Crowd control:

Companies and projects find backing through crowd funding

1307

Egged on:

Pioneer of egg stem cells looks to the fertility clinic

1311

Coming of phage:

Genetic engineering promises better phage therapy

1318

Consumer gene tests poised for regulatory green light

When US lawmakers hauled direct-to-consumer (DTC) genetic testing companies into congressional hearings in July 2010, it seemed clear that the industry was in for a shakedown. The US Food and Drug Administration (FDA) had already mailed stern letters to 20 different firms warning that their genetic testing services appeared to meet the definition of a device. The agency also invited company representatives to meet with FDA officials to discuss ways to make their products legit in the eyes of the government. Two years on, those behind-the-scenes negotiations seem to have paid off.

On 29 June, 23andMe, the most popular provider of personal gene tests, filed the industry's first application for FDA clearance—a move that onlookers say may yield a glimpse into the FDA's future policies on the issue of DTC genetics. "I think this is a great thing," says David Kaufman, director of research and statistics at the Genetics & Public Policy Center in Washington, DC. "It demonstrates that both the FDA and industry want to go about this the right way."

Consumer genetic testing roared into the limelight in May 2010 when Pathway Genomics, a San Diego-based firm, said it would start selling mail-in saliva sampling kits for genetic analysis through Walgreen's, one of the largest pharmacy chains in the US. The company's product never hit the shelves, though. The FDA pushed within days for stronger oversight of the field, and, just two months later, leading companies were called in to account for themselves. Although firms have continued to sell their tests since the hearings, the industry has been caught up in regulatory limbo ever since.

23andMe has now attempted to move past the deadlock by requesting clearance for seven single nucleotide polymorphism-based health reports. The Mountain View, California-based company plans to submit around 100 more for review by the end of the year. The reports—all of which are already offered online directly to consumers—broadly measure one of three different kinds of traits: Mendelian disease carrier status,

complex disease risk or pharmacogenetic drug response.

The company's 'Personal Genome Service' will be evaluated on two main fronts. The FDA will first assess analytical validity to ensure that the technology is identifying gene variants and mutations accurately. More challengingly, given the ever-evolving understanding of the genetic basis of many diseases, the agency will then review the claims made by 23andMe about correlations between specific genes and associated risks.

A regulatory decision is expected by the end of September. "We are hopeful and confident [of FDA clearance]," says Ashley Gould, vice president of corporate development and chief legal officer at 23andMe.

Show me the evidence (you want)

Others in the field—including companies in the clinical diagnostic space who are developing gene tests for use exclusively by healthcare professionals—have their fingers crossed, as well. "A clearance [for 23andMe] would give us some guidelines as to how to fashion our tests and what level of evidence is going to be required by the FDA," says David Becker, Pathway Genomics's chief scientific officer. For example, summary documents that would be published upon clearance of the tests could provide insight into when clinical trial data is needed to support a claim, when literature backing will suffice and when clearance is not needed.

Genetic testing firms are also keenly awaiting industry-wide guidance from the FDA that will more fully answer their questions, although the agency has not provided a timeline for official publication. The FDA declined to comment for this story, other than noting by e-mail that "the agency continues to work with companies who have an interest in making their direct-to-consumer product widely available."

Ultimately, regulatory clearance or not, the industry will have to demonstrate to the larger medical community that having genetic test results in hand can actually help people become healthier. "I would not peg

Spitting distance: DTC tests near approval.

the lack of a clear regulatory pathway as the sole reason that DTC genetic testing has not turned into a big successful industry," says New York-based attorney Dan Vorhaus, editor of the *Genomics Law Report*, a publication of the law firm Robinson, Bradshaw & Hinson.

Some of the first research studies investigating whether the benefits of gene testing are worth the additional costs are already underway, notes Gould. She hopes that a first regulatory clearance of 23andMe's tests could speed those efforts along.

"The FDA submission is not a goal in and of itself," Gould says. "It is a point on a spectrum that we hope will get people to understand genetic information and its value and get people participating in research."

Asher Mullard

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