Size of the direct-to-consumer genomic testing market

Caroline F. Wright, PhD, and Shelley Gregory-Jones, MBA

Abstract: There has been enormous interest in the recent development of consumer genomics services, but very little is known about their impact. Using publicly available information, we estimate that the market for genetic susceptibility tests for complex diseases is much smaller than previously suggested, and hence consider that regulation through restrictive statutory legislation may be excessive. *Genet Med* 2010;12(9):594.

Key Words: DTC, consumer genomics, genetic susceptibility testing, common disease market

The advent of direct-to-consumer (DTC) personal genomic testing available through the internet has provoked both media attention and widespread debate.^{1–10} In addition to criticisms regarding a lack of evidence of clinical validity or utility and issues relating to the ethical use of genetic data, one concern commonly expressed by the medical community is that such tests will have major implications for state- or third party-funded health systems. This is due to additional “knock-on” costs, such as the use of physician time to help consumers understand their results^{11,12} and unnecessary follow-up tests. However, to date, little information is publicly available about the number of DTC genetic tests sold and, therefore, the potential size or urgency of this problem.

Therefore, we set out to estimate the size of the DTC genomic testing market for assessment of disease susceptibility (we excluded unrelated markets such as forensic and paternity testing). Because these companies are not publicly traded, little information is available regarding their business volume and practices. Therefore, we used Compete.com to assess internet traffic on the websites of the three most prominent genome profiling companies as a rough proxy for commercial activity. 23andme was the clear leader (averaging 78% of the unique visitors per month in 2009), followed by Navigenics (15%) and deCODEme (7%). The total number of unique visitors to all three of these websites across the whole of 2009 was 662,007.

In October 2009, 23andme announced that its database held 30,000 “active” genomes.¹³ In addition, data published in March 2010 suggested that deCODEme and Navigenics had <10,000 and 20,000 customers, respectively, many of whom were given free or discounted tests.¹⁴ Assuming that these databases grew steadily since the companies were launched around 2 years previously, we estimate that ~20,000–30,000 people purchased a test from one of these three companies during 2009 (<5% of those visiting the websites) at a cost of US \$400–1000. This suggests that the market for these three providers in 2009 was around US \$10–20 million. A similar conclusion can be reached using internet traffic as a

proxy for market segmentation to supplement the data from 23andme, even allowing for an additional 10% of the market for other providers. Although this market figure is approximate, importantly, it is an order of magnitude smaller than earlier estimates of US \$730 million.¹⁵

In the absence of data to the contrary from the relevant companies, we therefore, conclude that current demand for genomic profiling tests for susceptibility to common complex diseases is fairly small. As such, the impact of these tests on health systems must also be small, although not negligible. Given outstanding questions over the utility of such tests, we find no evidence to support the assertion that falling sequencing costs will necessarily alter this conclusion in the near future. However, alternative DTC genomics offerings—such as carrier testing¹⁶ or whole genome sequencing—may yet prove to have a larger impact, although the market for these products remains to be tested.

ACKNOWLEDGMENTS

Both the authors C.W. and S.G.J. are funded by the PHG Foundation, a charitable company registered in England and Wales, charity No. 1118664, company No. 5823194. The authors wish to thank Marcus Askew, Nelson Liew, Jennifer Macdonald, Myung Jin Nam, and Jawad Warraich at the University of Cambridge Judge Business School for their input to this work.

REFERENCES

- Evans JP, Green RC. Direct to consumer genetic testing: avoiding a culture war. *Genet Med* 2009;11:568–569.
- Foster MW, Mulvihill JJ, Sharp RR. Evaluating the utility of personal genomic information. *Genet Med* 2009;11:570–574.
- Grosse SD, McBride CM, Evans JP, Khoury MJ. Personal utility and genomic information: look before you leap. *Genet Med* 2009;11:575–576.
- Gurwitz D, Bregman-Eschet Y. Personal genomics services: whose genomes? *Eur J Hum Genet* 2009;17:883–889.
- Khoury MJ, McBride CM, Schully SD, et al. The Scientific Foundation for Personal Genomics: recommendations from a National Institutes of Health-Centers for Disease Control and Prevention Multidisciplinary Workshop. *Genet Med* 2009;11:559–567.
- McGuire AL, Burke W. An unwelcome side effect of direct-to-consumer personal genome testing: raiding the medical commons. *JAMA* 2008;300:2669–2671.
- Mihaescu R, van Hoek M, Sijbrands EJJ, et al. Evaluation of risk prediction updates from commercial genome-wide scans. *Genet Med* 2009;11:588–594.
- Offit K. Genomic profiles for disease risk: predictive or premature? *JAMA* 2008;299:1353–1355.
- Patch C, Sequeiros J, Cornel MC. Genetic horoscopes: is it all in the genes? Points for regulatory control of direct-to-consumer genetic testing. *Eur J Hum Genet* 2009;17:857–859.
- Prainsack B, Reardon J, Hindmarsh R, Gottweis H, Naue U, Lunshof JE. Personal genomes: misdirected precaution. *Nature* 2008;456:34–35.
- McGuire AL, Diaz CM, Wang T, Hilsenbeck SG. Social networkers' attitudes toward direct-to-consumer personal genome testing. *Am J Bioeth* 2009;9:3–10.
- Kolor K, Liu T, St.Pierre J, Khoury MJ. Health care provider and consumer awareness, perceptions, and use of direct-to-consumer personal genomic tests, United States, 2008. *Genet Med* 2009;11:595.
- 2009 by the numbers. *Nat Med* 2009;15:1351–1352.
- Pollack A. Consumers slow to embrace the age of genomics. The New York Times, March 19, 2010:201.
- Schickedanz AD, Herdman RC. Direct-to-consumer genetic testing: the need to get retail genomics right. *Clin Pharmacol Ther* 2009;86:17–20.
- Balaji S, Srinivasan, Jason F, Patterson AS, et al. A universal carrier test for the long tail of Mendelian disease. *Nature Precedings* 2010;hdl:10101/npre.2010.4192.1.

From the PHG Foundation, Cambridge, United Kingdom.

Caroline F. Wright, PHG Foundation, 2 Worts Causeway, Cambridge CB1 8RN, United Kingdom. E-mail: caroline.wright@phgfoundation.org.

Disclosure: The authors declare no conflict of interest.

Submitted for publication May 27, 2010.

Accepted for publication May 30, 2010.

Published online ahead of print August 6, 2010.

DOI: 10.1097/GIM.0b013e3181ead743