

# Regulations Pertaining to the Emerging Area of Nutrigenetic Testing

*Sarah Scott*

## **Introduction**

Nutrigenetic testing would seem to be a natural application of genetic testing in a preventative healthcare context. If scientists and medical researchers are already aware of genes which determine how individuals process compounds in foods, it makes sense that some individuals would be interested in discovering how their bodies react to these particular compounds. Having a basic knowledge of the foods your body has difficulty breaking down or could use more of to optimize your health could be very helpful in planning an appropriate diet and preventing future disease.

These direct-to-consumer genetic tests are raising concerns for many individuals within industrialized nations. Consumer rights groups worry that the claims made by companies offering such tests are not substantiated.<sup>1</sup> Although we have mapped the human genome, there is still much that is not known about the interplay between different genes and about the human genome in general.<sup>2</sup> For this reason, some individuals claim that these tests, which only look at twelve to fifteen genes in an individual, cannot be relied on as a means of planning lifestyle or predicting overall health.<sup>3</sup> Even if the determination of certain gene variants could be linked to an increased risk of a disorder, there are still concerns regarding the clinical validity of such tests. At the present time, some countries do not have a system of regulations in place to ensure that the genetic tests are being performed by trained laboratory personnel. There are gaps in regulatory assurance of the laboratories themselves in regard to quality assurance and safety protocols. It is also important to consider who is responsible for viewing and interpreting the test results. There are not always assurances in place stipulating what kind of health care professional—if any—is undertaking this duty.<sup>4</sup>

There are several large companies operating out of the United States that offer nutrigenetic tests. These

corporations include Sciona<sup>5</sup> and Genelex.<sup>6</sup> Most nutrigenetic tests are offered through a company's website. Typically, the site explains to the customer what the particular metabolic disorders or genetic traits are that are being investigated, and what the results could mean for a person's overall long term health. The tests normally consist of a swab kit that the customer must use to obtain cheek cells and then send back to the company along with a completed survey regarding his or her eating and fitness habits. The company will then run the genetic test in its laboratories. The tests are normally concerned with twelve to fifteen different genes, including ones which have been known to be associated with certain disorders—cardiovascular disease, diabetes and the inability to break down certain compounds present in foods, for example. The laboratory staff, which can include medical doctors, will assess the outcome of the genetic test in light of the information given by the customer on their information survey. The laboratory then sends back information to the customer regarding what lifestyle changes should be made or what foods to avoid or increase in his or her diet. Services such as these can cost anywhere from 200 to 1000 dollars US.<sup>7</sup>

Industrialized countries are aware of these companies and have taken different approaches to the regulation of their services. To provide an example of a regulatory framework that catches nutrigenetic tests, the current framework in Australia will be discussed. The legislation governing the manufacture and licensing of medical devices covers in vitro diagnostic devices (IVDs) such as nutrigenetic tests. The *Therapeutic Goods Act*<sup>8</sup> and Regulations<sup>9</sup> outline the basic regulatory structure. The Therapeutic Goods Administration (TGA) is responsible for enforcing this legislation and operates through the Department of Health and Ageing. There are three categories which IVDs may fall under based on their risk classification: registerable, listable, or exempt<sup>10</sup>. The TGA has anticipated the need for a regulatory scheme which administers nutrigenetic tests and has therefore

addressed them in a March 2007 guidance document.<sup>11</sup> This document states that some nutrigenetic tests will fall under the listable IVD group, which includes devices for home use and those containing material of human origin. For approval to manufacture and sell listable IVDs, the manufacturer must show evidence of good manufacturing practices regarding the device, as well as instructions for use and promotional and product information. Some nutrigenetic tests may also fall into the exempt category if they are designed for use in a health care setting or by a health care professional.

This categorization and regulatory approach were only intended to serve as a temporary means of fitting nutrigenetic tests into the 1989 Act and Regulations. The Australian government was undergoing an amalgamation of its therapeutic device regulation system with New Zealand, but plans were temporarily set aside in July 2007 until there was sufficient support for the proposed changes from the New Zealand Parliament.<sup>12</sup> The Australian and New Zealand medical device regulation regime was to be replaced with a new joint regulatory office called the Australia New Zealand Therapeutic Products Authority.<sup>13</sup> Both countries were also scheduled to release new undated medical device Acts and Regulations,<sup>14</sup> which were to incorporate directions from the Global Harmonization Task Force<sup>15</sup> and were intended to more clearly regulate in vitro diagnostic devices such as nutrigenetic tests.

At the present time, the only new legislation relating to in vitro diagnostic devices is the *Therapeutic Goods Advertising Code*,<sup>16</sup> which was released in February 2007. The *Code* applies only to manufacturers marketing goods directly to consumers and does not apply to those marketed to health care professionals only. This Code aims to prevent advertisers from exploiting a lack of knowledge on the consumer's part and resorting to the use of unsubstantiated claims or fear tactics to encourage the use of their products.<sup>17</sup> In order to enforce the *Code*, complaints against advertisements may be heard by the Therapeutic Goods Advertising Code Council.

It would seem at this point that the future of regulatory control of nutrigenetic tests will depend on their popularity in coming years. Governments will be less concerned with a small percentage of the population using these services so long as the companies offering the tests are not making false health claims or failing to practise due diligence with regard to the protection of their customers' privacy— by not properly protecting their personal or genetic information, for instance. From a public health perspective, the use that is occurring at the present time would not seem to create a serious risk to society at large. Given the interest in preventative healthcare, however, it is likely that the

demand for nutrigenetic testing services will grow. Governments worldwide will have to re-assess the regulatory framework that is in place now in light of the risk associated with the use of these tests.<sup>18</sup> Attempts to repair any gaps in the regulations surrounding the marketing and use of nutrigenetic tests will also have to account for the ability on the part of companies to use the internet to market the tests globally.

*Sarah Scott is a 3rd Year Common Law Student at the University of Ottawa.*

1. Helen Wallace, *Your Diet Tailored to Your Genes: Preventing Diseases or Misleading Marketing?* (Tideswell, U.K.: GeneWatch UK, 2006), online: <<http://www.genewatch.org/uploads/fo3c6d66a9b354535738483c/c3d49c4/Nutrigenomics.pdf>>.
2. Elaine Trujillo, Cindy Davis & John Milner, "Nutrigenomics, Proteomics, Metabolomics, and the Practice of Dietetics" (2006) 106 *Journal of the American Dietetic Association* 403.
3. Lenore Arab, "Individualized nutritional recommendations: do we have the measurements needed to assess risk and make dietary recommendations?" (2004) 63 *Proceedings of the Nutrition Society* 167.
4. Hilary Burton & Alison Stewart, eds., *Nutrigenomics: Report of a workshop hosted by The Nuffield Trust and organised by the Public Health Genetics Unit on 5 February 2004* (London: The Nuffield Trust, 2005), online: <<http://www.nuffieldtrust.org.uk/ecomms/files/Nutrigenomics.pdf>> [Guidance Document].
5. See the Sciona Mycellf program, online: <<http://www.mycellf.com/index.aspx>>.
6. See the Genelex Corporation Health and DNA Nutritional Genetics service, online: <<http://www.healthanddna.com/nutrigeneticstest.html>>.
7. Gautam Naik, "As Gene Tests Spread, Questions Follow" *The Wall Street Journal* (13 December 2007), online: *The Wall Street Journal Online* <[http://online.wsj.com/article\\_email/SB119750960000325443-1MyQjAxMDE3OTE3MzUxMDM5Wj.html](http://online.wsj.com/article_email/SB119750960000325443-1MyQjAxMDE3OTE3MzUxMDM5Wj.html)>.
8. *Therapeutic Goods Act 1989* (Cth.).
9. *Therapeutic Goods Regulations 1990* (Cth.) and *Therapeutic Goods (Medical Devices) Regulation 2002* (Cth.).
10. *Therapeutic Goods Regulations 1990*, *ibid.* at Sch. 3, Part 2 and Sch. 4, Part 1.
11. Therapeutic Goods Administration, *The regulation of nutrigenetic tests in Australia: Guidance document* (Woden: Therapeutic Goods Administration, 2007), online: *Therapeutic Goods Administration* <<http://www.tga.gov.au/devices/ivd-nutrigenetic.htm>>.



12. Therapeutic Goods Administration, "Australia New Zealand Therapeutic Products Authority (ANZTPA)", online: Therapeutic Goods Administration <<http://www.anztpa.org/>>.
13. See Australia and New Zealand Therapeutic Products Authority website, online: <<http://www.anztpa.org/>>.
14. Therapeutic Goods Administration, *Australian Medical Devices Guidelines: Transitional Arrangements for the Introduction of the New Medical Devices Regulatory System: Guidance Document Number 9 Version 1.6* (Woden: Commonwealth of Australia, 2003) online: <<http://www.tga.gov.au/docs/pdf/devguid9.pdf>>.
15. See the Global Harmonization Task Force website, online: <<http://www.ghrf.org/>>.
16. *Therapeutic Goods Advertising Code 2007* (Cth.), enacted under s.3(1) of the *Therapeutic Goods Act 1989* (Cth.), online: <[http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrument1.nsf/0/C93181A65F7FCC7CCA25729700024748/\\$file/F2007L00576TherapeuticGoodsAdvertisingCode2007.pdf](http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrument1.nsf/0/C93181A65F7FCC7CCA25729700024748/$file/F2007L00576TherapeuticGoodsAdvertisingCode2007.pdf)>
17. *Ibid.* at s. 4.
18. Nola M. Ries, "Regulation of human stem cell research in Japan and Canada: a comparative analysis" (2005) U.N.B.L.J. 62.