

What lies within

The personal genetic-testing industry is under fire, but happier days lie ahead.



“BY ALL accounts, I’m a medical miracle,” says Ozzy Osbourne, an ageing rock star who once bit the head off a live bat. For four decades Mr Osbourne (pictured above in his prime) drank too much and took prodigious quantities of drugs. Yet he survived. Now a reformed man, he is getting his entire genome sequenced by Knome, an American genetic-testing firm, for clues to how his body coped with such prolonged abuse.

He is not alone in wondering what mysteries genetic testing might unlock. 23andMe, a genetics start-up in Silicon Valley financed partly by Google, has held “spit parties” for the rich and famous. It compared the genes of Warren Buffett and Jimmy Buffet to see if the billionaire and the musician are related (they are not). The personal genetics business is hardly four years old, but it has already made a splash. Many customers hope that, by analysing their genes, they will learn more about their risk of contracting a disease, getting fat or suffering from some other ailment.

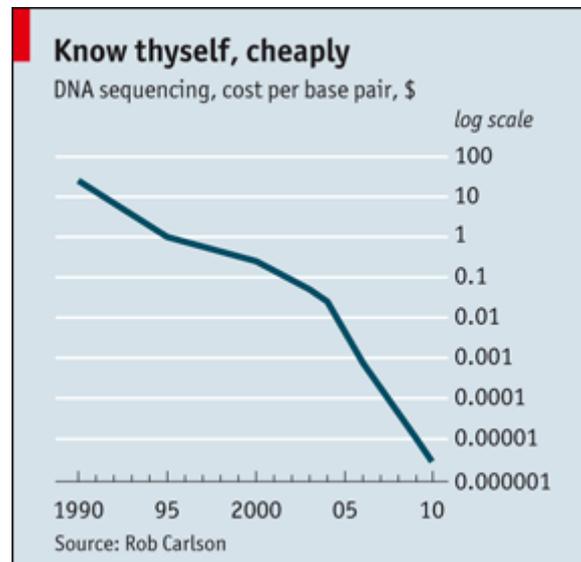
But how useful are the tests on offer? In America in recent weeks both the Food and Drug Administration (FDA) and Congress have held hearings on the need for stricter regulation of how genetic tests are conducted and how the results are interpreted. A report from the Government Accountability Office (GAO), an official watchdog, found that many test results were “misleading and of little or no practical use to consumers”.

Much of the duff information came from ignorant sales people and junior staff. Some said that a child’s DNA could predict which sports he might be good at, a claim that an expert quoted in the GAO’s report called “complete garbage”. One told a customer that her genes meant that she was “in the high risk of pretty much getting” breast cancer—a wild overstatement.

Some people argue that the sale of genetic tests directly to consumers should be banned. Arthur Beaudet of Texas’s Baylor College of Medicine explains why in the latest edition of *Nature*. “The interpretation of findings that might warrant medical intervention requires a level of expertise that is currently beyond the capacity of even most physicians,” he says.

A squeeze is more likely than a ban, however. “Genetic tests are medical devices and must be regulated,” says Alberto Gutierrez of the FDA. If medical claims are made for a genetic test, the agency will police the way that test is marketed, just as it polices the claims made by drugmakers, he says. As the agency regulates more assertively, standards will become clearer, he predicts. Testing for frivolous purposes, such as to trace your ancestry or find out if you are “compatible” with your lover, will remain unregulated.

Closer scrutiny could be good news. “[Some] firms will fail, but we need regulation to keep the field healthy,” says Harvard’s George Church, a geneticist with interests in various start-ups. Jorge Conde, head of Knome, adds that the FDA crackdown “is a natural response to fast innovation”. But it is not clear that regulators will be able to keep up with such a rapidly changing industry.



So far, direct-to-consumer genetics firms have struggled to make money. Only about 100,000 people have paid to have their genes sequenced, estimates Eric Topol of the Scripps Research Institute in San Diego. Most have paid a few hundred dollars for tests on only a few genes, to see if they are likely to contract a specific disease. They might learn more if they had their entire genome sequenced. A decade ago this would have cost a billion dollars—a bit pricey for most consumers. But the cost is falling so fast that whole-genome sequencing could one day be affordable to anyone who can spit into a cup (see chart).

Investors have taken note. Pacific Biosciences, a Californian firm with a promising approach to whole-genome sequencing, is backed by such heavyweight investors as Blackstone Group and Kleiner, Perkins, Caufield & Byers. In a short time, it has raised more than \$369m in financing. Complete Genomics, a local rival, has come up with a novel business model: it offers rapid sequencing as a centralised service, rather than selling sequencing machines. It filed to go public on July 30th.

In 2007 Knome charged \$350,000 to sequence a human genome. Today it charges \$40,000. Mr Conde predicts that by 2015 the price will have fallen below \$1,000. Complete Genomics charges about \$10,000 to sequence more than 90% of a genome. It too predicts that the cost will drop below \$1,000 within five years.

As costs plummet, firms will start to offer better tests. One area that promises rich rewards is pharmacogenomics. Researchers are devising genetic tests that can predict patients’ responses to certain drugs, thus helping doctors and patients decide what should be taken and in what dose. Already perhaps a tenth of all prescription medication—cancer drugs, blood thinners, epilepsy treatments and so on—has labels alerting you to companion genetic tests. Many more are on the way. Kathy Hudson of America’s National Institutes of Health says this approach could yield big health benefits even in the short term, never mind the distant future.

Big drug firms are secretly less than thrilled, says Dr Topol. Some fear that pharmacogenomics could cut the market for their products into ever-smaller slices. Rather than selling one drug to

everyone with a particular disease, firms may have to tailor treatments for small groups of genetically similar people—at great cost.

But pharmacy benefit managers (PBMs), the powerful middlemen who manage the drug purchases of the employees of big American companies, are keenly promoting pharmacogenomics. CVS Caremark and Medco, the two biggest PBMs, which manage drug-buying for about 100m Americans, have persuaded employers that paying for such tests will save money, because drugs will be used only when they benefit patients. They are winning patients over too, for testing can warn them of likely side effects from a drug.

Ryan Phelan, the head of DNA Direct, a genetic-testing firm that was bought by Medco in February, predicts that the current regulatory kerfuffle will prove “just a blip” on the path to consumers gaining access to their genetic information. As scientists learn how to interpret all these data, the benefits could be immense.

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