Regulating 23andMe to Death Won't Stop the New Age of Genetic Testing

- By Larry Downes and Paul Nunes
- 1/1/14

http://www.wired.com/opinion/2014/01/the-fda-may-win-the-battle-this-holiday-season-but-23andme-will-win-the-war/

Market disruptions often occur — or not — as the direct result of unintended collisions between breakthrough technologies and their more incremental regulators. In the latest dust-up, the U.S. Food and Drug Administration (FDA) last month ordered startup 23andMe to stop marketing its $99 genetic analysis kit, just before the Christmas shopping season kicked into high gear.

To date, over half a million customers have taken the swab in return for detailed ancestry data and personalized information on 248 genetic traits and health conditions. The company, which launched in 2007 with substantial backing from Google, has been working closely — albeit more slowly than the FDA would have liked — with the FDA to ensure it complies with federal health and safety regulations. But the agency concluded in its recent warning letter that 23andMe was marketing a "device" that was "intended for use in the diagnosis of diseases or other conditions," and as such, its marketing materials required pre-approval from the FDA, which includes extensive research studies.

23andMe is an example of what we call a "Big Bang Disruption" — a product or service innovation that undermines existing markets and industries seemingly overnight by being simultaneously better and cheaper than the competition. What's happening in genomic testing (and healthcare in general) is consistent with our research in over 30 different industry segments, from manufacturing to financial services to consumer products.

When technologies improve exponentially, many industry incumbents — and the regulators who oversee them — are kept constantly off-balance. That's because incumbents have been indoctrinated by a generation of academic literature and MBA training to ignore disruptive products until they had a chance to mature in the market, assuming they would first appear as cheaper but inferior substitutes that would only appeal to niche market segments.

Doctors — who are also incumbents in this situation — are struggling to respond to disruptive medical technologies that change the power dynamic in the patient relationship. Several 23andMe users have reported taking the FDA's advice of reviewing their genetic results with their physicians, only to find the doctors unprepared, unwilling, or downright hostile to helping interpret the data.

Often, incumbents' only competitive response — or the only one they can think of — is to run to the regulators. That's what's has been happening to car-sharing services such as Uber, Lyft, and Sidecar; to private drone makers; and casual accommodation services such as Airbnb, to name just a few examples. And now it's happening to 23andMe, one of hundreds of new startups aimed at giving healthcare consumers more and better information about their own bodies — information that has long been under the exclusive and increasingly expensive control of medical professionals.

Absent any real law on the subject, the agency has strained credulity to categorize 23andMe's product as a diagnostic "device" — making it subject to its most stringent oversight. The FDA's letter focuses intently on the potential that consumers will both under- and over-react to the genetic information revealed. The agency fears that users will pressure their doctors for potentially unnecessary surgery or medication to treat

conditions for which they are genetically pre-disposed, for example. And it assumes that the costs of such information abuse outweigh any benefits — none of which are mentioned in the agency's analysis.

The company, of course, has agreed to comply with the FDA's stern warning, and has ceased providing its customers with anything other than hereditary data. For now. Perhaps it will reach some accommodation with the agency, or perhaps the FDA's ire will prove untamable, an end to the innovative startup and whatever value its technology might have delivered.

But as with every Big Bang Disruptor in our study, winning the battle and winning the war are two very different things.

The FDA is applying a least common denominator standard to 23andMe, and applying it arbitrarily. Already, an explosion of monitoring, testing, and sensing devices are coming on the market, providing consumers with instant analysis of their fitness, blood chemistry, sleep patterns and food intake. It's only a matter of time before regulators feel compelled by consumer demand to find a way to accommodate better and cheaper innovations, and for slowly changing industries to dramatically restructure themselves in the face of overwhelming new opportunities. The long-term potential of vast databases of genomic data to improve health outcomes, reduce costs, and reorient the debate on medical priorities is too valuable to be held back for long — and arguably the biggest transformation for the healthcare industry since the discovery of antibiotics in the early 20th century.

The information flood is coming. If not this Christmas season, then one in the near future. Before long, $100 will get you sequencing of not just the million genes 23andMe currently examines, but all of them. Regulators and medical practitioners must focus their attention not on raising temporary obstacles, but on figuring out how they can make the best use of this inevitable tidal wave of information.

Whatever the outcome for 23andMe, this is a losing battle for industry incumbents who believe they can hold back the future forever.

Larry Downes & Paul Nunes

Larry Downes and Paul Nunes are co-authors of *Big Bang Disruption: Strategy in the Age of Devastating Innovation* (Penguin Portfolio 2014). Downes is Research Fellow with the Accenture Institute for High Performance, where Nunes serves as its Global Managing Director of Research. Their book has been selected as a 2014 book of the year by the Consumer Electronics Association.