

Response to 'Europe and direct-to-consumer genetic tests'

Larry J. Kricka, Paolo Fortina, Yuan Mai and George P. Patrinos

In response to our Ethics watch published in this journal (Ethics watch: Direct-access genetic testing: the view from Europe. *Nature Reviews Genetics* **12**, 670 (2011))¹, the Correspondence by Howard and Borry (Europe and direct-to-consumer genetic tests. *Nature Reviews Genetics* 13 Dec 2011 (doi:10.1038/nrg3073-c1)² summarized the steps that have been undertaken in Europe to address the controversy surrounding direct-to-consumer (DTC) genetic testing. The ongoing debate on DTC genetic testing is due in part to the lack or limited regulation of the current genetic tests in Europe¹. We agree that this situation is more adequately tackled in most northern European countries, where national bioethics committees have already addressed, or are currently working to address, this issue. Also, at the European level, the European Society of Human Genetics (ESHG) has considered this issue several times³. Furthermore, 82.1% of the general public and 87.3% of the health-care professionals that responded to a recent survey strongly oppose DTC genetic testing⁴. This raises the question of how DTC genetic-testing laboratories in Greece (and probably in other countries) attract so many tests from the general public and, most importantly, how they communicate the scientific information to the parties that undertake these tests.

We feel that the root of current controversies in DTC testing is linked to a lack of a proper regulatory framework in most European countries, a lack of proper genetics education of health-care practitioners

and a poor awareness of the general public regarding genetic testing services. Recent surveys in Greece show a lack of genetics education in health-care professionals; this was highlighted by the finding that, although health-care professionals would be willing to, in principle, recommend that their patients undergo genetic and pharmacogenomic testing, the actual percentage that had actually recommended a genetic analysis to their patients is far less^{4,5}.

How this issue can be addressed? Given that substantially more steps have been undertaken in northern European countries compared with other countries in Europe^{1,2}, it is evident that there is an urgent need to synergize efforts between scientists from different parts of Europe in an effort to critically evaluate the understanding of the public and other stakeholders (for example, health-care professionals, commercial and public providers of genetic-testing services, patient organizations, data protection agencies, organizers of open science initiatives and activists). This approach is needed in order to: understand the current status of genetic-testing services in Europe; identify possible benefits of the application of genetic-testing services in the clinic and, importantly, in the research laboratory; identify and tackle problems, such as gaps in legislation and regulation that delay the full adoption of genetics in modern medical practice (in the clinic and beyond); and ultimately provide the means to create the necessary legal and regulatory framework to govern and harmonize genetic services in Europe, with the aim of achieving

personalized medicine. Such a pan-European effort, involving many research groups from all parts of Europe that will operate in concert with regulatory agencies, European research consortia (for example, [EuroGenTest](#) and [OrphaNet](#)) and patient organizations would allow detailed mapping of the genetic-testing situation in various European countries.

Larry J. Kricka is at the Department of Pathology and Laboratory Medicine, University of Pennsylvania School of Medicine, Philadelphia, Pennsylvania, USA.

Paolo Fortina is at the Laboratory for Cancer Genomics, Kimmel Cancer Center, Jefferson Medical College, Thomas Jefferson University, 233 South 10th Street, BLSB-1009, Philadelphia, USA; and the Department of Molecular Medicine, University Sapienza School of Medicine, Rome, Italy.

Yuan Mai and George P. Patrinos are at the Department of Pharmacy, School of Health Sciences, University of Patras, Rion GR-265 04, Patras, Greece.

Correspondence to P.F. and G.P.P.
e-mails: paolo.fortina@jefferson.edu;
gpatrinos@upatras.gr

doi:10.1038/nrg3073-c2

Published online 13 December 2011

1. Kricka, L. J., Fortina, P., Mai, Y. & Patrinos, G. P. Ethics watch: Direct-access genetic testing: the view from Europe. *Nature Rev. Genet.* **12**, 670 (2011).
2. Howard, H. C. & Borry, P. Europe and direct-to-consumer genetic tests. *Nature Rev. Genet.* 13 Dec 2011 (doi:10.1038/nrg3073-c1).
3. European Society of Human Genetics. Statement of the ESHG on direct-to-consumer genetic testing for health-related purposes. *Eur. J. Hum. Genet.* **18**, 1271–1273 (2010).
4. Mai, Y. *et al.* A critical view of the general public's awareness and physicians' opinion of the trends and potential pitfalls of genetic testing in Greece. *Per. Med.* **8**, 551–561 (2011).
5. Sagia, A. *et al.* A critical appraisal of the private genetic and pharmacogenomic testing environment in Greece. *Per. Med.* **8**, 413–420 (2011).

Acknowledgements

This work has been encouraged and partly supported by the Golden Helix Institute of Biomedical Research.

Competing interests statement

The authors declare no competing financial interests.

FURTHER INFORMATION

EuroGenTest: <http://www.eurogenetest.org>

OrphaNet: <http://www.orpha.net/consor/cgi-bin/index.php>

ALL LINKS ARE ACTIVE IN THE ONLINE PDF