Essay Topic 2: Cutting-Edge Blood Tests

Case: You are a *philosopher of science* at the University of Toronto and are an expert on the Laws of Scientific Change. You come across the following editorial from *Nature* and feel compelled to respond.

Question: How do the Laws of Scientific Change shed light on the episodes and arguments in the article? Write a letter to the CEO of Theranos to help her understand the resistance her company is facing and perhaps advise her as to how the company might move forward.

Burst Bubbles

From time to time in most industries, the conventional approach is challenged by upstarts. Often backed by entrepreneurs and investors, these firms promise to use new technology to overturn and revolutionize. Some succeed and some do not, and there are fields in which the challenge to newcomers is proving stiffer than others. One of these is health care, and events over the past week or so demonstrate both the difficulties and the opportunities.

Theranos and 23andMe are two medical-technology companies with their origins in Silicon Valley. Both have made headlines recently. Their stories may seem similar. But the differences offer an important lesson for would-be health disruptors: this industry can change, just not as quickly as entrepreneurs and their investors might hope, and only if those offering the change can also offer data to back up their claims.

Theranos in Palo Alto promised to upend medicine with a device that can perform hundreds of diagnostic tests on just a few drops of blood. 23andMe, in Mountain View, California, sells genetic tests directly to consumers. Both are led by charismatic female founders: Elizabeth Holmes at Theranos and Anne Wojcicki at 23andMe. Both want to revolutionize the health-care industry and argue that patients should have access to their data. They have strong backing from Silicon Valley investors, and were hyped early on: a US$9-billion valuation for Theranos, and lavish parties with media tycoons for 23andme.

But both have seen their bubbles burst. On 16 October, The Wall Street Journal reported that the Theranos technology was not working as billed, and that the firm was using conventional machines to perform most of its tests. The company has disputed some of the

article's claims. Holmes says that the company is now in a "pause period" because of scrutiny from US regulators.

23andMe's bubble burst in November 2013, when the US Food and Drug Administration (FDA) banned the inclusion of medically relevant results in the company's consumer genetic tests. On 21 October, however, 23andMe relaunched consumer genetic tests that give a limited amount of medical information, with FDA approval. The new tests offer information for 36 diseases about a customer's status as a 'carrier' of genetic glitches that could cause disease if passed down.

Theranos could learn a lot from how 23andMe returned to the regulators' good graces. 23andMe has always been fairly open about its science; it publishes research papers in peer-reviewed journals and collaborates with scientists. Theranos, by contrast, has been tight-lipped about its data. Apart from detailed data for one herpesvirus test, approved by the FDA, the company has published only aggregate test performances on its website, not the primary data. 23andMe says that coming back from its early mistakes with the FDA was an arduous process – requiring it to hire staff with expertise in health regulation and to compile detailed dossiers of data to prove that its tests work as advertised. The company previously had been slow to respond to the FDA's entreaties – and that tone-deafness seems – to have been part of the reason that the agency eventually cracked down.

These experiences do not mean that health care cannot be disrupted. Indeed, 23andMe is the first company to gain FDA approval to sell a health-related genetic test without a doctor's order. That's a real change. Still, the new tests offer less information than before and at a higher price. With a few exceptions, carrier tests do not say anything about the health of the individual tested, and they are mainly for rare diseases – a far cry from the risk-prediction scores the company previously offered for cancer and Alzheimer's disease.

Time and again, new health-care firms are forced to realize that it helps no one to be secretive with data. Even if it turns out that the Theranos technology does not work as well as advertised, the company would hardly be the first to find itself in that situation. Releasing more information earlier might have forced Theranos to confront shortcomings. Instead, it finds itself trying to recover from a regulatory and public-relations hole. This is not an insurmountable situation, as 23andMe knows. The challenge now is for Theranos to show us the data.