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False dawns: implications for patients of the Theranos debacle

It's not hard to see why patients and the public, and their doctors, were tempted by Theranos, says **Tessa Richards**

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Corporate scandals don't get much bigger than Theranos.¹ The *Wall Street Journal* investigative journalist John Carreyrou charted how Elizabeth Holmes, founder and chief executive of Theranos, persuaded the good, great, and wealthy to invest hundreds of millions of dollars in a flawed and fraudulent blood testing technology. In his recent podcast *Bad Blood: The Final Chapter*,² covering Holmes's trial, he illuminates how jurors struggled to agree a verdict on the 11 counts against her, before finding her guilty of investor fraud, but not of defrauding patients.

Theranos began marketing its cheap, rapid diagnostic tests directly to the public in 2013. It talked up an innovative technology which, it claimed, could run over 200 tests on a small sample of blood collected from a single finger prick. It operated from testing centres opened in around 40 Walgreens pharmaceutical stores. Its offer to empower people to "diagnose potential disease earlier" was coupled with an appealing vision of how its new diagnostic technology would improve care of casualties in the battlefield and operating theatres. Over the ensuing three years around 1.5 million tests were done on thousands of people.

It took time to uncover the inaccuracy of these tests, and the fact that many samples were diluted and run on conventional analysers. This is because, historically, in vitro diagnostic tests developed and used within the same laboratory, as in this case, have been regarded as relatively low risk and subject to less stringent regulatory requirements. Oversight was conducted by the Centers for Medicare and Medicaid Services (CMS) on a rolling retrospective basis. Regulatory reforms have now been proposed to reduce the risk of patients making "perhaps irreversible medicine decisions on the basis of inaccurate test results."³

The CMS sent a warning letter to Theranos in 2016 stating its "deficient laboratory practices" posed "an immediate jeopardy to patient health and safety."⁴ But it was not until the Food and Drug Administration (FDA) declared Theranos's nanotainer blood collection tube to be an "uncleared medical device"—as Benjamin Mazer, a US pathologist, pointed out in an article in *The Atlantic*—that regulators were able to "protect thousands of additional patients from receiving potentially inaccurate diagnostic tests."⁵

The covid-19 pandemic has highlighted the trade off between early availability of tests and their validity. In his article, Mazer points to the difficulty of striking an optimum regulatory balance. At the onset of the pandemic, the FDA tightened the regulatory bar for

laboratories making diagnostic tests for coronavirus. But criticism of its "slow and cumbersome" processes eventually led it to lower that bar. Its actions, Mazer suggests, account for why the US has only six home based tests, whereas Germany has over 60, most of them less costly. Going forward, the debate in the US on where to set the bar for approval of new diagnostic tests will, he says, depend on the fate of two competing bills before Congress.

It's not hard to see why patients and the public, and their doctors, were tempted by the Theranos offer. Patients rarely get the option to choose what tests to undergo, when, and where, and delays are built into the system at every turn. Furthermore, it is not common to be told when results will be sent on, and often hard to access them without going through a further layer of process. I have ischaemic heart disease, mild hyperlipidaemia, and a history of hyperparathyroidism. If I could go to my local pharmacy and self-monitor my lipids and calcium levels, I'd be for it.

Patients are being encouraged to take charge of their health and self-manage medical conditions. More people are, and will increasingly be, making their own decisions about their health, including what tests to undergo. As more home based tests are made available it will be harder and harder to see the wood for the trees. People are confronted with a barrage of information which overtly, or covertly, pushes the message that they will benefit from more tests, more monitoring, and more treatment. Few (and that goes for many doctors, too) can critically appraise the reliability and utility of new tests and technologies. They assume regulators do this.

Hope makes us vulnerable to hype

People who are worried about their health are vulnerable. When my (rare) adrenal cancer recurred in the caudate lobe of the liver six years ago, surgeons agreed major surgery was too dangerous. Adjuvant chemotherapy to shrink the tumour and so reduce the operative risk had little chance of working. The toxic basket of drugs recommended looked set to destroy my quality of life. I explored the possibility of taking thalidomide, a repurposed drug, but funding was turned down. I talked to a palliative care doctor about the end game.

Serendipity then led me to a company which plumbs the depths of the grey literature, alongside conventional resources. I was put in touch with a centre in the US that has experience of treating patients with adrenal cancer, and one in Germany. Through them I heard about several promising, but largely unproven, new treatments and clinical trials.

I agreed to undergo a costly blood test which purported to be able to identify cancer cells from a single peripheral blood sample and test their susceptibility to a raft of chemotherapeutic agents. When the detailed results were sent to me, I was sceptical and shared them with an oncologist at the clinical trials unit I was attending. His view was that the technology was implausible and the results unreliable.

I felt foolish for having taken the test: surely as a doctor I should know better? But I was desperate, and I don't regret my foray into the private sector. It was an illuminating journey and ultimately resulted in my finding out about nanoknife ablation, a non-invasive procedure I have now successfully undergone twice. At the time, my NHS tertiary oncology centre had not heard of this technology and has only just begun to offer it to selected patients.

I was lucky. Undertaking an unproven test did not damage my health. The same cannot be said for many of the patients who paid for and took action on the basis of the estimated one in 10 inaccurate Theranos tests.⁶ Patients were harmed. Some took lawsuits out against the company, but there is no prospect of the full impact on patients being quantified. At her recent trial Holmes was found guilty of investor fraud, but not of defrauding patients.

Entrepreneurs, venture capitalists, Harvard academics, and experts in laboratory medicine have been musing about the lessons to be learnt from the Theranos debacle.^{7 8} It's also put the spotlight on how the development and marketing of ever more sensitive tests fuels overdiagnosis and overtreatment. It's easy to believe that "persistent techno-optimism and bio-naivete" may well result in another Theranos.⁹

So where does this leave patients? Many are already sceptical about vested interests in our medical-industrial health systems. This example of failure to protect them as a result of poor regulatory processes will erode trust further. Oversight of new diagnostic tests and technologies must be more rigorous and transparent, and patients must add another item to their list of questions to doctors: how reliable, reproducible, and clinically useful are the tests you have suggested I undergo?

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