Direct-to-consumer genomic testing concerns explored

February 18 2014

Image courtesy of Blausen Medical

(HealthDay)—Various concerns relate to direct-to-consumer genomic testing, according to an ideas and opinions piece published online Feb. 10 in the *Annals of Internal Medicine*.

In August 2013, the company 23andMe launched an advertising campaign to sell its Personal Genome Service (PGS). Michael F. Murray, M.D., from the Geisinger Health System in Danville, Pa., discusses the U.S. Food and Drug Administration warning letter issued to 23andMe to discontinue marketing the PGS until it received FDA approval.

The author explains that 23andMe receives DNA samples in the mail and provides detailed analyses of genomic data for consumers, including reports on 254 diseases and conditions. However, these reports are

mainly based on genome-wide association studies. For most of the conditions in the reports, there is no evidence that the results of the association studies can be applied as appropriate screening tests. In addition, concerns relating to direct-to-consumer PGS include economic concerns, such as increased health care costs for managing patients post-testing, and a concern that overregulation may limit innovation in this arena.

"Physicians should push for the building of patient-centered infrastructure to assist them in delivering valid genome-directed care as it develops," the author writes. "As for 23andMe, it would seem logical for the company to invest in research that determines the actual clinical value of their tests, and they should be expected to meet the same evidence standards as other device manufacturers under FDA jurisdiction."

More information: Full Text (subscription or payment may be required)