

Faulty Blood Test Suits Pile Up Against Theranos, Walgreens

By **Shayna Posses**

Law360, New York (July 19, 2016, 2:29 PM ET) -- Walgreens and Theranos Inc. were hit with another proposed class action Monday in Arizona federal court, as a consumer blasted the companies for touting the startup's troubled blood tests as "revolutionary" and misleading patients into thinking the results were accurate.

An Arizona resident identified only as R.C. became the latest to bring claims against Theranos and Walgreens Boots Alliance Inc., which **ended its partnership** with the embattled company last month in light of **government investigations** and a **slew of lawsuits** over the efficacy of the Edison blood testing device.

Theranos burst onto the lab testing scene in 2013 with the announcement of a partnership with Walgreens, scoring \$50 million in financing and opening a number of wellness centers that supposedly conducted less-invasive "tiny blood tests" for analysis on the revolutionary Edison device, according to the complaint.

"Bolstered by the enhanced retail presence and credibility provided through its partnership with Walgreens, Theranos had performed roughly 1.8 million lab tests by the end of 2015," the complaint says. "However, despite the hype, Theranos's Edison system did not work, and the tests were inaccurate."

CEO Elizabeth Holmes founded Theranos in 2003, introducing what the company said was a new way of drawing and testing blood, the complaint says. Instead of using the traditional needles, tubes and vials, Theranos' system purportedly only required a few drops of blood gathered through a pinprick to the finger, which were then to be tested on a device called the Edison that could supposedly generate results in minutes, R.C. said.

After Holmes — who admits to being afraid of needles — spent roughly a decade building the company, Theranos announced its partnership with Walgreens, offering blood tests through more than 40 wellness centers within months, the complaint says. Both companies told customers that the tests were accurate and compliant with federal guidelines, according to R.C.

"What Walgreens failed to disclose was that it in its desire to expand by 'transform[ing] community pharmacy' through a venture into the blood-testing business with Theranos's technology, it had not fully validated Theranos's technology," the complaint says. "Indeed, Walgreens entered into its partnership with Theranos and began promoting the Theranos blood tests and all their big claims without ever even seeing the magical testing device."

Though some of Walgreens' executives and outside advisers expressed doubts about the secretive company, Theranos asked for — and received — more control as the process went forward, the complaint says.

Concerns about the company's blood testing system started to pile up, with the Wall Street Journal reporting in October 2015 that Theranos had stopped using the Edison system months earlier and was secretly using conventional lab machines to conduct testing and even outsourcing tests to third-party labs, according to R.C.

However, the complaint says, this was just the tip of the iceberg.

The U.S. Food and Drug Administration issued two reports in September, noting issues with Theranos' devices and procedures, according to the complaint.

Then, in January, the Centers for Medicaid and Medicare Services **released a 121-page report** detailing a number of violations of federal regulations in Theranos' Newark, California, lab, citing failures in regards to hematology, analytics and staffing, the complaint alleges.

By mid-May, the company **had voided** two years of results from tens of thousands of tests, the complaint says.

R.C. was one of many whose test results were invalidated, according to the complaint. Under orders from his doctor, he took a Theranos blood test at an Arizona Walgreens in February 2015 to check on his heart health and was informed that the results were normal, the complaint says.

Based on the results, R.C.'s doctor recommended that he stay on the same medication regimen, he alleges. Less than a month later, he had a heart attack and had to have two stents placed, according to the complaint.

The patient, who seeks to represent all purchasers of Theranos lab panels and blood-testing services, brings a slew of claims, including negligence, unjust enrichment, breach of contract and Arizona Consumer Fraud Act violations. Among a number of requests, he asks for injunctive relief, punitive damages, restitution and disgorgement.

The latest lawsuit comes weeks after **CMS banned Holmes** from owning or operating a lab business for at least two years in light of the Newark lab inspection that found a litany of shoddy lab practices, some of which allegedly placed patients in "immediate jeopardy."

Theranos said in a Tuesday statement that patient safety and clinical quality are the company's top priorities.

"This matter involves ongoing litigation which will resolve itself in due course," the company said. "In the meantime, we remain committed to the highest standards across all our labs and look forward to continuing to bring access to high-integrity, affordable health information to every person."

Representatives for the other parties didn't immediately return request for comment Tuesday.

R.C. is represented by Mark D. Samson, Ron Kilgard, Lynn Lincoln Sarko, Gretchen Freeman Cappio and T. David Copley of

Keller Rohrback LLP.

Counsel information for Theranos and Walgreens wasn't immediately available.

The suit is R.C. et al. v. Theranos et al., suit number 2:16-cv-02373, in the U.S. District Court for the District of Arizona.

--Additional reporting by John Kennedy and Jeff Overley. Editing by Kelly Duncan.

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