To ban or not to ban?

Clinical geneticists' views on the regulation of direct-to-consumer genetic testing

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The past four years have seen a steady increase in the number of companies that offer direct-to-consumer (DTC) genetic testing services and in the number of such tests for genetic risk factors, including a wide range of diseases and other non-disease-related traits. These companies sell their tests outside the traditional healthcare setting and often do not involve healthcare professionals for either the initial sale of the test or when they inform consumers about the results—usually over the internet. Among other purposes, tests are being sold to determine consumers' genetic risk of developing Mendelian disorders, such as cystic fibrosis, as well as complex diseases including cancer, diabetes and Alzheimer disease.

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DTC genetic testing has also triggered a debate over the clinical utility and clinical validity of these services, and the ethical, legal and social issues that they raise. For an informed discussion to occur, it is necessary to gauge the opinion of professionals in the field, but little is known about how clinical geneticists view DTC genetic testing. The studies published so far focus primarily on physicians in general [1,2], or on genetic counsellors [3,4]. One study does include a relatively large subgroup of Japanese clinical geneticists, but they were not the focus of the study *per se* [5]. We conducted a brief survey among European clinical geneticists about their awareness, experiences

and attitudes regarding DTC genetic tests, including their views on whether certain tests should be banned. This is particularly relevant in the light of calls for increased regulation of DTC genetic testing both in Europe and in the USA.

Most of the 131 European clinical geneticists who responded believe that a subset of DTC genetic tests—genome scans and prenatal gender tests—should be banned. Their views varied greatly with respect to the type of testing offered (Table 1). Twenty-seven per cent of respondents somewhat or strongly agreed with banning of genetic tests sold for genealogy, and 36% neither agreed nor disagreed with banning this form of DTC test. Meanwhile, 69% and 62% of respondents agreed—either somewhat or strongly—with banning prenatal gender tests and genome scans, respectively. Views regarding preconception carrier testing and genetic tests that claim to measure performance in sports were rather less polarized. Fifty-three and fifty-four per cent agreed strongly or somewhat, respectively, that these tests should be banned. Overall, 86% of respondents were aware of DTC genetic testing services, and 45% of them had been approached by at least one patient who had purchased such services.

In Europe, this attitude is consistent with the legislation of various countries. France, Germany, Portugal and Switzerland have specific legislation stating that genetic tests for medical purposes can only be carried out by a physician after informing patients about the nature, meaning and consequences of the test, and after the patient has given consent, thereby effectively prohibiting DTC genetic tests [6]. However, as most of these countries regulate the offer of genetic tests in their national territories, rather than regulating their purchase

or use by consumers, there is little that can be done to stop European consumers from purchasing DTC tests over the internet from US companies. A notable exception is France, which adopted a Bioethics Law in June 2011 that also regulates the use of DTC genetic testing. The French Public Health code (Article L.1133-4-1) prohibits individuals from requesting a genetic test outside the conditions laid down by the law with fines of up to €3,750 [7]. It still remains to be seen whether this law can and will be enforced in practice.

According to a survey of general DTC services performed by the Genetics and Public Policy Centre (Johns Hopkins University, Baltimore, Maryland, USA) 13 states in the USA do not permit DTC tests, whilst 12 states permit only some subsets of DTC tests. In the remaining 25 states and in the District of Columbia, the sale of DTC genetic tests is not illegal [8]. In spring 2010 and May 2011, the Food and Drug Association (FDA) contacted many DTC genetic testing companies and stated that their products might require formal FDA review before they can legally be sold [9]. In March 2011, the FDA's expert panel on Molecular and Clinical Genetics held a public meeting [10] to discuss regulatory issues pertaining to DTC genetic testing. However, at the time of writing, neither the FDA nor the federal government have announced further attempts to regulate DTC genetic testing.

Various factors might help to explain the rather negative attitude of professionals, and the policy reactions in Europe and the USA, that favour regulating DTC genetic testing. We think that among these, two factors might have a major influence on professionals' acceptance of DTC genetic tests: healthcare systems and advertising for prescription drugs.

Table 1 | Clinical geneticists' views regarding the legal ban of some types of DTC genetic tests

Type of genetic test	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
Genetic ancestry testing, such as that offered by Family Tree DNA (www.familytreedna.com), should be legally banned	20% 22/113	18% 20/113	36% 41/113	8% 9/113	19% 21/113
Genome scans (hundreds of thousands to millions of SNPs are genotyped across the genome and disease risk calculated for multiple conditions and traits), such as that offered by 23andme (www.23andme.com), should be legally banned	9% 10/112	11% 12/112	18% 20/112	15% 17/112	47% 53/112
Preconceptional carrier testing, such as that offered by Counsyl (www.counsyl.com), should be legally banned	14% 16/114	19% 21/114	14% 16/114	18% 20/114	35% 39/114
Genetic tests that claim to measure performance in sports, such as those offered by Atlas Sports Genetics (http://www.atlasgene.com/), should be legally banned	9% 19/113	15% 17/113	22% 25/113	23% 26/114	31% 35/114
A prenatal gender test (from seven weeks after conception), such as that offered by Nimble Diagnostics (www.nimblediagnosics.eu), should be legally banned	13% 14/112	5% 6/114	13% 15/112	9% 10/112	60% 67/112

Physicians were told that "The following statements are about genetic tests sold directly-to-consumers by companies. Please choose the option that best represents your agreement with each statement." SNP, single-nucleotide polymorphism.

Traditionally, European healthcare systems emphasize the collective responsibility of society for the health needs of the individual. Based on the concept of solidarity, mechanisms of redistributive justice were developed that emphasize the importance of universal access to health care. According to this view, health care is a public and social good for which states, societies, institutions and healthcare professionals are responsible. By contrast, the genetic testing services provided by DTC companies become a private or personal commodity, such as any other goods or service, that are bought and sold between individuals for one's satisfaction or necessity without external involvement. DTC genetic testing companies therefore emphasize a form of 'active consumerism' [11]: the tests are advertised with the underlying argument that consumers have a right to know their genetic information and take appropriate preventive actions [12]. The provision of these services outside the traditional healthcare system might be considered by DTC genetic testing companies, and their consumers, as a realization of their individual right to pursue services that they consider to be in their own best interests or merely because of their own preferences.

European healthcare professionals might well regard this activity as a threat to both public health and collective welfare. As most of the tests offered lack proven clinical validity and utility, they could lead to unsubstantiated health decisions and have further impacts on healthcare systems. The notion

of healthcare services as commodities, and individuals as consumers of health goods, might clash with European healthcare professionals and policy-makers' views on health care, and might be interpreted as a lack of responsibility to wider health interests. Although we did not ask specifically about this issue in our survey, one respondent did comment: "Genetic testing is a matter for medicine, not for commercial purposes".

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The second factor is the advertising of prescription drugs in the USA, which has been a fertile ground for advertisement of health-related services, such as DTC genetic testing. By contrast, the advertisement of prescription-only medicines is subject to regulatory restrictions in Europe. Here, DTC advertising has been considered an inappropriate means for pharmaceutical companies to communicate with patients, because the probable detriments outweigh the unproven benefits [13] and because of concerns over inappropriate demand for unsuitable medications. Moreover, research shows that advertising for drugs can be misleading and overstate effectiveness or minimize risks, thus leading to inadequate changes in medication, diet or lifestyle by consumers [14–16]. In line with this, one respondent wrote about DTC genetic

testing companies: "the advertisements give false ideas and hopes for the public, and therefore they are unethical."

It would be tempting to assume that the opposing European and American perspectives on DTC genetic testing are based on the differences between EU and US healthcare systems, and the regulation of drug advertising, but the reality is more complex and the lines drawn between proponents and opponents of DTC genetic testing do not really lie at national or geographical borders. Although information regarding the views of US clinical geneticists has yet to be published in a full length article or manuscript, many US physicians and researchers also seem to disagree with unregulated DTC genetic testing. A survey among members of the American Society of Human Genetics (ASHG) presented in 2011 at the ASHG annual meeting in Montreal, Canada, revealed that a clear majority (93.6%) of the 1,517 respondents agreed or strongly agreed that "regulation of DTC genetic tests is important" and 51.9% disagreed or strongly disagreed that "current regulations are sufficient" [17]. The differences in wording between the European and US survey should be noted; "banning" and "regulation" are not synonymous; however, results from both surveys indicate that genetic professionals feel that there is a need for more regulation. Moreover, two-thirds of the American survey respondents (67.7%) agreed or strongly agreed "that the involvement of a healthcare provider should be required when using

DTC genetic tests" [17]. Respondents made statements regarding the need of some type of counselling and input from a healthcare professional in their open-ended comments. For example, one commented: "without 'true' genetic counselling, what is the benefit of these analyses, apart [from] the economic advantage for the companies selling the tests? Is a computer monitor a good substitute [for] an experienced doctor?"

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Furthermore, professional guidelines including those from the American Medical Association (<http://www.ama-assn.org/>) and the American Congress of Obstetricians and Gynaecologists (<http://www.acog.org/>) emphasize the need for individualized care from a qualified medical professional. In addition, the American Medical Association sent a letter to an FDA expert panel recommending that "genetic testing, except under

the most limited circumstances, should be carried out under the personal supervision of a qualified health care professional" [18].

Meanwhile, proponents of DTC genetic testing regard the mandatory involvement of physicians or other healthcare professionals as paternalistic, and claim that physicians want to keep their "traditional monopoly over the interpretation of genetic information" [19]. Although the comments provided by the respondents to our survey do not suggest that this is an underlying reason for agreeing with a legal ban of some DTC genetic tests, we concede that any professional group could have a vested interest in trying to maintain their client and patient base. Taking this into account, even if DTC genetic testing companies operate without involving clinical geneticists and genetic counsellors, it is not a given that this commercial activity would necessarily affect the workload of clinical geneticists. In fact, it might even increase their workload, given that many DTC genetic testing users consult

healthcare professionals after receiving their results from companies [20]. Furthermore, there are no data suggesting that consumers who purchase genome-wide testing, as offered by companies such as 23andme and deCODE, are the same individuals who would show up for individual gene testing in a clinical setting. Finally, there might already be too few genetic counsellors [21] and clinical geneticists [22] to deal with the present demand, and the demand for genetic and genomic testing is expected to increase in the future [22]. Therefore, it would seem that even if DTC genetic testing companies do continue operations, there might be no shortage of work for clinical geneticists.

Another reason to exclude healthcare professionals from the model of provision is based on the claim that consumers have a right to access their genetic information and should be able to do this outside the context of the healthcare system. However, "[p]eople may indeed have a right to their genetic information, but it does not follow that we should not regulate the process to make sure that information is appropriately provided" [23].

Our results highlight the discrepancy between the minimal regulatory oversight of DTC genetic testing and the views of European experts, who feel that at least a subset of these services should be banned. Furthermore, it raises a fundamental question about what constitutes responsible medical genetic care. Until a few years ago, genetic testing was only available through the healthcare system and through professional clinical geneticists or genetic counsellors. Commercialization of genetics has shown a tendency towards excluding healthcare professionals, which raises some relevant questions: does the fact that private companies can offer (cheaper) testing for (more) genetic variants mean that there is no need for medical consultation? Are there genetic tests for which healthcare professional supervision is not needed—for example, ancestry testing or tests for non-health-related phenotypes such as eye colour? Some respondents did express nuanced views based on the type of test offered and their perceived consequences. For example, one geneticist stated: “I am for banning in conditions which have a strong impact on the person’s life, but I can accept testing for ‘curiosities’”. Another wrote: “if it makes no harm, let people do what they want with their money; but if there is a risk of harm for the applicant, spouse or child, there should be regulations.”

In the light of the increasing number of genomic tests that are available, debates about how to establish preventive genomics in a medically and socially responsible way have just begun. Some respondents actually suggest that banning DTC genetic testing might not even be necessary: “[I] don’t agree that legal banning is the answer; it would be difficult to implement as the internet goes across many jurisdictions and [doing so is] therefore not practical. [It is] [m]ore appropriate to offer guidance on appropriate use.” Other respondents expressed clearly the importance of banning DTC genetic testing services: “genetic testing is not a game. Impacts, benefits, advantages and disadvantages have to be carefully and individually discussed before testing.” The question of whether to ban or not to ban DTC genetic testing services, however, might distract from the more important problem of applying genome-based technologies in the clinic and for public health in a responsible way, and of defining indispensable criteria for this to happen.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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