Stanford eCorner

Disruptors Cause Controversy

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23andMe Co-Founder Anne Wojcicki talks about the intense scrutiny that her company received from regulators when its DNA testing kits debuted. The fact that they were sold directly to consumers raised the most controversy, just as birth-control tests once did, according to Wojcicki. The Federal Drug Administration's warning, she says, was an encouraging sign: "To really drive change, you have to change the system."

Transcript

- And I can see in my mind this world of, like, consumer-driven affordable healthcare.. And so we have to sort of create that.. So we have to teach the consumer.. The regulatory side, when we launched we believed, like, really simply, I own myself, it's my body, and my genome is just the digital representation of me.. And so like, of course I can get access to it, why would I not be able to, that seems crazy.. Like why would there be any prohibition? And then my taxpayer dollars go to all this genetics research, so why wouldn't I be able to get access to that? Like, all I want to do is connect my own body, my genome, and understand what's happening with all this research, and like I already paid for that research, I want to see what it is.. So the idea was, like, we're not interpreting, like we're just, we're connecting the dots for you.. Sorry, I have a slight cold.. And so we just felt like it was information.. It was almost like this is your first amendment right, like you couldn't see..

And from a lab perspective, we felt like we fell under CLIA, which is the Clinical Laboratory Information Act, managed by Medicare as a laboratory involved test.. And so, you know, lots of blood tests, like blood tests today and most genetic tests are all LDTs, so we felt like we were under that pathway.. Clearly, one of the things that's interesting for me is like, especially from an academic perspective, the history of medicine is so interesting.. And you know, birth control tests used to be super controversial, and any time the consumers at the point of interraction, like it's a direct to consumer, that's really controversial.. So we realized, we were just getting, there was a lot of controversy around us because of the direct to consumer.. And so we did have, sort of, what's now known as the most well-read ever warning letter by the FDA's history, which I actually in some ways am really proud of.. Like I think that that was a sign that we're doing something really different.. It was sort of radical.. Like, it's the change that we want.. And our approach to it has been to work with the agency and say, you know what, trying to fight with the agency, or like, sort of that arrogance of like, well we'll show you, part of it is that you, to really drive change, you have to change the system..

And so for me the best thing that we've done is then partner, partner's not the right word, but that we actually listened.. We listened to the FDA, we said we're going to do all the things you've asked us to do and we're going to get a direct to consumer approval for our test...