FDA Panel: Physicians Key in DTC Genetic Tests

BY ALICIA AULT

FROM THE FDA'S MOLECULAR AND CLINICAL GENETICS ADVISORY COMMITTEE MEETING

GAITHERSBURG, MD. – The Food and Drug Administration should require that genetic tests sold directly to consumers should in some cases be ordered by a trained health care professional, and that such professionals should interpret results of most of these tests, an advisory committee to the agency has urged.

The panel did not take any formal votes during the meeting, but discussed a variety of issues related to tests that are currently sold, almost without any regulation, to consumers over the Internet. Last year, the FDA notified manufacturers of such tests that they must comply with agency rules, and the agency is working with companies now to help them win approval.

The tests run the gamut from diagnostics that determine carrier status for diseases like cystic fibrosis, to those that test for the presence of a specific mutation like BRCA or assess the risk of developing cardiovascular disease or certain cancers. A number of tests on the market have no scientific evidence to substantiate their claims for being able to predict outcomes such as whether a child will excel at sports.

Test makers and the consumer member of the panel said that Americans have the right to their own genetic data, and that in all likelihood, consumers would consult with a physician.

In July 2010, the agency estimated that as many as 700 laboratories offer such direct-to-consumer (DTC) genetic tests.

During the course of the 2-day meeting, the 22 committee members struggled over whether the benefits of consumers' having access to such data outweigh the risks of their being unable to understand the results, or perhaps their becoming falsely reassured or upset by them. The panelists gave the agency some suggestions on how the risks of poor communication or bad test design could be mitigated.

But most of the debate centered on the role of physicians or trained health care professionals, and most of the panelists believed that professionals should be centrally involved at some point in the process. Test makers and the consumer member of the panel, for their part, said that Americans have the right to their own genetic data, and that in all likelihood, consumers would consult with a physician, especially if it were for a serious condition such as Huntington's disease.

"As a patient, if I got a test result like that, I'd take it to my doctor," said Tiffany House, the panelist's consumer representative. "I'd think they'd probably run to their doctor with this information," said Ms. House, who is a board member of the International Pompe Association.

After the meeting, FDA officials acknowledged that there was no real consensus on what role physicians should play. "We got lots of diverse advice," said Alberto Gutierrez, Ph.D., director of the Office of In Vitro Diagnostic Device Evaluation and Safety at the FDA's Center for Devices and Radiological Health.

He said that the agency would likely have to review each genetic test to determine whether it should be directly available to a consumer, and if so, whether a physician should order it or receive results directly. With so many opinions expressed, it may take awhile for things to settle out, said Elizabeth Mansfield, Ph.D., director of the personalized medicine staff in that same CDRH office. "We need to digest what came out of this meeting."

The FDA usually follows its panels' advice, but is not required to do so.

The FDA asked the panel to assess five test categories (carrier tests, "presymptomatic" tests, susceptibility tests, pharmacogenetic tests, and nutrigenic tests). The agency wanted to know whether some categories should be

classified as lower or higher risk and thus be subject to more regulatory restrictions.

The panel did not feel comfortable with the selling of carrier tests (that is, those that identify cystic fibrosis, Tay-Sachs disease, and other conditions) directly to consumers.

"Many of these disorders have a spectrum of communication that can't be well communicated outside of clinical consultation," said panelist Ira Lubin, Ph.D., a clinical molecular geneticist at the Centers for Disease Control and Prevention.

For tests that assess the risk of common conditions such as cancer, Alzheimer's, or cardiovascular disease, the panel was concerned that the results might be falsely reassuring or might discount environmental or lifestyle factors that might also contribute to risk.

"I don't think any of us are saying the patient or the consumer doesn't have a right to know," said panelist Joann Boughman, Ph.D., CEO of the American Society of Human Genetics.

"I would suggest we are not ready yet to put this directly into the consumers' hands," he said.

Former FDA official Mary Pendergast, who now works as a food and drug consultant and adviser to some companies that seek to market genetic tests, said that the panel was being paternalistic in its insistence on looking for a way to keep the tests from being sold directly to consumers.

"There is an alternative to this highly paternalistic approach; that information in and of itself is not harmful," said Ms. Pendergast.

A government-sponsored study that was presented at the meeting seemed to back her assertion. The National Human Genome Research Institute's Multiplex Initiative found that people who underwent tests for eight common diseases were highly satisfied with the results – regardless of what those results showed – and that they felt as if they understood the implications and limitations of the tests.

The 266 people who took the tests tended to have more positive than negative emotions in the wake of receiving results, said Colleen McBride, Ph.D., the study's designer and a senior investigator at the institute's Social and Behavioral Research Branch. ■