



U.S. lab testing industry braces for new FDA role

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By Kim Dixon

CHICAGO, Oct 9 - Medical laboratories and companies that make genetic tests are bracing for more oversight from U.S. regulators, which are concerned that inaccurate results from genetic tests could pose a risk to patient safety.

Most diagnostic tests to check for conditions like high cholesterol or diseases like AIDS cannot make their way to market before getting clearance by the U.S. Food and Drug Administration, which requires years of clinical trials.

But a growing segment of advanced genetic tests developed by labs like Quest Diagnostics and companies like Genomic Health Inc. use software programs to interpret results. Regarded as a service rather than a product, such tests have not fallen under the FDA's purview.

But the agency last month said it intended to begin regulating these tests, which can guide treatment for cancers, Alzheimer's and heart disease. Because such oversight could significantly prolong the product development process, the industry is reeling.

"New drugs and medical devices go through a review process that can take years and years, and cost millions of dollars," said Richard Samp, lawyer for the [Washington Legal Foundation](#), a free-market group that filed a petition late last month protesting a greater FDA role.

Chuck Silverman, director of government and regulatory affairs at Quest, the biggest U.S. lab company, said new agency oversight would stifle medical practice and jeopardize the use of tests already accepted by the medical community.

"We are an innovator and our concern is that at that cutting edge, it will restrict access," Silverman said.

The gene and protein-based tests are part of a movement toward "personalized medicine," which seeks to better target the most effective drugs for each patient population.

Use of the tests has grown exponentially since the mapping of the human genome, experts said. That project, completed in 2003, identified 30,000 genes located in human DNA.

The tests in question "answer a treatment decision like 'Should I do chemo or should I not do chemo?'" said Gail Javitt, law and policy director of the Genetics and Public Policy Center at Johns Hopkins University. "Figuring out a way to access clinical validity ... in a scientifically rigorous way is important."

The FDA put its regulatory guidance out on Sept. 5 and will take public comments until December.

LARGE STUDIES LACKING

The U.S. Centers for Medicare and Medicaid has long regulated the laboratories, but not the tests they perform.

Agency inspectors certify quality processes at the labs every two years or so. That is far less demanding than the long human trials the FDA requires for many tests.

"I think it's fair to say that clinical laboratories have not done the large-scale studies and have not always established efficacy," said Jeff Gibbs, a Washington lawyer who represents labs and medical device makers.

About 1,000 gene-based are in use today, according to genetests.org (<http://www.genetests.org>), a voluntary registration site funded by the U.S. National Institutes of Health.

Critics of the tests worry that if a result is inaccurate, a misguided -- and potentially harmful -- treatment decision could follow.

"We don't have data on the utility of these tests," said pharmacist Larry Sasich, who consults for the Public Citizen consumer group. "It is conceivable you could come up with a wrong result that would lead to a wrong decision."

The FDA defines the tests as those that use data, algorithms and software to get to a result to diagnose, treat or prevent disease.

An agency spokeswoman said tests likely to be regulated include those with significant potential to cause patient harm or death, based on use of the results in medical decision making.

A DIFFERENT ANIMAL?

The industry says a greater FDA role will remove the discretion used by laboratories to nimbly respond to the testing environment.

"A lab is a little bit of a different animal" from the drugs and medical devices regulated by FDA, said Alan Mertz, president of the American Clinical Laboratory Association, a trade group.

For example, a few years ago doctors began noticing that patients were developing resistance to certain HIV drugs and needed to switch treatments or their condition would deteriorate.

Mertz said that labs stepped in -- free of FDA regulation -- and developed tests that gauged HIV resistance, helping patients know when they needed to change drugs.

"Until you knew which drugs worked on which patients, they were shooting in the dark," he said.

Genomic Health makes a test called Oncotype DX, which helps predict whether women with estrogen-sensitive tumors will benefit from chemotherapy.

The Redwood City, California-based company said it was evaluating the FDA guidance, but noted that it tested Oncotype DX in 2,600 patients before marketing the product in 2004.

It was not required to do so, however.

"Overly burdensome regulations can stifle innovation," Johns Hopkins' Javitt said. "But at the same time, as a patient, as a consumer, as a doctor, you want to make sure the test is being performed correctly."