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Theranos, Walgreen Blood-Test Suits Consolidated In Ariz.

By **Brandon Lowrey**

Law360, Los Angeles (October 12, 2016, 6:51 PM EDT) -- An Alaska federal judge on Wednesday consolidated four proposed class actions in Arizona federal court alleging ailing blood-testing startup Theranos and pharmacy giant Walgreen Co. misled consumers about the accuracy of Theranos' tests and appointed Keller Rohrbach LLP and Lieff Cabraser Heimann & Bernstein LLP as interim co-lead counsel in the litigation.

U.S. District Judge H. Russel Holland granted a motion to transfer and consolidate the cases but said the appointment of lead counsel in the case was premature and should be revisited later.

The consolidated consumer class action is just one of many problems that Theranos Inc. faces. The California company announced it would close down its clinical labs and in-store "wellness centers" after actions from regulators over allegedly shoddy lab practices, a move it said would affect about 340 employees. The Centers for Medicare & Medicaid Services has banned the company's founder from owning or operating a lab business for two years, and an investment fund is suing in hopes of rescinding its stock purchase agreement based on the company's alleged fraudulent misrepresentations.

The startup 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 one of the Arizona consumer complaints.

"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, one of the plaintiffs, identified as "R.C.", said in one of the complaints.

After Holmes — who says she is 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' 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 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 problems with Theranos' devices and procedures, according to the complaint.

Then, in January, CMS 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.'s 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 maintain his medication regimen, he alleges. Less than a month later, he had a heart attack and had to have two stents implanted, according to the complaint.

Among other issues, Theranos also pulled a request for emergency clearance for a Zika virus blood test from the U.S. Food and Drug Administration after an FDA inspection revealed that data sent to the agency had been collected without a patient-safety protocol in place, according to a report from the Wall Street Journal.

The data had been run through the company's new miniLab device, which Holmes had said could get accurate results from a few drops of blood and could be used outside of a laboratory setting.

The company has also run into issues with its proprietary "Edison" blood-testing device and "nanotainer" technology, which promised to revolutionize diagnostic tests by using just a few drops of blood instead of multiple vials. But an investigation by the Wall Street Journal raised serious doubts about the accuracy of Theranos' tests and whether the company was even using nontraditional technology to perform most of them. Problems snowballed in the following months, leading Forbes to list Holmes' net worth as zero and Walgreens to end the partnership.

The plaintiffs are represented by Keller Rohrback LLP and Lief Cabraser Heimann & Bernstein LLP.

Theranos is represented by Amy J. Mauser, Evan Edmund North, Kory A. Langhofer, and Michael A. Brille of Boies Schiller & Flexner LLP, and Sean Eskovitz of Wilkinson Walsh & Eskovitz LLP. Walgreens is represented by Adam S. Tolin, Bambo Obaro, David R. Singh, and Diane P. Sullivan of Weil Gotshal & Manges LLP, and Brianna Lynn Long and Patricia Lee Refo of Snell & Wilmer LLP.

The consolidated case is In re: Arizona Theranos Inc. Litigation, case number 2:16-cv-02138, in the U.S. District Court for the District of Arizona.

--Additional reporting by John Kennedy, Bonnie Eslinger, Jeff Overley, Emily Field and Dani Kass. Editing by Patricia K. Cole.

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