

Helena Jochem

Direct-to-Consumer Genetic Testing in New Zealand

LLM RESEARCH PAPER

LAWS 582: MASTERS LEGAL WRITING

FACULTY OF LAW

TE WHARE WĀNANGA O TE ŪPOKO O TE IKA A MĀUI



VICTORIA
UNIVERSITY OF WELLINGTON

2016

Table of Contents

I	INTRODUCTION	4
II	THE SERVICE OF GENETIC TESTING COMPANIES	5
	A How Does the Service of Genetic Testing Companies Work?	5
	B The Genetic Science Behind the Service	7
	C The Validity and Usefulness of the DTC Genetic Testing Results	9
	D Four Key Characteristics	11
III	A CALL FOR A SPECIFIC REGULATION OF THE DTC GENETIC TESTING MARKET?	13
	A Arguments for an Unrestricted Market: Consumer Autonomy and Promotion of Research	13
	B Concerns that Call For Specific Legal Intervention	16
	1 Consumers are misled about the validity and usefulness of the product.....	16
	(a) Misled about validity of the test	16
	(b) Misled about usefulness of test results	17
	2 Concerns about informed consent.....	19
	(a) Does the concept of informed consent apply to DTC genetic testing?.....	19
	(b) Possible issues in relation to informed consent?	20
	3 Psychological harm.....	23
	4 Negative effects on society and burden for public health care	24
IV	POSSIBLE REGULATION	25
	A Reducing the Risk of Misleading Information through Quality Assurance	27
	1 Existing fragmentary coverage by consumer protection law and medical law.....	28
	2 Recommendations.....	31
	(a) Industry self-regulation as interim solution.....	31
	(b) Incorporation of DTC genetic testing into a new statute for therapeutic products	31
	B Improving the Informed Consent Process	34
	1 Status quo.....	34
	(a) General provisions.....	34
	(b) Provisions applying to testing of minors and involuntary testing	35
	2 Recommendations.....	36
	(a) Mandatory pre-test counselling	36
	(b) Prescription requirement for testing of minors and additional ban of advertisement	38
	C Reducing the Risk of Psychological Harm and Fulfilling Responsibilities to Society	38
V	CONCLUSION	39

Abstract

This paper examines the direct-to-consumer genetic testing industry against the background of the current regulatory framework in New Zealand. Direct-to-consumer genetic testing refers to genetic testing services sold directly to consumers mainly via the Internet without the involvement of health care professionals. This paper focuses on disease predisposition genetic tests that calculate a personal risk to develop a disease based on genetic information.

After an analysis of the peculiarities of DTC genetic testing services, the paper contrasts the main arguments for no further state intervention with the concerns about DTC genetic testing that call for more governmental oversight. The main part of the paper argues that the current partial coverage of the existing regulatory framework in New Zealand is insufficient. The paper presents possible recommendations for legislative reform, taking into account recently released details regarding a new Therapeutic products Bill.

Word length

The text of this paper (excluding abstract, table of contents, footnotes and bibliography) comprises exactly 11999 words.

Subjects and Topics

Therapeutic Products Bill

Medicines Act 1981

Medical devices

Consumer Law

Ethics and Law

Genetic Testing

Direct-to-Consumer

I Introduction

“Do you have a history of a genetic disease in the family or perhaps want to take better control of your health? Why not be more pro-active and manage your own health to the max by doing a genetic health test? Our genetic health test will determine your predisposition to 34 different diseases.”¹

The above slogan from the genetic testing company *EasyDNA* sounds promising. Words such as “better control”, “pro-active” and “max” management imply that the test offered is a feature of today’s cutting edge field of personalised health care.

There is no question that the knowledge that researchers have gained about human genetic information in the past decades is remarkable. The completion of the Human Genome Project, which presented a mapping of the entire human DNA in 2003, was a cornerstone for further research exploring the influence of genetic material on the development of common diseases such as cancer, as well as on effectiveness or tolerability of specific medicine.

The research is still in its initial stages. Nevertheless, private companies have discovered a new market: direct-to-consumer (DTC) genetic testing services. This term refers to genetic testing services sold directly to consumers via the Internet or other marketing venues without the involvement of healthcare professionals.² According to industry analysts, the worldwide market of DTC genetic testing will have a value of USD 230 million by 2018.³ While the offered purpose of genetic analysis is manifold, from well-known paternity testing, to ancestry tests right through to animal tests;⁴ this paper will focus solely on health-related tests. Of particular interest are predictive tests that are marketed as a means to obtain a personalised risk assessment for the development of a certain disease.⁵

¹ See slogan on www.easydna.co.nz (accessed on 22nd of March 2016).

² Pascal Su “Direct-to-Consumer Genetic Testing: A comprehensive View” (2013) 86 *Yale Journal of Biology and Medicine* 359 at 359.

³ “Future of Direct-to-Consumer (DTC) Genetic Testing Market Remains Fraught with Challenges, According to New Report by Global Industry Analysts, Inc.” (8 August 2012) <www.prweb.com>.

⁴ Easydna offers genetic tests for animals, however this kind of test is currently not available on the New Zealand website.

⁵ Other forms of health related tests are pharmacogenetic tests, which measure individual variability in drug metabolism and nutrigenomic tests that make claims for personalized diet and nutrition for optimal weight loss.

This paper aims to evaluate DTC genetic testing for consumers from a New Zealand perspective. The first part of the paper gives an introduction to the DTC service and explains the current scientific background of the tests. The chapter ultimately identifies the main peculiarities of DTC genetic testing. The following part contrasts the idea of a free market access for DCT genetic tests with current concerns that call for particular regulation of this new industry. It concludes that the main factors that make an unregulated market problematic are the high risk of consumers being misled about the validity and the usefulness of the test results, the issue of informed consent in a business-consumer relationship and possible negative impacts on individuals and society. The main part of the paper argues that there is a lack of the current regulatory landscape to sufficiently address these issues and makes recommendations as to how an appropriate level of regulatory oversight can be reached.⁶ The recommended approach is one that focuses on quality requirements, pre-market approval and partial involvement of health care professionals. The current revision of the Medicines Act 1981 is an opportunity to reform the law so that it comprehensively deals with the issues of genetic testing.

II The Service of Genetic Testing Companies

To answer the question whether and to what extent the business model of DTC genetic testing needs regulatory intervention, it is important to know the basic function of the service, as well as the science behind the service.

A How Does the Service of Genetic Testing Companies Work?

Two DTC genetic testing companies, which operate on the New Zealand market, serve to illustrate the service.⁷ Both companies, *EasyDNA* and *International Biosciences (IB)* operate their business internationally with a branch office in New Zealand.⁸ The so-called DNA Health Test (*EasyDNA*) or Genetic Predisposition Test (*IB*) is offered for 695 NZD and claims to “reveal invaluable information about your lifetime risk towards 34 major diseases”.⁹ The list of diseases includes *inter alia* Multiple Sclerosis, heart diseases,

⁶ The paper acknowledges the potential privacy issues related to DTC genetic testing services but the issue is not covered by the paper due to word count restraints.

⁷ See www.ibdna.co.nz and www.easydna.co.nz.

⁸ According to their New Zealand website both companies provide a company address in Auckland: International Biosciences Inc “Contact us” <www.ibdna.co.nz>; EasyDNA “Contact us” <www.easydna.co.nz>.

⁹ EasyDNA “Why take our DNA health test?” <www.easydna.co.nz>.

Alzheimer’s disease, obesity, migraine, diabetes and different kinds of cancer, including breast cancer.

After ordering online, consumers get a genetic sample collection kit sent to their home address. Consumers do a simple cheek swab with the provided cotton swab and send the sample, along with a signed consent form, back to the company’s address in New Zealand.¹⁰ Genetic counselling by a health care professional prior to the test is not mandatory, however, both companies provide a call back service if assistance is needed. *EasyDNA* additionally provides the possibility of a Live Chat with a DNA Consultant. Yet, information about the qualification of the employed consultants is not available on *EasyDNA*’s website.

After analysis of the sample by the testing companies’ partner laboratories, consumers receive their results online. *EasyDNA* does only provide a small image cut-out of the complete test result report on their website. Surprisingly, the report-excerpt provided by *EasyDNA* is identically to the sample result report available on *IB*’s website. Although evidence to validate this hypothesis could not be found, a collaboration of both companies regarding the interpretation of the test results is possible. The first page is an introductory page with general information. On the next page consumers see a summary table showing each disease with the corresponding average risk in population next to the calculated personal risk of disease. The following image shows one example of the detailed description for each disease that is provided after the summary:



¹⁰ EasyDNA “DNA Sample Collection Instructions” <www.easydna.co.nz>; International Biosciences “Genetic Predisposition Test Sample Collection” <www.ibdna.co.nz>.

At the end of the report, there is a section headed ‘Scientific Information’ with the raw data of the test. This section includes the different genetic markers, which the sample was tested for, and shows corresponding absence or presence in the sample. The information consists of a sequence of numbers and letters. The scientific information alone is of questionable value for lay consumers, as they will need further assistance to understand the meaning of the number combinations.

B The Genetic Science Behind the Service

The scientific information section with the raw analysis of the sample provides the starting point of DTC genetic testing. Contrary to what a person encountering the idea of DTC genetic testing for the first time may think, companies do not yet sequence the whole human genome. Despite constantly declining costs for an entire sequencing process, the majority of companies still do not consider whole genome sequencing as an economically viable mass product.¹¹ Instead, the two companies taken as example in this paper, search for single nucleotide polymorphisms (SNPs). To understand the existence of SNPs in human body cells, it is useful to provide a short introduction into human genetics.

The human genome is the information embodied in the 23 pairs of chromosomes found in the nuclei of most cells in the human body. Each chromosome consists of two intertwining strings of deoxyribonucleic acid (DNA). Each DNA string consists of a series of nucleotides (up to 250 millions of nucleotides in one DNA string). There are four different types of nucleotides, which differ only in respect to their bases (adenine, thymine, cytosine or guanine).¹² For simplification we name them A-,T-,C- or G-nucleotide. What we refer to as genes is a specific region within the DNA strand or sequence of nucleotides. Those DNA regions lead alone, in cooperation with other parts of DNA and/or in interaction with environmental factors to certain biological traits.

SNPs are alternations in the explained sequences of nucleotides in DNA strings. For example, a sequence that consisted of an A-nucleotide followed by a C- followed by a T-nucleotide (ACT) is changed by replacing the A-nucleotide with a G-nucleotide (ACG). Such variations can occur during the copying process of body cells if the base of

¹¹ The first company to advertise sequencing of the entire human genome as a DTC-Service is advertised Sure Genomics. The US-based company offers its service for 2,500 USD and is currently taking pre-orders. The website does not contain any information whether the service will be available for non-US-citizens. <www.suregenomics.com>.

¹² Stephanie Bair “Direct-to-Consumer Genetic Testing: Learning from the Past and Looking toward the Future” (2012) 67 Food & Drug LJ 413 at 414.

nucleotides is miscoded. They are common in population and do not necessarily have a deleterious effect. In fact there are around 10 million SPNs in the whole genome and around 1 mutation in every 300 nucleotides.¹³

In practice, companies use chips to track particular known SNPs in the DNA sample. The interesting question is: How do companies associate specific gene mutations with certain diseases and how do they assess a personal risk of disease accordingly? Not surprisingly companies rely on the current state of scientific knowledge.

Genetic science can give definite results concerning monogenic diseases. Monogenic diseases are diseases that are caused by one particular gene mutation (or nucleotide sequence mutation) and lead to a one hundred per cent chance of developing the condition. Presence of the gene mutation is equivalent to a diagnosis to develop the disease in later life. Fortunately those single gene mutations that result in severe diseases are rather rare in population.¹⁴ Examples for monogenetic diseases are Huntington's disease or Cystic Fibrosis.¹⁵

In contrast, research is still in its initial phase regarding common multifactorial diseases. These diseases, which private genetic testing companies focus on, are caused by an complex interaction of different factors, where genetic mutations are – if at all – only one factor beside environmental causes and lifestyle.¹⁶

Researchers hope to gain insight into the molecular aetiology of common diseases such as diabetes or cancer with so called genome-wide association (GWA) studies. GWA studies involve whole DNA sequencing of a large group of individuals with a particular disease and a control group without the disease in order to find common SNPs in the group of ill

¹³ “What are single nucleotide polymorphisms (SNPs)?” (28 March 2016) Genetics Home Reference <www.ghr.nlm.nih.gov>.

¹⁴ See World Health Organization “Monogenic diseases” Genomic Resource Centre <www.who.org>; Currently there are approximately 10,000 diseases known to be monogenic. The global prevalence of all monogenic diseases at birth is approximately 10/1000.

¹⁵ National Human Genome Research Institute “Learning about Cystic Fibrosis” (last updated 27 December 2013) and National Human Genome Research Institute “Learning about Huntington's disease” (last updated 17 November 2011) <www.genome.gov>.

¹⁶ National Human Genome Research Institute “What are genetic disorders” (last updated 10 November 2015) <www.genome.gov>.

participants.¹⁷ Congruent SNPs among ill participants are said to be associated with the condition; however, they do indicate merely an increased risk to develop the disease, not a diagnosis. This means that the existence of the SNP does not imply that one will develop the disease, nor does its absence indicate that the person will not. Private companies use the SNPs that have been found in GWA studies to test genetic samples of their consumers exactly for those mutations and use algorithm programs to interpret the raw-data into a personal risk figure.

C The Validity and Usefulness of the DTC Genetic Testing Results

Unfortunately GWA studies at the current level of research have certain limitations that also have an impact on the validity and usefulness of DTC genetic testing results. The first important limitation of GWA studies is the risk of false positive associations.¹⁸ In fact, research shows that results of GWA studies are often disproved over time. As one example, among 32 SNPs associated with breast cancer none may actually be relevant for an increased risk to develop the condition, since, over time, subsequent GWA studies did not succeed in confirming the results.¹⁹ One possible reason for this development is the fact that early studies often focus on testing persons that have a strong familiar background of the particular disease, however, once general patients populations are assessed the SNP has a far smaller influence than initially assumed.²⁰

As a second limitation, GWA studies often show weak results in a sense that the relative increase of risk associated with the SNP is small compared to the non-carrier population.²¹ An analysis of 260 SNPs, which are associated with one or more common

¹⁷ National Human Genome Research Institute “Genome Wide Association Studies” Frequently Asked Questions About Genetic disorders (last updated 27 August 2015) <www.genome.gov>.

¹⁸ Michelle D Irick “Age of an Information Revolution: The Direct-to-Consumer Genetic Testing Industry and the Need for a Holistic Regulatory Approach” (2012) 49 San Diego L Rev 279 at 303.

¹⁹ Helen Wallace “Direct-to-Consumer Testing” in Ulf Kristofferson, Jörg Schmidtke and JJ Cassiman (eds.) *Quality Issues in Clinical Genetic Services* (Springer Science & Business Media, 2010) 191 at 195.

²⁰ Giving this example for genetic predisposition for cancer: Peter Paul Yu, Julie M Vose and Daniel F Hayes “Genetic Cancer Susceptibility Testing: Increased Technology, increased Complexity” (2015) *Journal of Clinical Oncology* 1 at 2.

²¹ There are a few exceptions like the breast cancer associated gene BRCA, however even as regards BRCA, doctors at the moment require as a second risk factor a strong familiar history of breast cancer: See Julian Barwell and Anirudh Kumar “Genomic Testing and Genomic Care: Are They Talking to Each Other?” (2015) 6(6) *J Clin Res Bioeth* 1 at 2.

diseases, found that the odd ratio is often only between 1.04 and 1.5.²² The odd ratio is a numerical expression, used in clinical research studies, to describe the odds of a condition given a particular exposure compared to the odds of the condition in the absence of that exposure. Hence, an odd ratio of 1.5 means that one has a fifty per cent increased risk if you carry a particular SNP. Fifty per cent does sound a lot, but the impression changes if one puts the result in relation to the often also low odds in the control group. If the risk in the control group is one per cent, the risk in the group with the SNP increases to 1.5 per cent.²³ Another interesting detail is that even if all known SNPs for one specific disorder are taken together, they explain usually less than five to ten per cent of the prevalence of a disease, meaning that our knowledge about the influence of genes on disorders is still very limited.²⁴ For example, 49 gene variations are known that contribute to an increased risk for the multifactorial disease type 2 diabetes, however, it is also true that the body mass index has a substantially higher influence on absolute risk than the genetic predisposition.²⁵

One explanation for the poor results of GWA studies could be that the whole picture of how genetic predisposition influences disease onset requires further discovery of relevant SNPs and – even more important – an intensive study on the interaction between multiple SNPs and/or interactions between SNPs and environmental factors.²⁶ Another explanation could be that the influence of SNPs with a large prevalence in population on common diseases is in fact low and that the important SNPs that significantly impact on risk are rare in population. Unfortunately, GWA studies are not designed to detect SNPs which have little frequency in population.²⁷

All in all, based on the current low level of knowledge about the interplay of genetics, environment and lifestyle in regard to common diseases, the accuracy with which a test is able to predict a clinical condition is low. The so-called low clinical validity of most

²² Michael Krawczak “Clinical Validity and Utility of Genetic Testing in Common Multifactorial Diseases” Ulf Kristofferson, Jörg Schmidtke and JJ Cassiman (eds.) *Quality Issues in Clinical Genetic Services* (Springer Science & Business Media, 2010) 157 at 162.

²³ Matthew Piehl “Regulating Hype and Hope: A Business Ethics Model Approach to Potential Oversight of Direct-to-Consumer Genetic Testing” (2011-2012) 16 Mich St U J Med & L 59 at 84, n 193.

²⁴ José A Riancho “Genome-Wide Association Studies (GWAS) in Complex Diseases: Advantages and Limitations” (2012) 8 (2) *Reumatol Clin* 56 at 57 <www.reumatologiaclinica.org>.

²⁵ Wylie Burke and Susan Brown Trinidad “The Deceptive Appeal of Direct-to-Consumer Genetics” (2016) *Ann Intern Med* (forthcoming).

²⁶ Wallace, above n 19, at 195.

²⁷ Krawczak, above n 22, at 162.

predictive genetic tests also explains why genetic testing for common diseases has not yet become a regular procedure in public healthcare systems.

D Four Key Characteristics

From the previous sections it is possible to identify a few characteristics of DTC genetic testing. Taken together, those characteristics create a service where consumers are particularly vulnerable and might need more protection than with normal consumer goods and services.

Firstly, human DNA as the source that DTC genetic testing companies use, has some features that, in their combination, distinguish this kind of information source from other sources that are used to obtain predictive information in medicine.²⁸ The human DNA is characterized by its eternity and unique nature. Genetic information cannot be altered; hence, any predictive medical information derived from the analysis of human DNA – provided its accuracy – has lifelong influence and is irreversible. In addition, despite the uniqueness of the human DNA, genetic information allows conclusions to be drawn about possible inherited risk factors for relatives.²⁹ Furthermore, genetic information bears the risk of stigmatisation of particular ethnic groups if deleterious mutations of DNA can be associated with ethnicities.

For any of the above-mentioned features, existing ways of medical risk prediction may have similar or the same effects. To name but one example, family anamnesis can also reveal irreversible risk factors for an individual. However, DNA bundles the aforementioned characteristics together and has, at least in this regard, a special role in predictive medicine.³⁰ Additionally genetic testing will predominantly target consumers who do not show any disease symptoms. By contrast, traditional predictive medicine is often closely related to existing symptoms. The fact that consumers get the information

²⁸ All of the following arguments are also recognized by United Nations Educational, Scientific and Cultural Organization (UNESCO) *International Declaration of Human Genetic Data* 32 C/Resolution 24 (adopted on 16 October 2003), Art 4.

²⁹ One example is the heritability of the BRCA gene mutation, which leads to a 80% risk increase to develop breast cancer. The possibility that a BRCA is passed to children by a parent-carrier is 50%: Chiyan Lau and Graeme Suthers “BRCA testing for familial breast cancer” (2011) 34 (2) *Austr Presc* 49 at 49.

³⁰ See Reinhard Damm and Steffen König “Rechtliche Regulierung prädiktiver Gesundheitsinformation und genetischer Exzeptionalismus” (translation: Legal Regulation of predictive health information and genetic exceptionalism) (2008) 26 *MedR* 62-70 who give a good overview of the related controversial discussion whether the special status of genetic information calls for special legal regulation.

‘out of the blue’ may influence how they apprehend and absorb the results of DTC genetic testing.³¹

Another key feature of DTC genetic testing is the still developing scientific background upon which the test results are based on. Even if private companies have the best intentions in regard to clinically valid results and even if they use only SNPs that have a valid scientific substance, the black whole is enormous, because the SNPs currently known explain only a small fraction of the causation of diseases.³² For example, a calculated decreased risk due to the absence of a SNP may be wrong if the person carries other gene mutations whose relevance is not yet known. The insecurity in the scientific background is also reflected in ambiguous result reports. The Government Accountability Office (GAO), a US government agency, investigated the DTC genetic testing market in the United States under cover in 2010. The agency sent identical DNA samples to different companies in the United States.³³ In their report they claim that results were “misleading and of no or no practical use to consumers” as “different companies often provide different results for identical DNA”.³⁴ This finding is not surprising. The report itself concludes that contradictory results may be a result of a wide range of different possible SNPs that are used in testing or may occur due to self-made algorithms, which lead to different risk calculations if multiple SNPs for one disease are combined. Genetic experts in the GAO report confirmed that “each company’s results may be internally consistent, but not tell the full story” and that tests are “promising for research but the application is premature”.³⁵ Following the report, the Federal Drug Agency has turned its attention to the DTC genetic testing industry since 2010 (see below IV).³⁶

Thirdly, the service of DTC genetic testing companies is characterised by a complete shift from a clinical setting to a commercial setting. Whereas traditionally the access to genetic testing was lead through a consultation with a doctor who ordered the test from a

³¹ Damm and König, above n 30, 65.

³² Wallace, above n 19, at 195.

³³ United States Government *Accountability Office Direct-to-Consumer Genetic Tests: Misleading Test Results are Further Complicated by Deceptive Marketing and Other Questionable Practices* (22 July 2010).

³⁴ At 4–5.

³⁵ At 8.

³⁶ An overview of the developments in the USA gives Chelsea Weiermiller “The Future of Direct-to-Consumer Genetic Testing: Regulation and Innovation” (2014) 16 *NCJL & Tech On* 137; and Flavia Horvath Chen “23andMe and the FDA: Negotiating Conceptions of Benefit in the Direct-to-Consumer Genetic Testing Regulatory Debate” (Thesis, University of Washington, 2014).

known laboratory, the DTC genetic testing market is based on a pure business-costumer relationship.

Lastly the service is highly accessible, mostly anonymous and the entire process, from ordering until receiving the results, is handled by long distance communication. In contrast to a medical environment, the relationship between a company and a consumer lacks a long-term character. In most cases the interaction will be a one-off transaction.³⁷

III A Call for a Specific Regulation of the DTC Genetic Testing Market?

Against the backdrop of the previous section, this section explores the arguments for and against further legal intervention to regulate the DTC genetic testing industry. It will first assess the arguments of the proponents of a DTC genetic testing market with as little intervention as possible. It concludes that the arguments of a highly accessible market are in parts acknowledged and should be considered during the development of any regulatory approach, however, the concerns that are consequences of the explored key characteristics call for a legal solution that goes beyond consumer protection for ordinary goods and services.

A Arguments for an Unrestricted Market: Consumer Autonomy and Promotion of Research

The central argument for little state intervention in the market that DTC genetic testing companies point out is individual autonomy and empowerment.³⁸ From a health related point of view, free access to genetic information allows individuals to engage actively with their healthcare management and to take action where appropriate.³⁹ Knowing one's genetic risk factors, one can consider preventive measures as regular screenings or even prophylactic surgeries such as a mastectomy.⁴⁰ Even if the genetic mutations are of little overall influence or their influence is not yet fully explored, individuals can try to minimise potential hazardous environmental factors and change their lifestyle accordingly.⁴¹ From a public health perspective such preventive measures may save resources and strengthen the sustainability of the healthcare system in the long term.

³⁷ Piehl, above n 23, at 86.

³⁸ See as one example the advertising slogans of one of the worlds largest DTC genetic testing companies 23andme: "More than knowledge. Knowing what you can do." <www.23andme.com>.

³⁹ Bair, above n 12, at 424.

⁴⁰ An extreme example in case of the breast cancer BRCA gene variation.

⁴¹ Jennifer A Gniady "Regulating Direct-to-Consumer Genetic Testing: Protecting the Consumer Without Quashing a Medical Revolution" (2007-2008) 76 Fordham L Rev 2429 at 2436.

Interestingly, in a study in the United States of America, which accompanied test takers for a three-month and one year period, participants did not show any actual behaviour change after having received test results.⁴² Long-term studies are needed to show whether there is a beneficial impact on consumers' health.

Irrespective of an existing health benefit, either because the majority of test takers do not seem to adopt lifestyle changes or because there is simply no medical intervention available, one author argues for a wider notion of autonomy.⁴³ Loi defines autonomy in a moral way. Individuals are the owners of their bodies and hence also the moral owners of their genetic materials as part of their bodies. As a consequence, it is a natural right of all individuals to do with their genetic material whatever they want, including paying for a genetic test, as long as they do not harm others.⁴⁴ That right exists prior and independent from the quality of the information they receive from the test. According to this argument, it is indeed irrelevant whether the test results are useful for personal medical intervention. State authorities should not interfere with that right to ownership, unless there are considerations that justify restrictions such as negative effects to public health or another persons' rights.

It is a valid point that one should be able to explore genetic information that is inherently "personal" and that consumers have a right of ownership over their genetic material, which includes access to testing. However, even if one acknowledges such a right, state regulation may be necessary to enable consumers to make a decision about whether to use their genetic material in the first place. Governmental oversight would not pursue a restriction of access, but rather the creation of fair market conditions that ensure that consumers understand the chances and limits (especially regarding the clinical validity) of the test. Additionally accepting the argument that access should not be restricted due to lack of clinical utility leaves open the possibility to for other reasons. Interestingly even the proponents of a prima facie right to test do not deny that governmental intervention may be necessary to balance consumer's market position.⁴⁵

⁴² Loredana Covolo and others "Internet-Based Direct-to-Consumer Genetic Testing: A Systematic Review" (2015) 17 (12) J Med Internet Res 1 at 5, n 92 and n 93.

⁴³ Michele Loi "Direct to consumer genetic testing and the libertarian right to test" (2016) J Med Ethics (forthcoming, published online first 23 March 2016) 1.

⁴⁴ At 1.

⁴⁵ At 3.

Consumer's empowerment is also the basis of the second argument for a free DTC genetic testing market: The (perceived) benefit of having absolute control over their own data. DTC testing services, as they currently operate, offer the apparent advantage that consumers can decide whether or not to share the results with third persons, including their doctor. By contrast, the results of a genetic testing that are ordered by a physician become part of patients' official medical records. Common concerns are that life insurance companies or employers can get legal or illegal access to this data and use it to a patient's detriment. The results of a survey conducted amongst 1046 consumers of DTC genetic testing in the United States reflect a (perceived) feeling of a high standard of privacy protection in the DTC genetic testing industry. 36 per cent of the participants believed that their data was better protected in the private sector than it would be in the public sector.⁴⁶

This sense of control over the own data could be misconceived. There are new perils for data privacy that result just from the private, profit-driven market. Without going into detail, companies do currently not offer any information about what happens with data when a company goes bankrupt or mergers with another company.⁴⁷ Considering that the generated risk reports are an extremely valuable company asset, it is not unlikely that personal data may fall into hands of third parties without consumer's consent.

A further argument for little state intervention in the DTC genetic testing industry is the use of collected data as primary research tool.⁴⁸ The US based company *23andme*, which currently excludes New Zealand consumers from their testing service, offers the possibility for customers to contribute their test results to a research database.⁴⁹ *23andme* has recently partnered with two big pharmaceutical companies, inter alia for research on Parkinson's disease.⁵⁰ However, *23andme*'s motives seem far from altruistic. In an interview in 2013, Patrick Chung, a member of the company's board, said "once you have the data, [the company] does actually become the Google of personalised health

⁴⁶ Juli Murphy Bollinger, Robert C Green and David Kaufman "Attitudes About Regulation Among Direct-to-Consumer Genetic Testing Customers" (2013) 17 *Genetic Testing and Molecular Biomarkers* 424 at 426.

⁴⁷ See as an example for many: European Academies Science Advisory Council and Federation of European Academics of Medicine *Direct-to-consumer genetic testing for health related purposes in the European Union* (July 2012) at 4.3.

⁴⁸ At 2.6; with further references. The report acknowledges the chance of enhanced research but also sees the necessity to establish appropriate rules for obtaining informed consent.

⁴⁹ 23andMe "Accelerating research. A new way" (2016) <www.23andme.com>.

⁵⁰ 23andMe "Accelerating research. A new way" (2016) <www.23andme.com>.

care”.⁵¹ One can conclude from this statement that genetic testing companies consider the data as an extremely profitable company asset, probably economically more attractive than their primary field of business, the selling of testing kits. Having this financial interest in mind, it is especially important that current concerns (see following section B 2) about obtaining proper consumer’s consent are addressed.

B Concerns that Call For Specific Legal Intervention

The arguments that proponents claim in favour of a free DTC genetic testing market are offset by an extensive list of concerns, which are shared by people working in the health care sector as well as scientists and scholars in the field of ethical and medical law.

1 Consumers are misled about the validity and usefulness of the product

One peril of DTC genetic testing is that the interpretation and communication of test results bear a high risk that consumers are misled about the validity of the test as well as the usefulness of the test.⁵²

(a) Misled about validity of the test

Regarding the validity of the test, the results might suggest a clinical validity that currently cannot be achieved.⁵³ Clinical validity, as described in the first part of this paper (see above B), refers to how well a genetic variant is related to the risk of a certain disease. Due to the complexity of genetic science and a general asymmetry of knowledge between consumers and the company, it is barely possible for consumers to assess the reliability and accuracy of the test and it is likely that consumers consider the results to have a greater significance than they actually do. A close look on the websites of *EasyDNA* and *IB* reveals that information is often incomplete and the design of the test results are likely to result in consumers misunderstanding the validity of results.

Prior to the purchase of the test, *EasyDNA*’s website does not contain any information about the SNPs that are included in the test or how the company calculates the overall risk if – as in most cases – more than one mutation is relevant for the disease. By

⁵¹ Quote from Patrick Chung, a companies board member cited in Charles Seife “23andMe is Terrifying, but not for the Reasons the FDA Thinks” (27 November 2013) Scientific American <www.scientificamerican.com>.

⁵² This point is made often in the literature, see: Nuffield Council on Bioethics *Medical profiling and online medicine: the ethics of ‘personalized healthcare’ in a consumer age* (Nuffield Press, Oxfordshire, 2010) 142 at 158; Irick, above n 18, at 305; but Kathryn Schleckser “Physician Participation in Direct-to-Consumer Genetic Testing: Pragmatism or Paternalism” (2012-2013) 26 Harv J L & Tech 695.

⁵³ Irick, above n 18, at 305.

contrast, *IB* informs consumers on their website, in a prominently placed paragraph, about the nature and the limits of genetic testing and includes that “rare variations that affect certain diseases may not be covered by a SNP test as they still have not been discovered, or because their incidence is very low”.⁵⁴ According to *IB*, results are based on “latest scientific research” and the used studies “yield[s] a lot of confidence”, however, *IB* admits that this does not “exclude the possibility that future research may improve upon the accuracy of the results”.⁵⁵ Although better than *EasyDNA*, it is worth noting that the company only mentions the improvement of accuracy through further research, not the possibility that the association of an SNP with a disease could be disproved and thus results may lose any significance at all.

Additionally it is doubtful whether a simple disclaimer is sufficient for consumers to understand the uncertainty inherent in current genetic knowledge. Even if information is provided on the website, as one writer points out “businesses exploit the persuasive power that scientific information tends to have on lay individuals”.⁵⁶ That argument refers to the risk analysis report. As explained in the first chapter, companies do not only report the existence of SNPs, they also interpret results in a graphic way together with explicit percentage information. The use of a definite number itself has the potential to represent an accuracy and validity that allows prior warnings about the inherent insecurities recede into the background. Consumers are used to numbers in science and usually they are the result of precise calculation. What remains in consumers’ mind is more likely to be the number or graphic, not a disclaimer at the end of the page.⁵⁷

(b) Misled about usefulness of test results

As a consequence of the perceived validity of the test, consumers may also be misled about the usefulness of a test. To answer the question of when consumers are likely to be deceived about the utility of the test, it first has to be considered what consumers consider to be a useful test and whether their expectations are met by the test results.

⁵⁴ International Bioscience Inc “Genetic Predisposition Test” (accessed 11 April 2016) <www.ibdna.co.nz>.

⁵⁵ International Bioscience Inc “Genetic Predisposition Test” (accessed 11 April 2016) <www.ibdna.co.nz>.

⁵⁶ Irick, above n 18, at 284.

⁵⁷ Along these lines is also the argument of Sophie Yohe quoted in Bryon Nelson “The Big Sell: Direct to consumer tests promise patients more abundant and accessible information, but potential pitfalls abound” (2016) 126(1) *Cancer Cytopathology* 7 at 8, who said “Numbers can be kind of deceiving if you don’t really know what they mean or have the proper context, and I think that’s one of the problems with a lot of direct-to-consumer tests.”

A direct answer to this question is difficult considering that the usefulness of a test is something subjective that depends on the purpose of the test and the value of results in relation to the purpose. Traditionally a test is considered useful if it shows clinical utility. This term refers to the ability of the test to lead to improved health outcomes for the patient.⁵⁸ An improved health outcome can consist of medical intervention by preventive or therapeutic options. However, even if no clinical intervention is possible, e.g. with the Huntington's disease, genetic testing is considered clinically useful if it has beneficial psychological and practical benefits for the test taker that outweigh potential harms. Certainly, the assessment whether the results are useful from a health care perspective takes into consideration the clinical validity of the test and a cost-benefit analysis, too. As an example, genetic testing for Alzheimer's disease is not considered as valid enough to present reliable information. Consequently it cannot provide clinically useful information and public resources should not be spent on such testing.

In DTC genetic testing, however, utility should be defined in a broader sense as personal utility.⁵⁹ To argue that results have no subjective value because they cannot be considered clinically useful (yet), ignores that consumers do not rely on public resources and are in general allowed to spend their money on anything they want. Just because a physician does not consider the result useful, does not mean that a consumer cannot consider it useful. However, consumers are misled if they consider the genetic test to have a perceived utility that the test actually does not have. The following example will show that the threshold to be misled can be low due to the complexity of genetic testing: Assume that a woman undertakes a genetic testing for the BRCA1 or BRCA2 gene that, according to current research, increases the risk to develop breast cancer. Assume that the test comes back negative. It is likely that the woman feels relieved that she is not at a higher risk for breast cancer. The perceived utility of the test is to feel reassured about breast cancer. However, the test is in fact only useful to the extent that it shows that this specific mutation does not exist and does not say anything about another, perhaps still unknown, mutation that may put the woman at the same risk.⁶⁰

A wrong perception about the usefulness of the test can also be obtained after the purchase of the testing kit following a misinterpretation of the test's significance. One must differentiate between the motive to take the test in the first place and the perceived

⁵⁸ Eline M Bunnik, A Cecile JW Janssens and Maartje HN Schermer "Personal utility in genomic testing: Is there such a thing?" (2015) 41 J Med Ethics 322 at 322.

⁵⁹ See for this new term in regard to DTC genetic testing Bunnik, Janssens and Schermer, above n 58.

⁶⁰ Example taken from Bunnik, Janssens and Schermer, above n 58, at 325.

value a person put on results after taking the test. In fact various studies show that one of the main reasons why consumers participate in DTC genetic is the mere curiosity about their genetic make up.⁶¹ However, once they get the interpretation of their genetic raw data, there is a danger that they will draw their own conclusions and relate the results to their health status. It is the task of legislators to evaluate how much further information or assistance consumers need to assess the informative value correctly.

2 *Concerns about informed consent*

One of the most important concerns about DTC genetic testing is whether companies outside a medical setting can guarantee effective informed consent of consumers regarding the analysis of their DNA and the disclosure of results.⁶² Firstly, this part of the paper explores why the ethical duty of informed consent, traditionally developed in a health care environment, should also apply to the business-consumer relationship of DTC genetic testing. After that it points out why current DTC genetic testing providers in a highly unregulated market are unlikely to meet the requirements of informed consent. Apart from general deficiencies of information disclosure, the particular case of testing of minors and companies' additional use of genetic data for research purposes is discussed.

(a) Does the concept of informed consent apply to DTC genetic testing?

Informed consent is the realisation of autonomy in a health care environment. It is ethically required for any medical intervention and consists of the patient's autonomous decision to pursue a particular treatment. As the term *informed* consent implies, it is the result of a process. This process includes the disclosure of all relevant information, including benefits and risks of the treatment, and their understanding by the patient to enable him to make an autonomous decision.⁶³ Hence, the concept of informed concept is different from an autonomous decision in a day-to-day purchase, because it is the ethical duty of the doctor to disclose necessary information and to establish understanding in a situation where a knowledge asymmetry exists. Doctors act on a fiduciary basis and are obligated to neutrally inform the patient in their best interest.⁶⁴

⁶¹ Mauro Turrini and Barbara Prainsack „Beyond clinical utility: The multiple values of DTC genetics“ (2016) 8 Applied & Translational Genomics 4 at 5.

⁶² This argument can be found often in literature, see: Bair, above n 12, at 417; and Elinne M Bunnik, A Cecile and Maartje Schwermer “Informed Consent in Direct-to-Consumer Personal Genome Testing: The Outline of a Model Between Specific And Generic Consent” (2014) 28 Bioethics 343–351.

⁶³ Bunnik, Cecile and Schwermer, above n 62, at 344–345.

⁶⁴ See for example New Zealand Medical Association *Code of Ethics for the New Zealand Medical Profession* (May 2014), which lays down principles of ethical behaviour, applicable to all doctors including

At first glance, one could ask whether any DTC genetic testing should be subject to the special requirements of medical informed consent at all. After all, the DTC genetic services companies act outside the traditional medical environment and emphasise that their services do not provide any health care but only present information for educational or informational purpose.⁶⁵ Perhaps DTC genetic testing is no different from any other sales contract. Similar to financial service contracts, risks can be disclosed in an appropriate form on the website. Commercial providers have – in contrast to doctors – not taken an oath to act in the interest of consumers and consumers know this. If DTC genetic testing services are seen like this then there should be no obligation on the service providers to put consumers’ interests before their own business interests. Normal constraints applying to false or misleading claims for DTC genetic testing should be considered sufficient.⁶⁶

The idea that DTC genetic testing services are outside the medical arena and like any other consumer service is unconvincing. The health-related purpose of genetic testing cannot be denied. The companies themselves make numerous health-related claims on their websites.⁶⁷ The results may be informative, but companies interpret the information with regard to health care. The mere fact that they operate on a commercial model is not sufficient to exclude enhanced ethical requirements. Due to the peculiarities of genetic data and the possible negative psychological and social effects, genetic testing services are in their nature different from other risk-related consumer contracts. In the same way that companies profit from blurring the boundaries between commerce and medicine, they should also have to accept that they are obligated to comply with medical ethical standards.⁶⁸

(b) Possible issues in relation to informed consent?

The first issue is the form of disclosure of information. Due to the lack of mandatory pre-counselling by a trained professional, consumers are left with only the written information on the website. Written information is not always less effective than

those who may not be engaged directly in clinical practice. It also includes recommendations for ethical practice.

⁶⁵ See International Bioscience “Scope of Genetic Testing” Genetic Predisposition Test <www.ibdna.co.nz>; See EasyDNA “Terms and Conditions: Genetic Predisposition Test” <www.easydna.co.nz>.

⁶⁶ Bunnik, Cecile and Schwermer, above n 62, at 346.

⁶⁷ See introductory quote, above n 1.

⁶⁸ Bunnik, Cecile and Schwermer, above n 62, at 348.

information provided in a face-to-face conversation. Written information can be scrutinised carefully and be read several times in order to fully comprehend the content. On the other hand, online disclosure means that it is up to the consumer to search for all available information and to combine information where it is necessary. Furthermore, in case of additional questions, it is a bigger obstacle for consumers to email or call the company than it would be in a face-to-face conversation.

Additionally, because of the commercial character of DTC genetic testing, information is often presented in the form of Terms and Conditions (TAC). *EasyDNA* presents its TAC at the last step of the order in form of a box click mechanism. TAC can voluntarily be accessed by a click, but to process the order it is only necessary to a click a box. Ignoring the fact that most consumers are reluctant to study TAC in online purchase contracts, opponents rightly claim that “TAC are not associated with the moral obligation to ensure understanding in the way in which informed consent is”.⁶⁹ TAC are used on a contract law basis to exclude liability, define duties and rights and as a written documentation in case of a dispute. They have certain informational value but they are not written to promote understanding of the service.

The second issue refers to the content of information that is disclosed by DTC genetic testing companies. Here again, the blurring of boundaries between medicine and commerce is a challenge. Undoubtedly, information provided in a commercial environment is given to inform as well as to persuade. Even if companies disclose risks, this may appear in small font in the TAC or with a disclaimer, whereas benefits are presented prominently. In contrast to the fiduciary relationship in a clinical setting, the appearance of a conflict of interest between the aim of profit maximisation and a balanced information disclosure is more likely. In a medical setting a potential conflict between financial interest and ethical standards may also arise, however, it is more often tempered by intermediaries such as insurance payments, which guarantee that professional advice is not jeopardised by potential financial motivations.⁷⁰ As a practical example of poor risk disclosure, the website of *EasyDNA* does not mention the risk of possible psychological consequences upon knowledge of test results, nor does it address the issue of consumer’s possible duty to disclose results to insurance companies or the issue of data theft once the results are processed online. Quite the contrary, *Easy DNA* explicitly excludes any liability for consequences of test taking in its TACs. *EasyDNA*

⁶⁹ Bunnik, Cecile and Schwermer, above n 62, at 348.

⁷⁰ Piehl, above n 23, at 85.

does not seem to be the exception. Studies, which analysed various providers in the US market, affirm poor risk information dissemination.⁷¹

The last issue does not focus on the preconditions for informed consent but rather highlights the question whether DTC genetic testing can ensure informed consent at all. Because of the anonymous environment of the transaction, providers can never totally ensure that the source of the sample and the consumer of the service are identical. This opens the possibility that samples are analysed without any consent at all.

In the case of testing of minors, proper consent seems especially challenging. The process of informed consent also includes the option not to undertake a certain test. The right not to know is strictly personal, so that a child should be preserved the right to make an autonomous decision as an adult.⁷² However, in regard to genetic tests exceptions to this general rule of a “right to an open future” apply, when a genetic test is deemed to provide effective intervention possibilities that outweigh possible harm.⁷³ In this case, consent by the legal representatives is sufficient. It is important to recognise that traditionally it is the medical professional who safeguards the child’s right not to know and may possibly decide against parents’ wish for testing.

In the context of commercial DTC genetic testing such safeguards are absent. Furthermore, companies, such as *EasyDNA*, offer a “Children’s DNA Discovery Test” and encourage genetic testing of minors with advertising claims like “Thinking of testing your family or loved one at the same time? We offer discounts for tests involving more than one person”.⁷⁴ In regard to predisposition testing, one can argue that genetic testing for children is overall beneficial with the philosophy “the sooner the better”. Despite the low clinical validity of current tests, results could still be used for adoption of a healthier lifestyle, which admittedly can only be beneficial to a child. Furthermore the test itself (a cheek swab) bears no risk at all. However, one may justifiably wonder whether there is a

⁷¹ Covolo and others, above n 42, at 8, n 115,116,122,128.

⁷² Pascal Borry and Heidi Carmen Howard “Is There a Right Time to Know?: The Right Not to Know and Genetic Testing in Children” (2014) 42 J L Med & Ethics 19 at 21.

⁷³ There are several guidelines for healthcare professionals that clarify when genetic testing of minors is ethically justified, see for Australasia: Human Genetics Society of Australasia “Guideline: Pre-symptomatic and Predictive Testing for Children and Young Adults” (August 2014) <www.hgsa.org.au>; for Europe: European Society of Human Genetics “Genetic testing in asymptomatic minors: recommendations of the European Society of Human Genetics” (2009) 17 European Journal of Human Genetics 720–721.

⁷⁴ EasyDNA “DNA Health Test” <www.easydna.co.nz>.

need for a genetic test to enable a healthy way of living and whether this argument is equally valid in regard to diseases with no possibility of intervention.

The Children's DNA Discovery Test does not focus on disease risk prediction but rather includes harmless sounding information about possible physical and behavioural traits. The company claims to indicate the height of the children, what kind of sports may suit them the most, their capacity of memory or whether they are a night owl or an early bird and lure parents with the idea of parental support tailored to a child's strength and weaknesses.⁷⁵ Irrespective of the doubtful clinical validity of the mentioned tests, such tests are more likely to serve the curiosity of parents than provide actual benefits for children. Moreover, potential harm for children is not only the loss of future adult autonomy, but also an impact on the child's self-esteem and personal development, a distortion of the family's perception of the child and the possibility of future discrimination.⁷⁶ State regulations could help to safeguard the right of each individual to decide autonomously on the use of their own genetic data.

Ultimately, the current practice of *EasyDNA* obtaining consent for use of the genetic data in research should be considered. According to the specific TAC for the Genetic Predisposition test, samples "may be disposed of or retained indefinitely for research (by your choice)".⁷⁷ Consumers are asked to indicate their choice in a form sent together with the testing kit. Yet, TAC also state that a "failure to indicate (my) preference will be taken as an acceptance to use (my) samples".⁷⁸ Such an assumption of consent is contrary to the idea of deliberate choice as the result of the informed consent process. Companies should be forbidden to include informed consent requirements in their TAC.

3 *Psychological harm*

A further issue is the psychological effect that the test results can have. It cannot be ruled out that knowledge about an increased risk of disease can be a heavy burden for the test taking person itself as well as for relatives. To know that one has an increased risk can be as distressing as to have a definitive diagnosis or even worse, because it does not present a definite answer. The psychological effect can be of particular importance in the case of severe diseases with no possibility for medical intervention. One example is the currently

⁷⁵ EasyDNA "Children's DNA Discovery" <www.easydna.co.nz>.

⁷⁶ Borry and Howard, above n 72, at 24.

⁷⁷ It is worthy of mention that the Terms and Conditions provided via link at the last step of the purchase process vary from those Terms and Conditions provided on the bottom of the main page. The latter appears to relate more likely to genetic testing with other purposes, eg paternity testing.

⁷⁸ See EasyDNA "Terms and Conditions: Genetic predisposition test" <www.easydna.co.nz>.

offered testing for mutations of the APOE gene, which is said to increase the risk for Alzheimer's.⁷⁹ Knowing one's personal risk factor could also have a social impact. Do I feel obligated to tell my partner that I am on a high risk to develop an incurable disease? Do I feel guilty because I know that my carrier status of the breast cancer gene BRCA is likely to have been passed on to my daughter?

DTC genetic testing companies often rightly invoke the fact that most studies at the moment seem to rebut a negative psychological impact. In one US study fewer than 30 per cent declared to feel anxious about a test result that showed increased risk.⁸⁰ Other studies revealed that initial anxiety tends to reduce over time and is equal to non-test takers one year after test taking.⁸¹ However, current studies have an important limitation: They are usually based on a small sample size, low response rates and participants were prevalingly highly educated in the field of genomics (e.g. employees of health and technology companies).⁸² Therefore, findings may not be representative for the general public. Furthermore, studies at the moment are not able to display a long-term impact due to the rather new industry.

4 Negative effects on society and burden for public health care

A long-term negative impact on society is another concern of DTC genetic testing. As shown, consumers of DTC genetic testing are mostly healthy individuals who do not show any disease symptoms. If consumers overestimate the strength of the risk-assessments, society could develop a "worried well" attitude. This term relates to a scenario where individuals rely more on their genetic predisposition than on their actual state of health. Even if they show no clinical signs of disease, they perceive their genetic predisposition as "inevitable destiny". In that way society could also change its perception towards illness and label the mere existence of certain mutations as pathological.

One may rightly counter that the scenario of a worried well culture is an overly pessimistic view without evidence. Nevertheless, two things should be stressed: Firstly, DTC genetic testing is a rather new phenomenon, which inevitably leads to the fact that no definite evidence based claims can be made about future social impact. Secondly, the

⁷⁹ See www.easydna.co.nz.

⁸⁰ Covolo and others, above n 42, at 5, n 90 and 94. This article provides an excellent review of recent research on different impacts of DTC genetic testing.

⁸¹ At 5, n 88.

⁸² At 12.

government arguably has the responsibility to prevent a situation where DTC genetic testing lays the foundation for such a social development, even if harm is not yet evident. That responsibility is toward today's society, especially against the background of a possible future integration of genetic testing in public health care, but also toward future generations whose social values will depend on our approach to DTC genetic testing.

Lastly DTC genetic testing could be a burden on health care if consumers take their results to their doctor. Consumers could ask for preventive screenings that have not been medically indicated. However, early research does not provide reliable results proving a negative impact of DTC genetic testing on public health care.⁸³ Additionally, to get a balanced view, one must also consider possible cost savings for public health care, where the onset of disease can be prevented with medical intervention.⁸⁴

Another impact could be less concerning from an economic point of view, but reveals challenges regarding the approach medical professionals take towards DTC genetic testing. If medical professionals are confronted with DTC genetic testing results, they will most likely be reluctant to give medical advice upon results, because there is currently no way for doctors to verify the clinical validity of tests. At the moment health professionals in New Zealand are rarely confronted with DTC test results, however with decreased costs for testing and development towards whole genome sequencing, doctors will be in the front line to deal with this overlap between industry and medicine.⁸⁵

IV Possible Regulation

Before going into detail, it can be said that the general aim of every governmental intervention with the DTC genetic testing market should be to provide a solution that minimises the above-mentioned concerns, but also acknowledges that any restriction of the personal right to access genetic information must be as minimal as possible.

⁸³ Covolo and others, above n 42, at 5–6.

⁸⁴ Bair, above n 12, at 423.

⁸⁵ Gemma R Brett and others “An exploration of genetic health professionals’ experience with direct-to-consumer genetic testing in their clinical practice” (2012) 20 *European Journal of Human Genetics* 825 at 826; In that survey conducted between 168 genetic health professionals in 2011 in Australia and New Zealand only 11 per cent of the participants reported one or more clients referred to them after undertaking DTC genetic testing. Likewise only 7 per cent felt confident in explaining and interpreting DTC genetic testing results.

Surprisingly perhaps, New Zealand has overlooked the issue of DTC genetic testing during the last decade. In fact, the last time the issue of genetic testing was on the political schedule was in 2003, when the National Advisory Committee on Health and Disability issued its report about Molecular Genetic Testing in New Zealand.⁸⁶ Although the report only reviewed genetic testing in a clinical setting, the experts already highlighted certain risks, as for example the lack of quality assessment for genetic tests.⁸⁷ Certainly, this issue is even more urgent in a DTC environment.

A comparative view shows that several jurisdictions have grappled with setting an appropriate level of regulation. Solutions are diverse and still developing. Representing an extreme protective approach, Germany has enacted the Human Genetic Diagnostics Act (Gendiagnostikgesetz). It provides for genetic testing exclusively in a medical setting and contains extensive provisions in regard to mandatory pre- and post counselling and the disclosure of the results through a medical professional.⁸⁸ However, in several other European countries, the marketing and purchase of DTC genetic tests is still legal.⁸⁹ Since 2012 the European Union has been working on the creation of a harmonised approach. Current negotiations demonstrate how controversial the topic is. Whereas the amendments made by the European Parliament correspond to a large extent with the German position because the proposal requires medical prescription for any genetic testing and bans DTC advertising of genetic tests, the Council of the EU has a different view. The European body representing Member States governments did not accept the inclusion of those amendments in its proposal.⁹⁰ The European Parliament's proposal was also criticised by stakeholders as a disproportionate solution because it fails to take into

⁸⁶ See National Advisory Committee on Health and Disability "Molecular Genetic Testing in New Zealand" (October 2003). The National Advisory Committee is a part of the ministry of health and provide independent expert advice to the Minister of Health.

⁸⁷ At 6.

⁸⁸ Gendiagnostikgesetz (GenDG).

⁸⁹ Countries where currently no specific legislation that relates to DTC genetic testing exists are, for example, the United Kingdom and the Netherlands. See for an overview of current legislation in Europe Pascal Borry and others "Legislation on direct-to-consumer genetic testing in seven European countries" (2012) 20 Eur J Hum Genet 715–721.

⁹⁰ See for the proposed amendments by the European Parliament: European Parliament *Legislative resolution of 2 April 2014 on the proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices* P7_TA(2014)0267 (2 April 2014) <www.europarl.europa.eu>. In contrast see for Council's position: Council of the European Union *Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices* (21 September 2015) (12042/15 PHARM 37 SAN 282MI 568 COMPET 411 CODEC 1194).

consideration that each type of test bears different risks and benefits for consumers.⁹¹ In the United States, the Federal Drug Agency was initially reluctant to intervene, because DTC genetic test services were classified as Laboratory Developed Tests, which are tests that are usually not subject to pre market approval. However, in 2013 the agency started to classify the tests as high-risk medical devices and requires pre-market approval, which includes the submission of clinical evidence.⁹² In Australia the supply of DTC genetic testing has been prohibited since 2014.⁹³ There are voices in the literature, which favour an equally strict approach in New Zealand.⁹⁴ Due to the possible future ethical, social and personal risks, one should “keep[ing] the genie in the bottle until such time as its magic powers can be adequately assessed”.⁹⁵

The following chapter will assess whether, and to what extent existing New Zealand law already applies to DTC genetic testing and how a balanced approach between an extreme protective state intervention and an overly liberal approach can be found. The discussion is structured upon the topics identified as the major concerns of DTC genetic testing.

A Reducing the Risk of Misleading Information through Quality Assurance

Irrespective of the type of goods, consumers expect to get what they have paid for. Hence, the aim must be to avoid consumers being misled about what they are buying and what it can be used for. That aim applies to information given in advertisements prior to the purchase decision as well as to the information provided by the test results. The industry of DTC genetic tests must comply with general consumer protection laws. However, considering the difficult scientific information, more positive regulation is needed. Especially in regard to the most essential part of the test, the test report, product quality standard is absent. The current provisions of the Medicines Act 1981 do not apply to the information provided in the risk-report. Therefore the focus of the recommendations lies on a certain level of clinical validity, meaning a valid link between the disorder and the genetic variant that should be guaranteed.

⁹¹ Philippa Brice “EU legal amendments threaten genomic medicine and research” (23 October 2013) <www.phgfoundation.org>.

⁹² Weiermiller, above n 36, at 143–144.

⁹³ See Section 41BEA of the Therapeutic Goods Act 1989 in conjunction with the Therapeutic Goods (Excluded purposes) Specification 2010.

⁹⁴ Dee Magin, Ben Hudson and Les Toop “Direct-to-Consumer Genetic Testing: Letting the Genie out of the Bottle” (2012) 125 NZMJ 7.

⁹⁵ At 10.

1 Existing fragmentary coverage by consumer protection law and medical law

General consumer protection laws apply to the advertising of DTC testing as well as to the quality of the test results to a certain degree. If companies offer the delivery of a genetic risk report for a certain disease without a valid link between disorder and gene mutation, they violate s11 and s13(b) of the Fair Trading Act 1986. According to those provisions companies must not engage in conduct that is likely to mislead consumers about the suitability for a purpose, or use any false or misleading representation about the quality of a service. Additionally s8 and s29 of the Consumer Guarantees Act 1993 require companies to deliver goods and services that are fit for the particular purpose. Apart from obviously fraudulent offers, the question of whether a DTC genetic testing company has been misleading about the predictive value of its test is difficult to answer. The inherent scientific insecurity raises particular problems for any assessment. What quality must scientific evidence have? How many GWA studies are considered sufficient to speak of reliable predictive value? The scientific insecurity also makes it difficult to assess when test results can be considered fit for the claimed purpose of risk-prediction. Similar problems of assessment apply to the possible misleading character of the utility of the test. Is it deceptive to claim the possibility “to take truly control of your health and long-term well-being”, when the advice that results from the test do not go beyond general tips for a healthy lifestyle?⁹⁶

A further problem is the monitoring and enforcement of any of the above-mentioned provisions in regard to DTC genetic testing. In case of the Fair Trading Act 1986, the Commerce Commission, as the responsible agency for monitoring, will most likely lack the knowledge to validate the association of a SNP with a disease. Furthermore *EasyDNA* does not even disclose the relevant data on its website, but only after the purchase of the test in its report. Even if consumers are guaranteed that the testing service is fit for purpose, they are unlikely to have the necessary knowledge to understand that the test results are of little or no reliability.

In comparison to absolute negative boundaries for advertising and trade conduct, positive regulation that requires the disclosure of certain information could be more useful to prevent any deceptive character. In regard to advertisements the Therapeutic Products and Therapeutic Services Advertising Codes establish some standards.⁹⁷ Because of their health-related purpose DTC genetic tests are subject to the industry-self regulating Codes of Practice. A mandatory pre-vetting process for any publication of advertisements in the

⁹⁶ Statement used by EasyDNA as advertising for their DNA Health Test <www.easydna.co.nz>.

⁹⁷ Both codes are available at <www.asa.co.nz>.

New Zealand media promotes a high standard of compliance with the Codes.⁹⁸ Irrespective of the question whether the standards in the mentioned Code of Practice are sufficiently specific for DTC genetic testing, the main deficiency is that companies advertise entirely through their websites. Whereas print advertising would be refused without evidence of pre-vetting, information on company owned websites cannot be controlled. The responsible agency Association of New Zealand Advertisers (ANZA) acknowledges this problem and encourages providers to get the agency's approval before websites are launched in New Zealand.⁹⁹ Yet, the incentive to get prior approval is limited.

In regard to the information presented in the risk report, one may rightly ask whether New Zealand law does not require a certain degree of quality in specific legislation. Because genetic testing is traditionally viewed from a medical setting, one would expect to find provisions in the Medicines Act 1981 and the Medicines Regulations 1984. However, in regard to DTC genetic testing there are two problems. One is a question of scope of application, second is the absence of any kind of pre-approval process.

The Medicines Act 1981 applies to medical devices which are defined as “any device, instrument or other article that is intended to be used in, on, or for human beings for a therapeutic purpose”.¹⁰⁰ Therapeutic purpose includes “testing the susceptibility of persons to a disease or ailment”.¹⁰¹ The problem with DTC genetic testing is that the testing kit is certainly covered by the definition of medical device; however, the cotton swab itself is not the area of concern. Rather it is the service of providing a risk analysis report. In regard to health related DTC-products such a distinction between device and service is new. Taking the example of a pregnancy test, the result is shown on a display, so that any regulation for the device would incorporate the clinical validity of the test results. This is appropriate, because information is the main purpose of the test. With genetic testing, the test results are closely related to the device, however, test results are not part of the device, but are provided by an additional service. Similar loopholes have

⁹⁸ The responsible agency is the Association of New Zealand Advertisers (ANZA). See for more information on the pre-vetting process: Association of New Zealand Advertisers “TAPS Pre-vetting system” <www.anza.co.nz>.

⁹⁹ Association of New Zealand Advertisers “Guideline No. 14 - Advertising Therapeutic Products on Websites originating in New Zealand” <www.anza.co.nz>.

¹⁰⁰ Section 3A(a) of the Medicines Act 1981.

¹⁰¹ Section 4(c) of the Medicines Act 1981.

been detected in European legislation and there are plans to incorporate health-related informational services.¹⁰²

Furthermore, even if related services to medical devices formed part of the scope of application of the Medicines Act 1981, the current regulatory system in New Zealand for medical devices relies almost completely on the industry's voluntary compliance with international standards.¹⁰³ Those standards are commonly known as ISO standards and do not yet cover genetic testing services.¹⁰⁴ It is the manufacturers' responsibility to assess the conformity and there is no pre-market approval for any sort of medical device.

In this regard, DTC genetic tests fall through the current regulatory net. A quality assurance for a valid association between a gene mutation and an increased risk for the development of a disease is not yet established. Therefore, consumers find themselves entirely on their own in assessing the quality of the service offered. A task that is impossible without expert knowledge in the field of genetics.

This finding is not surprising. In fact, the Ministry of Health concluded in its set of recently published cabinet papers, containing key elements for a new therapeutic products legislative regime, that current legislation has "significant gaps in coverage", is "dated and inflexible" and gene technology is one example of "rapid development of new products that "are challenging the capacity and currency of regulatory systems globally".¹⁰⁵

¹⁰² The current revision of the relevant Directive 98/79/EC would expand regulatory oversight on clinical validity and utility of the service undertaken by genetic testing companies. European requirements would apply irrespective of the physical basis of the laboratory or company whenever the service is offered to European costumers.

¹⁰³ The Medicines Act 1981 contains provisions regarding the quality and standard of medical devices in its s 35–s 42. Section 40 requires the compliance with prescribed standards for medicines and medical devices. Section 37 empower the Director General to prohibit the import of medical devices for a limited period of one year, whereas s 38 concerns the power to require evidence of the safety of a medical device and constitutes further sales before supplying the required evidence as a offense. Section 4 of the Medicines Regulations 1984 contains an equally broad "a medical device that is described as conforming to a particular description should conform to that description". Section 62 of the Medicines Act 1981 prohibits the sale of medical devices that claim to operate with any form of radiation.

¹⁰⁴ The International Organization for Standardization (ISO) is an international, independent, non-governmental organization consisting of 164 member countries, which has set over 21,000 standards in a wide range of industry fields, including health care.

¹⁰⁵ See Minister of Health *Therapeutic Products Regulation Paper 1: Context and Overview* (Ministry of Health, 28 April 2016) at [11]–[12].

2 Recommendations

This paper recommends that DTC genetic testing be on the schedule of both, industry regulators as well as government agencies.

(a) Industry self-regulation as interim solution

Regarding existing industry self-regulation for advertisement of therapeutic products and services, industry self-regulatory bodies as ANZA should take a more active role. ANZA should contact companies that are operating ‘co.nz’ websites and advise them that they have to comply with the existing Code of Practice. Such procedure should be feasible considering that the quantity of co.nz operating websites is relatively small. ANZA should complain about any lack of available evidence for clinical validity of the offered tests, as well as about the unbalanced information disclosure concerning benefits and limits of the test. At least, the approach would send a clear message that regulators expect companies advertising to New Zealand consumers to comply with the already existing industry codes.

Furthermore, while developing a possible incorporation of DTC genetic testing in the new therapeutic products legislation (see below b)), it seems prudent to enter into a dialogue with DTC genetic testing companies with the aim of creating an industry code of conduct. There are several proposals from organisations and bodies of different countries.¹⁰⁶ However, the industry itself is often not part of the negotiations. Interestingly, 23andMe, a large US based company has recently issued self-established guidelines about criteria for the inclusion of SNPs in their test and appropriate forms of result communication.¹⁰⁷ An active approach towards collaboration could therefore be successful.

(b) Incorporation of DTC genetic testing into a new statute for therapeutic products

Although the development of an industry Code of Conduct and an active engagement of self-regulatory bodies as ANZA is a feasible short-term goal, a legislative regulation is considered the preferable option in order to give the industry a compulsory legal

¹⁰⁶ See for Australia: National Pathology Accreditation Advisory Council *The Provision of Direct to Consumer Genetic Tests: Guiding Principles for Providers* (May 2014); for the United Kingdom: UK Human Genetics Commission *A Common Framework of Principles for direct-to-consumer genetic testing services* (September 2009).

¹⁰⁷ Sheel Dandekar and others “White Paper 23-07: Guidelines on Vetting and Reporting Variants with Strong Effects on Health” (19 September 2014) 23andMe <eu.customercare.23andme.com>.

framework. The current review of the Medicines Act 1981 and the Medicines Regulations 1984 provides an excellent opportunity to give particular attention to the issue of genetic testing services.

The incorporation of genetic tests into a comprehensive regulatory regime for therapeutic products is preferable to a separate statute for genetic testing services. Medicines, traditional medical devices and new hybrid products as genetic tests that are combined by a product and a related service share all one feature: a therapeutic purpose. Whether the device itself achieves this therapeutic purpose or a related service is not decisive. What is important is the safety and quality of the product or related service.

Therefore, as a first step, any definition of therapeutic products should explicitly include DTC genetic tests. Additionally, it should be clarified that genetic tests include the related service of delivering health-related information. The issue of clinical validity of test results would become part of the scope of application. A broader scope of application for a new therapeutic products legislation is also the preferred policy option in the Regulatory Impact Statement, which states that “all products and *activities* having a therapeutic purpose are subject to regulation”.¹⁰⁸

Secondly, it is crucial to establish requirements for a certain level of clinical validity of the test before it is placed on the market. Exact boundaries as to how many clinical studies must be done and the level of quality required to claim clinical validity of a genetic test is a difficult task. However, it is important to define exact criteria in order to perform a balancing act between the inherent scientific insecurities and the lack of specific knowledge of consumers. MedSafe should take advantage of the opportunity to promote international cooperation and coordination, encouraging foreign regulators such as the FDA and the European Medicines Agency to enter in dialogue regarding a potential set of minimum requirements. Already existing tools can serve as guidelines to determine a threshold for the validity of a gene-disease association, such as the Venice criteria.¹⁰⁹ A desirable long-term objective is the creation of an ISO standard that considers the service of DTC genetic testing companies and possibly contains standards for the presentation of the results and a uniform calculation tool for personal risk

¹⁰⁸ Minister of Health *Therapeutic Products Regulation Paper 2: Proposals for a Therapeutic Products Bill* (Ministry of Health, 28 April 2016) at [19] and Ministry of Health *Regulatory Impact Statement: Therapeutic Products Regulation* (28 April 2016) at [90] and [93], (emphasis by author).

¹⁰⁹ Carolin F Wright, Allison Hall and Ron L Zimmern “Regulating direct-to-consumer genetic tests: What is all the fuss about?” (2011) 13 *Genet Med* 295 at 299, n 42.

assessment.¹¹⁰ Detailed requirements should be incorporated in subordinate law in regulations or regulator-made instruments in order to be flexible enough to cope with further developments in technology.¹¹¹

In regard to the pre-market approval the policy proposal for a new therapeutic product regulatory scheme follows the internationally recognised risk based classification of therapeutic products.¹¹² This proposal is to be welcomed and would mean that different levels of pre-market control are put on all therapeutic products according to their risk classification.¹¹³ Depending on public budget and administrative costs, mandatory pre-market approval by the responsible regulator could be limited to mid to high-risk products whereas low-risk products could be self-certified. Future international cooperation would also offer the possibility to accept foreign countries' approval for the New Zealand market. In this way, public money is saved and the administrative burden for companies is reduced.

There are two possibilities for how genetic tests should be assigned to risk groups. One is to make an assessment according to the severity of the condition that the test is associated with. The other possibility is to focus on the material that is analysed and therefore to group all genetic tests into one group. The latter approach is favoured in the current proposal of the European Parliament.¹¹⁴ This approach can be explained by the exceptional character of DNA, as explained in the first part of this paper. There are good reasons to treat genetic tests carefully because of the information tested, however, this paper supports the first option as a more proportionate and feasible solution. From a medical perspective, potential harm for consumers is influenced by the condition tested for. Whereas cancer and Alzheimer's are severe conditions and no intervention is possible for the latter, results concerning obesity, migraine or diabetes present less

¹¹⁰ Christine Hauskeller "Direct to Consumer Genetic Testing" (2011) *BMJ* 342 at 342.

¹¹¹ This flexible approach is in line with the current proposal of the Ministry of Health regarding possible classification of therapeutic products; see Minister of Health, *Therapeutic Products Regulation Paper 2*, above n 108, at [27].

¹¹² In the US and Europe the market approval for genetic tests is classified according to their risk class: see for the US: Federal Food Drug and Cosmetic Act 21 USC § 360c and for Europe: European Commission *Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices* COM(2012) 541 final (26 September 2012) Chapter VI art 39–46.

¹¹³ *Regulatory Impact Statement: Therapeutic Products Regulation* (28 April 2016) at [124].

¹¹⁴ European Parliament *Legislative resolution of 2 April 2014 on the proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices* P7_TA(2014)0267 (2 April 2014) Chapter 1 Art 1 Number 6b(a).

psychological risks. Certainly, the boundaries are often blurred and what is considered as a severe condition may also be influenced by personal experiences. However, in this way tests for the most harmful conditions could be effectively monitored. Similar to quality requirements, details of classification (which disease is considered as severe etc.) should be made in regulations.

Importantly, enforcement will remain the main problem of DTC genetic testing due to a global market without any restriction of access, as acknowledged in the current European debate.¹¹⁵ However, international collaboration is a first step in the right direction and industry will be prompted to notice that it will not be permitted to ‘slip through the net. Furthermore, there should be enhanced public education to make consumers aware of the risks of ordering DTC genetic testing services online, especially from websites outside New Zealand.

B Improving the Informed Consent Process

1 Status quo

The second issue that was identified was the assurance of valid informed consent for DTC genetic testing. At first glance, New Zealand seems well prepared with a wide ranging Code of Health and Disability Services Consumers’ Rights (Code of Rights) as part of the Regulations under the Health and Disability Commissioner Act 1994 (HDC Act), and specific provisions in the Human Tissue Act 2008.

(a) General provisions

The Code of Rights uses the terms ‘consumer’ and ‘provider’ and provides for certain rights of the consumer and corresponding duties of the provider. Provider is defined as health care provider and is according to the relevant definition in the HDC Act 1994 every person who provides health services to the public.¹¹⁶ The frequently heard argument of DTC genetic testing companies, that they do not provide any health care, is likely to be dismissed because s 2(1) of the Act defines the term health treatment (as a

¹¹⁵ Louiza Kalokairinou, Heidi C Howard and Pascal Borry “Current developments in the regulation of direct-to-consumer genetic testing in Europe” (2015) 15 *Medical Law International* 97 at 105.

¹¹⁶ The definitions for terms used but not explicitly defined in the Code of Rights itself, must be read in light of the related statute law, the HDC Act 1994. This is by virtue of s 34 of the Interpretation Act 1999, which provides:

“A word or expression used in a regulation, Order in Council, Proclamation, notice, rule, bylaw, Warrant, or other instrument made under an enactment has the same meaning as it has in the enactment under which it is made.”

subcategory of health service) to include taking of human tissue for educational purposes. Even if the intention of legislator was probably the collection of tissue for anatomy courses etc., it can be argued that DTC genetic companies provide at least an educational service to their costumers when they provide the genetic profile information. In regard to informed consent, the Code provides in Right 6 for an extensive right to be fully informed about the service and in Right 7(1) for mandatory informed consent prior to any service. Furthermore para 6 requires written consent for any participation in research and para 10 refers explicitly to the use of body material. Furthermore s 19(1)(b) and (c) of the Human Tissue Act 2008 require informed consent for the collection, as well as for the analysis of non-health care tissue. DTC Genetic Testing Services fall within that denomination.¹¹⁷

Irrespective of the wide application of the mentioned statutes, it is still questionable whether overseas-based companies will comply with the provisions. Companies can argue that they use choice of law clauses in their TAC (consumers often agree to US American law to govern their contract) and are therefore not subject to specific legislation in New Zealand. In regard to the TAC of EasyDNA, the provision about deemed consent for participation in research (see above III B 2(b)) seems particularly questionable. It is certainly not the intention of the Code of Rights that companies can privately contract out of the provisions of the Code. In fact, to include such substantive information in the mass of TAC contradicts the duty of the provider to disclose information in a comprehensive way. Furthermore, it is important to consider whether more positive regulation is needed to give guidance as to what is expected from commercial companies in order to comply with their duties under the Code of Rights.

(b) Provisions applying to testing of minors and involuntary testing

In regard to DTC genetic testing of minors and involuntary testing, s 33 (2) of the Human Tissue Act 2008 always requires the informed consent of the person tested, therefore prohibits any consent on behalf of minors. Furthermore s 23 declares any collection or use of human tissue without the required informed an offence with a possible conviction to imprisonment for 1 year or a fine not exceeding \$50,000 NZD.

¹¹⁷ Section 6 defines non-health-care tissue as human tissue that is collected from a human body but outside of a health care procedure and donor analysis according to s 6 includes analysis with the purpose to provide information (also genetic information) about an actual or potential condition or trait of the individual.

2 Recommendations

(a) Mandatory pre-test counselling

The question as to how far intervention should go to achieve a safer informed consent process is a delicate one.

One solution could be more balanced and understandable information by positive regulation for mandatory information to be provided on websites. Indeed, the policy should not create an information overload, as this would not serve the purpose of consumer's understanding of the information. However, mandatory disclosure could ensure that companies do not hide negative information in disclaimers in their TAC. Some authors consider a system of mandatory information disclosure as sufficient and proportional regulation of DTC genetic testing.¹¹⁸

However, this paper argues for a stricter approach than only positive informational obligations. There should be the safeguard of a human interaction to ensure informed consent. Despite the obvious enforcement problem, this paper argues at least for a mandatory pre-test counselling.¹¹⁹ In comparison to the European proposal, this recommendation does not require a medical prescription but a consultation meeting. Additionally, despite the mandatory pre-counselling, the disclosure of the results would still be available without the involvement of a physician. However, it would be desirable that some form of deliberate consumer action (extra click) is needed before test results for severe conditions (e.g. Alzheimer's disease and all forms of cancer) are displayed. Voluntary post-counselling would give consumers the benefit of privacy whereas pre-counselling could provide an incentive to discuss results in a follow-up session with the health care professional.

Such a regulatory approach certainly intervenes to a larger extent with the business of DTC companies and channels the access to DTC genetic testing for consumers. However, this paper argues that it is negligent to wait for the evidence of harm where risks are not only to individuals themselves but also society as a whole. Waiting for evidence would mean acceptance of the occurrence of damage. A careful and proactive approach seems preferable.

¹¹⁸ See for example proposals in Bunnik, Cecile and Schwermer, above n 62, at 349 who propose a combined tiered-layered-staged model of informed consent applicable to online offers; See also Nuffield Council on Bioethics, above n 52, at 158, who argues that further evidence of actual harm is needed for stricter state regulation and propose a combination of an Industry Code of Practice, strict regulatory oversight of advertising claims and public education.

¹¹⁹ See with the same approach in the US: Piehl, above n 23, at 92.

Mandatory pre-counselling offers a chance to minimise the issues in relation to informed consent. Doctors as a human intermediary and a neutral information source could assure that risks and benefits are understood. With a conformation number or similar evidence, consumers could then purchase the test. Especially when consumers make their purchase decision out of curiosity, written information may be overlooked. The benefits of a human interaction in comparison to self-study of written information are persuasive. A medical professional could give tailored advice and information according to the consumer's motive for testing. Hence, a woman who considers testing for BRCA mutation could get more detailed information about the current stage of scientific evidence, which can clear any misunderstanding about the test's significance.

It has to be clear that a mandatory pre-counselling service would not mean a complete shift of responsibility from the commercial companies to doctors; rather companies would remain responsible for sufficient and balanced information, however, the doctor would be a further safeguard ensuring consumers understand the information and misinterpretations are detected before the purchase. A benefit of such partial involvement of medical professionals in the DTC genetic testing service is therefore an increased incentive for companies to refrain from using exaggerated advertising on their websites and to obtain available quality seals in the future. To avoid any conflict of interest, pre-counselling must not be provided by company-employed doctors but rather by a list of independent medical professional available on the website.

Undoubtedly there are challenges with the proposed pre-counselling. One is a practical question of financing. It does not seem fair that public funds are used for the benefit of private companies. Companies should be obligated to pay a user fee for every consumer into a public fund. A further problem is a potential evasive attitude of medical professional who are forced into a 'marriage' with the genetic testing industry. Considering that most tests do not show clinical utility, some argue that mandatory medical advice is useless.¹²⁰ However, it is already a reality that genetic testing has an influence on traditional medical health care. With further development and growing demand, doctors will be more often confronted with commercial offers. The already proposed establishment of certain quality criteria for clinical validity and pre-market approval is also beneficial for effective consultation.

¹²⁰ Wright, Hall and Zimmern, above n 109, at 299.

The mandatory pre-counselling should be incorporated in the current review of the Medicines Act. The cabinet papers already propose to introduce a system similar to the current classification of medicine (prescription only, pharmacy-only, general sale) applicable to all therapeutic products. E.g. the term ‘prescription’ is defined more broadly as ‘available on the authority of a health practitioner’.¹²¹ In this section the legislation could refer specifically to genetic testing services and introduce a counselling requirement.

(b) Prescription requirement for testing of minors and additional ban of advertisement

In line with the existing provisions, DTC genetic testing of minors should only be available with a medical prescription. In contrast to adult testing, a clear medical benefit for the minor should be the result of any test. This restriction is necessary to ensure the minor’s right not to know and to avoid any negative impact on a child’s personality and development. Additionally advertising for genetic testing of minors should be banned completely.

Furthermore consumers should be warned in an explicit manner during ordering process that any sending of samples without the required consent of the source is an offence and can be prosecuted. Admittedly, such warning statements cannot provide absolute certainty and in particular, the protection of minors may be an argument to justify a prescription requirement for all genetic tests, especially considering the fast development of the genetic science.

C Reducing the Risk of Psychological Harm and Fulfilling Responsibilities to Society

Finally, the combination of the policy recommendations in the last two sections can, to a certain extent, reduce the risk of psychological harm. Pre-counselling can prevent unnecessary concerns due to misunderstanding of the test results’ significance. Additionally, quality requirements for genetic tests help to make the market more transparent for consumers. With the channeling of consumers through a human intermediary government can also meet its responsibility towards current and future society, because policy makers are able to better monitor the long-term development of the industry and its impact on society.

¹²¹ Minister of Health *Therapeutic Products Regulation Paper 2*, above n 108, at [32].

V Conclusion

This paper has made recommendations on how to achieve adequate consumer protection without compromising potential benefits of the new DTC genetic testing industry. The proposals include a broader scope of application for the new therapeutic products legislation, a partial involvement of a health care professional as well as legislative requirements for pre-market approval and quality criteria that ensure a certain level of clinical validity despite the inherent scientific insecurities. However, it is acknowledged that this framework may need further economic analysis and is to some extent also influenced by value judgments, such as the requirement to protect sensitive genetic information and a responsibility towards future generations and society.

The current revision of New Zealand's therapeutic products regimen provides an excellent opportunity to engage in a political dialogue and to set the right course in a new regulatory framework. Furthermore, against the backdrop of an online market place, consumers would greatly benefit from international co-ordination and cooperation. With a holistic approach, New Zealand can set the standards to be best prepared both for today's and for future developments in the genetic testing industry.

A Legislation

1 New Zealand

Code of Health and Disability Services Consumers' Rights.

Consumer Guarantees Act 1993.

Fair Trading Act 1986.

Health and Disability Commissioner Act 1994.

Human Tissue Act 2008.

Medicines Act 1981.

Medicines Regulations 1984.

Medicines (Database of Medical devices) Regulations 2003.

2 Australia

Therapeutic Goods Act 1989.

Therapeutic Goods (Excluded purposes) Specification 2010.

3 Germany

Gendiagnostikgesetz (GenDG).

4 European Union

Directive 98/79/EC on in vitro diagnostic medical devices [1998] OJ L331/1.

5 United States of America

Federal Food Drug and Cosmetic Act 21 USC.

B Books and Chapters in Books

Helen Wallace “Direct-to-Consumer Testing” in Ulf Kristofferson, Jörg Schmidtke and JJ Cassiman (eds.) *Quality Issues in Clinical Genetic Services* (Springer Science & Business Media, 2010) 191.

Michael Krawczak “Clinical Validity and Utility of Genetic Testing in Common Multifactorial Diseases” Ulf Kristofferson, Jörg Schmidtke and JJ Cassiman (eds.) *Quality Issues in Clinical Genetic Services* (Springer Science & Business Media, 2010) 157.

C Journal Articles

Pawan Acharya and Rupesh Gautam “Ethical perspectives of direct-to-consumer genetic testing” (2015) 11 (1) *Online Journal of Health Ethics*.

Stephanie Bair “Direct-to-Consumer Genetic Testing: Learning from the Past and Looking toward the Future” (2012) 67 *Food & Drug LJ* 413.

Julian Barwell and Anirudh Kumar “Genomic Testing and Genomic Care: Are They Talking to Each Other?” (2015) 6(6) *J Clin Res Bioeth* 1.

Juli Murphy Bollinger, Robert C Green and David Kaufman “Attitudes About Regulation Among Direct-to-Consumer Genetic Testing Customers” (2013) 17 *Genetic Testing and Molecular Biomarkers* 424.

Gemma R Brett and others “An exploration of genetic health professionals’ experience with direct-to-consumer genetic testing in their clinical practice” (2012) 20 *European Journal of Human Genetics* 825.

Pascal Borry and Heidi Carmen Howard “Is There a Right Time to Know? The Right Not to Know and Genetic Testing in Children” (2014) 42 *J L Med & Ethics* 19.

Pascal Borry and others “Legislation on direct-to-consumer genetic testing in seven European countries” (2012) 20 *Eur J Hum Genet* 715.

Eline M Bunnik, A Cecile JW Janssens and Maartje HN Schermer “Personal utility in genomic testing: Is there such a thing?” (2015) 41 J Med Ethics 322.

Eline M Bunnik, A Cecile and Maartje Schwermer “Informed Consent in Direct-to-Consumer Personal Genome Testing: The Outline of a Model Between Specific And Generic Consent” (2014) 28 Bioethics 343.

Wylie Burke and Susan Brown Trinidad “The Deceptive Appeal of Direct-to-Consumer Genetics” (2016) Ann Intern Med (forthcoming).

Adrian Burton “Are we ready for direct-to-consumer genetic testing?” (2015) 14 The Lancet 138.

Loredana Covolo and others “Internet-Based Direct-to-Consumer Genetic Testing: A Systematic Review” (2015) 17 (12) J Med Internet Res 1.

Reinhard Damm and Steffen König “Rechtliche Regulierung prädiktiver Gesundheitsinformation und genetischer Exzeptionalismus” (English: Legal Regulation of predictive health information and genetic exceptionalism) (2008) 26 MedR 62.

European Society of Human Genetics “Genetic testing in asymptomatic minors: recommendations of the European Society of Human Genetics” (2009) 17 European Journal of Human Genetics 720.

Sjef Gevers “The Role of Law with Respect to Self-testing” (1999) 6 European Journal of Health Law 155.

Jennifer A Gniady “Regulating Direct-to-Consumer Genetic Testing: Protecting the Consumer Without Quashing a Medical Revolution” (2007-2008) 76 Fordham L Rev 2429.

Yulong Gu and Jim Warren “The Diversity of Genetic Services Delivery Models New Zealand” (2009) 13(4) Health Care and Informatics Review Online 28.

Christine Hauskeller “Direct to Consumer Genetic Testing” (2011) BMJ 342.

Michelle D Irick “Age of an Information Revolution: The Direct-to-Consumer Genetic Testing Industry and the Need for a Holistic Regulatory Approach” (2012) 49 *San Diego L Rev* 279.

Louiza Kalokairinou, Heidi C Howard and Pascal Borry “Current developments in the regulation of direct-to-consumer genetic testing in Europe” (2015) 15 *Medical Law International* 97.

Chiyan Lau and Graeme Suthers “BRCA testing for familial breast cancer” (2011) 34 (2) *Austr Presc* 49.

Michele Loi “Direct to consumer genetic testing and the libertarian right to test” (2016) *J Med Ethics* (forthcoming, published online first 23 March 2016) 1.

Dee Magin, Ben Hudson and Les Toop “Direct-to-Consumer Genetic Testing: Letting the Genie out of the Bottle” (2012) 125 *NZMJ* 7.

Bryon Nelson “The Big Sell: Direct to consumer tests promise patients more abundant and accessible information, but potential pitfalls abound” (2016) 126(1) *Cancer Cytopathology* 7.

Dianne Nicol and others “Time to Get Serious About Privacy Policies: The Special Case of Genetic Privacy” (2014) 42 *Fed L Rev* 149.

Matthew Piehl “Regulating Hype and Hope: A Business Ethics Model Approach to Potential Oversight of Direct-to-Consumer Genetic Testing” (2011-2012) 16 *Mich St U J Med & L* 59.

José A Riancho “Genome-Wide Association Studies (GWAS) in Complex Diseases: Advantages and Limitations” (2012) 8 (2) *Reumatol Clin* 56.

Andrew S Robertson “Taking Responsibility: Regulations and Protections in Direct-to-Consumer Genetic Testing” (2009) 24 *Berkeley Tech LJ* 213.

Kathryn Schleckser “Physician Participation in Direct-to-Consumer Genetic Testing: Pragmatism or Paternalism” (2012-2013) 26 *Harv J L & Tech* 695.

Pascal Su “Direct-to-Consumer Genetic Testing: A comprehensive View” (2013) 86 Yale Journal of Biology and Medicine 359.

Sivan Tamir “Direct-to-Consumer Genetic Testing: Ethical-Legal Perspectives and Practical Considerations” (2010) 18 Medical Law Review 213.

Ronald Trent “Direct-to-consumer DNA genetic testing and the GP” (2014) 43 Australian Family Physician 436.

Mauro Turrini and Barbara Prainsack “Beyond clinical utility: The multiple values of DTC genetics” (2016) 8 Applied & Translational Genomics 4.

Chelsea Weiermiller “The Future of Direct-to-Consumer Genetic Testing: Regulation and Innovation” (2014) 16 NCJL & Tech On 137.

Carolin F Wright, Allison Hall and Ron L Zimmern “Regulating direct-to-consumer genetic tests: What is all the fuss about?” (2011) 13 Genet Med 295.

Peter Paul Yu, Julie M Vose and Daniel F Hayes “Genetic Cancer Susceptibility Testing: Increased Technology, increased Complexity” (2015) Journal of Clinical Oncology 1.

D Official material (reports, parliamentary materials)

1 New Zealand

Minister of Health *Therapeutic Products Regulation Paper 1: Context and Overview* (Ministry of Health, 28 April 2016).

Minister of Health *Therapeutic Products Regulation Paper 2: Proposals for a Therapeutic Products Bill* (Ministry of Health, 28 April 2016).

Ministry of Health *Regulatory Impact Statement: Therapeutic Products Regulation* (28 April 2016).

National Advisory Committee on Health and Disability “Molecular Genetic Testing in New Zealand” (October 2003).

2 *European Union*

European Commission *Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices* COM(2012) 541 final (26 September 2012).

European Parliament *Legislative resolution of 2 April 2014 on the proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices* P7_TA(2014)0267 (2 April 2014).

Council of the European Union *Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices* (21 September 2015) (12042/15 PHARM 37 SAN 282MI 568 COMPET 411 CODEC 1194).

3 *United Nations Educational, Scientific and Cultural Organization (UNESCO)*

United Nations Educational, Scientific and Cultural Organization (UNESCO) *International Declaration of Human Genetic Data* 32 C/Resolution 24 (adopted on 16 October 2003).

4 *United States of America*

United States Government *Accountability Office Direct-to-Consumer Genetic Tests: Misleading Test Results are Further Complicated by Deceptive Marketing and Other Questionable Practices* (22 July 2010).

E *Unpublished Papers*

Flavia Horvath Chen “23andMe and the FDA: Negotiating Conceptions of Benefit in the Direct-to-Consumer Genetic Testing Regulatory Debate” (Thesis, University of Washington, 2014).

F Internet Resources

Philippa Brice “EU legal amendments threaten genomic medicine and research” (23 October 2013) <www.phgfoundation.org>.

Sheel Dandekar and others “White Paper 23-07: Guidelines on Vetting and Reporting Variants with Strong Effects on Health” (19 September 2014) 23andMe <eu.customercare.23andme.com>.

Emergo “MedSafe Medical Device Regulation in New Zealand” <www.emergogroup.com>.

“Future of Direct-to-Consumer (DTC) Genetic Testing Market Remains Fraught with Challenges, According to New Report by Global Industry Analysts, Inc.” (8 August 2012) <www.prweb.com>.

Human Genetics Society of Australasia “Guideline: Pre-symptomatic and Predictive Testing for Children and Young Adults” (August 2014) <www.hgsa.org.au>.

National Human Genome Research Institute “All about the Human Genome Project” (last updated October 2015) <www.genome.gov>.

National Human Genome Research Institute “Genome Wide Association Studies” Frequently Asked Questions About Genetic disorders (last updated 27 August 2015) <www.genome.gov>.

National Human Genome Research Institute “Learning about Cystic Fibrosis” (last updated 27 December 2013) <www.genome.gov>.

National Human Genome Research Institute “Learning about Huntington’s disease” (last updated 17 November 2011) <www.genome.gov>.

National Human Genome Research Institute “What are genetic disorders” (last updated 10 November 2015) <www.genome.gov>.

Charles Seife “23andMe is Terrifying, but not for the Reasons the FDA Thinks” (27 November 2013) Scientific American <www.scientificamerican.com>.

Eric Topol “Who Should Have Access to Your DNA” (23 January 2015) <www.backchannel.com>.

“What are single nucleotide polymorphisms (SNPs)?” (28 March 2016) Genetics Home Reference <www.ghr.nlm.nih.gov>.

World Health Organization “Monogenic diseases” Genomic Resource Centre <www.who.org>.

23andMe “Accelerating research. A new way” (2016) <www.23andme.com>.

<www.easydna.co.nz>.

<www.ibdna.co.nz>.

<www.anza.co.nz>.

<www.asa.co.nz>.

<www.iso.org>.

<www.suregenomics.com>.

G Other Resources

Advertising Standards Authority *Therapeutic Products Advertising Code* (2014).

Advertising Standards Authority *Therapeutic Services Advertising Code* (2014).

European Academies Science Advisory Council and Federation of European Academics of Medicine *Direct-to-consumer genetic testing for health related purposes in the European Union* (July 2012).

National Pathology Accreditation Advisory Council *The Provision of Direct to Consumer Genetic Tests: Guiding Principles for Providers* (May 2014).

New Zealand Medical Association *Code of Ethics for the New Zealand Medical Profession* (May 2014).

Nuffield Council on Bioethics *Medical profiling and online medicine: the ethics of 'personalized healthcare' in a consumer age* (Nuffield Press, Oxfordshire, 2010).

UK Human Genetics Commission *A Common Framework of Principles for direct-to-consumer genetic testing services* (September 2009).