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LETTER

Direct to consumer genetic tests

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We would like to respond to the editorial published alongside the commentary that we wrote for *European Journal of Human Genetics*.[1,2] We feel that Professor Brand has missed the point of the commentary and misrepresented its conclusions. This has unnecessarily placed it in an adversarial position with the article by Gurwitz and Bregman.[3] Although there may be different policy implications, these two contributions are complementary and contribute constructively to an informed dialogue. Both call for partnership working between the various stakeholders, which include industry, health service providers and purchasers, the medical and genetics community and the general consumer. As the following quote illustrates, Gurwitz and Bregman[3] are, like we do, recommending a sensible control of the processes involved in bringing personal genomics to market, which includes self-regulation by code of practice.

Although 'free-market forces' will be among the decisive factors about the success or failure of such DTC personal genomics and health databasing services, we call upon national regulators and international organizations such as the OECD to consider carefully through which means undesired effects including privacy risks could best be avoided. Yet, as this young industry is rapidly evolving and the spectrum of its societal impact is still unclear, meaning that such regulation may take several years to implement, urgent interim steps must meanwhile be taken. These include self-regulation and the establishment of best practices guidelines, potentially coordinated through a dedicated association of the DTC personal genomics providers.

Our commentary described current initiatives in this area and did not, as Professor Brand presents it, make an argument for prohibition and statutory regulation of all aspects of test provision. Instead, it lists some concerns and also the various points at which some control might be applied to tests for health-care purposes. These include premarket review, which is subject to regulation, review by purchaser, which for health-care provision does require evidence of efficacy, and issues of concern to the consumer for those tests that are supplied without medical intervention. We consider the proposals of Gurwitz and Bregman[3] entirely complementary to ours. We would furthermore like to add that the OECD has already included issues of validity and utility in its guidelines.

Rather than polarising these issues, as might be the effect of Professor Brand's contrasting presentation of the two contributions, like Gurwitz and Bregman[3], we propose to work with the various partners to ensure that the delivery of effective technologies within health-care settings is facilitated and the companies and investors are able to bring effective products to market efficiently. This is happening with the work of the UK Human Genetics Commission (HGC), which is attempting to develop a common framework of principles in relation to DTC. The Professional and Public Policy Committee of the European Society of Human Genetics (ESHG) was represented at an expert workshop in March 2009 at the European Parliament organised by the Science and Technology Options Assessment panel, together with The European Technology Assessment Group, where a variety of experts from industry, ESHG, HGC, the European Commission and the public interest groups discussed these issues. These discussions are also supported by the industry partners who seem to want clear processes to ensure that effective products are distinguished from ineffective ones. In addition, other issues relating to the evaluation of evidence for diagnostics are being actively considered at the policy level with health-care providers and purchasers. These initiatives are, as mentioned before, being developed with constructive partnerships at the policy level rather than being rooted in a historical adversarial position.

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2 Brand A: Integrative genomics, personal-genome tests and personalized healthcare: the future is being built today. *Eur J Hum Genet*, (advance online publication, 4 March 2009; doi: 10.1038/ejhg.2009.32).
3 Gurwitz D, Bregman-Eschet Y: Personal genomics services: whose genomes? *Eur J Hum Genet*, (advance online publication 4 March 2009; doi:10.1038/ejhg.2008.254).