

More regulatory control for the personal genomics industry?

Fortune Tellers under Pressure

Illegal fortune telling? A popular part of the base pair business – the offering of genome-sequencing tests to consumers – has operated in a grey area for years. Recently, however, public authorities in the US have demanded answers to unpleasant questions.

Look out, Decode Genetics and buddies! Times are getting rougher for those who make money by genotyping individual genomes and analysing them using bioinformatics tools. Despite being without regulatory control since their very beginning three years ago (when Decode started the first web-based service to offer a genome scan, associated with an online analysis of an individual's DNA), such base pair business faces growing attention from public health agencies.

In June, for example, the US Food and Drug Administration's (FDA's) tone became decidedly unpleasant, after it became known that the largest US drugstore chain, Walgreens (see photo right), was soon to sell over-the-counter genetic assays. According to a *LA Times* report, these saliva collection kits, delivered by San Diego-based start-up firm Pathway Genomics, would have been sold for an equivalent of €16 to €25 each (not including additional charges for the genetic tests themselves, such as risk factors for diseases, the effectiveness of drugs, or the presence of genes that cause genetic disorders and could be passed along to offspring).

Genetic tests distributed by your local pill dealer? Not yet. This time, the FDA put a spoke in Walgreens' wheels.

Unpleasant tone

On May 10th James Woods, a FDA Deputy Director for Patient Safety and Product Quality, wrote the following to James Planter, Pathway Genomics' Founder and CEO:

"It has come to our attention that you are currently marketing [...] a home-use saliva collection kit, intended to report [...] personal genetic health disposition results for more than 70 health conditions [...]. We have [...] been unable to identify any FDA clearance or approval number for [your product]. We request that you provide us with [it]. We would

appreciate a response within 15 days from the date of this letter."

In other words, such consumer genomics kits are to be reviewed under the same procedure used for medical devices, making it highly questionable whether they remain on the market.

On May 25th, the FDA deadline expired without news from Pathway Genomics. In addition, several requests to the Californian company, made by *Lab Times* in June by e-mail, didn't result in any response.



"... and soon we'll also have genetic assays". That's not much good; for the moment, the FDA has scotched the selling of direct-to-consumer tests by local pill dealers.

Strange. Usually, Pathway's messages are loud and clear, especially when it comes to garish sales promotion ("Learn the secrets inside your genes and start improving your future with Pathway's Health Kit!"). By the way, the FDA remained silent, too. *Lab Times* will deliver more detailed information as soon as possible on whether Pathway's products are legally valid.

Grey area operations

There is evidence, however, that the personal genomics business did operate in a legal grey area for years, in the light of the fact that four weeks later, on June 10th, the FDA wrote similar letters to five additional personal genomics companies. The execu-

tives of Navigenics, Illumina, Decode Genetics, 23andMe and Knome read the following:

"The FDA has determined that your firm manufactures [...] a device [...] that is intended for use in the diagnosis of disease [...]. It is important that [such products] are analytically and clinically accurate so that individuals are not misled by incorrect test results or unsupported clinical interpretations. [Your Company] has never submitted information on the analytical or clinical validity of its tests to FDA for clearance or approval. [...] You should take prompt action to respond to this letter."

Modest medical value

Whether or not these companies take prompter action than Pathway genomics and regardless of whether the FDA will allow them to keep their products on the market, one thing is already obvious: Direct-to-consumer genetic tests are no more convincing than reading tea leaves, at least when it comes to medical issues. Every reputable geneticist and every serious physician shake their heads at claims that they can, "predict the risk for diseases based on mutations in your DNA". There are hundreds of these tests available, but only a few of them are scientifically verified.

Even worse, usually neither a professional with genetics expertise is around to help the customer to interpret the results and point out the limitations of genetic testing, nor a counseling psychologist to handle the psychological consequences (if there are any).

Anyway, the FDA's measure appears somewhat peculiar, in light of the fact that personal genomic companies such as Decode Genetics and 23andMe have been selling such testing kits directly to consumers over the internet for years.

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