

InterGenetics works to overcome delay Rules changed just a month before launch



THE ASSOCIATED PRESS Craig Shimasaki, president and chief executive officer of Oklahoma City-based InterGenetics, is shown in the company's laboratory at the Presbyterian Health Foundation Research Park. , AP

By Jim Stafford
Business Writer

After testing 8,000 women and conducting 13 years of research into a genetic test that can assess a woman's breast cancer risk, Oklahoma City-based InterGenetics was ready to launch its OncoVue test nationwide last January.

Then the Food and Drug Administration called and summoned InterGenetics Chief Executive Officer Craig Shimasaki to Washington.

The rules had changed one month before the scheduled commercial launch at 50 breast cancer centers nationwide. InterGenetics had to put its commercial launch plans on hold.

Shimasaki was told that the CLIA — an acronym for federal Clinical Laboratory Improvement Amendments — guidelines under which InterGenetics had built its testing procedures and laboratory were no longer sufficient for the FDA.

Shimasaki had outlined for the FDA four years earlier every step that InterGenetics was taking to move its OncoVue test into the commercial market. The test consists of a mouthwash that a woman swishes and then spits into a cup. A specimen is sent to the InterGenetics lab where technicians use a special algorithm, or formula, to assess her risk of developing breast cancer.

"They said the algorithm, the software, makes the whole thing regulated by the FDA," Shimasaki said. "I paused for a minute and said, 'this is not the direction I received four years ago and it's also a contradiction to all the things that are being done right now.'"

The FDA was adamant. InterGenetics was forced to delay the launch.

Anticipated income from thousands of tests at \$397 each did not materialize and Shimasaki went back into the venture capital market to raise another round of investment capital that would carry the company until it could begin actual sales.

Shimasaki had already raised about \$12.5 million in capital, but now is putting the finishing touches on another investment round of approximately \$5 million to \$7 million.

An FDA spokeswoman said the agency did not issue new rules by which it regulated InterGenetics. It merely developed "guidance" to clarify the definition and status of what it calls in vitro diagnostic device multi-variant index assays.

"It does not introduce any new 'rules' for IVDMIAs; rather it clarifies that laws and regulations that apply to medical devices in general also applies to IVDMIAs," said Heidi Valetkevitch. "They are designed to provide the added assurance of safety and effectiveness in actual clinical use of new products.

"We believe this complements, rather than contradicts, the controls already in place by CLIA and (the Centers for Medicare and Medicaid Services)."

Meanwhile, the company won an investigational device exemption from the FDA and launched the OncoVue tests last month on a limited basis in seven labs nationwide, including two in the Oklahoma City area.

"(The new requirements) caused the centers to have more administrative responsibilities," Shimasaki said. "We lost some of the centers that really couldn't handle that kind of extra administrative work load."

Shimasaki wrote a five-page letter to the agency outlining how the company developed the breast cancer test around earlier FDA guidance and the impact of the sudden shift in regulation. Other companies were affected, too, he said.

For now, InterGenetics is earning income from the tests being conducted in Oklahoma City, Edmond, Chicago, Boise, Idaho, and elsewhere, Shimasaki said. It is unclear when the FDA will declare the test period over and let the company roll OncoVue out unrestricted.

"Even though I do believe that regulation and FDA oversight is going to be helpful, the method by which they are doing this is inappropriate and also questionable," he said.