

## Ethics watch

## DIRECT-ACCESS GENETIC TESTING: THE VIEW FROM EUROPE

The issues surrounding direct-to-consumer (DTC) genetic testing in North America have received much attention, but far less has been written about how these issues relate to Europe. Here we highlight some key contrasts between the two regions.

In the United States, DTC genetic testing has received intense scrutiny in terms of its legality, the role of the medical practitioner, the reliability of the tests and their benefits to the patient<sup>1</sup>. In some US states, there are no laws specifically regulating DTC genetic tests. However, in other states, the only tests that are legal are those that have already been approved by the US Food and Drug Administration (FDA) as over-the-counter tests or those for which the ordering of the test and receipt of the results can only be done through licensed practitioners<sup>2</sup>.

In the United States, DTC genetic tests are available on the Internet from over 60 companies<sup>3,4</sup>, but direct sale of kits in retail stores has been blocked (the FDA prevented Walmart from stocking Pathway Genomics test kits because the kit was considered a 'medical device'). In a portent of a possible direction for future regulations, the FDA's Molecular and Clinical Genetics Advisory Panel has taken the view that consumers should only be able to access clinical genetic tests (except for nutrigenetic tests) through a doctor in order to avoid any misunderstanding about the significance of the results<sup>5</sup>.

In Europe, DTC genetic testing services are being offered by a substantially smaller number of companies and, in some countries, test kits are being freely sold over the counter in pharmacies<sup>6</sup>. In contrast to the situation in the United States, few European countries have established regulatory frameworks for DTC genetic testing, and substantial differences exist among individual countries. Also, European consumer rights and protection in relation to these tests vary substantially owing to differences in the legal framework between countries. A recent report published by the Human Genetics Commission in the United Kingdom<sup>7</sup> lays out the principles that it is hoped may lead to the development of codes of practice for consumer-purchased genetic tests in Europe.

How do attitudes to DTC genetic testing differ between Europe and North America?

An online survey of >1,000 DTC customers in the United States found that most were satisfied with the testing experience and found their test results easy to understand<sup>8</sup>. By contrast, a recent European survey of doctors and the general public revealed strong opposition to DTC testing, and responders preferred a physician rather than a pharmacist to refer DTC testing<sup>9</sup>. Only a small proportion of respondents from the general public had been encouraged to undergo genetic testing, allaying some concerns about private laboratory involvement in DTC testing and the marketing used to attract new customers. Concerns that DTC genetic test results may generate anxiety are not supported by a recent US study of DTC customers<sup>10</sup>; however, similar information is currently missing from Europe. Lack of reimbursement for genetic testing by insurance companies may discourage the use of genetic testing services in the short term. In the European survey, over half of the general public expressed their willingness to take a genetic test even if the costs would not be reimbursed<sup>9</sup>. By contrast, a recent Canadian survey indicated that few respondents were willing to pay more than 500 Canadian dollars for genetic testing<sup>11</sup>.

Importantly, unlike in the United States, where DTC genetic testing mostly involves whole-genome SNP analysis, the vast majority of European companies perform DTC testing on a gene-by-gene basis. This involves testing a considerably smaller number of SNPs, thereby weakening disease risk prediction. Currently, even genome-wide SNP analysis is limited, as the technology is a surrogate for whole-genome sequencing. Plummeting sequencing costs may propel us towards inexpensive personal whole-genome-sequencing services, such as those available from Illumina (currently ~US\$18,500 per genome) and Complete Genomics (currently ~\$9,500 per genome); however, with technology rapidly improving, an all-inclusive price of \$1,000 per genome is soon likely to become a reality<sup>12</sup>. It is evident that there is an urgent need, both in Europe and elsewhere, to understand the potential benefits and pitfalls of genetic testing, to assess the landscape of genetic-testing services and, at the same time, to safeguard this vital service from improper exploitation.



Overall, there are many differences in DTC genetic testing between the United States and Europe. To bridge these differences, there is an urgent need for a detailed investigation of all aspects of DTC testing to enable enforcement of a more targeted regulation of DTC testing in Europe.

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The authors declare no competing financial interests.

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