



# UPDATE: GENETIC TESTING: ETHICS, REGULATION, AND ONLINE ACCESSIBILITY

BY COURTNEY THIELE, LEGAL INTERN (2010-2011)

People are often uncomfortable with the unknown. This is even more the case with our health, where people want to know as much as possible about potential diseases. With the rapid advances in medical science and technologies, notably the completion of the Human Genome Project in 2003, people are turning to their genetic make-up to fill in some of the answers. Yet, caught up in the desire to find out all we can about ourselves, we may unwittingly create more unknowns in the process.

During May 2010 a national drug store chain planned to begin selling over-the-counter, direct-to-consumer (DTC) genetic testing kits. The kits ranged from \$20 - \$30 in addition to the report fee costs, which ranged from \$79 - \$249.<sup>1</sup> When the FDA began investigating DTC genetic testing companies, the drug store chain reversed course, postponing the availability of the kits.<sup>2</sup>

Postnatal genetic testing, or adult genetic testing, is frequently employed for the purpose of screening whether or not an individual is the carrier of a disease that could either be passed down to his or her children or that could be expressed in him or herself.<sup>3</sup> Genetic testing has the potential to become accessible to the masses with the production and marketing of DTC genetic testing kits. These kits were on the market for a short period of time at the beginning of last summer (2010) when the FDA launched an investigation into the kits.<sup>4</sup> The discussion of DTC genetic tests continued with an FDA meeting on March 8-9, 2011, investigating the implications, benefits, and risks associated with DTC genetic tests. Subsequently, the FDA panel recommended that many types of genetic tests, in particular pre-symptomatic tests with a “high predictor for disease,” should only be available by medical prescription.<sup>5</sup> Other recommendations from the panel include having confirmatory tests for rare genetic disorders and having genetic counselors available for follow-up through the DTC testing companies.<sup>6</sup>

DTC kits, however, can still be purchased through websites such as 23andMe.<sup>7</sup> With the claim, “all it takes is a little spit,” 23andMe offers genetic information to the consumer requiring minimal effort: a little saliva and the purchase of a genetic sequencing package for \$199 plus a nominal monthly fee. This package includes testing results for 189 genetic tests as well as receiving updates about your own genomics as new findings are released.<sup>8</sup> Another company, Pathway Genomics, currently offers five different genetic testing packages and breaks down their genetic testing offerings into eleven genetic markers

for drug response and seventy-two different pre-pregnancy diagnoses.<sup>9</sup>

Ethical concerns regarding genetic testing, particularly DTC genetic testing, need to be weighed carefully. In many cases these genetic tests are used when a major health concern or decision is at hand. For individuals who have a family history of a particular genetic disorder, they may want to see what the likelihood is of developing the disease themselves. Other times the results of genetic testing are used in making reproductive decisions. Clearly in these scenarios major life concerns are being addressed. The potential effects from the results of genetic testing can be significant in a person’s life. Concern is particularly amplified with DTC genetic testing kits. Issues of inaccuracy, interpretation, and risk-benefit analysis require careful consideration. The average consumer often does not have the knowledge base or the access to obtain the appropriate information for properly understanding the results of DTC genetic tests.

We must note that genetic testing is not inherently negative. There is potential for significant good to come from the increase of information available through genetic testing. Identifying genetic diseases and conditions at an early stage when intervention is possible is clearly a great benefit to the patient. As Leon Kass recognizes, the foreknowledge of treatable genetic propensities would be greatly beneficial.<sup>10</sup> We must consider, however, if the proposed benefits outweigh the present concerns. ●●●

1 Douglas Podolsky, “Should You Screen Your Genes at Walgreens?” *Consumer Reports*, May 12, 2010, <http://news.consumerreports.org/health/2010/05/at-home-genetic-test-kits-should-you-screen-your-genes-at-walgreens.html> (accessed May 11, 2011).

2 Ibid.

3 Pat Millmoe McCarrick, “Genetic Testing and Screening,” Bioethics Research Library, <http://bioethics.georgetown.edu/publications/scopenotes/sn22.htm> (accessed May 31, 2011).

4 Bartha Maria Knopper, et al., “Direct-to-Consumer Genetic Testing: Driving Choice?” *Expert Reviews of Molecular Diagnostics*. 10(2010): 965–968.

5 Department of Health & Human Services, “Summary from the Molecular & Clinical Genetics Panel Meeting – March 8 & 9, 2011” <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/MolecularandClinicalGeneticsPanel/UCM246907.pdf> (accessed May 11, 2011).

6 Ibid.

7 Company Homepage, [www.23andme.com](http://www.23andme.com) (accessed May 11, 2011).

8 “How it works,” <https://www.23andme.com/pgs/> (accessed May 11, 2011).

9 “DNA Reports,” <https://www.pathway.com/dna-reports/full-list-of-conditions> (accessed May 11, 2011).

10 Leon Kass, *Life, Liberty and the Defense of Dignity* (San Francisco: Encounter Books, 2002), 130.