



HEALTH CARE

23andMe is jumping back into the market

By Mitchell Hartman

October 21, 2015 | 5:00 AM



23andMe, a DNA service, wants to collect valuable genetic data to tell consumers more about their health. - Brendan Lim/Flickr

After two years of being out in the cold with the Food and Drug Administration, the direct-to-consumer genetic testing company 23andMe is jumping back into the market again. The company says FDA has now approved it to offer genetic tests to consumers to determine if they are carriers of 36 relatively rare genetically-linked diseases, including sickle cell anemia and cystic fibrosis. The company will still not be able to offer consumers tests of their own risk of developing more common, and potentially serious, conditions, such as Alzheimer's and breast cancer.

Arthur Caplan, a medical ethicist at New York University, said that 23andMe started out pitching consumers on so-called 'recreational' genetics — tests to reveal information about a consumer's ancestry, for instance. Then, they moved into genetic testing to reveal health and disease-risk information. The halt of that business line came when FDA demanded the company show their testing was safe and effective.

“To prove it’s safe: Is it accurate enough to be useful?” Caplan explained. “And to prove it’s effective: Can the test information be understood? Can it be actionable? Do you know what to do if someone tells you, ‘You’re at twice the risk for this,’ or, ‘You don’t have to worry about that.’”

Now 23andMe has said it has FDA’s OK to test consumers for carrying genetically-linked diseases that they could pass on to their offspring. Dan Mendelson follows the industry at Avalere Health.

“Consumers want this information,” said Menelson. “They want to understand more about themselves and their bodies and they want to know what’s on their genome. This information will whet the demand of consumers for more information.”

Mendelson and Caplan agree that in the future consumers will have more and more access to detailed information about their own genome, if they want it. And both say that companies like 23andMe will need to offer consumers high-quality genetic counseling, to help them understand and use the information.

Dr. Robert Green, a geneticist and researcher at Harvard Medical School, has studied how consumers use direct-to-consumer genetic information about themselves. “Consumers who elect to purchase these services, at least at this stage, do a very good job of understanding the strengths and limitations of the information that they’re receiving—at least so far,” said Green. “I think this is something that has to be monitored as these services expand their market to less-sophisticated individuals.”

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