Mathews R., Carter A., Hall W. Response to commentaries: slowing down the rush to translation in personal genomics. *Addiction* 2012; **107**: 2081

All commentators agree with our argument [1] that genomic testing is of little clinical utility in predicting complex behavioural phenotypes in individuals, including addiction [2-5]. Ware & Munafo [4] argue that random or stochastic events raise serious doubts about whether genetic tests will ever predict an individual's risks of developing complex diseases or disorders such as addiction.

Borry [5] and Saunders & Ashcroft [2] argue that clinical utility is not the only reason why individuals have their genomes screened. They may simply be curious or find the idea amusing, in which case direct-to-consumer (DTC) genomics should be seen as part of the entertainment industry. Saunders & Ashcroft argue accordingly that DTC genetic tests should be provided under the same protections afforded other commodities in society; namely, let the buyer beware [2]. We do not, they argue, attempt to regulate clairvoyants and soothsayers.

We would have fewer objections to genomic testing that disclaimed all medical utility and advertised itself as a purely recreational pursuit, a genomic variant of astrology [6, 7]. However, defenders of DTC genetic tests do claim to provide clinically useful information [8], and companies that make such claims should be subject to the same premarket approval processes as other medical diagnostic technologies and test results should be provided under similar conditions (e.g. by qualified health practitioners).

It is also not clear that these companies are fully disclosing to the public the limited utility and efficacy of their products. Customers are not told, for example, that tests of the same genes in an individual by different companies may agree on fewer than 50% of occasions [9]. Some DTC genetic companies provide disclaimers about the limited clinical utility of their tests for health-related decisions, but these are often contradicted implicitly in advertisements.

Barbara Koenig shares many of our concerns about the rapid translation of DTC genetic testing to the market-place, but believes it is too late to regulate the DTC market. She argues (as do Saunders & Ashcroft) that national regulations will not be able to stop global online marketing of DTC testing [3]. We agree that regulation is no panacea, but we should not allow failure to achieve a regulatory ideal to justify regulatory surrender. It will be difficult for legislators to prevent determined individuals from circumventing national regulations, but this is true of the regulation of pharmaceuticals. The abandonment of all national efforts to regulate these commodities would make a bad situation much worse. Regulation, while imperfect, may serve a useful role in public education and perhaps slow down companies' unseemly haste to ‘translate’ genomic discoveries into the clinic that was identified by Barbara Koenig.

Advocates of genomic medicine also have an interest in slowing the rush to market genetic testing directly to consumers. There is a real danger that the proliferation of poorly regulated DTC genomic testing will undermine the appropriate use of clinically useful forms of genomic testing that may be developed, such as the pharmacogenetic testing outlined by Ware & Munafo [5].

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