Expert opinions divided on FDA approval of 23andMe's DTC genetic test

On February 19, the US Food and Drug Administration (FDA) authorized 23andMe to market a direct-to-consumer (DTC) carrier test for Bloom syndrome, one of the "Jewish genetic diseases" offered in test panels. The agency's decision to classify such carrier screening tests as class II medical devices, and exempting them from premarket review, may pave the way for a return of DTC genetic testing. The decision garnered mixed reviews from genetic counsellors and clinicians.

"The greater impact is not in returning carrier testing for Bloom syndrome specifically, but in laying the framework for reporting carrier status of all single gene recessive conditions," said Joshua Petrikin, MD, director of Neonatal Genomics at the Center for Pediatric Genomic Medicine at Children's Mercy Kansas City, Missouri. "This is a useful step in empowering consumers with knowledge of their genetic predispositions and beneficial as a starting place for patients' discussions with their physicians."

Joy Larsen Haidle, MS, president of the National Society of Genetic Counselors and genetic counselor at the Humphrey Cancer Center in Minneapolis, Minnesota, disagreed. "This new policy is a slippery slope and might unwittingly set a dangerous precedent. Why not just add a bunch of other genes? Genetic testing is not a one-size-fits-all option," she toldMedscape Medical News.

Carrier testing for Bloom syndrome provides information on reproductive options, such as prenatal diagnosis, and is actionable. Several people interviewed agreed however, that predictive DTC testing would never be appropriate for a late-onset dominant genetic condition without treatment or prevention options, such as Huntington disease (HD).

Read full, original story: FDA Clearance of DTC Genetic Test Gets Mixed Reviews