



US officials ban Theranos CEO from running laboratories for two years

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US federal regulators have banned Elizabeth Holmes, the founder and chief executive officer of the biotechnology company Theranos, from operating blood testing laboratories for at least two years and have revoked the company's laboratory certification, a company press release announced on 7 July.

The California based company's executives had promised to revolutionize the blood testing industry with a technology that Theranos said would make it possible to run multiple tests on a few drops of blood collected with a simple finger prick.

Holmes founded Theranos in 2003 after dropping out of Stanford University, aged 19. By 2014 the company was valued at \$9bn (£6.9bn; €8.1bn), while Holmes herself was estimated to be worth \$4.7bn. However, Theranos was scrutinized last fall when reports emerged that the company was using its technology on only a small fraction of tests and was instead relying on standard devices made by other companies to test the blood samples it received.

After inspections by federal regulators of the company's laboratory in California, the Centers for Medicare and Medicaid Services (CMS) sent a warning letter to Theranos stating that its laboratory did not comply with federal regulations and engaged in practices that posed "immediate jeopardy to patient

health and safety." The federal agency warned that unless the issues raised by its inspectors were dealt with, the laboratory's certificate would be revoked and company officials sanctioned.¹

In its press release Theranos said that, in addition to the revocation of the laboratory's certificate and the ban on the laboratory's owners from operating and directing a laboratory for at least two years, the company will have to pay an unspecified civil penalty.

In a statement Holmes said that the company accepted full responsibility for the problems cited by the agency and promised to rebuild the laboratory, appoint new leadership, and implement enhanced quality and training procedures.

She said, "While we are disappointed by CMS' decision, we take these matters very seriously and are committed to fully resolving all outstanding issues with CMS and to demonstrating our dedication to the highest standards of quality and compliance."

1 McCarthy M. US officials threaten to sanction firm that promised to revolutionize blood testing. *BMJ* 2016;353:i2189. doi:10.1136/bmj.i2189 pmid:27084803.

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