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Democracy Dies in Darkness

Theranos blood test: The insanely influential Stanford professor who called the company out for its 'stealth research'

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When Theranos chief executive Elizabeth Holmes announced Thursday that her company's finger-stick blood test had won clearance from the Food and Drug Administration, the outcome of the review wasn't the news. It was that she had gone to the FDA in the first place.

Holmes's company, a Silicon Valley darling estimated to be worth $9 billion, has been poised to upend the blood-testing business since Theranos began offering its tests to the public in 2013. With just a few drops of blood, dozens of disease and conditions can reportedly be scanned for near instantaneously. But for a company that has received so much attention, there has been surprisingly little information about how its technology works, and the company has maintained -- and still maintains -- that it is not required to seek regulatory approval for its products.

Competitors and others in the medical community had criticized the company for its lack of transparency, but it wasn't until this February when the issue became a public relations crisis. That's when John Ioannidis, a professor at Stanford University's medical school, singled out the company for what he called "stealth research."

Writing in the Journal of the American Medical Association, Ioannidis said this phenomenon "creates total ambiguity about what evidence can be trusted in a mix of possibly brilliant ideas, aggressive corporate announcements, and mass media hype."

He added:

> Theranos is just one example among many for which major efforts and major claims about biomedical progress seem to be happening outside the peer-reviewed scientific literature. Many of these efforts and claims have a biotechnology flavor, and the people involved often include a

> blend of engineers, physical scientists, and venture capitalists. The main motive appears to be to develop products and services, rather than report new discoveries as research scholarship. Products, services, and profit appear to be more important than scientific publications.

[FDA approves Theranos' $9 finger stick blood test for herpes]

Ioannidis is known throughout the world for his work on the credibility of medical studies and his research is regularly shared via e-mail among Silicon Valley's elite. In a 2010 article, the Atlantic described him as perhaps "one of the most influential scientists alive."

> He and his team have shown, again and again, and in many different ways, that much of what biomedical researchers conclude in published studies—conclusions that doctors keep in mind when they prescribe antibiotics or blood-pressure medication, or when they advise us to consume more fiber or less meat, or when they recommend surgery for heart disease or back pain—is misleading, exaggerated, and often flat-out wrong. He charges that as much as 90 percent of the published medical information that doctors rely on is flawed. His work has been widely accepted by the medical community; it has been published in the field's top journals, where it is heavily cited; and he is a big draw at conferences.

In an interview last year with The Washington Post, venture capitalist Vinod Khosla said he had been following Ioannidis's work for well over a decade, before the professor had made his way to the United States and was still in Greece at the University of Ioannina medical school. Khosla, a Sun Microsystems co-founder who has invested many millions in health-care startups, credits Ioannidis for inspiring his work in the sector.

"What has influenced me is Dr. Ioannidis on how arbitrary the state of medicine is today and how arbitrary the results of medical studies," Khosla said.

On Thursday, Ioannidis said he hoped Theranos's application to the FDA would encourage other companies to do the same. "However, I still believe that it is important also to have the full information available in the scientific community through peer-reviewed publications on methods and results, with access of other scientists to the raw data and protocols," he said an an e-mail to The Post.

Holmes said the company had voluntarily decided to go through the FDA process because Theranos is "deeply committed to ensuring that our systems and all of our laboratory developed tests are of the highest quality, and that patients and their physicians have access to the most accurate information about their health."

As part of its approval process, the company is making public some details of how an assay to detect herpes simplex virus (HSV-1) works. Theranos said it has submitted information about other tests to the FDA and hopes they will also receive approval.

A Theranos spokesperson in a statement said: "We have been committed to, engaged with and publicly advocating for the FDA – the gold standard for review of performance and accuracy of lab tests -- since prior to launching our consumer facing laboratory services in 2013.

"There is no higher quality or more comprehensive standard for lab testing than FDA's. We believe strongly and have been publicly advocating that these standards need to begin to be embraced for all laboratory testing."

Elizabeth Holmes's TEDMED talk in 2014 explaining her vision for how to empower consumers by making it easier for them to get blood tests done:

This post has been updated.

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