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Commercialisation of Genomic Research: The Issue of Public Trust

Christine Critchley and Dianne Nicol[*]

Introduction

The large investment of public funds into the Human Genome Project and related research is starting to pay off.[1] A whole new field of precision medicine has emerged, the aim of which is to deliver personalised health care, tailored to an individual's genetic characteristics, health status and family history.[2] Yet there are still large gaps in our knowledge of how our genomes and our physical environment affect our health and wellbeing.[3] Much more research needs to be done, and the results of that research need to be translated to the clinic and the pharmacy in a timely fashion. The many ethical, legal and social concerns raised by this research effort are well recognised, and there has been an extensive body of policy and academic analysis of appropriate regulatory responses.[4]

One issue that continues to confound is how to provide the appropriate incentives to ensure that translation of genomic research is efficient, effective and equitable. If publicly funded research is simply handed over to the private sector for translation, the efficiency and effectiveness of this process is likely to be offset by lack of equitable access to the products of translation. But if the private sector is not provided with adequate incentive to be involved in translation, product development may never actually occur because it is too risky and too expensive for the public purse. It has been posited that commercial involvement in translational genomic research and development is an inevitability.[5] Yet it is clear from an extensive body of research that commercialisation concerns members of the public, leading to a diminution in

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1 See, eg, Eric S Lander, 'Initial Impact of the Sequencing of the Human Genome' (2011) 470 *Nature* 187.

2 See, eg, US Food and Drug Administration, *Paving the Way for Personalized Medicine: FDA's Role in a New Era of Medical Product Development* (Washington, 2013).

3 Eric D Green, James D Watson and Francis S Collins, 'Human Genome Project: Twenty-five Years of Big Biology' (2015) 526 *Nature* 29.

4 Don Chalmers, Dianne Nicol, Margaret Otlowski and Christine Critchley, 'Personalised Medicine in the Genome Era' (2013) 20 *Journal of Law and Medicine* 577.

5 See, eg, Dianne Nicol, Christine Critchley, Rebekah McWhirter and Tess Whitton, 'Understanding Public Reactions to Commercialization of Biobanks and Use of Biobank Resources' (2016) 162 *Social Science and Medicine* 79; Timothy Caulfield et al, 'The Commercialization of Biobanks: Scoping the Policy Issues' (2014) 1 *Journal of Law and the Biosciences* 94.