

Experts Consider Issue of At-Home Genetic Tests

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WASHINGTON — The use of at-home genetic tests raises ethical dilemmas for both patients and physicians, several speakers said at a forum sponsored by the Johns Hopkins University Genetics and Public Policy Center.

"Let's be practical," said Richard T. Scott Jr., M.D., who is a founding partner of Reproductive Medicine Associates of New Jersey in Morristown. "I'm fortunate because I'm a subspecialist—when I meet with my patients, I usually get an hour. But now you're an internist—you have 7 to 10 minutes. The patients are going to walk in with their letter [summarizing their test results], and you've got 7 minutes to get through that, it's going to create a problem."

In general, "things which move patients toward being better informed so they have

Dr. Mennuti, who is also president-elect of the American College of Obstetricians and Gynecologists. "Here you're communicating with someone who has an employer-employee relationship with the laboratory. There is a potential for a conflict of interest."

Customers have several reasons for using at-home tests, Ms. Phelan said.

"One is access to a test that their physician did not know about, did not choose to offer, or did not recommend. Number

two is to get it interpreted by experts who actually understand the nuances. And third is insurance discrimination or worry about insurance discrimination," she explained.

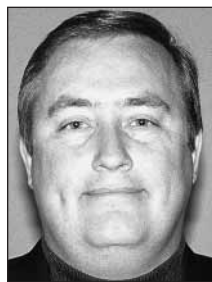
Physicians' lack of genetic knowledge is a real issue, said R. Alta Charo, professor of law and medical ethics at the University of Wisconsin at Madison.

She noted that when she worked for the now-defunct Federal Office of Technology Assessment about 15 years ago, the of-

fice did a study on sperm donation and surveyed physicians about their choices of men they would allow to donate for their patients.

"We discovered a woeful lack of understanding of basic genetics," she said.

"They would screen out perfectly healthy men who had first-degree relatives with hemophilia—apparently not recognizing that if they were healthy they couldn't have the hemophilia mutation—but would allow in men who had



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DR. SCOTT

a better understanding of their circumstances and make better decisions in their life, including treatment decisions, have to be good," he added.

"But when it comes to putting these tests together, the real question will be what tests are you going to offer, and how are you going to decide if those tests are appropriate?" he said.

Whether physicians want them or not, at-home genetic tests are out there. Many of the tests available are for fertility- or gynecologic-related conditions.

One company, San Francisco-based DNA Direct, offers tests for *BRCA* mutations, thrombophilia, hemochromatosis, cystic fibrosis, and α_1 -antitrypsin deficiency. Prices for the tests range from \$199 to \$3,311 and include a "personalized report" of the results and phone consultation with a genetic expert.

Many of the tests are done with a cheek swab; the sample is sent through the mail.

For tests that require a blood sample, the customer is directed to a federally certified lab that collects the sample and then ships it in the manner required, according to Ryan Phelan, DNA Direct's founder and CEO. In either case, the customer remains anonymous throughout the process.

Michael Mennuti, M.D., chair of the obstetrics and gynecology department at the Hospital of the University of Pennsylvania in Philadelphia, also expressed concerns.

For instance, "when you have laboratory tests available to patients who have a problem, and you report a normal result [on the first test], then the patient's next question is, 'Well, what is causing this problem, and what's the next test?'" said

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- Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders.
- Patients started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior.
- Cymbalta is not approved for use in pediatric patients.

Cymbalta should not be used concomitantly with monoamine oxidase inhibitors (MAOIs) or thioridazine and not in patients with uncontrolled narrow-angle glaucoma.

Clinical worsening and suicide risk: All adult and pediatric patients being treated with an antidepressant for any indication should be observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially when initiating drug therapy and when increasing or decreasing the dose. A health professional should be immediately notified

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Cymbalta should not be administered to patients with any hepatic insufficiency or patients with end-stage renal disease (requiring dialysis) or severe renal impairment ($\text{CrCl} < 30 \text{ mL/min}$).

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Most common adverse events ($\geq 5\%$ and at least twice placebo) in MDD clinical trials were: nausea, dry mouth, constipation, fatigue, decreased appetite, somnolence, and increased sweating. Most common adverse events in diabetic peripheral neuropathic pain (DPNP) clinical trials were: nausea, somnolence, dizziness, constipation, dry mouth, increased sweating, decreased appetite, and asthenia.

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parents with Huntington's chorea and who were young enough not have presented [with symptoms]."

Although medical schools have since made great strides in these areas, "I would suspect that there is still a relative lack of sophisticated understanding of modern genetics prevalent among many physicians, and therefore they may not pick up the kind of things patients might have that would explain their symptoms," Ms. Charo continued.

"One of the advantages [of at-home tests] is that people may detect something that may otherwise go overlooked," she said.

Some panelists expressed concern at the lack of regulation of at-home genetic tests.

Gail Javitt, policy analyst at the Genetics and Public Policy Center, noted that state laws applying to at-home tests vary greatly.

"Some states require a health care provider to order a test and get the results back; other states don't require this," Ms. Javitt pointed out. But "even when a provider's involvement is required, it does not necessarily have to be the patient's personal physician. It can be a provider associated with the company offering the test."

As for the actual tests, there is little government oversight, she continued. "Most genetic tests are provided by clinical laboratories, and the laboratory director decides when to offer the tests and what tests to offer.

"Labs are subject to general quality standards, but these are not genetic test-specific. Of the more than 800 tests currently out there, only a handful are regulated by the [Food and Drug Administration]. Indeed, FDA provides more oversight for home pregnancy tests than it does today for most genetic tests," she said.

Steve Gutman of the FDA's Office of In

Vitro Diagnostics, who was in the audience, said that the FDA is "not disinterested" in this area.

The agency "is not unaware of very colorful array of forces that are operating here, and it does not have easy answers. The unanswered question is how the FDA might move from the small set of commercial tests it now regulates to broader regulation of building blocks of home-brewed tests or the home-brewed tests themselves.

"I can't make any promise about timelines, but I can make a promise that the last chapter hasn't been written. It's a novel in progress," he noted ■



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