood that you will drink in a manner that results in addiction. [2]

The poster child for this, at least in my world of vascular surgery is clopidogrel or Plavix – a

medication that interferes with blood clotting by hindering the aggregation of platelets and benefits patients undergoing arterial surgery or angioplasty. But 20-25% of individuals have genetic variations that made Plavix less effective. [3] By utilizing a genetic test, I can more readily identify those patients and choose more effective alternatives. At this point, the FDA has identified over 100 such medications. The new genetic sequencing by 23andMe provides consumers with their genetic sequences for some genetic variants associated with increased or decreased drug metabolism.

Because these are genes, their presence varies with race. Here is a quick table for genetic variation of the 2C19 gene, a common “influencer” of metabolism. [4]

Variation	Caucasian/White	African/Black	Asian	
Slower metabolism		3-5%	3%	15-20%
Faster metabolism		About 20%	About 20%	Less than 5%

So roughly a quarter of our population has some variation in this particular gene that impacts drugs given for psychiatric conditions. Now, back to our story.

The Treat

To gain FDA approval, 23andMe had to demonstrate the accuracy and reproducibility of these tests, according to their press release it was 99%. And because this information needs to be interpreted and understood, they also had to demonstrate that patients reading these reports duly comprehended the information they were given, 90% was the stated number. In their words, FDA approval

“... enables 23andMe to provide customers with information on whether they are predicted to be fast or slow metabolizers based on their genetics.”

To foreshadow the coming “trick,” 23andMe also states that, “Studies showed that more than 97 percent of users understood that they ***should not use the report to make any changes to treatment without consulting their doctor.***” (Italics added) It turns out that the FDA views this new 23andMe report as a moderate risk and has limited its use.

The Trick

Here are the conditions and limitations of these tests according to the FDA.[5]

“This test should be used appropriately because it does not determine whether a medication is appropriate for a patient, does not provide medical advice and does

not diagnose any health conditions. Consumers should not use this test to make treatment decisions on their own. Any medical decisions should be made only after discussing the results with a licensed health care provider, and results have been confirmed using clinical pharmacogenetic testing.”

Tim Stenzel, director of the Office of In Vitro Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health

Given all of these caveats, the new 23andMe test is more educational entertainment than any diagnostic let alone therapeutic help. And 24 hours after its initial announcement, the FDA felt compelled to issue an additional statement about similar genetic testing that have not be approved.

“We believe, with more scientific study, there is great potential for pharmacogenetics. We have so much more to learn about the use of these tests for specific medications, what the results mean, and how we can apply the information to improve a patient’s health. While we are committed to supporting innovation in this area, we will also be vigilant in protecting against the potential risks.”
[6]

Pharmacogenetics role in more precisely guiding care is growing, but is this approval a way to further science or provide another entertainment venue? The wholly appropriate FDA limitations make the test useful in raising awareness, and concern. The 23andMe report, at this juncture, is a self-administered screening tool and the science about screening tools is clear. They generate benefits in proportion to how many individuals have the “problem” and they generate unnecessary health care costs for those who do not. 23andMe has not determined when they will make this new information available to consumers. It would be nice to see a cost-benefit analysis of the report's impact on improving health care.

[1] [News Release](#) [2]- 23andMe Granted The First and Only FDA Authorization For Direct-to-Consumer Pharmacogenetic Reports

[2] [The Genetics of Alcohol Metabolism: Role of Alcohol Dehydrogenase and Aldehyde Dehydrogenase Variants](#) [3]

[3] [Clinical Implementation Of CYP2C19-genotype Guided Antiplatelet Therapy Reduces Cardiovascular Events After PCI](#) [4]

[4] [Genetics of CYP2D6 and CYP2C19 Drug Response](#) [5]

[5] [News Release](#) [6]- FDA authorizes first direct-to-consumer test for detecting genetic variants that may be associated with medication metabolism

[6] [FDA Statement](#) [7]- Jeffrey Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health and Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research on agency's warning to consumers about genetic tests that claim to predict patients' responses to specific medications

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Links

[1] <https://www.flickr.com/photos/pedroferrer/3615212504>

[2] <https://mediacenter.23andme.com/press-releases/23andme-granted-the-first-and-only-fda-authorization-for-direct-to-consumer-pharmacogenetic-reports/>

[3] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3860432/>

[4] https://www.ahajournals.org/doi/abs/10.1161/circ.132.suppl_3.11802

[5] <http://services.dnadirect.com/grc/patient-site/psychiatric-drug-response/genetics-of-cyp2d6-and-cyp2c19-drug-response.html>

[6] <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm624753.htm>

[7] <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm624794.htm>