Measuring Health Risks

What to consider before taking a genetic test at home

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Last spring, the Food and Drug Administration (FDA) allowed 23andMe, a private biotechnology company based in Mountain View, California, to market genetic health risk (GHR) tests for 10 diseases or conditions directly to consumers for the first time.

The agency noted that this would enable individuals to access information about their genetic risks for certain illnesses, including Alzheimer's and Parkinson's diseases, but counseled caution. "It is important that people understand that genetic risk is just one piece of the bigger puzzle," says Jeffrey Shuren, MD, the director of the agency's Center for Devices and Radiological Health. "It does not mean they will or won't ultimately develop a disease."

Typically, direct-to-consumer (DTC) genetic tests analyze DNA from a sample of an individual's saliva or blood or from a cheek swab that's been sent to a lab. According to the Federal Trade Commission, prices of these tests can range from less than $100 to a few thousand dollars. But because diseases are caused by complex interactions in the body, results shouldn't be used to diagnose a condition or determine decisions about treatment.

Furthermore, users should consult a health care professional if they have questions or concerns about test outcomes, the FDA advises.

The agency recently relaxed its regulation of DTC genetic tests and now requires only a one-time review in order to ensure that screenings meet FDA requirements. After that, companies may enter the market with new GHR tests without further review, says Scott Gottlieb, the agency's commissioner.